# FINAL REGISTRATION REPORT

## Part B

## Section 9

## Ecotoxicology

Detailed summary of the risk assessment

Product code: **102000012886**

Product name(s): **fluopyram + trifloxystrobin SC 500**
(Active substance(s)): **(250 + 250 g/L)**

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

**CORE ASSESSMENT**

**(Re-authorisation)**

Applicant: **Bayer CropScience Division**

Submission date: **30/06/2020**
**Updated February 2021, July 2021,**

MS Finalisation date: **November 2021, February 2022**

M-687617-02-1

# Version history

| When | What |
|---|---|
| **February 2021** | **Critical GAP table simplified with crop grouping, whenever possible, allowing risk envelop assessment. Modification highlithed in yellow** |
| June 2020 | Original Bayer submission |
| July 2021 | Walk-in tunnel /low tunnel shelter identified as *F* in GAP table.<br>No registration on Golf course use in CZE. Uses 124 removed including all related assessment |
| November 2021 | Finalisation of the assessment by zRMS-PL. |
| February 2022 | Final Version after Commentting period |

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The product fluopyram + trifloxystrobin SC 500 (250+250 g/L) (FLU + TFS SC 500 / Product Code 102000012886) was not the representative formulation during the renewal of approval of trifloxystrobine. All data and information assessed during the EU re-evaluation of trifloxystrobine is considered EU peer-renewed data.

Non renewed substance fluopyram: according to the guidance SANCO/2010/13170 rev. 14, 7 October 2016, for product containing two or more substances, there is no need to evaluate data related to the « non-renewed » substance(s). It is therefore our understanding that only data pertaining to combitox assessment will be taken into consideration.

# 9 Ecotoxicology (KCP 10)

## 9.1 Critical GAP and overall conclusions

### Table 9.1-1: Table of critical GAPs

**The table bellow presents the same grouping of crops (whenever possible) as presented in table 8.8 of the dRR Part B8. For detailed uses please refers to part B0**

| 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 safener/ synergist per ha | **Conclusion** | | | | | | |
| | | | | | Method / Kind | Timing / Growth stage of crop & season | Max. number a) per use b) per crop/ season | Min. interval between applications (days) | kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season | g or kg 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 | Soil organisms | Non-target plants |
| **Zonal uses (field or outdoor uses, certain types of protected crops)** | | | | | | | | | | | | | | | | | | | | |
| 1 | AUT | Asparagus (ASPOF) | F | BOTRCI, PLEOHE, PUCCAS | Spraying (foliar) | ~~23~~ **40**-87 (Post harvest to appearance of symptoms) | a) 2 b) 2 | 10 | a) 0.8 b) 1.6 | a) FLU 200 + TFS 200 b) FLU 400 + TFS 400 | 300-600 | | | | | | | | | |
| 1 | AUT | Asparagus (ASPOF) | F | BOTRCI, PLEOHE, PUCCAS | Spraying (foliar) | ~~23~~ **40**-87 (Post harvest to appearance of symptoms) | a) 2 b) 2 | 10 | a) 0.8 b) 1.6 | a) FLU 200 + TFS 200 b) FLU 400 + TFS 400 | 300-600 | | Reduced window of application for acceptable metabolite PECgw | | | | | | | |
| 3,4 | NLD, SVK | Asparagus (ASPOF) | F | SCLESP, BOTRSP | Spraying (foliar) | 51-95 (June-Nov) | a) 1 b) 1 | - | a) 0.8 b) 0.8 | a) FLU 200 + TFS 200 b) FLU 200 + TFS 200 | 500-800 | | | | | | | | | |

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 7, 8, 10, 13, 16, 604 | POL | Beans, | F | BOTRCI, SCLESC | Spraying (foliar) | 59-89 | a) 2<br>b) 2 | 7 | a) 0.8<br>b) 1.6 | a) FLU 200 + TFS 200<br>b) FLU 400 + TFS 400 | 200-800 | | | | | | | | | |
| 6, 9, 12, 14, 15, 17, 19, 174, 177-179, 181, 182 | AUT | Beans, Peas | F | BOTRCI, SCLESC | Spraying (foliar) | 55-79 | a) 2<br>b) 2 | 14 | a) 0.8<br>b) 1.6 | a) FLU 200 + TFS 200<br>b) FLU 400 + TFS 400 | 200-800 | | | | | | | | | |
| 176, 180, 183 | BEL | Peas | F | BOTRCI, SCLESC | Spraying (foliar) | 55-79 | a) 2<br>b) 2 | 7 | a) 0.8<br>b) 1.6 | a) FLU 200 + TFS 200<br>b) FLU 400 + TFS 400 | 200-800 | | | | | | | | | |
| 21 *22* 23, 28, *31,* 32, *33, 34, 39, 45,* 52, *57, 59*, 63, *64, 65* 66, *67, 70, 76-78, 83, 89-91, 96, 102,* 107, *109,* 125, *126, 127, 132, 137, 165, 166,* 191, *192, 193 198, 204, 211, 213,* 605, 606, 608, *609* | AUT | Bushberries, | F/*F* | BOTRCI, DIDYAP | Spraying (foliar) | 15-89 | a) 2<br>b) 2 | 7 | a) 0.8<br>b) 1.6 | a) FLU 200 + TFS 200<br>b) FLU 400 + TFS 400 | 200-1200 | | | | | | | | | |
| 24, *25, 26*, 35, *36, 37*, 53, *54, 55, 67,68,* 79, *80, 81,* 92, *93, 94*, 128, *129, 130*, 194, *195, 196* | BEL | Bushberries, | F/*F* | BOTRCI | Spraying (foliar) | 51-69 | a) 2<br>b) 2 | 7 | a) 0.6s<br>b) 1.2 | a) FLU 150 + TFS 150b) FLU 300 + TFS 300 | 200-1200 | | | | | | | | | |
| 29, 40, *41,* 71, *72,* 84, *85,* 97, *98,* 133, *135*, 199, *200* | POL | Bushberries, | F/*F* | BOTRCI, DIDYAP, PHRARU, PODOAP | Spraying (foliar) | 57-87 | a) 2<br>b) 2 | 14 | a) 0.8<br>b) 1.6 | a) FLU 200 + TFS 200<br>b) FLU 400 + TFS 400 | 200-1200 | | | | | | | | | |
| 38, 44, 56, 58, 69, 75, 82, 88, 95, 101, 108, 110, 131, 136, 167, 168, 210, 212, | NLD | Bushberries | F | BOTRCI | Spraying (foliar) | 15-89 | a) 2<br>b) 2 | 14 | a) 0.6s<br>b) 1.2 | a) FLU 150 + TFS 150b) FLU 300 + TFS 300 | 200-1200 | | | | | | | | | |
| 27, 30, 105, 106, 197, 203, | NLD | Bushberries | F | BOTRCI, DIDYAP | Spraying (foliar) | 40-69 | a) 2<br>b) 2 | 21 | a) 0.6<br>b) 1.2 | a) FLU 150 + TFS 150<br>b) FLU 300 + TFS 300 | 200-1200 | | | | | | | | | |
| 226, 227, *228, 230*, | NLD | Strawberry | F/*F* | BOTRCI, SPHRMA | Spraying | 40-89 | a) 2 | 7 | a) 0.8 | a) FLU 200 | 300-600 | 1 | | | | | | | | |

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 232, 236-239 | | | | | (foliar) | | b) 2 | | b) 1.6 | + TFS 200<br>b) FLU 400<br>+ TFS 400 | | | | | | | | | | |
| 47,48 | NLD | Celeriac (APUGR) | F | SCLESP, SEPTAP | Spraying (foliar) | 40-49 (June-Nov) | a) 2<br>b) 2 | 14 | a) 0.5<br>b) 1 | a) FLU 125<br>+ TFS 125<br>b) FLU 250<br>+ TFS 250 | 200-800 | 14 | | | | | | | | |
| *60, 142, 148*, *158, 159*, 161, *162, 163, 205*, *607* | AUT | Lettuce and other leafy crops | F/*F* | BOTRCI, RHIZSP, SCLESC | Spraying (foliar) | 12-49 | a) 2<br>b) 2 | 7 | a) 0.8<br>b) 0.8 | a) FLU 200<br>+ TFS 200<br>b) FLU 400<br>+ TFS 400 | 500-1000 | 7 | | | | | | | | |
| 49, *50* 51, 61, 62, 112, 113, *114,* 115, 116, 143, *144*, 145, 146, 147, 149, *150*, 151, *152, 154,* 157, *158, 159*, 160, 164, 189, *190*, 206, *207*, 208, 209, 214, 215 | AUT | Lettuce and other leafy crops | F/*F* | BOTRCI, RHIZSP, SCLESC | Spraying (foliar) | 12-49 | a) 1<br>b) 1 | - | a) 0.8<br>b) 0.8 | a) FLU 200<br>+ TFS 200<br>b) FLU 200<br>+ TFS 200 | 500-1000 | | | | | | | | | |
| 138-140 | NLD | Grape (VITVI) | F | UNCINE, PSPZTR | Spraying (foliar) | 15-73 (Mar-July) | a) 2<br>b) 2 | 14 | a) 0.2<br>b) 0.4 | a) FLU 50<br>+ TFS 50<br>b) FLU 100<br>+ TFS 100 | 400-1200 | | | | | | | | | |
| 141 | POL | Hop (HUMLU) | F | SPHRFU | Spraying (foliar) | 37-79 | a) 2<br>b) 2 | 14 | a) 0.6<br>b) 1.2 | a) FLU 150<br>+ TFS 150<br>b) FLU 300<br>+ TFS 300 | 2000-3000 | | | | | | | | | |
| 241 | POL | Tobacco (NIOTA) | F | SCLESC | Spraying (foliar) | 11-39 | a) 1<br>b) 1 | - | a) 0.8<br>b) 0.8 | a) FLU 200<br>+ TFS 200<br>b) FLU 200<br>+ TFS 200 | 300-500 | | | | | | | | | |
| 118,119, | NLD | Flower bulbs, | F | BOTRSP | Spraying (foliar) | 12-91 (Mar-Oct) | a) 5<br>b) 5 | 7 | a) 0.3<br>b) 1.5 | a) FLU 75<br>+ TFS 75<br>b) FLU 375<br>+ TFS 375 | 150-400 | | | | | | | | | |
| 117, 120 | CZE | Flower bulbs (3UNCLK) | F | BOTRSP | Spraying (foliar) | 12-91 | a) ~~5~~ **2**<br>b) ~~5~~ **2** | 7 | a) 0.3<br>b) 0.6 | a) FLU 75<br>+ TFS 75<br>b) FLU ~~375~~ **150** + TFS ~~375~~ **150** | 150-400 | | | | | | | | | |

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 119, 121-123, 170-174, *184,* 187, 188, 216-218, *219, 220,* 221, *224, 225, 242* | NLD | Flower bulbs, Ornamentals, tree nursery, seed production crops | F/*F* | SCLESP | Spraying (foliar) | 12-91 (Mar-Oct) | a) 1<br>b) 1 | - | a) 0.8<br>b) 0.8 | a) FLU 200 + TFS 200<br>b) FLU 200 + TFS 200 | 150-400 | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | |

FLU: Fluopyram TFS: Trifloxystrobin

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

Explanation for column 15 – 21 “Conclusion”

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

**Remarks table:**

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

## Critical GAP assessed during EU approval of trifloxystrobin

### Table 9.1-2: Assessed (critical) uses during approval of trifloxystrobin

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Use-No. | Member state(s) | Crop and/or situation (crop destination / purpose of crop) | F, Fn, Fpn G, Gn, Gpn or I ** | Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group) | **Application** | | | | **Application rate** | | | PHI (days) | Remarks: e.g. g safener/ synergist per ha |
| | | | | | Method / Kind | Timing / Growth stage of crop & season | Max. number a) per use b) per crop/ season | Min. interval between applications (days) | kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season | g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season | Water L/ha min/max | | |
| | Germany | Apple, Pear, Quince | F | GLEOSP, PODOLE, VENTIN, VENTPI, ALTEAL, NECTGA | Tractor mounted/ trailed broadcast air assisted sprayer | BBCH 53-87 | 3 | 10 | a) 0.050 – 0.150<br>b) 0.150– 0.450 | a) 0.025 – 0.075<br>b) 0.075 – 0.225 | 500 - 1500 | 14 | 0.05 kg product/ha and per m crown-high in 500 L water with max 3 m crown-high<br><br>Representative formulation: Trifloxystrobin WG 50 |
| | Slovakia | Apple | F | PODOLE, VENTIN | Tractor mounted/ trailed broadcast air assisted sprayer | BBCH 31-89 | 3 | 10 | a) 0.150<br>b) 0.450 | a) 0.075<br>b) 0.225 | 200 – 1000 | 14 | Representative formulation: Trifloxystrobin WG 50 |
| | Netherlands | Grape | F | PLASVI | Tractor mounted/ trailed broadcast air assisted sprayer | BBCH 12-89 | 3 | 10 | a) 0.250<br>b) 0.750 | a) 0.125<br>b) 0.375 | 400 – 1200 | 14 | Representative formulation: Trifloxystrobin WG 50 |
| | Slovakia | Grape | F | BOTRCI, CONLDI, PLASVI, UNCIN | Tractor mounted/ trailed broadcast air assisted sprayer | BBCH 14-89 | 3 | 10 | a) 0.250<br>b) 0.750 | a) 0.125<br>b) 0.375 | 200 – 1000 | 14 | Representative formulation: Trifloxystrobin WG 50 |
| | Germany | Grape | F | UNCINE, PHOPVI, GUIGBI, PSPZTR | Tractor mounted/ trailed broadcast air | BBCH 13-83 | 3 | 10 | a) 0.240<br>b) 0.720 | a) 0.120<br>b) 0.360 | 400 – 1600 | 35 | Representative formulation: Trifloxystrobin WG 50 |

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Use-No. | Member state(s) | Crop and/or situation (crop destination / purpose of crop) | F, Fn, Fpn G, Gn, Gpn or I ** | Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group) | **Application** | | | | **Application rate** | | | PHI (days) | Remarks: e.g. g safener/ synergist per ha |
| | | | | | Method / Kind | Timing / Growth stage of crop & season | Max. number a) per use b) per crop/ season | Min. interval between applications (days) | kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season | g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season | Water L/ha min/max | | |
| | | | | | assisted sprayer | | | | | | | | |
| | Germany | Strawberry | F G | DIPCEA, MYCOFR, SPHRMA | Tractor mounted/ trailed equipment: boom sprayer Manual equipment: hand held lance | BBCH 55-89 | 2 | 7 | a) 0.300 b) 0.600 | a) 0.150 b) 0.300 | 1000 – 2000 | 1 | Representative formulation: Trifloxystrobin WG 50 |
| | Poland | Strawberry | F | MYCOFR, SPHRMA | Tractor mounted/ trailed equipment: boom sprayer | BBCH 10-92 | 2 | 7 | a) 0.250 b) 0.500 | a) 0.125 b) 0.250 | 600 - 1200 | 1 | BBCH 99 treatments of plants after harvest complete<br><br>Representative formulation: Trifloxystrobin WG 50 |
| | Italy | Apple, Pear | F | PODOLE, VENTIN | Tractor mounted/trailed broadcast air assisted sprayer | BBCH 61-85 | 3 | 10 | a) 0.225 b) 0.675 | a) 0.1125 b) 0.3375 | 1500 | 14 | Spray Interval: 10 day until BBCH 74; 10-14 from BBCH 74 to 85<br><br>Representative formulation: Trifloxystrobin WG 50 |
| | Spain | Apple, Pear | F | PODOLE, VENTIN | Tractor mounted/trailed broadcast air assisted sprayer | BBCH 55-87 | 3 | 10 | a) 0.225 b) 0.675 | a) 0.1125 b) 0.3375 | 1000 – 1500 | 14 | 0.0075% - 0.01% product /ha<br><br>Representative formulation: Trifloxystrobin WG 50 |
| | Italy | Grape | F | UNCINE, GUIGBI | Tractor mounted/trailed broadcast air | BBCH 61-69 | 3 | 10 | a) 0.25 b) 0.75 | a) 0.125 b) 0.375 | 1000 | 14 | Representative formulation: Trifloxystrobin WG 50 |

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Use-No. | Member state(s) | Crop and/or situation (crop destination / purpose of crop) | F, Fn, Fpn G, Gn, Gpn or I ** | Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group) | **Application** | | | | **Application rate** | | | PHI (days) | Remarks: e.g. g safener/ synergist per ha |
| | | | | | Method / Kind | Timing / Growth stage of crop & season | Max. number a) per use b) per crop/ season | Min. interval between applications (days) | kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season | g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season | Water L/ha min/max | | |
| | | | | | assisted sprayer | | | | | | | | |
| | Spain | Grape | F | UNCINE | Tractor mounted/trailed broadcast air assisted sprayer | BBCH 69-85 | 3 | 10 | a) 0.225<br>b) 0.675 | a) 0.1125<br>b) 0.3375 | 200 – 1500 | 14 | 0.0125% - 0.015% product/ha<br><br>Representative formulation: Trifloxystrobin WG 50 |
| | Spain | Strawberry | F | DIPCEA, MYCOFR, SPHRMA | Tractor mounted/trailed equipment: boom sprayer | BBCH 19-89 | 2 | 7 | a) 0.300<br>b) 0.600 | a) 0.150<br>b) 0.300 | 500 - 1200 | 1 | 0.025% product/ha<br><br>Representative formulation: Trifloxystrobin WG 50 |

** 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

### 9.1.1 Overall conclusions

This dossier is supporting the application for the renewal of authorisation of Fluopyram + Trifloxystrobin SC 500 (250+250 g/L) after the renewal of the approval of the active substance Trifloxystrobin.
For the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009, the following guidance is given in the Document SANCO/2010/13170 for products containing two or more active substances:

- *"when the 1st substance is renewed- there is no need to evaluate data related to the 2nd substance"*
- *"once the 2nd substance is renewed- there is no need to evaluate data related to the 1st substance because this has already been performed in the frame of the re-authorisation of the PPP following the renewal of the 1st active substance"*
- *"Where necessary a combitox assessment should be performed."*

In consequence, only data on the renewed active substance Trifloxystrobin will be evaluated for Post AR review and data on the partner (non-renewed ) active substance(s) should be submitted only for the areas of assessments where combined risk assessments are required.

A summary of the conclusions and risk mitigation measures for the risk assessments conducted in this document is provided below.

All the general data and EU agreed endpoints mentioned for each active substance assessed in this Section 9 can be found in the respective DAR and EFSA Conclusions published for the EU review of the active substances (references provided in Appendix 1 of this document).

**zRMS comments:**
This report was prepared following renewal of the active substance Trifloxystrobin.
As a result all authorisations of plant protection products containing Trifloxystrobin have to be renewed in order to comply with the new list of endpoints (EFSA 2017).
Formulation Luna Sensation contains two active compounds: Trifloxystrobin and Fluopyram.
Only data on the renewed active substance Trifloxystrobin was evaluated for Post AR review and data on non-renewed active substance –fluopyram was used by zRMS only for the areas of assessments for mammals and aquatic organism where combined risk assessments are required.
In case of combitox risk assessment for birds due to the fact that the endpoint for Trifloxystrobin did not change after renewal it is justified to conclude that also the combined risk assessment of the previous registration remains valid and no additional risk assessment is needed.
Higher tier refinement for Fluopyram which was evaluated in the previous registration of the product Luna Sensation by each co-MSs and their conclusions (i.e. restrictions or mitigations) are still apply for Fluopyram for GAP evaluated at MSs level.

This document is based on the information provided by Applicant and reflects the Appli-cant's opinion. Clarifications and conclusions of the zRMS are presented in the comment-ing boxes Amend-ments/corrections by zRMS are marked in blue.
The zRMS has focused the review on the elements which are crucial for the risk assessment and decision-making; hence, minor errors of no importance for the overall conclusion, or the specific phrasing of the text may not have been commented upon. Not agreed or not relevant information is struck through and shaded for transparency.

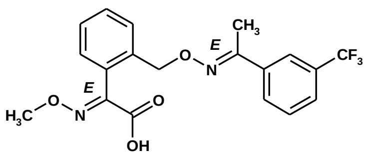
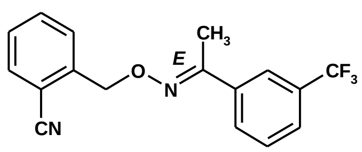
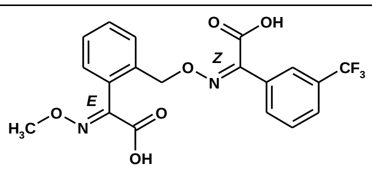
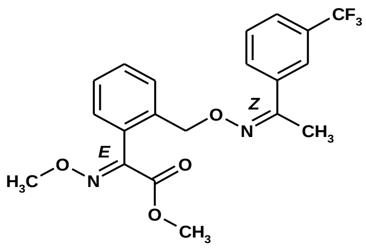
A list of metabolites found in environmental compartments is provided below. The need for conducting a metabolite-specific risk assessment in the context of the evaluation of FLU + TFS SC 500 is indicated in the table.

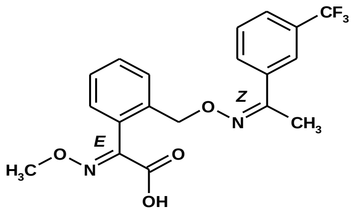
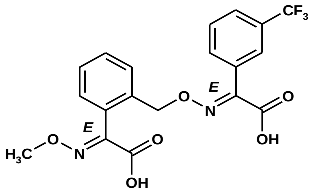
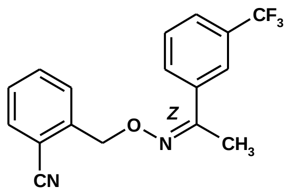
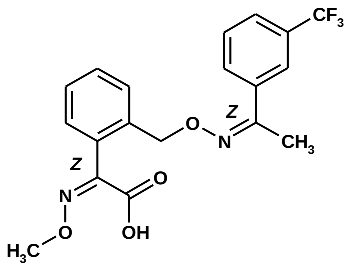
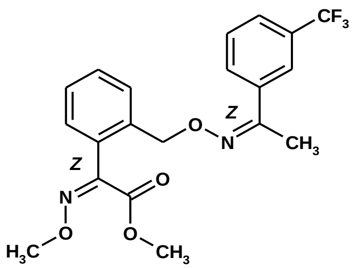
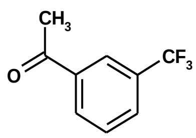
### 9.1.1.1 For the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009, the following guidance is given in the Document SANCO/2010/13170 for products containing two or more active substances:

- "when the 1st substance is renewed- there is no need to evaluate data related to the 2nd substance"
- "once the 2nd substance is renewed- there is no need to evaluate data related to the 1st substance because this has already been performed in the frame of the re-authorisation of the PPP following the renewal of the 1st active substance"
- "Where necessary a combitox assessment should be performed."

In consequence, metabolites of Fluopyram are not considered in the risk assessment as this would be out of scope of SANCO/2010/13170

**Table 9.1-3: Metabolites of trifloxystrobin**

| **Metabolite** | **Molar mass** | **Chemical structure** | **Maximum observed occurrence in compartments** | **Risk assessment required?** |
|---|---|---|---|---|
| CGA 321113 (EE-isomer) | 394.4 g/mole |  | <u>Soil</u>:<br>96.8% (lab)<br>51.2% (field soil studies, surface applied)<br><u>Water/sediment</u>:<br>(100% assumed for PECsw calc.) | Yes, groundwater, soil and aquatic organisms |
| CGA 357276 (E-isomer) | 318.3 g/mole |  | <u>Soil</u>:<br>5.6% (lab)<br>2.3% (field soil studies, incorporated)<br><u>Water/sediment</u>:<br>10.4% (hydrolysis) | Yes, groundwater, soil and aquatic organisms |
| NOA 413161 (ZE-isomer) | 424.3 g/mole |  | <u>Soil</u>:<br>13.6% (lab)<br>5.7% (field soil studies, surface applied)<br><u>Water/sediment</u>: 0% | Yes, groundwater, soil and aquatic organisms |
| CGA 357261 (TFS ZE-isomer) | 408.4 g/mole |  | <u>Soil</u>:<br>15.5% (field soil studies, surface applied)<br><u>Water/sediment</u>:<br>51.5% | Yes, groundwater, soil and aquatic organisms |

| **Metabolite** | **Molar mass** | **Chemical structure** | **Maximum observed occurrence in compartments** | **Risk assessment required?** |
|---|---|---|---|---|
| CGA 373466 (ZE-isomer) | 394.4 g/mole |  | Soil:<br>42.5% (lab)<br>31% (field soil studies, surface applied)<br>Water/sediment:<br>34.7% (photolysis) | Yes, groundwater, soil and aquatic organisms |
| NOA 413163 (EE-isomer) | 424.3 g/mole |  | Soil:<br>6.0% (lab soil photolysis)<br>Water/sediment:<br>0% | Yes, groundwater, soil and aquatic organisms |
| NOA 409480 (Z-isomer) | 318.3 g/mole |  | Soil:<br>9.3% (lab soil photolysis)<br>Water/sediment:<br>0% | Yes, groundwater, soil and aquatic organisms |
| CGA 381318 (ZZ-isomer) | 394.4 g/mole |  | Soil:<br>6.2% (lab soil photolysis)<br>Water/sediment:<br>0% | Yes, groundwater, soil and aquatic organisms |
| CGA 357262 (TFS ZZ-isomer) | 408.4 g/mole |  | Soil: 0%<br>Water/sediment:<br>10.1% (photolysis) | Yes, aquatic organisms |
| CGA 107170 | 188.1 g/mole |  | Soil: 0%<br>Water/sediment:<br>53.8% (photolysis) | Yes, aquatic organisms |

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

Effects on birds

According to the Guidance is given in the Document SANCO/2010/13170 only the renewed mixing partner has to be evaluated for the renewal of authorisations according to article 43 of Regulation (EC) No 1107/2009. A combitox assessment might still be considered. This leaves different opinions and options how to present the risk assessment for birds and thus leads to different conclusions.

The acute and long-term risk assessment for Trifloxystrobin indicates acceptable risk for all registered uses of FLU+TFS SC500. Furthermore, the assessment of the effects of exposure via drinking water and secondary poisoning indicate acceptable risk. Since the endpoint for Trifloxystrobin did not change after re-approval it is justified to conclude that also the combined risk assessment of the previous registration remains valid and no additional risk assessment for Fluopyram is needed.

In case this justification is not acceptable for all member states a single acute and long-term risk assessment for Fluopyram is available to provide TER values for the combined risk assessment. The acute risk assessment for Fluopyram and the combined toxicity assessment results in TER values above the trigger already at the screening step. In the combined long-term risk assessment, Fluopyram is idenditified as risk driver in the second step (risk per fraction). Therefore, no further assessment is necessary for combined toxicity. **The higher tier refinement for Fluopyram was already addressed in the previous registration**. Thus, no further higher tier risk assessment has to be performed and previous conclusions (i.e. restrictions or mitigations) still apply for Fluopyram.
zRMS comments:
Due to the fact that higher tier refinement for Fluopyram was evaluated in the previous registration of the product Luna Sensation by each co-MSs, therefore the previous conclusions (i.e. restrictions or mitigations) still apply for Fluopyram for GAP evaluated at MSs level. The new data for a.s-fluopyram was not considered by zRMS in the current dossier in the context of art. 43 for risk assessment for Trifloxystrobin.
Therefore, since the endpoint for Trifloxystrobin did not change after renewal it is justified to conclude that also the combined risk assessment of the previous registration remains valid and no additional risk assessment for Fluopyram is needed.

In case this justification is not acceptable for all member states refinements for the long-term risk assessment of Fluopyram are included for some generic focal species, especially for omnivorous, insectivorous and herbivorous species. Taking into account field studies and measured $DT_{50}$ in different matrices, acceptable risk, either for fluopyram or for the combined toxicity assessment, for the current use pattern is demonstrated, except for berries (use group D and E). For an acceptable risk it is proposed to restrict the use rate for use groups D and E to one application and, if necessary, to lower the the registered use rate (i.e.1 x 0.6 L product /ha).
zRMS comments:
In reference to not acceptable justification provided by the applicant - the MSs should check the refined parameters for Flupyram previously accepted in their Registration report for Luna Sensation at national level.
The new data for fluopyram was not evaluated by zRMS in the current dossier in the context of art.43 of renewal of TFS risk assessment.

Performed evaluation covers also indoor uses ( walk-in tunnels/ low tunnel shelter).

~~Under these assumptions, it can be concluded that the risk associated with the recommended use of FLU + TFS SC 500 is acceptable for birds.~~

<u>Effects on mammals</u>

The acute risk assessment for both active substances and the combined toxicity assessment results in TER values above the trigger already at the screening step. Long-term TER values need refinements for voles, lagomorph and frugivorous species either for the active substances or due to the combined toxicity assessment.
According to the Guidance given in the Document SANCO/2010/13170 only the renewed mixing partner has to be evaluated for the renewal of authorisations according to article 43 of Regulation (EC) No 1107/2009. A combitox assessment might still be considered. This leaves different opinions and options how to present the risk assessment for mammals and thus leads to different conclusions.

In case the assessment of combined toxicity and the non renewed mixing partner should not be addressed, acceptable risk for the current use pattern is demonstrated when data from field studies, measured DT50 values in monocotyledonous and dicotyledonous for trifloxystrobin is considered - except for small herbivorous mammal (vole) in:

- leafy vegetables (use group A)
- nurseries and rosehip (use group I)
- elderberry and mulberry (use group M)

The TER values for the concerned use groups are just slightly below the trigger of 5 indicating an overall acceptable risk. Since the relevance of the vole scenario, or at least the acceptability of the resulting TER value, deviates among the member states no further refinement may be required.
If this is not acceptable the following GAP adaptations should lead to a TER > 5:

- leafy vegetables (use group A): Reduction to 1 use (1 x 0.8 L product/ha)
- nurseries and rosehip (use group I): Reduction to 1 use (1 x 0.8 L product/ha) or GAP adaptation to BBCH 50-91 (2 x 0.8 L product/ha)
- elderberry and mulberry (use group M): Reduction to 1 use (1 x 0.8 L product/ha) or rate reduction (2 x 0.6 L product /ha)

In case the combined toxicity should be addressed for both compounds, including the risk assessment for Fluopyram, a TER > 5 for the current use pattern is demonstrated when field studies, measured DT50 values in monocotyledonous and dicotyledonous for Trifloxystrobin and Fluopyram is considered, except for small herbivorous mammal (vole) in:

- leafy vegetables (use group A), TER < 5 for TFS, FLU and combined toxicity
- leafy vegetables (use group B), TER < 5 for combined toxicity
- berries (use group D), TER < 5 for combined toxicity
- berries (use group E), TER < 5 for combined toxicity
- strawberries (use group F), TER < 5 for combined toxicity
- nurseries and rosehip (use group I) TER < 5 for TFS, FLU and combined toxicity
- elderberry and mulberry (use group M): TER < 5 for combined toxicity
- elderberry, mulberry (use group N): TER < 5 for combined toxicity

The TER values for the concerned use groups are just slightly below the trigger of 5 indicating an overall acceptable risk. Since the relevance of the vole scenario, or at least the acceptability of the resulting TER value, deviates among the member states no further refinement may be required.
If this is not acceptable the following GAP adaptations should lead to a TER > 5.

- leafy vegetables (use group A): Reduction to 1 use (1 x 0.8 L product/ha)
- berries (use group D): Reduction to 1 use (1 x 0.8 L product/ha)
- berries (use group E): Reduction to 1 use (1 x 0.6 L product/ha)
- strawberries (use group F): Interval adaptation to 14 days
- nurseries and rosehip (use group I): Reduction to 1 use (1 x 0.8 L product/ha)
- elderberry and mulberry (use group M): Reduction to 1 use (1 x 0.8 L product/ha)
- elderberry, mulberry (use group N): Reduction to 1 use (1 x 0.6 L product/ha)

No further adaptation is proposed for the uses in leafy vegetables (use group B) as the TER is < 5 only for mixtox and already very close to the trigger value. Further, regarding the combined toxicity the $TER_{MIX}$ may still be slightly below the trigger of 5. But overall the risk is acceptable.

Based on the obtained results the use of the product in grapes (use group H), celeriac (use group L) and hops (use group R) is considered to be safe already at screening or Tier 1 level for both active substances.

Refined risk assessments are needed for the following generic focal species:

Trifloxystrobin:

- Small herbivorous mammal “vole” in leafy vegetables (use group A), berries (use group D), strawberries (use group F), nurseries and rosehip (use group I), tobacco (use group K), elderberry and mulberry (use group M), flower bulbs (use group O)

Fluopyram:

- Small herbivorous mammal “vole” in leafy vegetables (use group A), beans and peas (use group C), berries (use group D), strawberries (use group F), nurseries and rosehip (use group I), tobacco (use group K), elderberry and mulberry (use group M), flower bulbs (use group O and P.

In case of flupyram the co-MSs should check the refinement options accepted in the previously Registration Report for Luna Sensation for fluopyram to birds..

It should be noted that zRMS in the current dossier for Luna Sensation for non-renewed a.s -flupyram used in combitox risk assessment the refined parameters which were previously accepted by zRMS-NL in the Zonal Registration Report for Luna Sensation, July 2018.
The new data submitted for not rewiewd a.s.- fluopyram was not evaluated by zRMS-PL in the context of art. 43 for the assessment for the a.s.- Trifloxystrobin.

**Overllall conclusion for the risk assessment for <u>only renewed a.s.-TFS for vole.</u>**

The risk assessment for a.s.- TFS shouldd be further refined for vole for the following scenarios:
- Group A, 2 x 200 g a.s/ha, 7 days interval
- Group B, 1 x 200 g a.s./ha, 2 x 150 g a.s/ha with 7-14 d interval, 1 x 200 g a.s./ha
- Group D, 2 x 200 g a.s./ha and **BBCH 10-19** with 7 d and 14 d interval
- Group I, 2 x 200 g a.s./ha and **BBCH 40-49**, 2 x 150 g a.s./ha and BBCH 40-49
- Group J, 1 x200 g a.s./ha and **BBCH 40-49**
- Group K, 1 x 200 g a.s./ha and **BBCH 10-29**
- Group M, 2 x 200 g a.s./ha and **BBCH 10-40**
- Group N, 2 x 150 g a.s./ha and 14 d interval, **BBCH 10-19**

Insufficient information was provided to resolve the long term risk to small herbivorous mammal (vole) from trifloxystrobin. However, the small herbivorous mammal may not be a relevant species to all concerned Member States in the central zone. Individual MS are invited to consider this as part of their national assessment.

**Overllall conclusion for the risk assessment for <u>only renewed a.s.-TFS for frugivorous mammals:</u>**
The risk is considered as acceptable.
**Overllall conclusion for the risk assessment for <u>only renewed a.s.-TFS for lagomorph:</u>**
The risk is considered as acceptable

**Performed evaluation covers also indoor uses ( walk-in tunnels/low tunnel shelter ).**

**Overview of relevant generic focal species per use group with respect to the outcome of the combined toxicity assessment**

| **Use group / Use rate** | **Small herbivorous mammal “vole”** | **Large herbivorous mammal “lagomorph”** | **Small insectivorous mammal “shrew”** | **Small omnivorous mammal “mouse”** | **Frugivorous mammal "dormouse"** |
|---|---|---|---|---|---|
| Leafy vegetables (use group A) 2 × 0.8 L | TERmix =**1.50** | $TER_{mix}$= 5.2 | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 | - |

| **Use group / Use rate** | **Small herbivorous mammal "vole"** | **Large herbivorous mammal "lagomorph"** | **Small insectivorous mammal "shrew"** | **Small omnivorous mammal "mouse"** | **Frugivorous mammal "dormouse"** |
|---|---|---|---|---|---|
| product/ha, 7 days interval | | | 5 | | |
| Leafy vegetables (use group B) 1 × 0.8 L product/ha | Risk envelope: covered with use group A<br><br>TERmix = **2.70** | Risk envelope: covered with use group A | Risk envelope: covered with use group A | Risk envelope: covered with use group A | - |
| Beans, peans (use group C) 2 × 0.8 L product/ha, 7 days interval | TERmix = 5 | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [4] | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 | - |
| Berries (use group D) 2 × 0.8 L product/ha, 7 days interval | TERmix=**2.5** (BBCH 10-19) TERmix=**2.94** (BBCH 20-39)<br><br>TERmix= 4.78 (BBCH>40) ( risk accepted by zRMS) | - | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 | $TER_{MIX}$ = 5.3 [5] |
| Berries (use group E) 2 × 0.6 L product/ha | Risk envelope: covered with use group D<br><br>TERmix = **4.16** (BBCH 10-19) TERmix= 6.25 (BBCH>20) | Risk envelope: covered with use group D | Risk envelope: covered with use group D | Risk envelope: covered with use group D | Risk envelope: covered with use group D |
| Strawberries, blueberries, cranberries (use group F) 2 × 0.8 L product/ha, 7 days interval | TERmix =**3.70** | $TER_{MIX}$ = 7.2 [7]<br>TERmix = 7.69 | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 | - |
| Blueberries, cranberries (use group G) 2 × 0.6 L product/ha, 7 days interval | Risk envelope: covered with use group F, 7 days interval TERmix=6.25 | Risk envelope: covered with use group F, 7 days interval | Risk envelope: covered with use group F, 7 days interval | Risk envelope: covered with use group F, 7 days interval | - |
| Grapes (use group H) 2 × 0.2 L product/ha, 14 days interval | $TER_{MIX}$ = 5.4 [8] | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [8] | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 | - |
| Nurseries, rosehip (use group I) 2 × 0.8 L | TERmix =**1.42** (BBCH<50, 40-49) | - | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 | - |

| Use group / Use rate | Small herbivorous mammal "vole" | Large herbivorous mammal "lagomorph" | Small insectivorous mammal "shrew" | Small omnivorous mammal "mouse" | Frugivorous mammal "dormouse" |
|---|---|---|---|---|---|
| product/ha, 7 days interval | TERmix= 4.76 (BBCH>50) (risk accepted by zRMS) | | 5 | | |
| Nurseries, rosehip (use group J) 1 × 0.8 L product/ha | Risk envelope: covered with use group I<br><br>TERmix=**2.94** **(**BBCH<50, 40-49)<br><br>TERmix=8.47 (BBCH>50) | - | Risk envelope: covered with use group I | Risk envelope: covered with use group I | - |
| Tobacco (use group K) 1 × 0.8 L product/ha | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [10]<br>TERmix=**2.32** (BBCH<30, 10-29)<br><br>TERmix=5.10 (BBCH>30) | - | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 | - |
| Celeriac (use group L) 2 × 0.5 L product/ha, 14 days interval | TERmix=4.90 ( risk accepted by zRMS) | - | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 | - |
| Elderberry, mulberry (use group M) 2 × 0.8 L product/ha, 7 days interval | TERmix= **1.81** (BBCH>10)<br>TERmix= **2.5** (BBCH>20)<br><br>TERmix= 4.78 (BBCH>40) (risk acceptedm by zRMS) | TERmix **=** 7.69 | - | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 | Risk needs further refinement |
| Elderberry, mulberry (use group N) 2 × 0.6 L product/ha, 7 days interval | Risk envelope: covered with use group M<br><br>TERmix= **2.70** (BBCH>10)<br><br>TERmix= **3.57** (BBCH>20)<br><br>TERmix= 7.14 (BBCH>40) | Risk envelope: covered with use group M | - | Risk envelope: covered with use group M | Risk envelope: covered with use group M<br>Risk needs further refinement |
| Flower bulbs | $TER_{LT}$ for both a.s. | - | $TER_{LT}$ for | $TER_{LT}$ for both | - |

| Use group / Use rate | Small herbivorous mammal "vole" | Large herbivorous mammal "lagomorph" | Small insectivorous mammal "shrew" | Small omnivorous mammal "mouse" | Frugivorous mammal "dormouse" |
|---|---|---|---|---|---|
| (use group O)<br>1 × 0.8 L product/ha | > 10, i.e. $TER_{MIX}$ > 5<br>TERmix= 4.35 | | both a.s. > 10, i.e. $TER_{MIX}$ > 5 | a.s. > 10, i.e. $TER_{MIX}$ > 5 | |
| Flower bulbs<br>(use group P)<br>5 × 0.3 L product/ha, 7 days interval | TERmix= 4.34<br>(5 x 0.3L/ha)<br>TERmix=6.25<br>( 2 x 0.3 L/ha) | - | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 | - |
| Hops<br>(use group R)<br>2 × 0.6 L product/ha,<br>14 days interval | TERmix =7.14 | - | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 | - |

The final decision referred to the combined long-term risk to mammals if left at MSs level.
It should be noted that RMS-PL used refined parameters for fluopyram agreed by zRMS –NL for previous Registration Report for Luna Sensation 500 SC, July 2018. No new data provided by the applicant for fluopyram were evealuated by zRMS-PL in the context of art.43 for risk assessmet for renewed a.s. TFS.
We would like to stressed out that if the other MSs are of a diffrent opinion refered to a.s. for fluopyram they can considered it further at National level.

Furthermore, the assessment of the effects of exposure via drinking water and secondary poisoning indicate acceptable risk. Overall, it can be concluded that the risk associated with the recommended use of FLU + TFS SC 500 is acceptable for mammals.

### 9.1.1.3 Effects on aquatic organisms (KCP 10.2)

For all intended uses the trigger value of 1 is not met for all tested species when the risk assessment with the active substance trifloxystrobin is considered. Therefore, a FOCUS Step 4 risk assessment was needed considering mitigation measures which are summarized in the table below.
In the combined toxicity assessment, it is shown that the toxicity of the product is clearly driven by trifloxystrobin. Thus, the aquatic risk assessment for the product is acceptable when mitigation measures are used that derived from the risk assessment for trifloxystrobin.

**Table 9.1-1: Overview of mitigation measures per use group and crop**

| Use group | Crops | Critical use ID | Modelling use | Mitigation options for worst case scenarios |
|---|---|---|---|---|
| X | Asparagus, Garden cress, Flower tubers, Ornamentals, Paeony, Sea lavender<br>(1 × 0.8 L prod./ha BBCH 11-95) | 4, 62, 123, 172, 174, 215 | Field beans I (early/late) | 10 m drift buffer <u>or</u> 75% drift reduction <u>or</u> 5 m drift buffer with 50% drift reduction<br>(D2 ditch/stream, D3 ditch, D4 stream, D6 ditch, R1 stream, R2 stream, R3 stream, R4 stream) |
| Y | Beans, Nurseries<br>(2 × 0.8 L prod./ha, | 19, 169 | Field beans II (early/late) | 10 m drift buffer <u>or</u> 75% drift reduction <u>or</u> 5 m drift buffer with |

| Use group | Crops | Critical use ID | Modelling use | Mitigation options for worst case scenarios |
|---|---|---|---|---|
| | 14 d interval<br>BBCH 19-89) | | | 50% drift reduction<br>(D2 ditch/stream, D3 ditch, D4 stream, D6 ditch, R1 stream, R2 stream, R3 stream)<br>10 m VFS buffer (R4 stream) |
| Z | Asparagus<br>(2 × 0.8 L prod./ha,<br>10 d interval<br>BBCH 23-95) | 1 | Field beans III (early/late) | 10 m drift buffer or 75% drift reduction or 5 m drift buffer with 50% drift reduction<br>(D2 ditch/stream, D3 ditch, D4 stream, D6 ditch, R1 stream, R2 stream, R3 stream, R4 stream) |
| AA | Baby leaf crops, Beans, Garden cress, Strawberries<br>(2 × 0.8 L prod./ha,<br>7 d interval<br>BBCH 40-89) | 5, 7, 60, 239 | Field beans IV (early/late) | 10 m drift buffer or 75% drift reduction or 5 m drift buffer with 50% drift reduction<br>(D2 ditch/stream, D3 ditch, D4 stream, D6 ditch, R1 stream, R2 stream, R3 stream)<br>10 m VFS buffer (R4 stream) |
| AB | Golf courses<br>(2 × 0.5 L prod./ha,<br>14 d interval<br>BBCH 29-33) | 124 | Grass (March, Jun, Sep, Dec) | 10 m drift buffer or 75% drift reduction or 5 m drift buffer with 50% drift reduction<br>(D2 stream) |
| AC | Peas<br>(2 × 0.8 L prod./ha,<br>7 d interval<br>BBCH 59-89) | 183 | Legumes I | 10 m drift buffer or 75% drift reduction or 5 m drift buffer with 50% drift reduction<br>(D3 ditch, D4 stream, D5 stream, D6 ditch, R1 stream, R2 stream, R3 stream, R4 stream) |
| AD | Peas<br>(2 × 0.8 L prod./ha,<br>14 d interval<br>BBCH 59-79) | 178 | Legumes II | 10 m drift buffer or 75% drift reduction or 5 m drift buffer with 50% drift reduction<br>(D3 ditch, D4 stream, D5 stream, D6 ditch, R1 stream, R2 stream, R3 stream, R4 stream) |
| AE | Celeriac<br>(2 × 0.5 L prod./ha,<br>14 d interval<br>BBCH 40-49) | 47 | Sugar beets I (June – November) | 5 m drift buffer or 75% drift reduction<br>(D3 ditch, R3 stream) |
| AF | Chicory, suggar loaf<br>(1 × 0.8 L prod./ha<br>BBCH 13-49) | 49 | Sugar beets II (early, late) | 10 m drift buffer or 75% drift reduction or 5 m drift buffer with 50% drift reduction<br>(D3 ditch, D4 stream, R1 stream, R3 stream) |
| AG | Flower bulbs<br>(1 × 0.8 L prod./ha<br>BBCH 12-91) | 121 | VegBulb I (early, middle, late) | 10 m drift buffer or 90% drift reduction or 5 m drift buffer with 50% drift reduction (D3 ditch, D4 stream, R1 stream, R2 stream, R3 stream)<br>10 m VFS buffer (R4 stream) |
| W | Flower bulbs<br>(5 × 0.3 L prod./ha,<br>7 d interval | 120 | VegBulb II (early, late) | 5 m drift buffer or 50% drift reduction<br>(D3 ditch, D4 stream, D6 ditch, |

| Use group | Crops | Critical use ID | Modelling use | Mitigation options for worst case scenarios |
|---|---|---|---|---|
| | BBCH 12-91) | | | R1 stream, R2 stream, R3 stream, R4 stream) |
| V | Chokeberry, Elderberry *, Tree nursery<br>(2 × 0.8 L prod./ha,<br>7 d interval<br>BBCH 12-91) | 52, 109 *, 242 | Pome and stone fruit (early, late) | 50 m drift buffer <u>or</u> 30 m drift buffer with 75% drift reduction <u>or</u> 20 m drift buffer with 90% drift reduction (D3 ditch, D4 stream, D5 stream, R1 stream, R2 stream, R3 stream, R4 stream) |
| AH | Elderberry *<br>(2 × 0.6 L prod./ha,<br>14 d interval<br>BBCH 15-91) | 110 * | Pome and stone fruit (early, late) | 50 m drift buffer <u>or</u> 30 m drift buffer with 75% drift reduction <u>or</u> 20 m drift buffer with 90% drift reduction (D5 stream, R2 stream, R3 stream) |
| AI | Lamb's lettuce, Lettuce, Rocket salad<br>(2 × 0.8 L prod./ha,<br>7 d interval<br>BBCH 12-49) | 142, 158, 205 | Vegetable leafy (early/late) | 10 m drift buffer <u>or</u> 90% drift reduction <u>or</u> 5 m drift buffer with 50% drift reduction (D3 ditch, D4 stream, R1 stream, R2 stream, R3 stream)<br>10 m VFS buffer (R4 stream) |
| AJ | Endive, Lamb's lettuce, Lettuce, Radicchio, Rocket salad<br>(1 × 0.8 L prod./ha<br>BBCH 12-49) | 113, 143, 151, 189, 206 | Vegetables leafy (early/late) | 10 m drift buffer <u>or</u> 90% drift reduction <u>or</u> 5 m drift buffer with 50% drift reduction (D3 ditch, D4 stream, R1 stream, R2 stream, R3 stream)<br>10 m VFS buffer (R4 stream) |
| AK | Tobacco<br>(1 × 0.8 L prod./ha<br>BBCH 11-39) | 241 | Tobacco | 10 m drift buffer <u>or</u> 75% drift reduction <u>or</u> 5 m drift buffer with 50% drift reduction<br>(R3 stream) |
| AL | Hops<br>(2 × 0.6 L prod./ha,<br>14 d interval<br>BBCH 37-79) | 141 | Hops (early, late) | 30 m drift buffer <u>or</u> 20 m drift buffer with 75% drift reduction <u>or</u> 10 m drift buffer with 90% drift reduction<br>(R1 stream) |
| AM | Blackberry, Blueberry, Cranberry, Currant, Gooseberry, Raspberry (berries)<br>(2 × 0.6 L prod./ha,<br>7 d interval<br>BBCH 15-89) | 24, 35, 53, 79, 128, 194 | Vines I (early, middle, late) | 20 m drift buffer <u>or</u> 10 m drift buffer with 75% drift reduction <u>or</u> 5 m drift buffer with 90% drift reduction (D6 ditch) |
| AN | Blackberry, Blueberry, Cranberry, Currant, Dewberry, Gooseberry, Mulberry, Raspberry, Rosehip, Elderberry * (berries)<br>(2 × 0.8 L prod./ha,<br>7 d interval<br>BBCH 15-89) | 21, 32, 59, 63, 103, 125, 166, 191, 213, 109 * | Vines II (early, middle, late) | 30 m drift buffer <u>or</u> 20 m drift buffer with 50% drift reduction <u>or</u> 10 m drift buffer with 75% drift reduction <u>or</u> 5 m drift buffer with 90% drift reduction (D6 ditch, R2 stream, R3 stream) |
| AO | Blueberry, Cranberry, Currant, Gooseberry, Mulberry, Rosehip, | 44, 58, 75, 136, 168, 212, 110 * | Vines III (early, middle, late) | 20 m drift buffer <u>or</u> 90% drift reduction <u>or</u> 10 m drift buffer with 75% drift reduction (D6 ditch, R2 |

| Use group | Crops | Critical use ID | Modelling use | Mitigation options for worst case scenarios |
|---|---|---|---|---|
| | Elderberry * (berries)<br>(2 × 0.6 L prod./ha,<br>14 d interval<br>BBCH 15-89) | | | stream, R3 stream) |
| AP | Blackberry, Blueberry, Currant, Gooseberry, Raspberry (berries)<br>(2 × 0.8 L prod./ha,<br>14 d interval<br>BBCH 15-89) | 29, 40, 71, 133, 199 | Vines IV (early, middle, late) | 30 m drift buffer <u>or</u> 20 m drift buffer with 50% drift reduction <u>or</u> 10 m drift buffer with 75% drift reduction <u>or</u> 5 m drift buffer with 90% drift reduction (R2 stream, R3 stream) |
| AQ | Blackberry, Dewberry, Raspberry (berries)<br>(2 × 0.6 L prod./ha,<br>21 d interval<br>BBCH 40-69) | 30, 106, 203 | Vines V (late) | 20 m drift buffer <u>or</u> 90% drift reduction <u>or</u> 10 m drift buffer with 75% drift reduction (D6 ditch, R2 stream, R3 stream) |
| AR | Grapes<br>(2 × 0.2 L prod./ha,<br>14 d interval<br>BBCH 15-85) | 140 | Vines VI (early/middle/late) | 10 m drift buffer <u>or</u> 75% drift reduction (R2 stream, R3 stream) |

* <u>Please note</u>: The surrogate crop for modelling for elderberries differs in some member states. In Austria, elderberries belong to orchards whereas in all other member states elderberries are covered by vines. Thus, elderberries are listed in this table with the surrogate crop orchards as well as vines. Thus, the mitigation measures for the use of the product in elderberries vary in different member states.

Performed evaluation covers also indoor uses ( walk-in tunnels/ low tunnel shelter).
The final risk mitifation measures for aquatic organism should be considered at MSs level.

### 9.1.1.4 Effects on bees (KCP 10.3.1)

A safe use to bees can be demonstrated based on the low toxicity of trifloxystrobin and the product FLU+TFS SC 500, the outcome of the tier 1 risk assessment (HQ calculation) ~~and the additional information provided on chronic toxicity to adult honey bees and immature life stages obtained from laboratory and semi-field testing with trifloxystrobin, fluopyram and FLU+TFS SC 500.~~
Performed evaluation covers also indoor uses ( walk-in tunnels/ low tunnel shelter).
According to Reg. 284/2009 the chronic tests for adult bees and larvae should be provided by the applicant.

### 9.1.1.5 A safe use to bees can be demonstrated based on the low toxicity of trifloxystrobin and the product FLU+TFS SC 500, the outcome of the tier 1 risk assessment (HQ calculation) and the additional information provided on chronic toxicity to adult honey bees and immature life stages obtained from laboratory and semi-field testing with trifloxystrobin, fluopyram and FLU+TFS SC 500.

### 9.1.1.6 Effects on arthropods other than bees (KCP 10.3.2)

The risk assessment based on extended laboratory data indicate acceptable in- and off-field risk for *Typhlodromus pyri*, *Aphidius rhopalosiphi* and *Chrysoperla carnea* and acceptable off-field risk for *Orius laevigatus* for all use groups except for use group M (2 × 0.8 L prod./ha in elderberry and mulberry). For the in-field risk for *Orius laevigatus*, a refined risk assessment based on an aged residue study was conducted and showed that a recovery is possible within 21 days after the last application for all use

groups.
Performed evaluation covers also indoor uses ( walk-in tunnels/ low tunnel shelter).

Risk mitigation needed:

- For the use in elderberry and mulberry (2 x 0.8 L product/ha, use group M), a 5 m no-spray buffer zone or 1 m buffer zone +90% drift reduction nozzels to non – crop area is needed for a safe use of the product.

The use of the product in all other use groups is acceptable without risk mitigation measures.

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

The risk assessment demonstrates that the use of FLU + TFS SC 500 on the intended crops is unlikely to result in an unacceptable risk to earthworm, other soil macro- and mesofauna and to the soil microbial activity. Performed evaluation covers also indoor uses ( walk-in tunnels/ low tunnel shelter).

#### 9.1.1.8 Effects on non-target terrestrial plants (KCP 10.6)

The risk assessment demonstrates that the use of FLU + TFS SC 500 on the intended uses is unlikely to result in an unacceptable risk to non-target terrestrial plants if it is applied according to the GAP.
The use of the product in all use groups is acceptable without the use of risk mitigation measures. Performed evaluation covers also indoor uses ( walk-in tunnels/ low tunnel shelter).

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

No further information is available or considered to be necessary.
Performed evaluation covers also indoor uses ( walk-in tunnels/ low tunnel shelter).

### 9.1.2 Grouping of intended uses for risk assessment

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

**Table 9.1-2: Critical use pattern of FLU + TFS SC 500 grouped according to crop**

| **Grouping according to crops and application rates** | | | |
|---|---|---|---|
| **Group** | **Intended uses** | **Relevant use parameters for grouping** | **Relevant parameter or value for sorting** |
| A | Asparagus, Baby leaf crops, Cress (garden), Lamb's lettuce, Lettuce, Rocket salad<br>2 × 0.8 L prod./ha<br>7 d interval, BBCH 12-49<br>Use ID: 1, *60*, *142*, *148, 158, 159, 162, 163, 205, 607* | Crop type: Leafy vegetables | Same application rate and number of applications, 7 days interval in lettuce (use 158) is used as worst case and covers the interval of 10 days in asparagus (use 1) |

| Grouping according to crops and application rates | | | |
|---|---|---|---|
| **Group** | **Intended uses** | **Relevant use parameters for grouping** | **Relevant parameter or value for sorting** |
| B | Asparagus, Chicory (sugar loaf/witloof), Cress (garden), Endive (winter), lettuce, lambs lettuce, radicchio, rocket salad<br>1 × 0.8 L prod./ha<br>BBCH 12-49<br>Use ID: 3, 4, 49, *50*, 62, 113, *114*, 143, *144*, *150*, 151, *152*, *153*, *154*, 189, *190*, 206, *207* | Crop type: Leafy vegetables | Same application rate and number of applications, application rate of 0.6 L product/ha in witloof chicory is covered by the higher application rate |
| C | Beans (broad, field, fresh, with pods, without pods), peas (with pods, without pods, field)<br>2 × 0.8 L/ha<br>7 d interval, BBCH 59-89<br>Use ID: 7, 19, 178, 183 | Crop type: Pulses | Same application rate and number of applications, 7 days interval is used as worst case and covers the interval of 14 days (use ID 19) |
| D | Blackberry, chokeberry (red), currant (black, red, white), dewberry, gooseberry, raspberry<br>2 × 0.8 L prod./ha<br>7 d interval, BBCH 15-89<br>Use ID: 21, *28*, 29, *31*, 52, *54*, 63, *67*, *70*, 71, *76*, *83*, *89*, *96*, *102*, 103, 125, *132*, 133, *137*, 191, *198*, 199, *204* | Crop type: Bush and cane fruit | Same application rate and number of applications, 7 days interval is used as worst case and covers the interval of 14 days |
| E | Blackberry, currant (red, white), dewberry, gooseberry, raspberry<br>2 × 0.6 L prod./ha<br>7 d interval, BBCH 15-89<br>Use ID: 24, *25*, *26*, 30, *68*, 75, 79, *80*, *81*, *93*, *94* 106, 128, *129*, *130*, 136, 194, *195*, *130*, 203 | Crop type: Bush and cane fruit | Same application rate and number of applications, 7 days interval is used as worst case and covers the intervals of 14 days and 21 days |
| F | Strawberry, blueberry, cranberry<br>2 × 0.8 L prod./ha<br>7 d interval, BBCH 15-89<br>Use ID: 32, *39*, 40, *45*, *57*, 59, *228*, *230*, *231*, 239 | Crop type: Strawberries | Same application rate and number of applications, 7 days interval is used as worst case and covers the interval of 14 days |
| G | Blueberry, cranberry<br>2 × 0.6 L prod./ha<br>7 d interval, BBCH 15-89<br>Use ID: 35, *36*, *37*, 44, 53, *53*, *55*, 58 | Crop type: Strawberries | Same application rate and number of applications, 7 days interval is used as worst case and covers the interval of 14 days |
| H | Grape<br>2 × 0.2 L prod./ha<br>14 d interval, BBCH 15-75<br>Use ID: 140 | Crop type: Vineyards | Same application rate, number of applications and application interval in all relevant member states |
| I | Nurseries, rosehip<br>2 × 0.8 L prod./ha<br>7 d interval, BBCH 12-91<br>Use ID: 169, 242, *211*, 212, *213* | Crop type: Ornamentals/nursery | Same application rate and number of applications, 7 days interval is used as worst case and covers the interval of 14 days. Application rate of 0.6 L product/ha is covered by the higher application rate. |

| **Grouping according to crops and application rates** | | | |
|---|---|---|---|
| **Group** | **Intended uses** | **Relevant use parameters for grouping** | **Relevant parameter or value for sorting** |
| J | Ornamentals, paeony, sea lavender, flower tubers<br>1 × 0.8 L prod./ha<br>BBCH 12-91<br>Use ID: 123, 172, 174, 188, 215 | Crop type: Ornamentals/nursery | Same application rate and number of applications in all relevant member states |
| K | Tobacco<br>1 × 0.8 L prod./ha<br>BBCH 11-39<br>Use ID: 241 | Crop type: Maize | -<br>(Relevant in one member state) |
| L | Celeriac<br>2 × 0.5 L prod./ha<br>14 d interval, BBCH 40-49<br>Use ID: 47 | Crop type: Rooting vegetables | Same application rate, number of applications and application interval in all relevant member states |
| M | Elderberry, mulberry<br>2 × 0.8 L prod./ha<br>7 d interval, BBCH 15-89<br>Use ID: *109,111*, *165*, 166 | Crop type: Orchards | Same application rate, number of applications and application interval in all relevant member states |
| N | Elderberry, mulberry<br>2 × 0.6 L prod./ha<br>14 d interval, BBCH 15-89<br>Use ID: *110,* 168 | Crop type: Orchards | Same application rate, number of applications and application interval in all relevant member states |
| O | Flower bulbs<br>1 × 0.8 L prod./ha<br>BBCH 12-91<br>Use ID: 119, 121 | Crop type: Bulbs and onion like crops | Same application rate, number of applications and application interval in all relevant member states |
| P | Flower bulbs<br>5 × 0.3 L prod./ha<br>7 d interval, BBCH 12-91<br>Use ID: 120 | Crop type: Bulbs and onion like crops | Same application rate, number of applications and application interval in all relevant member states |
| R | Hops<br>2 × 0.6 L prod./ha<br>14 d interval, BBCH 37-79<br>Use ID: 141 | Crop type: Hops | -<br>(Relevant in one member state) |
| S | Chicory, endive, lettuce, radicchio, rocket salad<br>2 × 0.8 L prod./ha<br>7 d interval, BBCH 12-49<br>Use ID: 49, 51, 113, 143, *148,* 151, *158*, *159, 162, 163,* 189, 205, 206, 607 | Crop type (FOCUS groundwater): Cabbage | Same application rate, number of applications and application interval in all relevant member states. This use group is relevant for soil organisms and secondary poisoning in birds and mammals. |
| T | Elderberry, chokeberry, tree nursery<br>2 × 0.8 L prod./ha<br>7 d interval, BBCH 12-91<br>Use ID: 52, *109*, 110, *111,* 242, *243* | Crop type (FOCUS groundwater): Apples | Same application rate, number of applications and application interval in all relevant member states. This use group is relevant for soil organisms and secondary poisoning in birds and mammals. |
| U | Flower bulbs<br>5 × 0.3 L prod./ha<br>7 d interval, BBCH 12-91<br>Use ID: 120 | Crop type (FOCUS groundwater): Onions | Same application rate, number of applications and application interval in all relevant member states. This use group is relevant for soil organisms and secondary |

| **Grouping according to crops and application rates** | | | |
|---|---|---|---|
| **Group** | **Intended uses** | **Relevant use parameters for grouping** | **Relevant parameter or value for sorting** |
| | | | poisoning in birds and mammals. |
| V | Chokeberry, elderberry, tree nursery<br>2 × 0.8 L prod./ha<br>7 d interval; BBCH 12-91<br>Use ID: 52, *109*, 110, *111,* 242, *243* | Crop type (FOCUS surface water): Pome and stone fruit | Same application rate, number of applications and application interval in all relevant member states. This use group is relevant for aquatic organisms and secondary poisoning in birds and mammals. |
| W | Flower bulbs<br>5 × 0.3 L prod./ha<br>7 d interval, BBCH 12-91<br>Use ID: 120 | Crop type (FOCUS surface water): VegBulb II | Same application rate, number of applications and application interval in all relevant member states. This use group is relevant for aquatic organisms and secondary poisoning in birds and mammals. |
| X | Asparagus, garden cress, flower tubers, ornamentals, Paeony, Sea lavender<br>1 × 0.8 L prod./ha<br>BBCH 11-95<br>Use ID: 4, 62, 123, 172, 174, 215 | Crop type (FOCUS surface water): Field beans I | Same application rate and number of applications in all relevant member states. This use group is relevant for aquatic organisms. |
| Y | Beans, nurseries<br>2 × 0.8 L prod./ha<br>14 d interval, BBCH 19-89<br>Use ID: 19, 169 | Crop type (FOCUS surface water): Field beans II | Same application rate, number of applications and application interval in all relevant member states. This use group is relevant for aquatic organisms. |
| Z | Asparagus<br>2 × 0.8 L prod./ha<br>10 d interval, BBCH 23-95<br>Use ID: 1 | Crop type (FOCUS surface water): Field beans III | Same application rate, number of applications and application interval in all relevant member states. This use group is relevant for aquatic organisms. |
| AA | Baby leaf crops, beans, garden cress, strawberries<br>2 × 0.8 L prod./ha<br>7 d interval, BBCH 40-89<br>Use ID: 5, 7, *60*, 239 | Crop type (FOCUS surface water): Field beans IV | Same application rate, number of applications and application interval in all relevant member states. This use group is relevant for aquatic organisms. |
| AC | Peas<br>2 × 0.8 L prod./ha<br>7 day interval, BBCH 59-89<br>Use ID: 183 | Crop type (FOCUS surface water): Legumes I | Same application rate, number of applications and application interval in all relevant member states. This use group is relevant for aquatic organisms. |
| AD | Peas<br>2 × 0.8 L prod./ha<br>14 day interval, BBCH 59-79<br>Use ID: 178 | Crop type (FOCUS surface water): Legumes II | Same application rate, number of applications and application interval in all relevant member states. This use group is relevant for aquatic organisms. |
| AE | Celeriac<br>2 × 0.5 L prod./ha<br>14 d interval, BBCH 40-49<br>Use ID: 47 | Crop type (FOCUS surface water): Sugar beets I | Same application rate, number of applications and application interval in all relevant member states. This use group is relevant for aquatic organisms. |

| **Grouping according to crops and application rates** | | | |
|---|---|---|---|
| **Group** | **Intended uses** | **Relevant use parameters for grouping** | **Relevant parameter or value for sorting** |
| AF | Chicory<br>1 × 0.8 L prod./ha<br>BBCH 13-49<br>Use ID: 49 | Crop type (FOCUS surface water): Sugar beets II | Same application rate and number of applications in all relevant member states. This use group is relevant for aquatic organisms. |
| AG | Flower bulbs<br>1 × 0.8 L prod./ha<br>BBCH 12-91<br>Use ID: 121 | Crop type (FOCUS surface water): VegBulb I | Same application rate and number of applications in all relevant member states. This use group is relevant for aquatic organisms. |
| AH | Elderberry<br>2 × 0.6 L prod./ha<br>14 d interval, BBCH 15-91<br>Use ID: 110 | Crop type (FOCUS surface water): Pome and stone fruit | Same application rate, number of applications and application interval in all relevant member states. This use group is relevant for aquatic organisms. |
| AI | Lamb's lettuce, lettuce, rocket salad<br>2 × 0.8 L prod./ha<br>7 d interval, BBCH 12-49<br>Use ID: *142*, *148, 158, 159, 162, 163, 205, 607* | Crop type (FOCUS surface water): Vegetable leafy | Same application rate, number of applications and application interval in all relevant member states. This use group is relevant for aquatic organisms. |
| AJ | Endive, Lamb's lettuce, lettuce, radicchio, rocket salad<br>1 × 0.8 L prod./ha<br>BBCH 12-49<br>Use ID: 113, *114,* 143,*144, 150,* 151, *152, 153, 154,* 189, 206, *207* | Crop type (FOCUS surface water): Vegetables leafy | Same application rate and number of applications in all relevant member states. This use group is relevant for aquatic organisms. |
| AK | Tobacco<br>1 × 0.8 L prod./ha<br>BBCH 11-39<br>Use ID: 241 | Crop type (FOCUS surface water): Tobacco | -<br>(Relevant in one member state) This use group is relevant for aquatic organisms. |
| AL | Hops<br>2 × 0.6 L prod./ha<br>14 d interval, BBCH 37-79<br>Use ID: 141 | Crop type (FOCUS surface water): Hops | -<br>(Relevant in one member state) This use group is relevant for aquatic organisms. |
| AM | Blackberry, blueberry, cranberry, currant, gooseberry, raspberry (berries I)<br>2 × 0.6 L prod./ha<br>7 d interval, BBCH 15-89<br>Use ID: 24, *25, 26*, 35, *36, 37*, 53, *54, 55* , *68,* 79, *80, 81,93, 94* 128, *129, 130,* 194, *195*, *196* | Crop type (FOCUS surface water): Vines I | Same application rate, number of applications and application interval in all relevant member states. This use group is relevant for aquatic organisms. |
| AN | Blackberry, blueberry, cranberry, currant, dewberry, gooseberry, mulberry, raspberry, rosehip (berries II)<br>2 × 0.8 L prod./ha<br>7 d interval, BBCH 15-89<br>Use ID: 21, *22, 23, 28, 31,* 32, *33, 34, 39, 45, 57, 59,* 63, *64, 65, 67,* | Crop type (FOCUS surface water): Vines II | Same application rate, number of applications and application interval in all relevant member states. This use group is relevant for aquatic organisms. |

| Grouping according to crops and application rates | | | |
|---|---|---|---|
| **Group** | **Intended uses** | **Relevant use parameters for grouping** | **Relevant parameter or value for sorting** |
| | *70, 76, 77, 78, 83, 89, 90,91, 96 , 102, 103*, 125, *126, 127, 132, 137, 165, 166*, 191, *192, 193, 198, 213, 609* | | |
| AO | Blueberry, cranberry, currant, gooseberry, mulberry, rosehip (berries III)<br>2 × 0.6 L prod./ha<br>14 d interval, BBCH 15-89<br>Use ID: 44, 58, 75, 136, 168, 212 | Crop type (FOCUS surface water): Vines III | Same application rate, number of applications and application interval in all relevant member states. This use group is relevant for aquatic organisms. |
| AP | Blackberry, blueberry, currant, gooseberry, raspberry (berries IV)<br>2 × 0.8 L prod./ha<br>14 d interval, BBCH 15-89<br>Use ID: 29, 40, *41, 42, 43*, 71, *72, 73, 74, 85, 86, 87, 98, 99, 100*, 133, *135*, 199, *200, 201, 202* | Crop type (FOCUS surface water): Vines IV | Same application rate, number of applications and application interval in all relevant member states. This use group is relevant for aquatic organisms. |
| AQ | Blackberry, dewberry, raspberry (berries V)<br>2 × 0.6 L prod./ha<br>21 d interval, BBCH 40-69<br>Use ID: 30, 106, 203 | Crop type (FOCUS surface water): Vines V | Same application rate, number of applications and application interval in all relevant member states. This use group is relevant for aquatic organisms. |
| AR | Grapes<br>2 × 0.2 L prod./ha<br>14 d interval, BBCH 15-85<br>Use ID: 140 | Crop type (FOCUS surface water): Vines VI | Same application rate, number of applications and application interval in all relevant member states. This use group is relevant for aquatic organisms. |

### 9.1.3 Consideration of metabolites

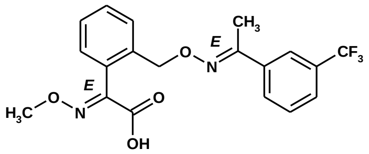
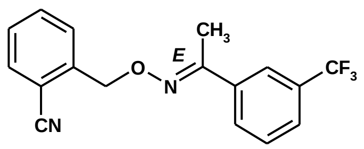
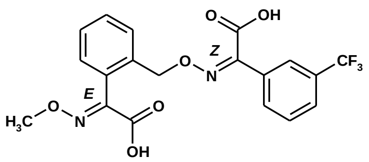
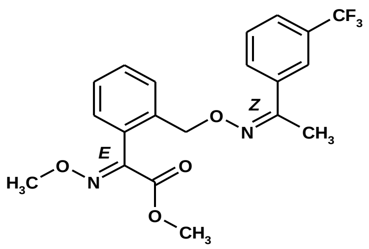
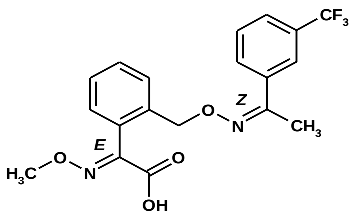
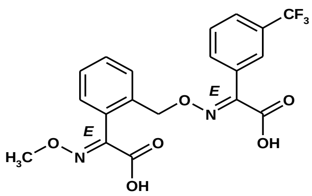
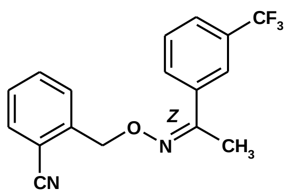
A list of metabolites found in environmental compartments is provided below. The need for conducting a metabolite-specific risk assessment in the context of the evaluation of FLU + TFS SC 500 is indicated in the table.

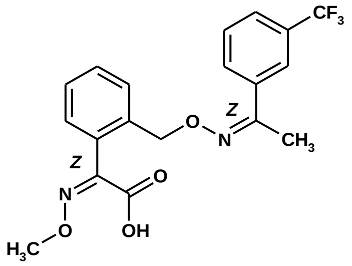
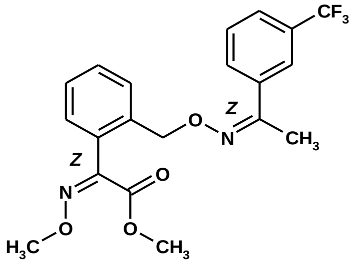
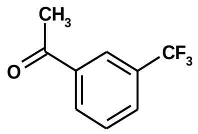
For the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009, the following guidance is given in the Document SANCO/2010/13170 for products containing two or more active substances:

- “when the 1st substance is renewed- there is no need to evaluate data related to the 2nd substance”
- “once the 2nd substance is renewed- there is no need to evaluate data related to the 1st substance because this has already been performed in the frame of the re-authorisation of the PPP following the renewal of the 1st active substance”
- “Where necessary a combitox assessment should be performed.”

In consequence, metabolites of Fluopyram are not considered in the risk assessment as this would be out of scope of SANCO/2010/13170

**Table 9.1-3: Metabolites of trifloxystrobin**

| **Metabolite** | **Molar mass** | **Chemical structure** | **Maximum observed occurrence in compartments** | **Risk assessment required?** |
|---|---|---|---|---|
| CGA 321113 (EE-isomer) | 394.4 g/mole |  | <u>Soil</u>:<br>96.8% (lab)<br>51.2% (field soil studies, surface applied)<br><u>Water/sediment</u>:<br>(100% assumed for PECsw calc.) | Yes, groundwater, soil and aquatic organisms |
| CGA 357276 (E-isomer) | 318.3 g/mole |  | <u>Soil</u>:<br>5.6% (lab)<br>2.3% (field soil studies, incorporated)<br><u>Water/sediment</u>:<br>10.4% (hydrolysis) | Yes, groundwater, soil and aquatic organisms |
| NOA 413161 (ZE-isomer) | 424.3 g/mole |  | <u>Soil</u>:<br>13.6% (lab)<br>5.7% (field soil studies, surface applied)<br><u>Water/sediment</u>: 0% | Yes, groundwater, soil and aquatic organisms |
| CGA 357261 (TFS ZE-isomer) | 408.4 g/mole |  | <u>Soil</u>:<br>15.5% (field soil studies, surface applied)<br><u>Water/sediment</u>:<br>51.5% | Yes, groundwater, soil and aquatic organisms |
| CGA 373466 (ZE-isomer) | 394.4 g/mole |  | <u>Soil</u>:<br>42.5% (lab)<br>31% (field soil studies, surface applied)<br><u>Water/sediment</u>:<br>34.7% (photolysis) | Yes, groundwater, soil and aquatic organisms |
| NOA 413163 (EE-isomer) | 424.3 g/mole |  | <u>Soil</u>:<br>6.0% (lab soil photolysis)<br><u>Water/sediment</u>:<br>0% | Yes, groundwater, soil and aquatic organisms |
| NOA 409480 (Z-isomer) | 318.3 g/mole |  | <u>Soil</u>:<br>9.3% (lab soil photolysis)<br><u>Water/sediment</u>:<br>0% | Yes, groundwater, soil and aquatic organisms |

| **Metabolite** | **Molar mass** | **Chemical structure** | **Maximum observed occurrence in compartments** | **Risk assessment required?** |
|---|---|---|---|---|
| CGA 381318 (ZZ-isomer) | 394.4 g/mole |  | Soil:<br>6.2% (lab soil photolysis)<br>Water/sediment:<br>0% | Yes, groundwater, soil and aquatic organisms |
| CGA 357262 (TFS ZZ-isomer) | 408.4 g/mole |  | Soil: 0%<br>Water/sediment:<br>10.1% (photolysis) | Yes, aquatic organisms |
| CGA 107170 | 188.1 g/mole |  | Soil: 0%<br>Water/sediment:<br>53.8% (photolysis) | Yes, aquatic organisms |

## 9.2 Effects on birds (KCP 10.1.1)

### 9.2.1 Toxicity data

Avian toxicity studies have been carried out with fluopyram and trifloxystrobin. Full details of these studies are provided in the respective EU DAR or RAR and related documents as well as in Appendix 2 of this document when new studies are submitted.

Effects on birds of FLU + TFS SC 500 were not evaluated as part of the EU assessment of any of the active substances. The submission of further data on the formulation FLU + TFS SC 500 is not considered necessary, because studies done with mammals indicate that the formulation is not more toxic than expected based on its active substances (see 9.3.1). For this reason, including animal welfare, no acute oral toxicity study with the preparation was deemed necessary.

The studies and endpoints used for the risk assessment are in line with the endpoints listed for the EU review of the concerned active substances. Justifications for new BCF values for trifloxystrobin metabolites are provided below.

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

| Species | Substance | Exposure System | Results | Reference |
|---|---|---|---|---|
| Bobwhite quail | Trifloxystrobin | Oral, 1d, Acute | $LD_{50}$ > 2000 mg/kg bw | KCA 8.1.1.1/01 RAR & EFSA 2017 [a] |
| Bobwhite quail | Trifloxystrobin | Oral, 1d, Acute | $LD_{50}$/10 = 200 mg/kg bw | - |
| Mallard duck | Trifloxystrobin | Oral, 1d, Acute | $LD_{50}$ > 2250 mg/kg bw | KCA 8.1.1.1/02 RAR & EFSA 2017 [a] |
| Bobwhite quail | Trifloxystrobin | Dietary Reproductive toxicity | NOEL ≥ 31 mg/kg bw/d (320 ppm) | KCA 8.1.1.3/01 RAR & EFSA 2017 [a] |
| Mallard duck | Trifloxystrobin | Dietary Reproductive toxicity | NOEL = 500 ppm | KCA 8.1.1.3/02 RAR & EFSA 2017 [a] |

[a] Refer to Appendix 1 – List of data submitted or referred to and relied on, but already evaluated at EU peer review

**Table 9.2-2: Fluopyram - Endpoints and effect values relevant for the risk assessment for birds**

| Species | Substance | Exposure System | Results | Reference |
|---|---|---|---|---|
| Bobwhite quail | Fluopyram | Oral, 14d, Acute | $LD_{50}$ > 2000 mg a.s./kg bw | EFSA Journal 2013;11(4):3052 |
| Bobwhite quail | Fluopyram | Dietary<br>22 w<br>Reproductive toxicity | NOEL = 4.5 mg a.s./kg bw/d<br>NOAEL = 7.2 mg a.s./kg bw/d*<br>(Effects on offspring survival and body weight) | EFSA Journal 2013;11(4):3052 |

* Population-relevant endpoint can be used for refined risk assessment

### 9.2.1.1 Justification for new endpoints

Trifloxystrobin: The avian reproductive risk assessment endpoint (320 ppm equivalent to 31 mg/kg bw/d) is unbound and is therefore employed as ≥ 31 mg/kg bw/d (no effects observed at the top test level).

Trifloxystrobin metabolites: Fish BCF values for the trifloxystrobin metabolites CGA 357261, CGA 357262, NOA 409480 and CGA 357276 were generated via QSAR because these metabolites have a log $P_{ow}$ >3 and therefore, these metabolites need to be addressed in the secondary poisoning assessment.

### 9.2.2 Risk assessment for spray applications

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

- use group A also covers group B,
- use group D covers use group E,

- use group F covers use group G,
- use group I covers use group J and
- use group M covers use group N (see 9.1.2).

It should be noted that Fluopyram has always been the driver of the risk assessment for birds in the previous registrations. In almost all cases higher tier risk assessments for Fluopyram were needed to justify a safe use. As the chronic and acute endpoints for Trifloxystrobin did not change after the re-approval it might be justified to exclude the risk assessment for birds since the basic assumptions (i.e. guidance, endpoints etc.), which were already included in former risk assessments, remain the same. However, if considered necessary, the risk assessment for birds is included below.

According to the guidance provided in document SANCO/2010/13170 for products containing two or more active substances there is no need to evaluate data related to the non-renewed substance but if necessary, a combitox assessment should be performed. As TER values from the single compound assessment is needed to assess the combined toxicity a risk assessment for Fluopyram and Trifloxystrobin is included below.

In case higher tier refinements are needed, additional information for Fluopyram is provided. Additional data is needed to address latest feed back from member states and guidance for higher tier approaches. It should be noted that the higher tier data is not yet completely EU evaluated but will be submitted for the upcoming re-evaluation of Fluopyram.
Both compounds are completely addressed for reasons of transparency but the option to exclude Fluopyram or Trifloxystrobin from the evaluation, as discussed above, remains. Further justification is provided below and in the overall conclusion.

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

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

**Screening step**

**Table 9.2-3: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in leafy vegetables (use group A)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | | Leafy vegetables | | | |
| **Active substance/product** | | **Trifloxystrobin** | | | |
| **Application rate (kg/ha)** | | 2 × 0.2, 7 days interval | | | |
| **Acute toxicity (mg/kg bw)** | | >2000 | | | |
| **TER criterion** | | 10 | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Leafy vegetables | Small omnivorous bird | 158.8 | 1.4 | 44.5 | >45.0 |
| **Reprod. toxicity (mg/kg bw/d)** | | ≥ 31 | | | |
| **TER criterion** | | 5 | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Leafy vegetables | Small omnivorous bird | 64.8 | 1.6 × 0.53 | 11.0 | **≥ 2.82** |

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 9.2-4: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in leafy vegetables (use group A)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | | Leafy vegetables | | | |
| **Active substance/product** | | **Fluopyram** | | | |
| **Application rate (kg/ha)** | | 2 × 0.2, 7 days interval | | | |
| **Acute toxicity (mg/kg bw)** | | >2000 | | | |
| **TER criterion** | | 10 | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Leafy vegetables | Small omnivorous bird | 158.8 | 1.4 | 44.5 | >45.0 |
| **Reprod. toxicity (mg/kg bw/d)** | | 4.5 | | | |
| **TER criterion** | | 5 | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Leafy vegetables | Small omnivorous bird | 64.8 | 1.6 × 0.53 | 11.0 | **0.409** |

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 9.2-5: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in beans and peas (use group C)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Beans, peas | | | | |
| **Active substance/product** | Trifloxystrobin | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Acute toxicity (mg/kg bw)** | >2000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Pulses | Small omnivorous bird | 158.8 | 1.4 | 44.5 | >45.0 |
| **Reprod. toxicity (mg/kg bw/d)** | ≥ 31 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Pulses | Small omnivorous bird | 64.8 | 1.6 × 0.53 | 11.0 | ≥ **2.82** |

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 9.2-6: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in beans and peas (use group C)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Beans, peas | | | | |
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Acute toxicity (mg/kg bw)** | >2000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Pulses | Small omnivorous bird | 158.8 | 1.4 | 44.5 | >45.0 |
| **Reprod. toxicity (mg/kg bw/d)** | 4.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Pulses | Small omnivorous bird | 64.8 | 1.6 × 0.53 | 11.0 | **0.409** |

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 9.2-7: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in berries (use group D)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Berries | | | | |
| **Active substance/product** | Trifloxystrobin | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Acute toxicity (mg/kg bw)** | >2000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Bush & cane fruit | Small frugivorous bird | 46.3 | 1.4 | 13.0 | >154 |
| **Reprod. toxicity (mg/kg bw/d)** | ≥ 31 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Bush & cane fruit | Small frugivorous bird | 23.0 | 1.6 × 0.53 | 3.90 | ≥ 7.95 |

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 9.2-8: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in berries (use group D)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Berries | | | | |
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Acute toxicity (mg/kg bw)** | >2000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Bush & cane fruit | Small frugivorous bird | 46.3 | 1.4 | 13.0 | >154 |
| **Reprod. toxicity (mg/kg bw/d)** | 4.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Bush & cane fruit | Small frugivorous bird | 23.0 | 1.6 × 0.53 | 3.90 | **1.15** |

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 9.2-9: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in strawberries, blueberries and cranberries (use group F)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Strawberries, blueberries, cranberries | | | | |
| **Active substance/product** | **Trifloxystrobin** | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Acute toxicity (mg/kg bw)** | >2000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Strawberries | Small omnivorous bird | 158.8 | 1.4 | 44.5 | >45.0 |
| **Reprod. toxicity (mg/kg bw/d)** | 31 | | | | |
| **TER criterion** | ≥ 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Strawberries | Small omnivorous bird | 64.8 | 1.6 × 0.53 | 11.0 | ≥ **2.82** |

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 9.2-10: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in strawberries, blueberries and cranberries (use group F)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Strawberries, blueberries, cranberries | | | | |
| **Active substance/product** | **Fluopyram** | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Acute toxicity (mg/kg bw)** | >2000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Strawberries | Small omnivorous bird | 158.8 | 1.4 | 44.5 | >45.0 |
| **Reprod. toxicity (mg/kg bw/d)** | 4.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Strawberries | Small omnivorous bird | 64.8 | 1.6 × 0.53 | 11.0 | **0.409** |

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 9.2-11: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in grapes (use group H)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Grapes | | | | |
| **Active substance/product** | **Trifloxystrobin** | | | | |
| **Application rate (kg/ha)** | 2 × 0.05, 14 days interval | | | | |
| **Acute toxicity (mg/kg bw)** | >2000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Vineyards | Small omnivorous bird | 95.3 | 1.2 | 5.72 | >350 |
| **Reprod. toxicity (mg/kg bw/d)** | ≥ 31 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Vineyards | Small omnivorous bird | 38.9 | 1.4 × 0.53 | 1.44 | ≥ 21.5 |

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

**Table 9.2-12: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in grapes (use group H)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Grapes | | | | |
| **Active substance/product** | **Fluopyram** | | | | |
| **Application rate (kg/ha)** | 2 × 0.05, 14 days interval | | | | |
| **Acute toxicity (mg/kg bw)** | >2000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Vineyards | Small omnivorous bird | 95.3 | 1.2 | 5.72 | >350 |
| **Reprod. toxicity (mg/kg bw/d)** | 4.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Vineyards | Small omnivorous bird | 38.9 | 1.4 × 0.53 | 1.44 | **3.12** |

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 9.2-13: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in nurseries and rosehip (use group I)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Nurseries, rosehip | | | | |
| **Active substance/product** | **Trifloxystrobin** | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Acute toxicity (mg/kg bw)** | >2000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Ornamentals/nursery | Small insectivorous bird | 46.8 | 1.4 | 13.1 | >153 |
| **Reprod. toxicity (mg/kg bw/d)** | ≥ 31 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Ornamentals/nursery | Small insectivorous bird | 18.2 | 1.6 × 0.53 | 3.09 | ≥ 10.0 |

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 9.2-14: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in nurseries and rosehip (use group I)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Nurseries, rosehip | | | | |
| **Active substance/product** | **Fluopyram** | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Acute toxicity (mg/kg bw)** | >2000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Ornamentals/nursery | Small insectivorous bird | 46.8 | 1.4 | 13.1 | >153 |
| **Reprod. toxicity (mg/kg bw/d)** | 4.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Ornamentals/nursery | Small insectivorous bird | 18.2 | 1.6 × 0.53 | 3.09 | **1.46** |

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 9.2-15: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in tobacco (use group K)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Tobacco | | | | |
| **Active substance/product** | **Trifloxystrobin** | | | | |
| **Application rate (kg/ha)** | 1 × 0.2 | | | | |
| **Acute toxicity (mg/kg bw)** | >2000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Maize | Small omnivorous bird | 158.8 | 1.0 | 31.8 | >63.0 |
| **Reprod. toxicity (mg/kg bw/d)** | ≥ 31 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Maize | Small omnivorous bird | 64.8 | 1.0 × 0.53 | 6.87 | ≥ **4.51** |

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 9.2-16: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in tobacco (use group K)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Tobacco | | | | |
| **Active substance/product** | **Fluopyram** | | | | |
| **Application rate (kg/ha)** | 1 × 0.2 | | | | |
| **Acute toxicity (mg/kg bw)** | >2000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Maize | Small omnivorous bird | 158.8 | 1.0 | 31.8 | >63.0 |
| **Reprod. toxicity (mg/kg bw/d)** | 4.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Maize | Small omnivorous bird | 64.8 | 1.0 × 0.53 | 6.87 | **0.655** |

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 9.2-17: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in celeriac (use group L)**

| **Intended use** | Celeriac | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | **Trifloxystrobin** | | | | |
| **Application rate (kg/ha)** | 2 × 0.125, 14 days interval | | | | |
| **Acute toxicity (mg/kg bw)** | >2000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Root & stem vegetables | Small omnivorous bird | 158.8 | 1.2 | 23.8 | >84.0 |
| **Reprod. toxicity (mg/kg bw/d)** | ≥ 31 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Root & stem vegetables | Small omnivorous bird | 64.8 | 1.4 × 0.53 | 6.01 | ≥ 5.16 |

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 9.2-18: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in celeriac (use group L)**

| **Intended use** | Celeriac | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | **Fluopyram** | | | | |
| **Application rate (kg/ha)** | 2 × 0.125, 14 days interval | | | | |
| **Acute toxicity (mg/kg bw)** | >2000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Root & stem vegetables | Small omnivorous bird | 158.8 | 1.2 | 23.8 | >84.0 |
| **Reprod. toxicity (mg/kg bw/d)** | 4.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Root & stem vegetables | Small omnivorous bird | 64.8 | 1.4 × 0.53 | 6.01 | **0.749** |

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 9.2-19: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in elderberry and mulberry (use group M)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Elderberry, mulberry | | | | |
| **Active substance/product** | **Trifloxystrobin** | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Acute toxicity (mg/kg bw)** | >2000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Orchards | Small insectivorous bird | 46.8 | 1.4 | 13.1 | >153 |
| **Reprod. toxicity (mg/kg bw/d)** | ≥ 31 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Orchards | Small insectivorous bird | 18.2 | 1.6 × 0.53 | 3.09 | ≥ 10.0 |

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 9.2-20: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in elderberry and mulberry (use group M)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Elderberry, mulberry | | | | |
| **Active substance/product** | **Fluopyram** | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Acute toxicity (mg/kg bw)** | >2000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Orchards | Small insectivorous bird | 46.8 | 1.4 | 13.1 | >153 |
| **Reprod. toxicity (mg/kg bw/d)** | 4.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Orchards | Small insectivorous bird | 18.2 | 1.6 × 0.53 | 3.09 | **1.46** |

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 9.2-21: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in flower bulbs (use group O)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Flower bulbs | | | | |
| **Active substance/product** | **Trifloxystrobin** | | | | |
| **Application rate (kg/ha)** | 1 × 0.2 | | | | |
| **Acute toxicity (mg/kg bw)** | >2000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Bulbs & onion like crops | Small omnivorous bird | 158.8 | 1.0 | 31.8 | >63.0 |
| **Reprod. toxicity (mg/kg bw/d)** | ≥ 31 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Bulbs & onion like crops | Small omnivorous bird | 64.8 | 1.0 × 0.53 | 6.87 | ≥ **4.51** |

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 9.2-22: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in flower bulbs (use group O)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Flower bulbs | | | | |
| **Active substance/product** | **Fluopyram** | | | | |
| **Application rate (kg/ha)** | 1 × 0.2 | | | | |
| **Acute toxicity (mg/kg bw)** | >2000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Bulbs & onion like crops | Small omnivorous bird | 158.8 | 1.0 | 31.8 | >63.0 |
| **Reprod. toxicity (mg/kg bw/d)** | 4.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Bulbs & onion like crops | Small omnivorous bird | 64.8 | 1.0 × 0.53 | 6.87 | **0.655** |

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 9.2-23: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in flower bulbs (use group P)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Flower bulbs | | | | |
| **Active substance/product** | **Trifloxystrobin** | | | | |
| **Application rate (kg/ha)** | 5 × 0.075, 7 days interval | | | | |
| **Acute toxicity (mg/kg bw)** | >2000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Bulbs & onion like crops | Small omnivorous bird | 158.8 | 1.9 | 22.6 | >88.4 |
| **Reprod. toxicity (mg/kg bw/d)** | ≥ 31 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Bulbs & onion like crops | Small omnivorous bird | 64.8 | 2.4 × 0.53 | 6.18 | ≥ 5.01 |

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 9.2-24: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in flower bulbs (use group P)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Flower bulbs | | | | |
| **Active substance/product** | **Fluopyram** | | | | |
| **Application rate (kg/ha)** | 5 × 0.075, 7 days interval | | | | |
| **Acute toxicity (mg/kg bw)** | >2000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Bulbs & onion like crops | Small omnivorous bird | 158.8 | 1.9 | 22.6 | >88.4 |
| **Reprod. toxicity (mg/kg bw/d)** | 4.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Bulbs & onion like crops | Small omnivorous bird | 64.8 | 2.4 × 0.53 | 6.18 | **0.728** |

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 9.2-25: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in golf courses (use group Q)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | | Golf courses | | | |
| **Active substance/product** | | **Trifloxystrobin** | | | |
| **Application rate (kg/ha)** | | 2 × 0.125, 14 days interval | | | |
| **Acute toxicity (mg/kg bw)** | | >2000 | | | |
| **TER criterion** | | 10 | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Grassland | Large herbivorous bird | 30.5 | 1.2 | 4.58 | >437 |
| **Reprod. toxicity (mg/kg bw/d)** | | ≥ 31 | | | |
| **TER criterion** | | 5 | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Grassland | Large herbivorous bird | 16.2 | 1.4 × 0.53 | 1.50 | ≥ 20.6 |

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 9.2-26: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in golf courses (use group Q)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | | Golf courses | | | |
| **Active substance/product** | | **Fluopyram** | | | |
| **Application rate (kg/ha)** | | 2 × 0.125, 14 days interval | | | |
| **Acute toxicity (mg/kg bw)** | | >2000 | | | |
| **TER criterion** | | 10 | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Grassland | Large herbivorous bird | 30.5 | 1.2 | 4.58 | >437 |
| **Reprod. toxicity (mg/kg bw/d)** | | 4.5 | | | |
| **TER criterion** | | 5 | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Grassland | Large herbivorous bird | 16.2 | 1.4 × 0.53 | 1.50 | **2.99** |

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 9.2-27: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in hops (use group R)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Hops | | | | |
| **Active substance/product** | **Trifloxystrobin** | | | | |
| **Application rate (kg/ha)** | 2 × 0.15, 14 days interval | | | | |
| **Acute toxicity (mg/kg bw)** | >2000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Hops | Small granivorous bird | 24.7 | 1.2 | 4.45 | >450 |
| **Reprod. toxicity (mg/kg bw/d)** | ≥ 31 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Hops | Small granivorous bird | 11.4 | 1.4 × 0.53 | 1.27 | ≥ 24.4 |

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 9.2-28: Screening assessment of the acute and long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in hops (use group R)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Hops | | | | |
| **Active substance/product** | **Fluopyram** | | | | |
| **Application rate (kg/ha)** | 2 × 0.15, 14 days interval | | | | |
| **Acute toxicity (mg/kg bw)** | >2000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Hops | Small granivorous bird | 24.7 | 1.2 | 4.45 | >450 |
| **Reprod. toxicity (mg/kg bw/d)** | 4.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Hops | Small granivorous bird | 11.4 | 1.4 × 0.53 | 1.27 | **3.55** |

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.

The acute risk assessment for all crop groups passes the risk assessment already at the screening step whereas for the long-term exposure, a Tier 1 risk assessment is needed.

### Tier 1 (long-term)

**Table 9.2-29: First-tier assessment of the long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in leafy vegetables (use group A)**

| **Intended use** | Leafy vegetables | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | **Trifloxystrobin** | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | ≥ 31 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Leafy vegetables BBCH 10–49 | Small granivorous bird “finch” | 12.6 | 1.6 × 0.53 | 2.14 | ≥ 14.5 |
| Leafy vegetables BBCH 10–49 | Small omnivorous bird “lark” | 10.9 | 1.6 × 0.53 | 1.85 | ≥ 16.8 |
| Leafy vegetables Leaf development BBCH 10-19 | Medium herbivorous/granivorous bird “pigeon” | 22.7 | 1.6 × 0.53 | 3.85 | ≥ 8.05 |
| Leafy vegetables BBCH 10–19 | Small insectivorous bird “wagtail” | 11.3 | 1.6 × 0.53 | 1.92 | ≥ 16.2 |

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 9.2-30: First-tier assessment of the long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in leafy vegetables (use group A)**

| **Intended use** | Leafy vegetables | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | **Fluopyram** | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 4.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Leafy vegetables BBCH 10–49 | Small granivorous bird “finch” | 12.6 | 1.6 × 0.53 | 2.14 | **2.11** |
| Leafy vegetables BBCH 10–49 | Small omnivorous bird “lark” | 10.9 | 1.6 × 0.53 | 1.85 | **2.43** |
| Leafy vegetables Leaf development BBCH 10-19 | Medium herbivorous/granivorous bird “pigeon” | 22.7 | 1.6 × 0.53 | 3.85 | **1.17** |
| Leafy vegetables BBCH 10–19 | Small insectivorous bird “wagtail” | 11.3 | 1.6 × 0.53 | 1.92 | **2.35** |

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.

**Combined toxicity for birds Tier 1 –Group A**

| **Crop scenario Growth stage** | **Generic focal species** | **$TER_{LT}$ Trifloxystrobin** | **$TER_{lt}$ Flupyram** | **TERmix** |
|---|---|---|---|---|
| Leafy vegetables BBCH 10–49 | Small granivorous bird “finch” | ≥ 14.5 | **2.11** | **1.85** |
| Leafy vegetables BBCH 10–49 | Small omnivorous bird “lark” | ≥ 16.8 | **2.43** | **2.12** |
| Leafy vegetables Leaf development BBCH 10-19 | Medium herbivorous/granivorous bird “pigeon” | ≥ 8.05 | **1.17** | **1.03** |
| Leafy vegetables BBCH 10–19 | Small insectivorous bird “wagtail” | ≥ 16.2 | **2.35** | **2.08** |

Based on Tier 1 the $TER_{LT}$ values for Flupyram are below trigger of 5 indicating needs for further refinement for max application dose of 2 x 200 g a.s./ha for leafy crops for at BBCH 40-49.
The combitox risk assessment needs further refinement for max application dose of 2 x 200 g a.s./ha for leafy crops for all species.

**Table 9.2-31: First-tier assessment of the long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in beans and peas (use group C)**

| **Intended use** | Beans, peas | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | **Trifloxystrobin** | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | ≥ 31 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Pulses BBCH ≥ 50 | Small granivorous bird “finch” | 3.4 | 1.6 × 0.53 | 0.577 | ≥ 53.8 |
| Pulses BBCH ≥ 50 | Small omnivorous bird “lark” | 3.3 | 1.6 × 0.53 | 0.560 | ≥ 55.4 |
| Pulses BBCH ≥ 20 | Small insectivorous bird “wagtail” | 9.7 | 1.6 × 0.53 | 1.65 | ≥ 18.8 |

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 9.2-32: First-tier assessment of the long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in beans and peas (use group C)**

| **Intended use** | Beans, peas | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | **Fluopyram** | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 4.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Pulses BBCH ≥ 50 | Small granivorous bird “finch” | 3.4 | 1.6 × 0.53 | 0.577 | 7.80 |
| Pulses BBCH ≥ 50 | Small omnivorous bird “lark” | 3.3 | 1.6 × 0.53 | 0.560 | 8.04 |
| Pulses BBCH ≥ 20 | Small insectivorous bird “wagtail” | 9.7 | 1.6 × 0.53 | 1.65 | **2.74** |

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.

**Combined toxicity for birds Tier 1 –Group C**

| Crop scenario Growth stage | Generic focal species | $TER_{LT}$ Trifloxystrobin | $TER_{lt}$ Flupyram | TERmix |
|---|---|---|---|---|
| Pulses BBCH ≥ 50 | Small granivorous bird “finch” | ≥ 53.8 | 7.80 | 6.85 |
| Pulses BBCH ≥ 50 | Small omnivorous bird “lark” | ≥ 55.4 | 8.04 | 7.04 |
| Pulses BBCH ≥ 20 | Small insectivorous bird “wagtail” | ≥ 18.8 | **2.74** | **2.4** |

Based on Tier 1 the $TER_{LT}$ values for Flupyram are below trigger of 5 indicating needs for further refinement for max application dose of 2 x 200 g a.s./ha for pulses, BBCH >20 for wagtail.
The combitox risk assessment needs further refinement for max application dose of 2 x 200 g a.s./ha for pulses for wagtail , BBCH>20.

**Table 9.2-33: First-tier assessment of the long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in berries (use group D)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Berries | | | | |
| **Active substance/product** | **Trifloxystrobin** | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | ≥ 31 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Bush & cane fruit Fruit stage BBCH 71-79 currants | Frugivorous bird “blackcap” | 23.0 | 1.6 × 0.53 | 3.90 | ≥ 7.95 |
| Bush & cane fruit Whole season BBCH 00-79 Currants | Small insectivorous bird “warbler” | 20.3 | 1.6 × 0.53 | 3.44 | ≥ 9.00 |

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 9.2-34: First-tier assessment of the long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in berries (use group D)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Berries | | | | |
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 4.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Bush & cane fruit Fruit stage BBCH 71- | Frugivorous bird “blackcap” | 23.0 | 1.6 × 0.53 | 3.90 | **1.15** |

| | | | | | |
|---|---|---|---|---|---|
| 79 currants | | | | | |
| Bush & cane fruit Whole season BBCH 00-79 Currants | Small insectivorous bird "warbler" | 20.3 | 1.6 × 0.53 | 3.44 | **1.31** |

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.

**Combined toxicity for birds Tier 1 –Group D**

| Crop scenario Growth stage | Generic focal species | $TER_{LT}$ Trifloxystrobin | $TER_{lt}$ Flupyram | TERmix |
|---|---|---|---|---|
| Bush & cane fruit Fruit stage BBCH 71-79 currants | Frugivorous bird "blackcap" | ≥ 7.95 | **1.15** | **1.01** |
| Bush & cane fruit Whole season BBCH 00-79 Currants | Small insectivorous bird "warbler" | ≥ 9.00 | **1.31** | **1.15** |

Based on Tier 1 the $TER_{LT}$ values for Flupyram are below trigger of 5 indicating needs for further refinement for max application dose of 2 x 200 g a.s./ha for Bush and cane fruits
The combitox risk assessment needs further refinement for max application dose of 2 x 200 g a.s./ha for Bush and cane fruits.

**Table 9.2-35: First-tier assessment of the long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in strawberries, blueberries and cranberries (use group F)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Strawberries, blueberries, cranberries | | | | |
| **Active substance/product** | **Trifloxystrobin** | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | ≥ 31 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Strawberries BBCH 10–39 | Small omnivorous bird "lark" | 10.9 | 1.6 × 0.53 | 1.85 | ≥ 16.8 |
| Strawberries Late (flowering/development of fruit/maturity of fruit) BBCH 61-89 | Frugivorous bird "starling" | 13.4 | 1.6 × 0.53 | 2.27 | ≥ 13.6 |

| | | | | | |
|---|---|---|---|---|---|
| Strawberries<br>BBCH 10–19 | Small insectivorous bird "wagtail" | 11.3 | 1.6 × 0.53 | 1.92 | ≥ 16.2 |

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 9.2-36: First-tier assessment of the long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in strawberries, blueberries and cranberries (use group F)**

| **Intended use** | Strawberries, blueberries, cranberries | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 4.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario<br>Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Strawberries<br>BBCH 10–39 | Small omnivorous bird "lark" | 10.9 | 1.6 × 0.53 | 1.85 | **2.43** |
| Strawberries<br>Late (flowering/development of fruit/maturity of fruit) BBCH 61-89 | Frugivorous bird "starling" | 13.4 | 1.6 × 0.53 | 2.27 | **1.98** |
| Strawberries<br>BBCH 10–19 | Small insectivorous bird "wagtail" | 11.3 | 1.6 × 0.53 | 1.92 | **2.35** |

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

**Combined toxicity for birds Tier 1 –Group F**

| **Crop scenario<br>Growth stage** | **Generic focal species** | **$TER_{LT}$ Trifloxystrobin** | **$TER_{lt}$ Flupyram** | **TERmix** |
|---|---|---|---|---|
| Strawberries<br>BBCH 10–39 | Small omnivorous bird "lark" | ≥ 16.8 | **2.43** | **2.12** |
| Strawberries<br>Late (flowering/development of fruit/maturity of fruit) BBCH 61-89 | Frugivorous bird "starling" | ≥ 13.6 | **1.98** | **1.72** |
| Strawberries<br>BBCH 10–19 | Small insectivorous bird "wagtail" | ≥ 16.2 | **2.35** | **2.08** |

Based on Tier 1 the $TER_{LT}$ values for Flupyram are below trigger of 5 indicating needs for further refinement for max application dose of 2 x 200 g a.s./ha for strawberries, blueberries, cranberries
The combitox risk assessment needs further refinement for max application dose of 2 x 200 g a.s./ha for strawberries, blueberries, cranberries.

**Table 9.2-37: First-tier assessment of the long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in grapes (use group H)**

| **Intended use** | Grapes | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | **Trifloxystrobin** | | | | |
| **Application rate (kg/ha)** | 2 × 0.05, 14 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | ≥ 31 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Vineyards BBCH 10–19 | Small insectivorous species “redstart” | 11.5 | 1.4 × 0.53 | 0.427 | ≥ 72.7 |
| Vineyards BBCH 10–19 | Small granivorous bird "finch" | 6.9 | 1.4 × 0.53 | 0.256 | ≥ 121 |
| Vineyards Ripening | Frugivorous bird “thrush/starling” | 14.4 | 1.4 × 0.53 | 0.534 | ≥ 58.0 |
| Vineyards BBCH 10–19 | Small omnivorous bird “lark” | 6.5 | 1.4 × 0.53 | 0.241 | ≥ 129 |

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 9.2-38: First-tier assessment of the long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in grapes (use group H)**

| **Intended use** | Grapes | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (kg/ha)** | 2 × 0.05, 14 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 4.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Vineyards BBCH 10–19 | Small insectivorous species “redstart” | 11.5 | 1.4 × 0.53 | 0.427 | 10.5 |
| Vineyards BBCH 10–19 | Small granivorous bird "finch" | 6.9 | 1.4 × 0.53 | 0.256 | 17.6 |
| Vineyards Ripening | Frugivorous bird “thrush/starling” | 14.4 | 1.4 × 0.53 | 0.534 | 8.42 |
| Vineyards | Small omnivorous bird “lark” | 6.5 | 1.4 × 0.53 | 0.241 | 18.7 |

| | | | | | |
|---|---|---|---|---|---|
| BBCH 10–19 | | | | | |

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.

**Combined toxicity for birds Tier 1 –Group H**

| **Crop scenario Growth stage** | **Generic focal species** | **$TER_{LT}$ Trifloxystrobin** | **$TER_{lt}$ Flupyram** | **TERmix** |
|---|---|---|---|---|
| Vineyards BBCH 10–19 | Small insectivorous species “redstart” | ≥ 72.7 | 10.5 | 9.25 |
| Vineyards BBCH 10–19 | Small granivorous bird "finch" | ≥ 121 | 17.6 | 16.66 |
| Vineyards Ripening | Frugivorous bird “thrush/starling” | ≥ 58.0 | 8.42 | 7.40 |
| Vineyards BBCH 10–19 | Small omnivorous bird “lark” | ≥ 129 | 18.7 | 16.66 |

Based on Tier 1 the $TER_{LT}$ values for both a.s. are above the trigger of 5 indicating needs for further refinement for max application dose of 2 x 0.05 kg a.s./ha for grapes.
The combitox risk for max application dose of 2 x 0.05 kg a.s./ha is considered acceptable.

**Table 9.2-39: First-tier assessment of the long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in nurseries and rosehip (use group I)**

| **Intended use** | Nurseries, rosehip | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | **Trifloxystrobin** | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | ≥ 31 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Ornamentals/nursery Application to plant | Small insectivorous bird “tit” | 18.2 | 1.6 × 0.53 | 3.09 | ≥ 10.0 |
| Ornamentals/nursery Application to plant – exposure to underlying ground | Small insectivorous/worm feeding species “thrush” | 2.7 | 1.6 × 0.53 | 0.458 | ≥ 67.7 |

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.

**Table 9.2-40: First-tier assessment of the long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in nurseries and rosehip (use group I)**

| **Intended use** | Nurseries, rosehip | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 4.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Ornamentals/nursery Application to plant | Small insectivorous bird “tit” | 18.2 | 1.6 × 0.53 | 3.09 | **1.46** |
| Ornamentals/nursery Application to plant – exposure to underlying ground | Small insectivorous/worm feeding species “thrush” | 2.7 | 1.6 × 0.53 | 0.458 | 9.83 |

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.

**Combined toxicity for birds Tier 1 –Group I**

| **Crop scenario Growth stage** | **Generic focal species** | **$TER_{LT}$ Trifloxystrobin** | **$TER_{lt}$ Flupyram** | **TERmix** |
|---|---|---|---|---|
| Ornamentals/nursery Application to plant | Small insectivorous bird “tit” | ≥ 10.0 | **1.46** | **1.28** |
| Ornamentals/nursery Application to plant – exposure to underlying ground | Small insectivorous/worm feeding species “thrush” | ≥ 67.7 | 9.83 | 8.7 |

Based on Tier 1 the $TER_{LT}$ values for fluopyram and combitox assessment is below the trigger of 5 indicating needs for further refinement for max application dose of 2 x 200 g a.s./ha for Tit for use in Ornamentals/nursery Application to plant

**Table 9.2-41: First-tier assessment of the long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in tobacco (use group K)**

| **Intended use** | Tobacco | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | **Trifloxystrobin** | | | | |
| **Application rate (kg/ha)** | 1 × 0.2 | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | ≥ 31 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Maize BBCH 10–29 | Medium granivorous bird “gamebird” | 3.0 | 1.0 × 0.53 | 0.318 | ≥ 97.5 |
| Maize Leaf development BBCH 10-19 | Small insectivorous/worm feeding species “thrush” | 5.7 | 1.0 × 0.53 | 0.604 | ≥ 51.3 |
| Maize | Small omnivorous bird “lark” | 10.9 | 1.0 × 0.53 | 1.16 | ≥ 26.8 |

| | | | | | |
|---|---|---|---|---|---|
| BBCH 10–29 | | | | | |
| Maize<br>BBCH 10–29 | Medium herbivorous/granivorous bird "pigeon" | 22.7 | 1.0 × 0.53 | 2.41 | ≥ 12.9 |
| Maize<br>BBCH 10–19 | Small insectivorous bird "wagtail" | 11.3 | 1.0 × 0.53 | 1.20 | ≥ 25.9 |

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 9.2-42: First-tier assessment of the long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in tobacco (use group K)**

| **Intended use** | Tobacco | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (kg/ha)** | 1 × 0.2 | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 4.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Maize<br>BBCH 10–29 | Medium granivorous bird "gamebird" | 3.0 | 1.0 × 0.53 | 0.318 | 14.2 |
| Maize<br>Leaf development BBCH 10-19 | Small insectivorous/worm feeding species "thrush" | 5.7 | 1.0 × 0.53 | 0.604 | 7.45 |
| Maize<br>BBCH 10–29 | Small omnivorous bird "lark" | 10.9 | 1.0 × 0.53 | 1.16 | **3.89** |
| Maize<br>BBCH 10–29 | Medium herbivorous/granivorous bird "pigeon" | 22.7 | 1.0 × 0.53 | 2.41 | **1.87** |
| Maize<br>BBCH 10–19 | Small insectivorous bird "wagtail" | 11.3 | 1.0 × 0.53 | 1.20 | **3.76** |

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.

**Combined toxicity for birds Tier 1 –Group K**

| **Crop scenario Growth stage** | **Generic focal species** | **$TER_{LT}$ Trifloxystrobin** | **$TER_{lt}$ Flupyram** | **TERmix** |
|---|---|---|---|---|
| Maize<br>BBCH 10–29 | Medium granivorous bird "gamebird" | ≥ 97.5 | 14.2 | 12.5 |
| Maize<br>Leaf development BBCH 10-19 | Small insectivorous/worm feeding species "thrush" | ≥ 51.3 | 7.45 | 6.66 |
| Maize<br>BBCH 10–29 | Small omnivorous bird "lark" | ≥ 26.8 | **3.89** | **3.44** |
| Maize<br>BBCH 10–29 | Medium herbivorous/granivorous bird "pigeon" | ≥ 12.9 | **1.87** | **1.63** |
| Maize<br>BBCH 10–19 | Small insectivorous bird "wagtail" | ≥ 25.9 | **3.76** | **3.28** |

Based on Tier 1 the $TER_{LT}$ values for fluopyram and combitox assessment is below the trigger of 5 indicating needs for further refinement for max application dose of 2 x 200 g a.s./ha for lark, pigeon and wagtail for use in Tabocco.

**Table 9.2-43: First-tier assessment of the long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in celeriac (use group L)**

| **Intended use** | Celeriac | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | **Trifloxystrobin** | | | | |
| **Application rate (kg/ha)** | 2 × 0.125, 14 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | ≥ 31 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Root & stem vegetables BBCH ≥ 40 | Small granivorous bird “finch” | 3.4 | 1.4 × 0.53 | 0.315 | ≥ 98.3 |
| Root & stem vegetables BBCH ≥ 40 | Small omnivorous bird “lark” | 3.3 | 1.4 × 0.53 | 0.306 | ≥ 101 |
| Root & stem vegetables BBCH ≥ 20 | Small insectivorous bird “wagtail” | 9.7 | 1.4 × 0.53 | 0.900 | ≥ 34.5 |

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

**Table 9.2-44: First-tier assessment of the long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in celeriac (use group L)**

| **Intended use** | Celeriac | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (kg/ha)** | 2 × 0.125, 14 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 4.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Root & stem vegetables BBCH ≥ 40 | Small granivorous bird “finch” | 3.4 | 1.4 × 0.53 | 0.315 | 14.3 |
| Root & stem vegetables BBCH ≥ 40 | Small omnivorous bird “lark” | 3.3 | 1.4 × 0.53 | 0.306 | 14.7 |
| Root & stem vegetables BBCH ≥ 20 | Small insectivorous bird “wagtail” | 9.7 | 1.4 × 0.53 | 0.900 | 5.00 |

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.

**Combined toxicity for birds Tier 1 – Group L**

| **Crop scenario Growth stage** | **Generic focal species** | **$TER_{LT}$ Trifloxystrobin** | **$TER_{lt}$ Flupyram** | **TERmix** |
|---|---|---|---|---|
| Root & stem vegetables BBCH ≥ 40 | Small granivorous bird "finch" | ≥ 98.3 | 14.3 | 12.5 |
| Root & stem vegetables BBCH ≥ 40 | Small omnivorous bird "lark" | ≥ 101 | 14.7 | 12.82 |
| Root & stem vegetables BBCH ≥ 20 | Small insectivorous bird "wagtail" | ≥ 34.5 | 5.00 | **4.38** |

Based on Tier 1 the $TER_{LT}$ values for both a.s. and combitox assessment are above the trigger of 5 indicating an acceptable risk except the combitox risk assessment for wagtail. Further refinment is needed.

**Table 9.2-45: First-tier assessment of the long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in elderberry and mulberry (use group M)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Elderberry, mulberry | | | | |
| **Active substance/product** | **Trifloxystrobin** | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | ≥ 31 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Orchards Spring Summer | Small insectivorous bird "tit" | 18.2 | 1.6 × 0.53 | 3.09 | ≥ 10.0 |
| Orchards Crop directed application BBCH 10–19 | Small insectivorous/worm feeding species "thrush" | 2.1 | 1.6 × 0.53 | 0.356 | ≥ 87.0 |
| Orchards Crop directed application BBCH 10–19 | Small granivorous bird "finch" | 10.1 | 1.6 × 0.53 | 1.71 | ≥ 18.1 |

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 9.2-46: First-tier assessment of the long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in elderberry and mulberry (use group M)**

| **Intended use** | Elderberry, mulberry | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 4.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Orchards Spring Summer | Small insectivorous bird “tit” | 18.2 | 1.6 × 0.53 | 3.09 | **1.46** |
| Orchards Crop directed application BBCH 10–19 | Small insectivorous/worm feeding species “thrush” | 2.1 | 1.6 × 0.53 | 0.356 | 12.6 |
| Orchards Crop directed application BBCH 10–19 | Small granivorous bird “finch” | 10.1 | 1.6 × 0.53 | 1.71 | **2.63** |

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.

**Combined toxicity for birds Tier 1 – Group M**

| **Crop scenario Growth stage** | **Generic focal species** | **$TER_{LT}$ Trifloxystrobin** | **$TER_{lt}$ Flupyram** | **TERmix** |
|---|---|---|---|---|
| Orchards Spring Summer | Small insectivorous bird “tit” | ≥ 10.0 | **1.46** | **1.28** |
| Orchards Crop directed application BBCH 10–19 | Small insectivorous/worm feeding species “thrush” | ≥ 87.0 | 12.6 | 11.11 |
| Orchards Crop directed application BBCH 10–19 | Small granivorous bird “finch” | ≥ 18.1 | **2.63** | **2.32** |

Based on Tier 1 the $TER_{LT}$ values for fluopyram and combitox assessment are below the trigger of 5 for finch and tit. Further refinment is needed.

**Table 9.2-47: First-tier assessment of the long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in flower bulbs (use group O)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Flower bulbs | | | | |
| **Active substance/product** | **Trifloxystrobin** | | | | |
| **Application rate (kg/ha)** | 1 × 0.2 | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | ≥ 31 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Bulbs & onion like crops BBCH 10–39 | Small granivorous bird “finch” | 11.4 | 1.0 × 0.53 | 1.21 | ≥ 25.7 |
| Bulbs & onion like crops BBCH 10–39 | Small omnivorous bird “lark” | 10.9 | 1.0 × 0.53 | 1.16 | ≥ 26.8 |
| Bulbs & onion like crops BBCH 10–19 | Small insectivorous bird “wagtail” | 11.3 | 1.0 × 0.53 | 1.20 | ≥ 25.9 |

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 9.2-48: First-tier assessment of the long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in flower bulbs (use group O)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Flower bulbs | | | | |
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (kg/ha)** | 1 × 0.2 | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 4.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Bulbs & onion like crops BBCH 10–39 | Small granivorous bird “finch” | 11.4 | 1.0 × 0.53 | 1.21 | **3.72** |
| Bulbs & onion like crops BBCH 10–39 | Small omnivorous bird “lark” | 10.9 | 1.0 × 0.53 | 1.16 | **3.89** |
| Bulbs & onion like crops BBCH 10–19 | Small insectivorous bird “wagtail” | 11.3 | 1.0 × 0.53 | 1.20 | **3.76** |

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.

**Combined toxicity for birds Tier 1 – Group 0**

| **Crop scenario Growth stage** | **Generic focal species** | **$TER_{LT}$ Trifloxystrobin** | **$TER_{lt}$ Flupyram** | **TERmix** |
|---|---|---|---|---|
| Bulbs & onion like crops BBCH 10–39 | Small granivorous bird “finch” | ≥ 25.7 | **3.72** | **3.33** |
| Bulbs & onion like crops BBCH 10–39 | Small omnivorous bird “lark” | ≥ 26.8 | **3.89** | 3.44 |
| Bulbs & onion like crops BBCH 10–19 | Small insectivorous bird “wagtail” | ≥ 25.9 | **3.76** | **3.33** |

Based on Tier 1 the $TER_{LT}$ values for fluopyram and combitox assessment are below the trigger of 5 for finch and wagtail. Further refinment is needed.

**Table 9.2-49: First-tier assessment of the long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in flower bulbs (use group P)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Flower bulbs | | | | |
| **Active substance/product** | **Trifloxystrobin** | | | | |
| **Application rate (kg/ha)** | 5 × 0.075, 7 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | ≥ 31 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Bulbs & onion like crops BBCH 10–39 | Small granivorous bird “finch” | 11.4 | 2.4 × 0.53 | 1.09 | ≥ 28.5 |
| Bulbs & onion like crops BBCH 10–39 | Small omnivorous bird “lark” | 10.9 | 2.4 × 0.53 | 1.04 | ≥ 29.8 |
| Bulbs & onion like crops BBCH 10–19 | Small insectivorous bird “wagtail” | 11.3 | 2.4 × 0.53 | 1.08 | ≥ 28.8 |

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 9.2-50: First-tier assessment of the long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in flower bulbs (use group P)**

| **Intended use** | Flower bulbs | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (kg/ha)** | 5 × 0.075, 7 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 4.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Bulbs & onion like crops BBCH 10–39 | Small granivorous bird “finch” | 11.4 | 2.4 × 0.53 | 1.09 | **4.14** |
| Bulbs & onion like crops BBCH 10–39 | Small omnivorous bird “lark” | 10.9 | 2.4 × 0.53 | 1.04 | **4.33** |
| Bulbs & onion like crops BBCH 10–19 | Small insectivorous bird “wagtail” | 11.3 | 2.4 × 0.53 | 1.08 | **4.17** |

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

**Combined toxicity for birds Tier 1 – Group P**

| **Crop scenario Growth stage** | **Generic focal species** | **$TER_{LT}$ Trifloxystrobin** | **$TER_{lt}$ Flupyram** | **TERmix** |
|---|---|---|---|---|
| Bulbs & onion like crops BBCH 10–39 | Small granivorous bird “finch” | ≥ 28.5 | **4.14** | **3.7** |
| Bulbs & onion like crops BBCH 10–39 | Small omnivorous bird “lark” | ≥ 29.8 | **4.33** | **3.84** |
| Bulbs & onion like crops BBCH 10–19 | Small insectivorous bird “wagtail” | ≥ 28.8 | **4.17** | **3.70** |

Based on Tier 1 the $TER_{LT}$ values for fluopyram and combitox assessment are below the trigger of 5 for finch, lark and wagtail. Further refinment is needed.

.

~~**Table 9.2-51: First-tier assessment of the long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in golf courses (use group Q)**~~

| | | | | | |
|---|---|---|---|---|---|
| ~~**Intended use**~~ | ~~Golf courses~~ | | | | |
| ~~**Active substance/product**~~ | ~~**Trifloxystrobin**~~ | | | | |
| ~~**Application rate (kg/ha)**~~ | ~~2 × 0.125, 14 days interval~~ | | | | |
| ~~**Reprod. toxicity (mg/kg bw/d)**~~ | ~~≥ 31~~ | | | | |
| ~~**TER criterion**~~ | ~~5~~ | | | | |
| ~~**Crop scenario Growth stage**~~ | ~~**Generic focal species**~~ | ~~**$SV_m$**~~ | ~~**$MAF_m$ × TWA**~~ | ~~**$DDD_m$ (mg/kg bw/d)**~~ | ~~**$TER_{lt}$**~~ |
| ~~Grassland Growing shoots~~ | ~~Large herbivorous bird "goose"~~ | ~~16.2~~ | ~~1.4 × 0.53~~ | ~~1.50~~ | ~~≥ 20.6~~ |
| ~~Grassland Growing shoots~~ | ~~Small insectivorous bird "wagtail"~~ | ~~11.3~~ | ~~1.4 × 0.53~~ | ~~1.05~~ | ~~≥ 29.6~~ |

~~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 9.2-52: First-tier assessment of the long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in golf courses (use group Q)**~~

| | | | | | |
|---|---|---|---|---|---|
| ~~**Intended use**~~ | ~~Golf courses~~ | | | | |
| ~~**Active substance/product**~~ | ~~Fluopyram~~ | | | | |
| ~~**Application rate (kg/ha)**~~ | ~~2 × 0.125, 14 days interval~~ | | | | |
| ~~**Reprod. toxicity (mg/kg bw/d)**~~ | ~~4.5~~ | | | | |
| ~~**TER criterion**~~ | ~~5~~ | | | | |
| ~~**Crop scenario Growth stage**~~ | ~~**Generic focal species**~~ | ~~**$SV_m$**~~ | ~~**$MAF_m$ × TWA**~~ | ~~**$DDD_m$ (mg/kg bw/d)**~~ | ~~**$TER_{lt}$**~~ |
| ~~Grassland Growing shoots~~ | ~~Large herbivorous bird "goose"~~ | ~~16.2~~ | ~~1.4 × 0.53~~ | ~~1.50~~ | ~~**2.99**~~ |
| ~~Grassland Growing shoots~~ | ~~Small insectivorous bird "wagtail"~~ | ~~11.3~~ | ~~1.4 × 0.53~~ | ~~1.05~~ | ~~**4.29**~~ |

~~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 9.2-53: First-tier assessment of the long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in hops (use group R)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Hops | | | | |
| **Active substance/product** | **Trifloxystrobin** | | | | |
| **Application rate (kg/ha)** | 2 × 0.15, 14 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | ≥ 31 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Hops BBCH ≥ 20 | Small insectivorous bird "finch" | 10.6 | 1.4 × 0.53 | 1.18 | ≥ 26.3 |

| | | | | | |
|---|---|---|---|---|---|
| Hops<br>BBCH 20-39 | Small granivorous bird "finch" | 5.7 | 1.4 × 0.53 | 0.634 | ≥ 48.9 |

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 9.2-54:** **First-tier assessment of the long-term/reproductive risk for birds due to the use of FLU+TFS SC 500 in hops (use group R)**

| **Intended use** | Hops | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (kg/ha)** | 2 × 0.15, 14 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 4.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Hops<br>BBCH ≥ 20 | Small insectivorous bird "finch" | 10.6 | 1.4 × 0.53 | 1.18 | **3.81** |
| Hops<br>BBCH 20-39 | Small granivorous bird "finch" | 5.7 | 1.4 × 0.53 | 0.634 | 7.09 |

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.

**Combined toxicity for birds Tier 1 – Group R**

| **Crop scenario Growth stage** | **Generic focal species** | **$TER_{LT}$ Trifloxystrobin** | **$TER_{lt}$ Flupyram** | **TERmix** |
|---|---|---|---|---|
| Hops<br>BBCH ≥ 20 | Small insectivorous bird "finch" | ≥ 26.3 | **3.81** | **3.33** |
| Hops<br>BBCH 20-39 | Small granivorous bird "finch" | ≥ 48.9 | 7.09 | 6.25 |

Based on Tier 1 the $TER_{LT}$ values for fluopyram and combitox assessment are below the trigger of 5 for finch. Further refinment is needed.

**Tier 1 conclusion for Trifloxystrobin**

For Trifloxystrobin the tier 1 long-term risk assessment is considered to be safe. Effects on birds following exposure to Trifloxystrobin are acceptable for all generic focal species relevant for the assessed uses. In case the non renewed mixing partner Fluopyram does not need to be addressed in the risk assessment a higher tier risk assessment is not necessary.

**zRMS comments:**

We agree with the risk assessment provided by the applicant for a.s. – Trifloxystrobin. The $TER_A$ and $TER_{LT}$ values are above trigger values 10 and 5, respectivetly, indicated an acceptable for all generic focal species relevant for the assessed uses.

Since the endpoint for Trifloxystrobin did not change after reapproval it is justified to conclude that also the combined risk assessment of the previous registration remains valid and no additional risk assessment for Fluopyram is needed.

**Tier 1 conclusion for Fluopyram**

For Fluopyram the use of the product in grapes (use group H) and celeriac (use group L) is considered to be safe. For the other uses several $TER_{LT}$ are below the trigger of five. The following generic focal species need a refined risk assessment:

- small granivorous bird “finch” in leafy vegetables (use group A), elderberry/mulberry (use group M) and flower bulbs (use groups O and P),
- small omnivorous bird “lark” in leafy vegetables (use group A), strawberries (use group F), tobacco (use group K) and flower bulbs (use groups P and Q),
- medium herbivorous/granivorous bird “pigeon” in leafy vegetables (use group A) and tobacco (use group K),
- small insectivorous bird “wagtail” in leafy vegetables (use group A), beans and peas (use group C), strawberries (use group F), tobacco (use group K), flower bulbs (use groups O and P) and golf courses (use group Q),
- small insectivorous bird “tit” in nurseries and rosehip (use group I) and elderberry/mulberry (use group M),
- frugivorous bird “blackcap” in berries (use group D),
- frugivorous bird “starling” in strawberries (use group F),
- small insectivorous bird “warbler” in berries (use group D),
- large herbivorous bird “goose” in golf courses (use group Q) and
- small insectivorous bird “finch” in hops (use group R).

As indicated in the introduction in 9.2.2, TER values are needed to address the combined toxicity of the renewed and non-renewed mixing partner. The combined risk assessment can be addressed based on TER values from the screening step and tier 1 risk assessments (see below). Since Fluopyram is the non-renewed mixing partner further refinement of the tier 1 risk assessment might not be needed since this will include the evaluation of additional data, which is not in line with the guidance given in the Document SANCO/2010/13170. As indicated above the refinement was already included in the previous registration and the additional data provided here for Fluopyram will also be included for the re-approval of Fluopyram on EU-Level and can be evaluated later.
However, in case the risk assessment for Fluopyram should be further refined a higher tier risk assessment is provided below.

**Birds - Assessment of combined toxicity**
~~As higher tier risk assessments were conducted, the assessment of combined toxicity is presented in 9.2.2.2.~~

| **zRMS comment:**<br><br>Since Fluopyram is the non-renewed active substance further refinement of the tier 1 risk assessment was not evaluated by zRMS since this will include the evaluation of additional data, which is not in line with the guidance given in the Document SANCO/2010/13170.<br>As indicated by the applicant the refinement risk assessment for fluopyram were included in the previous registrations of the product FLU +TFS SC 500. However, it should be noted that different GAPs and different approaches of the refinement risk to birds for fluopyram were accepted by MSs during previous registrations ( PT, PD , ftwa parameters) of the product and in consequence it is not posible to harmonise the evaluation for this a.s. fluopyram in this Core Doosier.<br>It should be also indicated that the new additional data provided here by the applicant for Fluopyram were not evaluated by zRMS in the context of Art. 43 for the risk assessment of Trifloxystrobin.<br>Therefore, for fluopyram the previous refined risk assessment provided at each MSs level is still valid.<br>The refined combitox assessment with refined parameter for fluopyram for birds should be checked at |
|---|

MSs level in their previously evaluated Registration report for Luna Sensation.

### 9.2.2.2 Higher-tier risk assessment

**Ecotoxicologically relevant endpoint for fluopyram**

The reproductive NOEL of 4.5 mg a.s./kg bw/d is considered too conservative, since the effects observed at the LOEL level were minor and unlikely to cause an impact on a population level. According to EFSA Journal 2013;11(4):3052, a population-relevant reproductive NOAEL of 7.2 mg a.s./kg bw/d can be used for the refined risk assessment.

**Measured $DT_{50}$ values of fluopyram in different matrices**

$DT_{50}$ in seeds

The residue decline of fluopyram from treated seeds has been evaluated in two field studies (see Appendix 2) that were targeting the exposure scenario of residues on treated cereal seeds and in germinated shoots. For use in the current assessment, only the $DT_{50}$ values for dissipation of fluopyram from the seeds are employed as summarised in the table below.

**Table 9.2-55: Residue dissipation from seeds studies conducted with fluopyram**

| Source | Seed type | Trial site location | $DT_{50}$ [d] |
|---|---|---|---|
| Appendix 2 Rossbach, 2014, M-486407-03-1 | Wheat seeds | West Germany | 5.78 |
| | | Southern Germany | 12.2 |
| | | Eastern Germany | 4.60 |
| Appendix 2 xxx, 2014, M-499850-01-1 | Barley seeds | Eastern Germany | 3.99 |
| | | Southern Germany | 1.66 |
| | | **Geometric mean** | **4.64** |

Based on measured residue decline of fluopyram from treated seeds, a refined $DT_{50}$ value of 4.64 days is used to refine MAF and 21-d TWA values (with moving time window according to EFSA, 2009).
The following refined MAF and TWA (21 d) values for seeds are used for the refined TER calculation.

**Table 9.2-56: Fluopyram: MAF and TWA (21 d) calculated for different application scenarios based on a $DT_{50}$ of 4.64 d in seeds**

| Number of applications / Application interval | Refined MAF | Refined TWA (21 d) |
|---|---|---|
| 5 / 7 days | 1.53 | 0.61 |
| 2 / 7 days | 1.35 | 0.43 |
| 1 / - | 1.00 | 0.30 |

DT$_{50}$ in dicotyledonous

For non-grass herbs, the exposure assumption can be reduced by including the available refined DT$_{50}$ value of 3.05 days as given in the EFSA Conclusion for fluopyram (EFSA Journal 2013;11(4):3052). Based on the measured DT$_{50}$ of 3.05 days, the following MAF and 21-d TWA values can be used for the refinement of herbivorous (non-grass eating) birds.

**Table 9.2-57: Fluopyram: MAF and TWA (21 d) calculated for different application scenarios based on a DT$_{50}$ of 3.05 d in dicots representing non-grass weeds**

| Number of applications / Application interval | Refined MAF | Refined TWA (21 d) |
|---|---|---|
| 5 / 7 days | 1.26 | 0.50 |
| 2 / 14 days | 1.04 | 0.36 |
| 2 / 7 days | 1.20 | 0.34 |
| 1 / - | 1.00 | 0.21 |

DT$_{50}$ in monocotyledonous

For grass (monocots) a new kinetic study (Kley, C.; Ellerich, C.; 2018; M-617837-01-1, Appendix 2) evaluates an appropriate DT$_{50}$ for young cereals (representative for grass). The evaluation gives an ecotoxicologically relevant DT$_{50}$ of **2.6 days. For** the evaluation rainfall was not excluded as this will also occur in the field. Therefore, the evaluated DT$_{50}$ is appropriate to be used in the refined risk assessment for herbivorous birds and mammals eating grass. The respective refined MAF and TWA values relevant for this refined risk assessment are presented in the next table.

**Table 9.2-58: Fluopyram: MAF and TWA (21 d) calculated for different application scenarios based on a DT$_{50}$ of 2.6 d in young cereals representing monocot weeds**

| Number of applications / Application interval | Refined MAF | Refined TWA (21 d) |
|---|---|---|
| 5 / 7 days | 1.18 | 0.45 |
| 2 / 14 days | 1.02 | 0.32 |
| 2 / 7 days | 1.15 | 0.31 |
| 1 / - | 1.00 | 0.18 |

DT$_{50}$ on arthropods

Residue decline studies of fluopyram on foliage dwelling arthropods after spray application in vine resulted in a worst case DT$_{50}$ on arthropods of 5.63 d (Final addendum to the Draft Assessment Report (DAR), Revision 2 after commenting on final addendum, Revision to Addendum 4 August 2017 – amended November 2017, B9 Ecotoxicology, page 993) (based on Rossbach, A.; 2013; M-453376-01-1 (study report), Kley, C.; Zerbe, P.; 2016; M-544286-01-1 (kinetic evaluation)).

**Table 9.2-59: Fluopyram: MAF and TWA (21 d) calculated for different application scenarios based on a DT$_{50}$ of 5.63 d on foliar dwelling arthropods**

| Number of applications / Application interval | Refined MAF | Refined TWA (21 d) |
|---|---|---|
| 5 / 7 days | 1.71 | 0.65 |
| 2 / 14 days | 1.18 | 0.49 |
| 2 / 7 days | 1.42 | 0.47 |
| 1 / - | 1.00 | 0.36 |

Two further residue decline studies for fluopyram are available, one study was conducted in oilseed rape in Germany (Rossbach, A.; Lelle, M.; 2015; M-544190-01-1 (study report), Kley, C.; Ellerich, C.; 2016; M-545077-01-1 (kinetic evaluation)) and one in pome fruit orchards in Germany (Rossbach, A.; 2018; M-644049-01-1). The resulting $DT_{50}$ values are listed in the next table. These values are used for the geometric mean calculation of all reported $DT_{50}$ values.

**Table 9.2-60: Overview on fluopyram residue decline on foliage dwelling invertebrates**

| Study [1] | Crop | Best fit kinetic | SFO: $DT_{50}$<br>DFOP: $DT_{50}$ (1)<br>FOMC: alpha<br>HS: $DT_{50}$ (1) | SFO: -<br>DFOP: $DT_{50}$ (2)<br>FOMC: beta<br>HS: $DT_{50}$ (2) | SFO: -<br>DFOP: g<br>FOMC: -<br>HS: tb | $DT_{90}$ | Pseudo-SFO as $DT_{90}$/3.32 |
|---|---|---|---|---|---|---|---|
| 1 Plot 1 | Vine | DFOP | 1.107 | 17.38 | 0.75204 | 22.77 | 6.86 |
| 1 Plot 2 | Vine | SFO | 5.6257 | | | 18.69 | 5.63 |
| 1 Plot 3 | Vine | FOMC | 1.7542 | 2.894 | | 7.86 | 2.37 |
| 2 Plot 1 | OSR | SFO | 0.685 | | | 0.685 | 0.21 |
| 2 Plot 2 | OSR | HS | 0.378 | 5.876 | 1.0966 | 3.580 | 1.08 |
| 2 Plot 3 | OSR | HS | 0.488 | 2.954 | 0.8957 | 5.292 | 1.59 |
| 3 Plot 1 | Pome | SFO | 4.10 | | | 13.7 | 4.13 |
| 3 Plot 2 | Pome | FOMC | 0.6052 | 0.2056 | | 9.0 | 2.71 |
| 3 Plot 3 | Pome | FOMC | 0.765 | 0.922 | | 17.8 | 5.36 |
| | | | | | **Geomean** | All crops | 2.32 |
| | | | | | | High crops | 4.20 |
| | | | | | | Arable crops | 0.71 |

[1] References:
Study 1: Study report: xxx. (2013): Residue decline of Fluopyram on arthropods after spray application in vines in Germany. Doc No: M-453376-01-1.
Kinetic evaluation providing DFOP and FOMC fits tabled above: Kley & Zerbe (2016) Kinetic Evaluation of Fluopyram residues in Foliage Dwellers and Flying Insects in Vines. Doc. No: M-544286-01-1
Study 2: Study report: Rossbach& Lelle (2015): Residue decline of fluopyram and prothioconazole on arthropods after spray application on oilseed rape fields in Western Germany. Doc No: M-544190-01-1.
Kinetic evaluation providing HS fits tabled above: Kley & Ellerich 2016 Kinetic Evaluation of Fluopyram residues in Foliage Dwellers and Flying Insects in Oilseed Rape. Doc No: M-545077-01-1.
Study 3: Study report incl. kinetic evaluation providing FOMC fits abled above: Rossbach (2018 Residue decline of fluopyram and tebuconazole on arthropods after spray applications in pome fruit orchards in Germany. Doc No: M-644049-01-1.

**Table 9.2-61: Illustrative comparison of simulations with best fit kinetic versus (pseudo-) SFO (based on $DT_{90}$/3.32): pseudo-SFO approx. 10 % higher (conservative).**

| | | Best fit (2 applications, 7d interval) | | | (Pseudo-) SFO fit (2 applications, 7d interval) | |
|---|---|---|---|---|---|---|
| **Study** | **Crop** | **Kinetic type** | **MAF** | **fTWA** | **MAF** | **fTWA** |
| 1 Plot 1 | Vine | DFOP | 1.197 | 0.34 | 1.493 | 0.52 |
| 1 Plot 2 | Vine | SFO | 1.422 | 0.47 | 1.422 | 0.47 |
| 1 Plot 3 | Vine | FOMC | 1.116 | 0.25 | 1.129 | 0.29 |
| 2 Plot 1 | OSR | SFO | 1.001 | 0.09 | 1.000 | 0.03 |
| 2 Plot 2 | OSR | HS | 1.067 | 0.13 | 1.011 | 0.15 |
| 2 Plot 3 | OSR | HS | 1.067 | 0.15 | 1.047 | 0.21 |
| 3 Plot 1 | Pome | SFO | 1.306 | 0.40 | 1.309 | 0.41 |
| 3 Plot 2 | Pome | FOMC | 1.116 | 0.21 | 1.167 | 0.31 |
| 3 Plot 3 | Pome | FOMC | 1.193 | 0.32 | 1.404 | 0.46 |
| | | Geomean | 1.159 | 0.233 | 1.210 | 0.25 |
| | | | MAF x $f_{TWA}$ = 0.270 | | MAF x $f_{TWA}$ = 0.303 | |

Conclusion: For sake of simplicity, the pseudo-SFO $DT_{50}$ for fluopyram can be used as surrogate for the best fit kinetics since the difference for MAF and TWA calculation is small and not underprotective. Using the geomean pseudo-SFO $DT_{50}$ of 4.2 days from high crops is also protective for arable crops.

**Table 9.2-62: Fluopyram: MAF and TWA (21 d) calculated for different application scenarios based on a geometric mean $DT_{50}$ of 4.2 d on foliage dwelling arthropods**

| Number of applications / Application interval | Refined MAF | Refined TWA (21 d) |
|---|---|---|
| 5 / 7 days | 1.46 | 0.59 |
| 2 / 14 days | 1.10 | 0.43 |
| 2 / 7 days | 1.31 | 0.41 |
| 1 / - | 1.00 | 0.28 |

Residue data on ground dwelling arthropods are not available and thus, the default $DT_{50}$ of 10 days is used in the refined risk assessment.

**Leafy vegetables (use group A)**

Small granivorous bird "finch"

A field radiotracking study (xxx.; 2019; M-655399-01-1, Appendix 2) was conducted to determine the potential foraging time (PT) of linnet and serin in leafy vegetable fields in Southern Germany. The mean PT of linnets (all potential consumers) in leafy vegetable fields was about 9% (90$^{th}$ percentile 20.4%). The mean PT of serins (all potential consumers) in leafy vegetable fields was about 4% (90$^{th}$ percentile 9.8%). For the refined risk assessment for finch, a PT of 0.204 (90$^{th}$ percentile for confirmed consumer linnets) is used as worst case.

**Table 9.2-63: Higher-tier assessment of the long-term/reproductive risk for small granivorous birds – linnet - due to the use of FLU+TFS SC 500 in leafy vegetables (use group A) – refined parameter (*) are further described and justified in the text**

| **Intended use** | Leafy vegetables | | | | | |
|---|---|---|---|---|---|---|
| **Active substance/product** | Fluopyram | | | | | |
| **Application rate (g/ha)** | 2 × 0.2, 7 days interval | | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 7.2 * | | | | | |
| **TER criterion** | 5 | | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **PT** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Leafy vegetables BBCH 10-49 | Small granivorous bird "finch" | 12.6 | 1.35 × 0.43 [a)] * | 0.204 * | 0.298 | 24.1 |

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio.
[a)] With $DT_{50}$ of 4.64 d, 2 applications with 7 d interval (Table 9.2-56)

Small omnivorous bird

The wood lark is the generic focal species in leafy vegetables but the skylark is the real focal species in leafy vegetables, as confirmed in several focal species studies (xxx; 2007; M-291775-01-1, xxx 2016; M-572583-01-1 and xxx 2013; M-497434-02-1)
Based on a generic monitoring study of birds in vegetable field in Great Britain (xxx, 2008, M-302416-01-1, Appendix 2), the diet of skylarks foraging in a landscape of vegetable fields consisted at 61.5% (dry weight) of invertebrates, 27.4% (dry weight) of weed seeds and 11.1% (dry weight) of plant leaf material. After conversion into wet weight percentages with the UBA calculator, FIR/bw (g/g w/w) for a 40 g skylark amounts to 0.38 for ground invertebrates, 0.18 for plant leaves (non-grass weeds) and 0.06 for weed seeds in leafy vegetable fields.
The refined risk assessment is furthermore based on the refined $DT_{50}$ values for crop leaves and weed seeds.
Based on the field study (xxx, 2008, M-302416-01-1, Appendix 2), the maximum individual PT value of 0.477 (consumers approach) in lettuce is applied in the refined risk assessment for the skylark.

**Table 9.2-64: Higher-tier assessment of the long-term/reproductive risk for small omnivorous bird – skylark - due to the use of FLU + TFS SC 500 in leafy vegetables (use group A) – refined parameter (*) are further described and justified in the text**

| **Feed item (dry weight)** | **AR (kg/ha)** | **FIR/bw** | **RUD** | **MAF** | **21-d TWA** | **PT** | **DDD** | **NOAEL (mg/kg bw/d)** | **TER** |
|---|---|---|---|---|---|---|---|---|---|
| 11.1% non-grass herbs (dicots) * | 0.200 | 0.18 * | 28.7 | 1.20 [a)] * | 0.34 [a)] * | 0.477 * | 0.202 | | |
| 61.5% ground invertebrates * | 0.200 | 0.38 * | 7.5 | 1.6 | 0.53 | 0.477 * | 0.231 | | |
| 27.4% weed seeds * | 0.200 | 0.06 * | 40.2 | 1.35 [b)] * | 0.43[b)] * | 0.477 * | 0.132 | | |
| Total diet | | | | | | | Σ = 0.565 | 7.2 * | 12.8 |

a) With $DT_{50}$ of 3.05 d, 2 applications with 7 d interval (Table 9.2-57)
b) With $DT_{50}$ of 4.64 d, 2 applications with 7 d interval (Table 9.2-56)

Medium herbivorous/granivorous bird

Based on a generic radiotracking study for birds in vegetable fields in Great Britain (xxx, 2008, M-302416-01-1, Appendix 2), the maximum individual PT value of 0.492 (consumers approach) in lettuce is applied in the refined risk assessment for the wood pigeon.
Furthermore, the measured $DT_{50}$ of 3.05 d in dicotyledonous and the refined endpoint are used for the refined risk assessment of medium herbivorous birds in leafy vegetables.

**Table 9.2-65: Higher-tier assessment of the long-term/reproductive risk for medium herbivorous bird – wood pigeon - due to the use of FLU + TFS SC 500 in leafy vegetables (use group A) – refined parameter (*) are further described and justified in the text**

| | | | | | | |
|---|---|---|---|---|---|---|
| **Intended use** | Leafy vegetables | | | | | |
| **Active substance/product** | Fluopyram | | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 7.2 * | | | | | |
| **TER criterion** | 5 | | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **PT** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Leafy vegetables Leaf development BBCH 10-19 | Medium herbivorous/granivorous bird "pigeon" | 22.7 | 1.20 × 0.34 a) * | 0.492 * | 0.911 | 7.9 |

a) With $DT_{50}$ of 3.05 d, 2 applications with 7 d interval (Table 9.2-57)

Small insectivorous bird

Based on a generic radiotracking study for birds in vegetable fields in Great Britain (xxx, 2008, M-302416-01-1, Appendix 2), a PT value of 0.446 (90th percentile as more than 10 consumers have been observed, consumers approach) in lettuce is applied in the refined risk assessment for the yellow wagtail in leafy vegetables.
Furthermore, the $DT_{50}$ in foliar dwelling arthropods of 5.63 d (additionally also presented with the geometric mean $DT_{50}$ of 4.2 d) and the default of 10 d in ground dwelling arthropods is used for the refined risk assessment. According to Appendix A of EFSA/2009/1438, the diet of small insectivorous bird "wagtail" consists of 50% ground arthropods (without interception) and 50% foliar arthropods.

**Table 9.2-66: Higher-tier assessment of the long-term/reproductive risk for small insectivorous bird – yellow wagtail - due to the use of FLU + TFS SC 500 in leafy vegetables (use group A) – refined parameter (*) are further described and justified in the text**

| Feed item | AR (kg/ha) | FIR/bw | RUD | MAF | 21-d TWA | PT | DDD | NOAEL (mg/kg bw/d) | TER |
|---|---|---|---|---|---|---|---|---|---|
| 50% ground dwelling invertebrates | 0.200 | 0.39 | 7.5 | 1.6 | 0.53 | 0.446 * | 0.221 | | |
| 50% foliar dwelling invertebrates | 0.200 | 0.39 | 21.0 | 1.42 [a] * 1.31 [b] * | 0.47 [a] * 0.41 [b] * | 0.446 * | 0.500 0.339 | | |
| Total diet | | | | | | | Σ = 0.721 0.560 | 7.2 * | 9.98 12.9 |

[a] With $DT_{50}$ of 5.63 d, 2 applications with 7 d interval (Table 9.2-59)
[b] With the geometric mean $DT_{50}$ of 4.2 d, 2 applications with 7 d interval (Table 9.2-62)

**Beans, peas (use group C)**

Small insectivorous bird
According to the refined risk assessment of wagtails in leafy vegetables, the refinement for wagtails in pulses is based on the generic radiotracking study for birds in vegetable fields in Great Britain (xxx, 2008, M-302416-01-1, Appendix 2) but the PT value for wagtails in all vegetables combined is considered (lack of crop-specific sessions). The refinement is based on the PT value of 0.87 (90th percentile, consumers, all vegetables combined), the $DT_{50}$ in foliar dwelling arthropods of 5.63 d (geometric mean $DT_{50}$ of 4.2 d) and the default of 10 d in ground dwelling arthropods. According to Appendix A of EFSA/2009/1438, the diet of small insectivorous bird "wagtail" consists of 50% ground arthropods and 50% foliar arthropods.

In the Tier 1 risk assessment, the default RUD with interception was employed for ground invertebrates, according to the recommendations of the EFSA GD for uses on pulses at BBCH stages ≥ 20. However, the recommended uses of FLU + TFS SC 500 in beans and peas all fall into late BBCH growth stages 59 - 89. In the "*context of a higher-tier assessment*", the EFSA GD (2009, Appendix E) notes that "*the more detailed values of the FOCUS groundwater report (FOCUS, 2000) may be used*". The interception in pulses at BBCH ≥ 50 is already very high (70%) according to the FOCUS groundwater report (Table 2 in Appendix E of EFSA/2009/1438). Therefore, in the refined risk assessment for the wagtail the default RUD (without interception) of 7.5 is employed for ground invertebrates, and a deposition factor of 0.3 is applied on the RUD resulting in refined RUD = 7.5 x 0.3 = 2.25.

**Table 9.2-67: Higher-tier assessment of the long-term/reproductive risk for small insectivorous bird – yellow wagtail - due to the use of FLU + TFS SC 500 in pulses (use group C) – refined parameter (*) are further described and justified in the text**

| Feed item | AR (kg/ha) | FIR/bw | RUD | MAF | 21-d TWA | PT | DDD | NOAEL (mg/kg bw/d) | TER |
|---|---|---|---|---|---|---|---|---|---|
| 50% ground dwelling invertebrates | 0.200 | 0.39 | 2.25 * | 1.6 | 0.53 | 0.87 * | 0.129 | | |
| 50% foliar dwelling invertebrates | 0.200 | 0.39 | 21.0 | 1.42 [a)] * 1.31 [b)] * | 0.47 [a)] * 0.41 [b)] * | 0.87 * | 0.974 0.778 | | |
| Total diet | | | | | | | Σ = 1.10 0.907 | 7.2 * | 6.5 7.9 |

[a)] With $DT_{50}$ of 5.63 d, 2 applications with 7 d interval (Table 9.2-59)
[b)] With the geometric mean $DT_{50}$ of 4.2 d, 2 applications with 7 d interval (Table 9.2-62)

**Berries (use group D)**

Frugivorous bird
On the SETAC conference held in 2019, Hahne et al. presented a poster on new proposed residues on fruits (RUD's) for frugivore scenarios in EFSA bird and mammal risk assessment (Hahne, J.; Schabacker, J.; Foudoulakis, M.; Ludwigs, J. D.; Murfitt, R.; Ristau, K.; 2019; M-665829-01-1, Appendix 2). In this poster, a RUD of 5.0 mg a.s./kg berries is proposed for currants, raspberries and gooseberries. This refined RUD is used in the refined risk assessment for frugivorous birds in berries.

**Table 9.2-68: Higher-tier assessment of the long-term/reproductive risk for frugivorous bird due to the use of FLU + TFS SC 500 in berries (use group D) – refined parameter (*) are further described and justified in the text**

| | | | | | | |
|---|---|---|---|---|---|---|
| **Intended use** | Berries | | | | | |
| **Active substance/product** | Fluopyram | | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 7.2 * | | | | | |
| **TER criterion** | 5 | | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **FIR/bw** | **RUD** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Bush & cane fruit Fruit stage BBCH 71-79 currants | Frugivorous bird "blackcap" | 2.77 | 5.0 * | 1.6 × 0.53 | 2.35 | **3.06** |

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.

Small insectivorous bird
According to Appendix A of EFSA/2009/1438, the diet of small insectivorous bird "warbler" consists of 100% foliar arthropods. Thus, the $DT_{50}$ in foliar dwelling arthropods of 5.63 d (geometric mean $DT_{50}$ of 4.2 d) is considered for the refined risk assessment.

**Table 9.2-69: Higher-tier assessment of the long-term/reproductive risk for small insectivorous bird due to the use of FLU + TFS SC 500 in berries (use group D) – refined parameter (*) are further described and justified in the text**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Berries | | | | |
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 7.2 * | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Bush & cane fruit Whole season BBCH 00-79 Currants | Small insectivorous bird "warbler" | 20.3 | 1.42 × 0.47 [a)] *<br>1.31 × 0.41 [b)] * | 2.71<br>2.18 | **2.6**<br>**3.3** |

[a)] With $DT_{50}$ of 5.63 d, 2 applications with 7 d interval (Table 9.2-59)
[b)] With the geometric mean $DT_{50}$ of 4.2 d, 2 applications with 7 d interval (Table 9.2-62)

**Strawberries, blueberries, cranberries (use group F)**

Small omnivorous bird
According to xxx et al (2013, M-497434-02-1, Appendix 2) the relevant real focal species representing small omnivorous birds in strawberry fields is the Skylark (*Alauda arvensis*).
Based on a field study (xxx, 2006, M-342897-01-1, Appendix 2), the diet of skylarks foraging in a landscape of strawberry fields consisted at 56.7% (dry weight) of invertebrates, 32.5% (dry weight) of (large cereal) seeds and 10.8% (dry weight) of small seeds. After conversion into wet weight percentages with the UBA calculator, FIR/bw (g/g w/w) for a 40 g skylark amounts to 0.36 for ground invertebrates, 0.08 for seeds (large, cereal grains) and 0.02 for small seeds in strawberry fields.

The measured $DT_{50}$ of 4.64 d in seeds and the default value of 10 d in ground dwelling arthropods are used for the skylark diet.

Based on a field study in strawberry fields (xxx, 2006, M-342897-01-1, Appendix 2), a highly conservative PT value of 0.99 (90$^{th}$ percentile) is applied in the refined risk assessment for the Skylark.

**Table 9.2-70: Higher-tier assessment of the long-term/reproductive risk for small omnivorous bird – skylark - due to the use of FLU + TFS SC 500 in strawberries, blueberries and cranberries (use group F) – refined parameter (*) are further described and justified in the text**

| Feed item (dry weight) | AR (kg/ha) | FIR/bw | RUD | MAF | 21-d TWA | PT | DDD | NOAEL (mg/kg bw/d) | TER |
|---|---|---|---|---|---|---|---|---|---|
| 56.7% ground invertebrates * | 0.200 | 0.36 * | 7.5 | 1.6 | 0.53 | 0.99 * | 0.453 | | |
| 32.5% large seeds * | 0.200 | 0.08 * | 40.2 | 1.35 [a)] * | 0.43 [a)] * | 0.99 * | 0.351 | | |
| 10.8% weed seeds * | 0.200 | 0.02 * | 40.2 | 1.35 [a)] * | 0.43 [a)] * | 0.99 * | 0.110 | | |
| Total diet | | | | | | | Σ = 0.914 | 7.2 * | 7.87 |

[a)] With $DT_{50}$ of 4.64 d, 2 applications with 7 d interval (Table 9.2-56)

Frugivorous bird
In the EFSA Conclusion for fluopyram (EFSA Journal 2013;11(4):3052) a RUD of 1.3 is evaluated for strawberries (GAP: 2 x 250 g a.s./ha at BBCH 61-89, 7 day interval). This refined RUD is used for the following higher tier risk assessment.

**Table 9.2-71: Higher-tier assessment of the long-term/reproductive risk for frugivorous bird due to the use of FLU + TFS SC 500 in strawberries, blueberries and cranberries (use group F) – refined parameter (*) are further described and justified in the text**

| Feed item (dry weight) | AR (kg/ha) | FIR/bw | RUD | $MAF_m$ × TWA | PT | DDD | NOAEL (mg/kg bw/d) | TER |
|---|---|---|---|---|---|---|---|---|
| 100% Fruits | 0.200 | 1.62 | 1.3 * | 1.6 × 0.53 | 1 | 0.357 | 7.2 * | 20.2 |

Small insectivorous bird

In a field study in strawberry fields in Germany (xxx, 2006, M-342897-01-1, Appendix 2), a highly conservative PT value of 0.94 (90th percentile, consumers) was determined for yellow wagtails. Using this PT and also the measured $DT_{50}$ of 5.63 d (geometric mean $DT_{50}$ of 4.2 d) on foliar dwelling arthropods and the default value of 10 d for ground dwelling arthropods, the following refined TER value were calculated:

**Table 9.2-72: Higher-tier assessment of the long-term/reproductive risk for small insectivorous bird – yellow wagtail - due to the use of FLU + TFS SC 500 in strawberries, blueberries and cranberries (use group F) – refined parameter (*) are further described and justified in the text**

| Feed item | AR (kg/ha) | FIR/bw | RUD | MAF | 21-d TWA | PT | DDD | NOAEL (mg/kg bw/d) | TER |
|---|---|---|---|---|---|---|---|---|---|
| 50% ground dwelling invertebrates | 0.200 | 0.39 | 7.5 | 1.6 | 0.53 | 0.94 * | 0.466 | | |
| 50% foliar dwelling invertebrates | 0.200 | 0.39 | 21.0 | 1.42 [a] *<br>1.31 [b] * | 0.47 [a] *<br>0.41 [b] * | 0.94 * | 1.053<br>0.841 | | |
| Total diet | | | | | | | Σ = 1.52<br>1.31 | 7.2 * | **4.74**<br>5.51 |

[a] With $DT_{50}$ of 5.63 d, 2 applications with 7 d interval (Table 9.2-59)
[b] With the geometric mean $DT_{50}$ of 4.2 d, 2 applications with 7 d interval (Table 9.2-62)

As the risk envelope approach for wagtails based on the $DT_{50}$ in foliar dwelling invertebrates fails the risk assessment, TER calculations with the same refined parameters were done for **use group G** (2 x 0.6 L product/ha, 7 days interval).

**Table 9.2-73: Higher-tier assessment of the long-term/reproductive risk for small insectivorous bird – yellow wagtail - due to the use of FLU + TFS SC 500 in blueberries and cranberries (use group G) – refined parameter (*) are further described and justified in the text**

| Feed item | AR (kg/ha) | FIR/bw | RUD | MAF | 21-d TWA | PT | DDD | NOAEL (mg/kg bw/d) | TER |
|---|---|---|---|---|---|---|---|---|---|
| 50% ground dwelling invertebrates | 0.150 | 0.39 | 7.5 | 1.6 | 0.53 | 0.94 * | 0.350 | | |
| 50% foliar dwelling invertebrates | 0.150 | 0.39 | 21.0 | 1.42 [a] *<br>1.31 [b] * | 0.47 [a] *<br>0.41 [b] * | 0.94 * | 0.790<br>0.631 | | |
| Total diet | | | | | | | Σ = 1.14<br>0.981 | 7.2 * | 6.32<br>7.34 |

[a] With $DT_{50}$ of 5.63 d, 2 applications with 7 d interval (Table 9.2-59)
[b] With the geometric mean $DT_{50}$ of 4.2 d, 2 applications with 7 d interval (Table 9.2-62)

Due to the combined toxicity assessment, the risk assessment for trifloxystrobin for this use group for small insectivorous birds is presented in the next table. According to the risk assessment for fluopyram, a PT of 0.94 is considered also in the refined exposure estimate for trifloxystrobin.

**Table 9.2-74: Trifloxystrobin: Higher-tier assessment of the long-term/reproductive risk for small insectivorous bird – yellow wagtail - due to the use of FLU + TFS SC 500 in blueberries and cranberries (use group G) – refined parameter (*) are further described and justified in the text**

| | | | | | | |
|---|---|---|---|---|---|---|
| **Intended use** | Blueberries, cranberries | | | | | |
| **Active substance/product** | Trifloxystrobin | | | | | |
| **Application rate (kg/ha)** | 2 × 0.15, 7 days interval | | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 31 | | | | | |
| **TER criterion** | 5 | | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **PT** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Strawberries BBCH 10–19 | Small insectivorous bird "wagtail" | 11.3 | 1.6 × 0.53 | 0.94 * | 1.35 | 22.9 |

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.

**Nurseries and rosehip (use group I)**

Small insectivorous bird

According to Appendix A of EFSA/2009/1438, the diet of a small insectivorous bird "tit" consists of 100% foliar arthropods. Thus, the $DT_{50}$ in foliar dwelling arthropods of 5.63 d (geometric mean $DT_{50}$ of 4.2 d) is considered for the refined risk assessment.

Additional refinement potential can be employed by incorporating a PT value for blue tits in orchards as reported by Finch *et al.* (2006). A recalculation of these data has been provided in xxx (2010, M-429545-01-1, Appendix 2): 90th percentile PT for blue tits in orchards: 0.53 for all birds, 0.57 for consumers. The use of a PT in orchards is considered acceptable as the habitat structure of tits in orchards and nurseries are comparable: the landscape consists of trees on which foliage dweller are living that are preyed upon by insectivorous birds like tits. The higher PT of 0.57 can therefore be extrapolated to nurseries and is used for the refined risk assessment of tits in nurseries.

For illustration, below the screenshot of Table 3 on page 13 of xxx (2010), providing highly conservative PT – value recommendations for tits in orchards is included.

**Screenshot Table 3 on page 13 of xxx (2010):**

**Table 3 PT values for passerine birds in orchards, with modelled 90th and 95th percentiles and their confidence limits. Consumers only.**

| Season | Species | No. of individuals | 90th percentile PT value (95% CLs) | 95th percentile PT value (95% CLs) |
|---|---|---|---|---|
| Summer (April – September) | Blackbird | 28 | 0.73 (0.61 – 0.86) | 0.83 (0.71 – 0.93) |
| | Blue tit | 16 | 0.57 (0.43 – 0.75) | 0.66 (0.52 – 0.84) |
| | Chaffinch | 24 | 0.8 (0.69 – 0.91) | 0.87 (0.77 – 0.96) |
| | Robin | 24 | 0.54 (0.43 – 0.69) | 0.65 (0.52 – 0.80) |

**Table 9.2-75: Higher-tier assessment of the long-term/reproductive risk for small insectivorous bird – blue tit - due to the use of FLU + TFS SC 500 in nurseries and rosehip (use group I) – refined parameter (*) are further described and justified in the text**

| | | | | | | |
|---|---|---|---|---|---|---|
| **Intended use** | Nurseries, rosehip | | | | | |
| **Active substance/product** | Fluopyram | | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 7.2 * | | | | | |
| **TER criterion** | 5 | | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **PT** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Ornamentals/nursery Application to plant | Small insectivorous bird – blue tit | 18.2 | 1.42 × 0.47 [a)] *<br>1.31 × 0.41 [b)] * | 0.57 * | 1.38<br>1.11 | 5.2<br>6.5 |

[a)] With $DT_{50}$ of 5.63 d, 2 applications with 7 d interval (Table 9.2-59)
[b)] With the geometric mean $DT_{50}$ of 4.2 d, 2 applications with 7 d interval (Table 9.2-62)

**Tobacco (use group K)**

Small omnivorous bird

According to Appendix A of EFSA/2009/1438, the diet of woodlarks (*Lullula arborea*) in maize fields (maize is used as surrogate crop for tobacco as tobacco is not considered in EFSA/2009/1438) consists of 25% leaves, 25% weed seeds and 50% ground arthropods. The respective measured $DT_{50}$ values are used for the refined risk assessment of larks in tobacco. Calculations of FIR/bw are done using the UBA calculator.

**Table 9.2-76: Higher-tier assessment of the long-term/reproductive risk for small omnivorous bird - woodlark - due to the use of FLU + TFS SC 500 in tobacco (use group K) – refined parameter (*) are further described and justified in the text**

| Feed item (dry weight) | AR (kg/ha) | FIR/bw | RUD | MAF | 21-d TWA | PT | DDD | NOAEL (mg/kg bw/d) | TER |
|---|---|---|---|---|---|---|---|---|---|
| 25% non-grass herbs * | 0.200 | 0.47 * | 40.2 | 1.0 | 0.21 [a] * | 1 | 0.557 | | |
| 25% weed seeds * | 0.200 | 0.06 * | 40.2 | 1.0 | 0.30 [b] * | 1 | 0.150 | | |
| 50% ground invertebrates * | 0.200 | 0.36 * | 7.5 | 1.0 | 0.53 | 1 | 0.286 | | |
| Total diet | | | | | | | Σ = 0.993 | 7.2 * | 7.25 |

[a] With $DT_{50}$ of 3.05 d, single application (Table 9.2-57)
[b] With $DT_{50}$ of 4.64 d, single application (Table 9.2-56)

Medium herbivorous/granivorous bird

The refined risk assessment for pigeons in tobacco feeding on 100% leaves (Appendix A of EFSA/2009/1438) is based on the measured $DT_{50}$ of 3.05 d in dicotyledonous plants.

**Table 9.2-77: Higher-tier assessment of the long-term/reproductive risk for medium herbivorous bird due to the use of FLU + TFS SC 500 in tobacco (use group K) – refined parameter (*) are further described and justified in the text**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Tobacco | | | | |
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (kg/ha)** | 1 × 0.2 | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 7.2 * | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Maize BBCH 10–29 | Medium herbivorous/granivorous bird “pigeon” | 22.7 | 1.0 × 0.21 [a] * | 0.953 | 7.55 |

[a] With $DT_{50}$ of 3.05 d, 1 application (Table 9.2-57)

Small insectivorous bird

Using the measured $DT_{50}$ of 5.63 d (geometric mean $DT_{50}$ of 4.2 d) on foliar dwelling arthropods and the default value of 10 d for ground dwelling arthropods, the following refined TER value was calculated for wagtails feeding on 50% foliar dwelling arthropods and 50% ground arthropods (Appendix A of EFSA/2009/1438):

**Table 9.2-78: Higher-tier assessment of the long-term/reproductive risk for small insectivorous bird – yellow wagtail - due to the use of FLU + TFS SC 500 in tobacco (use group K) – refined parameter (*) are further described and justified in the text**

| Feed item | AR (kg/ha) | FIR/bw | RUD | MAF | 21-d TWA | PT | DDD | NOAEL (mg/kg bw/d) | TER |
|---|---|---|---|---|---|---|---|---|---|
| 50% ground dwelling invertebrates | 0.200 | 0.39 | 7.5 | 1.0 | 0.53 | 1 | 0.310 | | |
| 50% foliar dwelling invertebrates | 0.200 | 0.39 | 21.0 | 1.0 | 0.36 [a] *<br>0.28 [b] * | 1 | 0.593<br>0.464 | | |
| Total diet | | | | | | | Σ = 0.903<br>0.774 | 7.2 * | 7.97<br>9.30 |

[a] With $DT_{50}$ of 5.63 d, single application (Table 9.2-59)
[b] With the geometric mean $DT_{50}$ of 4.2 d, single application (Table 9.2-62)

**Elderberry & mulberry (use group M)**

Small insectivorous bird

According to Appendix A of EFSA/2009/1438, the diet of a small insectivorous bird “tit” consists of 100% foliar arthropods. Thus, the $DT_{50}$ in foliar dwelling arthropods of 5.63 d (geometric mean $DT_{50}$ of 4.2 d) is considered for the refined risk assessment.

Additional refinement potential can be employed by incorporating a PT value for blue tits in orchards as reported by Finch *et al.* (2006). A recalculation of these data has been provided in xxx (2010, M-429545-01-1, Appendix 2): 90th percentile PT for blue tits in orchards: 0.53 for all birds, 0.57 for consumers. The higher PT of 0.57 is used for the refined risk assessment.

For illustration, below the screenshot of Table 3 on page 13 of xxx (2010), providing highly conservative PT – value recommendations for tits in orchards is included.

**Screenshot Table 3 on page 13 of xxx (2010):**

**Table 3 PT values for passerine birds in orchards, with modelled 90$^{th}$ and 95$^{th}$ percentiles and their confidence limits. Consumers only.**

| Season | Species | No. of individuals | 90$^{th}$ percentile PT value (95% CLs) | 95$^{th}$ percentile PT value (95% CLs) |
|---|---|---|---|---|
| Summer (April – September) | Blackbird | 28 | 0.73 (0.61 – 0.86) | 0.83 (0.71 – 0.93) |
| | Blue tit | 16 | 0.57 (0.43 – 0.75) | 0.66 (0.52 – 0.84) |
| | Chaffinch | 24 | 0.8 (0.69 – 0.91) | 0.87 (0.77 – 0.96) |
| | Robin | 24 | 0.54 (0.43 – 0.69) | 0.65 (0.52 – 0.80) |

**Table 9.2-79: Higher-tier assessment of the long-term/reproductive risk for small insectivorous bird – blue tit - due to the use of FLU + TFS SC 500 in elderberry and mulberry (use group M) – refined parameter (*) are further described and justified in the text**

| **Intended use** | Elderberry, mulberry | | | | | |
|---|---|---|---|---|---|---|
| **Active substance/product** | Fluopyram | | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 7.2 * | | | | | |
| **TER criterion** | 5 | | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **PT** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Orchards Spring Summer | Small insectivorous bird "tit" | 18.2 | 1.42 × 0.47 [a)] *<br>1.31 × 0.41 [b)] * | 0.57 * | 1.38<br>1.11 | 5.20<br>6.46 |

[a)] With $DT_{50}$ of 5.63 d, 2 applications with 7 d interval (Table 9.2-59)
[b)] With the geometric mean $DT_{50}$ of 4.2 d, 2 applications with 7 d interval (Table 9.2-62)

Small granivorous bird

According to Appendix A of EFSA/2009/1438, small granivorous birds feed on 100% seeds. The measured $DT_{50}$ in seeds of 4.64 d is used for the refined risk assessment.

**Table 9.2-80: Higher-tier assessment of the long-term/reproductive risk for small granivorous birds due to the use of FLU+TFS SC 500 in elderberry and mulberry (use group M) – refined parameter (*) are further described and justified in the text**

| **Intended use** | Elderberry, mulberry | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (g/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 7.2 * | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Orchards Crop directed application BBCH 10–19 | Small granivorous bird “finch” | 10.1 | 1.35 × 0.43 [a)] * | 1.17 | 6.14 |

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio.
[a)] With $DT_{50}$ of 4.64 d, single application (Table 9.2-56)

**Flower bulbs (use group O)**

Small granivorous bird
According to Appendix A of EFSA/2009/1438, small granivorous birds feed on 100% small seeds. The measured $DT_{50}$ in seeds of 4.64 d is used for the refined risk assessment.

**Table 9.2-81: Higher-tier assessment of the long-term/reproductive risk for small granivorous birds due to the use of FLU+TFS SC 500 in flower bulbs (use group O) – refined parameter (*) are further described and justified in the text**

| **Intended use** | Flower bulbs | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (g/ha)** | 1 × 0.2 | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 7.2 * | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Bulbs & onion like crops BBCH 10–39 | Small granivorous bird “finch” | 11.4 | 1.0 × 0.30 [a)] * | 0.684 | 10.5 |

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio.
[a)] With $DT_{50}$ of 4.64 d, single application (Table 9.2-56)

Small omnivorous bird

Based on the field radiotracking study in vegetable field in Great Britain (xxx, 2008, M-302416-01-1, Appendix 2), a highly conservative PT value of 0.97 (90th percentile, consumers, all vegetables combined) is applied in the refined risk assessment for the skylark.

According to Appendix A of EFSA/2009/1438, the diet of the generic focal species woodlark (*Lullula arborea*) consists of 25% crop leaves, 25% weed seeds and 50% ground arthropods. FIR/bw was calculated using the UBA calculator. The refinement for small omnivorous birds in flower bulbs is therefore based on measures $DT_{50}$ values in dicotyledonous leaves and seeds.

**Table 9.2-82: Higher-tier assessment of the long-term/reproductive risk for small omnivorous bird – woodlark - due to the use of FLU + TFS SC 500 in flower bulbs (use group O) – refined parameter (*) are further described and justified in the text**

| Feed item (dry weight) | AR (kg/ha) | FIR/bw | RUD | MAF | 21-d TWA | PT | DDD | NOAEL (mg/kg bw/d) | TER |
|---|---|---|---|---|---|---|---|---|---|
| 25% crop leaves | 0.200 | 0.47 | 28.7 | 1.0 | 0.21 [a)] * | 0.97 * | 0.550 | | |
| 25% weed seeds | 0.200 | 0.06 | 40.2 | 1.0 | 0.30 [b)] * | 0.97 * | 0.140 | | |
| 50% ground invertebrates | 0.200 | 0.36 | 7.5 | 1.0 * | 0.53 | 0.97 * | 0.278 | | |
| Total diet | | | | | | | Σ = 0.968 | 7.2 * | 7.44 |

a) With $DT_{50}$ of 3.05 d, single application (Table 9.2-57)
b) With $DT_{50}$ of 4.64 d, single application (Table 9.2-56)

Small insectivorous bird

A highly conservative PT value of 0.87 (90th percentile, consumers, all vegetables combined) (xxx, 2008, M-302416-01-1, Appendix 2) is used for the following refinement as well as measured $DT_{50}$ in foliar dwelling arthropods (i.e. 5.63 d (geometric mean $DT_{50}$ of 4.2 d)) and the default $DT_{50}$ in ground dwelling arthropods (i.e. 10 d) for small insectivorous bird feeding on ground dwelling arthropods and foliar arthropods (50% of their diet each, Appendix A of EFSA/2009/1438).

**Table 9.2-83: Higher-tier assessment of the long-term/reproductive risk for small insectivorous bird – yellow wagtail - due to the use of FLU + TFS SC 500 in flower bulbs (use group O) – refined parameter (*) are further described and justified in the text**

| Feed item | AR (kg/ha) | FIR/bw | RUD | MAF | 21-d TWA | PT | DDD | NOAEL (mg/kg bw/d) | TER |
|---|---|---|---|---|---|---|---|---|---|
| 50% ground dwelling invertebrates | 0.200 | 0.39 | 7.5 | 1.0 | 0.53 | 0.87 * | 0.270 | | |
| 50% foliar dwelling invertebrates | 0.200 | 0.39 | 21.0 | 1.0 | 0.36 [a)] *<br>0.28 [b)] * | 0.87 * | 0.516<br>0.403 | | |
| Total diet | | | | | | | Σ = 0.786<br>0.673 | 7.2 * | 9.16<br>10.7 |

a) With $DT_{50}$ of 5.63 d, single application (Table 9.2-59)
b) With the geometric mean $DT_{50}$ of 4.2 d, single application (Table 9.2-62)

**Flower bulbs (use group P)**

The input parameter for the refined risk assessment for use group R is identical to the refinement of use group O. TER calculations have been adapted to an application of 5 × 0.075 kg a.s./ha with a 7 day interval.

Small granivorous bird

**Table 9.2-84: Higher-tier assessment of the long-term/reproductive risk for small granivorous birds due to the use of FLU+TFS SC 500 in flower bulbs (use group P) – refined parameter (*) are further described and justified in the text**

| **Intended use** | Flower bulbs | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (g/ha)** | 5 × 0.075, 7 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 7.2 * | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Bulbs & onion like crops BBCH 10–39 | Small granivorous bird “finch” | 11.4 | 1.53 × 0.61 [a] * | 0.798 | 9.02 |

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio.
[a] With $DT_{50}$ of 4.64 d, 5 applications with 7 d interval (Table 9.2-56)

Small omnivorous bird

**Table 9.2-85: Higher-tier assessment of the long-term/reproductive risk for small omnivorous bird – woodlark - due to the use of FLU + TFS SC 500 in flower bulbs (use group P) – refined parameter (*) are further described and justified in the text**

| **Feed item (dry weight)** | **AR (kg/ha)** | **FIR/bw** | **RUD** | **MAF** | **21-d TWA** | **DDD** | **NOAEL (mg/kg bw/d)** | **TER** |
|---|---|---|---|---|---|---|---|---|
| 25% crop leaves | 0.075 | 0.47 | 28.7 | 1.26 [a] * | 0.50 [a] * | 0.637 | | |
| 25% weed seeds | 0.075 | 0.06 | 40.2 | 1.53 [b] * | 0.61 [b] * | 0.169 | | |
| 50% ground invertebrates | 0.075 | 0.36 | 7.5 | 2.4 | 0.53 | 0.258 | | |
| Total diet | | | | | | Σ = 1.06 | 7.2 * | 6.77 |

[a] With $DT_{50}$ of 3.05 d, 5 applications with 7 d interval (Table 9.2-57)
[b] With $DT_{50}$ of 4.64 d, 5 applications with 7 d interval (Table 9.2-56)

Small insectivorous bird

**Table 9.2-86: Higher-tier assessment of the long-term/reproductive risk for small insectivorous bird – yellow wagtail - due to the use of FLU + TFS SC 500 in flower bulbs (use group P) – refined parameter (*) are further described and justified in the text**

| Feed item | AR (kg/ha) | FIR/bw | RUD | MAF | 21-d TWA | PT | DDD | NOAEL (mg/kg bw/d) | TER |
|---|---|---|---|---|---|---|---|---|---|
| 50% ground dwelling invertebrates | 0.075 | 0.39 | 7.5 | 2.4 | 0.53 | 0.87 * | 0.243 | | |
| 50% foliar dwelling invertebrates | 0.075 | 0.39 | 21.0 | 1.71 a) * 1.46 b) * | 0.65 a) * 0.59 b) * | 0.87 * | 0.603 0.461 | | |
| Total diet | | | | | | | Σ = 0.846 0.704 | 7.2 * | 8.51 10.2 |

a) With $DT_{50}$ of 5.63 d, 5 applications with 7 d interval (Table 9.2-59)
b) With the geometric mean $DT_{50}$ of 4.2 d, 5 applications with 7 d interval (Table 9.2-62)

~~**Golf courses (use group Q)**~~

~~Large herbivorous bird~~
~~According to Appendix A of EFSA/2009/1438, the diet of the generic focal species goose consists of 100% grass leaves. Therefore, the measured $DT_{50}$ of 2.6 d in young cereals is used for the refined risk assessment.~~

~~**Table 9.2-87: Higher-tier assessment of the long-term/reproductive risk for Large herbivorous birds due to the use of FLU+TFS SC 500 in golf courses (use group Q) – refined parameter (*) are further described and justified in the text**~~

| | | | | | |
|---|---|---|---|---|---|
| ~~**Intended use**~~ | ~~Golf courses~~ | | | | |
| ~~**Active substance/product**~~ | ~~Fluopyram~~ | | | | |
| ~~**Application rate (kg/ha)**~~ | ~~2 × 0.125, 14 days interval~~ | | | | |
| ~~**Reprod. toxicity (mg/kg bw/d)**~~ | ~~7.2 *~~ | | | | |
| ~~**TER criterion**~~ | ~~5~~ | | | | |
| ~~**Crop scenario Growth stage**~~ | ~~**Generic focal species**~~ | ~~**$SV_m$**~~ | ~~**$MAF_m$ × TWA**~~ | ~~**$DDD_m$ (mg/kg bw/d)**~~ | ~~**$TER_{lt}$**~~ |
| ~~Grassland Growing shoots~~ | ~~Large herbivorous bird "goose"~~ | ~~16.2~~ | ~~1.02 × 0.32 a) *~~ | ~~0.661~~ | ~~10.9~~ |

~~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.~~
~~a) With $DT_{50}$ of 2.6 d, 2 applications with 14 d interval (Table 9.2-58)~~

Small insectivorous bird

Using the measured $DT_{50}$ of 5.63 d (geometric mean $DT_{50}$ of 4.2 d) on foliar dwelling arthropods and the default $DT_{50}$ of 10 d for ground dwelling arthropods, the following refined TER value was calculated for wagtails feeding on 50% foliar dwelling arthropods and 50% ground arthropods (Appendix A of EFSA/2009/1438):

**Table 9.2-88: Higher-tier assessment of the long-term/reproductive risk for small insectivorous bird – yellow wagtail - due to the use of FLU + TFS SC 500 in golf courses (use group Q) – refined parameter (*) are further described and justified in the text**

| Feed item | AR (kg/ha) | FIR/bw | RUD | MAF | 21-d TWA | PT | DDD | NOAEL (mg/kg bw/d) | TER |
|---|---|---|---|---|---|---|---|---|---|
| 50% ground dwelling invertebrates | 0.125 | 0.39 | 7.5 | 1.4 | 0.53 | 1 | 0.271 | | |
| 50% foliar dwelling invertebrates | 0.125 | 0.39 | 21.0 | 1.18 [a] *<br>1.10 [b] * | 0.49 [a] *<br>0.43 [b] * | 1 | 0.602<br>0.495 | | |
| Total diet | | | | | | | Σ = 0.873<br>0.766 | 7.2 * | 8.24<br>9.40 |

[a] With $DT_{50}$ of 5.63 d, 2 applications with 14 d interval (Table 9.2-59)
[b] With the geometric mean $DT_{50}$ of 4.2 d, 2 applications with 14 d interval (Table 9.2-62)

**Hops (use group R)**

Small insectivorous bird

According to Appendix A of EFSA/2009/1438, the diet of small insectivorous bird "finch" consists of 50% ground arthropods (without interception) and 50% foliar arthropods. Thus, the measured $DT_{50}$ of 5.63 d (geometric mean $DT_{50}$ of 4.2 d) on foliar dwelling arthropods and the default $DT_{50}$ of 10 d for ground dwelling arthropods are used in the refined risk assessment.

**Table 9.2-89: Higher-tier assessment of the long-term/reproductive risk for small insectivorous birds – chaffinch - due to the use of FLU + TFS SC 500 in hops (use group R) – refined parameter (*) are further described and justified in the text**

| Feed item | AR (kg/ha) | FIR/bw | RUD | MAF | 21-d TWA | PT | DDD | NOAEL (mg/kg bw/d) | TER |
|---|---|---|---|---|---|---|---|---|---|
| 50% ground dwelling invertebrates | 0.150 | 0.37 | 7.5 | 1.4 | 0.53 | 1 | 0.309 | | |
| 50% foliar dwelling invertebrates | 0.150 | 0.37 | 21.0 | 1.18 [a] *<br>1.10 [b] * | 0.49 [a] *<br>0.43 [b] * | 1 | 0.682<br>0.560 | | |
| Total diet | | | | | | | Σ = 0.991<br>0.869 | 7.2 * | 7.27<br>8.29 |

[a] With $DT_{50}$ of 5.63 d, 2 applications with 14 d interval (Table 9.2-59)
[b] With the geometric mean $DT_{50}$ of 4.2 d, 2 applications with 14 d interval (Table 9.2-62)

**Higher tier risk assessment conclusion**

For Fluopyram the use of the product is considered to be safe in elderberry/mulberry (use group A), beans and peas (use group c), strawberries (use group F), nurseries, rosehip (use group I), tobacco (use group K), elderberry/mulberry (use group M), flower bulbs (use groups O and P) ~~and golf courses (use group Q)~~

For uses in blackberry, chokeberry (red), currant (black, red, white), dewberry, gooseberry and raspberry (use group D) a safe use of Fluopyram can't be concluded for the registered GAP. In case the higher tier risk assessment for Fluopyram is necessary (please see above), it is proposed to restrict the use rate to one application and to the lower range of the registered use rate (i.e.1 x 0.6 L product /ha) – a rate reduction is necessary in case a dose range is not already registered.

For uses in blackberry, currant (red, white), dewberry, gooseberry, raspberry (use group E) a safe use of Fluopyram can't be concluded for the registered GAP. In case the higher tier risk assessment for Fluopyram is necessary (please see above), it is proposed to restrict the use rate to one application.

**Birds - Assessment of combined toxicity**

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

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

These conditions are assessed following a step-wise approach. A detailed description of this approach is presented in a separate document (xxx, 2016, M-571377-02-1). Note that for the calculation only the scenario with the lowest TER values was considered (most critical scenario). This safely covers all other scenarios.

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

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

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

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 $TER_{MIX} \geq 10$ (acute) or 5 (long-term)
Assessment: The combined toxicity risk ($TER_{MIX}$) with concentration-addition is estimated based on the following equation:

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

Please note: For the acute combined toxicity assessment, TER values for the screening step are used whereas TER values calculated at Tier 1 or in the refined risk assessment are used for the long-term/reproductive combined toxicity assessment. The combined toxicity assessment is done as risk envelope: use group A covers use group B, use group D covers use group E, use group F covers use group G, use group I covers use group J and use group M covers use group N.

The risk to birds due to the mixture toxicity assessment is deemed to be acceptable, as fluopyram clearly drives the toxicity of the product as shown by a rpf of ≥ 87%. This value is numerically only very slightly below the 90% which triggers the assignment of one active substance as the “toxicity-driver” or the “risk-driver”, and allows to refrain from assessing a combined toxicity of the product. Furthermore, the toxicity endpoint for trifloxystrobin that is used in the combined toxicity or risk evaluation is based on the NOEC of ≥ 320 ppm in Bobwhite quails (NOEL ≥ 31 mg a.s./kg bw/d). At this highest dietary concentration test, no treatment related effects were observed (please refer to the RAR for Trifloxystrobin, Volume 3 – B.9 (AS), 2016). The reproduction study with a second avian species, the Mallard duck, did not show any treatment related effects at the highest test concentration of 500 ppm. Thus, trifloxystrobin is not toxic to birds at the tested concentrations and the predicted toxicity of the product is caused by fluopyram with a clearly lower NOEL of 4.5 mg a.s./kg bw/d. So overall the assessment of combined toxicity is already addressed after step 2 (see below).
Nevertheless, a combined toxicity assessment including step 3 is presented below.

**zRMS comment:**

Due to the fact that higher tier refinement for Fluopyram was evaluated in the previous registration of the product Luna Sensation by each co-MSs, therefore the previous conclusions (i.e. restrictions or mitigations) still apply for Fluopyram for GAP evaluated at MSs level .
Therefore, since the endpoint for Trifloxystrobin did not change after renewal it is justified to conclude that also the combined risk assessment of the previous registration remains valid and no additional risk assessment for Fluopyram is needed.
In case this justification is not acceptable for all member states refinements for the long-term risk assessment of Fluopyram - the MSs should check the refined parameters for Flupyram previously accepted in their Registration report for Luna Sensation at national level and final conclusion should be made in NA, if nesessery.
For this reason the combined risk for birds was left for MSs level.
However, the new data for the renewad active substance – Trifloxystrobin were evaluated by zRMS. Therfore, in zRMS opinion these data can be used in the refined combined risk assessment**.**

**Table 9.2-90: Combined toxicity assessment – birds in leafy vegetables (use group A)**

| Intended use | Leafy vegetables | | | | |
|---|---|---|---|---|---|
| Active substances | Trifloxystrobin (TFS) + Fluopyram (FLU) | | | | |
| Application rate (L/ha) | 2 × 0.8, 7 days interval | | | | |
| Scenario / Generic focal species | **TER values** [1] | | **1st step** | **2nd step** | **3rd step** |
| | **TFS** | **FLU** | **all TER ≥ trigger × n** | **Rpf$_{max}$** | **TER$_{MIX}$** |
| Acute / Small omnivorous bird (Screening step) | >45.0 | >45.0 | Yes | Not needed | Not needed |
| Long-term / Small granivorous bird "finch" | ≥ 14.5 | 24.1 [2] | Yes | Not needed | Not needed |
| Long-term / Small omnivorous bird "lark" | ≥ 16.8 | 12.8 [3] | Yes | Not needed | Not needed |
| Long-term / Medium herbivorous/granivorous bird "pigeon" | ≥ 8.1 | 7.9 [4] (1.17) | No | ≥ 0.87 (FLU) | **≥ 4.0** [6] |
| Long-term / Small insectivorous bird "wagtail" | ≥ 16.2 | 9.98 12.9 [5] (2.35) | No Yes | ≥ 0.87 (FLU) Not needed | ≥ 6.2 Not needed |

[1] Differing TER values used for rpf calculations to fulfil the criterion of identical refinement levels are shown in brackets
[2] Refined TER (please refer to Table 9.2-63)
[3] Refined TER (please refer to Table 9.2-64)
[4] Refined TER (please refer to Table 9.2-65)
[5] Refined TER (please refer to Table 9.2-66)
[6] A refined TER$_{MIX}$ is presented below (Table 9.2-106)

**Table 9.2-91: Combined toxicity assessment – birds in beans and peas (use group C)**

| Intended use | Beans, peas | | | | |
|---|---|---|---|---|---|
| Active substances | Trifloxystrobin (TFS) + Fluopyram (FLU) | | | | |
| Application rate (L/ha) | 2 × 0.8, 7 days interval | | | | |
| Scenario / Generic focal species | **TER values** [1] | | **1st step** | **2nd step** | **3rd step** |
| | **TFS** | **FLU** | **all TER ≥ trigger × n** | **Rpf$_{max}$** | **TER$_{MIX}$** |

| | | | | | |
|---|---|---|---|---|---|
| Acute / Small omnivorous bird (Screening step) | >45.0 | >45.0 | Yes | Not needed | Not needed |
| Long-term / Small granivorous bird "finch" | ≥ 53.8 | 7.80 | No | ≥ 0.87 (FLU) | 6.8 |
| Long-term / Small omnivorous bird "lark" | ≥ 55.4 | 8.04 | No | ≥ 0.87 (FLU) | 7.0 |
| Long-term / Small insectivorous bird "wagtail" | ≥ 18.8 | 6.5<br>7.9 [2]<br>(2.74) | No | ≥ 0.87 (FLU) | ≥ **4.8**<br>≥ 5.6 [3] |

[1] Differing TER values used for rpf calculations to fulfil the criterion of identical refinement levels are shown in brackets
[2] Refined TER (please refer to Table 9.2-67)
[3] A refined $TER_{MIX}$ is presented below (Table 9.2-108)

**Table 9.2-92: Combined toxicity assessment – birds in berries (use group D)**

| Intended use | Berries | | | | |
|---|---|---|---|---|---|
| Active substances | Trifloxystrobin (TFS) + Fluopyram (FLU) | | | | |
| Application rate (L/ha) | 2 × 0.8, 7 days interval | | | | |
| Scenario / Generic focal species | **TER values [1]** | | **1st step** | **2nd step** | **3rd step** |
| | **TFS** | **FLU** | **all TER ≥ trigger × n** | **$Rpf_{max}$** | **$TER_{MIX}$** |
| Acute / Small frugivorous bird (Screening step) | >154 | >154 | Yes | Not needed | Not needed |
| Long-term / Frugivorous bird "blackcap" | ≥ 7.95 | **3.06** [2]<br>(1.15) | No | ≥ 0.87 (FLU) | **2.2** |
| Long-term / Small insectivorous bird "warbler" | ≥ 9.00 | **2.6** [3]<br>**3.3** [3]<br>(1.31) | No | ≥ 0.87 (FLU) | **2.0**<br>**2.4** |

[1] Differing TER values used for rpf calculations to fulfil the criterion of identical refinement levels are shown in brackets
[2] Refined TER (please refer to Table 9.2-68)
[3] Refined TER (please refer to Table 9.2-69)

**Table 9.2-93: Combined toxicity assessment – birds in strawberries, blueberries and cranberries (use group F)**

| Intended use | Strawberries, blueberries, cranberries | | | | |
|---|---|---|---|---|---|
| Active substances | Trifloxystrobin (TFS) + Fluopyram (FLU) | | | | |
| Application rate (L/ha) | 2 × 0.8, 7 days interval | | | | |
| Scenario / Generic focal species | **TER values [1]** | | **1st step** | **2nd step** | **3rd step** |
| | **TFS** | **FLU** | **all TER ≥ trigger × n** | **$Rpf_{max}$** | **$TER_{MIX}$** |
| Acute / Small omnivorous bird (Screening step) | >45.0 | >45.0 | Yes | Not needed | Not needed |
| Long-term / Small omnivorous bird "lark" | ≥ 16.8 | 7.87 [2]<br>(2.43) | No | ≥ 0.87 (FLU) | ≥ 5.4 |
| Long-term / Frugivorous bird "starling" | ≥ 13.6 | 20.2 [3] | Yes | Not needed | Not needed |
| Long-term / Small insectivorous bird "wagtail" | ≥ 16.2 | **4.74**<br>5.51 [4]<br>(2.35) | No | ≥ 0.87 (FLU) | ≥ **3.7**<br>≥ **4.1** [5] |

[1] Differing TER values used for rpf calculations to fulfil the criterion of identical refinement levels are shown in brackets
[2] Refined TER (please refer to Table 9.2-70)

[3] Refined TER (please refer to Table 9.2-71)
[4] Refined TER (please refer to Table 9.2-72)
[5] A refined $TER_{MIX}$ is presented below (Table 9.2-110)

**Table 9.2-94: Combined toxicity assessment – birds in blueberries and cranberries (use group G)**

| | | | | | |
|---|---|---|---|---|---|
| Intended use | Blueberries, cranberries | | | | |
| Active substances | Trifloxystrobin (TFS) + Fluopyram (FLU) | | | | |
| Application rate (L/ha) | 2 × 0.6, 7 days interval | | | | |
| Scenario / Generic focal species | **TER values [1]** | | **1st step** | **2nd step** | **3rd step** |
| | **TFS** | **FLU** | **all TER ≥ trigger × n** | **$Rpf_{max}$** | **$TER_{MIX}$** |
| Acute / Small omnivorous bird (Screening step) | Risk envelope: covered with use group F | | | | |
| Long-term / Small omnivorous bird "lark" | Risk envelope: covered with use group F | | | | |
| Long-term / Frugivorous bird "starling" | Risk envelope: covered with use group F | | | | |
| Long-term / Small insectivorous bird "wagtail" | ≥ 22.9 [1] | 6.32<br>7.34 [2] | Not applicable | Not applicable | ≥ **5.0**<br>≥ 5.6 |

[1] Refined TER (please refer to Table 9.2-74)
[2] Refined TER (please refer to Table 9.2-73)

**Table 9.2-95: Combined toxicity assessment – birds in grapes (use group H)**

| | | | | | |
|---|---|---|---|---|---|
| Intended use | Grapes | | | | |
| Active substances | Trifloxystrobin (TFS) + Fluopyram (FLU) | | | | |
| Application rate (L/ha) | 2 × 0.2, 14 days interval | | | | |
| Scenario / Generic focal species | **TER values** | | **1st step** | **2nd step** | **3rd step** |
| | **TFS** | **FLU** | **all TER ≥ trigger × n** | **$Rpf_{max}$** | **$TER_{MIX}$** |
| Acute / Small omnivorous bird (Screening step) | >350 | >350 | Yes | Not needed | Not needed |
| Long-term / Small insectivorous bird "redstart" | ≥ 72.7 | 10.5 | Yes | Not needed | Not needed |
| Long-term / Small granivorous bird "finch" | ≥ 121 | 17.6 | Yes | Not needed | Not needed |
| Long-term / Frugivorous bird "thrush/starling" | ≥ 58.0 | 8.42 | No | ≥ 0.87 (FLU) | ≥ 7.4 |
| Long-term / Small omnivorous bird "lark" | ≥ 129 | 18.7 | Yes | Not needed | Not needed |

**Table 9.2-96: Combined toxicity assessment – birds in nurseries and rosehip (use group I)**

| Intended use | Nurseries, rosehip | | | | |
|---|---|---|---|---|---|
| Active substances | Trifloxystrobin (TFS) + Fluopyram (FLU) | | | | |
| Application rate (L/ha) | 2 × 0.8, 7 days interval | | | | |
| Scenario / Generic focal species | **TER values [1]** | | **1st step** | **2nd step** | **3rd step** |
| | **TFS** | **FLU** | **all TER ≥ trigger × n** | **$Rpf_{max}$** | **$TER_{MIX}$** |
| Acute / Small insectivorous bird (Screening step) | >153 | >153 | Yes | Not needed | Not needed |
| Long-term / Small insectivorous bird "tit" | ≥ 10.0 | 5.2<br>6.5 [2]<br>(1.46) | No | ≥ 0.87 (FLU) | **≥ 3.4**<br>≥ 3.9 [3] |
| Long-term / Small insectivorous/worm feeding species "thrush" | ≥ 67.7 | 9.83 | No | ≥ 0.87 (FLU) | ≥ 8.6 |

[1] Differing TER values used for rpf calculations to fulfil the criterion of identical refinement levels are shown in brackets
[2] Refined TER (please refer to Table 9.2-75)
[3] A refined $TER_{MIX}$ is presented below (Table 9.2-112)

**Table 9.2-97: Combined toxicity assessment – birds in tobacco (use group K)**

| Intended use | Tobacco | | | | |
|---|---|---|---|---|---|
| Active substances | Trifloxystrobin (TFS) + Fluopyram (FLU) | | | | |
| Application rate (L/ha) | 1 × 0.8 | | | | |
| Scenario / Generic focal species | **TER values [1]** | | **1st step** | **2nd step** | **3rd step** |
| | **TFS** | **FLU** | **all TER ≥ trigger × n** | **$Rpf_{max}$** | **$TER_{MIX}$** |
| Acute / Small omnivorous bird (Screening step) | >63.0 | >63.0 | Yes | Not needed | Not needed |
| Long-term / Small granivorous bird "gamebird" | ≥ 97.5 | 14.2 | Yes | Not needed | Not needed |
| Long-term / Small insectivorous/worm feeding species "thrush" | ≥ 51.3 | 7.45 | No | ≥ 0.87 (FLU) | ≥ 6.5 |
| Long-term / Small omnivorous bird "lark" | ≥ 26.8 | 7.25 [2]<br>(3.89) | No | ≥ 0.87 (FLU) | ≥ 5.7 |
| Long-term / Medium herbivorous/granivorous bird "pigeon" | ≥ 12.9 | 7.55 [3]<br>(1.87) | No | ≥ 0.87 (FLU) | ≥ **4.8** [5] |
| Long-term / Small insectivorous bird "wagtail" | ≥ 25.9 | 7.97<br>9.30 [4]<br>(3.76) | No | ≥ 0.87 (FLU) | ≥ 6.1<br>≥ 6.8 |

[1] Differing TER values used for rpf calculations to fulfil the criterion of identical refinement levels are shown in brackets
[2] Refined TER (please refer to Table 9.2-76)
[3] Refined TER (please refer to Table 9.2-77)
[4] Refined TER (please refer to Table 9.2-78)
[5] A refined $TER_{MIX}$ is presented below (Table 9.2-114)

**Table 9.2-98: Combined toxicity assessment – birds in celeriac (use group L)**

| Intended use | Celeriac | | | | |
|---|---|---|---|---|---|
| Active substances | Trifloxystrobin (TFS) + Fluopyram (FLU) | | | | |
| Application rate (L/ha) | 2 × 0.5, 14 days interval | | | | |
| Scenario / Generic focal species | **TER values** | | **1st step** | **2nd step** | **3rd step** |
| | **TFS** | **FLU** | **all TER ≥ trigger × n** | **$Rpf_{max}$** | **$TER_{MIX}$** |
| Acute / Small omnivorous bird (Screening step) | >84.0 | >84.0 | Yes | Not needed | Not needed |
| Long-term / Small granivorous bird "finch" | ≥ 98.3 | 14.3 | Yes | Not needed | Not needed |
| Long-term / Small omnivorous bird "lark" | ≥ 101 | 14.7 | Yes | Not needed | Not needed |
| Long-term / Small insectivorous bird "wagtail" | ≥ 34.5 | 5.00 | No | ≥ 0.87 (FLU) | ≥ **4.4** [1] |

[1] A refined $TER_{MIX}$ is presented below (Table 9.2-116)

**Table 9.2-99: Combined toxicity assessment – birds in elderberry and mulberry (use group M)**

| Intended use | Elderberry, mulberry | | | | |
|---|---|---|---|---|---|
| Active substances | Trifloxystrobin (TFS) + Fluopyram (FLU) | | | | |
| Application rate (L/ha) | 2 × 0.8, 7 days interval | | | | |
| Scenario / Generic focal species | **TER values** [1] | | **1st step** | **2nd step** | **3rd step** |
| | **TFS** | **FLU** | **all TER ≥ trigger × n** | **$Rpf_{max}$** | **$TER_{MIX}$** |
| Acute / Small insectivorous bird (Screening step) | >153 | >153 | Yes | Not needed | Not needed |
| Long-term / Small insectivorous bird "tit" | ≥ 10.0 | 5.20 6.46 [2] (1.46) | No | ≥ 0.87 (FLU) | ≥ **3.4** ≥ **3.9** [4] |
| Long-term / Small insectivorous/worm feeding bird "thrush" | ≥ 87.0 | 12.6 | Yes | Not needed | Not needed |
| Long-term / Small granivorous bird "finch" | ≥ 18.1 | 6.14 [3] (2.63) | No | ≥ 0.87 (FLU) | ≥ **4.6** |

[1] Differing TER values used for rpf calculations to fulfil the criterion of identical refinement levels are shown in brackets
[2] Refined TER (please refer to Table 9.2-79)
[3] Refined TER (please refer to Table 9.2-80)
[4] A refined $TER_{MIX}$ is presented below (Table 9.2-118)

**Table 9.2-100: Combined toxicity assessment – birds in flower bulbs (use group O)**

| Intended use | Flower bulbs | | | | |
|---|---|---|---|---|---|
| Active substances | Trifloxystrobin (TFS) + Fluopyram (FLU) | | | | |
| Application rate (L/ha) | 1 × 0.8 | | | | |
| Scenario / Generic focal species | **TER values** [1] | | **1st step** | **2nd step** | **3rd step** |
| | **TFS** | **FLU** | **all TER ≥ trigger × n** | $Rpf_{max}$ | $TER_{MIX}$ |
| Acute / Small omnivorous bird (Screening step) | >63.0 | >63.0 | Yes | Not needed | Not needed |
| Long-term / Small granivorous bird "finch" | ≥ 25.7 | 10.5 [2] | Yes | Not needed | Not needed |
| Long-term / Small omnivorous bird "lark" | ≥ 26.8 | 7.44 [3] (3.89) | No | ≥ 0.87 (FLU) | ≥ 5.8 |
| Long-term / Small insectivorous bird "wagtail" | ≥ 25.9 | 9.16 10.7 [4] (3.76) | No Yes | ≥ 0.87 (FLU) Not needed | ≥ 6.8 Not needed |

[1] Differing TER values used for rpf calculations to fulfil the criterion of identical refinement levels are shown in brackets
[2] Refined TER (please refer to Table 9.2-81)
[3] Refined TER (please refer to Table 9.2-82)
[4] Refined TER (please refer to Table 9.2-83)

**Table 9.2-101: Combined toxicity assessment – birds in flower bulbs (use group P)**

| Intended use | Flower bulbs | | | | |
|---|---|---|---|---|---|
| Active substances | Trifloxystrobin (TFS) + Fluopyram (FLU) | | | | |
| Application rate (L/ha) | 5 × 0.3, 7 days interval | | | | |
| Scenario / Generic focal species | **TER values** [1] | | **1st step** | **2nd step** | **3rd step** |
| | **TFS** | **FLU** | **all TER ≥ trigger × n** | $Rpf_{max}$ | $TER_{MIX}$ |
| Acute / Small omnivorous bird (Screening step) | >88.4 | >88.4 | Yes | Not needed | Not needed |
| Long-term / Small granivorous bird "finch" | ≥ 28.5 | 9.02 [2] (4.14) | No | ≥ 0.87 (FLU) | ≥ 6.9 |
| Long-term / Small omnivorous bird "lark" | ≥ 29.8 | 6.77 [3] (4.33) | No | ≥ 0.87 (FLU) | ≥ 5.5 |
| Long-term / Small insectivorous bird "wagtail" | ≥ 28.8 | 8.51 10.2 [4] | No Yes | ≥ 0.87 (FLU) Not needed | ≥ 6.6 Not needed |

[1] Differing TER values used for rpf calculations to fulfil the criterion of identical refinement levels are shown in brackets
[2] Refined TER (please refer to Table 9.2-84)
[3] Refined TER (please refer to Table 9.2-85)
[4] Refined TER (please refer to Table 9.2-86)

**Table 9.2-102: Combined toxicity assessment – birds in golf courses (use group Q)**

| Intended use | Golf courses | | | | |
|---|---|---|---|---|---|
| Active substances | Trifloxystrobin (TFS) + Fluopyram (FLU) | | | | |
| Application rate (L/ha) | 2 × 0.5, 14 days interval | | | | |
| Scenario / Generic focal species | **TER values [1]** | | **1st step** | **2nd step** | **3rd step** |
| | **TFS** | **FLU** | **all TER ≥ trigger × n** | **$Rpf_{max}$** | **$TER_{MIX}$** |
| Acute / Large herbivorous bird (Screening step) | >437 | >437 | Yes | Not needed | Not needed |
| Long-term / Large herbivorous bird “goose” | ≥ 20.6 | 10.9 [2] | Yes | Not needed | Not needed |
| Long-term / Small insectivorous bird “wagtail” | ≥ 29.6 | 8.24<br>9.40 [3]<br>(4.29) | No | ≥ 0.87 (FLU) | ≥ 6.4<br>≥ 7.1 |

[1] Differing TER values used for rpf calculations to fulfil the criterion of identical refinement levels are shown in brackets
[2] Refined TER (please refer to Table 9.2-87)
[3] Refined TER (please refer to Table 9.2-88)

**Table 9.2-103: Combined toxicity assessment – birds in hops (use group R)**

| Intended use | Hops | | | | |
|---|---|---|---|---|---|
| Active substances | Trifloxystrobin (TFS) + Fluopyram (FLU) | | | | |
| Application rate (L/ha) | 2 × 0.6, 14 days interval | | | | |
| Scenario / Generic focal species | **TER values [1]** | | **1st step** | **2nd step** | **3rd step** |
| | **TFS** | **FLU** | **all TER ≥ trigger × n** | **$Rpf_{max}$** | **$TER_{MIX}$** |
| Acute / Small granivorous bird (Screening step) | >450 | >450 | Yes | Not needed | Not needed |
| Long-term / Small insectivorous bird “finch” | ≥ 26.3 | 7.27<br>8.29 [2]<br>(3.81) | No | ≥ 0.87 (FLU) | ≥ 5.7<br>≥ 6.3 |
| Long-term / Small granivorous bird “finch” | ≥ 48.9 | 7.09 | No | ≥ 0.87 (FLU) | ≥ 6.2 |

[1] Differing TER values used for rpf calculations to fulfil the criterion of identical refinement levels are shown in brackets
[2] Refined TER (please refer to Table 9.2-89)

**Refined assessment of combined toxicity**

A refined risk assessment due to the combined toxicity assessment is needed for the following scenarios:
- medium herbivorous/granivorous bird “pigeon” in leafy vegetables (use group A),
- small insectivorous bird “wagtail” in beans and peas (use group C) (if refined TER for fluopyram is based on $DT_{50}$ of 5.63 d on foliage dweller),
- frugivorous bird “blackcap” and small insectivorous bird “warbler” in berries (use group D),
- small insectivorous bird “wagtail” in strawberries, blueberries and cranberries (use group F),
- small insectivorous bird “tit” in nurseries and rosehip (use group I),
- medium herbivorous/granivorous bird “pigeon” in tobacco (use group K),
- small insectivorous bird “wagtail” in celeriac (use group L) and
- small insectivorous bird “tit” and small granivorous bird “finch” in elderberry and mulberry (use group M).

For this refined combined assessment, refinements are also applied for trifloxystrobin (that were not needed for the single substance assessment).

**Leafy vegetables (use group A)**

Medium herbivorous bird
According to the refined risk assessment for fluopyram, the maximum individual PT value of 0.492 (consumers approach) for the wood pigeon in lettuce (xxx, 2008, M-302416-01-1, Appendix 2) is also applied in the refined risk assessment for trifloxystrobin.

For leaves of dicotyledonous plants, a kinetic study is submitted (Reinken, G.; Alt, F.; 2015; M-519770-01-1, Appendix 2) evaluating an appropriate $DT_{50}$ for lettuce. The kinetic evaluation gives a geometric mean $DT_{50}$ of 3.35 days. MAF and 21-day TWA values were calculated considering the time moving window.

**Table 9.2-104: Trifloxystrobin: MAF and TWA (21 d) calculated for different application scenarios based on a geometric mean $DT_{50}$ of 3.35 d on dicotyledonous leaves**

| Number of applications / Application interval | Refined MAF | Refined TWA (21 d) |
|---|---|---|
| 2 / 7 days | 1.23 | 0.36 |
| 1 / - | 1.00 | 0.23 |

The refined risk assessment for pigeons in leafy vegetables feeding on 100% leaves (Appendix A of EFSA/2009/1438) is based on the measured $DT_{50}$ of 3.35 d in dicotyledonous plants.

**Table 9.2-105: Trifloxystrobin: Higher-tier assessment of the long-term/reproductive risk for medium herbivorous bird – wood pigeon - due to the use of FLU + TFS SC 500 in leafy vegetables (use group A) – refined parameter (*) are further described and justified in the text**

| **Intended use** | Leafy vegetables | | | | | |
|---|---|---|---|---|---|---|
| **Active substance/product** | Trifloxystrobin | | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | ≥ 31 | | | | | |
| **TER criterion** | 5 | | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **PT** | **$DDD_m$ (mg/kg bw/ d)** | **$TER_{lt}$** |
| Leafy vegetables Leaf development BBCH 10-19 | Medium herbivorous/granivorous bird “pigeon” | 22.7 | 1.23 [a)] * × 0.36 [a)] * | 0.492 * | 0.989 | ≥ 31.3 |

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.
[a)] With $DT_{50}$ of 3.35 d, 2 applications with 7 days interval (Table 9.2-104)

Refined combined toxicity assessment

**Table 9.2-106: Refined combined toxicity assessment– birds in leafy vegetables (use group A)**

| Generic focal species | TER values | | $TER_{MIX}$ refined |
|---|---|---|---|
| | Trifloxystrobin | Fluopyram | |
| **Long-term** | | | |
| Medium herbivorous bird – wood pigeon | 31.3 [2] | 7.9 [3] | 6.3 |

[2] Refined TER (please refer to Table 9.2-105)
[3] Refined TER (please refer to Table 9.2-65)

**Beans, peas (use group C)**

Small insectivorous bird

According to the refined risk assessment for fluopyram, a PT value of 0.87 (90th percentile, consumers, , all vegetables combined) for yellow wagtails in vegetable fields in Great Britain (xxx, 2008, M-302416-01-1, Appendix 2) is also applied in the refined risk assessment for trifloxystrobin.

**Table 9.2-107: Trifloxystrobin: Higher-tier assessment of the long-term/reproductive risk for small insectivorous bird – yellow wagtail - due to the use of FLU + TFS SC 500 in beans and peas (use group C) – refined parameter (*) are further described and justified in the text**

| | | | | | | |
|---|---|---|---|---|---|---|
| **Intended use** | Beans, peas | | | | | |
| **Active substance/product** | Trifloxystrobin | | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | ≥ 31 | | | | | |
| **TER criterion** | 5 | | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **PT** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Strawberries BBCH 10–19 | Small insectivorous bird “wagtail” | 9.7 | 1.6 × 0.53 | 0.87 * | 1.43 | ≥ 21.7 |

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.

Refined combined toxicity assessment

**Table 9.2-108: Refined combined toxicity assessment– birds in beans and peas (use group C)**

| Generic focal species | TER values | | $TER_{MIX}$ refined |
|---|---|---|---|
| | Trifloxystrobin | Fluopyram | |
| **Long-term** | | | |
| Small insectivorous bird – yellow wagtail | ≥ 21.7 [1] | 6.5<br>7.9 [2] | ≥ 5.0<br>≥ 5.8 |

[1] Refined TER (please refer to Table 9.2-107)
[2] Refined TER (please refer to

Table 9.2-67)

**Strawberries, blueberries, cranberries (use group F)**

Small insectivorous bird

According to the refined risk assessment for fluopyram, a PT value of 0.94 (90th percentile, consumers) for yellow wagtails in strawberry fields (xxx, 2006, M-342897-01-1, Appendix 2) is also applied in the refined risk assessment for trifloxystrobin.

**Table 9.2-109: Trifloxystrobin: Higher-tier assessment of the long-term/reproductive risk for small insectivorous bird – yellow wagtail - due to the use of FLU + TFS SC 500 in strawberries, blueberries and cranberries (use group F) – refined parameter (*) are further described and justified in the text**

| | | | | | | |
|---|---|---|---|---|---|---|
| **Intended use** | Strawberries, blueberries, cranberries | | | | | |
| **Active substance/product** | Trifloxystrobin | | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | ≥ 31 | | | | | |
| **TER criterion** | 5 | | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **PT** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Strawberries BBCH 10–19 | Small insectivorous bird "wagtail" | 11.3 | 1.6 × 0.53 | 0.94 * | 1.80 | ≥ 17.2 |

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.

Refined combined toxicity assessment

**Table 9.2-110: Refined combined toxicity assessment– birds in strawberries, blueberries and cranberries (use group F)**

| | **TER values** | | **$TER_{MIX}$ refined** |
|---|---|---|---|
| **Generic focal species** | **Trifloxystrobin** | **Fluopyram** | |
| **Long-term** | | | |
| Small insectivorous bird – yellow wagtail | ≥ 17.2 [1] | **4.74** 5.51 [2] | **≥ 3.7** **≥ 4.2** |

[1] Refined TER (please refer to Table 9.2-109)
[2] Refined TER (please refer to Table 9.2-72)

**Nurseries and rosehip (use group I)**

Small insectivorous bird
According to the refined risk assessment for fluopyram, a PT value of 0.57 (90th percentile, consumers) for blue tits in orchards (xxx, 2010, M-429545-01-1, Appendix 2) is also applied in the refined risk assessment for trifloxystrobin.

**Table 9.2-111: Trifloxystrobin: Higher-tier assessment of the long-term/reproductive risk for small insectivorous bird – blue tit - due to the use of FLU + TFS SC 500 in nurseries and rosehip (use group I) – refined parameter (*) are further described and justified in the text**

| **Intended use** | Nurseries, rosehip | | | | | |
|---|---|---|---|---|---|---|
| **Active substance/product** | Trifloxystrobin | | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | ≥ 31 | | | | | |
| **TER criterion** | 5 | | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **PT** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Ornamentals/nursery Application to plant | Small insectivorous bird – blue tit | 18.2 | 1.6 × 0.53 | 0.57 * | 1.76 | ≥ 17.6 |

<u>Refined combined toxicity assessment</u>

**Table 9.2-112: Refined combined toxicity assessment– birds in nurseries and rosehip (use group I)**

| | **TER values** | | **$TER_{MIX}$ refined** |
|---|---|---|---|
| **Generic focal species** | **Trifloxystrobin** | **Fluopyram** | |
| **Long-term** | | | |
| Small insectivorous bird – blue tit | ≥ 17.6 [1] | 5.2<br>6.5 [2] | ≥ **4.0**<br>≥ **4.7** |

[1] Refined TER (please refer to Table 9.2-111)
[2] Refined TER (please refer to Table 9.2-75)

**Tobacco (use group K)**

<u>Medium herbivorous/granivorous bird</u>

According to the refined risk assessment for fluopyram, a refinement is performed for trifloxystrobin. The refined risk assessment for pigeons in tobacco feeding on 100% leaves (Appendix A of EFSA/2009/1438) is based on the measured $DT_{50}$ of 3.35 d in dicotyledonous plants.

**Table 9.2-113: Trifloxystrobin: Higher-tier assessment of the long-term/reproductive risk for medium herbivorous bird due to the use of FLU + TFS SC 500 in tobacco (use group K) – refined parameter (*) are further described and justified in the text**

| **Intended use** | Tobacco | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | Trifloxystrobin | | | | |
| **Application rate (kg/ha)** | 1 × 0.2 | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | ≥ 31 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Maize BBCH 10–29 | Medium herbivorous/granivorous | 22.7 | 1.0 × 0.23 [a)] * | 1.04 | ≥ 29.7 |

| | | | | | |
|---|---|---|---|---|---|
| | bird "pigeon" | | | | |

a) With $DT_{50}$ of 3.35 d, 1 application (Table 9.2-104)

Refined combined toxicity assessment

**Table 9.2-114: Refined combined toxicity assessment– birds in tobacco (use group K)**

| | TER values | | $TER_{MIX}$ refined |
|---|---|---|---|
| **Generic focal species** | **Trifloxystrobin** | **Fluopyram** | |
| **Long-term** | | | |
| Medium herbivorous/granivorous bird "pigeon" | ≥ 29.7 [1] | 7.55 [2] | ≥ 6.0 |

[1] Refined TER (please refer to Table 9.2-113)
[2] Refined TER (please refer to Table 9.2-77)

**Celeriac (use group L)**

Small insectivorous bird

For fluopyram, the $DT_{50}$ in foliar dwelling arthropods of 5.63 d (geometric mean $DT_{50}$ of 4.2 d) and of 10 d in ground dwelling arthropods is used for the refined risk assessment. According to Appendix A of EFSA/2009/1438, the diet of small insectivorous bird "wagtail" in root and stem vegetables at BBCH ≥ 20 consists of 50% ground arthropods (with interception) and 50% foliar arthropods.

**Table 9.2-115: Fluopyram: Higher-tier assessment of the long-term/reproductive risk for small insectivorous bird – yellow wagtail - due to the use of FLU + TFS SC 500 in celeriac (use group L) – refined parameter (*) are further described and justified in the text**

| Feed item | AR (kg/ha) | FIR/bw | RUD | MAF | 21-d TWA | PT | DDD | NOAEL (mg/kg bw/d) | TER |
|---|---|---|---|---|---|---|---|---|---|
| 50% ground dwelling invertebrates | 0.125 | 0.39 | 3.5 | 1.4 | 0.53 | 1 | 0.127 | | |
| 50% foliar dwelling invertebrates | 0.125 | 0.39 | 21.0 | 1.18 a) * <br> 1.10 b) * | 0.49 a) * <br> 0.43 b) * | 1 | 0.602 <br> 0.495 | | |
| Total diet | | | | | | | Σ = 0.729 <br> 0.622 | 7.2 * | 9.88 <br> 11.6 |

a) With $DT_{50}$ of 5.63 d, 2 applications with 14 d interval (Table 9.2-59)
b) With the geometric mean $DT_{50}$ of 4.2 d, 2 applications with 14 d interval (Table 9.2-62)

Refined combined toxicity assessment

**Table 9.2-116: Refined combined toxicity assessment– birds in celeriac (use group L)**

| | TER values | | $TER_{MIX}$ refined |
|---|---|---|---|
| **Generic focal species** | **Trifloxystrobin** | **Fluopyram** | |
| **Long-term** | | | |
| Small insectivorous bird – yellow wagtail | ≥ 34.5 | 9.88 <br> 11.6 [1] | ≥ 7.7 <br> ≥ 8.7 |

[1] Refined TER (please refer to Table 9.2-115)

**Elderberry & mulberry (use group M)**

Small insectivorous bird

According to the refined risk assessment for fluopyram, a PT of 0.57 can be used for blue tits in orchards (xxx, 2010, M-429545-01-1, Appendix 2) also for trifloxystrobin.

**Table 9.2-117: Trifloxystrobin: Higher-tier assessment of the long-term/reproductive risk for small insectivorous bird – blue tit - due to the use of FLU + TFS SC 500 in elderberry and mulberry (use group M) – refined parameter (*) are further described and justified in the text**

| **Intended use** | Elderberry, mulberry | | | | | |
|---|---|---|---|---|---|---|
| **Active substance/product** | Trifloxystrobin | | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | ≥ 31 | | | | | |
| **TER criterion** | 5 | | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m \times TWA$** | **PT** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Orchards Spring Summer | Small insectivorous bird “tit” | 18.2 | 1.6 × 0.53 | 0.57 * | 1.76 | ≥ 17.6 |

Refined combined toxicity assessment

**Table 9.2-118: Refined combined toxicity assessment– birds in elderberry and mulberry (use group M)**

| | **TER values** | | **$TER_{MIX}$ refined** |
|---|---|---|---|
| **Generic focal species** | **Trifloxystrobin** | **Fluopyram** | |
| **Long-term** | | | |
| Small insectivorous bird – blue tit | ≥ 17.6 [1] | 5.20<br>6.46 [2] | **≥ 4.0**<br>**≥ 4.7** |

[1] Refined TER (please refer to Table 9.2-117)
[2] Refined TER (please refer to Table 9.2-79)
[3] Refined TER (please refer to Table 9.2-80)

Considerations on combined toxicity assessment for small granivorous birds and small insectivorous birds in elderberry and mulberry

The risk to birds due to the mixture toxicity assessment is deemed to be acceptable, as fluopyram clearly drives the toxicity of the product as shown by a rpf of ≥ 87%. This value is numerically slightly below the 90% which triggers that one active substance is considered as “toxicity-driver”, allowing to refrain from a combined toxicity assessment. The NOEL for trifloxystrobin is based on a NOEC of ≥ 320 ppm in Bobwhite quails (NOEL ≥ 31 mg a.s./kg bw/d). At this highest dietary concentration test, no treatment related effects were observed (please refer to the RAR for Trifloxystrobin, Volume 3 – B.9 (AS), 2016). The reproduction study with a second avian species, the Mallard duck, did not show any treatment related effects at the highest test concentration of 500 ppm. Thus, trifloxystrobin is not toxic to birds at the tested concentrations and the predicted toxicity of the product is caused by fluopyram with a clearly lower NOEL of 4.5 mg a.s./kg bw/d and a further refined combined toxicity risk assessment is not necessary.

Summary

The following table summarises the outcome of the combined toxicity assessment. As the acute combined toxicity assessment passes the risk assessment in the screening step, only $TER_{MIX}$ values for the long-term risk assessment are considered.

**Table 9.2-119: Overview of relevant generic focal species per use group with respect to the outcome of the combined toxicity assessment (long-term assessment)**

| Use group / Use rate | Small granivorous bird | Small omnivorous bird | Medium herbivorous/ granivorous bird | Small insectivorous bird | Frugivorous bird | Large herbivorous bird |
|---|---|---|---|---|---|---|
| Leafy vegetables (use group A) 2 × 0.8 L product/ha, 7 days interval | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [1] | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [1] | $TER_{MIX}$ = 6.3 [2] (Wood pigeon) | $TER_{MIX}$ = 6.2 [1] | - | - |
| Leafy vegetables (use group B) 1 × 0.8 L product/ha | Risk envelope: covered with use group A | Risk envelope: covered with use group A | Risk envelope: covered with use group A | Risk envelope: covered with use group A | - | - |
| Beans, peans (use group C) 2 × 0.8 L product/ha, 7 days interval | $TER_{MIX}$ = 6.8 [3] | $TER_{MIX}$ = 7.0 [3] | - | $TER_{MIX}$ = 5.0 / 5.8 [21] | - | - |
| Berries (use group D) 2 × 0.8 L product/ha, 7 days interval | - | - | - | $TER_{MIX}$ = **2.0** / **2.4** [4] (TER for FLU < 5) | $TER_{MIX}$ = **2.2** [4] (TER for FLU < 5) | - |
| Berries (use group E) 2 × 0.6 L product/ha | - | - | - | Risk envelope: covered with use group D | Risk envelope: covered with use group D | - |
| Strawberries, blueberries, cranberries (use group F) 2 × 0.8 L product/ha, 7 days interval | - | $TER_{MIX}$ = 5.4 [5] | - | $TER_{MIX}$ = **3.7** / **4.2** [15] (Yellow wagtail) | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [5] | - |

| **Use group / Use rate** | **Small granivorous bird** | **Small omnivorous bird** | **Medium herbivorous/ granivorous bird** | **Small insectivorous bird** | **Frugivorous bird** | **Large herbivorous bird** |
|---|---|---|---|---|---|---|
| Blueberries, cranberries (use group G) 2 × 0.6 L product/ha, 7 days interval | - | Risk envelope: covered with use group F | - | $TER_{MIX}$ = **5.0 / 5.6** [20] (Yellow wagtail) | Risk envelope: covered with use group F | - |
| Grapes (use group H) 2 × 0.2 L product/ha, 14 days interval | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [6] | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [6] | - | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [6] | $TER_{MIX}$ = 5.4 [6] | - |
| Nurseries, rosehip (use group I) 2 × 0.8 L product/ha, 7 days interval | - | - | - | $TER_{MIX}$ = **4.0 / 4.7** [16] (Blue tit) $TER_{MIX}$ = 8.6 [7] ("thrush") | - | - |
| Nurseries, rosehip (use group J) 1 × 0.8 L product/ha | - | - | - | Risk envelope: covered with use group I | - | - |
| Tobacco (use group K) 1 × 0.8 L product/ha | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [8] | $TER_{MIX}$ = 5.7 [8] | $TER_{MIX}$ = 6.0 [17] | $TER_{MIX}$ = 6.5 [8] ("thrush") $TER_{MIX}$ = 6.1 / 6.8 [8] ("wagtail") | - | - |
| Celeriac (use group L) 2 × 0.5 L product/ha, 14 days interval | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [9] | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [9] | - | $TER_{MIX}$ = 7.7 / 8.7 [18] | - | - |
| Elderberry, mulberry (use group M) 2 × 0.8 L product/ha, 7 days interval | $TER_{MIX}$ = **4.6** [10, 21] | - | - | $TER_{MIX}$ = **4.0 / 4.7** [19, 21] (Blue tit)<br><br>$TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [10] ("thrush") | - | - |
| Elderberry, mulberry (use group N) 2 × 0.6 L product/ha, 7 days interval | Risk envelope: covered with use group M | - | - | Risk envelope: covered with use group M | - | - |
| Flower bulbs (use group O) 1 × 0.8 L product/ha | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [11] | $TER_{MIX}$ = 5.8 [11] | - | $TER_{MIX}$ = 6.8 [11] / $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [11] | - | - |

| **Use group / Use rate** | **Small granivorous bird** | **Small omnivorous bird** | **Medium herbivorous/ granivorous bird** | **Small insectivorous bird** | **Frugivorous bird** | **Large herbivorous bird** |
|---|---|---|---|---|---|---|
| Flower bulbs (use group P) 5 × 0.3 L product/ha, 7 days interval | $TER_{MIX}$ = 6.9 [12] | $TER_{MIX}$ = 5.5 [12] | - | $TER_{MIX}$ = 6.6 [12] / $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [12] | - | - |
| ~~Golf courses (use group Q) 2 × 0.5 L product/ha, 14 days interval~~ | - | - | - | ~~$TER_{MIX}$ = 6.4 / 7.1 [13]~~ | - | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [13] |
| Hops (use group R) 2 × 0.6 L product/ha, 14 days interval | $TER_{MIX}$ = 6.2 [14] | - | - | $TER_{MIX}$ = 5.7 / 6.3 [14] | - | - |

[1] Please refer to Table 9.2-90
[2] Please refer to Table 9.2-106
[3] Please refer to Table 9.2-91
[4] Please refer to Table 9.2-92
[5] Please refer to Table 9.2-93
[6] Please refer to Table 9.2-95
[7] Please refer to Table 9.2-96
[8] Please refer to Table 9.2-97
[9] Please refer to Table 9.2-98
[10] Please refer to Table 9.2-99
[11] Please refer to Table 9.2-100
[12] Please refer to Table 9.2-101
[13] Please refer to Table 9.2-102
[14] Please refer to Table 9.2-103
[15] Please refer to Table 9.2-110
[16] Please refer to Table 9.2-112
[17] Please refer to Table 9.2-114
[18] Please refer to Table 9.2-116
[19] Please refer to Table 9.2-118
[20] Please refer to Table 9.2-94
[21] Please refer to Table 9.2-108

**Conclusion for the combined risk assessment**

The risk to birds due to the mixture toxicity assessment is deemed to be acceptable, as fluopyram clearly drives the toxicity of the product as shown by a rpf of 87%. This value is numerically slightly below the 90% which triggers that one active substance can be considered as “toxicity-driver, allowing to refrain from assessing the combined toxicity and risk. The NOEL for trifloxystrobin is based on a NOEC of ≥ 320 ppm in Bobwhite quails (NOEL ≥ 31 mg a.s./kg bw/d). At this highest dietary concentration test, no treatment related effects were observed (please refer to the RAR for Trifloxystrobin, Volume 3 – B.9 (AS), 2016). The reproduction study with a second avian species, the Mallard duck, did not show any treatment related effects at the highest test concentration of 500 ppm. Thus, trifloxystrobin is not toxic to birds at the tested concentrations and the predicted toxicity of the product is caused by fluopyram with a clearly lower NOEL of 4.5 mg a.s./kg bw/d. So overall the assessment of combined toxicity is already addressed after the second step (risk per fraction).

However, in case this is not acceptable the following conclusion can be made after the third step (TER mix calculation):

For the combined risk assessment of the product a safe use can be concluded in elderberry/mulberry (use group A), leafy vegetables (use group B), grapes (use group H), tobacco (use group K), celeriac (use group L), flower bulbs (use groups O and P), golf courses (use group Q) and hops (use group R).

Further refinement was needed (please see section 9.2.2.2) to conclude about a safe use for beans and peas (use group C), strawberries (use group F), blueberries, cranberries (use group G), nurseries, rosehip (use group I), elderberry/mulberry (use group M).

For berries (use group D and use group E) it is proposed to restrict the use rate to one application and to the lower range of the registered use rate (i.e.1 x 0.6 L product /ha) – a rate reduction is necessary in case a dose range is not already registered.

**zRMS comments:**

The refined combitox risk assessment for birds should be checked at MSs level in the previuous Registration report for Luna Sensation.

### 9.2.2.3 Drinking water exposure

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

**Leaf scenario**

Since FLU + TFS SC 500 is 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 must be considered.
To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for leafy vegetables (use group B) also covers the risk for birds from all other intended uses (see 9.1.2) due to the lowest water application rate.

| | | | | | | |
|---|---|---|---|---|---|---|
| Intended use<br>Active substance<br>Application rate (g/ha) | | | Leafy vegetables (use group B)<br>Trifloxystrobin<br>1 × 200 | | | |
| Acute toxicity (mg/kg bw)<br>TER criterion | | | >2000<br>10 | | | |
| (Single) applic. rate<br>(g/ha) | Water applic. rate<br>(L/ha) | $C_{spray-sol.}$<br>(mg/L) | $PEC_{leaf-whorl}$ =<br>$C_{spray-sol.}$/5<br>(mg/L) | DW uptake<br>(L/kg bw/d) | Daily dose<br>(mg/kg bw/d) | $TER_a$ |
| 200 | 200 | 1000 | 200 | 0.46 | 92.0 | >21.7 |

**Puddle scenario**

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

With a K(f)oc of 2287, trifloxystrobin belongs to the group of more sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for leafy vegetables (use group A) also covers the risk for birds from all other intended uses (see 9.1.2).

Trifloxystrobin

| | | | |
|---|---|---|---|
| Effective application rate (g/ha) = | 200[1] | | |
| Acute toxicity (mg/kg bw) = | > 2000 | quotient = | < 0.1 |
| Reprod. toxicity (mg/kg bw/d) = | ≥ 31 | quotient = | ≤ 6.45 |

[1] AR × $MAF_m$ = 200 g/ha × 1 = 200 g/ha; $MAF_m$ based on $DT_{50, soil}$ = 0.52 d and 2 applications with a 7 day interval

**zRMS comments:**

We agree that since the ratio of the total annual application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed the relevant critical value for at least one use scenario, a quantitative risk assessment (calculation of TER values) is not necessary.

### 9.2.2.4 Effects of secondary poisoning

Risk assessments for effects due to secondary poisoning are provided below for the substance(s) with a log $P_{ow}$ which exceeds the trigger value of 3. For the metabolites, only those with a log $P_{ow}$ > 3 and relevant to the media have been considered, in accordance with EFSA/2009/1438.

**Trifloxystrobin**

The log $P_{OW}$ of trifloxystrobin was determined to be 4.5 thereby triggering an assessment for the potential risk through secondary poisoning (EFSA/2009/1438). For the metabolites, only those with a log $P_{OW}$ > 3 and relevant to the media have been considered, in accordance with EFSA/2009/1438.

**Table 9.2-120: log $P_{OW}$ values for trifloxystrobin and all relevant metabolites**

| Substance | log $P_{OW}$ | Trigger value | Risk assessment required? | Compartment |
|---|---|---|---|---|
| Trifloxystrobin | 4.5 * | 3 | yes | Soil, surface water |
| CGA 357261 | 3.86 (pH 7) | | yes | Soil, surface water |
| CGA 357262 | 5.39 (pH 7) | | yes | Surface water |
| CGA 357276 | 4.7 * | | yes | Soil, surface water |
| NOA 409480 | 4.2 * | | yes | Soil, surface water |

* No pH dependency

**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, resulting in FIR/bw = 1.05 for earthworm eating birds. 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 use in lettuce and rocket salad (use group S) (see 9.1.2) also covers the risk for birds from all other intended uses for trifloxystrobin and its metabolites CGA 357261 and NOA 409480. For the metabolite CGA 357276, the assessment for use in flower bulbs (use group U) (see 9.1.2) also covers the risk for birds from all other intended uses.

**Table 9.2-121: Assessment of the risk for earthworm-eating birds due to exposure to trifloxystrobin via bioaccumulation in earthworms (secondary poisoning) for the intended use in lettuce and rocket salad (use group S) (2 x 200 g a.s./ha; 7 day interval)**

| Parameter | Trifloxystrobin | comments |
|---|---|---|
| PECsoil (twa = 21 d) (mg/kg soil) | 0.121 | Maximum PECsoil (twa = 21 d) value resulting from PECsoil, plateau (< 0.001 mg/kg, 20 cm mixing depth) and the maximum 21d-TWAsoil value (0.121 mg/kg, multiple application in FOCUS crop cabbage) (see Part B8, chapter 8.7.2) |
| log Pow / Pow | 4.5 / 32000 | |
| Koc | 2287 | Mean (n = 6) |
| foc | 0.02 | Default |
| BCFworm | 8.4 | BCFworm/soil = (PECworm,ww/PECsoil,dw) = (0.84 + 0.012 × Pow) / foc × Koc |
| PECworm | 1.02 | PECworm = PECsoil × BCFworm/soil |
| Daily dietary dose (mg/kg bw/d) | 1.07 | DDD = PECworm × 1.05 |
| NOEL (mg/kg bw/d) | ≥ 31 | |
| TERlt | ≥ 29.0 | |

TER values shown in bold fall below the relevant trigger.

**Table 9.2-122: Assessment of the risk for earthworm-eating birds due to exposure to trifloxystrobin metabolite CGA 357261 via bioaccumulation in earthworms (secondary poisoning) for the intended use in lettuce and rocket salad (use group S) (2 x 200 g a.s./ha; 7 day interval)**

| Parameter | CGA 357261 | comments |
|---|---|---|
| PECsoil (twa = 21 d) (mg/kg soil) | 0.008 | Maximum PECsoil (twa = 21 d) value resulting from PECsoil, plateau (< 0.001 mg/kg, 20 cm mixing depth) and the maximum 21d-TWAsoil value (0.008 mg/kg, multiple application in FOCUS crop cabbage) (see Part B8, chapter 8.7.2) |
| log Pow / Pow | 3.86 / 7190 | |
| Koc | 487 | Mean (n = 6) |
| foc | 0.02 | Default |
| BCFworm | 8.9 | BCFworm/soil = (PECworm,ww/PECsoil,dw) = (0.84 + 0.012 × Pow) / foc × Koc |
| PECworm | 0.07 | PECworm = PECsoil × BCFworm/soil |
| Daily dietary dose (mg/kg bw/d) | 0.08 | DDD = PECworm × 1.05 |
| NOEL (mg/kg bw/d) | ≥ 3.1 | NOEL/10 of parent endpoint trifloxystrobin |
| TERlt | ≥ 41.3 | |

TER values shown in bold fall below the relevant trigger.

**Table 9.2-123: Assessment of the risk for earthworm-eating birds due to exposure to trifloxystrobin metabolite CGA 357276 via bioaccumulation in earthworms (secondary poisoning) for the intended use in flower bulbs (use group U) (5 x 75 g a.s./ha; 7 day interval)**

| Parameter | CGA 357276 | comments |
|---|---|---|
| PECsoil (twa = 21 d) (mg/kg soil) | 0.016 | Maximum PECsoil (twa = 21 d) value resulting from PECsoil, plateau (< 0.001 mg/kg, 20 cm mixing depth) and the maximum 21d-$TWA_{soil}$ value (0.016 mg/kg, multiple application in FOCUS crop onions) (see Part B8, chapter 8.7.2) |
| log Pow / Pow | 4.7 / 50000 | |
| Koc | 8170 | Mean (n = 6) |
| foc | 0.02 | Default |
| BCFworm | 3.7 | BCFworm/soil = (PECworm,ww/PECsoil,dw) = (0.84 + 0.012 × Pow) / foc × Koc |
| PECworm | 0.06 | PECworm = PECsoil × BCFworm/soil |
| Daily dietary dose (mg/kg bw/d) | 0.06 | DDD = PECworm × 1.05 |
| NOEL (mg/kg bw/d) | ≥ 3.1 | NOEL/10 of parent endpoint trifloxystrobin |
| TERlt | ≥ 50.2 | |

TER values shown in bold fall below the relevant trigger.

**Table 9.2-124: Assessment of the risk for earthworm-eating birds due to exposure to trifloxystrobin metabolite NOA 409480 via bioaccumulation in earthworms (secondary poisoning) for the intended use in lettuce and rocket salad (use group S) (2 x 200 g a.s./ha; 7 day interval)**

| Parameter | NOA 409480 | comments |
|---|---|---|
| PECsoil (twa = 21 d) (mg/kg soil) | 0.024 | Maximum PECsoil (twa = 21 d) value resulting from PECsoil, plateau (< 0.001 mg/kg, 20 cm mixing depth) and the maximum 21d-TWAsoil value (0.024 mg/kg, multiple application in FOCUS crop cabbage) (see Part B8, chapter 8.7.2) |
| log Pow / Pow | 4.2 / 15800 | |
| Koc | 2356 | Mean (n = 6) |
| foc | 0.02 | Default |
| BCFworm | 4.0 | BCFworm/soil = (PECworm,ww/PECsoil,dw) = (0.84 + 0.012 × Pow) / foc × Koc |
| PECworm | 0.10 | PECworm = PECsoil × BCFworm/soil |
| Daily dietary dose (mg/kg bw/d) | 0.10 | DDD = PECworm × 1.05 |
| NOEL (mg/kg bw/d) | ≥ 3.1 | NOEL/10 of parent endpoint trifloxystrobin |
| TERlt | ≥ 30.4 | |

TER values shown in bold fall below the relevant trigger.

### 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, resulting in FIR/bw = 0.159 for fish eating birds. Bioaccumulation in fish is estimated based on predicted concentrations in surface water.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use in chokeberry, elderberry and tree nurseries (use group V) also covers the risk for birds from all other intended uses for trifloxystrobin and its metabolites CGA 357261, CGA 357262 and CGA 357276 (see 9.1.2). For the metabolite NOA 409480, the assessment for the use in flower bulbs (use group W) covers the risk for birds from all other intended uses.

**Table 9.2-125: Assessment of the risk for fish-eating birds due to exposure to trifloxystrobin via bioaccumulation in fish (secondary poisoning) for the intended use in chokeberry, elderberry and tree nurseries (use group V) (2 x 200 g a.s./ha; 7 day interval)**

| Parameter | Trifloxystrobin | comments |
|---|---|---|
| $PEC_{sw}$ (twa = 21 d) (mg/L) | 0.00116 | Maximum $PEC_{sw}$ (twa = 21 d) value resulting from FOCUS Step 2, Northern-/Southern-Europe, application in FOCUS crop pome and stone fruit, spring (see Part B8, chapter 8.9.2). |
| $BCF_{fish}$ | 431 | EFSA Journal 2017;15(10):4989 |
| BMF | - | biomagnification factor (relevant for BCF ≥ 2000) |
| $PEC_{fish}$ | 0.50 | $PEC_{fish} = PEC_{water} \times BCF_{fish}$ |
| Daily dietary dose (mg/kg bw/d) | 0.08 | DDD = $PEC_{fish} \times 0.159$ |
| NOEL (mg/kg bw/d) | ≥ 31 | |
| $TER_{lt}$ | ≥ 390 | |

TER values shown in bold fall below the relevant trigger.

**Table 9.2-126: Assessment of the risk for fish-eating birds due to exposure to trifloxystrobin metabolite CGA 357261 via bioaccumulation in fish (secondary poisoning) for the intended use in chokeberry, elderberry and tree nurseries (use group V) (2 x 200 g a.s./ha; 7 day interval)**

| Parameter | CGA 357261 | comments |
|---|---|---|
| $PEC_{sw}$ (twa = 21 d) (mg/L) | 0.0110 | Maximum $PEC_{sw}$ (twa = 21 d) value resulting from FOCUS Step 2, Northern-/Southern-Europe, application in FOCUS crop pome and stone fruit, spring (see Part B8, chapter 8.9.2). |
| $BCF_{fish}$ | 164 | EFSA Journal 2017;15(10):4989 |
| BMF | - | biomagnification factor (relevant for BCF ≥ 2000) |
| $PEC_{fish}$ | 1.80 | $PEC_{fish} = PEC_{water} \times BCF_{fish}$ |
| Daily dietary dose (mg/kg bw/d) | 0.29 | DDD = $PEC_{fish} \times 0.159$ |
| NOEL (mg/kg bw/d) | ≥ 3.1 | NOEL/10 of parent endpoint trifloxystrobin |
| $TER_{lt}$ | ≥ 10.8 | |

TER values shown in bold fall below the relevant trigger.

**Table 9.2-127-1: Assessment of the risk for fish-eating birds due to exposure to trifloxystrobin metabolite CGA 357261 via bioaccumulation in fish (secondary poisoning) for the intended use in chokeberry, elderberry and tree nurseries (use group V) (2 x 200 g a.s./ha; 7 day interval)**

| Parameter | CGA 357261 | comments |
|---|---|---|
| $PEC_{sw}$ (twa = 21 d) (mg/L) | 0.0110 | Maximum $PEC_{sw}$ (twa = 21 d) value resulting from FOCUS Step 2, Northern-/Southern-Europe, application in FOCUS crop pome and stone fruit, spring (see Part B8, chapter 8.9.2). |
| $BCF_{fish}$ | 431 | BCF value of the active substance<br><br>EFSA Journal 2017;15(10):4989 |
| BMF | - | biomagnification factor (relevant for BCF ≥ 2000) |
| $PEC_{fish}$ | 4.74 | $PEC_{fish} = PEC_{water} \times BCF_{fish}$ |
| Daily dietary dose (mg/kg bw/d) | 0.753 | $DDD = PEC_{fish} \times 0.159$ |
| NOEL (mg/kg bw/d) | ≥ 3.1 | NOEL/10 of parent endpoint trifloxystrobin |
| $TER_{lt}$ | ≥ 4.11 | |

**Table 9.2-128: Assessment of the risk for fish-eating birds due to exposure to trifloxystrobin metabolite CGA 357262 via bioaccumulation in fish (secondary poisoning) for the intended use in chokeberry, elderberry and tree nurseries (use group V) (2 x 200 g a.s./ha; 7 day interval)**

| Parameter | CGA 357262 | comments |
|---|---|---|
| $PEC_{sw}$ (twa = 21 d) (mg/L) | 0.00341 | Maximum $PEC_{sw}$ (twa = 21 d) value resulting from FOCUS Step 2, Northern-/Southern-Europe, application in FOCUS crop pome and stone fruit, spring (see Part B8, chapter 8.9.2). |
| $BCF_{fish}$ | 807 | EFSA Journal 2017;15(10):4989 |
| BMF | - | biomagnification factor (relevant for BCF ≥ 2000) |
| $PEC_{fish}$ | 2.75 | $PEC_{fish} = PEC_{water} \times BCF_{fish}$ |
| Daily dietary dose (mg/kg bw/d) | 0.44 | $DDD = PEC_{fish} \times 0.159$ |
| NOEL (mg/kg bw/d) | ≥ 3.1 | NOEL/10 of parent endpoint trifloxystrobin |
| $TER_{lt}$ | ≥ 7.08 | |

TER values shown in bold fall below the relevant trigger.

**Table 9.2-129-1: Assessment of the risk for fish-eating birds due to exposure to trifloxystrobin metabolite CGA 357262 via bioaccumulation in fish (secondary poisoning) for the intended use in chokeberry, elderberry and tree nurseries (use group V) (2 x 200 g a.s./ha; 7 day interval)**

| Parameter | CGA 357262 | comments |
|---|---|---|
| $PEC_{sw}$ (twa = 21 d) (mg/L) | 0.00341 | Maximum $PEC_{sw}$ (twa = 21 d) value resulting from FOCUS Step 2, Northern-/Southern-Europe, application in FOCUS crop pome and stone fruit, spring (see Part B8, chapter 8.9.2). |
| $BCF_{fish}$ | 431 | BCF value of the active substance<br><br>EFSA Journal 2017;15(10):4989 |
| BMF | - | biomagnification factor (relevant for BCF ≥ 2000) |
| $PEC_{fish}$ | 1.47 | $PEC_{fish} = PEC_{water} \times BCF_{fish}$ |
| Daily dietary dose (mg/kg bw/d) | 0.23 | $DDD = PEC_{fish} \times 0.159$ |
| NOEL (mg/kg bw/d) | ≥ 3.1 | NOEL/10 of parent endpoint trifloxystrobin |
| $TER_{lt}$ | ≥ 13.47 | |

TER values shown in bold fall below the relevant trigger.

**Table 9.2-130: Assessment of the risk for fish-eating birds due to exposure to trifloxystrobin metabolite CGA 357276 via bioaccumulation in fish (secondary poisoning) for the intended use in chokeberry, elderberry and tree nurseries (use group V) (2 x 200 g a.s./ha; 7 day interval)**

| Parameter | CGA 357276 | comments |
|---|---|---|
| $PEC_{sw}$ (twa = 21 d) (mg/L) | 0.000427 | Maximum $PEC_{sw}$ (twa = 21 d) value resulting from FOCUS Step 2, Southern-Europe, application in FOCUS crop pome and stone fruit, spring (see Part B8, chapter 8.9.2). |
| $BCF_{fish}$ | 586 | EFSA Journal 2017;15(10):4989 |
| BMF | - | biomagnification factor (relevant for BCF ≥ 2000) |
| $PEC_{fish}$ | 0.25 | $PEC_{fish} = PEC_{water} \times BCF_{fish}$ |
| Daily dietary dose (mg/kg bw/d) | 0.04 | $DDD = PEC_{fish} \times 0.159$ |
| NOEL (mg/kg bw/d) | ≥ 3.1 | NOEL/10 of parent endpoint trifloxystrobin |
| $TER_{lt}$ | ≥ 77.9 | |

TER values shown in bold fall below the relevant trigger.

**Table 9.2-131-1: Assessment of the risk for fish-eating birds due to exposure to trifloxystrobin metabolite CGA 357276 via bioaccumulation in fish (secondary poisoning) for the intended use in chokeberry, elderberry and tree nurseries (use group V) (2 x 200 g a.s./ha; 7 day interval)**

| Parameter | CGA 357276 | comments |
|---|---|---|
| $PEC_{sw}$ (twa = 21 d) (mg/L) | 0.000427 | Maximum $PEC_{sw}$ (twa = 21 d) value resulting from FOCUS Step 2, Southern-Europe, application in FOCUS crop pome and stone fruit, spring (see Part B8, chapter 8.9.2). |
| $BCF_{fish}$ | 431 | BCF value of the active substance<br><br>EFSA Journal 2017;15(10):4989 |
| BMF | - | biomagnification factor (relevant for BCF ≥ 2000) |
| $PEC_{fish}$ | 0.184 | $PEC_{fish} = PEC_{water} \times BCF_{fish}$ |
| Daily dietary dose (mg/kg bw/d) | 0.029 | $DDD = PEC_{fish} \times 0.159$ |
| NOEL (mg/kg bw/d) | ≥ 3.1 | NOEL/10 of parent endpoint trifloxystrobin |
| $TER_{lt}$ | ≥ 106.90 | |

TER values shown in bold fall below the relevant trigger.

**Table 9.2-132: Assessment of the risk for fish-eating birds due to exposure to trifloxystrobin metabolite NOA 409480 via bioaccumulation in fish (secondary poisoning) for the intended use in flower bulbs (use group W) (5 x 75 g a.s./ha; 7 day interval)**

| Parameter | NOA 409480 | comments |
|---|---|---|
| $PEC_{sw}$ (twa = 21 d) (mg/L) | 0.0007402 | Maximum $PEC_{sw}$ (twa = 21 d) value resulting from FOCUS Step 2, Northern-Europe, application in FOCUS crop onions, autumn (see Part B8, chapter 8.9.2). |
| $BCF_{fish}$ | 274 | EFSA Journal 2017;15(10):4989 |
| BMF | - | biomagnification factor (relevant for BCF ≥ 2000) |
| $PEC_{fish}$ | 0.20 | $PEC_{fish} = PEC_{water} \times BCF_{fish}$ |
| Daily dietary dose (mg/kg bw/d) | 0.03 | $DDD = PEC_{fish} \times 0.159$ |
| NOEL (mg/kg bw/d) | ≥ 3.1 | NOEL/10 of parent endpoint trifloxystrobin |
| $TER_{lt}$ | ≥ 96.1 | |

TER values shown in bold fall below the relevant trigger.

**Table 9.2-133-1: Assessment of the risk for fish-eating birds due to exposure to trifloxystrobin metabolite NOA 409480 via bioaccumulation in fish (secondary poisoning) for the intended use in flower bulbs (use group W) (5 x 75 g a.s./ha; 7 day interval)**

| Parameter | NOA 409480 | comments |
|---|---|---|
| $PEC_{sw}$ (twa = 21 d) (mg/L) | 0.0007402 | Maximum $PEC_{sw}$ (twa = 21 d) value resulting from FOCUS Step 2, Northern-Europe, application in FOCUS crop onions, autumn (see Part B8, chapter 8.9.2). |
| $BCF_{fish}$ | 431 | EFSA Journal 2017;15(10):4989 |
| BMF | - | biomagnification factor (relevant for BCF ≥ 2000) |
| $PEC_{fish}$ | 0.31 | $PEC_{fish} = PEC_{water} \times BCF_{fish}$ |
| Daily dietary dose (mg/kg bw/d) | 0.05 | $DDD = PEC_{fish} \times 0.159$ |
| NOEL (mg/kg bw/d) | ≥ 3.1 | NOEL/10 of parent endpoint trifloxystrobin |
| $TER_{lt}$ | ≥ 62 | |

TER values shown in bold fall below the relevant trigger.

**zRMS comment:**

For the risk assessment of metabolites for fish-eating birds, applicant proposed BCF values calculated by modelling (refer to Appendix 2 for details).
zRMS followed the approach presented in the RAR of trifluxystrobin and used the BCF value of the active substance for the risk assessment of metabolites (marked in blue).
Based on this first step approach, risk is acceptable for all metabolites except metabolite CGA 357261.
In his case BCF for CGA 357261 of 164 can be used as a refinement option.
Taken into consideration this value the risk is considered as acceptable.

### 9.2.2.5 Biomagnification in terrestrial food chains

Not relevant

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

Not relevant

## 9.2.4 Overall conclusions

According to the Guidance as given in the Document SANCO/2010/13170 only the renewed mixing partner has to be evaluated for the renewal of authorisations according to article 43 of Regulation (EC) No 1107/2009. A combitox assessment might still be considered. This leaves different opinions and options how to present the risk assessment for birds and thus leads to different conclusions.

The acute and long-term risk assessment for Trifloxystrobin indicates acceptable risk for all registered uses of FLU+TFS SC500. Furthermore, the assessment of the effects of exposure via drinking water and secondary poisoning indicate acceptable risk. Since the endpoint for Trifloxystrobin did not change after re-approval it is justified to conclude that also the combined risk assessment of the previous registration remains valid and no additional risk assessment for Fluopyram is needed.

In case this justification is not acceptable for all member states a single acute and long-term dietary risk assessment for Fluopyram is available to provide TER values for the combined risk assessment. The acute risk assessment for Fluopyram and the combined toxicity assessment results in TER values above the trigger already at the screening step. In the combined long-term risk assessment, Fluopyram is idenditified as risk driver in the second step (risk per fraction). Therefore, no further assessment is necessary for combined toxicity. The higher tier refinement for Fluopyram was already addressed in the previous registration. Thus, no further higher tier risk assessment has to be performed and previous conclusions (i.e. restrictions or mitigations) still apply for Fluopyram.

In case this justification is not acceptable for all member states refinements for the long-term risk assessment of Fluopyram are included for some generic focal species, especially for omnivorous, insectivorous and herbivorous species. Taking into account field studies and measured DT50 in different matrices, acceptable risk, either for fluopyram or for the combined toxicity assessment, for the current use pattern is demonstrated, except for berries (use group D and E). For an acceptable risk it is proposed to restrict the use rate for use groups D and E to one application and, if necessary, to lower the the registered use rate (i.e.1 x 0.6 L product /ha).

Under these assumptions, it can be concluded that the risk associated with the recommended use of FLU + TFS SC 500 is acceptable for birds.

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

## 9.3.1 Toxicity data

Mammalian toxicity studies have been carried out with fluopyram, trifloxystrobin and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and RAR and related documents as well as in Section 6 (Mammalian Toxicology).

Effects on mammals of FLU + TFS SC 500 were not evaluated as part of the EU assessment of any of the active substances. New data submitted with this application in the core dossier are listed in Appendix 1 and summarised in Section 6 (Mammalian Toxicology).

The studies and endpoints used for the risk assessment are in line with the endpoints listed for the EU review of the concerned active substances.

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

| Species | Substance | Exposure System | Results | Reference |
|---|---|---|---|---|
| Rat | Trifloxystrobin | Oral, 14 d, Acute | $LD_{50}$ > 5000 mg/kg bw | KCA 5.2.1/01<br>RAR & EFSA, 2017[a] |
| Rat | Trifloxystrobin | Dietary Reproductive toxicity | $BMDL_5$ = 22.0 mg/kg bw/d | KCA 8/01<br>RAR & EFSA, 2017[a] |
| Rat | NOA 413161 | Oral, 14 d, Acute | $LD_{50}$ > 2000 mg/kg bw | KCA 5.8.1/13<br>RAR & EFSA, 2017[a] |
| Rat | CGA 373466 | Oral, 14 d, Acute | $LD_{50}$ > 2000 mg/kg bw | KCA 5.8.1/03<br>RAR & EFSA, 2017[a] |
| Rat | CGA 357261 | Oral, 14 d, Acute | $LD_{50}$ > 2000 mg/kg bw | KCA 5.8.1/01<br>RAR & EFSA, 2017[a] |
| Rat | NOA 414412 | Oral, 14 d, Acute | $LD_{50}$ > 2000 mg/kg bw | KCA 5.8.1/07<br>RAR & EFSA, 2017[a] |
| Rat | NOA 413163 | Oral, 14 d, Acute | $LD_{50}$ > 2000 mg/kg bw | KCA 5.8.1/09<br>RAR & EFSA, 2017[a] |

[a] Refer to Appendix 1

**Table 9.3-2: Fluopyram - Endpoints and effect values relevant for the risk assessment for mammals**

| Species | Substance | Exposure System | Results | Reference |
|---|---|---|---|---|
| Rat | Fluopyram | Oral, 14 d, Acute | $LD_{50}$ > 2000 mg a.s./kg bw | EFSA Journal 2013;11(4):3052 |
| Rat | Fluopyram | Dietary<br>Reproductive toxicity<br>Two-generation study | NOAEL = 14.5 mg a.s./kg bw/day<br>(male adults; effects on clinical chemistry parameters, kidney weight, liver weight) | EFSA Journal 2013;11(4):3052 |

**Toxicity of the formulated product**

**Table 9.3-3: Mammalian toxicity data of the formulated product FLU + TFS SC 500**

| Species | Substance | Exposure System | Results | Reference |
|---|---|---|---|---|
| Rat | FLU + TFS SC 500 | Oral<br>14 d<br>Acute | $LD_{50}$ > 2000 mg product/kg bw | See section B6<br>Schuengel, 2007*<br>M-287410-01-1 |

* The study has been summarised in the Part B Section 6 of this dossier, and is not repeated here.

**Table 9.3-4: Calculation of the acute mixed toxicity of the formulation to mammals according to Finney (GIFAP, 1990)**

| | FLU | TFS |
|---|---|---|
| Content within the product (%) [1] | 21.3 | 21.3 |
| $LD_{50}$ (mg a.s./kg bw) | > 2000 | > 5000 |
| $LD_{50}$ – mixed toxicity (mg product/kg bw) | > 6707 | |

[1] Based on a product density of 1174 g/L

A comparison of the acute $LD_{50}$ valued derived for the formulation with the $LD_{50}$ 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.

### 9.3.1.1 Justification for new endpoints

No deviation to EU agreed endpoints.

## 9.3.2 Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for 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 use groups with two applications also cover the risk for mammals from intended uses in groups with a single application or with lower application rates (see 9.1.2).
According to the guidance provided in document SANCO/2010/13170 for products containing two or more active substances there is no need to evaluate data related to the non-renewed substance but if necessary a combitox assessment should be performed. As TER values from the single compound assessment is needed to assess the combined toxicity a complete risk assessment for Flupyram and Trifloxystrobin is included below.

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

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

**Screening step**

**Table 9.3-5: Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in leafy vegetables (use group A)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | | Leafy vegetables | | | |
| **Active substance/product** | | Trifloxystrobin | | | |
| **Application rate (kg/ha)** | | 2 × 0.2, 7 days interval | | | |
| **Acute toxicity (mg/kg bw)** | | >5000 | | | |
| **TER criterion** | | 10 | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Leafy vegetables | Small herbivorous mammal | 136.4 | 1.4 | 38.2 | >131 |
| **Reprod. toxicity (mg/kg bw/d)** | | 22 | | | |
| **TER criterion** | | 5 | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Leafy vegetables | Small herbivorous mammal | 72.3 | 1.6 × 0.53 | 12.3 | **1.79** |

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 9.3-6: Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in leafy vegetables (use group A)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | | Leafy vegetables | | | |
| **Active substance/product** | | Fluopyram | | | |
| **Application rate (kg/ha)** | | 2 × 0.2, 7 days interval | | | |
| **Acute toxicity (mg/kg bw)** | | >2000 | | | |
| **TER criterion** | | 10 | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Leafy vegetables | Small herbivorous mammal | 136.4 | 1.4 | 38.2 | >52.4 |
| **Reprod. toxicity (mg/kg bw/d)** | | 14.5 | | | |
| **TER criterion** | | 5 | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Leafy vegetables | Small herbivorous mammal | 72.3 | 1.6 × 0.53 | 12.3 | **1.18** |

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 9.3-7: Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in beans and peas (use group C)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Beans, peas | | | | |
| **Active substance/product** | Trifloxystrobin | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Acute toxicity (mg/kg bw)** | >5000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Pulses | Small herbivorous mammal | 136.4 | 1.4 | 38.2 | >131 |
| **Reprod. toxicity (mg/kg bw/d)** | 22 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Pulses | Small herbivorous mammal | 72.3 | 1.6 × 0.53 | 12.3 | **1.79** |

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 9.3-8: Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in beans and peas (use group C)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Beans, peas | | | | |
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Acute toxicity (mg/kg bw)** | >2000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Pulses | Small herbivorous mammal | 136.4 | 1.4 | 38.2 | >52.4 |
| **Reprod. toxicity (mg/kg bw/d)** | 14.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Pulses | Small herbivorous mammal | 72.3 | 1.6 × 0.53 | 12.3 | **1.18** |

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 9.3-9: Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in berries (use group D)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Berries | | | | |
| **Active substance/product** | Trifloxystrobin | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Acute toxicity (mg/kg bw)** | >5000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Bush & cane fruit | Small herbivorous mammal | 81.9 | 1.4 | 22.9 | >218 |
| **Reprod. toxicity (mg/kg bw/d)** | 22 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Bush & cane fruit | Small herbivorous mammal | 43.4 | 1.6 × 0.53 | 7.36 | **2.99** |

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 9.3-10: Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in berries (use group D)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Berries | | | | |
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Acute toxicity (mg/kg bw)** | >2000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Bush & cane fruit | Small herbivorous mammal | 81.9 | 1.4 | 22.9 | >87.2 |
| **Reprod. toxicity (mg/kg bw/d)** | 14.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Bush & cane fruit | Small herbivorous mammal | 43.4 | 1.6 × 0.53 | 7.36 | **1.97** |

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 9.3-11: Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in strawberries, blueberries and cranberries (use group F)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Strawberries, blueberries, cranberries | | | | |
| **Active substance/product** | Trifloxystrobin | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Acute toxicity (mg/kg bw)** | >5000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Strawberries | Small herbivorous mammal | 118.4 | 1.4 | 33.2 | >151 |
| **Reprod. toxicity (mg/kg bw/d)** | 22 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Strawberries | Small herbivorous mammal | 48.3 | 1.6 × 0.53 | 8.19 | **2.69** |

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 9.3-12: Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in strawberries, blueberries and cranberries (use group F)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Strawberries, blueberries, cranberries | | | | |
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Acute toxicity (mg/kg bw)** | >2000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Strawberries | Small herbivorous mammal | 118.4 | 1.4 | 33.2 | >60.3 |
| **Reprod. toxicity (mg/kg bw/d)** | 14.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Strawberries | Small herbivorous mammal | 48.3 | 1.6 × 0.53 | 8.19 | **1.77** |

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 9.3-13: Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in grapes (use group H)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Grapes | | | | |
| **Active substance/product** | Trifloxystrobin | | | | |
| **Application rate (kg/ha)** | 2 × 0.05, 14 days interval | | | | |
| **Acute toxicity (mg/kg bw)** | >5000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Vineyards | Small herbivorous mammal | 136.4 | 1.2 | 8.18 | >611 |
| **Reprod. toxicity (mg/kg bw/d)** | 22 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Vineyards | Small herbivorous mammal | 72.3 | 1.4 × 0.53 | 2.68 | 8.20 |

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 9.3-14: Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in grapes (use group H)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Grapes | | | | |
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (kg/ha)** | 2 × 0.05, 14 days interval | | | | |
| **Acute toxicity (mg/kg bw)** | >2000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Vineyards | Small herbivorous mammal | 136.4 | 1.2 | 8.18 | >244 |
| **Reprod. toxicity (mg/kg bw/d)** | 14.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Vineyards | Small herbivorous mammal | 72.3 | 1.4 × 0.53 | 2.68 | 5.41 |

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 9.3-15: Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in nurseries and rosehip (use group I)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | | Nurseries, rosehip | | | |
| **Active substance/product** | | Trifloxystrobin | | | |
| **Application rate (kg/ha)** | | 2 × 0.2, 7 days interval | | | |
| **Acute toxicity (mg/kg bw)** | | >5000 | | | |
| **TER criterion** | | 10 | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Ornamentals/nursery | Small herbivorous mammal | 136.4 | 1.4 | 38.2 | >131 |
| **Reprod. toxicity (mg/kg bw/d)** | | 22 | | | |
| **TER criterion** | | 5 | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Ornamentals/nursery | Small herbivorous mammal | 72.3 | 1.6 × 0.53 | 12.3 | **1.79** |

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 9.3-16: Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in nurseries and rosehip (use group I)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | | Nurseries, rosehip | | | |
| **Active substance/product** | | Fluopyram | | | |
| **Application rate (kg/ha)** | | 2 × 0.2, 7 days interval | | | |
| **Acute toxicity (mg/kg bw)** | | >2000 | | | |
| **TER criterion** | | 10 | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Ornamentals/nursery | Small herbivorous mammal | 136.4 | 1.4 | 38.2 | >52.4 |
| **Reprod. toxicity (mg/kg bw/d)** | | 14.5 | | | |
| **TER criterion** | | 5 | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Ornamentals/nursery | Small herbivorous mammal | 72.3 | 1.6 × 0.53 | 12.3 | **1.18** |

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 9.3-17: Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in tobacco (use group K)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Tobacco | | | | |
| **Active substance/product** | Trifloxystrobin | | | | |
| **Application rate (kg/ha)** | 1 × 0.2 | | | | |
| **Acute toxicity (mg/kg bw)** | >5000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Maize | Small herbivorous mammal | 136.4 | 1.0 | 27.3 | >183 |
| **Reprod. toxicity (mg/kg bw/d)** | 22 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Maize | Small herbivorous mammal | 72.3 | 1.0 × 0.53 | 7.66 | **2.87** |

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 9.3-18: Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in tobacco (use group K)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Tobacco | | | | |
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (kg/ha)** | 1 × 0.2 | | | | |
| **Acute toxicity (mg/kg bw)** | >2000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Maize | Small herbivorous mammal | 136.4 | 1.0 | 27.3 | >73.3 |
| **Reprod. toxicity (mg/kg bw/d)** | 14.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Maize | Small herbivorous mammal | 72.3 | 1.0 × 0.53 | 7.66 | **1.89** |

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 9.3-19: Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in celeriac (use group L)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Celeriac | | | | |
| **Active substance/product** | Trifloxystrobin | | | | |
| **Application rate (kg/ha)** | 2 × 0.125, 14 days interval | | | | |
| **Acute toxicity (mg/kg bw)** | >5000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Root & stem vegetables | Small herbivorous mammal | 118.4 | 1.2 | 17.8 | >282 |
| **Reprod. toxicity (mg/kg bw/d)** | 22 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Root & stem vegetables | Small herbivorous mammal | 48.3 | 1.4 × 0.53 | 4.48 | **4.91** |

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 9.3-20: Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in celeriac (use group L)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Celeriac | | | | |
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (kg/ha)** | 2 × 0.125, 14 days interval | | | | |
| **Acute toxicity (mg/kg bw)** | >2000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Root & stem vegetables | Small herbivorous mammal | 118.4 | 1.2 | 17.8 | >113 |
| **Reprod. toxicity (mg/kg bw/d)** | 14.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Root & stem vegetables | Small herbivorous mammal | 48.3 | 1.4 × 0.53 | 4.48 | **3.24** |

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 9.3-21: Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in elderberry and mulberry (use group M)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Elderberry, mulberry | | | | |
| **Active substance/product** | Trifloxystrobin | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Acute toxicity (mg/kg bw)** | >5000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Orchards | Small herbivorous mammal | 136.4 | 1.4 | 38.2 | >131 |
| **Reprod. toxicity (mg/kg bw/d)** | 22 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Orchards | Small herbivorous mammal | 72.3 | 1.6 × 0.53 | 12.3 | **1.79** |

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 9.3-22: Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in elderberry and mulberry (use group M)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Elderberry, mulberry | | | | |
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Acute toxicity (mg/kg bw)** | >2000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Orchards | Small herbivorous mammal | 136.4 | 1.4 | 38.2 | >52.4 |
| **Reprod. toxicity (mg/kg bw/d)** | 14.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Orchards | Small herbivorous mammal | 72.3 | 1.6 × 0.53 | 12.3 | **1.18** |

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 9.3-23: Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in flower bulbs (use group O)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Flower bulbs | | | | |
| **Active substance/product** | Trifloxystrobin | | | | |
| **Application rate (kg/ha)** | 1 × 0.2 | | | | |
| **Acute toxicity (mg/kg bw)** | >5000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Bulbs & onion like crops | Small herbivorous mammal | 118.4 | 1.0 | 23.7 | >211 |
| **Reprod. toxicity (mg/kg bw/d)** | 22 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Bulbs & onion like crops | Small herbivorous mammal | 48.3 | 1.0 × 0.53 | 5.12 | **4.30** |

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 9.3-24: Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in flower bulbs (use group O)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Flower bulbs | | | | |
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (kg/ha)** | 1 × 0.2 | | | | |
| **Acute toxicity (mg/kg bw)** | >2000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Bulbs & onion like crops | Small herbivorous mammal | 118.4 | 1.0 | 23.7 | >84.5 |
| **Reprod. toxicity (mg/kg bw/d)** | 14.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Bulbs & onion like crops | Small herbivorous mammal | 48.3 | 1.0 × 0.53 | 5.12 | **2.83** |

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 9.3-25: Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in flower bulbs (use group P)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Flower bulbs | | | | |
| **Active substance/product** | Trifloxystrobin | | | | |
| **Application rate (kg/ha)** | 5 × 0.075, 7 days interval | | | | |
| **Acute toxicity (mg/kg bw)** | >5000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Bulbs & onion like crops | Small herbivorous mammal | 118.4 | 1.9 | 16.9 | >296 |
| **Reprod. toxicity (mg/kg bw/d)** | 22 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Bulbs & onion like crops | Small herbivorous mammal | 48.3 | 2.4 × 0.53 | 4.61 | **4.77** |

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 9.3-26: Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in flower bulbs (use group P)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Flower bulbs | | | | |
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (kg/ha)** | 5 × 0.075, 7 days interval | | | | |
| **Acute toxicity (mg/kg bw)** | >2000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Bulbs & onion like crops | Small herbivorous mammal | 118.4 | 1.9 | 16.9 | >119 |
| **Reprod. toxicity (mg/kg bw/d)** | 14.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Bulbs & onion like crops | Small herbivorous mammal | 48.3 | 2.4 × 0.53 | 4.61 | **3.15** |

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 9.3-27: Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in golf courses (use group Q)**

| | | | | | |
|---|---|---|---|---|---|
| ~~**Intended use**~~ | ~~Golf courses~~ | | | | |
| ~~**Active substance/product**~~ | ~~Trifloxystrobin~~ | | | | |
| ~~**Application rate (kg/ha)**~~ | ~~2 × 0.125, 14 days interval~~ | | | | |
| ~~**Acute toxicity (mg/kg bw)**~~ | ~~>5000~~ | | | | |
| ~~**TER criterion**~~ | ~~10~~ | | | | |
| ~~**Crop scenario Growth stage**~~ | ~~**Indicator species**~~ | ~~**SV90**~~ | ~~**MAF90**~~ | ~~**DDD90 (mg/kg bw/d)**~~ | ~~**TERa**~~ |
| ~~Grassland~~ | ~~Small herbivorous mammal~~ | ~~136.4~~ | ~~1.2~~ | ~~20.5~~ | ~~>244~~ |
| ~~**Reprod. toxicity (mg/kg bw/d)**~~ | ~~22~~ | | | | |
| ~~**TER criterion**~~ | ~~5~~ | | | | |
| ~~**Crop scenario Growth stage**~~ | ~~**Indicator species**~~ | ~~**SVm**~~ | ~~**MAFm × TWA**~~ | ~~**DDDm (mg/kg bw/d)**~~ | ~~**TERlt**~~ |
| ~~Grassland~~ | ~~Small herbivorous mammal~~ | ~~72.3~~ | ~~1.4 × 0.53~~ | ~~6.71~~ | ~~**3.28**~~ |

~~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 9.3-28: Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in golf courses (use group Q)**

| | | | | | |
|---|---|---|---|---|---|
| ~~**Intended use**~~ | ~~Golf courses~~ | | | | |
| ~~**Active substance/product**~~ | ~~Fluopyram~~ | | | | |
| ~~**Application rate (kg/ha)**~~ | ~~2 × 0.125, 14 days interval~~ | | | | |
| ~~**Acute toxicity (mg/kg bw)**~~ | ~~>2000~~ | | | | |
| ~~**TER criterion**~~ | ~~10~~ | | | | |
| ~~**Crop scenario Growth stage**~~ | ~~**Indicator species**~~ | ~~**$SV_{90}$**~~ | ~~**$MAF_{90}$**~~ | ~~**$DDD_{90}$ (mg/kg bw/d)**~~ | ~~**$TER_a$**~~ |
| ~~Grassland~~ | ~~Small herbivorous mammal~~ | ~~136.4~~ | ~~1.2~~ | ~~20.5~~ | ~~>97.8~~ |
| ~~**Reprod. toxicity (mg/kg bw/d)**~~ | ~~14.5~~ | | | | |
| ~~**TER criterion**~~ | ~~5~~ | | | | |
| ~~**Crop scenario Growth stage**~~ | ~~**Indicator species**~~ | ~~**$SV_m$**~~ | ~~**$MAF_m$ × TWA**~~ | ~~**$DDD_m$ (mg/kg bw/d)**~~ | ~~**$TER_{lt}$**~~ |
| ~~Grassland~~ | ~~Small herbivorous mammal~~ | ~~72.3~~ | ~~1.4 × 0.53~~ | ~~6.71~~ | ~~**2.16**~~ |

~~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 9.3-29: Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in hops (use group R)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Hops | | | | |
| **Active substance/product** | Trifloxystrobin | | | | |
| **Application rate (kg/ha)** | 2 × 0.15, 14 days interval | | | | |
| **Acute toxicity (mg/kg bw)** | >5000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Hops | Small herbivorous mammal | 81.9 | 1.2 | 14.7 | >339 |
| **Reprod. toxicity (mg/kg bw/d)** | 22 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Hops | Small herbivorous mammal | 43.4 | 1.4 × 0.53 | 4.83 | **4.55** |

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 9.3-30: Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in hops (use group R)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Hops | | | | |
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (kg/ha)** | 2 × 0.15, 14 days interval | | | | |
| **Acute toxicity (mg/kg bw)** | >2000 | | | | |
| **TER criterion** | 10 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_{90}$** | **$MAF_{90}$** | **$DDD_{90}$ (mg/kg bw/d)** | **$TER_a$** |
| Hops | Small herbivorous mammal | 81.9 | 1.2 | 14.7 | >136 |
| **Reprod. toxicity (mg/kg bw/d)** | 14.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Indicator species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Hops | Small herbivorous mammal | 43.4 | 1.4 × 0.53 | 4.83 | **3.00** |

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.

The acute risk assessment for all crop groups passes the risk assessment already at the screening step whereas for the long-term exposure, a Tier 1 risk assessment is needed.

### Tier 1 (long-term)

**Table 9.3-31: First-tier assessment of the long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in leafy vegetables (use group A)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Leafy vegetables | | | | |
| **Active substance/product** | Trifloxystrobin | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 22 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario**<br>**Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Leafy vegetables<br>BBCH 10 - 19 | Small insectivorous mammal<br>“shrew” | 4.2 | 1.6 × 0.53 | 0.712 | 30.9 |
| Leafy vegetables<br>BBCH 40-49 | Small herbivorous mammal<br>"vole" | 72.3 | 1.6 × 0.53 | 12.3 | **1.79** |
| Leafy vegetables<br>All season | Large herbivorous mammal<br>“lagomorph” | 14.3 | 1.6 × 0.53 | 2.43 | 9.07 |
| Leafy vegetables<br>BBCH 10-49 | Small omnivorous mammal<br>“mouse” | 7.8 | 1.6 × 0.53 | 1.32 | 16.6 |

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 9.3-32: First-tier assessment of the long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in leafy vegetables (use group A)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Leafy vegetables | | | | |
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 14.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Leafy vegetables BBCH 10 - 19 | Small insectivorous mammal “shrew” | 4.2 | 1.6 × 0.53 | 0.712 | 20.4 |
| Leafy vegetables BBCH 40-49 | Small herbivorous mammal "vole" | 72.3 | 1.6 × 0.53 | 12.3 | **1.18** |
| Leafy vegetables All season | Large herbivorous mammal “lagomorph” | 14.3 | 1.6 × 0.53 | 2.43 | 5.98 |
| Leafy vegetables BBCH 10-49 | Small omnivorous mammal “mouse” | 7.8 | 1.6 × 0.53 | 1.32 | 11.0 |

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 9.3-33: First-tier assessment of the long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in beans and peas (use group C)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Beans, peas | | | | |
| **Active substance/product** | Trifloxystrobin | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 22 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Pulses BBCH ≥ 20 | Small insectivorous mammal “shrew” | 1.9 | 1.6 × 0.53 | 0.322 | 68.3 |
| Pulses BBCH ≥ 50 | Small herbivorous mammal "vole" | 21.7 | 1.6 × 0.53 | 3.68 | 5.98 |
| Pulses BBCH ≥ 50 | Large herbivorous mammal “lagomorph” | 4.3 | 1.6 × 0.53 | 0.729 | 30.2 |
| Pulses Pre harvest seed BBCH 81-99 | Small omnivorous mammal “mouse” | 6.6 | 1.6 × 0.53 | 1.12 | 19.7 |
| Pulses BBCH ≥ 50 | Small omnivorous mammal “mouse” | 2.3 | 1.6 × 0.53 | 0.390 | 56.4 |

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 9.3-34: First-tier assessment of the long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in beans and peas (use group C)**

| **Intended use** | Beans, peas | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 14.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Pulses BBCH ≥ 20 | Small insectivorous mammal “shrew” | 1.9 | 1.6 × 0.53 | 0.322 | 45.0 |
| Pulses BBCH ≥ 50 | Small herbivorous mammal "vole" | 21.7 | 1.6 × 0.53 | 3.68 | **3.94** |
| Pulses BBCH ≥ 50 | Large herbivorous mammal “lagomorph” | 4.3 | 1.6 × 0.53 | 0.729 | 19.9 |
| Pulses Pre harvest seed BBCH 81-99 | Small omnivorous mammal “mouse” | 6.6 | 1.6 × 0.53 | 1.12 | 13.0 |
| Pulses BBCH ≥ 50 | Small omnivorous mammal “mouse” | 2.3 | 1.6 × 0.53 | 0.390 | 37.2 |

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 9.3-35: First-tier assessment of the long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in berries (use group D)**

| **Intended use** | Berries | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | Trifloxystrobin | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 22 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Bush & cane fruit BBCH 10 - 19 | Small insectivorous mammal “shrew” | 4.2 | 1.6 × 0.53 | 0.712 | 30.9 |
| Bush & cane fruit BBCH 10-19 | Small herbivorous mammal "vole" | 43.4 | 1.6 × 0.53 | 7.36 | **2.99** |
| Bush & cane fruit BBCH 20-39 | Small herbivorous mammal "vole" | 36.1 | 1.6 × 0.53 | 6.12 | **3.6** |
| Bush & cane fruit BBCH >40 | Small herbivorous mammal "vole" | 21.7 | 1.6 × 0.53 | 3.68 | 5.97 |
| Bush & cane fruit Fruit stage BBCH 71-79 currants | Frugivorous mammal "dormouse" | 9.7 | 1.6 × 0.53 | 1.65 | 13.4 |
| Bush & cane fruit BBCH 10-19 | Small omnivorous mammal “mouse” | 4.7 | 1.6 × 0.53 | 0.797 | 27.6 |

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 9.3-36: First-tier assessment of the long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in berries (use group D)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Berries | | | | |
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 14.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Bush & cane fruit BBCH 10 - 19 | Small insectivorous mammal “shrew” | 4.2 | 1.6 × 0.53 | 0.712 | 20.4 |
| Bush & cane fruit BBCH 10-19 | Small herbivorous mammal "vole" | 43.4 | 1.6 × 0.53 | 7.36 | **1.97** |
| Bush & cane fruit BBCH 20-39 | Small herbivorous mammal "vole" | 36.1 | 1.6 × 0.53 | 6.12 | **2.37** |
| Bush & cane fruit BBCH .40 | Small herbivorous mammal "vole" | 21.7 | 1.6 × 0.53 | 3.68 | **3.94** |
| Bush & cane fruit Fruit stage BBCH 71-79 currants | Frugivorous mammal "dormouse" | 9.7 | 1.6 × 0.53 | 1.65 | 8.81 |
| Bush & cane fruit BBCH 10-19 | Small omnivorous mammal “mouse” | 4.7 | 1.6 × 0.53 | 0.797 | 18.2 |

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 9.3-37: First-tier assessment of the long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in strawberry, blueberry and cranberry (use group F)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Strawberry, blueberry, cranberry | | | | |
| **Active substance/product** | Trifloxystrobin | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 22 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Strawberries BBCH 10 - 19 | Small insectivorous mammal “shrew” | 4.2 | 1.6 × 0.53 | 0.712 | 30.9 |
| Strawberries BBCH ≥ 40 | Small herbivorous mammal "vole" | 28.9 | 1.6 × 0.53 | 4.90 | **4.49** |
| Strawberries BBCH 10-39 | Large herbivorous mammal “lagomorph” | 14.3 | 1.6 × 0.53 | 2.43 | 9.07 |
| Strawberries | Small omnivorous mammal | 7.8 | 1.6 × 0.53 | 1.32 | 16.6 |

| | | | | | |
|---|---|---|---|---|---|
| BBCH 10-39 | "mouse" | | | | |

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 9.3-38: First-tier assessment of the long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in strawberry, blueberry and cranberry (use group F)**

| **Intended use** | Strawberry, blueberry, cranberry | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 14.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Strawberries BBCH 10 - 19 | Small insectivorous mammal "shrew" | 4.2 | 1.6 × 0.53 | 0.712 | 20.4 |
| Strawberries BBCH ≥ 40 | Small herbivorous mammal "vole" | 28.9 | 1.6 × 0.53 | 4.90 | **2.96** |
| Strawberries BBCH 10-39 | Large herbivorous mammal "lagomorph" | 14.3 | 1.6 × 0.53 | 2.43 | 5.98 |
| Strawberries BBCH 10-39 | Small omnivorous mammal "mouse" | 7.8 | 1.6 × 0.53 | 1.32 | 11.0 |

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 9.3-39: First-tier assessment of the long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in grapes (use group H)**

| **Intended use** | Grapes | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | Trifloxystrobin | | | | |
| **Application rate (kg/ha)** | 2 × 0.05, 14 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 22 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Vineyards BBCH 10-19 | Large herbivorous mammal "lagomorph" | 6.7 | 1.4 × 0.53 | 0.249 | 88.5 |
| Vineyards BBCH 10 - 19 | Small insectivorous mammal "shrew" | 4.2 | 1.4 × 0.53 | 0.156 | 141 |
| Vineyards Application crop directed BBCH 10 - 19 | Small herbivorous mammal "vole" | 43.4 | 1.4 × 0.53 | 1.61 | 13.7 |
| Vineyards Application crop directed BBCH 10 - | Small omnivorous mammal "mouse" | 4.7 | 1.4 × 0.53 | 0.174 | 126 |

| | | | | | |
|---|---|---|---|---|---|
| 19 | | | | | |

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 9.3-40: First-tier assessment of the long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in grapes (use group H)**

| **Intended use** | Grapes | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (kg/ha)** | 2 × 0.05, 14 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 14.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Vineyards BBCH 10-19 | Large herbivorous mammal “lagomorph” | 6.7 | 1.4 × 0.53 | 0.249 | 58.3 |
| Vineyards BBCH 10 - 19 | Small insectivorous mammal “shrew” | 4.2 | 1.4 × 0.53 | 0.156 | 93.1 |
| Vineyards Application crop directed BBCH 10 - 19 | Small herbivorous mammal "vole" | 43.4 | 1.4 × 0.53 | 1.61 | 9.01 |
| Vineyards Application crop directed BBCH 10 - 19 | Small omnivorous mammal “mouse” | 4.7 | 1.4 × 0.53 | 0.174 | 83.2 |

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 9.3-41: First-tier assessment of the long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in nurseries and rosehip (use group I)**

| **Intended use** | Nurseries, rosehip | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | Trifloxystrobin | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 22 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Ornamentals / nursery Application to plant – exposure to underlying ground | Small insectivorous mammal “shrew” | 1.9 | 1.6 × 0.53 | 0.282 | 78.0 |
| Ornamentals / nursery BBCH 40 - 49 | Small herbivorous mammal "vole" | 72.3 | 1.6 × 0.53 | 10.7 | **2.05** |
| Ornamentals / nursery BBCH >50 | Small herbivorous mammal "vole" | 36.1 | 1.6 × 0.53 | 6.12 | **3.59** |
| Ornamentals / nursery Application crop directed BBCH 10 - 49 | Small omnivorous mammal “mouse” | 7.8 | 1.6 × 0.53 | 1.16 | 19.0 |

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 9.3-42: First-tier assessment of the long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in nurseries and rosehip (use group I)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Nurseries, rosehip | | | | |
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 14.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Ornamentals / nursery Application to plant – exposure to underlying ground | Small insectivorous mammal “shrew” | 1.9 | 1.6 × 0.53 | 0.282 | 51.4 |
| Ornamentals / nursery BBCH 40 - 49 | Small herbivorous mammal "vole" | 72.3 | 1.6 × 0.53 | 10.7 | **1.35** |
| Ornamentals / nursery BBCH >50 | Small herbivorous mammal "vole" | 36.1 | 1.6 × 0.53 | 6.12 | **2.36** |
| Ornamentals / nursery Application crop directed BBCH 10 - 49 | Small omnivorous mammal “mouse” | 7.8 | 1.6 × 0.53 | 1.16 | 12.5 |

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

**Table 9.3-43: First-tier assessment of the long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in tobacco (use group K)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Tobacco | | | | |
| **Active substance/product** | Trifloxystrobin | | | | |
| **Application rate (kg/ha)** | 1 × 0.2 | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 22 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Maize BBCH 10 - 19 | Small insectivorous mammal “shrew” | 4.2 | 1.0 × 0.53 | 0.445 | 49.4 |
| Maize BBCH 10 -29 | Small herbivorous mammal "vole" | 72.3 | 1.0 × 0.53 | 7.66 | **2.87** |
| Maize BBCH 10-29 | Small omnivorous mammal “mouse” | 7.8 | 1.0 × 0.53 | 0.827 | 26.6 |

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 9.3-44: First-tier assessment of the long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in tobacco (use group K)**

| **Intended use** | Tobacco | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (kg/ha)** | 1 × 0.2 | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 14.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Maize BBCH 10 - 19 | Small insectivorous mammal “shrew” | 4.2 | 1.0 × 0.53 | 0.445 | 32.6 |
| Maize BBCH 10 -29 | Small herbivorous mammal "vole" | 72.3 | 1.0 × 0.53 | 7.66 | **1.89** |
| Maize BBCH 10-29 | Small omnivorous mammal “mouse” | 7.8 | 1.0 × 0.53 | 0.827 | 17.5 |

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

**Table 9.3-45: First-tier assessment of the long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in celeriac (use group L)**

| **Intended use** | Celeriac | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | Trifloxystrobin | | | | |
| **Application rate (kg/ha)** | 2 × 0.125, 14 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 22 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Root & stem vegetables BBCH ≥ 20 | Small insectivorous mammal “shrew” | 1.9 | 1.4 × 0.53 | 0.176 | 125 |
| Root & stem vegetables BBCH ≥ 40 | Small herbivorous mammal "vole" | 21.7 | 1.4 × 0.53 | 2.01 | 10.9 |
| Root & stem vegetables BBCH ≥ 40 | Small omnivorous mammal “mouse” | 2.3 | 1.4 × 0.53 | 0.213 | 103 |

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 9.3-46: First-tier assessment of the long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in celeriac (use group L)**

| **Intended use** | Celeriac | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (kg/ha)** | 2 × 0.125, 14 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 14.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Root & stem vegetables BBCH ≥ 20 | Small insectivorous mammal “shrew” | 1.9 | 1.4 × 0.53 | 0.176 | 82.3 |
| Root & stem vegetables BBCH ≥ 40 | Small herbivorous mammal "vole" | 21.7 | 1.4 × 0.53 | 2.01 | 7.20 |
| Root & stem vegetables BBCH ≥ 40 | Small omnivorous mammal “mouse” | 2.3 | 1.4 × 0.53 | 0.213 | 68.0 |

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 9.3-47: First-tier assessment of the long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in elderberry and mulberry (use group M)**

| **Intended use** | Elderberry, mulberry | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | Trifloxystrobin | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 22 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Orchards Application crop directed BBCH 10- 19 | Small herbivorous mammal "vole" | 57.8 | 1.6 × 0.53 | 9.80 | **2.24** |
| Orchards Application crop directed BBCH 20-40 | Small herbivorous mammal "vole" | 43.4 | 1.6 × 0.53 | 7.36 | **2.9** |
| Orchards Application crop directed BBCH >40 | Small herbivorous mammal "vole" | 21.7 | 1.6 × 0.53 | 3.68 | 5.97 |
| Orchards Fruit stage BBCH 71-79 currants | Frugivorous mammal "dormouse" | 22.7 | 1.6 × 0.53 | 3.85 | 5.71 |
| Orchards Application crop directed BBCH 10- 19 | Large herbivorous mammal “lagomorph” | 11.5 | 1.6 × 0.53 | 1.95 | 11.3 |
| Orchards Application crop | Small omnivorous mammal “mouse” | 6.2 | 1.6 × 0.53 | 1.05 | 20.9 |

| | | | | | |
|---|---|---|---|---|---|
| directed BBCH 10- 19 | | | | | |

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 9.3-48: First-tier assessment of the long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in elderberry and mulberry (use group M)**

| **Intended use** | Elderberry, mulberry | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 14.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Orchards Application crop directed BBCH 10- 19 | Small herbivorous mammal "vole" | 57.8 | 1.6 × 0.53 | 9.80 | **1.48** |
| Orchards Application crop directed BBCH 20-40 | Small herbivorous mammal "vole" | 43.4 | 1.6 × 0.53 | 7.36 | **1.97** |
| Orchards Application crop directed BBCH >40 | Small herbivorous mammal "vole" | 21.7 | 1.6 × 0.53 | 3.68 | **3.94** |
| Orchards Fruit stage BBCH 71-79 currants | Frugivorous mammal "dormouse" | 22.7 | 1.6 × 0.53 | 3.85 | **3.77** |
| Orchards Application crop directed BBCH 10- 19 | Large herbivorous mammal “lagomorph” | 11.5 | 1.6 × 0.53 | 1.95 | 7.43 |
| Orchards Application crop directed BBCH 10- 19 | Small omnivorous mammal “mouse” | 6.2 | 1.6 × 0.53 | 1.05 | 13.8 |

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 9.3-49: First-tier assessment of the long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in flower bulbs (use group O)**

| **Intended use** | Flower bulbs | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | Trifloxystrobin | | | | |
| **Application rate (kg/ha)** | 1 × 0.2 | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 22 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Bulbs & onion like crops BBCH 10 - 19 | Small insectivorous mammal “shrew” | 4.2 | 1.0 × 0.53 | 0.445 | 49.4 |
| Bulbs & onion like | Small herbivorous mammal | 43.4 | 1.0 × 0.53 | 4.60 | **4.78** |

| | | | | | |
|---|---|---|---|---|---|
| crops<br>BBCH ≥ 40 | "vole" | | | | |
| Bulbs & onion like crops<br>BBCH 10 - 39 | Small omnivorous mammal “mouse” | 7.8 | 1.0 × 0.53 | 0.827 | 26.6 |

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 9.3-50: First-tier assessment of the long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in flower bulbs (use group O)**

| **Intended use** | Flower bulbs | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (kg/ha)** | 1 × 0.2 | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 14.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Bulbs & onion like crops<br>BBCH 10 - 19 | Small insectivorous mammal “shrew” | 4.2 | 1.0 × 0.53 | 0.445 | 32.6 |
| Bulbs & onion like crops<br>BBCH ≥ 40 | Small herbivorous mammal "vole" | 43.4 | 1.0 × 0.53 | 4.60 | **3.15** |
| Bulbs & onion like crops<br>BBCH 10 - 39 | Small omnivorous mammal “mouse” | 7.8 | 1.0 × 0.53 | 0.827 | 17.5 |

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

**Table 9.3-51: First-tier assessment of the long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in flower bulbs (use group P)**

| **Intended use** | Flower bulbs | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | Trifloxystrobin | | | | |
| **Application rate (kg/ha)** | 5 × 0.075, 7 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 22 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Bulbs & onion like crops<br>BBCH 10 - 19 | Small insectivorous mammal “shrew” | 4.2 | 2.4 × 0.53 | 0.401 | 54.9 |
| Bulbs & onion like crops<br>BBCH ≥ 40 | Small herbivorous mammal "vole" | 43.4 | 2.4 × 0.53 | 4.14 | 5.31 |
| Bulbs & onion like crops | Small omnivorous mammal “mouse” | 7.8 | 2.4 × 0.53 | 0.744 | 29.6 |

| | | | | | |
|---|---|---|---|---|---|
| BBCH 10 - 39 | | | | | |

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 9.3-52: First-tier assessment of the long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in flower bulbs (use group P)**

| **Intended use** | Flower bulbs | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (kg/ha)** | 5 × 0.075, 7 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 14.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Bulbs & onion like crops BBCH 10 - 19 | Small insectivorous mammal “shrew” | 4.2 | 2.4 × 0.53 | 0.401 | 36.2 |
| Bulbs & onion like crops BBCH ≥ 40 | Small herbivorous mammal "vole" | 43.4 | 2.4 × 0.53 | 4.14 | **3.50** |
| Bulbs & onion like crops BBCH 10 - 39 | Small omnivorous mammal “mouse” | 7.8 | 2.4 × 0.53 | 0.744 | 19.5 |

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

~~**Table 9.3-53: First-tier assessment of the long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in golf courses (use group Q)**~~

| ~~**Intended use**~~ | ~~Golf courses~~ | | | | |
|---|---|---|---|---|---|
| ~~**Active substance/product**~~ | ~~Trifloxystrobin~~ | | | | |
| ~~**Application rate (kg/ha)**~~ | ~~2 × 0.125, 14 days interval~~ | | | | |
| ~~**Reprod. toxicity (mg/kg bw/d)**~~ | ~~22~~ | | | | |
| ~~**TER criterion**~~ | ~~5~~ | | | | |
| ~~**Crop scenario Growth stage**~~ | ~~**Generic focal species**~~ | ~~**$SV_m$**~~ | ~~**$MAF_m$ × TWA**~~ | ~~**$DDD_m$ (mg/kg bw/d)**~~ | ~~**$TER_{lt}$**~~ |
| ~~Grassland All season~~ | ~~Large herbivorous mammal “lagomorph”~~ | ~~17.3~~ | ~~1.4 × 0.53~~ | ~~1.60~~ | ~~13.7~~ |
| ~~Grassland late~~ | ~~Small insectivorous mammal “shrew”~~ | ~~1.9~~ | ~~1.4 × 0.53~~ | ~~0.176~~ | ~~125~~ |
| ~~Grassland All season~~ | ~~Small herbivorous mammal "vole"~~ | ~~72.3~~ | ~~1.4 × 0.53~~ | ~~6.71~~ | ~~**3.28**~~ |

~~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 9.3-54: First-tier assessment of the long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in golf courses (use group Q)**

| **Intended use** | Golf courses | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (kg/ha)** | 2 × 0.125, 14 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 14.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Grassland All season | Large herbivorous mammal “lagomorph” | 17.3 | 1.4 × 0.53 | 1.60 | 9.04 |
| Grassland late | Small insectivorous mammal “shrew” | 1.9 | 1.4 × 0.53 | 0.176 | 82.3 |
| Grassland All season | Small herbivorous mammal "vole" | 72.3 | 1.4 × 0.53 | 6.71 | **2.16** |

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 9.3-55: First-tier assessment of the long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in hops (use group R)**

| **Intended use** | Hops | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | Trifloxystrobin | | | | |
| **Application rate (kg/ha)** | 2 × 0.15, 14 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 22 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Hop BBCH ≥ 20 | Small insectivorous mammal “shrew” | 1.9 | 1.4 × 0.53 | 0.211 | 104 |
| Hop BBCH ≥ 40 | Small herbivorous mammal "vole" | 21.7 | 1.4 × 0.53 | 2.42 | 9.11 |
| Hop BBCH 20 - 39 | Small omnivorous mammal “mouse” | 3.9 | 1.4 × 0.53 | 0.434 | 50.7 |

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.

**Table 9.3-56: First-tier assessment of the long-term/reproductive risk for mammals due to the use of FLU+TFS SC 500 in hops (use group R)**

| **Intended use** | Hops | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (kg/ha)** | 2 × 0.15, 14 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 14.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Hop BBCH ≥ 20 | Small insectivorous mammal “shrew” | 1.9 | 1.4 × 0.53 | 0.211 | 68.6 |
| Hop BBCH ≥ 40 | Small herbivorous mammal "vole" | 21.7 | 1.4 × 0.53 | 2.42 | 6.00 |
| Hop BBCH 20 - 39 | Small omnivorous mammal “mouse” | 3.9 | 1.4 × 0.53 | 0.434 | 33.4 |

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.

The use of the product in grapes (use group H), celeriac (use group L) and hops (use group R) is considered to be safe already at screening or Tier 1 level. However, several $TER_{LT}$ for other uses are below the trigger value at Tier 1 and need further considerations. Refined risk assessments are needed for the following generic focal species:

Trifloxystrobin:

- Small herbivorous mammal "vole" in leafy vegetables (use group A), berries (use group D), strawberries (use group F), nurseries and rosehip (use group I), tobacco (use group K), elderberry and mulberry (use group M), flower bulbs (use group O) ~~and golf courses (use group Q).~~

Fluopyram:

- Small herbivorous mammal "vole" in leafy vegetables (use group A), beans and peas (use group C), berries (use group D), strawberries (use group F), nurseries and rosehip (use group I), tobacco (use group K), elderberry and mulberry (use group M), flower bulbs (use group O and P) and golf courses (use group Q),
- frugivorous mammal "dormouse" in elderberry and mulberry (use group M).

**zRMS comments:**

The use of the product in grapes (use group H), celeriac (use group L) and hops (use group R) is considered to be safe already at screening or Tier 1 level for both active substances.

**Refined risk assessments are needed for the following generic focal species:**

**Trifloxystrobin:**

- **Small herbivorous mammal "vole" in leafy vegetables (use group A), berries (use group D), strawberries (use group F), nurseries and rosehip (use group I), tobacco (use group K), elderberry and mulberry (use group M), flower bulbs (use group O)**

Fluopyram:

- Small herbivorous mammal "vole" in leafy vegetables (use group A), beans and peas (use group C), berries (use group D), strawberries (use group F), nurseries and rosehip (use group I), tobacco (use group K), elderberry and mulberry (use group M), flower bulbs (use group O and P.

In case of **flupyram** the co-MSs should check the refinement options accepted in the previously Registration Report for Luna Sensation.

It should be noted that zRMS in the current dossier for Luna Sensation for non-renewed a.s -flupyram used in combitox risk assessment the refined parameters which were previously accepted by zRMS-NL in the Zonal Registration Report for Luna Sensation, July 2018.
The new data submitted for not rewiewd a.s.- fluopyram was not evaluated by zRMS-PL in the context of art. 43 for the assessment for the a.s.- **Trifloxystrobin.**

**Mammals - Assessment of combined toxicity**
As higher tier risk assessments were conducted, the assessment of combined toxicity is presented in 9.3.2.2.

## 9.3.2.2 Higher-tier risk assessment

TER values for voles in different crops are below the trigger of 5 for trifloxystrobin as well as for fluopyram. Furthermore, a refinement for frugivorous mammals in elderberry and mulberry is needed for fluopyram. A refined risk assessment for these species is presented below considering measured $DT_{50}$ values in different matrices for trifloxystrobin and fluopyram.

**Measured $DT_{50}$ values of trifloxystrobin in different matrices**

$DT_{50}$ in monocotyledonous
A kinetic study is submitted (Reinken, G.; Alt, F.; 2015; M-520275-01-1 (Appendix 2)) evaluating an appropriate $DT_{50}$ for cereals (monocot leaves). A further kinetic study is submitted (Reinken, G.; Kallweit, W.; 2019; M-659518-01-1 (Appendix 2) also evaluating an appropriate $DT_{50}$ for cereals (monocot leaves). The kinetic evaluation gives a combined geometric mean $DT_{50}$ of 3.56 days (see Table 9.3-57) when considering residues for the Northern Europe Residue Zone only, which is considered to be used in an ecotoxicological context and therefore for the refined risk assessment for herbivorous mammals.

**Table 9.3-57: Evaluation of $DT_{50}$ for trifloxystrobin for monocot leaves**

| **Trial code** | **Kinetic parameters** | | | | | **Ref.** |
|---|---|---|---|---|---|---|
| | **Model** | **SFO: $DT_{50}$ (d)<br>FOMC: alpha (-)<br>DFOP: $DT_{50,fast}$ (d)<br>HS: $DT_{50,fast}$ (d)** | **SFO: -<br>FOMC: beta (-)<br>DFOP: $DT_{50,slow}$ (d)<br>HS: $DT_{50,slow'}$(d)** | **SFO: -<br>FOMC: -<br>DFOP: g (-)<br>HS: $t_b$ (d)** | **$DT_{50,recalc}$ (d) a)** | |
| 2013/96 Switzerland | SFO | 4.05 | - | - | 4.05 | Appendix 2 Reinken & Alt 2015 M-520275-01-1 |
| FR0106 United Kingdom | SFO | 15.8 | - | - | 15.8 | |
| FR0796 Denmark | SFO | 7.51 | - | - | 7.51 | |
| FR1096 Denmark | SFO | 5.08 | - | - | 5.08 | |
| FR1196 Denmark | SFO | 8.18 | - | - | 8.18 | |
| 15-2953-01 France N | SFO | 2.22 | - | - | 2.22 | Appendix 2 Reinken & Kallweit 2019 M-659518-01-1 |
| 15-2953-02 UK | SFO | 5.36 | - | - | 5.36 | |
| 16-2951-01 France N | DFOP | 0.264 | 8.76 | 0.45829 | 6.42 a) | |
| 16-2951-02 Germany | SFO | 4.46 | - | - | 4.46 | |
| 16-2951-03 Belgium | SFO | 2.97 | - | - | 2.97 | |
| 16-2951-04 Germany | SFO | 4.93 | - | - | 4.93 | |
| 17-2950-01 Germany | SFO | 1.31 | - | - | 1.31 | |
| 17-2950-02 France N | FOMC | 1.16 | 0.3664 | - | 0.69 a) | |
| 17-2950-03 Netherlands | SFO | 1.97 | - | - | 1.97 | |
| 17-2950-04 Belgium | SFO | 1.04 | - | - | 1.04 | |
| **Geometric mean (n=15)** | | | | | **3.56** | |

a) $DT_{50,recalc} = DT_{90,trigger} / 3.32$ (FOMC, DFOP); for SFO no recalculation needed

Using the moving time window, the refined $MAF_m$ and TWA factor for different application scenarios are presented in the following table.

Table 9.3-58: Trifloxystrobin: MAF and TWA (21 d) calculated for different application scenarios based on a geometric mean $DT_{50}$ of 3.56 d on monocotyledonous leaves

| Number of applications / Application interval | Refined MAF | Refined TWA (21 d) |
|---|---|---|
| 5 / 7 days | 1.34 | 0.54 |
| 2 / 14 days | 1.07 | 0.40 |
| 2 / 7 days | 1.26 | 0.37 |

| | | |
|---|---|---|
| 1 / - | 1.00 | 0.24 |

**zRMS comments:**

RMS dosen't agree with refined values of twa and MAF based on $DT_{50}$ =3.56 d for dicot plants for Trifloxystrobin. Please see justification at Point 9.3.2.2.
The defult value of 10 d was used by zRMS.

$DT_{50}$ in dicotyledonous

A further kinetic study is submitted (Reinken, G.; Alt, F.; 2015; M-519770-01-1, Appendix 2) evaluating an appropriate $DT_{50}$ for lettuce (dicots). The kinetic evaluation gives a geometric mean $DT_{50}$ of 3.35 days which is considered to be used in an ecotoxicological content and therefore for the refined risk assessment for herbivorous mammals.

Table 9.3-59: Trifloxystrobin: MAF and TWA (21 d) calculated for different application scenarios based on a geometric mean $DT_{50}$ of 3.35 d on dicotyledonous leaves

| Number of applications / Application interval | Refined MAF | Refined TWA (21 d) |
|---|---|---|
| 5 / 7 days | 1.31 | 0.53 |
| 2 / 14 days | 1.06 | 0.38 |
| 2 / 7 days | 1.23 | 0.36 |
| 1 / - | 1.00 | 0.23 |

**zRMS comments:**

zRMS agrees with refined values of twa and MAF based on $DT_{50}$ =3.35 d for dicot plants for renewed active substance Trifloxystrobin, previously accepted in Registration Report for Luna Sensation, July 2018, zRMS-NL.

**Measured $DT_{50}$ values of fluopyram in different matrices**

According to the higher tier risk assessment for birds, measured $DT_{50}$ values are available for non-grass herbs ($DT_{50}$ = 3.05 days) and for young cereals representing grassy ground vegetation ($DT_{50}$ = 2.6 days). These refined $DT_{50}$ values are used for the refined risk assessment for voles (resulting MAF and TWA (21 d) values are presented in Table 9.2-57 and Table 9.2-58).

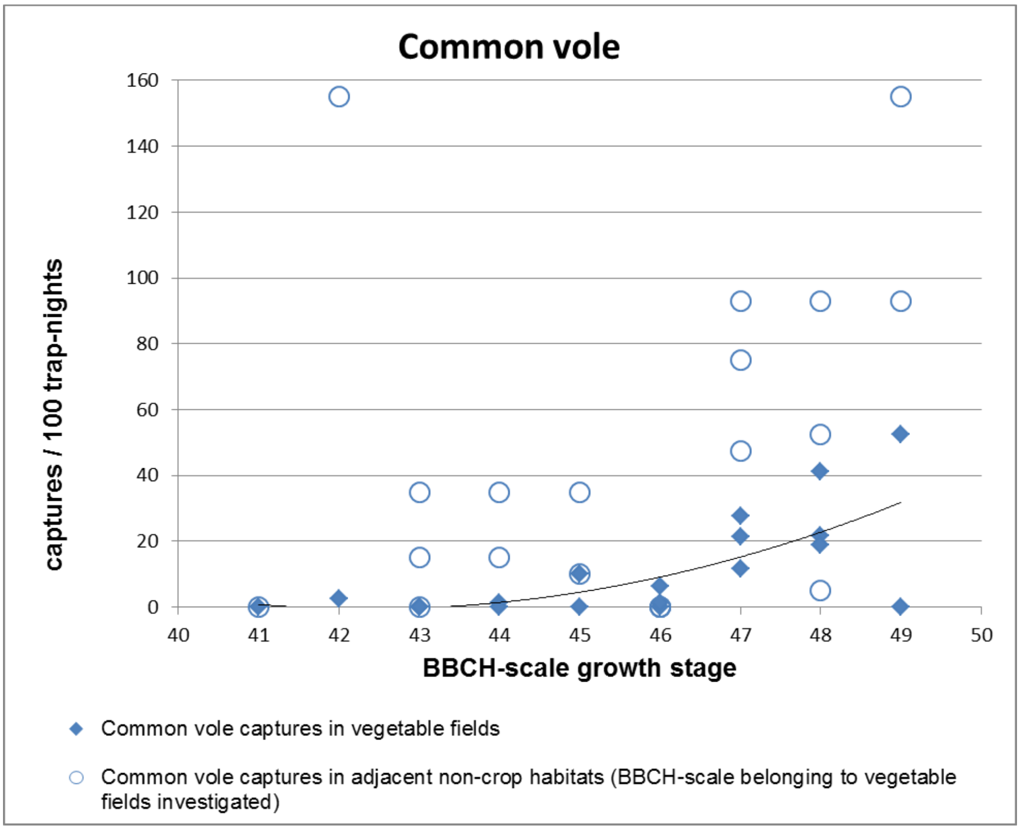
**zRMS comments:**

zRMS agrees with refined values of twa based and MAF on $DT_{50}$ =2.6 d for monocot plants and $DT_{50}$=3.18 d for dicot plants for fluopyram, previously accepted in the Registration report for Luna Sensation by zRMS –NL, July 2018.

**Leafy vegetables (use group A)**

Small herbivorous mammal "vole"
A field study in leafy vegetables (xxx, 2013; M-449690-01-1, Appendix 2) demonstrates that plotting the vole in-field abundance against the BBCH stage of the vegetable field suggests that colonisation is typically not observed before BBCH 45.
Leafy vegetables are typically harvested at BBCH stage 49. Vole populations cannot survive on post-harvest fields that lack cover and food after removal of the crop. Thus, leafy vegetable fields serve only for a very short time as habitat for voles (i.e. from BBCH 45 to 49) and thus a lower level of protection for voles during that short time before the harvest of the crop plants may be deemed acceptable.

**Figure 1: Common voles in fields with leafy vegetables**




However, a refined risk assessment was performed for voles in leafy vegetables considering a diet of 100% crop leaves as there is little other diet for voles in leafy vegetable fields as determined in a field study (~~xxx 2019; M-655399-01-1~~, ~~xxx; 2016; R1540015; M-570937-01-1~~ Appendix 2) . In 63 leafy vegetable fields weed seed and seed-bearing weed plant counts were performed. This included broccoli, cauliflower, broccoli/cauliflower mix, red cabbage, white cabbage, Chinese cabbage, lettuce, and parsley fields. Weed counts resulted in on average 7.18 non-flowering plants, 0.52 flowering plants and 0.09 seed-bearing plants per $m^2$. The mean coverage of weed plants was 4%. This is not considered sufficient to sustain vole populations. Voles have very small activity ranges and need high amounts of food, so that the grassy weeds within their reach would very rapidly be depleted and not of relevance for a long-term risk assessment. However, there is ample supply of food in form of the leafy vegetable crop, and it has therefore to be assumed that the voles (if present) would eat in reality the leafy vegetables rather than grass.
The refined risk assessment is thus based on the measured $DT_{50}$ in dicotyledonous plants of 3.35 d for trifloxystrobin and of 3.05 d for fluopyram.

**zRMS comment:**

**Leafy crops**

The study xxx, R.; 2013; M-449690-01-1, Appendix 2 was evaluated in the previously Registration report for Luna Sensation by zRMS-NL, July 2018.
The vole cannot be eliminated as a focal species in-field. The results of the field study may be considered in a weight-of-evidence analysis (qualitatively), but will not be used in the quantitative risk assessment.

The applicant refereed to the the other study by xxxx. 2019

This study was concerned on PT values for birds linnet and serin for leafy vegetables in Central Europe (Germany).Report No.: R1740067, Edition Number: M-655399-01-1, List of studies provided to zRMS.). Therfore, no information provided for vole were found for leafy vegetables.

The study by xxx; 2016; R1540015; M-570937-01-1 was concerned on
the occurrence of voles inside the strawberry fields compared to off-crop habitats during all sessions in particular at early plant development stages i.e. BBCH 16-19 and 55-73.
The trapping efficiency was more than 100 times lower at BBCH 16 - 19 in in-crop areas compared to off-crop grass habitats. During later crop growth stages the number of captured voles also increased inside the strawberry fields; however it remained lower compared to off-crop grass habitats.
The results of the field study may be considered in a weight-of-evidence analysis (qualitatively), but will not be used in the quantitative risk assessment.
In addition, it should be indicated that refined risk assessment accepted by zRMS-PL based on the measured $DT_{50}$ in dicotyledonous plants of 3.35 d ( dicot) for trifloxystrobin and of 3.18 d ( dicot) for fluopyram as agreed in Registration Report for Luna Sensation, zRMS-NL , July 2018.

**Applicant's comments after Commenting period process:**
**Strawberry**

zRMS agreed that the study of xxx (2016; M-570937-01-1) shows that the occurrence of voles was low inside strawberry fields compared to off-crop habitats in particular during BBCH 16-19 and 55-73. During later growth stages, the number of captured voles increased inside the strawberry fields, however, it remained lower compared to off-crop grass habitats. zRMS agreed that this study can be considered in a weight-of-evidence analysis.
The applicant agrees that the study from xxx cannot be considered in a quantitative risk assessment, however, it should be used in a weight-of-evidence approach for example in the combined toxicity assessment of use group F (strawberries).
Since <1% of the investigated vole population during BBCH 16-19, ~ 8% during BBCH 55-73 and ~34% during BBCH 85-91 were found in-field, it can be expected that there is only a very small percentage of a vole population living in a strawberry field especially until BBCH 73. This shows that strawberry fields are very unattractive for voles especially in stages up to BBCH 73 and that the population stronghold is based off-crop. This should be acknowledged in the weight-of-evidence assessment of voles in strawberries up to BBCH 73.
Therefore, the applicant proposes to consider that in stages up to BBCH 73, less than 10% of the population is associated with an in-field risk with a TERmix of 4.39 (BBCH > 40; 14 d interval, refined TER based on accepted and proposed DT50 refinements from zRMS and a DT50 for TFS exposed monocots of 5.36 d as described above; TERmix according to zRMS = 4.16). In contrast, the part of the population living off-crop (> 90%), would be at acceptable risk considering a TERmix of 158 (based on refinements stated above and an assumed off-crop drift of 2.77%). Therefore, the applicant considers only a very small part of the population at risk with a TER close to the trigger of 5. For the main part of the population, the risk would be acceptable between BBCH 40 and 73.
After BBCH 73, the proportion of in-crop catches increases, and it is a risk management question whether the protection level for in-crop voles is sufficient with the achieved TER of 4.39, given that voles are essentially undesired in strawberry fields as they may transfer illnesses to humans during harvest (e.g. Desai et al 2007, https://doi.org/10.1086/597036).

**Lefy vegetables:**

The applicant wants to re-emphasize that due to a late settlement of voles in leafy vegetable fields, these vegetables are only used as food source by voles during short time period (BBCH 45-49) and that at BBCH 49, these vegetables are harvested. Therefore, this habitat is only available and used for a very short time period und thus, also the potential exposure is very short. After this time period (after harvesting), the voles from the former vegetable field would experience much higher risk from predation on the open field, and/or when they try to emigrate into other vegetated areas with enough shelter. Both ways, a high impact from harvest on the in-field vole population must be expected. Thus, the following conclusions should be considered in the refined risk assessment:

A risk for the in-field vole population during BBCH 45-49 cannot be excluded ($TER_{mix}$ 1.50 according to zRMS calculations; $TER_{mix}$ 1.59 based on proposed DT50 refinement for trifloxystrobin and monocots), but this population will anyway be diminished very soon by the consequences of harvest, and thus contribute very little to the long-term sustainability of the local population. This long-term sustainability of the local vole population depends effectively on the protection of the voles in off-crop habitats, and these voles are protected with an off-crop $TER_{mix}$ of 57.4 (based on spray drift calculations and proposed DT50 refinement for trifloxystrobin and monocots; off-crop $TER_{mix}$ of 51.5 without this refinement). Thus, the use of the product in leafy vegetables does not pose an unacceptable long-term risk on the population level.

**zRMS:**

The above information can be considered at MSs level.

## Group A

**Table 9.3-60: Higher-tier assessment of the long-term/reproductive risk for small herbivorous mammals for trifloxystrobin due to the use of FLU + TFS SC 500 in leafy vegetables (use group A) – refined parameters (*) are further described and justified in the text**

| Feed item | AR (kg/ha) | FIR/bw | RUD | MAF | 21-d TWA | DDD | NOAEL (mg/kg bw/d) | TER |
|---|---|---|---|---|---|---|---|---|
| 100% dicots | 0.200 | 1.62 | 28.7 | 1.23 [a] * | 0.36 [a] * | 4.127 | 22 | 5.3 |

[a] With $DT_{50}$ of 3.35 d, 2 applications with 7 d interval (**Table 9.3-59**)

**Table 9.3-61: Higher-tier assessment of the long-term/reproductive risk for small herbivorous mammals for fluopyram due to the use of FLU + TFS SC 500 in leafy vegetables (use group A) – refined parameters (*) are further described and justified in the text**

| Feed item | AR (kg/ha) | FIR/bw | RUD | MAF | 21-d TWA | DDD | NOAEL (mg/kg bw/d) | TER |
|---|---|---|---|---|---|---|---|---|
| 100% monocots | 0.200 | 1.62 | 28.71, | 1.20 [a] * | 0.34 [a] * | 3.793 | 14.5 | **3.8** |

[a] With $DT_{50}$ of 3.05 d, 2 applications with 7 d interval (Table 9.2-57)

**zRMS comment:**
**Group A**

In the previously evaluated report for Luna Sensation, July 2018 by zRMS-NL the diet for vole based on studies by Rinke (1991)[1] and Luthi (2010)[2], was set at 50/50 monocots/dicots in agricultural fields (like leafy vegetable crop fields) for the chronic risk assessment
The FIR/bw values was calculated by zRMS –NL according to Appendix G of the EFSA Guidance document are 0.73 and 0.73 for monocots and dicots.
The deposition factor is maintained at 1, as indicated for voles in leafy vegetables. Therefore, zRMS-PL provided the risk assessment for flupyram and trifloxystrobin based on the assumptions previously agreed.

**Refined risk assessment (herbivorous mammals "vole" BBCH 40-49, leafy vegetables, 2x200 g a.s./ha, BBCH 12-49, 7d interval)**

| | FLU | | TFS | |
|---|---|---|---|---|
| | | | | |
| **Food item** | Monocots | Dicots | Monocots | Dicots |
| **$DT_{50}$** | 2.6 d | 3.18 d | 10 d | 3.35 d |
| **AR** | 0.2 | 0.2 | 0.2 | 0.2 |
| **FIR/bw** | 0.73 | 0.73 | 0.73 | 0.73 |
| **RUD** | 54.2 | 28.7 | 54.2 | 28.7 |
| **$f_{DEP}$** | 1 | 1 | 1 | 1 |
| **MAF** | 0.35 | 0.42 | 1.6 | 0.44 |
| **21-d $f_{TWA}$** | | | 0.53 | |

[1] Percentage of volume versus number of species: Availability and intake of grasses and forbs in microtus arvalis. *Folia zoological* 40(2): 143-151
[2] Lüthi, M. et all. Nutritional ecology of Microtus arvalis (Pallas, 1779) in sown wild flower fields and quasi-natural habitats. *Revue suisse de Zoologie* 117 (4): 811-828; December 2010

| | | | | |
|---|---|---|---|---|
| **PT** | 1 | 1 | 1 | 1 |
| **DDD** | 2.76 | 1.76 | 6.71 | 1.84 |
| **total DDD** | 4.52 | | 8.55 | |
| **NOAEL** | 14.5 | | 22 | |
| **TER** | **3.2** | | **2.57** | |
| **TERmix** | **1.50** | | | |

The $TER_{LT}$ values for both a.s. are below trigger of 5 indicating needs for further refinement for max application dose of 2 x 200 g a.s./ha for leafy crops for vole at BBCH 40-49.
The combitox risk assessment needs further refinement for max application dose of 2 x 200 g a.s./ha for leafy crops for vole.

**Beans and peas (use group C)**

Small herbivorous mammal "vole"
In fact, real Common voles do not only feed on monocots as seemingly implied by the generic focal species scenario in the EFSA GD. A range of publications confirm that the EFSA Tier 1 generic focal species scenario ("voles eating only short grass") is only a simplified first tier assumption, since voles readily feed on dicotyledonous plants as well. For example in a study of xxx (2010, M-440511-01-1, Appendix 2) voles consumed a broad spectrum of feed (including dicots) and did not show a clear preference. The fact that voles feed on monocots and dicots is supported by several other publications, e.g. xxx (1998, M-228713-01-1, Appendix 2) or xxx (1990, M-228620-01-2, Appendix 2). Therefore, the refined risk assessment is calculated for 50% monocots and 50% dicots.
The refined exposure assessment is based on a mixed diet, with $DT_{50}$ values available for both fluopyram and trifloxystrobin on both monocots and dicots. The TER calculation was done with the Bird & Mammal TER calculator (UBA, 2012).
As the application of the product in beans and peas is at a late growth stage (BCH 59-89), crop interception in pulses at BBCH ≥ 50 is already very high (70%) according to the FOCUS groundwater report (Table 2 in Appendix E of EFSA/2009/1438). Thus, according to the Tier 1 risk assessment, a deposition of 30% is additionally considered in the refined risk assessment for voles in pulses.

**Table 9.3-62: Higher-tier assessment of the long-term/reproductive risk for small herbivorous mammals for <u>fluopyram</u> due to the use of FLU + TFS SC 500 in beans and peas (use group C) – refined parameters (*) are further described and justified in the text**

| Feed item | AR (kg/ha) | FIR/bw | RUD × Deposition factor * | MAF | 21-d TWA | DDD | NOAEL (mg/kg bw/d) | TER |
|---|---|---|---|---|---|---|---|---|
| 50% monocots | 0.200 | 0.73 | 54.2 × 0.3 * | 1.15 [a] * | 0.31 [a] * | 0.837 | | |
| 50% dicots | 0.200 | 0.73 | 28.7 × 0.3 * | 1.20 [b] * | 0.34 [b] * | 0.514 | | |
| Total diet | | | | | | Σ = 1.35 | 14.5 | 10.7 |

[a] With $DT_{50}$ of 2.6 d, 2 applications with 7 d interval (Table 9.2-58)
[b] With $DT_{50}$ of 3.05 d, 2 applications with 7 d interval (Table 9.2-57)

**zRMS comments:**

**Group C**

The risk assessment was verified by zRMS for pulses using the deposition factor indicated in the EFSA guidance document for voles in pulses (i.e. 0.3 for BBCH >50) and agreed refined MAF and ftwa parameters for both active substances.

**Refined risk assessment (herbivorous mammals “vole”, BBCH >50, pulses, 2x200 g a.s./ha, BBCH 59 89, 7d interval)**

| | FLU | | TFS | |
|---|---|---|---|---|
| | **BBCH 59-89** | | | |
| **Food item** | Monocots | Dicots | Monocots | Dicots |
| **$DT_{50}$** | 2.6 d | 3.18 d | 10 d | 3.35 d |
| **AR** | 0.2 | 0.2 | 0.2 | 0.2 |
| **FIR/bw** | 0.73 | 0.73 | 0.73 | 0.73 |
| **RUD** | 54.2 | 28.7 | 54.2 | 28.7 |
| **$f_{DEP}$** | 0.3 | 0.3 | 0.3 | 0.3 |
| **MAF** | 0.35 | 0.42 | 1.6 | 0.44 |
| **21-d $f_{TWA}$** | | | 0.53 | |
| **PT** | 1 | 1 | 1 | 1 |
| **DDD** | 0.83 | 0.528 | 2.01 | 0.553 |
| **total DDD** | 1.35 | | 2.57 | |
| **NOAEL** | 14.5 | | 22 | |
| **TER** | 10.74 | | 8.56 | |
| **TERmix** | 5 | | | |

The $TER_{LT}$ for both a.s. and $TER_{mix}$ values are above trigger value of 5 indicating an aceptable risk for vole.

In addition, zRMS calculated the risk with 14 d interval between applications.

**Refined risk assessment (herbivorous mammals “vole”, BBCH>50, beans, 2 x 200 g a.s./ha, BBCH 59-79, 14 d interval)**

| | **FLU** | | **TFS** | |
|---|---|---|---|---|
| | **Autumn** | | | |
| **Food item** | **Monocots** | **Dicots** | **Monocots** | **Dicots** |
| **$DT_{50}$** | 2.6 d | 3.18 d | 10 d | 3.35 d |
| **AR** | 0.2 | 0.2 | 0.2 | 0.2 |
| **FIR/bw** | 0.73 | 0.73 | 0.73 | 0.73 |
| **RUD** | 54.2 | 28.7 | 54.2 | 28.7 |
| **$f_{DEP}$** | 0.3 | 0.3 | 0.3 | 0.3 |
| **MAF** | 0.33 | 0.39 | (1.4*0.53=) 0.742 | 0.40 |
| **21-d $f_{TWA}$** | | | | |
| **PT** | 1 | 1 | 1 | 1 |
| **DDD** | 0.78 | 0.49 | 1.76 | 0.50 |
| **total DDD** | 1.27 | | 2.26 | |

| | | |
|---|---|---|
| **NOAEL** | 14.5 | 22 |
| **TER** | 11.4 | 9.72 |
| **TERmix** | 5.2 | |

The $TER_{LT}$ for both a.s. and $TER_{mix}$ values are above trigger value of 5 indicating an aceptable risk for vole.

**Berries (use group D)**

Small herbivorous mammal "vole"
The refined risk assessment for trifloxystrobin and fluopyram is done with the same refined parameter as for voles in beans and peas (use group C), i.e. the refined exposure assessment is based on a mixed diet (50% monocotyledonous and 50% dicotyledonous plants), with $DT_{50}$ values available for both fluopyram and trifloxystrobin on both monocots and dicots.
Additionally, crop interception in bush and cane fruit at BBCH ≥ 10 is 40% according to the FOCUS groundwater report (Table 2 in Appendix E of EFSA/2009/1438). Thus, according to the Tier 1 risk assessment a deposition of 60% is also considered in the refined risk assessment for voles in bush and cane fruit.

**Table 9.3-63: Higher-tier assessment of the long-term/reproductive risk for small herbivorous mammals for trifloxystrobin due to the use of FLU + TFS SC 500 in berries (use group D) – refined parameters (*) are further described and justified in the text**

| Feed item | AR (kg/ha) | FIR/bw | RUD × Deposition factor * | MAF | 21-d TWA | DDD | NOAEL (mg/kg bw/d) | TER |
|---|---|---|---|---|---|---|---|---|
| 50% monocots | 0.200 | 0.73 | 54.2 × 0.6 | 1.26 [a)] * | 0.37 [a)] * | 2.230 | | |
| 50% dicots | 0.200 | 0.73 | 28.7 × 0.6 | 1.23 [b)] * | 0.36 [b)] * | 1.119 | | |
| Total diet | | | | | | Σ = 3.35 | 22 | 6.6 |

a) With $DT_{50}$ of 3.56 d, 2 applications with 7 d interval (**Table 9.3-58**)
b) With $DT_{50}$ of 3.35 d, 2 applications with 7 d interval (**Table 9.3-59**)

**Table 9.3-64: Higher-tier assessment of the long-term/reproductive risk for small herbivorous mammals for fluopyram due to the use of FLU + TFS SC 500 in berries (use group D) – refined parameters (*) are further described and justified in the text**

| Feed item | AR (kg/ha) | FIR/bw | RUD × Deposition factor | MAF | 21-d TWA | DDD | NOAEL (mg/kg bw/d) | TER |
|---|---|---|---|---|---|---|---|---|
| 50% monocots | 0.200 | 0.73 | 54.2 × 0.6 | 1.15 [a)] * | 0.31 [a)] * | 1.675 | | |
| 50% dicots | 0.200 | 0.73 | 28.7 × 0.6 | 1.20 [b)] * | 0.34 [b)] * | 1.029 | | |
| Total diet | | | | | | Σ = 2.70 | 14.5 | 5.4 |

a) With $DT_{50}$ of 2.6 d, 2 applications with 7 d interval (Table 9.2-58)
b) With $DT_{50}$ of 3.05 d, 2 applications with 7 d interval (Table 9.2-57)

**zRMS comments:**

**Group D**

The risk assessment for the worst case scenario 2 x 200 g a.s./ha with 7 day interval and BBCH 15-89 was verified by zRMS for group bush and cane fruit , using the deposition factor indicated in the EFSA guidance document for voles in bush and cane fruit (i.e. 0.6 for BBCH >10) and agreed refined MAF and ftwa parameters for both active substances.

**Refined risk assessment (herbivorous mammals "vole", BBCH 10-19, Bush and cane fruits 2 × 200 g a.s./ha, 7 d interval, BBCH 15-89)**

| | FLU | | TFS | |
|---|---|---|---|---|
| **BBCH 10-19** | | | | |
| **Food item** | Monocots | Dicots | Monocots | Dicots |
| **$DT_{50}$** | 2.6 d | 3.18 d | 10 d | 3.35 d |
| **AR** | 0.2 | 0.2 | 0.2 | 0.2 |
| **FIR/bw** | 0.73 | 0.73 | 0.73 | 0.73 |
| **RUD** | 54.2 | 28.7 | 54.2 | 28.7 |
| **$f_{DEP}$** | 0.6 | 0.6 | 0.6 | 0.6 |
| **MAF** | 0.35 | 0.42 | 1.6 | 0.44 |
| **21-d $f_{TWA}$** | | | 0.53 | |
| **PT** | 1 | 1 | 1 | 1 |
| **DDD** | 1.66 | 0.981 | 4.03 | 1.01 |
| **total DDD** | 2.64 | | 5.04 | |
| **NOAEL** | 14.5 | | 22 | |
| **TER** | 5.5 | | **4.36** | |
| **TERmix** | **2.5** | | | |

The $TER_{LT}$ value for a.s. - TFS is below trigger of 5 indicating needs for further refinement max application dose of 2 x 200 g a.s./ha with 7 days interval for vole at BBCH 10-19.
The $TER_{mix}$ value is below the trigger value of 5 indicating needs for further refinement for vole.

Further assessment is conducted using the deposition factors indicated in the EFSA guidance document for voles in bush and cane fruit (i.e. 0.5 for BBCH 20-39 and 0.3 for BBCH >40).

**Refined risk assessment (herbivorous mammals "vole", BBCH 10-19, 2 × 200 g a.s./ha, 7 d interval, BBCH 15-89)**

| | FLU | | TFS | |
|---|---|---|---|---|
| **BBCH 20-39** | | | | |
| **Food item** | Monocots | Dicots | Monocots | Dicots |
| **$DT_{50}$** | 2.6 d | 3.18 d | 10 d | 3.35 d |
| **AR** | 0.2 | 0.2 | 0.2 | 0.2 |
| **FIR/bw** | 0.73 | 0.73 | 0.73 | 0.73 |
| **RUD** | 54.2 | 28.7 | 54.2 | 28.7 |
| **$f_{DEP}$** | 0.5 | 0.5 | 0.5 | 0.5 |
| **MAF** | 0.35 | 0.42 | 1.4 | 0.44 |
| **21-d $f_{TWA}$** | | | 0.53 | |
| **PT** | 1 | 1 | 1 | 1 |

| | | | | |
|---|---|---|---|---|
| **DDD** | 1.38 | 0.88 | 3.35 | 0.92 |
| **total DDD** | 2.26 | | 4.27 | |
| **NOAEL** | 14.5 | | 22 | |
| **TER** | 6.41 | | 5.15 | |
| **Combination TER** | **2.94** | | | |
| **BBCH >40** | | | | |
| **Food item** | Monocots | Dicots | Monocots | Dicots |
| **$DT_{50}$** | 2.6 d | 3.18 d | 10 d | 3.35 d |
| **AR** | 0.2 | 0.2 | 0.2 | 0.2 |
| **FIR/bw** | 0.73 | 0.73 | 0.73 | 0.73 |
| **RUD** | 54.2 | 28.7 | 54.2 | 28.7 |
| **$f_{DEP}$** | 0.3 | 0.3 | 0.3 | 0.3 |
| **MAF** | 0.35 | 0.42 | 1.6 | 0.44 |
| **21-d $f_{TWA}$** | | | 0.53 | |
| **PT** | 1 | 1 | 1 | 1 |
| **DDD** | 0.83 | 0.52 | 2.01 | 0.55 |
| **total DDD** | 1.35 | | 2.56 | |
| **NOAEL** | 14.5 | | 22 | |
| **TER** | 10.74 | | 8.59 | |
| **TERmix** | **4.78** | | | |

The $TER_{LT}$ values for both a.s. are above the trigger of 5 for application dose 2 x 200 g a.s./ha with 7 d interval and BBCH 20-39.
The TERmix value is below the trigger value of 5 for application dose 2 x 200 g a.s./ha with 7 d interval and BBCH 20-39 indicating needs for further refinement.

In the same time, the $TER_{LT}$ values are above trigger of 5 for both a.s. for application dose 2 x 200 g a.s./ha with 7 d interval and BBCH >40.
The $TER_{mix}$ is closed to value 5 for application dose 2 x 200 g a.s./ha with 7 d interval and BBCH >40 and the risk is considered acceptable by zRMS.

**Refined risk assessment (herbivorous mammals "vole", bush and cane fruits, 2x200 g a.s./ha, BBCH 15-89, 14d interval)**

| | FLU | | TFS | |
|---|---|---|---|---|
| **BBCH 10-19** | | | | |
| Food item | Monocots | Dicots | Monocots | Dicots |
| $DT_{50}$ | 2.6 d | 3.18 d | 10 d | 3.35 d |
| AR | 0.2 | 0.2 | 0.2 | 0.2 |
| FIR/bw | 0.73 | 0.73 | 0.73 | 0.73 |
| RUD | 54.2 | 28.7 | 54.2 | 28.7 |
| $f_{DEP}$ | 0.6 | 0.6 | 0.6 | 0.6 |
| MAF | 0.33 | 0.39 | 1.4 | 0.40 |
| 21-d $f_{TWA}$ | | | 0.53 | |
| PT | 1 | 1 | 1 | 1 |
| DDD | 1.56 | 0.98 | 3.52 | 1.01 |
| total DDD | 2.54 | | 4.53 | |
| NOAEL | 14.5 | | 22 | |

| | | | | |
|---|---|---|---|---|
| TER | 5.70 | | 4.85 | |
| TERmix | **2.7** | | | |
| **BBCH 20-39** | | | | |
| Food item | Monocots | Dicots | Monocots | Dicots |
| $DT_{50}$ | 10 d | 3.18 d | 10 d | 3.35 d |
| AR | 0.2 | 0.2 | 0.2 | 0.2 |
| FIR/bw | 0.73 | 0.73 | 0.73 | 0.73 |
| RUD | 54.2 | 28.7 | 54.2 | 28.7 |
| $f_{DEP}$ | 0.5 | 0.5 | 0.5 | 0.5 |
| MAF | 0.33 | 0.39 | 1.4 | 0.40 |
| 21-d $f_{TWA}$ | | | 0.53 | |
| PT | 1 | 1 | 1 | 1 |
| DDD | 1.30 | 0.81 | 1.16 | 0.83 |
| total DDD | 2.11 | | 2 | |
| NOAEL | 14.5 | | 22 | |
| TER | 6.87 | | 11 | |
| TERmix | **4.34** | | | |
| | FLU | | TFS | |
| **BBCH >40** | | | | |
| Food item | Monocots | Dicots | Monocots | Dicots |
| $DT_{50}$ | 2.6 d | 3.18 d | 10 d | 3.35 d |
| AR | 0.2 | 0.2 | 0.2 | 0.2 |
| FIR/bw | 0.73 | 0.73 | 0.73 | 0.73 |
| RUD | 54.2 | 28.7 | 54.2 | 28.7 |
| $f_{DEP}$ | 0.3 | 0.3 | 0.3 | 0.3 |
| MAF | 0.33 | 0.39 | 1.4 | 0.40 |
| 21-d $f_{TWA}$ | | | 0.53 | |
| PT | 1 | 1 | 1 | 1 |
| DDD | 0.78 | 0.49 | 1.76 | 0.50 |
| total DDD | 1.27 | | 2.26 | |
| NOAEL | 14.5 | | 22 | |
| TER | 11.41 | | 9.73 | |
| TERmix | 5.55 | | | |

The $TER_{LT}$ values for both a.s. are above the trigger of 5 for application dose 2 x 200 g a.s./ha with 14 d interval and BBCH 20-39.
The TERmix value is below the trigger value of 5 for application dose 2 x 200 g a.s./ha with 7 d interval and BBCH 20-39 indicating needs for further refinement.

The $TER_{LT}$ values for both a.s. are above the trigger of 5 for application dose 2 x 200 g a.s./ha with 14 d interval and BBCH >40.
The TERmix value is above the trigger value of 5 for application dose 2 x 200 g a.s./ha with 7 d interval and BBCH >40 indicating an acceptable risk to vole at BBCH>40.

**Strawberries, blueberries, cranberries (use group F)**

Small herbivorous mammal “vole”

The refined risk assessment for trifloxystrobin and fluopyram is done with the same refined parameter as for voles in beans and peas (use group C), i.e. the refined exposure assessment is based on a mixed diet (50% monocotyledonous and 50% dicotyledonous plants), with $DT_{50}$ values available for both fluopyram and trifloxystrobin on both monocots and dicots.
Additionally, crop interception in strawberries at **BBCH ≥ 40 is 60% according to the FOCUS groundwater report (Table 2 in Appendix E of EFSA/2009/1438). Thus, according to the Tier 1 risk assessment, a deposition of 40% is also considered in the refined risk assessment for voles in strawberries.**

**Table 9.3-65: Higher-tier assessment of the long-term/reproductive risk for small herbivorous mammals for <u>trifloxystrobin</u> due to the use of FLU + TFS SC 500 in strawberries, blueberries and cranberries (use group F) – refined parameters (*) are further described and justified in the text**

| Feed item | AR (kg/ha) | FIR/bw | RUD × Deposition factor | MAF | 21-d TWA | DDD | NOAEL (mg/kg bw/d) | TER |
|---|---|---|---|---|---|---|---|---|
| 50% monocots | 0.200 | 0.73 | 54.2 × 0.4 | 1.26 a) * | 0.37 a) * | 1.487 | | |
| 50% dicots | 0.200 | 0.73 | 28.7 × 0.4 | 1.23 b) * | 0.36 b) * | 0.746 | | |
| Total diet | | | | | | Σ = 2.23 | 22 | 9.9 |

a) With $DT_{50}$ of 3.56 d, 2 applications with 7 d interval (Table 9.3-58)
b) With $DT_{50}$ of 3.35 d, 2 applications with 7 d interval (Table 9.3-59)

**Table 9.3-66: Higher-tier assessment of the long-term/reproductive risk for small herbivorous mammals for <u>fluopyram</u> due to the use of FLU + TFS SC 500 in strawberries, blueberries and cranberries (use group F) – refined parameters (*) are further described and justified in the text**

| Feed item | AR (kg/ha) | FIR/bw | RUD × Deposition factor | MAF | 21-d TWA | DDD | NOAEL (mg/kg bw/d) | TER |
|---|---|---|---|---|---|---|---|---|
| 50% monocots | 0.200 | 0.73 | 54.2 × 0.4 | 1.15 a) * | 0.31 a) * | 1.117 | | |
| 50% dicots | 0.200 | 0.73 | 28.7 × 0.4 | 1.20 b) * | 0.34 b) * | 0.686 | | |
| Total diet | | | | | | Σ = 1.80 | 14.5 | 8.0 |

a) With $DT_{50}$ of 2.6 d, 2 applications with 7 d interval (Table 9.2-58)
b) With $DT_{50}$ of 3.05 d, 2 applications with 7 d interval (Table 9.2-57)

**zRMS comments:**

**<u>Group F</u>**

The risk assessment for both active substances was verified by zRMS for max application rate 2 x 200 g a.s./ha with 7 and 14 d intervals, BBCH 15-89.

**Refined risk assessment (herbivorous mammals "vole", BBCH>40 , strawberries, 2x200 g a.s./ha, BBCH 15-89, 7 d interval)**

| | FLU | | TFS | |
|---|---|---|---|---|
| **BBCH>40** | | | | |
| **Food item** | Monocots | Dicots | Monocots | Dicots |
| **$DT_{50}$** | 2.6 d | 3.18 d | 10 d | 3.35 d |
| **AR** | 0.2 | 0.2 | 0.2 | 0.2 |
| **FIR/bw** | 0.73 | 0.73 | 0.73 | 0.73 |

| | | | | |
|---|---|---|---|---|
| **RUD** | 54.2 | 28.7 | 54.2 | 28.7 |
| **$f_{DEP}$** | 0.4 | 0.4 | 0.4 | 0.4 |
| **MAF** | 0.35 | 0.42 | 1.6 | 0.44 |
| **21-d $f_{TWA}$** | | | 0.53 | |
| **PT** | 1 | 1 | 1 | 1 |
| **DDD** | 1.10 | 0.65 | 2.68 | 0.73 |
| **total DDD** | 1.75 | | 3.41 | |
| **NOAEL** | 14.5 | | 22 | |
| **TER** | 8.28 | | 6.45 | |
| **TERmix** | **3.70** | | | |

**Refined risk assessment (herbivorous mammals “vole” BBCH>40 , strawberries, 2x200 g a.s./ha, BBCH 15-89, 14 d interval)**

| | FLU | | TFS | |
|---|---|---|---|---|
| **BBCH >40** | | | | |
| **Food item** | Monocots | Dicots | Monocots | Dicots |
| **$DT_{50}$** | 2.6 d | 3.18 d | 10 d | 3.35 d |
| **AR** | 0.2 | 0.2 | 0.2 | 0.2 |
| **FIR/bw** | 0.73 | 0.73 | 0.73 | 0.73 |
| **RUD** | 54.2 | 28.7 | 54.2 | 28.7 |
| **$f_{DEP}$** | - | - | - | - |
| **MAF** | 0.33 | 0.39 | 1.4 | 0.40 |
| **21-d $f_{TWA}$** | | | 0.53 | |
| **PT** | 1 | 1 | 1 | 1 |
| **DDD** | 1.044 | 0.65 | 2.34 | 0.67 |
| **total DDD** | 1.7 | | 3.01 | |
| **NOAEL** | 14.5 | | 22 | |
| **TER** | 8.52 | | 7.30 | |
| **TERmix** | **4.16** | | | |

The $TER_{LT}$ values for both a.s. for vole are above trigger of 5 for BBCH >40 for max application dose of 2 x 200 g a.s./ha with 7 and 14 days interval.
In the same timethe $TER_{mix}$ value is below the trigger value of 5 indicating needs for further refinement for vole for BBCH>40.

**Further considerations on voles in strawberry fields:**

A field study to assess the presence and abundance of common voles in strawberry fields was conducted in Central Europe (xxx; 2016; M-570937-01-1, Appendix 2). The occurrence of voles was low inside the strawberry fields compared to off-crop habitats during all trapping sessions in particular at early plant development stages i.e. BBCH 16-19 and 55-73. The trapping efficiency was more than 100 times lower at BBCH 16-19 in in-crop areas compared to off-crop grass habitats (0.2 captures/100 trap nights in-crop versus 31.18 captures/100 trap nights off-crop). During later crop growth stages the number of captured voles also increased inside the strawberry fields. However, it remained lower compared to off-crop grass habitats and strawberry fields are not as attractive to voles as the off-crop habitat.
Typically, common voles are not very abundant in strawberry fields even if present in the surroundings, however where they occur they can present a risk of transmitting infectious diseases to professional

harvesters and other people picking the strawberries in the field so that rodent control measures are recommended (Desai et al. 2009 Resurgence of Field Fever in a Temperate Country: An Epidemic of Leptospirosis among Seasonal Strawberry Harvesters in Germany in 2007. Clinical Infectious Diseases, Volume 48, Issue 6, 15 March 2009, Pages 691–697, https://doi.org/10.1086/597036). Thus. A lower level of protection for voles inside strawberry fields may be deemed acceptable, given that vole eradication measures are likely to wipe out their in-field populations once established at a significant level. Thus, it is the off-field population which needs protection for long-term sustainability. No quantitative off-field TERs are calculated here since it is obvious that drift exposure allows for sufficient margins of safety.

**zRMS comment:**

The study by xxx 2016; M-570937-01-1, indicated that the occurrence of voles was low inside the strawberry fields compared to off-crop habitats during all sessions in particular at early plant development stages i.e. BBCH 16-19 and 55-73. The trapping efficiency was more than 100 times lower at BBCH 16- 19 in in-crop areas compared to off-crop grass habitats. During later crop growth stages the number of captured voles also increased inside the strawberry fields; however it remained lower compared to off-crop grass habitats.
In opinion of zRMS's the study can be used in the weight evidence approach.

**Nurseries and rosehip (use group I)**

Small herbivorous mammal "vole"
The refined risk assessment for trifloxystrobin and fluopyram is done with the same refined parameter as for voles in beans and peas (use group C), i.e. the refined exposure assessment is based on a mixed diet (50% monocotyledonous and 50% dicotyledonous plants), with $DT_{50}$ values available for both fluopyram and trifloxystrobin on both monocots and dicots.

**Table 9.3-67: Higher-tier assessment of the long-term/reproductive risk for small herbivorous mammals for trifloxystrobin due to the use of FLU + TFS SC 500 in nurseries and rosehip (use group I) – refined parameters (*) are further described and justified in the text**

| Feed item | AR (kg/ha) | FIR/bw | RUD × Deposition factor | MAF | 21-d TWA | DDD | NOAEL (mg/kg bw/d) | TER |
|---|---|---|---|---|---|---|---|---|
| 50% monocots | 0.200 | 0.73 | 54.2 × 1.0 | 1.26 [a] * | 0.37 [a] * | 3.716 | | |
| 50% dicots | 0.200 | 0.73 | 28.7 × 1.0 | 1.23 [b] * | 0.36 [b] * | 1.865 | | |
| Total diet | | | | | | Σ = 5.582 | 22 | **3.9** |

a) With $DT_{50}$ of 3.56 d, 2 applications with 7 d interval (Table 9.3-58)
b) With $DT_{50}$ of 3.35 d, 2 applications with 7 d interval (Table 9.3-59)

**Table 9.3-68: Higher-tier assessment of the long-term/reproductive risk for small herbivorous mammals for fluopyram due to the use of FLU + TFS SC 500 in nurseries and rosehip (use group I) – refined parameters (*) are further described and justified in the text**

| Feed item | AR (kg/ha) | FIR/bw | RUD × Deposition factor | MAF | 21-d TWA | DDD | NOAEL (mg/kg bw/d) | TER |
|---|---|---|---|---|---|---|---|---|
| 50% monocots | 0.200 | 0.73 | 54.2 × 1.0 | 1.15 [a] * | 0.31 [a] * | 2.791 | | |
| 50% dicots | 0.200 | 0.73 | 28.7 × 1.0 | 1.20 [b] * | 0.34 [b] * | 1.714 | | |
| Total diet | | | | | | Σ = 4.506 | 14.5 | **3.2** |

[a] With $DT_{50}$ of 2.6 d, 2 applications with 7 d interval (Table 9.2-58)
[b] With $DT_{50}$ of 3.05 d, 2 applications with 7 d interval (Table 9.2-57)

The risk assessment for use group I was done without consideration of crop interception. The product is applied to nurseries and rosehip at a large BBCH range between 12 and 91. At BBCH stages ≥ 50, a crop interception of 50% is considered in Appendix A of EFSA/2009/1438. Thus, the risk assessment presented above is very conservative for applications between BBCH 12 and 91 and TER values for application at BBCH ≥ 50 exceed the trigger of 5.

As the risk envelope approach failed the risk assessment, TER calculations with the same refined parameter were additionally done for use group J (1 x 0.8 L product/ha).

**zRMS comments:**

The risk assessment was verified by zRMS for both active substances for max application rate 2 x 200 g a.s./ha with 7 interval, BBCH 12-91. The DF was not used for vole for BBCH 40-49 according to EFSA GD for Birds and Mammals, 200 Appndix F.

**Grupa I**

**Refined risk assessment (herbivorous mammals "vole", BBCH 40-49, Nurseries, rosehip 2 × 200 g.a.s./ha with 7 days interval, BBCH 12-91)**

| | FLU | | TFS | |
|---|---|---|---|---|
| **BBCH<50 ( BBCH 40-49)** | | | | |
| **Food item** | Monocots | Dicots | Monocots | Dicots |
| **$DT_{50}$** | 2.6 d | 3.18 d | 10 d | 3.35 d |
| **AR** | 0.2 | 0.2 | 0.2 | 0.2 |
| **FIR/bw** | 0.73 | 0.73 | 0.73 | 0.73 |
| **RUD** | 54.2 | 28.7 | 54.2 | 28.7 |
| **$f_{DEP}$** | - | - | - | - |
| **MAF** / **21-d $f_{TWA}$** | 0.35 | 0.42 | 0.53 | 0.44 |
| **PT** | 1 | 1 | 1.6 | 1 |
| **DDD** | 2.76 | 1.75 | 6.71 | 1.84 |
| **total DDD** | 4.51 | | 8.55 | |
| **NOAEL** | 14.5 | | 22 | |
| **TER** | **3.21** | | **2.57** | |
| **TERmix** | **1.42** | | | |

The $TER_{LT}$ values for both a.s. are below trigger of 5 indicating needs for further refinement max

application dose of 2 x 200 g a.s./ha with 7 days interval for vole at BBCH 40-49.
The $TER_{mix}$ value is below the trigger value of 5 indicating needs for further refinemet risk for vole at BBCH 40-49.

Further assessment for vole is conducted using the deposition factors indicated in the EFSA guidance document for voles for Ornalentals/Nurseries being 0.3 for BBCH >50 BBCH.

**Refined risk assessment (herbivorous mammals "vole", BBCH >50- Nurseries, rosehip 2 x 200 g a.s./ha with 7 days, 12-91 BBCH )**

| | FLU | | TFS | |
|---|---|---|---|---|
| **BBCH >50** | | | | |
| **Food item** | **Monocots** | **Dicots** | **Monocots** | **Dicots** |
| **$DT_{50}$** | 2.6 d | 3.18 d | 10 d | 3.35 d |
| **AR** | 0.2 | 0.2 | 0.2 | 0.2 |
| **FIR/bw** | 0.73 | 0.73 | 0.73 | 0.73 |
| **RUD** | 54.2 | 28.7 | 54.2 | 28.7 |
| **$f_{DEP}$** | 0.3 | 0.3 | 0.3 | 0.3 |
| **MAF** / **21-d $f_{TWA}$** | 0.35 | 0.42 | 1.6 x 0.53 | 0.44 |
| **PT** | 1 | 1 | 1 | 1 |
| **DDD** | 0.83 | 0.52 | 2.013 | 0.55 |
| **total DDD** | 1.35 | | 2.56 | |
| **NOAEL** | 14.5 | | 22 | |
| **TER** | 10.74 | | 8.6 | |
| **TERmix** | **4.76** | | | |

The $TER_{LT}$ values for both a.s. are above the trigger of 5.
The $TER_{mix}$ values is slight below the trigger value of 5 at rate 2 x 200 g a.s./ha with 7 days interval with DF=0.3 and is considered acceptable by zRMS for BBCH >50.

**Group I**

**<u>2 x 150 g a.s./ha with 7 days interval</u>**

**Refined risk assessment (herbivorous mammals "vole", BBCH 40-49, Nurseries, rosehip 2 x 150 g a.s/ha, 12-91 BBCH with 7 days interval)**

| | FLU | | TFS | |
|---|---|---|---|---|
| **BBCH <50** | | | | |
| **Food item** | Monocots | Dicots | Monocots | Dicots |
| **$DT_{50}$** | 2.6 d | 3.18 d | 10 d | 3.35 d |
| **AR** | 0.15 | 0.15 | 0.15 | 0.15 |
| **FIR/bw** | 0.73 | 0.73 | 0.73 | 0.73 |
| **RUD** | 54.2 | 28.7 | 54.2 | 28.7 |
| **$f_{DEP}$** | - | - | - | - |
| **MAF** / **21-d $f_{TWA}$** | 0.35 | 0.42 | 1.6 x 0.53 | 0.44 |
| **PT** | 1 | 1 | 1 | 1 |
| **DDD** | 2.07 | 1.32 | 5.03 | 1.38 |

| | | |
|---|---|---|
| **total DDD** | 3.38 | 6.41 |
| **NOAEL** | 14.5 | 22 |
| **TER** | **4.28** | **3.43** |
| **TERmix** | **1.92** | |

**Refined risk assessment (herbivorous mammals "vole", BBCH 40-49, Nurseries, rosehip 2 x 0.150 g a.s./ha, BBCH 12-91 with 14 day interval)**

| | FLU | | TFS | |
|---|---|---|---|---|
| **BBCH<50** | | | | |
| **Food item** | Monocots | Dicots | Monocots | Dicots |
| **$DT_{50}$** | 2.6 d | 3.18 d | 10 d | 3.35 d |
| **AR** | 0.15 | 0.15 | 0.15 | 0.15 |
| **FIR/bw** | 0.73 | 0.73 | 0.73 | 0.73 |
| **RUD** | 54.2 | 28.7 | 54.2 | 28.7 |
| **$f_{DEP}$** | - | - | - | - |
| **MAF**<br>**21-d $f_{TWA}$** | 0.33 | 0.39 | 1.6 x 0.53 | 0.40 |
| **PT** | 1 | 1 | 1 | 1 |
| **DDD** | 1.95 | 1.22 | 5.03 | 1.25 |
| **total DDD** | 3.17 | | 6.28 | |
| **NOAEL** | 14.5 | | 22 | |
| **TER** | **4.57** | | **3.5** | |
| **TERmix** | **2.04** | | | |

The $TER_{LT}$ values for both a.s. are below trigger of 5 indicating needs for further refinement max application dose of 2 x 150 g a.s./ha BBCH <50 for vole.
The $TER_{mix}$ values are below the trigger value of 5 indicating needs for further refinement for vole.

Further assessment for vole is conducted using the deposition factors indicated in the EFSA guidance document for voles for Ornalentals/Nurseries being 0.3 for BBCH >50 BBCH.

**Refined risk assessment (herbivorous mammals "vole", BBCH >50, Nurseries, rosehip 2 x 0.150 g a.s./ha, 12-91, 7days interval)**

| | FLU | | TFS | |
|---|---|---|---|---|
| **BBCH > 50 BBCH** | | | | |
| **Food item** | Monocots | Dicots | Monocots | Dicots |
| **$DT_{50}$** | 2.6 d | 3.18 d | 10 d | 3.35 d |
| **AR** | 0.15 | 0.15 | 0.15 | 0.15 |
| **FIR/bw** | 0.73 | 0.73 | 0.73 | 0.73 |
| **RUD** | 54.2 | 28.7 | 54.2 | 28.7 |
| **$f_{DEP}$** | 0.3 | 0.3 | 0.3 | 0.3 |
| **MAF**<br>**21-d $f_{TWA}$** | 0.35 | 0.42 | 1.6 x 0.53 | 0.44 |
| **PT** | 1 | 1 | 1 | 1 |
| **DDD** | 0.62 | 0.52 | 1.5 | 0.41 |

| | | |
|---|---|---|
| **total DDD** | 1.14 | 1.91 |
| **NOAEL** | 14.5 | 22 |
| **TER** | 12.71 | 11.51 |
| **TERmix** | 6.25 | |

The $TER_{LT}$ values for both a.s. are above the trigger of 5.
The $TER_{mix}$ value is above the trigger value of 5 at rate 2 x 150 g a.s./ha with 7 days interval with DF=0.3 and is considered acceptable for vole by zRMS for BBCH >50.

**Table 9.3-69: Higher-tier assessment of the long-term/reproductive risk for small herbivorous mammals for trifloxystrobin due to the use of FLU + TFS SC 500 in nurseries and rosehip (use group J) – refined parameters (*) are further described and justified in the text**

| Feed item | AR (kg/ha) | FIR/bw | RUD | MAF | 21-d TWA | DDD | NOAEL (mg/kg bw/d) | TER |
|---|---|---|---|---|---|---|---|---|
| 50% monocots | 0.200 | 0.73 | 54.2 | 1.00 | 0.24 [a]* | 1.905 | | |
| 50% dicots | 0.200 | 0.73 | 28.7 | 1.00 | 0.23 [b]* | 0.953 | | |
| Total diet | | | | | | Σ = 2.858 | 22 | 7.7 |

[a] With $DT_{50}$ of 3.56 d, single application (**Table 9.3-58**)
[b] With $DT_{50}$ of 3.35 d, single application (**Table 9.3-59**)

**Table 9.3-70: Higher-tier assessment of the long-term/reproductive risk for small herbivorous mammals for fluopyram due to the use of FLU + TFS SC 500 in nurseries and rosehip (use group J) – refined parameters (*) are further described and justified in the text**

| Feed item | AR (kg/ha) | FIR/bw | RUD | MAF | 21-d TWA | DDD | NOAEL (mg/kg bw/d) | TER |
|---|---|---|---|---|---|---|---|---|
| 50% monocots | 0.200 | 0.73 | 54.2 | 1.00 | 0.18 [a]* | 1.410 | | |
| 50% dicots | 0.200 | 0.73 | 28.7 | 1.00 | 0.21 [b]* | 0.872 | | |
| Total diet | | | | | | Σ = 2.28 | 14.5 | 6.4 |

[a] With $DT_{50}$ of 2.6 d, single application (Table 9.2-58)
[b] With $DT_{50}$ of 3.05 d, single application (Table 9.2-57)

**zRMS comments:**

**Group J**

The risk assessment was verified by zRMS for both active substances for max application rate 1 x 200 g a.s./ha with 7 interval, BBCH 12-91. The DF was not used for BBCH 40-49.

**Refined risk assessment (herbivorous mammals "vole", BBCH 40-49, Nurseries, rosehip 1× 200 g a.s./ha, BBCH<50)**

| | FLU | | TFS | |
|---|---|---|---|---|
| **BBCH<50** | | | | |
| **Food item** | Monocots | Dicots | Monocots | Dicots |
| **$DT_{50}$** | 2.6 d | 3.18 d | 10 d | 3.35 d |

| | | | | |
|---|---|---|---|---|
| **AR** | 0.2 | 0.2 | 0.2 | 0.2 |
| **FIR/bw** | 0.73 | 0.73 | 0.73 | 0.73 |
| **RUD** | 54.2 | 28.7 | 54.2 | 28.7 |
| **$f_{DEP}$** | - | - | - | - |
| **MAF** / **21-d $f_{TWA}$** | 0.18 | 0.22 | 0.53 | 0.23 |
| **PT** | 1 | 1 | 1 | 1 |
| **DDD** | 1.42 | 0.27 | 4.19 | 0.96 |
| **total DDD** | 1.7 | | 5.15 | |
| **NOAEL** | 14.5 | | 22 | |
| **TER** | 8.53 | | **4.27** | |
| **TERmix** | **2.94** | | | |

The $TER_{LT}$ value for a.s. - TFS is below trigger of 5 indicating needs for further refinement max application dose of 1 x 200 g a.s./ha BBCH 40-49 for vole.
The $TER_{mix}$ values is below the trigger value of 5 indicating needs for further refinement for vole.

**Refined risk assessment (herbivorous mammals "vole", BBCH >50, Nurseries, rosehip 1× 200 g a.s./ha BBCH >50-91)**

| | FLU | | TFS | |
|---|---|---|---|---|
| **BBCH >50-91** | | | | |
| **Food item** | Monocots | Dicots | Monocots | Dicots |
| **$DT_{50}$** | 2.6 d | 3.18 d | 10 d | 3.35 d |
| **AR** | 0.2 | 0.2 | 0.2 | 0.2 |
| **FIR/bw** | 0.73 | 0.73 | 0.73 | 0.73 |
| **RUD** | 54.2 | 28.7 | 54.2 | 28.7 |
| **$f_{DEP}$** | 0.3 | 0.3 | 0.3 | 0.3 |
| **MAF** / **21-d $f_{TWA}$** | 0.18 | 0.22 | 0.53 | 0.23 |
| **PT** | 1 | 1 | 1 | 1 |
| **DDD** | 0.42 | 0.27 | 1.25 | 0.29 |
| **total DDD** | 0.70 | | 1.54 | |
| **NOAEL** | 14.5 | | 22 | |
| **TER** | 20.71 | | 14.28 | |
| **TERmix** | 8.47 | | | |

The $TER_{LT}$ values for both a.s. for vole are above trigger of 5 for **BBCH >50 -91** for max application dose of 1 x 200 g a.s./ha.
The $TER_{mix}$ values is above the trigger value of 5 indicating an acceptable risk for vole.

**Tobacco (use group K)**

<u>Small herbivorous mammal "vole"</u>
The refined risk assessment for trifloxystrobin and fluopyram is done with the same refined parameter as for voles in beans and peas (use group C), i.e. the refined exposure assessment is based on a mixed diet (50% monocotyledonous and 50% dicotyledonous plants), with $DT_{50}$ values available for both fluopyram and trifloxystrobin on both monocots and dicots. Additionally, crop interception in maize (as surrogate crop for tobacco) at BBCH ≥ 30 is 50% according to the FOCUS groundwater report (Table 2 in

Appendix E of EFSA/2009/1438). Thus, according to the Tier 1 risk assessment, a deposition of 50% is also considered in the refined risk assessment for voles in tobacco.

**Table 9.3-71: Higher-tier assessment of the long-term/reproductive risk for small herbivorous mammals for <u>trifloxystrobin</u> due to the use of FLU + TFS SC 500 in tobacco (use group K) – refined parameters (*) are further described and justified in the text**

| Feed item | AR (kg/ha) | FIR/bw | RUD × Deposition factor | MAF | 21-d TWA | DDD | NOAEL (mg/kg bw/d) | TER |
|---|---|---|---|---|---|---|---|---|
| 50% monocots | 0.200 | 0.73 | 54.2 × 0.5 | 1.0 | 0.24 a) * | 0.953 | | |
| 50% dicots | 0.200 | 0.73 | 28.7 × 0.5 | 1.0 | 0.23 b) * | 0.477 | | |
| Total diet | | | | | | Σ = 1.429 | 22 | 15.4 |

a) With $DT_{50}$ of 3.56 d, single application (Table 9.3-58)
b) With $DT_{50}$ of 3.35 d, single application (Table 9.3-59)

**Table 9.3-72: Higher-tier assessment of the long-term/reproductive risk for small herbivorous mammals for <u>fluopyram</u> due to the use of FLU + TFS SC 500 in tobacco (use group K) – refined parameters (*) are further described and justified in the text**

| Feed item | AR (kg/ha) | FIR/bw | RUD × Deposition factor | MAF | 21-d TWA | DDD | NOAEL (mg/kg bw/d) | TER |
|---|---|---|---|---|---|---|---|---|
| 50% monocots | 0.200 | 0.73 | 54.2 × 0.5 | 1.0 | 0.18 a) * | 0.705 | | |
| 50% dicots | 0.200 | 0.73 | 28.7 × 0.5 | 1.0 | 0.21 b) * | 0.436 | | |
| Total diet | | | | | | Σ = 1.14 | 14.5 | 12.7 |

a) With $DT_{50}$ of 2.6 d, single application (Table 9.2-58)
b) With $DT_{50}$ of 3.05 d, single application (Table 9.2-57)

**zRMS comments:**

**Group K**

**Tabocco**

The risk assessment was verified by zRMS for both active substances for max application rate 1 x 200 g a.s./ha with 7 interval, BBCH 13-39. The DF was not used for BBCH 10-29.

**Refined risk assessment (herbivorous mammals “vole”, BBCH 10-29, Tobacco 1 x 200 g.a./ha, BBCH 13-39)**

| | FLU | | TFS | |
|---|---|---|---|---|
| **BBCH <30** | | | | |
| **Food item** | Monocots | Dicots | Monocots | Dicots |
| **$DT_{50}$** | 2.6 d | 3.18 d | 10 d | 3.35 d |
| **AR** | 0.2 | 0.2 | 0.2 | 0.2 |
| **FIR/bw** | 0.73 | 0.73 | 0.73 | 0.73 |
| **RUD** | 54.2 | 28.7 | 54.2 | 28.7 |
| **$f_{DEP}$** | - | - | - | - |
| **MAF**<br>**21-d $f_{TWA}$** | 0.18 | 0.22 | 1 | 0.23 |

| | | | | |
|---|---|---|---|---|
| **PT** | 1 | 1 | 1 | 1 |
| **DDD** | 1.42 | 0.92 | 4.19 | 0.96 |
| **total DDD** | 2.34 | | 5.15 | |
| **NOAEL** | 14.5 | | 22 | |
| **TER** | 6.2 | | **4.27** | |
| **TERmix** | **2.32** | | | |

The $TER_{LT}$ value for a.s. – TFS is below trigger of 5, indicating needs for further refinement max application dose of 1 x 200 g a.s./ha and BBCH 10-29.
The $TER_{mix}$ value is below the trigger value of 5 indicating needs for further refinement for vole.

Further refinement of the risk assessment for Tabocco was provided using the deposition factor indicated in the EFSA guidance document for voles in maize -0.5 for BBCH >30 for both active substances.

**Refined risk assessment (herbivorous mammals "vole", BBCH >30,Tobacco 1 x200 g a.s./ha , BBCH > 13-39)**

| | FLU | | TFS | |
|---|---|---|---|---|
| **BBCH>30** | | | | |
| **Food item** | Monocots | Dicots | Monocots | Dicots |
| **$DT_{50}$** | 2.6 d | 3.18 d | 10 d | 3.35 d |
| **AR** | 0.2 | 0.2 | 0.2 | 0.2 |
| **FIR/bw** | 0.73 | 0.73 | 0.73 | 0.73 |
| **RUD** | 54.2 | 28.7 | 54.2 | 28.7 |
| **$f_{DEP}$** | 0.5 | 0.5 | 0.5 | 0.5 |
| **MAF**<br>**21-d $f_{TWA}$** | 0.18 | 0.22 | 0.53 | 0.23 |
| **PT** | 1 | 1 | 1 | 1 |
| **DDD** | 0.71 | 0.46 | 2.095 | 0.48 |
| **total DDD** | | | 2.57 | |
| **NOAEL** | 14.5 | | 22 | |
| **TER** | 12.4 | | 8.56 | |
| **TERmix** | 5.10 | | | |

The $TER_{LT}$ values for both a.s. for vole are above trigger of 5 for BBCH >30 for max application dose of 2 x 200 g a.s./ha.
The $TER_{mix}$ values is above the trigger value of 5 indicating needs for further refinement for vole.

**Elderberry & mulberry (use group M)**

<u>Small herbivorous mammal "vole"</u>
The refined risk assessment for trifloxystrobin and fluopyram is done with the same refined parameter as for voles in beans and peas (use group C), i.e. the refined exposure assessment is based on a mixed diet (50% monocotyledonous and 50% dicotyledonous plants), with $DT_{50}$ values available for both fluopyram and trifloxystrobin on both monocots and dicots.
Additionally, crop interception in orchards at BBCH ≥ 10 is 20% according to the FOCUS groundwater report (Table 2 in Appendix E of EFSA/2009/1438). Thus, according to the Tier 1 risk assessment, a deposition of 80% is also considered in the refined risk assessment for voles in elderberry and mulberry.

**Table 9.3-73: Higher-tier assessment of the long-term/reproductive risk for small herbivorous mammals for trifloxystrobin due to the use of FLU + TFS SC 500 in elderberry and mulberry (use group M) – refined parameters (*) are further described and justified in the text**

| Feed item | AR (kg/ha) | FIR/bw | RUD × Deposition factor | MAF | 21-d TWA | DDD | NOAEL (mg/kg bw/d) | TER |
|---|---|---|---|---|---|---|---|---|
| 50% monocots | 0.200 | 0.73 | 54.2 × 0.8 | 1.26 [a) *] | 0.37 [a) *] | 2.973 | | |
| 50% dicots | 0.200 | 0.73 | 28.7 × 0.8 | 1.23 [b) *] | 0.36 [b) *] | 1.492 | | |
| Total diet | | | | | | Σ = 4.47 | 22 | **4.9** |

a) With $DT_{50}$ of 3.56 d, 2 applications with 7 d interval (Table 9.3-58)
b) With $DT_{50}$ of 3.35 d, 2 applications with 7 d interval (Table 9.3-59)

**Table 9.3-74: Higher-tier assessment of the long-term/reproductive risk for small herbivorous mammals for fluopyram due to the use of FLU + TFS SC 500 in elderberry and mulberry (use group M) – refined parameters (*) are further described and justified in the text**

| Feed item | AR (kg/ha) | FIR/bw | RUD × Deposition factor | MAF | 21-d TWA | DDD | NOAEL (mg/kg bw/d) | TER |
|---|---|---|---|---|---|---|---|---|
| 50% monocots | 0.200 | 0.73 | 54.2 × 0.8 | 1.15 [a) *] | 0.31 [a) *] | 2.233 | | |
| 50% dicots | 0.200 | 0.73 | 28.7 × 0.8 | 1.20 [b) *] | 0.34 [b) *] | 1.371 | | |
| Total diet | | | | | | Σ = 3.61 | 14.5 | **4.0** |

a) With $DT_{50}$ of 2.6 d, 2 applications with 7 d interval (Table 9.2-58)
b) With $DT_{50}$ of 3.05 d, 2 applications with 7 d interval (Table 9.2-57)

The product is applied to elderberries and mulberries at a large BBCH range between 15 and 89. The risk assessment for use group M was done considering 20% crop interception for BBCH 10 - 19. According to Appendix A of EFSA/2009/1438, a crop interception of 40% is considered already at BBCH stages 20 - 40. Thus, the risk assessment presented above is very conservative for applications between BBCH 12 and 91 and TER values for applications at BBCH ≥ 20 exceed the trigger of 5.
As the risk envelope approach failed the risk assessment, TER calculations with the same refined parameter were additionally done for use group N (2 x 0.150 kg a.s./ha, 14 days interval).

**zRMS comment:**

**Group M**

The risk assessment was verified by zRMS for both active substances for max application rate 2 x 200 g a.s./ha with 7 interval, BBCH 15-89. The DF = 0.8 was used for BBCH >10, 0.6 for BBCH >20 and 0.3 for BBCH >40.

**Refined risk assessment (herbivorous mammals “vole”, BBCH 10-19, Mulberry, 2x200 g a.s./ha, BBCH 15-89, 7d interval)**

| | FLU | | TFS | |
|---|---|---|---|---|
| **Food item** | Monocots | Dicots | Monocots | Dicots |
| **$DT_{50}$** | 2.6 d | 3.18 d | 10 d | 3.35 d |
| **AR** | 0.2 | 0.2 | 0.2 | 0.2 |
| **FIR/bw** | 0.73 | 0.73 | 0.73 | 0.73 |
| **RUD** | 54.2 | 28.7 | 54.2 | 28.7 |

| | | | | |
|---|---|---|---|---|
| **$f_{DEP}$** | 0.8 | 0.8 | 0.8 | 0.8 |
| **MAF** | 0.35 | 0.42 | 1.6 | 0.44 |
| **21-d $f_{TWA}$** | | | 0.53 | |
| **PT** | 1 | 1 | 1 | 1 |
| **DDD** | 2.21 | 1.40 | 5.36 | 1.47 |
| **total DDD** | 3.61 | | 6.83 | |
| **NOAEL** | 14.5 | | 22 | |
| **TER** | **4.02** | | **3.22** | |
| **TERmix** | **1.81** | | | |

The $TER_{LT}$ values for both are below trigger of 5, indicating needs for further refinement max application dose of 2 x 200 g a.s./ha with 7 days interval for BBCH 10-19.
The $TER_{mix}$ values is below the trigger value of 5 indicating needs for further refinement for vole.

**Refined risk assessment (herbivorous mammals "vole", BBCH 20-40, Mulberry, 2x200 g a.s./ha, BBCH 15-89, 7d interval)**

| | FLU | | TFS | |
|---|---|---|---|---|
| **Food item** | Monocots | Dicots | Monocots | Dicots |
| **$DT_{50}$** | 2.6 d | 3.18 d | 10 d | 3.35 d |
| **AR** | 0.2 | 0.2 | 0.2 | 0.2 |
| **FIR/bw** | 0.73 | 0.73 | 0.73 | 0.73 |
| **RUD** | 54.2 | 28.7 | 54.2 | 28.7 |
| **$f_{DEP}$** | 0.6 | 0.6 | 0.6 | 0.6 |
| **MAF** | 0.35 | 0.42 | 1.6 | 0.44 |
| **21-d $f_{TWA}$** | | | 0.53 | |
| **PT** | 1 | 1 | 1 | 1 |
| **DDD** | 1.66 | 1.06 | 4.02 | 1.10 |
| **total DDD** | 2.72 | | 5.12 | |
| **NOAEL** | 14.5 | | 22 | |
| **TER** | 5.33 | | **4.3** | |
| **TERmix** | **2.5** | | | |

The $TER_{LT}$ value for TFS is below the trigger of 5, indicating needs for further refinement max application dose of 2 x 200 g a.s./ha with 7 days interval for BBCH>20.
The $TER_{mix}$ values is below the trigger value of 5 indicating needs for further refinement for vole.

Further refinement was considered fro BBCH > 40 and DF of 0.3 indicated in the EFSA guidance document for voles in orchards for both active substances.

**Refined risk assessment (herbivorous mammals "vole" BBCH >40, Mulberry, 2x200 g a.s./ha, BBCH 15-89, 7d interval)**

| | FLU | | TFS | |
|---|---|---|---|---|
| **Food item** | Monocots | Dicots | Monocots | Dicots |
| **$DT_{50}$** | 2.6 d | 3.18 d | 10 d | 3.35 d |
| **AR** | 0.2 | 0.2 | 0.2 | 0.2 |
| **FIR/bw** | 0.73 | 0.73 | 0.73 | 0.73 |

| | | | | |
|---|---|---|---|---|
| **RUD** | 54.2 | 28.7 | 54.2 | 28.7 |
| **$f_{DEP}$** | 0.3 | 0.3 | 0.3 | 0.3 |
| **MAF** | 0.35 | 0.42 | 1.6 | 0.44 |
| **21-d $f_{TWA}$** | | | 0.53 | |
| **PT** | 1 | 1 | 1 | 1 |
| **DDD** | 0.83 | 0.53 | 2.013 | 0.55 |
| **total DDD** | 1.35 | | 2.56 | |
| **NOAEL** | 14.5 | | 22 | |
| **TER** | 10.74 | | 8.6 | |
| **TERmix** | **4.78** | | | |

The $TER_{LT}$ values for both are above the trigger of 5.
The $TER_{mix}$ values is slight below the trigger value of 5 and is considered by zRMS as an acceptable risk for vole at BBCH>40.

**Table 9.3-75: Higher-tier assessment of the long-term/reproductive risk for small herbivorous mammals for <u>trifloxystrobin</u> due to the use of FLU + TFS SC 500 in elderberry and mulberry (use group N) – refined parameters (*) are further described and justified in the text**

| Feed item | AR (kg/ha) | FIR/bw | RUD × Deposition factor | MAF | 21-d TWA | DDD | NOAEL (mg/kg bw/d) | TER |
|---|---|---|---|---|---|---|---|---|
| 50% monocots | 0.150 | 0.73 | 54.2 × 0.8 | 1.07 [a] * | 0.40 [a] * | 2.008 | | |
| 50% dicots | 0.150 | 0.73 | 28.7 × 0.8 | 1.06 [b] * | 0.38 [b] * | 1.015 | | |
| Total diet | | | | | | Σ = 3.02 | 22 | 7.3 |

[a] With $DT_{50}$ of 3.56 d, 2 applications with 14 d interval (Table 9.3-58)
[b] With $DT_{50}$ of 3.35 d, 2 applications with 14 d interval (Table 9.3-59)

**Table 9.3-76: Higher-tier assessment of the long-term/reproductive risk for small herbivorous mammals for <u>fluopyram</u> due to the use of FLU + TFS SC 500 in elderberry and mulberry (use group N) – refined parameters (*) are further described and justified in the text**

| Feed item | AR (kg/ha) | FIR/bw | RUD × Deposition factor | MAF | 21-d TWA | DDD | NOAEL (mg/kg bw/d) | TER |
|---|---|---|---|---|---|---|---|---|
| 50% monocots | 0.150 | 0.73 | 54.2 × 0.8 | 1.02 [a] * | 0.32 [a] * | 1.564 | | |
| 50% dicots | 0.150 | 0.73 | 28.7 × 0.8 | 1.04 [b] * | 0.36 [b] * | 0.943 | | |
| Total diet | | | | | | Σ = 2.51 | 14.5 | 5.8 |

[a] With $DT_{50}$ of 2.6 d, 2 applications with 14 d interval (Table 9.2-58)
[b] With $DT_{50}$ of 3.05 d, 2 applications with 14 d interval (Table 9.2-57)

**zRMS comments:**

**Group N**

The risk assessment was verified by zRMS for both active substances for max application rate 2 x 150 g a.s./ha with 14 interval, BBCH 15-89. The DF=0.8 was used for BBCH >10, 0.6 for BBCH>20 and

0.3 for BBCH>40 as indicated in the EFSA guidance document for B&M, 2009, Appendix E for voles in orchards.

**Refined risk assessment (herbivorous mammals "vole" BBCH 10-19, Mulberry, 2 x 150 g a.s./ha, BBCH 15-89, 14 days interval)**

| | **FLU** | | **TFS** | |
|---|---|---|---|---|
| **BBCH>10** | | | | |
| **Food item** | **Monocots** | **Dicots** | **Monocots** | **Dicots** |
| **$DT_{50}$** | 2.6 d | 3.18 d | 10 d | 3.35 d |
| **AR** | 0.150 | 0.150 | 0.150 | 0.150 |
| **FIR/bw** | 0.73 | 0.73 | 0.73 | 0.73 |
| **RUD** | 54.2 | 28.7 | 54.2 | 28.7 |
| **$f_{DEP}$** | 0.8 | 0.8 | 0.8 | 0.8 |
| **MAF** | 0.33 | 0.39 | 1.4 | 0.40 |
| **21-d $f_{TWA}$** | | | 0.53 | |
| **PT** | 1 | 1 | 1 | 1 |
| **DDD** | 1.56 | 0.98 | 3.52 | 1.0 |
| **total DDD** | 2.54 | | 4.52 | |
| **NOAEL** | 14.5 | | 22 | |
| **TER** | 5.70 | | **4.86** | |
| **TERmix** | **2.70** | | | |

The $TER_{LT}$ value for a.s. –TFS are below trigger of 5, indicating needs for further refinement max application dose of 2 x 150 g a.s./ha with 14 days interval and BBCH 10-19.
The $TER_{mix}$ value is below the trigger value of 5 indicating needs for further refinement for vole.

**Refined risk assessment (herbivorous mammals "vole" BBCH 20-40, Mulberry, 2 x 150 g a.s./ha, BBCH 15-89, 14 days interval)**

| | **FLU** | | **TFS** | |
|---|---|---|---|---|
| **BBCH>20** | | | | |
| **Food item** | **Monocots** | **Dicots** | **Monocots** | **Dicots** |
| **$DT_{50}$** | 2.6 d | 3.18 d | 10 d | 3.35 d |
| **AR** | 0.150 | 0.150 | 0.150 | 0.150 |
| **FIR/bw** | 0.73 | 0.73 | 0.73 | 0.73 |
| **RUD** | 54.2 | 28.7 | 54.2 | 28.7 |
| **$f_{DEP}$** | 0.6 | 0.6 | 0.6 | 0.6 |
| **MAF** | 0.33 | 0.39 | 1.4 | 0.40 |
| **21-d $f_{TWA}$** | | | 0.53 | |
| **PT** | 1 | 1 | 1 | 1 |
| **DDD** | 1.17 | 0.73 | 2.64 | 0.75 |
| **total DDD** | 1.9 | | 3.39 | |
| **NOAEL** | 14.5 | | 22 | |
| **TER** | 7.63 | | 6.48 | |
| **TERmix** | **3.57** | | | |

The $TER_{LT}$ values for both a.s. are above the trigger of 5.
The $TER_{mix}$ value is below the trigger value of 5 indicating needs for further refinement for vole.

**Refined risk assessment (herbivorous mammals "vole" BBCH 10-19, Mulberry, 2 x 150 g a.s./ha, BBCH 15-89, 14 days interval, BBCH>40)**

| | FLU | | TFS | |
|---|---|---|---|---|
| | BBCH>40 | | | |
| **Food item** | **Monocots** | **Dicots** | **Monocots** | **Dicots** |
| **$DT_{50}$** | 2.6 d | 3.18 d | 10 d | 3.35 d |
| **AR** | 0.150 | 0.150 | 0.150 | 0.150 |
| **FIR/bw** | 0.73 | 0.73 | 0.73 | 0.73 |
| **RUD** | 54.2 | 28.7 | 54.2 | 28.7 |
| **$f_{DEP}$** | 0.3 | 0.3 | 0.3 | 0.3 |
| **MAF** | 0.33 | 0.39 | 1.4 | 0.40 |
| **21-d $f_{TWA}$** | | | 0.53 | |
| **PT** | 1 | 1 | 1 | 1 |
| **DDD** | 0.58 | 0.37 | 1.32 | 0.37 |
| **total DDD** | 0.95 | | 1.69 | |
| **NOAEL** | 14.5 | | 22 | |
| **TER** | 15.26 | | 13.03 | |
| **TERmix** | 7.14 | | | |

The $TER_{LT}$ for both a.s. and TERmix values are above the trigger of 5 fo max application dose of 2 x 150 g a.s./ha with 14 days interval and BBCH >40 indicting an acceptable risk to vole.

Frugivorous mammal "dormouse"
A refined risk assessment is also needed for frugivorous mammals being exposed to fluopyram. A mean RUD of 19.3 is used in the Tier 1 risk assessment for large fruits. As elderberries and mulberries are small berries, this value overestimates the residues in elderberries and mulberries and the refined RUD of 5 mg a.s./kg berries (Hahne, J.; Schabacker, J.; Foudoulakis, M.; Ludwigs, J. D.; Murfitt, R.; Ristau, K.; 2019; M-665829-01-1, Appendix 2) is used for the refined risk assessment for frugivorous mammals in elderberries and mulberries (use group M) according to the refinement of frugivorous birds in berries (use group D). The FIR/bw for dormouse eating on 100% fruits is 1.16 (Appendix A of EFSA/2009/1438).

**Table 9.3-77: Higher-tier assessment of the long-term/reproductive risk for frugivorous mammals for fluopyram due to the use of FLU + TFS SC 500 in elderberry and mulberry (use group M) – refined parameters (*) are further described and justified in the text**

| | | | | | | |
|---|---|---|---|---|---|---|
| **Intended use** | Elderberry, mulberry | | | | | |
| **Active substance/product** | Fluopyram | | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 14.5 | | | | | |
| **TER criterion** | 5 | | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **FIR/bw** | **Mean RUD** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Orchards Fruit stage BBCH 71-79 currants | Frugivorous mammal "dormouse" | 1.16 | 5.0 * | 1.6 × 0.53 | 0.984 | 14.7 |

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.

**zRMS comments:**
The proposed new residue values of 5 mg a.s/kg  was propsed by the applicant as a refinement RUD value for small berries based on very short summary  of  results from field data of fruit residue levels from applicatns of pesticide in different crops from 5 companies was not considered as acceptable.
In zRMS opinion  the RUD value given in  in EFSA GD for B &M, 2009 is still valid.
**Further refinement for frugivorous mammal "dormouse" is still required.**

**Applicant's  response after commenting period:**

In 2021, this RUD value has been published in a peer-reviewed publication giving comprehensive information about the underlying data (Schabacker, J.; Hahne, J.; Ludwigs, J. D.; Vallon, M.; Foudoulakis, M.; Murfitt, R.; Ristau, K.; 2021; M-780038-01-1).
Further, the Draft updated GD for B&M (2021) also gives updated RUD values for fruit food items ranging from 0.73 to 4.4 mg/kg which is significantly lower than the value of 19.3 currently used in the Tier 1 risk assessment according to the GD for B&M (2009).
Therefore, the applicant considers a refined RUD of 5 mg a.s./kg as reliable, leading to an acceptable risk for frugivorous mammals.
**zRMS comment:**
The publication by Schabacker, J.; Hahne, J.; Ludwigs, J. D.; Vallon, M.; Foudoulakis, M.; Murfitt, R.; Ristau, K.; 2021; M-780038-01-1). were not submitted to zRMS.
However we ara still in te opinion that only EU  agreed value should be used.

**Flower bulbs (use group ~~P~~ O)**

Small herbivorous mammal "vole"
The refined risk assessment for trifloxystrobin and fluopyram is done with the same refined parameter as for voles in beans and peas (use group C), i.e. the refined exposure assessment is based on a mixed diet (50% monocotyledonous and 50% dicotyledonous plants), with $DT_{50}$ values available for both fluopyram and trifloxystrobin on both monocots and dicots.
Additionally, crop interception in bulbs and onion like crops at BBCH ≥ 40 is 40% according to the FOCUS groundwater report (Table 2 in Appendix E of EFSA/2009/1438). Thus, according to the Tier 1 risk assessment, a deposition of 60% is also considered in the refined risk assessment for voles in flower bulbs.

**Table 9.3-78: Higher-tier assessment of the long-term/reproductive risk for small herbivorous mammals for trifloxystrobin due to the use of FLU + TFS SC 500 in flower bulbs (use group O) – refined parameters (*) are further described and justified in the text**

| Feed item | AR (kg/ha) | FIR/bw | RUD × Deposition factor | MAF | 21-d TWA | DDD | NOAEL (mg/kg bw/d) | TER |
|---|---|---|---|---|---|---|---|---|
| 50% monocots | 0.200 | 0.73 | 54.2 × 0.6 | 1.0 | 0.24 [a] * | 1.143 | | |
| 50% dicots | 0.200 | 0.73 | 28.7 × 0.6 | 1.0 | 0.23 [b] * | 0.572 | | |
| Total diet | | | | | | Σ = 1.72 | 22 | 12.8 |

[a] With $DT_{50}$ of 3.56 d, single application (Table 9.3-58)
[b] With $DT_{50}$ of 3.35 d, single application (Table 9.3-59)

**Table 9.3-79: Higher-tier assessment of the long-term/reproductive risk for small herbivorous mammals for fluopyram due to the use of FLU + TFS SC 500 in flower bulbs (use group O) – refined parameters (*) are further described and justified in the text**

| Feed item | AR (kg/ha) | FIR/bw | RUD × Deposition factor | MAF | 21-d TWA | DDD | NOAEL (mg/kg bw/d) | TER |
|---|---|---|---|---|---|---|---|---|
| 50% monocots | 0.200 | 0.73 | 54.2 × 0.6 | 1.0 | 0.18 [a] * | 0.846 | | |
| 50% dicots | 0.200 | 0.73 | 28.7 × 0.6 | 1.0 | 0.21 [b] * | 0.523 | | |
| Total diet | | | | | | Σ = 1.37 | 14.5 | 10.6 |

[a] With $DT_{50}$ of 2.6 d, single application (Table 9.2-58)
[b] With $DT_{50}$ of 3.05 d, single application (Table 9.2-57)

**zRMS comment:**

**Group O**

The risk assessment was verified by zRMS for both active substances for max application rate 1 x 200 g a.s./ha with 14 interval, BBCH 12-91. The DF 0.6 for BBCH > 40 was used as indicated in the EFSA guidance document for B&M, 2009, Appendix E, in Bulbs vegetables.

**Refined risk assessment (herbivorous mammals "vole"BBCH >40, Flower bulbs 1 x200 g a.s. /ha, BBCH 12-91)**

| | FLU | | TFS | |
|---|---|---|---|---|
| **BBCH >40** | | | | |
| **Food item** | Monocots | Dicots | Monocots | Dicots |
| **$DT_{50}$** | 2.6 d | 3.18 d | 10 d | 3.35 d |
| **AR** | 0.2 | 0.2 | 0.2 | 0.2 |
| **FIR/bw** | 0.73 | 0.73 | 0.73 | 0.73 |
| **RUD** | 54.2 | 28.7 | 54.2 | 28.7 |
| **$f_{DEP}$** | 0.6 | 0.6 | 0.6 | 0.6 |
| **MAF** / **21-d $f_{TWA}$** | 0.18 | 0.22 | 1 | 0.23 |
| **PT** | 1 | 1 | 0.53 | 1 |
| **DDD** | 0.85 | 0.55 | 2.51 | 0.57 |
| **total DDD** | 1.4 | | 3.08 | |
| **NOAEL** | 14.5 | | 22 | |

| | | |
|---|---|---|
| **TER** | 10.35 | 7.14 |
| **TERmix** | **4.35** | |

The $TER_{LT}$ values for both a.s. are above the trigger of 5.
The $TER_{mix}$ value is below the trigger value of 5 indicating needs for further refinement for vole.

**Flower bulbs (use group P)**

<u>Small herbivorous mammal "vole"</u>
The refined risk assessment for trifloxystrobin and fluopyram is done with the same refined parameter as for voles in beans and peas (use group C), i.e. the refined exposure assessment is based on a mixed diet (50% monocotyledonous and 50% dicotyledonous plants), with $DT_{50}$ values available for both fluopyram and trifloxystrobin on both monocots and dicots.
Additionally, crop interception in bulbs and onion like crops at BBCH ≥ 40 is 40% according to the FOCUS groundwater report (Table 2 in Appendix E of EFSA/2009/1438). Thus, according to the Tier 1 risk assessment, a deposition of 60% is also considered in the refined risk assessment for voles in flower bulbs.

**Table 9.3-80: Higher-tier assessment of the long-term/reproductive risk for small herbivorous mammals for <u>fluopyram</u> due to the use of FLU + TFS SC 500 in flower bulbs (use group P) – refined parameters (*) are further described and justified in the text**

| Feed item | AR (kg/ha) | FIR/bw | RUD × Deposition factor | MAF | 21-d TWA | DDD | NOAEL (mg/kg bw/d) | TER |
|---|---|---|---|---|---|---|---|---|
| 50% monocots | 0.075 | 0.73 | 54.2 × 0.6 | 1.18 [a] * | 0.45 [a] * | 0.897 | | |
| 50% dicots | 0.075 | 0.73 | 28.7 × 0.6 | 1.26 [b] * | 0.50 [b] * | 0.543 | | |
| Total diet | | | | | | Σ = 1.44 | 14.5 | 10.1 |

[a] With $DT_{50}$ of 2.6 d, 5 applications with 7 d interval (Table 9.2-58)
[b] With $DT_{50}$ of 3.05 d, 5 applications with 7 d interval (Table 9.2-57)

**zRMS comments:**

**<u>Group P</u>**

Further risk assessment was for both active substances for max application rate 5 x 75 g a.s./ha with 7d interval was considered with the DF of 0.6 for BBCH >40 as indicated in the EFSA guidance for B&M, Appendix E in Bulbs vegetables.

**Refined risk assessment (herbivorous mammals "vole"BBCH>40, Flower bulbs 5 x 150 g a.s.L/ha, 7 d interval)**

| | FLU | | TFS | |
|---|---|---|---|---|
| **BBCH 40-91** | | | | |
| **Food item** | Monocots | Dicots | Monocots | Dicots |
| **$DT_{50}$** | 2.6 d | 3.18 d | 10 d | 3.35 d |
| **AR** | 0.075 | 0.075 | 0.075 | 0.075 |
| **FIR/bw** | 0.73 | 0.73 | 0.73 | 0.73 |
| **RUD** | 54.2 | 28.7 | 54.2 | 28.7 |

| | | | | |
|---|---|---|---|---|
| **$f_{DEP}$** | 0.6 | 0.6 | 0.6 | 0.6 |
| **MAF** / **21-d $f_{TWA}$** | 0.54 | 0.65 | 2.4 | 0.69 |
| **PT** | 1 | 1 | 0.53 | 1 |
| **DDD** | 0.96 | 0.61 | 2.26 | 0.65 |
| **total DDD** | 1.57 | | 2.91 | |
| **NOAEL** | 14.5 | | 22 | |
| **TER** | 9.23 | | 7.56 | |
| **TERmix** | **4.34** | | | |

The $TER_{LT}$ values for both a.s. are above the trigger of 5.
The $TER_{mix}$ values is below the trigger value of 5 indicating needs for further refinement for vole.

**Golf courses (use group Q)**

Small herbivorous mammal "vole"
Voles on golf courses feed on 100% grass leaves. For the refinement are thus the $DT_{50}$ values in monocotyledonous for trifloxystrobin and fluopyram considered in the risk assessment.

**Table 9.3-81: Higher-tier assessment of the long-term/reproductive risk for small herbivorous mammals for trifloxystrobin due to the use of FLU + TFS SC 500 on golf courses (use group Q) – refined parameters (*) are further described and justified in the text**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Golf courses | | | | |
| **Active substance/product** | Trifloxystrobin | | | | |
| **Application rate (kg/ha)** | 2 × 0.125, 14 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 22 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Grassland All season | Small herbivorous mammal "vole" | 72.3 | 1.07 × 0.40 [a)] * | 3.87 | 5.7 |

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.

[a)] With $DT_{50}$ of 3.56 d, 2 applications with 14 d interval (Table 9.3-58)

~~**Table 9.3-82: Higher-tier assessment of the long-term/reproductive risk for small herbivorous mammals for fluopyram due to the use of FLU + TFS SC 500 on golf courses (use group Q) – refined parameters (*) are further described and justified in the text**~~

| | | | | | |
|---|---|---|---|---|---|
| ~~**Intended use**~~ | ~~Golf courses~~ | | | | |
| ~~**Active substance/product**~~ | ~~Fluopyram~~ | | | | |
| ~~**Application rate (kg/ha)**~~ | ~~2 × 0.125, 14 days interval~~ | | | | |
| ~~**Reprod. toxicity (mg/kg bw/d)**~~ | ~~14.5~~ | | | | |
| ~~**TER criterion**~~ | ~~5~~ | | | | |
| ~~**Crop scenario Growth stage**~~ | ~~**Generic focal species**~~ | ~~**$SV_m$**~~ | ~~**$MAF_m$ × TWA**~~ | ~~**$DDD_m$ (mg/kg bw/d)**~~ | ~~**$TER_{lt}$**~~ |
| ~~Grassland All season~~ | ~~Small herbivorous mammal "vole"~~ | ~~72.3~~ | ~~1.02 × 0.32 a) *~~ | ~~2.95~~ | ~~**4.9**~~ |

~~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.~~

~~a) With $DT_{50}$ of 2.6 d, 2 applications with 7 d interval (Table 9.2-58)~~

~~According to a study xxx 2010 (M-362381-01-1, Appendix 2) no voles could be found on greens, tees and fairways. Voles are only found in the surroundings (roughs) where the grass is higher. Therefore, the vole cannot be considered as species of concern on golf courses with application on greens, tees and fairways (where the grass is kept short and no nest entries are tolerated) only.~~
~~Additionally, the grass is highly managed and is kept short. After mowing, the cutted grass is removed from the course the grass grows again. Thus, residues considered in the risk assessment are very conservative.~~

**zRMS comments:**

**Group R**

**<u>Hops</u>**

zRMS provided in the Table below the $TER_{LT}$ for both a.s. and $TER_{mix}$ values for vole for the worst case scenario for Group R for max application rate 2 x 150 g a.s./ha /ha with 7 days interval, BBCH 37-79. Deposition factor of 0.3 was used for BBCH >40 indicated in the EFSA guidance document for use in Hops.

**Refined risk assessment (herbivorous mammals "vole" BBCH >40 , 2 x 150 g.a./ha /ha, 7 days interval, BBCH 37-79)**

| | FLU | | TFS | |
|---|---|---|---|---|
| **BBCH >40** | | | | |
| **Food item** | Monocots | Dicots | Monocots | Dicots |
| **$DT_{50}$** | 2.6 d | 3.18 d | 10 d | 3.35 d |
| **AR** | 0.15 | 0.15 | 0.15 | 0.15 |
| **FIR/bw** | 0.73 | 0.73 | 0.73 | 0.73 |
| **RUD** | 54.2 | 28.7 | 54.2 | 28.7 |
| **$f_{DEP}$** | 0.3 | 0.3 | 0.3 | 0.3 |
| **MAF** | 0.33 | 0.39 | 1.4 | 0.40 |
| **21-d $f_{TWA}$** | | | 0.53 | |
| **PT** | 1 | 1 | 1 | 1 |

| | | | | |
|---|---|---|---|---|
| **DDD** | 0.58 | 0.37 | 1.32 | 0.37 |
| **total DDD** | 0.95 | | 1.7 | |
| **NOAEL** | 14.5 | | 22 | |
| **TER** | 15.26 | | 12.94 | |
| **TERmix** | 7.14 | | | |

The $TER_{LT}$ values for for both a.s. are above the trigger of 5.
The $TER_{mix}$ value is below the trigger value of 5 indicating needs for further refinement for vole.

**Overll all conclusion for the risk assessment for renewed a.s.-TFS for vole**

The risk assessment for a.s.- TFS should be further refined for the following scenarios:
- Group A, 2 x 200 g a.s/ha, 7 days interval, BBCH 12-41
- Group B, 1 x 0.200 g a.s./ha, 2 x 150 g a.s/ha with 7 d interval
- Group D, 2 x 200 g a.s./ha and BBCH 10-19, 7 d and 14 d interval

- Group I, 2 x 200 g a.s./ha and BBCH 40-49, 2 x 150 g a.s./ha and BBCH 40-49
- Group J, 1 x200 g a.s./ha and BBCH 40-49
- Group K, 1 x 200 g a.s./ha and BBCH 10-29,
- Group M, 2 x 200 g a.s./ha and 10-40 BBCH
- Group N, 2 x 150 g a.s./ha and 14 d interval, BBCH 10-19

**Combitox risk assessmet for mammals**

The combitox risk assessment for mammals presented in the Tables above which was calculated by zRMS with consideration agreed parameters evaluated in Registration reprt for Luna Sensation by zRMS-NL in July 2018 was summerised below:
Where possible further refinement of the combitox risk assessment was provided by zRMS below.

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

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

These conditions are assessed following a step-wise approach. A detailed description of this approach is presented in a separate document (xxx, 2016, M-571377-02-1, Appendix 2). Note that for the calculation only the scenario with the lowest TER values was considered (most critical scenario). This safely covers all other scenarios.

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

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

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

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

**3rd step: $TER_{MIX}$ calculation**

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

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

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

Please note: For the acute combined toxicity assessment, TER values for the screening step are used whereas TER values calculated at Tier 1 or in the refined risk assessment are used for the long-term/reproductive combined toxicity assessment. The combined toxicity assessment is done as risk envelope: use group A covers use group B, use group D covers use group E, use group F covers use group G, use group I covers use group J and use group M covers use group N.

**Table 9.3-83: Combined toxicity assessment – mammals in leafy vegetables (use group A)**

| Intended use | Leafy vegetables | | | | |
|---|---|---|---|---|---|
| Active substances | Trifloxystrobin (TFS) + Fluopyram (FLU) | | | | |
| Application rate (L/ha) | 2 × 0.8, 7 days interval | | | | |
| Scenario / Generic focal species | **TER values [1]** | | **1st step** | **2nd step** | **3rd step** |
| | **TFS** | **FLU** | **all TER ≥ trigger × n** | **$Rpf_{max}$** | **$TER_{MIX}$** |
| Acute / Small herbivorous mammal (Screening step) | >131 | >52.4 | Yes | Not needed | Not needed |
| Long-term / Small insectivorous mammal "shrew" | 30.9 | 20.4 | Yes | Not needed | Not needed |
| Long-term / Small herbivorous mammal "vole" | ~~5.3~~ [2] **2.57** (1.79) | ~~**3.8**~~ **3.2** (1.18) | No | 0.60 (FLU) | ~~**2.2**~~ [4 *] **1.50** |
| Long-term / Large herbivorous mammal "lagomorph" | 9.07 | 5.98 | No | 0.60 (FLU) | **3.6** [5] |
| Long-term / Small omnivorous mammal "mouse" | 16.6 | 11.0 | 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
[2] ~~Refined TER (please refer to Table 9.3-60)~~
~~[3] Refined TER (please refer to Table 9.3-61)~~
[4] Real risk to voles is not considered high in leafy vegetables, please refer to Figure 1 and associated text
~~[5] A refined $TER_{MIX}$ is presented below (Table 9.3-98)~~

**zRMS comment:**

zRMS verified in the table above the $TER_{LT}$ and $TER_{mix}$ values for the worst case scenario for Group A- leafy vegeatbales 2 x 200 g a.s./ha with 7 days interval.
Based on the worst case scenario for Group A further refinment for combitox assessment was still required for :
**- Long-term / Small herbivorous mammal "vole"**
**- Long-term / Large herbivorous mammal "lagomorph**

The refined risk for large herbivorous mammal **"lagomorph''** for application rate 2 x 200 g a.s./ha with 7 day interval is provided by zRMS below:

**Refinement risk ( Long-term / Large herbivorous mammal "lagomorph for application 2 x 200 g a.sha with 7 day interval)**

| | FLU | TFS |
|---|---|---|

| **Food item** | Non-grass herbs | Non-grass herbs |
|---|---|---|
| **$DT_{50}$** | 3.18 d | 3.35 d |
| **AR** | 0.2 | 0.2 |
| **FIR/bw** | 0.5 | 0.5 |
| **RUD** | 28.7 | 28.7 |
| **$f_{DEP}$** | 1 | 1 |
| **MAF** | 0.42 | 0.44 |
| **21-d $f_{TWA}$** | | |
| **PT** | 1 | 1 |
| **DDD** | 1.21 | 1.26 |
| **total DDD** | 1.21 | 1.26 |
| **NOAEL** | 14.5 | 11.6 |
| **TER** | 12.0 | 9.2 |
| **TERmix** | 5.2 | |

*FIR/be agreed in Registration Reprt for Luna Sensation, July 2018.

The $TER_{LT}$ for both a.s. and $TER_{mix}$ values are above trigger value of 5 indicating an aceptable risk for
for lagomorph.

The risk for vole still needs further refinement for Group A.

**Group B**

The risk assessment was provided for application rate 1 x 200 g a.s./ha and 1 x 150 g a.s./ha.

**Refined risk assessment (herbivorous mammals "vole" 40-49, leafy vegetables, 1x 200 g a.s./ha, BBCH 12-49)**

| | FLU | | TFS | |
|---|---|---|---|---|
| | | | | |
| **Food item** | Monocots | Dicots | Monocots | Dicots |
| **$DT_{50}$** | 2.6 d | 3.18 d | 10 d | 3.35 d |
| **AR** | 0.2 | 0.2 | 0.2 | 0.2 |
| **FIR/bw** | 0.73 | 0.73 | 0.73 | 0.73 |
| **RUD** | 54.2 | 28.7 | 54.2 | 28.7 |
| **$f_{DEP}$** | 1 | 1 | 1 | 1 |
| **MAF** | 0.18 | 0.22 | 0.53 | 0.23 |
| **21-d $f_{TWA}$** | | | | |
| **PT** | 1 | 1 | 1 | 1 |
| **DDD** | 1.42 | 0.69 | 4.23 | 0.96 |
| **total DDD** | 2.11 | | 5.19 | |
| **NOAEL** | 14.5 | | 22 | |
| **TER** | 6.87 | | **4.23** | |
| **TERmix** | **2.70** | | | |

The $TER_{LT}$ value for a.s.- TFS is below trigger of 5 indicating needs for further refinement.
The $TER_{mix}$ value is below the trigger value of 5 indicating needs for further refinement for vole for application rate 1 x 200 g a.s./ha.

For Group B the refined risk assessment for lower application rate 1 x 150 g a.s./ha and BBCH 40-49 was considered below.

**Group B**

**Refined risk assessment (herbivorous mammals "vole" 40-49, leafy vegetables, 1x150 g a.s./ha, BBCH 40-49)**

| | FLU | | TFS | |
|---|---|---|---|---|
| **BBCH 40-49** | | | | |
| **Food item** | Monocots | Dicots | Monocots | Dicots |
| **$DT_{50}$** | 2.6 d | 3.18 d | 10 d | 3.35 d |
| **AR** | 0.15 | 0.15 | 0.15 | 0.15 |
| **FIR/bw** | 0.73 | 0.73 | 0.73 | 0.73 |
| **RUD** | 54.2 | 28.7 | 54.2 | 28.7 |
| **$f_{DEP}$** | 1 | 1 | 1 | 1 |
| **MAF** / **21-d $f_{TWA}$** | 0.18 | 0.22 | 0.53 | 0.23 |
| **PT** | 1 | 1 | 1 | 1 |
| **DDD** | 1.07 | 0.69 | 3.15 | 0.72 |
| **total DDD** | 1.76 | | 3.87 | |
| **NOAEL** | 14.5 | | 22 | |
| **TER** | 8.2 | | 5.7 | |
| **TERmix** | **3.4** | | | |

The $TER_{LT}$ values for both a.s. are above the trigger of 5.
The $TER_{mix}$ value is below the trigger value of 5 indicating needs for further refinement for vole.
In adition , refined risk assessment for herbivorous mammals "vole", leafy vegetables at rate 1 x 150 g a.s. /ha for BBCH 13-19 is not needed.

**Table 9.3-84: Combined toxicity assessment – mammals in beans and peas (use group C)**

| Intended use | Beans, peas | | | | |
|---|---|---|---|---|---|
| Active substances | Trifloxystrobin (TFS) + Fluopyram (FLU) | | | | |
| Application rate (L/ha) | 2 × 0.8, 7 days interval | | | | |
| Scenario / Generic focal species | **TER values [1]** | | **1st step** | **2nd step** | **3rd step** |
| | **TFS** | **FLU** | **all TER ≥ trigger × n** | **$Rpf_{max}$** | **$TER_{MIX}$** |
| Acute / Small herbivorous mammal (Screening step) | >131 | >52.4 | Yes | Not needed | Not needed |
| Long-term / Small insectivorous mammal "shrew" | 68.3 | 45.0 | Yes | Not needed | Not needed |
| Long-term / Small herbivorous mammal "vole" | 5.98 8.56 | 10.74 [2**] 8.56 (3.94) | No | 0.60 (FLU) | 3.8 [3**] 5 |
| Long-term / Large herbivorous mammal "lagomorph" | 30.2 | 19.9 | Yes | Not needed | Not needed |
| Long-term / Small omnivorous mammal "mouse" | 19.7 | 13.0 | Yes | Not needed | Not needed |
| Long-term / Small omnivorous | 56.4 | 37.2 | Yes | Not | Not |

| | | | | | |
|---|---|---|---|---|---|
| mammal “mouse” | | | | needed | needed |

[1] Differing TER values used for rpf calculations to fulfil the criterion of identical exposure levels are shown in brackets
[2] ~~Refined TER (please refer to Table 9.3-62)~~
[3] ~~A refined $TER_{MIX}$ is presented below (Table 9.3-100)~~

**zRMS comment:**

zRMS verified the $TER_{LT}$ and TERmix values for the worst case scenario for Group C 2 x 200 g a.s. /ha with 7 days interval. The risk is considered as acceptable. No further calculation are needed.

**Table 9.3-85: Combined toxicity assessment – mammals in berries (use group D)**

| Intended use | Berries | | | | |
|---|---|---|---|---|---|
| Active substances | Trifloxystrobin (TFS) + Fluopyram (FLU) | | | | |
| Application rate (L/ha) | 2 × 0.8, 7 days interval, | | | | |
| Scenario / Generic focal species | **TER values [1]** | | **1st step** | **2nd step** | **3rd step** |
| | **TFS** | **FLU** | **all TER ≥ trigger × n** | **$Rpf_{max}$** | **$TER_{MIX}$** |
| Acute / Small herbivorous mammal (Screening step) | >218 | >87.2 | Yes | Not needed | Not needed |
| Long-term / Small insectivorous mammal “shrew” | 30.9 | 20.4 | Yes | Not needed | Not needed |
| Long-term / Small herbivorous mammal "vole" | ~~6.6~~ [2]<br>4.36*<br>5.15**<br>8.59***<br>(2.99) | ~~5.4~~ [3]<br>5.5*<br>6.41**<br>10.74***<br>(1.97) | No* | 0.60 (FLU) | ~~**3.0**~~<br>**2.5***<br>**2.94****<br>4.78*** |
| Long-term / Frugivorous mammal "dormouse" | 13.4 | 8.81 | No | 0.60 (FLU) | 5.3 |
| Long-term / Small omnivorous mammal “mouse” | 27.6 | 18.2 | 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
[2] ~~Refined TER (please refer to Table 9.3-63)~~
[3] ~~Refined TER (please refer toTable 9.3-64)~~
*BBCH 10-19, DF=0.6
**BBCH 20-39, DF=0.5
***BBCH >40, DF=0.3

**zRMS comments:**

**Group D**

zRMS verified the $TER_{LT}$ and $TER_{mix}$ values in the Table above for the worst case scenario for Group D - 2 x 200 g a.s. /ha with 7 days interval and BBCH 15-89.

The risk assessment for vole for BBCH < 40 (BBCH 15-40) is below trigeer of 5 for combitox exposure indicating further refinement.
The risk assessment for vole for application from BBCH >40 is closed to trigger value of 5 for combitox exposure and is considered by zRMS as acceptable.

**Group E**

**Refined risk assessment (herbivorous mammals "vole" BBCH 10-19, Bush and cane fruits, 2x150 g a.s. /ha, BBCH 15 – 89, 7 d interval)**

| | FLU | | TFS | |
|---|---|---|---|---|
| **BBCH <40** | | | | |
| **Food item** | Monocots | Dicots | Monocots | Dicots |
| **$DT_{50}$** | 2.6 d | 3.18 d | 10 d | 3.35 d |
| **AR** | 0.15 | 0.15 | 0.15 | 0.15 |
| **FIR/bw** | 0.73 | 0.73 | 0.73 | 0.73 |
| **RUD** | 54.2 | 28.7 | 54.2 | 28.7 |
| **$f_{DEP}$** | 0.6 | 0.6 | 0.6 | 0.6 |
| **MAF / 21-d $f_{TWA}$** | 0.35 | 0.42 | 1.4*0.53 | 0.44 |
| **PT** | 1 | 1 | 1 | 1 |
| **DDD** | 1.24 | 0.79 | 1.4 | 0.83 |
| **total DDD** | 2.03 | | 2.23 | |
| **NOAEL** | 14.5 | | 22 | |
| **TER** | 7.14 | | 9.86 | |
| **TERmix** | **4.16** | | | |

The $TER_{LT}$ values for both a.s. for application dose 2 x 150 g a.s/ha with 7 d interval is above trigger of 5.
The $TER_{mix}$ value for application dose 2 x 150 g a.s/ha with 7 d interval is below trigger of 5 indicating needs for further refinement at BBCH<40.

The risk for vole was provided for BBCH>40 for application rate **Bush and cane fruits, 2x150 g a.s. /ha, BBCH 15 – 89, 7 d interval)**

**Refined risk assessment (herbivorous mammals "vole" BBCH >40, Bush and cane fruits, 2x150 g a.s./ha, BBCH 15 – 89, 7 d interval)**

| | FLU | | TFS | |
|---|---|---|---|---|
| **BBCH >40** | | | | |
| **Food item** | Monocots | Dicots | Monocots | Dicots |
| **$DT_{50}$** | 2.6 d | 3.18 d | 10 d | 3.35 d |
| **AR** | 0.15 | 0.15 | 0.15 | 0.15 |
| **FIR/bw** | 0.73 | 0.73 | 0.73 | 0.73 |
| **RUD** | 54.2 | 28.7 | 54.2 | 28.7 |
| **$f_{DEP}$** | 0.3 | 0.3 | 0.3 | 0.3 |
| **MAF / 21-d $f_{TWA}$** | 0.35 | 0.42 | 1.4*0.53 | 0.44 |
| **PT** | 1 | 1 | 1 | 1 |
| **DDD** | 0.62 | 0.39 | 1.32 | 0.41 |
| **total DDD** | 1.31 | | 1.73 | |
| **NOAEL** | 14.5 | | 22 | |
| **TER** | 11.06 | | 12.71 | |
| **TERmix** | | | | |

The $TER_{LT}$ values for both a.s. are above trigger of 5 for application dose 2 x 150 g

a.s/ha with 7 d interval .
The $TER_{mix}$ value for application dose 2 x 150 g a.s/ha with 7 d interval is above trigger of 5 indicating acceptable risk at BBCH>40.

In addition zRMS recalculated the risk for application dose 2x150 g a.s /ha, BBCH 40-69, 21d interval).

**Refined risk assessment (herbivorous mammals "vole"BBCH , cane fruits, 2x150 g a.s /ha, BBCH 40-69, 21d interval)**

| | FLU | | TFS | |
|---|---|---|---|---|
| **BBCH ≥40** | | | | |
| **Food item** | Monocots | Dicots | Monocots | Dicots |
| **$DT_{50}$** | 2.6 d | 3.18 d | 10 d | 3.35 d |
| **AR** | 0.15 | 0.15 | 0.15 | 0.15 |
| **FIR/bw** | 0.73 | 0.73 | 0.73 | 0.73 |
| **RUD** | 54.2 | 28.7 | 54.2 | 28.7 |
| **$f_{DEP}$** | 0.3 | 0.3 | 0.3 | 0.3 |
| **MAF** / **21-d $f_{TWA}$** | 0.18 | 0.22 | (1.4*0.53=) 0.742 | 0.23 |
| **PT** | 1 | 1 | 1 | 1 |
| **DDD** | 0.32 | 0.21 | 1.32 | 0.22 |
| **total DDD** | 0.53 | | 1.54 | |
| **NOAEL** | 14.5 | | 22 | |
| **TER** | 27.5 | | 14.3 | |
| **TERmix** | 6.3 | | | |

The $TER_{LT}$ values for both a.s. are above trigger of 5 for application dose 2 x 150 g a.s/ha with 21 d interval.
The $TER_{mix}$ value is above the trigger of 5 for application dose 2 x 150 g a.s/ha with 21 d interval for BBCH>40.

**Table 9.3-86: Combined toxicity assessment – mammals in strawberries, blueberries and cranberries (use group F)**

| | | | | | |
|---|---|---|---|---|---|
| Intended use | Strawberries, blueberries, cranberries | | | | |
| Active substances | Trifloxystrobin (TFS) + Fluopyram (FLU) | | | | |
| Application rate (L/ha) | 2 × 0.8, 7 days interval | | | | |
| Scenario / Generic focal species | **TER values [1]** **TFS** | **FLU** | **1st step** **all TER ≥ trigger × n** | **2nd step** **$Rpf_{max}$** | **3rd step** **$TER_{MIX}$** |
| Acute / Small herbivorous mammal (Screening step) | >151 | >60.3 | Yes | Not needed | Not needed |
| Long-term / Small insectivorous mammal "shrew" | 30.9 | 20.4 | Yes | Not needed | Not needed |
| Long-term / Small herbivorous mammal "vole" | ~~9.9~~ [2] 6.45** 7.30*** (4.49) | ~~8.0~~ 8.28** 8.52*** (2.96) | No | 0.60 (FLU) | ~~**4.4**~~ [4] **3.70**** **4.16***** |
| Long-term / Large herbivorous mammal "lagomorph" | 9.07 | 5.98 | No | 0.60 (FLU) | **3.6** [5] |

| | | | | | |
|---|---|---|---|---|---|
| Long-term / Small omnivorous mammal "mouse" | 16.6 | 11.0 | 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
[2] ~~Refined TER (please refer to Table 9.3-65)~~
[3] ~~Refined TER (please refer to Table 9.3-66)~~
[4] Real risk to voles is not considered high in strawberries, blueberries and cranberries, please refer to text below Table 9.3-66
[5] ~~A refined $TER_{MIX}$ is presented below (Table 9.3-103)~~
**BBCH >40, 2 x 200 g a.s./ha with 7 days interval
***BBCH >40, 2 x 200 g a.s./ha with 14 days interval

**zRMS comments:**

**Group F**

zRMS verified in the table above the $TER_{LT}$ and TERmix values for vole for the worst case scenario for Group F - 2 x 200 g a.s./ha with 7 and 14 days interval.

Further refinment for combitox assessment was still required for :

**-Long-term / Small herbivorous mammal "vole"**
**-Long-term / Large herbivorous mammal "lagomorph"**

The refined risk for large herbivorous mammal "lagomorph'' for application rate 2 x 200 g a.s./ha with 7 day interval is provided by zRMS below:

**Refined risk assessment (herbivorous mammals "lagomorph", strawberries, 2x200 g a.s. /ha, BBCH 15-89, 7 d interval)**

| | FLU | TFS |
|---|---|---|
| **Food item** | Non-grass herbs | Non-grass herbs |
| **$DT_{50}$** | 3.18 d | 3.35 d |
| **AR** | 0.2 | 0.2 |
| **FIR/bw** | 0.5 | 0.5 |
| **RUD** | 28.7 | 28.7 |
| **$f_{DEP}$** | 1 | 1 |
| **MAF** / **21-d $f_{TWA}$** | 0.42 | 0.44 |
| **PT** | 1 | 1 |
| **DDD** | 1.2 | 1.26 |
| **NOAEL** | 14.5 | 22 |
| **TER** | 12.08 | 17.46 |
| **TERmix** | 7.69 | |

The risk assessment for lagomorph is considered acceptable.

Further assessment for vole is conducted using the deposition factors indicated in the EFSA guidance document for voles for strawberry being 0.4 for BBCH >40 for reduced application dose to 1 x 200 g a.s./ha.

**Refined risk assessment (herbivorous mammals "vole" 40-49, strawberries 1x 200 g a.s./ha**

| | FLU | TFS |
|---|---|---|

| **BBCH >40** | | | | |
|---|---|---|---|---|
| **Food item** | Monocots | Dicots | Monocots | Dicots |
| **$DT_{50}$** | 2.6 d | 3.18 d | 10 d | 3.35 d |
| **AR** | 0.2 | 0.2 | 0.2 | 0.2 |
| **FIR/bw** | 0.73 | 0.73 | 0.73 | 0.73 |
| **RUD** | 54.2 | 28.7 | 54.2 | 28.7 |
| **$f_{DEP}$** | 0.4 | 0.4 | 0.4 | 0.4 |
| **MAF** | 0.18 | 0.22 | 1 | 0.23 |
| **21-d $f_{TWA}$** | | | 0.53 | |
| **PT** | 1 | 1 | 1 | 1 |
| **DDD** | 0.57 | 0.37 | 1.67 | 0.38 |
| **total DDD** | 0.94 | | 2.055 | |
| **NOAEL** | 14.5 | | 22 | |
| **TER** | 15.42 | | 10.70 | |
| **TERmix** | 6.66 | | | |

The $TER_{LT}$ values for both a.s. for vole are above trigger of 5 for BBCH >40 for application dose of 1 x 200 g a.s./ha with 7 days interval.
The $TER_{mix}$ value is above trigger value of 5 indicating an acceptable risk for vole.

**GROUP G**

**Refined risk assessment (herbivorous mammals “vole”BBCH 40-49 , 2x 150 g a.s. /ha, BBCH 15-89, 7 d interval)**

| | FLU | | TFS | |
|---|---|---|---|---|
| **BBCH>40** | | | | |
| **Food item** | Monocots | Dicots | Monocots | Dicots |
| **$DT_{50}$** | 2.6 d | 3.18 d | 10 d | 3.35 d |
| **AR** | 0.15 | 0.15 | 0.15 | 0.15 |
| **FIR/bw** | 0.73 | 0.73 | 0.73 | 0.73 |
| **RUD** | 54.2 | 28.7 | 54.2 | 28.7 |
| **$f_{DEP}$** | 0.4 | 0.4 | 0.4 | 0.4 |
| **MAF** | 0.35 | 0.42 | (1.6*0.53 | 0.44 |
| **21-d $f_{TWA}$** | | | | |
| **PT** | 1 | 1 | 1 | 1 |
| **DDD** | 0.83 | 0.52 | 2.013 | 0.55 |
| **total DDD** | 1.35 | | 2.56 | |
| **NOAEL** | 14.5 | | 22 | |
| **TER** | 20.74 | | 8.6 | |
| **TERmix** | 6.25 | | | |

The $TER_{LT}$ values for both a.s. for vole are above trigger of 5 for BBCH >40 for max application dose of 2 x 150 g a.s./ha with 7 id nterval.
The $TER_{mix}$ values is above the trigger value of 5 indicating an acceptable risk for vole.

**Table 9.3-87: Combined toxicity assessment – mammals in grapes (use group H)**

| Intended use | Grapes | | | | |
|---|---|---|---|---|---|
| Active substances | Trifloxystrobin (TFS) + Fluopyram (FLU) | | | | |
| Application rate (L/ha) | 2 × 0.2, 14 days interval | | | | |
| Scenario / Generic focal species | **TER values** | | **1st step** | **2nd step** | **3rd step** |
| | **TFS** | **FLU** | **all TER ≥ trigger × n** | **$Rpf_{max}$** | **$TER_{MIX}$** |
| Acute / Small herbivorous mammal (Screening step) | >611 | >244 | Yes | Not needed | Not needed |
| Long-term / Large herbivorous mammal "lagomorph" | 88.5 | 58.3 | Yes | Not needed | Not needed |
| Long-term / Small insectivorous mammal "shrew" | 141 | 93.1 | Yes | Not needed | Not needed |
| Long-term / Small herbivorous mammal "vole" | 13.7 | 9.01 | No | 0.60 (FLU) | 5.4 |
| Long-term / Small omnivorous mammal "mouse" | 126 | 83.2 | Yes | Not needed | Not needed |

**zRMS comment:**

We agree with the $TER_{LT}$ values. $TER_{mix}$ is considered as acceptable.

**Table 9.3-88: Combined toxicity assessment – mammals in nurseries and rosehip (use group I)**

| Intended use | Nurseries, rosehip | | | | |
|---|---|---|---|---|---|
| Active substances | Trifloxystrobin (TFS) + Fluopyram (FLU) | | | | |
| Application rate (L/ha) | 2 × 0.8, 7 days interval | | | | |
| Scenario / Generic focal species | **TER values** [1] | | **1st step** | **2nd step** | **3rd step** |
| | **TFS** | **FLU** | **all TER ≥ trigger × n** | **$Rpf_{max}$** | **$TER_{MIX}$** |
| Acute / Small herbivorous mammal (Screening step) | >131 | >52.4 | Yes | Not needed | Not needed |
| Long-term / Small insectivorous mammal "shrew" | 78.0 | 51.4 | Yes | Not needed | Not needed |
| Long-term / Small herbivorous mammal "vole" | ~~3.9~~ [2]<br>**2.57***<br>8.6**<br>(2.05) | ~~3.21~~ [3]<br>**3.21***<br>**10.74****<br>(1.35) | No* | 0.60 (FLU) | ~~1.8~~<br>**1.42***<br>4.76** |
| Long-term / Small omnivorous mammal "mouse" | 19.0 | 12.5 | 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
[2] Refined TER (please refer to Table 9.3-67)
[3] Refined TER (please refer to Table 9.3-68)
*BBCH <50 ( 40-49)
**BBCH>50

**zRMS comments:**

**Group I**

zRMS verified the $TER_{LT}$ and $TER_{mix}$ values for vole for the worst case scenario for Group I - 2 x 200 g a.s./ha with 7 days interval.
The $TER_{LT}$ and $TER_{mix}$ values for vole BBCH< 50 ( 40-49) are below trigeer of 5 indicating needs for further refinement.
However, when DFof 0.3 for BBCH > 50 the $TER_{mix}$ is closed to trigger value of 5 and the risk is considered as acceptable by zRMS.

**Table 9.3-89: Combined toxicity assessment – mammals in tobacco (use group K)**

| Intended use | Tobacco | | | | |
|---|---|---|---|---|---|
| Active substances | Trifloxystrobin (TFS) + Fluopyram (FLU) | | | | |
| Application rate (L/ha) | 1 × 0.8 | | | | |
| Scenario / Generic focal species | **TER values [1]** | | **1st step** | **2nd step** | **3rd step** |
| | **TFS** | **FLU** | **all TER ≥ trigger × n** | **$Rpf_{max}$** | **$TER_{MIX}$** |
| Acute / Small herbivorous mammal (Screening step) | >183 | >73.3 | Yes | Not needed | Not needed |
| Long-term / Small insectivorous mammal “shrew” | 49.4 | 32.6 | Yes | Not needed | Not needed |
| Long-term / Small herbivorous mammal "vole" | ~~15.4~~ [1] 4.27* 8.56** | ~~12.7~~ [2**] 6.2* 12.4** | ~~Yes~~ | ~~Not needed~~ | ~~Not needed**~~ **2.32*** 5.10** |
| Long-term / Small omnivorous mammal “mouse” | 26.6 | 17.5 | Yes | Not needed | Not needed |

* BBCH<30
** BBCH>30

**zRMS comments:**

zRMS verified in the Table above the $TER_{LT}$ and $TER_{mix}$ values for vole for the worst case scenario for Group K - 1 x 200 g a.s./ha and BBCH 11-39.

TERmix values for vole BBCH< 30 ( BBCH10-29) are below triger of 5 indicating needs for further refinement.
However, when DF of 0.5. for BBCH> 30 is used the the TERmix is above to trigger value of 5 and the risk is considered as acceptable.

**Table 9.3-90: Combined toxicity assessment – mammals in celeriac (use group L)**

| Intended use | Celeriac | | | | |
|---|---|---|---|---|---|
| Active substances | Trifloxystrobin (TFS) + Fluopyram (FLU) | | | | |
| Application rate (L/ha) | 2 × 0.5, 14 days interval | | | | |
| Scenario / Generic focal species | **TER values** | | **1st step** | **2nd step** | **3rd step** |
| | **TFS** | **FLU** | **all TER ≥ trigger × n** | **Rpf$_{max}$** | **TER$_{MIX}$** |
| Acute / Small herbivorous mammal (Screening step) | >282 | >113 | Yes | Not needed | Not needed |
| Long-term / Small insectivorous mammal "shrew" | 125 | 82.3 | Yes | Not needed | Not needed |
| Small herbivorous mammal "vole" | ~~10.9~~ 15.60* | ~~7.20~~ 7.07* | No | 0.60 (FLU) | ~~4.3~~ ~~[1]~~ 4.90* |
| Long-term / Small omnivorous mammal "mouse" | 103 | 68.0 | Yes | Not needed | Not needed |

[1] A refined TER$_{MIX}$ is presented below (Table 9.3-106)

*refined by zRMS

**zRMS comment:**
TER$_{LT}$ for both a.s. values are above trigger of 5.
TERmix for long-term / Small herbivorous mammal "vole is closed to trigger of 5 and is considered as acceptable by zRMS.

**Table 9.3-91: Combined toxicity assessment – mammals in elderberry and mulberry (use group M)**

| Intended use | Elderberry, mulberry | | | | |
|---|---|---|---|---|---|
| Active substances | Trifloxystrobin (TFS) + Fluopyram (FLU) | | | | |
| Application rate (L/ha) | 2 × 0.8, 7 days interval | | | | |
| Scenario / Generic focal species | **TER values [1]** | | **1st step** | **2nd step** | **3rd step** |
| | **TFS** | **FLU** | **all TER ≥ trigger × n** | **Rpf$_{max}$** | **TER$_{MIX}$** |
| Acute / Small herbivorous mammal (Screening step) | >131 | >52.4 | Yes | Not needed | Not needed |
| Long-term / Small herbivorous mammal "vole" | ~~**4.9**~~ [2] 3.22* 4.3** 8.6 *** (2.24) | ~~**4.0**~~ [3] 4.02* 5.33*8 10.74*** (1.48) | No | 0.60 (FLU) | ~~**2.2**~~ **1.81*** **2.5**** 4.78*** |
| Long-term / Frugivorous mammal "dormouse" | 5.71 | ~~14.7~~ [4] (3.77) | No | 0.60 (FLU) | ~~**4.1**~~ [5] **2.32** |
| Long-term / Large herbivorous mammal "lagomorph" | 11.3 | 7.43 | No | 0.60 (FLU) | **4.5** [5] |
| Long-term / Small omnivorous mammal "mouse" | 20.9 | 13.8 | 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
[2] ~~Refined TER (please refer to Table 9.3-73)~~
~~[3] Refined TER (please refer to Table 9.3-74)~~
~~[4] Refined TER (please refer to Table 9.3-77)~~
~~[5] A refined TER$_{MIX}$ is presented below (Table 9.3-110)~~
*BBCH>10
**BBCH>20

***BBCH >40

**zRMS comment:**

**Group M**

zRMS verified the $TER_{LT}$ and $TER_{mix}$ values for vole for the worst case scenario for Group M (elderberry and mulberry) - 2 x 200 g a.s./ha with 7 days interval, BBCH 15-89.
$TER_{mix}$ for vole is closed to trigger value of 5 for BBCH >40 and the risk is considered as acceptable by zRMS.
For application at earlier growth stages the risk for vole is unresoleved.
Further refinment for combitox assessment is still required for :

**- Long-term / Small herbivorous mammal "vole"/ Frugivorous mammal "dormouse" and lagomorph.**

The risk for vole was calculated by zRMS for lower application dose 1 x 200 g a.s./ha with consideration DF as indicated in the EFSA guidance document for voles in Mulberry and Elderberry(orchard)s for both active substances.

**Refined risk assessment (herbivorous mammals "vole" 10-19, Mulberry, Elderberry 1 x 200 g a.s./ha, BBCH 15-89), BBCH >10**

| | FLU | | TFS | |
|---|---|---|---|---|
| **Food item** | Monocots | Dicots | Monocots | Dicots |
| **$DT_{50}$** | 2.6d | 3.18 d | 10 d | 3.35 d |
| **AR** | 0.2 | 0.2 | 0.2 | 0.2 |
| **FIR/bw** | 0.73 | 0.73 | 0.73 | 0.73 |
| **RUD** | 54.2 | 28.7 | 54.2 | 28.7 |
| **$f_{DEP}$** | 0.8 | 0.8 | 0.8 | 0.8 |
| **MAF** | 0.18 | 0.22 | 1 | 0.23 |
| **21-d $f_{TWA}$** | | | 0.53 | |
| **PT** | 1 | 1 | 1 | 1 |
| **DDD** | 1.14 | 0.73 | 3.35 | 0.77 |
| **total DDD** | 1.87 | | 4.12 | |
| **NOAEL** | 14.5 | | 22 | |
| **TER** | 7.75 | | 5.33 | |
| **TERmix** | **3.22** | | | |

**Refined risk assessment (herbivorous mammals "vole" 20-39, Mulberry, Elderberry 1 x200 g a.s /ha, BBCH 15-89)**

| | FLU | | TFS | |
|---|---|---|---|---|
| **Food item** | Monocots | Dicots | Monocots | Dicots |
| **$DT_{50}$** | 2.6d | 3.18 d | 10 d | 3.35 d |
| **AR** | 0.2 | 0.2 | 0.2 | 0.2 |
| **FIR/bw** | 0.73 | 0.73 | 0.73 | 0.73 |
| **RUD** | 54.2 | 28.7 | 54.2 | 28.7 |
| **$f_{DEP}$** | 0.6 | 0.6 | 0.6 | 0.6 |
| **MAF** | 0.18 | 0.22 | 1 | 0.23 |
| **21-d $f_{TWA}$** | | | 0.53 | |
| **PT** | 1 | 1 | 1 | 1 |

| | | | | |
|---|---|---|---|---|
| **DDD** | 0.85 | 0.55 | 2.52 | 0.58 |
| **total DDD** | 1.4 | | 3.09 | |
| **NOAEL** | 14.5 | | 22 | |
| **TER** | 10.35 | | 7.12 | |
| **TERmix** | **4.34** | | | |

The $TER_{LT}$ values for both are above trigger of 5.
The $TER_{mix}$ values is below the trigger value of 5 indicating needs for further refinement for vole.

**Refined risk assessment (herbivorous mammals "vole"BBCH >40, Mulberry,Elderberry 1 x 200 g a.s./ha, BBCH 15-89)**

| | FLU | | TFS | |
|---|---|---|---|---|
| **Food item** | Monocots | Dicots | Monocots | Dicots |
| **$DT_{50}$** | 2.6d | 3.18 d | 10 d | 3.35 d |
| **AR** | 0.2 | 0.2 | 0.2 | 0.2 |
| **FIR/bw** | 0.73 | 0.73 | 0.73 | 0.73 |
| **RUD** | 54.2 | 28.7 | 54.2 | 28.7 |
| **$f_{DEP}$** | 0.3 | 0.3 | 0.3 | 0.3 |
| **MAF** | 0.18 | 0.22 | 1 | 0.23 |
| **21-d $f_{TWA}$** | | | 0.53 | |
| **PT** | 1 | 1 | 1 | 1 |
| **DDD** | 0.42 | 0.27 | 1.25 | 0.29 |
| **total DDD** | 0.7 | | 1.53 | |
| **NOAEL** | 14.5 | | 22 | |
| **TER** | 20.71 | | 14.37 | |
| **TERmix** | 8.54 | | | |

The $TER_{LT}$ values for both are above trigger of 5 for BBCH >10, BBCH>20 and BBCH>40.
The $TER_{mix}$ values is above the trigger value of 5 indicating an acceptable risk for vole only for BBCH >40.

**Risk for Frugivorous mammal "dormouse**

The combitox risk for Frugivorous mammal "dormouse" is remained unresolved.

**Risk for „Lagomorph''**

The combitox risk assessment for Lagomorph is provided below.

**Refined risk assessment (herbivorous mammals "lagomorph", mulberry 2x200 g a.s /ha, BBCH 15-89) – 7 d interval**

| | FLU | TFS |
|---|---|---|
| **Food item** | Non-grass herbs | Non-grass herbs |
| **$DT_{50}$** | 3.18 d | 3.35 d |
| **AR** | 0.2 | 0.2 |
| **FIR/bw** | 0.5 | 0.5 |
| **RUD** | 28.7 | 28.7 |
| **$f_{DEP}$** | 1 | 1 |

| | | |
|---|---|---|
| **MAF** | 0.42 | 0.44 |
| **21-d $f_{TWA}$** | | |
| **PT** | 1 | 1 |
| **DDD** | 1.2 | 1.26 |
| **NOAEL** | 14.5 | 22 |
| **TER** | 12.08 | 17.46 |
| **TERmix** | 7.69 | |

The $TER_{LT}$ values for both a.s. are above trigger of 5.
The $TER_{mix}$ value is above the trigger value of 5 indicating an acceptable risk for Lagomorph.

**Table 9.3-92: Combined toxicity assessment – mammals in flower bulbs (use group O)**

| Intended use | Flower bulbs | | | | |
|---|---|---|---|---|---|
| Active substances | Trifloxystrobin (TFS) + Fluopyram (FLU) | | | | |
| Application rate (L/ha) | 1 × 0.8 | | | | |
| Scenario / Generic focal species | **TER values** | | **1st step** | **2nd step** | **3rd step** |
| | **TFS** | **FLU** | **all TER ≥ trigger × n** | **$Rpf_{max}$** | **$TER_{MIX}$** |
| Acute / Small herbivorous mammal (Screening step) | >211 | >84.5 | Yes | Not needed | Not needed |
| Long-term / Small insectivorous mammal “shrew” | 49.4 | 32.6 | Yes | Not needed | Not needed |
| Long-term / Small herbivorous mammal "vole" | ~~12.8~~ [1] 7.14 * | 10.6 [2] 10.35 * | Yes | ~~Not needed~~ | ~~Not needed~~ 4.35* |
| Long-term / Small omnivorous mammal “mouse” | 26.6 | 17.5 | Yes | Not needed | Not needed |

~~Refined TER (please refer to Table 9.3-78)~~
~~[2] Refined TER (please refer to Table 9.3-79)~~
BBCH >40

**zRMS comment:**

**Group O**

zRMS verified the $TER_{LT}$ and $TER_{mix}$ values for vole for the worst case scenario for Group O 1 x 200 g a.s./ha for BBCH 12-91.
The $TER_{LT}$ values for both a.s. are above trigger of 5.
However, the $TER_{mix}$ for application dose 1 x 200 g a.s./ha is below trigger of 5 indicating needs for further refinement for vole.

**Table 9.3-93: Combined toxicity assessment – mammals in flower bulbs (use group P)**

| Intended use | Flower bulbs | | | | |
|---|---|---|---|---|---|
| Active substances | Trifloxystrobin (TFS) + Fluopyram (FLU) | | | | |
| Application rate (L/ha) | 5 × 0.3, 7 days interval | | | | |
| Scenario / Generic focal species | **TER values [1]** | | **1st step** | **2nd step** | **3rd step** |
| | **TFS** | **FLU** | **all TER ≥ trigger × n** | **$Rpf_{max}$** | **$TER_{MIX}$** |
| Acute / Small herbivorous mammal (Screening step) | >296 | >119 | Yes | Not needed | Not needed |
| Long-term / Small insectivorous mammal "shrew" | 54.9 | 36.2 | Yes | Not needed | Not needed |
| Long-term / Small herbivorous mammal "vole" | ~~5.31~~ 7.56** | ~~10.1~~ [2] 9.23** (3.50) | No | 0.60 (FLU) | ~~**3.5**~~ [3] **4.34**** |
| Long-term / Small omnivorous mammal "mouse" | 29.6 | 19.5 | 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
~~[2] Refined TER (please refer to Table 9.3-80)~~
~~[3] A refined TERmix is presented below (Table 9.3-112)~~

**zRMS comment:**

**Group P**

zRMS verified in the Table above the $TER_{LT}$ and $TER_{mix}$ values for vole for the worst case scenario for Group P for max application rate 5 x 0.075 g a.s./ha with 7 days interval.
The risk for vole needs further refinement.
Therefore, the risk was calculated by zRMS for reduced application rate to 2 x 0.075 g a.s./ha with 7 days interval, BBCH 19-91 for flower bulbs.

**Refined risk for vole BBCH>40 , Flower bulbs , 2 x 0.075 g a.s./ha with 7 day interval,**

| | FLU | | TFS | |
|---|---|---|---|---|
| | **BBCH>40** | | | |
| **Food item** | Monocots | Dicots | Monocots | Dicots |
| **$DT_{50}$** | 2.6 d | 3.18 d | 10 d | 3.35 d |
| **AR** | 0.075 | 0.075 | 0.075 | 0.075 |
| **FIR/bw** | 0.73 | 0.73 | 0.73 | 0.73 |
| **RUD** | 54.2 | 28.7 | 54.2 | 28.7 |
| **$f_{DEP}$** | 0.6 | 0.6 | 0.6 | 0.6 |
| **MAF** / **21-d $f_{TWA}$** | 0.35 | 0.42 | 1.6 x 0.53 | 0.44 |
| **PT** | 1 | 1 | 0.53 | 1 |
| **DDD** | 0.62 | 0.39 | 1.5 | 0.40 |
| **total DDD** | 1.01 | | 1.90 | |
| **NOAEL** | 14.5 | | 22 | |
| **TER** | 14.35 | | 11.57 | |
| **TERmix** | 6.25 | | | |

$TER_{LT}$ values for both a.s. and TERmix are above trigger of 5 indicating an acceptable risk for vole for BBCH>40 for max application rate for flower bulbs for 2 x 0.075 g a.s./ha with 7 day interval.

**Table 9.3-94: ~~Combined toxicity assessment – mammals in golf courses (use group Q)~~**

| | | | | | |
|---|---|---|---|---|---|
| ~~Intended use~~ | ~~Golf courses~~ | | | | |
| ~~Active substances~~ | ~~Trifloxystrobin (TFS) + Fluopyram (FLU)~~ | | | | |
| ~~Application rate (L/ha)~~ | ~~2 × 0.5, 14 days interval~~ | | | | |
| ~~Scenario / Generic focal species~~ | **~~TER values~~** [1] | | **~~1st step~~** | **~~2nd step~~** | **~~3rd step~~** |
| | **~~TFS~~** | **~~FLU~~** | **~~all TER ≥ trigger × n~~** | **~~$Rpf_{max}$~~** | **~~$TER_{MIX}$~~** |
| ~~Acute / Small herbivorous mammal (Screening step)~~ | ~~>244~~ | ~~>97.8~~ | ~~Yes~~ | ~~Not needed~~ | ~~Not needed~~ |
| ~~Long-term / Large herbivorous mammal "lagomorph"~~ | ~~13.7~~ | ~~9.04~~ | ~~No~~ | ~~0.60 (FLU)~~ | ~~5.4~~ |
| ~~Long-term / Small insectivorous mammal "shrew"~~ | ~~125~~ | ~~82.3~~ | ~~Yes~~ | ~~Not needed~~ | ~~Not needed~~ |
| ~~Long-term / Small herbivorous mammal "vole"~~ | ~~5.7~~ [2] ~~(3.28)~~ | **~~4.9~~** [3, 4] ~~(2.16)~~ | ~~No~~ | ~~0.60 (FLU)~~ | **~~2.6~~** [4] |

[1] ~~Differing TER values used for rpf calculations to fulfil the criterion of identical exposure levels are shown in brackets~~
[2] ~~Refined TER (please refer to Table 9.3-81)~~
[3] ~~Refined TER (please refer to Table 9.3-82)~~
[4] ~~Real risk to voles is not considered high on golf courses, please refer to text below Table 9.3-82~~

**Table 9.3-95: Combined toxicity assessment – mammals in hops (use group R)**

| Intended use | Hops | | | | |
|---|---|---|---|---|---|
| Active substances | Trifloxystrobin (TFS) + Fluopyram (FLU) | | | | |
| Application rate (L/ha) | 2 × 0.6, 14 days interval | | | | |
| Scenario / Generic focal species | **TER values** | | **1st step** | **2nd step** | **3rd step** |
| | **TFS** | **FLU** | **all TER ≥ trigger × n** | **$Rpf_{max}$** | **$TER_{MIX}$** |
| Acute / Small herbivorous mammal (Screening step) | >339 | >136 | Yes | Not needed | Not needed |
| Long-term / Small insectivorous mammal “shrew” | 104 | 68.6 | Yes | Not needed | Not needed |
| Long-term / Small herbivorous mammal "vole" | ~~9.11~~ 12.94 | ~~6.00~~ 15.26 | No | 0.60 (FLU) | **3.6** [1] 7.14 |
| Long-term / Small omnivorous mammal “mouse” | 50.7 | 33.4 | Yes | Not needed | Not needed |

~~[1] A refined TERmix is presented below (Table 9.3-115)~~
BBCH>40

**zRMS comments:**

**Group R**

zRMS verified the $TER_{LT}$ and $TER_{mix}$ values for vole for the worst case scenario for Group R for max application rate 2 x 150 g a.s./ha with 7 days interval and BBCH 37-91. The risk is considered as acceptable.

**zRMS comments:**

**Overllall conclusion for the risk assessment for <u>only renewed a.s.-TFS for vole .</u>**

The risk assessment for a.s.- TFS should be further refined for vole for the following scenarios:
- Group A, 2 x 200 g a.s/ha, 7 days interval
- Group B, 1 x 0.200 g a.s./ha, 2 x 150 g a.s/ha with 7-14 d interval, 1 x 200 g a.s./ha
- Group D, 2 x 200 g a.s./ha and BBCH 10-19 with 7 d and 14 d interval
- Group I, 2 x 200 g a.s./ha and BBCH 40-49, 2 x 150 g a.s./ha and BBCH 40-49
- Group J, 1 x200 g a.s./ha and BBCH 40-49
- Group K, 1 x 200 g a.s./ha and BBCH 10-29
- Group M, 2 x 200 g a.s./ha and 10-40 BBCH
- Group N, 2 x 150 g a.s./ha and 14 d interval, BBCH 10-19

**Overllall conclusion for the risk assessment for <u>only renewed a.s.-TFS for frugivorous mammals</u>**
The risk is considered as acceptable.
**Overllall conclusion for the risk assessment for <u>only renewed a.s.-TFS for lagomorph</u>**
The risk is considered as acceptable.

**Refined assessment of combined toxicity**

A refined risk assessment due to the combined toxicity assessment is needed for the following scenarios:
- large herbivorous mammal "lagomorph" in leafy vegetables (use group A), strawberries, blueberries and cranberries (use group F), elderberry and mulberry (use group M),
- small herbivorous mammal "vole" in beans and peas (use group C), celeriac (use group L), flower bulbs (use group P) and hops (use group R) and
- frugivorous mammal "dormouse" in elderberry and mulberry (use group M).

**Leafy vegetables (use group A)**

Large herbivorous mammal "lagomorph"

According to Appendix A of EFSA/2009/1438, lagomorph species in leafy vegetables feed exclusively on non-grass herbs. Thus, MAF and TWA values were recalculated using the measured $DT_{50}$ values in dicotyledonous leaves of 3.35 days for trifloxystrobin and 3.05 days for fluopyram.

**Table 9.3-96: Higher-tier assessment of the long-term/reproductive risk for large herbivorous mammals for trifloxystrobin due to the use of FLU + TFS SC 500 in leafy vegetables (use group A) – refined parameters (*) are further described and justified in the text**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Leafy vegetables | | | | |
| **Active substance/product** | Trifloxystrobin | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 22 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg b w/d)** | **$TER_{lt}$** |
| Leafy vegetables All season | Large herbivorous mammal "lagomorph" | 14.3 | 1.23 × 0.36 [a)] * | 1.27 | 17.4 |

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.
[a)] With $DT_{50}$ of 3.35 d, 2 applications with 7 d interval (Table 9.3-59)

**Table 9.3-97: Higher-tier assessment of the long-term/reproductive risk for large herbivorous mammals for fluopyram due to the use of FLU + TFS SC 500 in leafy vegetables (use group A) – refined parameters (*) are further described and justified in the text**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Leafy vegetables | | | | |
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 14.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Leafy vegetables All season | Large herbivorous mammal "lagomorph" | 14.3 | 1.20 × 0.34 [a)] * | 1.17 | 12.4 |

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.
[a)] With $DT_{50}$ of 3.05 d, 2 applications with 7 d interval (Table 9.2-57)

Refined combined toxicity assessment

**Table 9.3-98: Refined combined toxicity assessment– mammals in leafy vegetables (use group A)**

| Generic focal species | TER values | | $TER_{MIX}$ refined |
|---|---|---|---|
| | Trifloxystrobin | Fluopyram | |
| **Long-term** | | | |
| Large herbivorous mammal "lagomorph" | 17.4 [1] | 12.4 [2] | 7.2 |

[1] Refined TER (please refer to Table 9.3-96)
[2] Refined TER (please refer to Table 9.3-102)

**Beans and peas (use group C)**

Small herbivorous mammal "vole"

As the TER value for fluopyram used for the combined toxicity assessment is the result of a refined risk assessment, the TER for trifloxystrobin was recalculated in the following table according to the refined risk assessment for voles in beans and peas (use group C). Additionally, a deposition factor of 30% is considered according to the Tier 1 risk assessment for voles in pulses (please refer to the refined risk assessment for voles following exposure to fluopyram).

**Table 9.3-99: Higher-tier assessment of the long-term/reproductive risk for small herbivorous mammals for trifloxystrobin due to the use of FLU + TFS SC 500 in beans and peas (use group C) – refined parameters (*) are further described and justified in the text**

| Feed item | AR (kg/ha) | FIR/bw | RUD × Deposition factor | MAF | 21-d TWA | DDD | NOAEL (mg/kg bw/d) | TER |
|---|---|---|---|---|---|---|---|---|
| 50% monocots | 0.200 | 0.73 | 54.2 × 0.3 | 1.26 [a)] * | 0.37 [a)] * | 1.115 | | |
| 50% dicots | 0.200 | 0.73 | 28.7 × 0.3 | 1.23 [b)] * | 0.36 [b)] * | 0.560 | | |
| Total diet | | | | | | Σ = 1.68 | 22 | 13.1 |

[a)] With $DT_{50}$ of 3.56 d, 2 applications with 7 d interval (**Table 9.3-58**)
[b)] With $DT_{50}$ of 3.35 d, 2 applications with 7 d interval (**Table 9.3-59**)

Refined combined toxicity assessment

**Table 9.3-100: Refined combined toxicity assessment– mammals in beans and peas (use group C)**

| Generic focal species | TER values | | $TER_{MIX}$ refined |
|---|---|---|---|
| | Trifloxystrobin | Fluopyram | |
| **Long-term** | | | |
| Small herbivorous mammal "vole" | ~~13.1~~ [1] | 10.7 [2] | 5.9** |

[1] Refined TER (please refer to Table 9.3-99)
[2] Refined TER (please refer to Table 9.3-62)

**Strawberries, blueberries and cranberries (use group F)**

Large herbivorous mammal "lagomorph"

According to Appendix A of EFSA/2009/1438, lagomorph species in strawberries feed exclusively on non-grass herbs. Thus, MAF and TWA values were recalculated using the measured $DT_{50}$ values in dicotyledonous leaves of 3.35 days for trifloxystrobin and 3.05 days for fluopyram.

**Table 9.3-101: Higher-tier assessment of the long-term/reproductive risk for large herbivorous mammals for trifloxystrobin due to the use of FLU + TFS SC 500 in strawberry, blueberry and cranberry (use group F) – refined parameters (*) are further described and justified in the text**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Strawberry, blueberry, cranberry | | | | |
| **Active substance/product** | Trifloxystrobin | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 22 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | $SV_m$ | $MAF_m$ × TWA | $DDD_m$ (mg/kg bw/d) | $TER_{lt}$ |
| Strawberries BBCH 10-39 | Large herbivorous mammal "lagomorph" | 14.3 | 1.23 × 0.36 a) * | 1.27 | 17.4 |

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.
a) With $DT_{50}$ of 3.35 d, 2 applications with 7 d interval (Table 9.3-59)

**Table 9.3-102: Higher-tier assessment of the long-term/reproductive risk for large herbivorous mammals for fluopyram due to the use of FLU + TFS SC 500 in strawberry, blueberry and cranberry (use group F) – refined parameters (*) are further described and justified in the text**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Strawberry, blueberry, cranberry | | | | |
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 14.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | $SV_m$ | $MAF_m$ × TWA | $DDD_m$ (mg/kg bw/d) | $TER_{lt}$ |
| Strawberries BBCH 10-39 | Large herbivorous mammal "lagomorph" | 14.3 | 1.20 × 0.34 a) * | 1.17 | 12.4 |

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.
a) With $DT_{50}$ of 3.05 d, 2 applications with 7 d interval (Table 9.2-57)

<u>Refined combined toxicity assessment</u>

**Table 9.3-103: Refined combined toxicity assessment– mammals in strawberry, blueberry and cranberry (use group F)**

| Generic focal species | TER values | | $TER_{MIX}$ refined |
|---|---|---|---|
| | **Trifloxystrobin** | **Fluopyram** | |
| **Long-term** | | | |
| Large herbivorous mammal "lagomorph" | 17.4 [1] | 12.4 [2**] | ~~7.2~~** |

[1] Refined TER (please refer to Table 9.3-101)
[2] Refined TER (please refer to Table 9.3-102)

**Celeriac (use group L)**

<u>Small herbivorous mammal "vole"</u>
The refined risk assessment for trifloxystrobin and fluopyram is done with the same refined parameter as for voles in beans and peas (use group C), i.e. the refined exposure assessment is based on a mixed diet (50% monocotyledonous and 50% dicotyledonous plants), with $DT_{50}$ values available for both fluopyram and trifloxystrobin on both monocots and dicots.
Additionally, crop interception in root and stem vegetables at BBCH ≥ 40 is 70% according to the FOCUS groundwater report (Table 2 in Appendix E of EFSA/2009/1438). Thus, according to the Tier 1 risk assessment a deposition of 30% is also considered in the refined risk assessment for voles in root and stem vegetables.

**Table 9.3-104: Higher-tier assessment of the long-term/reproductive risk for small herbivorous mammals for <u>trifloxystrobin</u> due to the use of FLU + TFS SC 500 in celeriac (use group L) – refined parameters (*) are further described and justified in the text**

| Feed item | AR (kg/ha) | FIR/bw | RUD × Deposition factor | MAF | 21-d TWA | DDD | NOAEL (mg/kg bw/d) | TER |
|---|---|---|---|---|---|---|---|---|
| 50% monocots | 0.125 | 0.73 | 54.2 × 0.3 | 1.07 [a)] * | 0.40 [a)] * | 0.628 | | |
| 50% dicots | 0.125 | 0.73 | 28.7 × 0.3 | 1.06 [b)] * | 0.38 [b)] * | 0.317 | | |
| Total diet | | | | | | Σ = 0.945 | 22 | 23.3 |

[a)] With $DT_{50}$ of 3.56 d, 2 applications with 14 d interval (Table 9.3-58)
[b)] With $DT_{50}$ of 3.35 d, 2 applications with 14 d interval (Table 9.3-59)

**Table 9.3-105: Higher-tier assessment of the long-term/reproductive risk for small herbivorous mammals for <u>fluopyram</u> due to the use of FLU + TFS SC 500 in celeriac (use group L) – refined parameters (*) are further desFhopscribed and justified in the text**

| Feed item | AR (kg/ha) | FIR/bw | RUD × Deposition factor | MAF | 21-d TWA | DDD | NOAEL (mg/kg bw/d) | TER |
|---|---|---|---|---|---|---|---|---|
| 50% monocots | 0.125 | 0.73 | 54.2 × 0.3 | 1.02 [a)] * | 0.32 [a)] * | 0.489 | | |
| 50% dicots | 0.125 | 0.73 | 28.7 × 0.3 | 1.04 [b)] * | 0.36 [b)] * | 0.295 | | |
| Total diet | | | | | | Σ = 0.783 | 14.5 | 18.5 |

[a)] With $DT_{50}$ of 2.6 d, 2 applications with 14 d interval (Table 9.2-58)
[b)] With $DT_{50}$ of 3.05 d, 2 applications with 14 d interval (Table 9.2-57)

Refined combined toxicity assessment

**Table 9.3-106: Refined combined toxicity assessment– mammals in celeriac (use group L)**

| | TER values | | $TER_{MIX}$ refined |
|---|---|---|---|
| **Generic focal species** | **Trifloxystrobin** | **Fluopyram** | |
| **Long-term** | | | |
| Small herbivorous mammal "vole" | 23.3 [1] | 18.5 [2] | 10.3 |

[1] Refined TER (please refer to Table 9.3-104)
[2] Refined TER (please refer to Table 9.3-105)

**Elderberry & mulberry (use group M)**

Frugivorous mammal "dormouse"
As the TER value for fluopyram used for the combined toxicity assessment is the result of a refined risk assessment, the TER for trifloxystrobin was recalculated in the following table according to the refined risk assessment for frugivorous mammals following exposure to fluopyram. The RUD of 5.0 (Hahne, J.; Schabacker, J.; Foudoulakis, M.; Ludwigs, J. D.; Murfitt, R.; Ristau, K.; 2019; M-665829-01-1, Appendix 2) for "berries" is used for the refinement for a dormouse eating on 100% fruits and a FIR/bw of 1.16.

**Table 9.3-107: Higher-tier assessment of the long-term/reproductive risk for frugivorous mammals for trifloxystrobin due to the use of FLU + TFS SC 500 in elderberry and mulberry (use group M) – refined parameters (*) are further described and justified in the text**

| | | | | | | |
|---|---|---|---|---|---|---|
| **Intended use** | Elderberry, mulberry | | | | | |
| **Active substance/product** | Trifloxystrobin | | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | ~~22~~ | | | | | |
| **TER criterion** | 5 | | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **FIR/bw** | **Mean RUD** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Orchards Fruit stage BBCH 71-79 currants | Frugivorous mammal "dormouse" | 1.16 | 5.0 * | 1.6 × 0.53 | 0.984 | 22.4 |

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.

Large herbivorous mammal "lagomorph"
According to Appendix A of EFSA/2009/1438, lagomorph species in orchards feed exclusively on non-grass herbs. Thus, MAF and TWA values were recalculated using the measured $DT_{50}$ values in dicotyledonous leaves of 3.35 days for trifloxystrobin and 3.05 days for fluopyram.

**Table 9.3-108: Higher-tier assessment of the long-term/reproductive risk for large herbivorous mammals for trifloxystrobin due to the use of FLU + TFS SC 500 in elderberry and mulberry (use group M) – refined parameters (*) are further described and justified in the text**

| **Intended use** | Elderberry, mulberry | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | Trifloxystrobin | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 22 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Orchards Application crop directed BBCH 10-19 | Large herbivorous mammal "lagomorph" | 11.5 | 1.23 × 0.36 a) * | 1.02 | 21.6 |

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.
a) With $DT_{50}$ of 3.35 d, 2 applications with 7 d interval (Table 9.3-59)

**Table 9.3-109: Higher-tier assessment of the long-term/reproductive risk for large herbivorous mammals for fluopyram due to the use of FLU + TFS SC 500 in elderberry and mulberry (use group M) – refined parameters (*) are further described and justified in the text**

| **Intended use** | Elderberry, mulberry | | | | |
|---|---|---|---|---|---|
| **Active substance/product** | Fluopyram | | | | |
| **Application rate (kg/ha)** | 2 × 0.2, 7 days interval | | | | |
| **Reprod. toxicity (mg/kg bw/d)** | 14.5 | | | | |
| **TER criterion** | 5 | | | | |
| **Crop scenario Growth stage** | **Generic focal species** | **$SV_m$** | **$MAF_m$ × TWA** | **$DDD_m$ (mg/kg bw/d)** | **$TER_{lt}$** |
| Orchards Application crop directed BBCH 10-19 | Large herbivorous mammal "lagomorph" | 11.5 | 1.20 × 0.34 a) * | 0.938 | 15.5 |

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.
a) With $DT_{50}$ of 3.05 d, 2 applications with 7 d interval (Table 9.2-57)

Refined combined toxicity assessment

**Table 9.3-110: Refined combined toxicity assessment– mammals in elderberry and mulberry (use group M)**

| | **TER values** | | **$TER_{MIX}$ refined** |
|---|---|---|---|
| **Generic focal species** | **Trifloxystrobin** | **Fluopyram** | |
| **Long-term** | | | |

| | | | |
|---|---|---|---|
| Frugivorous mammal "dormouse" | 22.4 [1] | 14.7 [3] | 8.9 |
| Large herbivorous mammal "lagomorph" | 21.6 [2] | 15.5 [4] | 9.0 |

[1] Refined TER (please refer to Table 9.3-107)
[2] Refined TER (please refer toTable 9.3-108)
[3] Refined TER (please refer to Table 9.3-77)
[4] Refined TER (please refer to Table 9.3-109)

**Flower bulbs (use group P)**

Small herbivorous mammal "vole"

As the TER value for fluopyram used for the combined toxicity assessment is the result of a refined risk assessment, the TER for trifloxystrobin was recalculated in the following table according to the refined risk assessment for voles in beans and peas (use group C). Additionally, a deposition factor of 60% is considered according to the Tier 1 risk assessment for voles in flower bulbs (please refer to the refined risk assessment for voles following exposure to fluopyram).

**Table 9.3-111: Higher-tier assessment of the long-term/reproductive risk for small herbivorous mammals for trifloxystrobin due to the use of FLU + TFS SC 500 in flower bulbs (use group P) – refined parameters (*) are further described and justified in the text**

| Feed item | AR (kg/ha) | FIR/bw | RUD × Deposition factor | MAF | 21-d TWA | DDD | NOAEL (mg/kg bw/d) | TER |
|---|---|---|---|---|---|---|---|---|
| 50% monocots | 0.075 | 0.73 | 54.2 × 0.6 | 1.34 [a)] * | 0.54 [a)] * | 1.161 | | |
| 50% dicots | 0.075 | 0.73 | 28.7 × 0.6 | 1.31 [b)] * | 0.53 [b)] * | 0.586 | | |
| Total diet | | | | | | Σ = 1.75 | 22 | 12.6 |

[a)] With $DT_{50}$ of 3.56 d, 5 applications with 7 d interval (Table 9.3-58)
[b)] With $DT_{50}$ of 3.35 d, 5 applications with 7 d interval (Table 9.3-59)

Refined combined toxicity assessment

**Table 9.3-112: Refined combined toxicity assessment– mammals in flower bulbs (use group P)**

| | TER values | | |
|---|---|---|---|
| Generic focal species | Trifloxystrobin | Fluopyram | $TER_{MIX}$ refined |
| **Long-term** | | | |
| Small herbivorous mammal "vole" | 12.6 [1] | 10.1 [2] | ~~5.6~~ |

[1] Refined TER (please refer to Table 9.3-111)
[2] Refined TER (please refer to Table 9.3-80)

**Hops (use group R)**

Small herbivorous mammal "vole"

The refined risk assessment for trifloxystrobin and fluopyram is done with the same refined parameter as for voles in beans and peas (use group C), i.e. the refined exposure assessment is based on a mixed diet (50% monocotyledonous and 50% dicotyledonous plants), with $DT_{50}$ values available for both fluopyram and trifloxystrobin on both monocots and dicots.

Additionally, crop interception in hops at BBCH ≥ 40 is 70% according to the FOCUS groundwater report (Table 2 in Appendix E of EFSA/2009/1438). Thus, according to the Tier 1 risk assessment a deposition of 30% is also considered in the refined risk assessment for voles in hops.

**Table 9.3-113: Higher-tier assessment of the long-term/reproductive risk for small herbivorous mammals for trifloxystrobin due to the use of FLU + TFS SC 500 in hops (use group R) – refined parameters (*) are further described and justified in the text**

| Feed item | AR (kg/ha) | FIR/bw | RUD × Deposition factor | MAF | 21-d TWA | DDD | NOAEL (mg/kg bw/d) | TER |
|---|---|---|---|---|---|---|---|---|
| 50% monocots | 0.150 | 0.73 | 54.2 × 0.3 | 1.07 a) * | 0.40 a) * | 0.753 | | |
| 50% dicots | 0.150 | 0.73 | 28.7 × 0.3 | 1.06 b) * | 0.38 b) * | 0.381 | | |
| Total diet | | | | | | Σ = 1.13 | 22 | 19.4 |

a) With $DT_{50}$ of 3.56 d, 2 applications with 14 d interval (Table 9.3-58)
b) With $DT_{50}$ of 3.35 d, 2 applications with 14 d interval (Table 9.3-59)

**Table 9.3-114: Higher-tier assessment of the long-term/reproductive risk for small herbivorous mammals for fluopyram due to the use of FLU + TFS SC 500 in hops (use group R) – refined parameters (*) are further described and justified in the text**

| Feed item | AR (kg/ha) | FIR/bw | RUD × Deposition factor | MAF | 21-d TWA | DDD | NOAEL (mg/kg bw/d) | TER |
|---|---|---|---|---|---|---|---|---|
| 50% monocots | 0.150 | 0.73 | 54.2 × 0.3 | 1.02 a) * | 0.32 a) * | 0.586 | | |
| 50% dicots | 0.150 | 0.73 | 28.7 × 0.3 | 1.04 b) * | 0.36 b) * | 0.354 | | |
| Total diet | | | | | | Σ = 0.94 | 14.5 | 15.4 |

a) With $DT_{50}$ of 2.6 d, 2 applications with 14 d interval (Table 9.2-58)
b) With $DT_{50}$ of 3.05 d, 2 applications with 14 d interval (Table 9.2-57)

Refined combined toxicity assessment

**Table 9.3-115: Refined combined toxicity assessment– mammals in hops (use group R)**

| | TER values | | $TER_{MIX}$ refined |
|---|---|---|---|
| Generic focal species | Trifloxystrobin | Fluopyram | |
| Long-term | | | |
| Small herbivorous mammal "vole" | 19.4 [1] | 15.4 [2] | 8.6 |

[1] Refined TER (please refer to Table 9.3-113)
[1] Refined TER (please refer to Table 9.3-114)

The risk assessment for voles does not provide for a $TER_{MIX}$ of 5for some use groups. The following table summarises the outcome of the combined toxicity assessment.

**Table 9.3-116: Overview of relevant generic focal species per use group with respect to the outcome of the combined toxicity assessment**

| Use group / Use rate | Small herbivorous mammal "vole" | Large herbivorous mammal "lagomorph" | Small insectivorous mammal "shrew" | Small omnivorous mammal "mouse" | Frugivorous mammal "dormouse" |
|---|---|---|---|---|---|
| Leafy vegetables (use group A)<br>2 × 0.8 L product/ha, 7 days interval | ~~$TER_{MIX}$ = **2.2** [1, 21]~~<br>TERmix =**1.50** | ~~$TER_{MIX}$ = 7.2 [2]~~<br>$TER_{mix}$= 5.2 | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [1] | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [1] | - |
| Leafy vegetables (use group B)<br>1 × 0.8 L product/ha | Risk envelope: covered with use group A<br>~~$TER_{MIX}$ = **3.7**~~<br>TERmix = **2.70** | Risk envelope: covered with use group A | Risk envelope: covered with use group A | Risk envelope: covered with use group A | - |
| Beans, peans (use group C)<br>2 × 0.8 L product/ha, 7 days interval | ~~$TER_{MIX}$ = 5.9 [3]~~<br>TERmix = 5 | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [4] | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [4] | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [4] | - |
| Berries (use group D)<br>2 × 0.8 L product/ha, 7 days interval | ~~$TER_{MIX}$ = **3.0** [5]~~<br><br>TERmix=**2.5** (BBCH 10-19)<br>TERmix=**2.94** (BBCH 20-39)<br><br>TERmix= 4.78 (BBCH>40) (risk acceptable by zRMS) | - | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [5] | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [5] | $TER_{MIX}$ = 5.3 [5] |
| Berries (use group E)<br>2 × 0.6 L product/ha | Risk envelope: covered with use group D<br>~~$TER_{MIX}$ = **4.0**~~<br>TERmix = **4.16** (BBCH 10-19)<br><br>TERmix= 6.25 **(BBCH>20)** | Risk envelope: covered with use group D | Risk envelope: covered with use group D | Risk envelope: covered with use group D | Risk envelope: covered with use group D |
| Strawberries, blueberries, cranberries (use group F)<br>2 × 0.8 L product/ha, 7 days interval | ~~$TER_{MIX}$ = **4.4** [6, 22]~~<br>TERmix =**3.70** (BBCH>40)<br><br>TERmix=6.6 ( 1 x 200 g a.s./ha) | $TER_{MIX}$ = 7.2 [7]<br>TERmix = 7.69 | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [6] | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [6] | - |

| **Use group / Use rate** | **Small herbivorous mammal "vole"** | **Large herbivorous mammal "lagomorph"** | **Small insectivorous mammal "shrew"** | **Small omnivorous mammal "mouse"** | **Frugivorous mammal "dormouse"** |
|---|---|---|---|---|---|
| Blueberries, cranberries (use group G) 2 × 0.6 L product/ha, 7 days interval | Risk envelope: covered with use group F, 7 days interval ~~$TER_{MIX}$ = 6.3~~ $TER_{mix}$=6.25 | Risk envelope: covered with use group F, 7 days interval | Risk envelope: covered with use group F, 7 days interval | Risk envelope: covered with use group F, 7 days interval | - |
| Grapes (use group H) 2 × 0.2 L product/ha, 14 days interval | $TER_{MIX}$ = 5.4 [8] | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [8] | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [8] | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [8] | - |
| Nurseries, rosehip (use group I) 2 × 0.8 L product/ha, 7 days interval | ~~$TER_{MIX}$ = **1.8** [9]~~ $TER_{mix}$ =**1.42** **(BBCH<50,** 40-49) $TER_{mix}$= 4.76 (BBCH>50) (risk acceptable by zRMS) | - | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [9] | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [9] | - |
| Nurseries, rosehip (use group J) 1 × 0.8 L product/ha | Risk envelope: covered with use group I ~~$TER_{MIX}$ = **3.5**~~ $TER_{mix}$=**2.94** **(**BBCH<50, 40-49) $TER_{mix}$=8.47 (BBCH>50) | - | Risk envelope: covered with use group I | Risk envelope: covered with use group I | - |
| Tobacco (use group K) 1 × 0.8 L product/ha | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [10] $TER_{mix}$=**2.32** (BBCH<30, 10-29 ) $TER_{mix}$=5.10 (BBCH>30) (risk acceptable by zRMS) | - | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [10] | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [10] | - |
| Celeriac (use group L) 2 × 0.5 L product/ha, 14 days interval | ~~$TER_{MIX}$ = 10.3 [11]~~ $TER_{mix}$=4.90 ( risk acceptable by zRMS) | - | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [12] | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [12] | - |
| Elderberry, mulberry (use group M) 2 × 0.8 L product/ha, 7 days | ~~$TER_{MIX}$ = **2.2** [13]~~ $TER_{mix}$= **1.81** (BBCH>10) TERmix= **2.5** | $TER_{MIX}$ = 9.0 [14] TERmix = 7.69 | - | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [13] | ~~$TER_{MIX}$ = 8.9 [14]~~ Risk needs further refinement |

| **Use group / Use rate** | **Small herbivorous mammal "vole"** | **Large herbivorous mammal "lagomorph"** | **Small insectivorous mammal "shrew"** | **Small omnivorous mammal "mouse"** | **Frugivorous mammal "dormouse"** |
|---|---|---|---|---|---|
| interval | (BBCH>20)<br><br>$TER_{mix}$= 4.78 (BBCH>40)<br>(risk acceptable by zRMS) | | | | |
| Elderberry, mulberry (use group N)<br>2 × 0.6 L product/ha, 7 days interval | Risk envelope: covered with use group M<br>~~$TER_{MIX}$ = **3.0**~~<br><br>$TER_{mix}$= **2.70** (BBCH>10)<br><br>TERmix= **3.57** (BBCH>20)<br><br>TERmix= 7.14 (BBCH>40) | Risk envelope: covered with use group M | - | Risk envelope: covered with use group M | Risk envelope: covered with use group M<br>Risk needs further refinement |
| Flower bulbs (use group O)<br>1 × 0.8 L product/ha | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [15]<br>TERmix= 4.35 | - | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [15] | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [15] | - |
| Flower bulbs (use group P)<br>5 × 0.3 L product/ha, 7 days interval | ~~$TER_{MIX}$ = 5.6 [16]~~<br>$TER_{mix}$= 4.34 (5 x 0.3L/ha)<br>$TER_{mix}$=6.25 ( 2 x 0.3 L/ha) | - | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [17] | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [17] | - |
| ~~Golf courses (use group Q) 2 × 0.5 L product/ha, 14 days interval~~ | ~~$TER_{MIX}$ = **2.6** [18, 23]~~ | ~~$TER_{MIX}$ = 5.4 [18]~~ | ~~$TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [18]~~ | - | - |
| Hops (use group R)<br>2 × 0.6 L product/ha,<br>14 days interval | ~~$TER_{MIX}$ = 8.6 [19]~~<br>$TER_{mix}$ =7.14 | - | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [20] | $TER_{LT}$ for both a.s. > 10, i.e. $TER_{MIX}$ > 5 [20] | - |

[1] Please refer to Table 9.3-83; [2] Please refer to Table 9.3-98; [3] Please refer to Table 9.3-100;
[4] Please refer to Table 9.3-84; [5] Please refer to Table 9.3-85; [6] Please refer to Table 9.3-86;
[7] Please refer to Table 9.3-103; [8] Please refer to Table 9.3-87; [9] Please refer to Table 9.3-88;
[10] Please refer to Table 9.3-89; [11] Please refer to Table 9.3-106; [12] Please refer to * BBCH<30
** BBCH>30

**zRMS comments:**

zRMS verified in the Table above the $TER_{LT}$ and $TER_{mix}$ values for vole for the worst case scenario for Group K - 1 x 200 g a.s./ha and BBCH 11-39.

TERmix values for vole BBCH< 30 ( BBCH10-29) are below triger of 5 indicating needs for further refinement.
However, when DF of 0.5. for BBCH> 30 is used the the TERmix is above to trigger value of 5 and

| |
|---|
| the risk is considered as acceptable. |

Table 9.3-90;
[13] Please refer to Table 9.3-91; [14] Please refer to Table 9.3-110; [15] Please refer to Table 9.3-92;
[16] Please refer to Table 9.3-112; [17] Please refer to Table 9.3-93; [18] Please refer to Table 9.3-94;
[19] Please refer to Table 9.3-115; [20] Please refer to Table 9.3-95;
[21] Real risk to voles is not considered high in leafy vegetables, please refer to Figure 1 and associated text
[22] Real risk to voles is not considered high in strawberries, blueberries and cranberries, please refer to text below Table 9.3-66
[23] ~~Real risk to voles is not considered high on golf courses, please refer to text below Table 9.3-82~~

**zRMS comment:**

The above Table 9.3-13, including the overview of relevant generic focal species per use group with respect to the outcome of the combined toxicity assessment.
Further refinement of combitox risk assessment for species -vole should be decided by MSs at their national level.
It should be noted that $TER_{mix}$ values for voles exposed after application of the product in some of groups Group D, (BBCH >40), Group I (BBCH >50), Group M (BBCH>40), Group L are slightly below the trigger of 5 indicating potential unacceptable risk.
It should be, however, noted that in presented risk refinement PD, MAF and $f_{TWA}$ values were refined, and remaining parameter like PT was default, worst case parameter, as defined in EFSA (2009).
Moreover, it is not probable that voles will obtain 100% of their diet from the treated field and will also utilize adjacent fields and off-crop habitats. Refinement of PT parameter would result with acceptable risk and for this reason in this particular case on the basis of weight-of-evidence approach the risk is considered as sufficiently addressed.
In addition, it should be noted that the max. number of applications is 2.
Therefore, it is not probable that two applications will be done at the highest stage of BBCH indicated in the GAP for these groups.
In addition, the default value of $DT_{50}$ for TFS for monocot plants was considered as the worst case approach.
The combitox risk assessment for frugivorous mammals is still unresolved for Groups M ,N.

### 9.3.2.3 Drinking water exposure

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

**Puddle scenario**

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

With a K(f)oc of 2287, trifloxystrobin belongs to the group of more sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for leafy vegetables (use group A) also covers the risk for mammals from all other intended uses (see 9.1.2).

Trifloxystrobin

| | | | |
|---|---|---|---|
| Effective application rate (g/ha) = | 200[1] | | |
| Acute toxicity (mg/kg bw) = | > 5000 | quotient = | < 0.04 |

| | | | |
|---|---|---|---|
| Reprod. toxicity (mg/kg bw/d) = | 22 | quotient = | 9.09 |

[1] AR × $MAF_m$ = 200 g/ha × 1 = 200 g/ha; $MAF_m$ based on $DT_{50, soil}$ = 0.52 d and 2 applications with a 7 day interval

**zRMS comments:**

We agree that since the ratio of the total annual application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed the relevant critical value for at least one use scenario, a quantitative risk assessment (calculation of TER values) is not necessary.

### 9.3.2.4 Effects of secondary poisoning

Risk assessments for effects due to secondary poisoning are provided below for the substance(s) with a log $P_{ow}$ which exceeds the trigger value of 3 (refer to 9.2.2.4).

**Trifloxystrobin**
The log $P_{ow}$ of trifloxystrobin was determined to be 4.5 thereby triggering an assessment for the potential risk through secondary poisoning (EFSA/2009/1438). For the metabolites, only those with a log $P_{OW}$ > 3 and relevant to the media have been considered, in accordance with EFSA/2009/1438.

**Table 9.3-117: Log $P_{OW}$ values for trifloxystrobin and all relevant metabolites**

| Substance | log $P_{OW}$ | Trigger value | Risk assessment required? | Compartment |
|---|---|---|---|---|
| Trifloxystrobin | 4.5 * | 3 | yes | Soil, surface water |
| CGA 357261 | 3.86 (pH 7) | | yes | Soil, surface water |
| CGA 357262 | 5.39 (pH 7) | | yes | Surface water |
| CGA 357276 | 4.7 * | | yes | Soil, surface water |
| NOA 409480 | 4.2 * | | yes | Soil, surface water |

* No pH dependency

**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, resulting in FIR/bw = 1.28. 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 use in lettuce and rocket salad (use group S) (see 9.1.2) also covers the risk for mammals from all other intended uses for trifloxystrobin and its metabolites CGA 357261 and NOA 409480. For the metabolite CGA 357276, the assessment for use in flower bulbs (use group U) (see 9.1.2) also covers the risk for mammals from all other intended uses.

**Table 9.3-118: Assessment of the risk for earthworm-eating mammals due to exposure to trifloxystrobin via bioaccumulation in earthworms (secondary poisoning) for the intended use in lettuce and rocket salad (use group S) (2 x 200 g a.s./ha; 7 day interval)**

| Parameter | Trifloxystrobin | comments |
|---|---|---|
| PECsoil (twa = 21 d) (mg/kg soil) | 0.121 | Maximum $PEC_{soil}$ (twa = 21 d) value resulting from PECsoil, plateau (< 0.001 mg/kg, 20 cm mixing depth) and the maximum 21d-TWAsoil value (0.121 mg/kg, multiple application in FOCUS crop cabbage) (see Part B8, chapter 8.7.2) |
| log Pow / Pow | 4.5 / 32000 | |
| Koc | 2287 | Mean (n = 6) |
| foc | 0.02 | Default |
| BCFworm | 8.4 | BCFworm/soil = (PECworm,ww/PECsoil,dw)<br>= (0.84 + 0.012 × Pow) / foc × Koc |
| PECworm | 1.02 | PECworm = PECsoil × BCFworm/soil |
| Daily dietary dose (mg/kg bw/d) | 1.30 | DDD = PECworm × 1.28 |
| $BMDL_5$ (mg/kg bw/d) | 22.0 | |
| TERlt | 16.9 | |

TER values shown in bold fall below the relevant trigger.

**Table 9.3-119: Assessment of the risk for earthworm-eating mammals due to exposure to trifloxystrobin metabolite CGA 357261 via bioaccumulation in earthworms (secondary poisoning) for the intended use in lettuce and rocket salad (use group S) (2 x 200 g a.s./ha; 7 day interval)**

| Parameter | CGA 357261 | comments |
|---|---|---|
| PECsoil (twa = 21 d) (mg/kg soil) | 0.008 | Maximum PECsoil (twa = 21 d) value resulting from PECsoil, plateau (< 0.001 mg/kg, 20 cm mixing depth) and the maximum 21d-TWAsoil value (0.008 mg/kg, multiple application in FOCUS crop cabbage) (see Part B8, chapter 8.7.2) |
| log Pow / Pow | 3.86 / 7190 | |
| Koc | 487 | Mean (n = 6) |
| foc | 0.02 | Default |
| BCFworm | 8.9 | BCFworm/soil = (PECworm,ww/PECsoil,dw)<br>= (0.84 + 0.012 × Pow) / foc × Koc |
| PECworm | 0.07 | PECworm = PECsoil × BCFworm/soil |
| Daily dietary dose (mg/kg bw/d) | 0.09 | DDD = PECworm × 1.28 |
| NOEL (mg/kg bw/d) | 2.2 | NOEL/10 of parent endpoint trifloxystrobin |
| TERlt | 24.0 | |

TER values shown in bold fall below the relevant trigger.

**Table 9.3-120: Assessment of the risk for earthworm-eating mammals due to exposure to trifloxystrobin metabolite CGA 357276 via bioaccumulation in earthworms (secondary poisoning) for the intended use in flower bulbs (use group U) (5 x 75 g a.s./ha; 7 day interval)**

| Parameter | CGA 357276 | comments |
|---|---|---|
| PECsoil (twa = 21 d) (mg/kg soil) | 0.016 | Maximum PECsoil (twa = 21 d) value resulting from PECsoil, plateau (< 0.001 mg/kg, 20 cm mixing depth) and the maximum 21d-TWAsoil value (0.016 mg/kg, multiple application in FOCUS crop onions) (see Part B8, chapter 8.7.2) |
| log Pow / Pow | 4.7 / 50000 | |
| Koc | 8170 | Mean (n = 6) |
| foc | 0.02 | Default |
| BCFworm | 3.7 | BCFworm/soil = (PECworm,ww/PECsoil,dw)<br>= (0.84 + 0.012 × Pow) / foc × Koc |
| PECworm | 0.06 | PECworm = PECsoil × BCFworm/soil |
| Daily dietary dose (mg/kg bw/d) | 0.08 | DDD = PECworm × 1.28 |
| NOEL (mg/kg bw/d) | 2.2 | NOEL/10 of parent endpoint trifloxystrobin |
| TERlt | 29.2 | |

TER values shown in bold fall below the relevant trigger.

**Table 9.3-121: Assessment of the risk for earthworm-eating mammals due to exposure to trifloxystrobin metabolite NOA 409480 via bioaccumulation in earthworms (secondary poisoning) for the intended use in lettuce and rocket salad (use group S) (2 x 200 g a.s./ha; 7 day interval)**

| Parameter | NOA 409480 | comments |
|---|---|---|
| PECsoil (twa = 21 d) (mg/kg soil) | 0.024 | Maximum PECsoil (twa = 21 d) value resulting from PECsoil, plateau (< 0.001 mg/kg, 20 cm mixing depth) and the maximum 21d-TWAsoil value (0.024 mg/kg, multiple application in FOCUS crop cabbage) (see Part B8, chapter 8.7.2) |
| log Pow / Pow | 4.2 / 15800 | |
| Koc | 2356 | Mean (n = 6) |
| foc | 0.02 | Default |
| BCFworm | 4.0 | BCFworm/soil = (PECworm,ww/PECsoil,dw)<br>= (0.84 + 0.012 × Pow) / foc × Koc |
| PECworm | 0.10 | PECworm = PECsoil × BCFworm/soil |
| Daily dietary dose (mg/kg bw/d) | 0.12 | DDD = PECworm × 1.28 |
| NOEL (mg/kg bw/d) | 2.2 | NOEL/10 of parent endpoint trifloxystrobin |
| TERlt | 17.7 | |

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 mammal of 3000 g body weight with a daily food consumption of 425 g, resulting in FIR/bw = 0.142. Bioaccumulation in fish is estimated based on predicted concentrations in surface water.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use in chokeberry, elderberry and tree nurseries (use group V) also covers the risk for mammals from all other intended uses for trifloxystrobin and its metabolites CGA 357261, CGA 357262 and CGA 357276 (see 9.1.2). For the metabolite NOA 409480, the assessment for the use in flower bulbs (use group W) covers the risk for mammals from all other intended uses.

**Table 9.3-122: Assessment of the risk for fish-eating mammals due to exposure to trifloxystrobin via bioaccumulation in fish (secondary poisoning) for the intended use in chokeberry, elderberry and tree nurseries (use group V) (2 x 200 g a.s./ha; 7 day interval)**

| Parameter | Trifloxystrobin | comments |
|---|---|---|
| $PEC_{sw}$ (twa = 21 d) (mg/L) | 0.00116 | Maximum $PEC_{sw}$ (twa = 21 d) value resulting from FOCUS Step 2, Northern-/Southern-Europe, application in FOCUS crop pome and stone fruit, spring (see Part B8, chapter 8.9.2). |
| $BCF_{fish}$ | 431 | EFSA Journal 2017;15(10):4989 |
| BMF | - | biomagnification factor (relevant for BCF ≥ 2000) |
| $PEC_{fish}$ | 0.50 | $PEC_{fish} = PEC_{water} \times BCF_{fish}$ |
| Daily dietary dose (mg/kg bw/d) | 0.07 | DDD = $PEC_{fish} \times 0.142$ |
| $BMDL_5$ (mg/kg bw/d) | 22.0 | |
| $TER_{lt}$ | 310 | |

TER values shown in bold fall below the relevant trigger.

**Table 9.3-123: Assessment of the risk for fish-eating mammals due to exposure to trifloxystrobin metabolite CGA 357261 via bioaccumulation in fish (secondary poisoning) for the intended use in chokeberry, elderberry and tree nurseries (use group V) (2 x 200 g a.s./ha; 7 day interval)**

| Parameter | CGA 357261 | comments |
|---|---|---|
| $PEC_{sw}$ (twa = 21 d) (mg/L) | 0.0110 | Maximum PECsw (twa = 21 d) value resulting from FOCUS Step 2, Northern-/Southern-Europe, application in FOCUS crop pome and stone fruit, spring (see Part B8, chapter 8.9.2). |
| $BCF_{fish}$ | 164 | EFSA Journal 2017;15(10):4989 |
| BMF | - | biomagnification factor (relevant for BCF ≥ 2000) |
| $PEC_{fish}$ | 1.80 | $PEC_{fish} = PEC_{water} \times BCF_{fish}$ |
| Daily dietary dose (mg/kg bw/d) | 0.26 | DDD = $PEC_{fish} \times 0.142$ |
| NOEL (mg/kg bw/d) | 2.2 | NOEL/10 of parent endpoint trifloxystrobin |
| $TER_{lt}$ | 8.59 | |

TER values shown in bold fall below the relevant trigger.

**Table 9.3-124-1: Assessment of the risk for fish-eating mammals due to exposure to trifloxystrobin metabolite CGA 357261 via bioaccumulation in fish (secondary poisoning) for the intended use in chokeberry, elderberry and tree nurseries (use group V) (2 x 200 g a.s./ha; 7 day interval)**

| Parameter | CGA 357261 | comments |
|---|---|---|
| $PEC_{sw}$ (twa = 21 d) (mg/L) | 0.0110 | Maximum PECsw (twa = 21 d) value resulting from FOCUS Step 2, Northern-/Southern-Europe, application in FOCUS crop pome and stone fruit, spring (see Part B8, chapter 8.9.2). |
| $BCF_{fish}$ | 431 | BCF value of the active substance EFSA Journal 2017;15(10):4989 |
| BMF | - | biomagnification factor (relevant for BCF ≥ 2000) |
| $PEC_{fish}$ | 4.74 | $PEC_{fish} = PEC_{water} \times BCF_{fish}$ |
| Daily dietary dose (mg/kg bw/d) | 0.677 | DDD = $PEC_{fish} \times 0.142$ |
| NOEL (mg/kg bw/d) | 2.2 | NOEL/10 of parent endpoint trifloxystrobin |
| $TER_{lt}$ | **3.28** | |

TER values shown in bold fall below the relevant trigger.

**Table 9.3-125: Assessment of the risk for fish-eating mammals due to exposure to trifloxystrobin metabolite CGA 357262 via bioaccumulation in fish (secondary poisoning) for the intended use in chokeberry, elderberry and tree nurseries (use group V) (2 x 200 g a.s./ha; 7 day interval)**

| Parameter | CGA 357262 | comments |
|---|---|---|
| $PEC_{sw}$ (twa = 21 d) (mg/L) | 0.00341 | Maximum PECsw (twa = 21 d) value resulting from FOCUS Step 2, Northern-/Southern-Europe, application in FOCUS crop pome and stone fruit, spring (see Part B8, chapter 8.9.2). |
| $BCF_{fish}$ | 807 | EFSA Journal 2017;15(10):4989 |
| BMF | - | biomagnification factor (relevant for BCF ≥ 2000) |
| $PEC_{fish}$ | 2.75 | $PEC_{fish} = PEC_{water} \times BCF_{fish}$ |
| Daily dietary dose (mg/kg bw/d) | 0.39 | DDD = $PEC_{fish} \times 0.142$ |
| NOEL (mg/kg bw/d) | 2.2 | NOEL/10 of parent endpoint trifloxystrobin |
| $TER_{lt}$ | 5.63 | |

TER values shown in bold fall below the relevant trigger.

**Table 9.3-126-1: Assessment of the risk for fish-eating mammals due to exposure to trifloxystrobin metabolite CGA 357262 via bioaccumulation in fish (secondary poisoning) for the intended use in chokeberry, elderberry and tree nurseries (use group V) (2 x 200 g a.s./ha; 7 day interval)**

| Parameter | CGA 357262 | comments |
|---|---|---|
| $PEC_{sw}$ (twa = 21 d) (mg/L) | 0.00341 | Maximum PECsw (twa = 21 d) value resulting from FOCUS Step 2, Northern-/Southern-Europe, application in FOCUS crop pome and stone fruit, spring (see Part B8, chapter 8.9.2). |
| $BCF_{fish}$ | 431 | EFSA Journal 2017;15(10):4989 |
| BMF | - | biomagnification factor (relevant for BCF ≥ 2000) |
| $PEC_{fish}$ | 1.47 | $PEC_{fish} = PEC_{water} \times BCF_{fish}$ |
| Daily dietary dose (mg/kg bw/d) | 0.2 | DDD = $PEC_{fish} \times 0.142$ |
| NOEL (mg/kg bw/d) | 2.2 | NOEL/10 of parent endpoint trifloxystrobin |
| $TER_{lt}$ | 11 | |

TER values shown in bold fall below the relevant trigger.

**Table 9.3-127: Assessment of the risk for fish-eating mammals due to exposure to trifloxystrobin metabolite CGA 357276 via bioaccumulation in fish (secondary poisoning) for the intended use in chokeberry, elderberry and tree nurseries (use group V) (2 x 200 g a.s./ha; 7 day interval)**

| Parameter | CGA 357276 | comments |
|---|---|---|
| $PEC_{sw}$ (twa = 21 d) (mg/L) | 0.000427 | Maximum PECsw (twa = 21d) value resulting from FOCUS Step 2, Southern-Europe, application in FOCUS crop pome and stone fruit, spring (see Part B8, chapter 8.9.2). |
| $BCF_{fish}$ | 586 | EFSA Journal 2017;15(10):4989 |
| BMF | - | biomagnification factor (relevant for BCF ≥ 2000) |
| $PEC_{fish}$ | 0.25 | $PEC_{fish} = PEC_{water} \times BCF_{fish}$ |
| Daily dietary dose (mg/kg bw/d) | 0.04 | DDD = $PEC_{fish} \times 0.142$ |
| NOEL (mg/kg bw/d) | 2.2 | NOEL/10 of parent endpoint trifloxystrobin |
| $TER_{lt}$ | 61.9 | |

TER values shown in bold fall below the relevant trigger.

**Table 9.3-128-1: Assessment of the risk for fish-eating mammals due to exposure to trifloxystrobin metabolite CGA 357276 via bioaccumulation in fish (secondary poisoning) for the intended use in chokeberry, elderberry and tree nurseries (use group V) (2 x 200 g a.s./ha; 7 day interval)**

| Parameter | CGA 357276 | comments |
|---|---|---|
| $PEC_{sw}$ (twa = 21 d) (mg/L) | 0.000427 | Maximum PECsw (twa = 21d) value resulting from FOCUS Step 2, Southern-Europe, application in FOCUS crop pome and stone fruit, spring (see Part B8, chapter 8.9.2). |
| $BCF_{fish}$ | 431 | EFSA Journal 2017;15(10):4989 |
| BMF | - | biomagnification factor (relevant for BCF ≥ 2000) |
| $PEC_{fish}$ | 0.18 | $PEC_{fish} = PEC_{water} \times BCF_{fish}$ |
| Daily dietary dose (mg/kg bw/d) | 0.026 | DDD = $PEC_{fish} \times 0.142$ |
| NOEL (mg/kg bw/d) | 2.2 | NOEL/10 of parent endpoint trifloxystrobin |
| $TER_{lt}$ | 84.61 | |

TER values shown in bold fall below the relevant trigger.

**Table 9.3-129: Assessment of the risk for fish-eating mammals due to exposure to trifloxystrobin metabolite NOA 409480 via bioaccumulation in fish (secondary poisoning) for the intended use in flower bulbs (use group W) (5 x 75 g a.s./ha; 7 day interval)**

| Parameter | NOA 409480 | comments |
|---|---|---|
| $PEC_{sw}$ (twa = 21 d) (mg/L) | 0.0007402 | Maximum PECsw (twa = 21d) value resulting from FOCUS Step 2, Northern-Europe, application in FOCUS crop onions, autumn (see Part B8, chapter 8.9.2). |
| $BCF_{fish}$ | 274 | EFSA Journal 2017;15(10):4989 |
| BMF | - | biomagnification factor (relevant for BCF ≥ 2000) |
| $PEC_{fish}$ | 0.20 | $PEC_{fish} = PEC_{water} \times BCF_{fish}$ |
| Daily dietary dose (mg/kg bw/d) | 0.03 | DDD = $PEC_{fish} \times 0.142$ |
| NOEL (mg/kg bw/d) | 2.2 | NOEL/10 of parent endpoint trifloxystrobin |
| $TER_{lt}$ | 76.4 | |

TER values shown in bold fall below the relevant trigger.

**Table 9.3-130-1: Assessment of the risk for fish-eating mammals due to exposure to trifloxystrobin metabolite NOA 409480 via bioaccumulation in fish (secondary poisoning) for the intended use in flower bulbs (use group W) (5 x 75 g a.s./ha; 7 day interval)**

| Parameter | NOA 409480 | comments |
|---|---|---|
| $PEC_{sw}$ (twa = 21 d) (mg/L) | 0.0007402 | Maximum PECsw (twa = 21d) value resulting from FOCUS Step 2, Northern-Europe, application in FOCUS crop onions, autumn (see Part B8, chapter 8.9.2). |
| $BCF_{fish}$ | 431 | EFSA Journal 2017;15(10):4989 |
| BMF | - | biomagnification factor (relevant for BCF ≥ 2000) |
| $PEC_{fish}$ | 0.32 | $PEC_{fish} = PEC_{water} \times BCF_{fish}$ |
| Daily dietary dose (mg/kg bw/d) | 0.04 | $DDD = PEC_{fish} \times 0.142$ |
| NOEL (mg/kg bw/d) | 2.2 | NOEL/10 of parent endpoint trifloxystrobin |
| $TER_{lt}$ | 55 | |

TER values shown in bold fall below the relevant trigger.

**zRMS comment:**

For the risk assessment of metabolites for fish-eating birds, applicant proposed BCF values calculated by modelling (refer to Appendix 2 for details).
zRMS followed the approach presented in the RAR of trifluxystrobin and used the BCF value of the active substance for the risk assessment of metabolites (marked in blue).
Based on this first step approach, risk is acceptable for all metabolites except metabolite CGA 357261.
In case that some MS would accept this proposal (modelling) as a refinement, the risk presented by applicant can be considered. The all BCF values for metabolite were accepted/used for the dossier EXTERIS STRESSGARD (Central and Northern zones).

### 9.3.2.5 Biomagnification in terrestrial food chains

Not relevant.

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

Not relevant.

### 9.3.4 Overall conclusions

The acute risk assessment for both active substances and the combined toxicity assessment results in TER values above the trigger already at the screening step. Long-term TER values need refinements for voles, lagomorph and frugivorous species either for the active substances or due to the combined toxicity assessment.
According to the Guidance given in the Document SANCO/2010/13170 only the renewed mixing partner has to be evaluated for the renewal of authorisations according to article 43 of Regulation (EC) No 1107/2009. A combitox assessment might still be considered. ~~This leaves different opinions and options how to present the risk assessment for mammals and thus leads to different conclusions.~~

~~In case the assessment of combined toxicity and the non renewed mixing partner should not be addressed, acceptable risk for the current use pattern is demonstrated when data from field studies, measured DT50 values in monocotyledonous and dicotyledonous for trifloxystrobin is considered – except for small herbivorous mammal (vole) in:~~

- ~~leafy vegetables (use group A)~~
- ~~nurseries and rosehip (use group I)~~
- ~~elderberry and mulberry (use group M)~~

~~The TER values for the concerned use groups are just slightly below the trigger of 5 indicating an overall acceptable risk. Since the relevance of the vole scenario, or at least the acceptability of the resulting TER value, deviates among the member states no further refinement may be required.~~
~~If this is not acceptable the following GAP adaptations should lead to a TER > 5:~~

- ~~leafy vegetables (use group A): Reduction to 1 application (1 x 0.8 L product/ha)~~
- ~~nurseries and rosehip (use group I): Reduction to 1 application (1 x 0.8 L product/ha) **or** GAP adaptation to BBCH 50-91 (2 x 0.8 L product/ha)~~
- ~~elderberry and mulberry (use group M): Reduction to 1 application (1 x 0.8 L product/ha) **or** rate reduction (2 x 0.6 L product /ha)~~

~~In case the combined toxicity should be addressed for both compounds, including the risk assessment for Fluopyram, a TER > 5 for the current use pattern is demonstrated when field studies, measured DT50 values in monocotyledonous and dicotyledonous for Trifloxystrobin and Fluopyram is considered, except for small herbivorous mammal (vole) in:~~

- ~~leafy vegetables (use group A), TER < 5 for TFS, FLU and combined toxicity~~
- ~~leafy vegetables (use group B), TER < 5 for combined toxicity~~
- ~~berries (use group D), TER < 5 for combined toxicity~~
- ~~berries (use group E), TER < 5 for combined toxicity~~
- ~~strawberries (use group F), TER < 5 for combined toxicity~~
- ~~nurseries and rosehip (use group I) TER < 5 for TFS, FLU and combined toxicity~~
- ~~elderberry and mulberry (use group M): TER < 5 for combined toxicity~~
- ~~elderberry, mulberry (use group N): TER < 5 for combined toxicity~~

~~The TER values for the concerned use groups are just slightly below the trigger of 5 indicating an overall acceptable risk. Since the relevance of the vole scenario, or at least the acceptability of the resulting TER value, deviates among the member states no further refinement may be required.~~
~~If this is not acceptable the following GAP adaptations should lead to a TER > 5.~~

- ~~leafy vegetables (use group A): Reduction to 1 application (1 x 0.8 L product/ha)~~
- ~~berries (use group D): Reduction to 1 application (1 x 0.8 L product/ha)~~
- ~~berries (use group E): Reduction to 1 application (1 x 0.6 L product/ha)~~
- ~~strawberries (use group F): Interval adaptation to 14 days~~
- ~~nurseries and rosehip (use group I): Reduction to 1 application (1 x 0.8 L product/ha)~~
- ~~elderberry and mulberry (use group M): Reduction to 1 application (1 x 0.8 L product/ha)~~
- ~~elderberry, mulberry (use group N): Reduction to 1 application (1 x 0.6 L product/ha)~~

~~No further adaptation is proposed for the uses in leafy vegetables (use group B) as the TER is < 5 only for mixtox and already very close to the trigger value. Further, regarding the combined toxicity the $TER_{MIX}$ may still be slightly below the trigger of 5. But overall the risk is acceptable.~~

In conclusion:

The risk assessment for Combitox  risk assessment  for mammals should be further considered at MSs their national level level.

Furthermore, the assessment of the effects of exposure via drinking water and secondary poisoning indicate acceptable risk. Overall, it can be concluded that the risk associated with the recommended use of FLU + TFS SC 500 is acceptable for mammals.

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

Regarding the 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.

## 9.5 Effects on aquatic organisms (KCP 10.2)

### 9.5.1 Toxicity data

Studies on the toxicity to aquatic organisms have been carried out with all active substances and relevant metabolites. Full details of these studies are provided in the respective EU RAR or DAR and related documents, as well as in Appendix 2 of this document when new studies are submitted.

Effects on aquatic organisms of FLU + TFS SC 500 were not evaluated as part of the EU assessment of any of the active substances. New data submitted with this application in this core dossier are listed in Appendix 1 and summarised in Appendix 2.

Where 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 aquatic organisms – Trifloxystrobin and relevant metabolites**

| Species | Substance | Exposure System | Results | Reference |
|---|---|---|---|---|

| Species | Substance | Exposure System | Results | Reference |
|---|---|---|---|---|
| *Oncorhynchus mykiss* | Trifloxystrobin | 96 h, f | **$LC_{50}$ = 0.015 mg a.s./$L_{mm}$** | KCA 8.2.1/01<br>RAR & EFSA, 2017[a] |
| *Lepomis macrochirus* | Trifloxystrobin | 96 h, f | $LC_{50}$ = 0.054 mg a.s./$L_{mm}$ | KCA 8.2.1/03<br>RAR & EFSA, 2017[a] |
| *Cyprinodon variegatus* | Trifloxystrobin | 96 h, f | $LC_{50}$ = 0.078 mg a.s./$L_{mm}$ | KCA 8.2.1/04<br>RAR & EFSA, 2017[a] |
| *Oncorhynchus mykiss* | Trifloxystrobin | 95 d (ELS), f | **$NOEC_{swim\ up\ survival}$ = 0.0043 mg a.s./$L_{mm}$**<br>$EC_{10\ survival\ at\ 95d}$ = 0.0075 mg a.s./$L_{mm}$<br>$EC_{20\ survival\ at\ 95d}$ = 0.0079 mg a.s./$L_{mm}$ | KCA 8.2.2.1/01<br>RAR & EFSA, 2017[a] |
| *Daphnia magna* | Trifloxystrobin | 48 h, f | **$EC_{50}$ = 0.016 mg a.s./$L_{mm}$** | KCA 8.2.4.1/02<br>RAR & EFSA, 2017[a] |
| *Daphnia magna* | Trifloxystrobin | 48 h, f | $EC_{50}$ = 0.0253 mg a.s./$L_{mm}$ | KCA 8.2.4.1/01<br>RAR & EFSA, 2017[a] |
| *P. acutus acutus* | Trifloxystrobin | 96 h, f | $LC_{50}$ > 0.31 mg a.s./$L_{im}$ * | KCA 8.2.4/04<br>RAR & EFSA, 2017[a] |
| *Crassostrea virginica* | Trifloxystrobin | 96 h, f ** | $EC_{50\ (shell\ growth)}$ = 0.035 mg a.s./$L_{mm}$<br>$LC_{50\ (mortality)}$ > 0.0748 mg a.s./$L_{mm}$ | KCA 8.2.4/01<br>RAR & EFSA, 2017[a] |
| *Brachionus calyciflorus* | Trifloxystrobin | 24 h, s | $EC_{50}$ > 1.2577 mg a.s./$L_{mm}$ | Kosak & Hennecke (2018)<br>M-637834-01-1<br>see justification & Appendix 2 |
| *Thamnocephalus platyurus* | Trifloxystrobin | 24 h, s | $EC_{50}$ = 0.03705 mg a.s./$L_{mm}$ | Kosak & Hennecke (2018)<br>M-638530-01-1<br>see justification & Appendix 2 |
| *Daphnia longispina* | Trifloxystrobin | 48 h, ss | $EC_{50}$ = 0.00242 mg a.s./$L_{mm}$ | Hommen & Hennecke (2018)<br>M-638527-01-1<br>see justification & Appendix 2 |
| *Daphnia pulex* | Trifloxystrobin | 48 h, ss | $EC_{50}$ = 0.0305 mg a.s./$L_{mm}$ | Kosak & Hennecke (2018)<br>M-630875-01-1<br>see justification &Appendix 2 |
| *Chydorus sp* | Trifloxystrobin | 48 h, ss | $EC_{50}$ = 0.0838 mg a.s./$L_{mm}$ | Hommen & Hennecke (2018)<br>M-638519-01-1<br>see justification & Appendix 2 |
| *Cyclopidae* | Trifloxystrobin | 48 h, ss | $EC_{50}$ = 0.0450 mg a.s./$L_{mm}$ | Kosak & Hennecke (2018)<br>M-638524-01-1<br>see justification & Appendix 2 |
| *Hyalella azteca* | Trifloxystrobin | 96 h | $LC_{50}$ = 0.0247 mg a.s./$L_{mm}$ | KCA 8.2.4<br>RAR & EFSA, 2017[a] |
| *Chaoborus crystallinus* larvae | Trifloxystrobin | 48 h, ss | $EC_{50}$ = 0.01321 mg a.s./$L_{mm}$ | Kosak & Hennecke (2018)<br>M-637890-02-1<br>see justification<br>Not EU agreed, Appendix 2 |
| *Baetis rhodani*.larvae | Trifloxystrobin | 48 h, ss | $EC_{50}$ = 0.184 mg a.s./$L_{mm}$ | Kosak & Hennecke (2018)<br>M-637847-01-1<br>see justification & Appendix 2 |
| *Gammarus sp* | Trifloxystrobin | 48 h, ss | $EC_{50}$ = 0.1339 mg a.s./$L_{mm}$ | Kosak & Hennecke (2018)<br>M-638529-01-1<br>see justification & Appendix 2 |

| Species | Substance | Exposure System | Results | Reference |
|---|---|---|---|---|
| *Daphnia magna* | Trifloxystrobin | 21 d, f | **NOEC $_{reproduction}$= 0.00276 mg a.s./L$_{mm}$**<br>EC$_{10\ bodyweight\ F1}$ = 0.00328 mg a.s./L$_{mm}$<br>EC$_{20\ bodyweight\ F1}$ = 0.00459 mg a.s./L$_{mm}$ | KCA 8.2.5.1/01<br>RAR & EFSA, 2017[a] |
| *Chironomus riparius* | Trifloxystrobin | 28 d, s | NOEC $_{development\ \&\ emergence}$= 0.21 mg a.s./L$_{im}$<br>**EC$_{10\ emergence}$ = 0.14 mg a.s./L**<br>EC$_{20\ emergence}$ = 0.32 mg a.s./L | KCA 8.2.5.3/01<br>RAR & EFSA, 2017[a] |
| *Scenedesmus subspicatus* | Trifloxystrobin | 72 h, s | **E$_r$C$_{50}$ = 0.0174 mg a.s./L$_{mm}$**<br>E$_b$C$_{50}$ = 0.0053 mg a.s./L$_{mm}$<br>E$_r$C$_{10}$ = 0.0025 mg a.s./L$_{mm}$ | KCA 8.2.6.1/01<br>RAR & EFSA, 2017[a] |
| *Oncorhynchus mykiss* | CGA 321113 | 96 h, f | **LC$_{50}$ > 106 mg p.m./L$_{mm}$** | KCA 8.2.1/14<br>RAR & EFSA, 2017[a] |
| *Oncorhynchus mykiss* | CGA 321113 | 28 d, f | NOEC ≥ 100 mg p.m./L$_{nom}$ | KCA 8.2.2/01<br>RAR & EFSA, 2017[a] |
| *Daphnia magna* | CGA 321113 | 48 h, s | EC$_{50}$ > 100 mg p.m./L$_{nom}$ | KCA 8.2.4.1/05<br>RAR & EFSA, 2017[a] |
| *Daphnia magna* | CGA 321113 | 48 h, s | **EC$_{50}$ = 38 mg p.m./L$_{nom}$** | KCA 8.2.4.1/11<br>RAR & EFSA, 2017[a] |
| *Daphnia magna* | CGA 321113 | 21 d, ss | **NOEC = 9.92 mg p.m./L$_{nom}$** | Boerschig & Emnet (2019)<br>M-670324-02-1<br>see justification & Appendix 2 |
| *Chironomus riparius* | CGA 321113 | 28 d, s | NOEC $_{development\ and\ emergence}$ = 25 mg p.m./L$_{nom}$ | KCA 8.2.5.3/02<br>RAR & EFSA, 2017[a] |
| *Lumbriculus variegatus* | CGA 321113 | 28 d, s | NOEC =98.4 mg/kg dry sediment<br>NOEC$_{corr}$=49.2 mg/kg dry sediment | Egeler & Witte (2018)<br>M-630580-01-1<br>see justification & Appendix 2 |
| *Pseudokirchneriella subcapitata* | CGA 321113 | 72 h, s | **E$_r$C$_{50}$ > 100 mg p.m./L$_{nom}$**<br>E$_b$C$_{50}$ > 100 mg p.m./L$_{nom}$<br>NOEC = 18 mg p.m./L$_{nom}$ | KCA 8.2.6.1/04<br>RAR & EFSA, 2017[a] |
| *Oncorhynchus mykiss* | NOA 413161 | 96 h, s | **LC$_{50}$ > 100 mg p.m./L$_{nom}$** | KCA 8.2.1/17<br>RAR & EFSA, 2017[a] |
| *Daphnia magna* | NOA 413161 | 48 h, s | **EC$_{50}$ > 100 mg p.m./L$_{nom}$** | KCA 8.2.4.1/08<br>RAR & EFSA, 2017[a] |
| *Pseudokirchneriella subcapitata* | NOA 413161 | 72 h, s | **E$_r$C$_{50}$ > 100 mg p.m./L$_{nom}$**<br>E$_b$C$_{50}$ > 100 mg p.m./L$_{nom}$<br>NOEC = 21 mg p.m./L$_{nom}$ | KCA 8.2.6.1/07<br>RAR & EFSA, 2017[a] |
| *Oncorhynchus mykiss* | CGA 357261 | 96 h, ss | **LC$_{50}$ = 0.9 mg p.m./L$_{mm}$** | KCA 8.2.1/13<br>RAR & EFSA, 2017[a] |
| Fish | CGA 357261 | QSAR estimation | BCF = 164 L/kg | xxx (2018)<br>M-626557-01-1<br>see justification & Appendix 2 |
| *Daphnia magna* | CGA 357261 | 48 h, ss | EC$_{50}$ > 2.66 mg p.m./L$_{gm}$ | Riebschlaeger (2018)<br>M-630021-01-1<br>see justification & Appendix 2 |
| *Daphnia magna* | CGA 357261 | 21 d, ss | **NOEC = 0.101 mg p.m./L$_{mm}$** | Boerschig & Emnet (2019)<br>M-670322-02-1<br>see justification & Appendix 2 |
| *Desmodesmus* | CGA 357261 | 96 h, s | **E$_r$C$_{50\ (72h)}$ > 2.72 mg p.m./L$_{gm}$** | Kuhl (2018) |

| Species | Substance | Exposure System | Results | Reference |
|---|---|---|---|---|
| *subspicatus* | | | $E_yC_{50\ (72h)}$ > 2.72 mg p.m./$L_{gm}$<br>$E_bC_{50\ (72h)}$ not available<br>$NOE_rC_{\ (72h)}$ = 0.628 mg p.m./$L_{gm}$ | M-629680-01-1<br>see justification & Appendix 2 |
| *Oncorhynchus mykiss* | CGA 373466 | 96 h, s | **$LC_{50}$ > 200 mg p.m./$L_{nom}$** | KCA 8.2.1/15<br>RAR & EFSA, 2017[a] |
| *Daphnia magna* | CGA 373466 | 48 h, s | **$EC_{50}$ > 100 mg p.m./$L_{nom}$** | KCA 8.2.4.1/06<br>RAR & EFSA, 2017[a] |
| *Desmodesmus subspicatus* | CGA 373466 | 96 h, s | **$E_rC_{50}$ > 100 mg p.m./$L_{nom}$**<br>$E_yC_{50}$ > 100 mg p.m./$L_{nom}$<br>$E_bC_{50}$ > 100 mg p.m./$L_{nom}$<br>$NOE_rC$ =9.77 mg p.m./$L_{nom}$ | Kuhl (2018)<br>M-628915-01-1<br>see justification & Appendix 2 |
| *Oncorhynchus mykiss* | NOA 413163 | 96 h, s | **$LC_{50}$ > 100 mg p.m./$L_{nom}$** | KCA 8.2.1/18<br>RAR & EFSA, 2017[a] |
| *Daphnia magna* | NOA 413163 | 48 h, s | **$EC_{50}$ > 100 mg p.m./$L_{nom}$** | KCA 8.2.4.1/09<br>RAR & EFSA, 2017[a] |
| *Pseudokirchneriella subcapitata* | NOA 413163 | 72 h, s | **$E_rC_{50}$ > 100 mg p.m./$L_{nom}$**<br>$E_bC_{50}$ > 100 mg p.m./$L_{nom}$<br>NOEC = 45 mg p.m./$L_{nom}$ | KCA 8.2.6.1/08<br>RAR & EFSA, 2017[a] |
| *Oncorhynchus mykiss* | CGA 357262 | 96 h, s | **$LC_{50}$ > 5.51 mg p.m./$L_{mm}$** | KCA 8.2.1/22<br>RAR & EFSA, 2017[a] |
| Fish | CGA 357262 | QSAR estimation | BCF = 807 L/kg | xxx (2018)<br>M-626560-01-1<br>see justification & Appendix 2 |
| *Daphnia magna* | CGA 357262 | 48 h, s | **$EC_{50}$ > 2.24 mg p.m./$L_{mm}$** | KCA 8.2.4.1/16<br>RAR & EFSA, 2017[a] |
| *Pseudokirchneriella subcapitata* | CGA 357262 | 72 h, s | **$E_rC_{50}$ > 2.65 mg p.m./$L_{mm}$**<br>$E_bC_{50}$ > 2.65 mg p.m./$L_{mm}$<br>$E_yC_{50}$ > 2.65 mg p.m./$L_{mm}$<br>NOEC < 2.65 mg p.m./$L_{mm}$ | KCA 8.2.6.1/11<br>RAR & EFSA, 2017[a] |
| *Oncorhynchus mykiss* | CGA 107170 | 96 h, ss | **$LC_{50}$ = 13.6 mg p.m./$L_{mm}$** | KCA 8.2.1/16<br>RAR & EFSA, 2017[a] |
| *Daphnia magna* | CGA 107170 | 48 h, s | $EC_{50}$ = 22.7 mg p.m./$L_{nom}$ | KCA 8.2.4.1/07<br>RAR & EFSA, 2017[a] |
| *Daphnia magna* | CGA 107170 | 48 h, ss | **$EC_{50}$ = 10.7 mg p.m./$L_{nom}$** | Neuhahn (2017)<br>M-602375-01-1<br>see justification & Appendix 2 |
| *Desmodesmus subspicatus* | CGA 107170 | 96 h, s | **$E_rC_{50\ (72h)}$ = 13.9 mg p.m./$L_{mm}$**<br>$E_bC_{50\ (72h)}$ = 10.9 mg p.m./$L_{mm}$<br>$E_yC_{50\ (72h)}$ = 11.2 mg p.m./$L_{mm}$<br>$NOE_rC_{\ (72h)}$ = 2.52 mg p.m./$L_{mm}$ | Kuhl (2018)<br>M-629159-02-1<br>see justification & Appendix 2 |
| *Desmodesmus subspicatus* | CGA 107170 | 72 h, s | $E_rC_{50\ (72h)}$ = 29.0 mg p.m./$L_{mm}$<br>$E_yC_{50\ (72h)}$ = 22.0 mg p.m./$L_{mm}$<br>$NOE_rC_{\ (72h)}$ = 15.0 mg p.m./$L_{mm}$ | Spoo-Klöppel (2017)<br>M-602410-02-1<br>see justification & Appendix 2 |
| Fish | NOA 409480 | QSAR estimation | $LC_{50}$ = 1.92 mg p.m./L | xxx (2018)<br>M-627447-01-1<br>see justification & Appendix 2 |
| Fish | NOA 409480 | QSAR estimation | BCF = 274 L/kg | xxx (2018)<br>M-626562-01-1 |

| Species | Substance | Exposure System | Results | Reference |
|---|---|---|---|---|
| | | | | see justification & Appendix 2 |
| *Daphnia magna* | NOA 409480 | 48 h, s | **$EC_{50}$ = 2.25 mg p.m./$L_{mm}$** | KCA 8.2.4.1/18<br>RAR & EFSA, 2017[a] |
| *Pseudokirchneriella subcapitata* | NOA 409480 | 72 h, s | **$E_rC_{50}$ > 2.02 mg p.m./$L_{mm}$**<br>$E_bC_{50}$ = 1.292 mg p.m./$L_{mm}$<br>$E_yC_{50}$ = 1.292 mg p.m./$L_{mm}$<br>NOEC = 1.06 mg p.m./$L_{mm}$ | KCA 8.2.6.1/13<br>RAR & EFSA, 2017[a] |
| Fish | CGA 357276 | QSAR estimation | $LC_{50}$ = 0.983 mg p.m./L | xxx (2018)<br>M-627447-01-1<br>see justification & Appendix 2 |
| Fish | CGA 357276 | QSAR estimation | BCF = 586 L/kg | xxx (2018)<br>M-626564-01-1<br>see justification & Appendix 2 |
| *Daphnia magna* | CGA 357276 | 48 h, s | **$EC_{50}$ = 0.514 mg p.m./$L_{mm}$** | KCA 8.2.4.1/17<br>RAR & EFSA, 2017[a] |
| *Daphnia magna* | CGA 357276 | 21 d, ss | **NOEC = 0.00259 mg p.m./$L_{mm}$** | Boerschig & Emnet (2019)<br>M-670321-02-1<br>see justification & Appendix 2 |
| *Pseudokirchneriella subcapitata* | CGA 357276 | 72 h, s | **$E_rC_{50}$ > 5.88 mg p.m./$L_{mm}$**<br>$E_bC_{50}$ > 5.88 mg p.m./$L_{mm}$<br>$E_yC_{50}$ > 5.88 mg p.m./$L_{mm}$<br>NOEC = 0.381 mg p.m./$L_{mm}$ | KCA 8.2.6.1/12<br>RAR & EFSA, 2017[a] |
| **Higher plant** | | | | |
| No data, not required | | | | |
| **Additional endpoints** | | | | |
| Fish - acute; three species | Trifloxystrobin | 96 h | **$LC_{50}$ = 0.0398 mg a.s./L** with assessment factor of 100 | RAR & EFSA, 2017[a] |
| Aquatic invertebrates - acute; single species | Trifloxystrobin | Geometric mean of $EC_{50}$ from one species | **$EC_{50}$ = 0.020 mg a.s./L** with assessment factor of 100 | See justification |
| Acute toxic effects on tadpoles of *Xenopus laevis* | Trifloxystrobin | 48 h | $LC_{50}$ = 38.6 µg a.s./L<br>NOEC = 27.9 µg a.s./L | KCA 8.2.8/13<br>RAR & EFSA, 2017[a] |

[a] Refer to Appendix 1 – List of data submitted or referred to and relied on, but already evaluated at EU peer review
* Endpoint not suitable for calculating the geometric mean, as agreed at the peer review experts meeting (TC 147 (06 July 2017))
** Wrong study duration of 48 h given in EFSA Journal 2017;15(10):4989. The correct exposure time of 96 h given in study report is considered here.
f = flow-through system; s = static system; ss = semi static system; gm = geometric mean measured concentrations; nom = nominal concentrations; mm = mean measured concentrations

**Table 9.5-2: Endpoints and effect values relevant for the risk assessment for aquatic organisms – Fluopyram**

| Species | Substance | Exposure system | Results | Reference |
|---|---|---|---|---|
| *Cyprinodon variegatus* | Fluopyram | 96 h, s | $LC_{50}$ > 0.98 mg a.s./$L_{mm}$[a] | EFSA Journal 2013;11(4):3052 |

| **Species** | **Substance** | **Exposure system** | **Results** | **Reference** |
|---|---|---|---|---|
| *Oncorhynchus mykiss* | Fluopyram | 96 h, s | $LC_{50}$ > 1.82 mg a.s/$L_{mm}$[a] | DAR Fluopyram Volume 3 B.9; 2011 xxx, 2006; M-277770-02-1 |
| *Lepomis macrochirus* | Fluopyram | 96 h, s | $LC_{50}$ > 5.27 mg a.s/$L_{mm}$[a] | DAR Fluopyram Volume 3 B.9; 2011 xxx, 2006; M-278441-02-1 |
| *Pimephales promelas* | Fluopyram | 96 h, s | $LC_{50}$ > 4.95 mg a.s/$L_{mm}$[a] | DAR Fluopyram Volume 3 B.9; 2011 xxx, 2008; M-298918-01-1 |
| *Cyprinus carpio* | Fluopyram | 96 h, s | $LC_{50}$ = 30.5 mg a.s/$L_{mm}$[a] | DAR Fluopyram Volume 3 B.9; 2011 xxx, 2006; M-280108-01-1 |
| Geomean (fish) | Fluopyram | 96 h, s | $LC_{50}$ > 4.3 mg a.s/L[c] | See justification |
| *Pimephales promelas* | Fluopyram | 33 d, f | NOEC = 0.135 mg a.s./$L_{mm}$ | EFSA Journal 2013;11(4):3052 |
| *Daphnia magna* | Fluopyram | 48 h, s | $EC_{50}$ = 17 mg a.s./$L_{mm}$[a] | DAR Fluopyram Volume 3 B.9; 2011 Bruns, 2006; M-278709-01-1 |
| *Americamysis bahia* | Fluopyram | 48 h, s | $EC_{50}$ > 0.5 mg a.s./$L_{mm}$[b] | EFSA Journal 2013;11(4):3052 |
| GEOMEAN (aquatic invertebrates) | Fluopyram | 48 h, s | $LC_{50}$ > 2.9 mg a.s/L[c] | See justification |
| *Daphnia magna* | Fluopyram | 21 d, s | NOEC = 1.25 mg a.s./$L_{nom}$ | EFSA Journal 2013;11(4):3052 |
| *Chironomus riparius* | Fluopyram | 28 d, spiked water | NOEC = 1.39 mg a.s./$L_{nom}$ | EFSA Journal 2013;11(4):3052 |
| *Chironomus tentans* | Fluopyram | 54 d, spiked sediment | NOEC = 26 mg a.s./kg sed. $(dw)_{nom}$ | DAR Fluopyram Volume 3 B.9; 2011 Putt, 2008; M-298809-01-1 |
| *Skeletonema costatum* | Fluopyram | 72 h, s | $E_rC_{50}$ > 1.13 mg a.s./$L_{mm}$<br>$E_bC_{50}$ > 1.13 mg a.s./$L_{mm}$ | EFSA Journal 2013;11(4):3052 |
| *Pseudokirchneriella subcapitata* | Fluopyram | 72 h, s | $E_rC_{50}$ = 8.90 mg a.s./$L_{mm}$<br>$E_bC_{50}$ = 3.97 mg a.s./$L_{mm}$ | DAR Fluopyram Volume 3 B.9; 2011 Banman & Lam, 2007; M-286541-01-1 |
| *Lemna gibba* | Fluopyram | 7 d, s | $E_rC_{50\ \text{front no}}$= 2.51 mg a.s./$L_{nom}$<br>$E_bC_{50\ \text{frond area}}$ = 2.32 mg a.s./$L_{nom}$ | DAR Fluopyram Volume 3 B.9; 2011 Dorgerloh, 2007; M-283647-01-1 |

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
[a] Above the practical limit of water solubility
[b] Above the practical limit of water solubility ; species not considered as relevant endpoint but used as most sensitive endpoint in risk assessment, surrogate $LC_{50}$ based on 10% mortality in treatment

[c] Geometric means calculated for risk refinement

**Table 9.5-3: Endpoints and effect values relevant for the risk assessment for aquatic organisms – FLU + TFS SC 500**

| Species | Substance | Exposure System | Results | Reference |
|---|---|---|---|---|
| ~~*Oncorynchus mykiss*~~ | ~~FLU + TFS SC 500~~ | ~~96 h, s~~ | ~~$LC_{50}$ = 0.091 mg/$L_{nom}$~~ | ~~Appendix 2 xxx, 2007 M-294350-01-1~~ |
| *Oncorynchus mykiss* | FL + TFS SC 500 | 96 h, ss | $LC_{50}$ = 0.0884 mg/$L_{nom}$ correspond to $LC_{50}$= 0.044 mg a.s./L | Appendix 2 xxx, 2018 M-636236-01-1 |
| ~~*Daphnia magna*~~ | ~~FLU + TFS SC 500~~ | ~~48 h, s~~ | ~~$EC_{50}$ = 0.086 mg/$L_{nom}$~~ | ~~Appendix 2 Bruns, 2007 M-292365-01-1~~ |
| *Daphnia magna* | FLU + TFS SC 500 | 48 h, ss | $EC_{50}$ = 0.051 mg/$L_{nom}$ correspond to $EC_{50}$= 0.0255 mg a.s./L | Appendix 2 Börschig & Kobel, 2018 M-636231-01-1 |
| ~~*Pseudokirchneriella subcapitata*~~ | ~~FLU + TFS SC 500~~ | ~~72 h, s~~ | ~~$E_rC_{50}$ = 0.292 mg/$L_{nom}$~~ | ~~Appendix 2 Dorgerloh, 2007 M-292579-01-1~~ |
| *Pseudokirchneriella subcapitata* | FLU + TFS SC 500 | 72 h, s | ~~$E_rC_{50}$ = 4.25 mg/$L_{nom}$~~ $E_rC_{50}$(72h) =1.838 (1.363-2.594) mg formulation/L correspond to **$E_rC_{50}$(72h) 0.674 (0.5-0.953) mg (sum average % active substaces/L** | Appendix 2 Kuhl, 2018 M-615579-01-1 |
| *Pseudokirchneriella subcapitata* | FLU + TFS SC 500 | 72 h, s | ~~$E_rC_{50}$ = 0.419 mg/$L_{nom}$~~ **$E_rC_{50}$(72h) 0.157 (0.141-0.176) mg (sum average % active substaces/L** | Appendix 2 Börschig & Kobel, 2018 M-636234-01-1 |

s: static; ss: semi-static, nom: based on nominal concentrations

In the studies with the formulation from 2007, no analytical verification of trifloxystrobin was included whereas trifloxystrobin is known to be unstable in water and is the toxicity driver in this formulation. This was questioned by authorities, therefore the studies with, fish, *Daphnia* and algae were repeated and conducted in semi-static conditions when possible. The results of the new studies will be taken into account in the risk assessment.

A calculation of mixed toxicity endpoints and MDR (model deviation ratio) calculations according to the

Aquatic Guidance Document (EFSA, 2013) are presented below. For each organism group, only endpoints of the same species were considered.

**Table 9.5-4: Calculation of the acute mixed toxicity of the formulation according to Finney and comparison to product endpoint**

| | FLU | TFS | FLU + TFS SC 500 |
|---|---|---|---|
| Active substance proportion (%) [1] | 21.4 | 21.6 | -- |
| Effects on fish (*Oncorhynchus mykiss*) | | | |
| $LC_{50}$ (mg a.s./L) | > 1.82 | 0.015 | -- |
| $LC_{50}$ – mixed toxicity (mg product/L) | Expected $LC_{50}$ 0.069 | | Measured $LC_{50}$ 0.0884 mg product/L |
| Effects on aquatic invertebrates (*Daphnia magna*) | | | |
| $EC_{50}$ (mg a.s./L) | 17 | 0.016 | -- |
| $EC_{50}$ – mixed toxicity (mg product/L) | Expected $EC_{50}$ 0.074 | | Measured $EC_{50}$ 0.051 mg product/L |
| Effects on green algae | | | |
| $E_rC_{50}$ (mg a.s./L) | 8.90 | 0.0174 | -- |
| $E_rC_{50}$ – mixed toxicity (mg product/L) | Expected $E_rC_{50}$ = 0.080 | | Measured $E_rC_{50}$ ~~= 0.419~~ 0.157 mg (sum average % active substaces/L* |

[1] Based on a measured a.s. content

Since for trifloxystrobin the analytical measurements showed initial concentrations of 97 to 120% of nominal, but within the study duration the measured trifloxystrobin concentrations declined over the whole study with concentrations outside the 80%-120% of nominal the stats analusis with the sum of the average concentration of the nominal concentration of the two active substances per duration (72h and 96h) were provided

MDR = $ECx_{mix\text{-}CA}/ECx_{PPP}$.

~~Fish acute~~
~~MDR = 0.069/0.0884 = 0.78~~

~~*Daphnia* acute~~
~~MDR = 0.074/0.051 = 1.45~~

~~*Algae*~~
~~MDR = 0.080/0.419 = 0.19.~~
~~However, the endpoint of the formulation is based on nominal concentrations. It can be estimated based on geometric mean measured concentrations of trifloxystrobin which are 55, 57, 71, 77, 75, 78% of the nominal concentrations of 0.0089, 0.0286, 0.0916, 0.293, 0.938 and 3.00 mg product/L, respectively. Considering a mean of 69%, the endpoint for the formulation would be 0.287 mg product/L. The corresponding MDR would be 0.28.~~

$ECx_{mix\text{-}CA}$ calculation for FLU + TFL SC 500 according AGD , EFSA 2013

| Active substance | Tier I Endpoints of the same species | |
|---|---|---|
| **Fish (acute)** | | |
| Fluopyram | 1.82 | Go to STEP2 |
| Trifloxystrobin | 0.015 | |
| FLU + TFL SC 500(ECxPPP) | 0.0884 | |
| Mixtox-Endpoint (ECx mix-CA) | 0.03 | |

| | | |
|---|---|---|
| **Invertebrates (acute)** | | |
| Fluopyram | 17 | Go to STEP2 |
| Trifloxystrobin | 0.016 | |
| FLU + TFL SC 500(ECxPPP) | 0.051 | |
| Mixtox-Endpoint (ECx mix-CA) | 0.032 | |
| **Algae** | | |
| Fluopyram | 8.9 | Go to STEP2 |
| Trifloxystrobin | 0.0174 | |
| FLU + TFL SC 500(ECxPPP) | 0.157 | |
| Mixtox-Endpoint (ECx mix-CA) | 0.035 | |

**Step 2**

Check the plausibility of the measured formulation toxicity ($EC_{x\ PPP}$) against the calculated mixture toxicity $EC_{x\ mix-CA}$ (assuming CA, Equation 13) for exactly the mixture composition of the a.s. in the formulation ($EC_{x\ PPP}$) by means of the model deviation ratio (MDR = $EC_{x\ mix-CA}/EC_{x\ PPP}$).

| | | Triggers | | |
|---|---|---|---|---|
| Endpoint/Test species | Model deviation ratio (MDR = $EC_{x\ mix-CA}/EC_{x\ PPP}$) | <0.2 | 0.2-5 | >5 |
| LC50 fish | 0,67 | | Got to 3 | |
| EC50 daphnids | 1,25 | | Got to 3 | |
| ErC50 algae | 0,44 | | Got to 3 | |

The MDR calculations show that concentration addition (CA) holds for the mixture and that the toxicity of the mixture is in the same range than expected based on a.s. content.
STEP3

**Lower tier  PECsw Step 1**

Check whether the mixture composition in the formulation study giving the measured mixture toxicity ($EC_{x\ PPP}$) in terms of the relative proportions of the individual a.s. is similar to the mixture composition at the $PEC_{mix}$. As a direct comparison on the basis of the relative proportions of the a.s. at the $EC_{x\ PPP}$ with the relative proportion at the $PEC_{mix}$ is not informative as such, the comparison is done based on calculated mixture toxicity (assuming CA) for both mixture compositions. Therefore, calculate $EC_{x\ mix-CA}$ (see Equation 13) for the mixture composition of the a.s. at the $PEC_{mix}$ and compare with the estimate calculated for the formulation (as already done in step 2 above).

| | | Triggers | |
|---|---|---|---|
| Endpoint/Test species | $EC_{x\ mix-CA}$ (a.s. in product)/$EC_{x\ mix-CA}$ (a.s. in $PEC_{mix}$) | 0.8-1.2 | <0.8 or >1.2 |
| LC50 fish | 0,016 | | Go to 5 |
| EC50 daphnids | 0,002 | | Go to 5 |
| ErC50 algae | 0,004 | | Go to 5 |

**Step 5**

Check whether one mixture component clearly drives the toxicity if considering the measured mixture toxicity ($EC_{x\ PPP}$), that is, does the largest part of the sum of toxic units (Equation 14) calculated for the formulation (≥ 90 %) comes from a single a.s. ($TU_i$)?

| | | Active substance A | | Active substance B | | Active substance C | | Triggers | |
|---|---|---|---|---|---|---|---|---|---|
| Endpoint/Test species | Calculated mixture toxicity (a.s. in product) ($EC_{x\ mix\text{-}CA}$) [mg a.s./L] | Toxicity per fraction ($1/TU_i$) [mg a.s./L] | Deviation from mixture toxicity = $1\text{-}EC_{x\ mix\text{-}CA}$ x ($1/EC_{x\ mix\text{-}CA}\text{-}TU_i$) [%] | Toxicity per fraction ($1/TU_i$) [mg a.s./L] | Deviation from mixture toxicity = $1\text{-}EC_{x\ mix\text{-}CA}$ x ($1/EC_{x\ mix\text{-}CA}\text{-}TU_i$) [%] | Toxicity per fraction ($1/TU_i$) [mg a.s./L] | Deviation from mixture toxicity = $1\text{-}EC_{x\ mix\text{-}CA}$ x ($1/EC_{x\ mix\text{-}CA}\text{-}TU_i$) [%] | >=90% for one a.s. | >=90% for no a.s. |
| LC50 fish | 0,030 | 3,655 | 0,8% | 0,030 | 99,19% | | | Go to 6 | |
| EC50 daphnids | 0,032 | 34,137 | 0,1% | 0,032 | 99,91% | | | Go to 6 | |
| ErC50 algae | 0,035 | 17,872 | 0,2% | 0,035 | 99,8% | | | Go to 6 | |

**Step 6**

Conduct a RA based on single-substance toxicity data ($EC_{x\ a.s.}$) for the identified 'driver' of mixture toxicity, with the exposure-toxicity ratio ($ETR_{a.s.}$) being defined as the PECa.s. divided by the measured $EC_{x\ a.s.}$ and compare the outcome with the acceptability criterion (trigger value) decisive for the specific endpoint/exposure scenario combination.

**Covered by active substance assessment**

### 9.5.1.1 Justification for new endpoints

**Trifloxystrobin:**

Acute invertebrates endpoint for trifloxystrobin: In the List of Endpoints, the lowest endpoint for acute invertebrates is 0.0052 mg a.s./L from a *Daphnia magna* study with the formulation 50 WG. The risk assessment is further refined with the geometric mean of 2 studies on *Daphnia magna* with the active substance and this lowest endpoint from the formulation. Since, this formulation endpoint is not relevant for other trifloxystrobin containing formulations, the geometric mean has been recalculated without this endpoint. It is consequently based on the 2 studies with the active substance only and is 0.020 mg a.s./L (geometric mean of 0.016 and 0.0253 mg a.s./L).

**zRMS comment:** Agrees to use studies conducted with active substance to set acute RAC value for the active substance.

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

Acute fish toxicity for metabolites CGA 357276 and NOA 409480: In the List of Endpoints, the risk was assessed assuming that the acute toxicity on fish of these 2 metabolites was 10 times greater than the parent, in absence of specific data on these 2 metabolites. In those conditions, the risk was not acceptable and it was concluded in the data gap section of the EFSA conclusion "The risk for aquatic organisms should be further considered for metabolites CGA357276 and NOA409480". The applicant contacted the RMS to get approval to run acute fish tests on these metabolites, the RMS did not support new studies on vertebrates and recommended to use non-testing methods (Email exchange from 6th April 2018). Consequently, QSAR estimates are provided. Different QSAR approaches were used, the lowest endpoint is used in risk assessment.

**zRMS comment:** zRMS considered that the toxophore is lost for these two metabolites. Therefore, risk assessment is considered covered by risk assessment conducted for the active substance.

Acute test on *Daphnia magna* with metabolite CGA 357261: The existing study was rejected during the AIR process, consequently the study has been repeated.

Algae test for metabolites CGA 373466, CGA 357261 and CGA 107170: The existing studies did not meet the validity criteria of the new OECD 201 version. They have, therefore, been rejected during the AIR process. Consequently, new studies have been conducted.

Additional acute test on *Daphnia magna* and algae test for metabolite CGA 107170: Studies were originally conducted for registration under REACH, they are provided for transparency reasons.

Study on sediment dwelling organisms (*Lumbriculus variegatus*) with metabolite CGA 321113: The study is required to perform the risk assessment for sediment dwellers.

BCF for metabolites CGA 357261, CGA 357262, NOA 409480 and CGA 357276: Because these metabolites have a log Pow >3. QSAR estimates are provided to perform the required risk assessment for birds and mammals.

**zRMS comment:** BCF values were agreed for othe ppp Flint, ExterisStressgard ( for North and Central Zone). The studies's evaluation were provided in Appendix 2.

Acute tests on non standard invertebrates species with trifloxystrobin: The existing studies have been rejected during the AIR process. These studies have been repeated in order to refine the risk assessment.

Chronic tests on *Daphnia magna* for metabolites CGA 321113, CGA 357276 and CGA 357261: The chronic invertebrate risk assessment for metabolites is refined based on acute to chronic ratios. However, additional tests have been performed on selected metabolites to make sure that this non-testing approach was conservative enough. This is further discussed in the risk assessment part.

**zRMS comment:**

zRMS considered that the risk for metabolites is covered by the risk assessment for the parent (see zRMS comment on metabolites in 9.5.2 below for details).

**Fluopyram:**

**Table 9.5-5: Justification for new endpoints**

| Species | Substance | Exposure System | Justification |
|---|---|---|---|
| Fish, acute GEOMEAN (*Cyprinodon variegatus, Oncorhynchus mykiss, Lepomis macrochirus, Pimephales promelas, Cyprinus carpio)* | Fluopyram | 96 h, s | According to the Aquatic guidance document (EFSA Journal 2013;11(7):3290), the geomean approach is a possible tool for refinement if more data are available than requested in the data requirement. |
| Invertebrates, acute GEOMEAN (*A. bahia* and *D. magna*) | Fluopyram | 48 h, s | According to the Aquatic guidance document (EFSA Journal 2013;11(7):3290), the geomean approach is a possible tool for refinement if more data are available than requested in the data |

| Species | Substance | Exposure System | Justification |
|---|---|---|---|
| | | | requirement. |
| *Lemna gibba* | Fluopyram | 7 d, s | According to the Aquatic guidance document (EFSA Journal 2013;11(7):3290) the $EC_{50}$ based on growth rate is the preferred endpoint for risk assessment, therefore the $E_rC_{50}$ of 2.51 mg a.s./L is used in the risk assessment for fluopyram. |

### 9.5.2 Risk assessment

Fluopyram

For the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009, the following guidance is given in the Document SANCO/2010/13170 for products containing two or more active substances:

- "when the 1st substance is renewed- there is no need to evaluate data related to the 2nd substance"
- "once the 2nd substance is renewed- there is no need to evaluate data related to the 1st substance because this has already been performed in the frame of the re-authorisation of the PPP following the renewal of the 1st active substance"
- "Where necessary a combitox assessment should be performed."

To address the combined toxicity of Fluopyram and Trifloxystrobin an approach according to the aquatic guidance documents is presented below. However, a single risk assessment for Fluopyram is not performed as this would be out of scope of SANCO/2010/13170. Moreover, as the assessment of combined toxicity and the comparison of the most sensitive endpoints for Fluopyram and Trifloxystrobin clearly show that Trifloxystrobin is driving the risk assessment. If needed, PEC values for Fluopyram are presented in part B8.

Trifloxystrobin

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 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 $PEC_{SW}$ values used for the risk assessment covering the proposed use pattern and the resulting PEC/RAC ratios are presented in the tables below.

For all uses of trifloxystrobin, a risk assessment based on FOCUS Step 4 exposure values including risk mitigation measures is necessary. However, for formal reasons, risk assessments based on worst case exposure values from FOCUS Step 1 to 3 are included for all uses. As many risk assessment tables are included in this dRR it might be convenient to proceed directly with the risk assessment based on Step 4 exposure values.

Use groups for FOCUS Step 4 risk assessments are indicated in the table below:

**Table 9.5-6: Use groups for FOCUS Step 4 risk assessments**

| Use group | Crop type / critical use ID | Modelling use (crop) | Application rate |
|---|---|---|---|
| X | Asparagus, garden cress, flower tubers, ornamentals, Paeony, Sea lavender<br>Use ID: 4, 62, 123, 172, 174, 215 | Field beans I (early/late) | 1 × 0.200 kg a.s./ha<br>BBCH 11-95 |
| Y | Beans, nurseries<br>Use ID: 19, 169 | Field beans II (early/late) | 2 × 0.200 kg a.s./ha, 14 d interval<br>BBCH 19-89 |
| Z | Asparagus<br>Use ID: 1 | Field beans III (early/late) | 2 × 0.200 kg a.s./ha, 10 d interval<br>BBCH 23-95 |
| AA | Baby leaf crops, beans, garden cress, strawberries<br>Use ID: 5, 7, 60, 239 | Field beans IV (early/late) | 2 × 0.200 kg a.s./ha, 7 d interval<br>BBCH 40-89 |
| ~~AB~~ | ~~Golf courses~~<br>~~Use ID: 124~~ | ~~Grass (March, Jun, Sep, Dec)~~ | ~~2 × 0.125 kg a.s./ha, 14 d interval~~<br>~~BBCH 29-33~~ |
| AC | Peas<br>Use ID: 183 | Legumes I | 2 × 0.200 kg a.s./ha, 7 d interval<br>BBCH 59-89 |
| AD | Peas<br>Use ID: 178 | Legumes II | 2 × 0.200 kg a.s./ha, 14 d interval<br>BBCH 59-79 |
| AE | Celeriac<br>Use ID: 47 | Sugar beets I (June – November) | 2 × 0.125 kg a.s./ha, 14 d interval<br>BBCH 40-49 |
| AF | Chicory<br>Use ID: 49 | Sugar beets II (early, late) | 1 × 0.200 kg a.s./ha<br>BBCH 13-49 |
| AG | Flower bulbs<br>Use ID: 121 | VegBulb I (early, middle, late) | 1 × 0.200 kg a.s./ha<br>BBCH 12-91 |
| W | Flower bulbs<br>Use ID: 120 | VegBulb II (early, late) | 5 × 0.075 kg a.s./ha, 7 d interval<br>BBCH 12-91 |
| V | Chokeberry, elderberry *, tree nursery<br>Use ID: 52, 109 *, 242 | Pome and stone fruit (early, late) | 2 × 0.200 kg a.s./ha, 7 d interval<br>BBCH 12-91 |
| AH | Elderberry *<br>Use ID: 110 * | Pome and stone fruit (early, late) | 2 × 0.150 kg a.s./ha, 14 d interval<br>BBCH 15-91 |
| AI | Lamb's lettuce, lettuce, rocket salad<br>Use ID: 142, 158, 205 | Vegetable leafy (early/late) | 2 × 0.200 kg a.s./ha, 7 d interval<br>BBCH 12-49 |
| AJ | Endive, Lamb's lettuce, lettuce, radicchio, rocket salad<br>Use ID: 113, 143, 151, 189, 206 | Vegetables leafy (early/late) | 1 × 0.200 kg a.s./ha<br>BBCH 12-49 |
| AK | Tobacco<br>Use ID: 241 | Tobacco | 1 × 0.200 kg a.s./ha<br>BBCH 11-39 |
| AL | Hops<br>Use ID: 141 | Hops (early, late) | 2 × 0.150 kg a.s./ha, 14 d interval<br>BBCH 37-79 |
| AM | Blackberry, blueberry, cranberry, currant, gooseberry, raspberry (berries)<br>Use ID: 24, 35, 53, 79, 128, 194 | Vines I (early, middle, late) | 2 × 0.150 kg a.s./ha, 7 d interval<br>BBCH 15-89 |
| AN | Blackberry, blueberry, cranberry, currant, dewberry, gooseberry, mulberry, raspberry, rosehip, | Vines II (early, middle, late) | 2 × 0.200 kg a.s./ha, 7 d interval<br>BBCH 15-89 |

| **Use group** | **Crop type / critical use ID** | **Modelling use (crop)** | **Application rate** |
|---|---|---|---|
| | elderberry * (berries)<br>Use ID: 21, 32, 59, 63, 103, 125, 166, 191, 213, 109 * | | |
| AO | Blueberry, cranberry, currant, gooseberry, mulberry, rosehip, elderberry * (berries)<br>Use ID: 44, 58, 75, 136, 168, 212, 110 * | Vines III (early, middle, late) | 2 × 0.150 kg a.s./ha, 14 d interval<br>BBCH 15-89 |
| AP | Blackberry, blueberry, currant, gooseberry, raspberry (berries)<br>Use ID: 29, 40, 71, 133, 199 | Vines IV (early, middle, late) | 2 × 0.200 kg a.s./ha, 14 d interval<br>BBCH 15-89 |
| AQ | Blackberry, dewberry, raspberry (berries)<br>Use ID: 30, 106, 203 | Vines V (early, middle, late) | 2 × 0.150 kg a.s./ha, 21 d interval<br>BBCH 40-69 |
| AR | Grapes<br>Use ID: 140 | Vines VI (early/middle/late) | 2 × 0.050 kg a.s./ha, 14 d interval<br>BBCH 15-85 |

* Please note: The surrogate crop for modelling for elderberries differs in some member states. In Austria, elderberries belong to orchards whereas in all other member states elderberries are covered by vines. Thus, elderberries are listed in this table with the surrogate crop orchards as well as vines. Thus, the mitigation measures for the use of the product in elderberries vary in different member states.

In the following table, 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 and each organism group.

**Trifloxystrobin**
**FOCUS Step 1/2 risk assessment**

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for use in elderberry, chokeberry, mulberry and tree nursery (modelling use Pome and stone fruit 2×200g a.s./ha, 7d int., BBCH 12-91, early) covers the risk for aquatic organsism from all other intended uses (see 9.1.2).

**Table 9.5-7: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for trifloxystrobin for each organism group based on FOCUS Steps 1, 2 calculations for the use of FLU+TFS SC 500 in elderberry, chokeberry, mulberry, tree nursery (elderberry, chokeberry, mulberry, tree nursery; modelling use Pome and stone fruit 2x200 g/ha -- BBCH 12-91, early -- 2×200g a.s./ha, 7d int.)**

| Group | | Fish acute | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. acute | Inverteb. prolonged | Sed. dwell. prolonged | Algae* | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Fish acute*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Inverteb. acute*** | ***Daphnia magna*** | ***Chironomus riparius*** | ***Desmodesmus subspicatus*** | | |
| **Endpoint** <br> **(µg/L)** | | **$LC_{50}$** <br> **15** | **$LC_{50}$ (geomean)** <br> **39.8** | **NOEC** <br> **4.3** | **$EC_{50}$** <br> **16.0** | **$EC_{50}$ (geomean)** <br> **20.0** | **NOEC** <br> **2.76** | **$EC_{10}$** <br> **140** | **$ErC_{50}$** <br> **17.4** | | |
| **AF** | | **100** | **100** | **10** | **100** | **100** | **10** | **10** | **10** | | |
| **RAC (µg/L)** | | **0.15** | **0.398** | **0.43** | **0.16** | **0.20** | **0.276** | **14** | **1.74** | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 1** | | | | | | | | | | | |
| - - | 35.9 | **240** | **90.3** | **83.6** | **225** | **180** | **130** | **2.57** | **20.6** | | |
| **Step 2** | | | | | | | | | | | |
| Northern Europe Mar. - May(Spring) | 19.5 | **130** | **48.9** | **45.3** | **122** | **97.3** | **70.5** | **1.39** | **11.2** | | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Southern Europe Mar. - May(Spring ) | 19.5 | **130** | **48.9** | **45.3** | **122** | **97.3** | **70.5** | **1.39** | **11.2** | | |

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

## FOCUS Step 3 risk assessment

The FOCUS Step 3 risk assessment was done as risk envelope for the use in elderberry, chokeberry, mulberry and tree nursery resulting in maximum $PEC_{sw}$ values. The worst case FOCUS Step 3 risk assessment is presented for formal reasons as a FOCUS Step 4 risk assessment is needed for all use groups.

**Table 9.5-8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for trifloxystrobin for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in elderberry, chokeberry, mulberry, tree nursery (elderberry, chokeberry, mulberry, tree nursery; modelling use Pome and stone fruit 2x200 g/ha -- BBCH 12-91, early -- 2×0.2 kg a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. acute** | **Inverteb. prolonged** | **Sed. dwell. prolonged** | **Algae** | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Fish acute*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Inverteb. acute*** | ***Daphnia magna*** | ***Chironomus riparius*** | ***Desmodesmus subspicatus*** | | |
| **Endpoint** (µg/L) | | **$LC_{50}$** 15 | **$LC_{50}$ (geomean)** 39.8 | **NOEC** 4.3 | **$EC_{50}$** 16.0 | **$EC_{50}$ (geomean)** 20.0 | **NOEC** 2.76 | **$EC_{10}$** 140 | **$ErC_{50}$** 17.4 | | |
| **AF** | | **100** | **100** | **10** | **100** | **100** | **10** | **10** | **10** | | |
| **RAC (µg/L)** | | **0.15** | **0.398** | **0.43** | **0.16** | **0.20** | **0.276** | **14** | **1.74** | | |
| **FOCUS Scenario** | **$PEC_{gl\text{-}max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D3/Ditch | 15,5 | **103** | **39.0** | **36.1** | **96.9** | **77.6** | **56.2** | **1.11** | **8.91** | | |
| D4/Pond | 1,51 | **10.1** | **3.80** | **3.51** | **9.44** | **7.56** | **5.47** | 0.108 | 0.868 | | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| D4/Stream | 15,8 | **105** | **39.7** | **36.8** | **98.8** | **79.1** | **57.3** | **1.13** | **9.09** | | |
| D5/Pond | 1,51 | **10.0** | **3.78** | **3.50** | **9.41** | **7.53** | **5.46** | 0.108 | 0.866 | | |
| D5/Stream | 16,2 | **108** | **40.6** | **37.6** | **101** | **80.8** | **58.6** | **1.15** | **9.29** | | |
| R1/Pond | 1,51 | **10.0** | **3.78** | **3.50** | **9.41** | **7.53** | **5.46** | 0.108 | 0.866 | | |
| R1/Stream | 12,5 | **83.5** | **31.5** | **29.1** | **78.3** | **62.7** | **45.4** | 0.895 | **7.20** | | |
| R2/Stream | 16,6 | **111** | **41.8** | **38.7** | **104** | **83.2** | **60.3** | **1.19** | **9.56** | | |
| R3/Stream | 17,7 | **118** | **44.5** | **41.2** | **111** | **88.7** | **64.2** | **1.27** | **10.2** | | |
| R4/Stream | 12,6 | **84.1** | **31.7** | **29.3** | **78.8** | **63.1** | **45.7** | 0.901 | **7.25** | | |

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

**FOCUS Step 4 risk assessment**

Refinement for trifloxystrobin acute invertebrates risk assessment

Acute studies on several invertebrate species have been repeated following the rejection of former studies during the AIR process because of deficiencies in the analytics. The RMS mainly criticized the recalculation of nominal test concentrations based on the mean measured concentration in the highest treatment group. Therefore, in the repeated studies analysis of all tested concentrations were performed. Additionally, to ensure an optimal exposure of the tested organisms, the studies have been repeated under semi-static conditions.

The available data on invertebrates are summarised in the table below:

| Species | $EC_{50}$ (µg/L) | Taxonomic group | Comment |
|---|---|---|---|
| *Daphnia longispina* | 2.42 | Crustacea, Diplostaca | Used in SSD |
| *Daphnia magna* | 20.0 | Crustacea, Diplostaca | Used in SSD Geomean of 2 studies |
| *Chaoborus crystallinus* | 13.21 | Insect, Diptera | Used in SSD |
| *Hyalella azteca* | 24.7 | Crustacea, Amphipoda | Used in SSD Publication, evaluated as supplemental in RAR |
| *Daphnia pulex* | 30.5 | Crustacea, Diplostaca | Used in SSD |
| *Thamnocephalus platyurus* | 37.05 | Crustacea, Anostraca | Used in SSD |
| *Cyclopidae* | 45 | Crustacea, Copepoda | Used in SSD |
| *Crassostrea virginica* | > 74.8 | Mollusc | Mortality endpoint, not used in SSD, unbound value |
| *Chydorus sp* | 83.8 | Crustacea, Diplostaca | Used in SSD |
| *Gammarus sp* | 133.9 | Crustacea, Amphipoda | Used in SSD |
| *Baetis rhodani* | 184 | Insect, Ephemeroptera | Used in SSD |
| *Procambarus acutus acutus* | > 310 | Crustacea, Decapoda | Not used in SSD, unbound value |
| *Brachionus calyciflorus* | > 1257.7 | Rotifera | Not used in SSD, unbound value |

More than 8 species are available therefore an SSD can be constructed. Unbound values are not used for the SSD but the results can be used for the discussion of the safety factor (see below). The Webfram tool (developed by DEFRA) was used for the calculations.

The goodness of fit was accepted:

### Kolmogorov Smirnov

| P-Values | Critical Values For Test Statistic | Calculated Test Statistic | Accepted or Rejected |
|---|---|---|---|
| 0.1 | 0.819 | 0.4828 | Accepted |
| 0.05 | 0.895 | 0.4828 | Accepted |
| 0.025 | 0.995 | 0.4828 | Accepted |
| 0.01 | 1.035 | 0.4828 | Accepted |

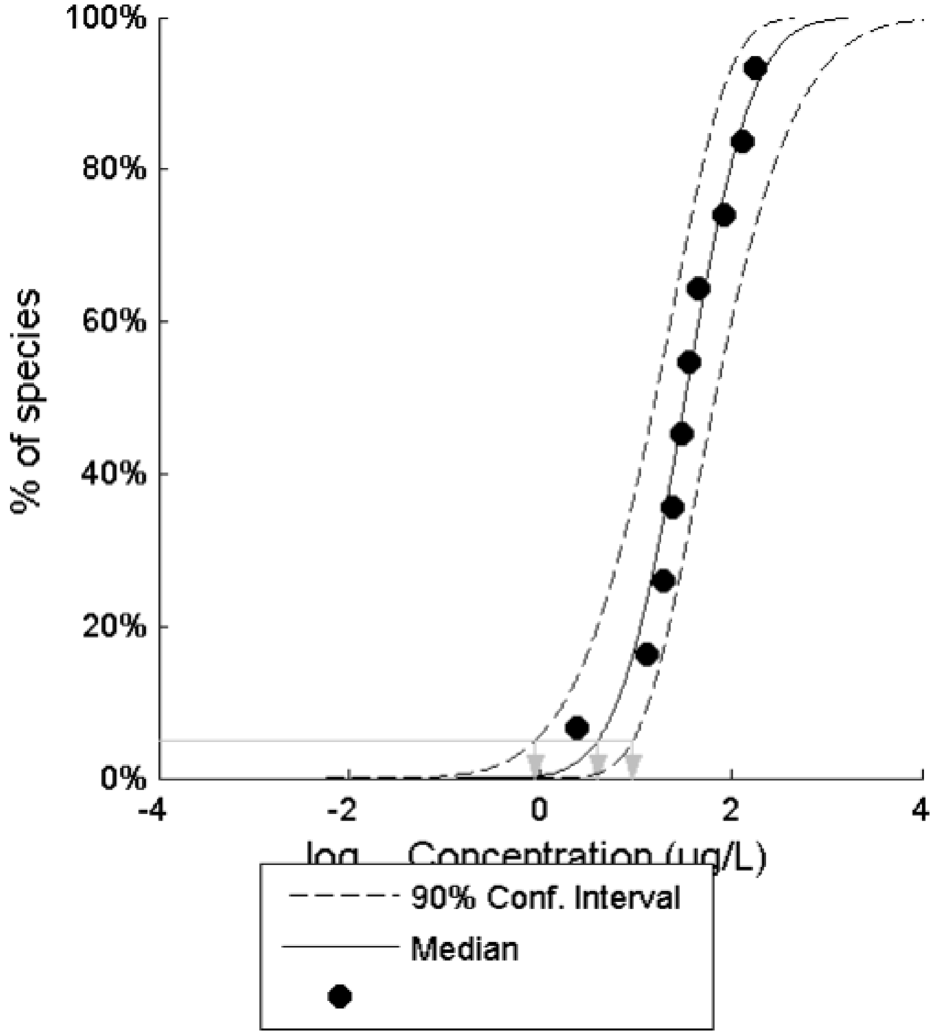
### Cramer Von Mises

| P-Values | Critical Values For Test Statistic | Calculated Test Statistic | Accepted or Rejected |
|---|---|---|---|
| 0.1 | 0.104 | 0.0255 | Accepted |
| 0.05 | 0.126 | 0.0255 | Accepted |
| 0.025 | 0.148 | 0.0255 | Accepted |
| 0.01 | 0.179 | 0.0255 | Accepted |

### Anderson Darling

| P-Values | Critical Values For Test Statistic | Accepted or Rejected |
|---|---|---|
| 0.1 | 0.631 | Accepted |
| 0.05 | 0.752 | Accepted |
| 0.025 | 0.873 | Accepted |
| 0.01 | 1.035 | Accepted |

**AD Stat: 0.2707**
**AD P-Val: 0.6755**



The $HC_5$ are as follows:

| Confidence Interval | HCx Values | | |
|---|---|---|---|
| | Lower | Median | Upper |
| 90% | 0.893 | 4.01 | 9.39 |

Discussion of the assessment factor to be applied to the $HC_5$ according to the the criteria of the Aquatic Guidance Document.
A factor between 3 and 6 is proposed in the AGD, for the discussion, they are calssified as follow: high factor: 5 or 6, medium: 4 or 5 and low 3 or 4.
1. The quality of the acute toxicity data used to construct the SSD.
As shown in the table above, different taxonomic groups were tested and data on 13 species are available, therefore a low factor can be selected.
2. The lower limit value of the $HC_5$.
The lower limit of the $HC_5$ is less than $1/3^{rd}$ of the median value: a high factor should be selected.
3. The lower tier RACs on the basis of standard toxicity data (tier 1), standard and additional toxicity data (Geomean approach) and tier 3 data.
This point is discussed below.
4. The position of the toxicity data in the lower tail of the SSD (around the $HC_5$).
The lowest endpoint is on the left side of the curve, but very close to the curve. Therefore, a medium range safety factor can be selected.
5. The steepness of the SSD curve.
The factor between the lowest and the highest point in the curve is less than 100. However, unbound values greater than the highest endpoint in the curve, have been excluded, so the curve has been artificially made steeper by selecting the most sensitive species. Therefore, a medium range safety factor can be selected.
6. Read-across information for compounds with a similar toxic mode of action.
No relevant information on higher tier studies (micro/mesocosm) is available on the other substance of the same family in Bayer'portfolio.
7. Considering information on chronic effects.
The acute to chronic ratio for trifloxystrobin on invertebrates in lower than 10. A lower factor can be selected.
To summarise, the factors selected for each criterion are as follows:

| Criterion | Factor |
|---|---|
| 1 | 3 - 4 |
| 2 | 5 - 6 |
| 4 | 4 - 5 |
| 5 | 4 - 5 |
| 7 | 3 - 4 |

The factor which the most commonly selected is 4, i.e. the lowest of the medium range since there are 2 criteria trigering a low factor and 2 trigering a medium factor against only one trigering a high factor.
**The $RAC_{ssd}$ for acute invertebrate risk assessment of trifloxystrobin is 1.0 µg a.s./L.**

According to criterion 3 of the AGD, this $RAC_{ssd}$ should not be lower than the Tier 1 RAC or a geomean RAC. No Tier 3 RAC is available for trifloxystrobin so no comparison can be made with higher tier.
The Tier 1 RAC is 0.20 µg a.s./L.
A geomean RAC based on all invertebrate species can be calculated: it is 0.33 µg/L (geomean of 33.3 µg a.s./L with an AF of 100).
This criteria is met when selecting an AF of 4 for trifloxystrobin.

In conclusion, the available $RAC_{ssd}$ of 1.0 µg a.s./L for acute invertebrates refines the Tier 1 RAC of 0.20 µg a.s./L for acute invertebrate. To reduce the amount of risk assessment tables in this dRR the

FOCUS Step 4 risk assessment is presented directly based on the next lowest RAC for chronic invertebrates of 0.276 µg a.s./L.

**zRMS comments:**

**Refined acute RAC for invertebrates for TFS was evauated for the other ppp TWIST 500 SC (Bayer Crip Science, zRMS-FR) which Core Dossier , B9 is avalible on Circa Platform.**

The endpoint derived from *Thamnocephalus platyurus* was not used for HC5 calculation because the study duration is only 24h, which is considerd as a too short exposure. In addition , the endpoint from *Hyalella azteca* came from a literature study and was considered only as supportive during the renewal of trifloxystrobin. Therefore, a data from a supportive study was considered as not robust enough to be used in the HC5 calculation.

zRMS-PL agrees with HC5 calculation comes from Registration Report for Twist 500 SC which is presented in the Table below:

**The endpoint used for HC5**

| Species | $EC_{50}$ (µg/L) | Taxonomic group | Comment |
|---|---|---|---|
| *Daphnia longispina* | 2.42 | Crustacea, Diplostaca | Used in SSD |
| *Daphnia magna* | 20.0 | Crustacea, Diplostaca | Used in SSD<br>Geomean of 2 studies |
| *Chaoborus crystallinus* | 13.21 | Insect, Diptera | Used in SSD |
| *Daphnia. pulex* | 30.5 | Crustacea, Diplostaca | Used in SSD |
| *Cyclopidae* | 45 | Crustacea, Copepoda | Used in SSD |
| *Chydorus sp* | 83.8 | Crustacea, Diplostaca | Used in SSD |
| *Gammarus sp* | 133.9 | Crustacea, Amphipoda | Used in SSD |
| *Baetis rhodani* | 184 | Insect, Ephemeroptera | Used in SSD |

The results:

| HC5 results | | | | |
|---|---|---|---|---|
| Name | Value | log10(Value) | Description | |
| LL HC5 | 0.38833631 | -0.410792 | lower estimate of the HC5 | |
| HC5 | 3.05131924 | 0.48448765 | median estimate of the HC5 | |
| UL HC5 | 8.87610288 | 0.94822233 | upper estimate of the HC5 | |
| sprHC5 | 22.8567418 | 1.35901432 | spread of the HC5 estimate | |

Statisctic evaluation:

**Anderson-Darling test for normality**

| Sign. level | Critical | Normal? | | |
|---|---|---|---|---|
| 0.1 | 0.631 | Accepted | | |
| 0.05 | 0.752 | Accepted | AD Statis-tic: | 0.22823744 |
| 0.025 | 0.873 | Accepted | n: | 8 |
| 0.01 | 1.035 | Accepted | | |

**Kolmogorov-Smirnov test for normality**

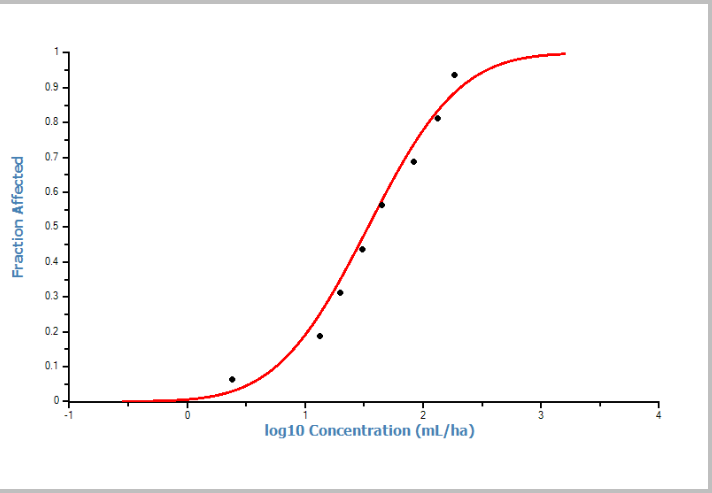
| Sign. level | Critical | Normal? | | |
|---|---|---|---|---|
| 0.1 | 0.819 | Accepted | | |
| 0.05 | 0.895 | Accepted | KS Statis-tic: | 0.38958539 |
| 0.025 | 0.995 | Accepted | n: | 8 |

| | | |
|---|---|---|
| 0.01 | 1.035 | Accepted |

Cramer von Mises test for normality

| Sign. level | Critical | Normal? |
|---|---|---|
| 0.1 | 0.104 | Accepted |
| 0.05 | 0.126 | Accepted |
| 0.025 | 0.148 | Accepted |
| 0.01 | 0.179 | Accepted |

CM Statistic: 0.01456784
n: 8




The HC5 value determined by the zRMS –FR was 3.05 µg/L.

A factor between 3 and 6 is proposed in the AGD, for the discussion, they are calssified as follow: high factor : 5 or 6, medium: 4 or 5 and low 3 or 4.

1. The quality of the acute toxicity data used to construct the SSD.

After considering the value, the zRMS-FR selected only 8 endpoint for the construction of the SSD which is the minimum number of value to conduct an SSD.

2. The lower limit value of the $HC_5$.

The lower limit of the $HC_5$ is less than 1/3$^{rd}$ of the median value: a high factor should be selected.

Lower limit HC5: 0.39

1/3$^{rd}$ of the median value : 1.02

3. According to criterion 3 of the AGD, this $RAC_{ssd}$ should not be lower than the Tier1 RAC or a geomean RAC. 3.05

The Tier 1 RAC is 0.16 µg a.s./L.

A geomean RAC based on all invertebrate species can be calculated: it is 0.34 µg/L (geomean of 34 µg a.s./L with an AF of 100).

| RAC | Factor |
|---|---|
| 3.05 | 1 |
| 1.53 | 2 |
| 1.02 | 3 |
| 0.76 | 4 |

| | |
|---|---|
| 0.61 | 5 |
| 0.51 | 6 |

This criteria is met when selecting an AF from 1 to 6.

4. The position of the toxicity data in the lower tail of the SSD (around the $HC_5$).

   The lowest endpoint is on the left side of the curve, but very close to the curve. Therefore, a medium range safety factor can be selected.

5. The steepness of the SSD curve.

   The factor between the lowest and the highest point in the curve is less than 100 (76 for the HC5 calculated by the zRMS). However, unbound values greater than the highest endpoint in the curve, have been excluded, so the curve has been artificially made steeper by selecting the most sensitive species. Therefore, a medium range safety factor can be selected.

6. Read-across information for compounds with a similar toxic mode of action.

   No relevant information on higher tier studies (micro/mesocosm) is available on the other substance of the same family.

7. Considering information on chronic effects.

   The acute to chronic ratio for trifloxystrobin on invertebrates in lower than 10 (1.2)  A lower factor can be selected.

To summarise, the factors selected for each criterion were as follows:

| Criterion | Factor |
|---|---|
| 1 | 3 - **4** |
| 2 | 5 - **6** |
| 4 | **4** - 5 |
| 5 | **4** - 5 |
| 7 | **3** - 4 |

Hence  agreed factor  was 4.

**The $RAC_{ssd}$ for acute invertebrate risk assessment of trifloxystrobin is  agreed  0.76 µg a.s./L.**

Considering the refine acute RAC for aquatic invertebrates ($RAC_{ssd}$ = 0.76 µg a.s./L), the lowest RAC which has to be used in the refined risk assessment is the chronic RAC value of 0.276 µg a.s./L for aquatic invertebrates.

A FOCUS Step 4 risk assessment is presented for all crops as different mitigation measures per crop group are needed.

**Table 9.5-9: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in asparagus, garden cress, flower tubers and ornamentals (asparagus, garden cress, flower tubers, ornamentals; modelling use field beans I -- field beans (early) -- 0.2 kg a.s./ha)**

| **Intended use** | | asparagus, garden cress, flower tubers, ornamentals | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 1 x 200 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 | D2 Ditch | 1.05 | 0.345 | 0.183 | 0.095 | 0.183 | 0.095 | | |
| 50 % | | 0.526 | 0.172 | 0.091 | 0.048 | 0.091 | 0.048 | | |
| 75 % | | 0.263 | 0.086 | 0.046 | 0.024 | 0.046 | 0.024 | | |
| 90 % | | 0.105 | 0.034 | 0.018 | 0.010 | 0.018 | 0.010 | | |
| None | D2 Stream | 0.876 | 0.369 | 0.196 | 0.102 | 0.196 | 0.102 | | |
| 50 % | | 0.438 | 0.185 | 0.098 | 0.051 | 0.098 | 0.051 | | |
| 75 % | | 0.219 | 0.092 | 0.049 | 0.025 | 0.049 | 0.025 | | |
| 90 % | | 0.088 | 0.037 | 0.020 | 0.010 | 0.020 | 0.010 | | |
| None | D3 Ditch | 1.05 | 0.343 | 0.182 | 0.095 | 0.182 | 0.095 | | |
| 50 % | | 0.524 | 0.172 | 0.091 | 0.047 | 0.091 | 0.047 | | |
| 75 % | | 0.262 | 0.086 | 0.046 | 0.024 | 0.046 | 0.024 | | |
| 90 % | | 0.105 | 0.034 | 0.018 | 0.010 | 0.018 | 0.010 | | |
| None | D4 Pond | 0.042 | 0.038 | 0.027 | 0.018 | 0.027 | 0.018 | | |
| 50 % | | 0.021 | 0.019 | 0.014 | 0.009 | 0.014 | 0.009 | | |
| 75 % | | 0.011 | 0.009 | 0.007 | 0.005 | 0.007 | 0.005 | | |
| 90 % | | 0.004 | 0.004 | 0.003 | 0.002 | 0.003 | 0.002 | | |
| None | D4 Stream | 0.841 | 0.354 | 0.188 | 0.098 | 0.188 | 0.098 | | |
| 50 % | | 0.420 | 0.177 | 0.094 | 0.049 | 0.094 | 0.049 | | |
| 75 % | | 0.210 | 0.089 | 0.047 | 0.024 | 0.047 | 0.024 | | |
| 90 % | | 0.084 | 0.035 | 0.019 | 0.010 | 0.019 | 0.010 | | |
| None | D6 Ditch | 1.04 | 0.340 | 0.180 | 0.094 | 0.180 | 0.094 | | |
| 50 % | | 0.519 | 0.170 | 0.090 | 0.047 | 0.090 | 0.047 | | |
| 75 % | | 0.259 | 0.085 | 0.045 | 0.023 | 0.045 | 0.023 | | |
| 90 % | | 0.104 | 0.034 | 0.018 | 0.009 | 0.018 | 0.009 | | |
| None | D6 Ditch 2nd | 1.03 | 0.336 | 0.178 | 0.093 | 0.178 | 0.093 | | |
| 50 % | | 0.513 | 0.168 | 0.089 | 0.046 | 0.089 | 0.046 | | |
| 75 % | | 0.257 | 0.084 | 0.045 | 0.023 | 0.045 | 0.023 | | |
| 90 % | | 0.103 | 0.034 | 0.018 | 0.009 | 0.018 | 0.009 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| None | R1 Pond | 0.042 | 0.038 | 0.027 | 0.018 | 0.027 | 0.018 | | |
| 50 % | | 0.021 | 0.019 | 0.014 | 0.009 | 0.014 | 0.009 | | |
| 75 % | | 0.011 | 0.009 | 0.007 | 0.005 | 0.007 | 0.005 | | |
| 90 % | | 0.004 | 0.004 | 0.003 | 0.002 | 0.003 | 0.002 | | |
| None | R1 Stream | 0.722 | 0.304 | 0.161 | 0.084 | 0.161 | 0.084 | | |
| 50 % | | 0.361 | 0.152 | 0.081 | 0.042 | 0.081 | 0.042 | | |
| 75 % | | 0.181 | 0.076 | 0.040 | 0.021 | 0.040 | 0.021 | | |
| 90 % | | 0.072 | 0.030 | 0.016 | 0.008 | 0.016 | 0.008 | | |
| None | R2 Stream | 0.956 | 0.402 | 0.213 | 0.111 | 0.213 | 0.111 | | |
| 50 % | | 0.478 | 0.201 | 0.107 | 0.055 | 0.107 | 0.055 | | |
| 75 % | | 0.239 | 0.101 | 0.053 | 0.028 | 0.053 | 0.028 | | |
| 90 % | | 0.096 | 0.040 | 0.021 | 0.011 | 0.021 | 0.011 | | |
| None | R3 Stream | 1.02 | 0.430 | 0.228 | 0.119 | 0.228 | 0.119 | | |
| 50 % | | 0.511 | 0.215 | 0.114 | 0.059 | 0.114 | 0.059 | | |
| 75 % | | 0.255 | 0.108 | 0.057 | 0.030 | 0.057 | 0.030 | | |
| 90 % | | 0.102 | 0.043 | 0.023 | 0.012 | 0.023 | 0.012 | | |
| None | R4 Stream | 0.724 | 0.305 | 0.162 | 0.084 | 0.162 | 0.084 | | |
| 50 % | | 0.362 | 0.152 | 0.081 | 0.042 | 0.081 | 0.042 | | |
| 75 % | | 0.181 | 0.076 | 0.040 | 0.039 | 0.040 | 0.021 | | |
| 90 % | | 0.072 | 0.039 | 0.039 | 0.039 | 0.018 | 0.009 | | |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D2 Ditch | **3.81** | **1.25** | 0.662 | 0.344 | 0.662 | 0.344 | | |
| 50 % | | **1.90** | 0.624 | 0.331 | 0.172 | 0.331 | 0.172 | | |
| 75 % | | 0.952 | 0.312 | 0.166 | 0.086 | 0.166 | 0.086 | | |
| 90 % | | 0.381 | 0.125 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | D2 Stream | **3.18** | **1.34** | 0.709 | 0.368 | 0.709 | 0.368 | | |
| 50 % | | **1.59** | 0.668 | 0.354 | 0.184 | 0.354 | 0.184 | | |
| 75 % | | 0.794 | 0.334 | 0.177 | 0.092 | 0.177 | 0.092 | | |
| 90 % | | 0.317 | 0.134 | 0.071 | 0.037 | 0.071 | 0.037 | | |
| None | D3 Ditch | **3.79** | **1.24** | 0.659 | 0.342 | 0.659 | 0.342 | | |
| 50 % | | **1.90** | 0.622 | 0.330 | 0.171 | 0.330 | 0.171 | | |
| 75 % | | 0.948 | 0.311 | 0.165 | 0.086 | 0.165 | 0.086 | | |
| 90 % | | 0.379 | 0.124 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | D4 Pond | 0.153 | 0.137 | 0.098 | 0.066 | 0.098 | 0.066 | | |
| 50 % | | 0.076 | 0.068 | 0.049 | 0.033 | 0.049 | 0.033 | | |
| 75 % | | 0.038 | 0.034 | 0.025 | 0.016 | 0.025 | 0.016 | | |
| 90 % | | 0.015 | 0.014 | 0.010 | 0.007 | 0.010 | 0.007 | | |
| None | D4 Stream | **3.05** | **1.28** | 0.680 | 0.353 | 0.680 | 0.353 | | |
| 50 % | | **1.52** | 0.641 | 0.340 | 0.177 | 0.340 | 0.177 | | |
| 75 % | | 0.761 | 0.321 | 0.170 | 0.088 | 0.170 | 0.088 | | |
| 90 % | | 0.304 | 0.128 | 0.068 | 0.036 | 0.068 | 0.036 | | |
| None | D6 Ditch | **3.76** | **1.23** | 0.654 | 0.339 | 0.654 | 0.339 | | |
| 50 % | | **1.88** | 0.616 | 0.327 | 0.170 | 0.327 | 0.170 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 75 % | | 0.940 | 0.308 | 0.163 | 0.085 | 0.163 | 0.085 | | |
| 90 % | | 0.376 | 0.123 | 0.065 | 0.034 | 0.065 | 0.034 | | |
| None | D6 Ditch 2nd | **3.72** | **1.22** | 0.646 | 0.336 | 0.646 | 0.336 | | |
| 50 % | | **1.86** | 0.609 | 0.323 | 0.168 | 0.323 | 0.168 | | |
| 75 % | | 0.929 | 0.305 | 0.162 | 0.084 | 0.162 | 0.084 | | |
| 90 % | | 0.372 | 0.122 | 0.064 | 0.034 | 0.064 | 0.034 | | |
| None | R1 Pond | 0.153 | 0.137 | 0.098 | 0.066 | 0.098 | 0.066 | | |
| 50 % | | 0.076 | 0.068 | 0.049 | 0.033 | 0.049 | 0.033 | | |
| 75 % | | 0.038 | 0.034 | 0.025 | 0.016 | 0.025 | 0.016 | | |
| 90 % | | 0.015 | 0.014 | 0.010 | 0.007 | 0.010 | 0.007 | | |
| None | R1 Stream | **2.62** | **1.10** | 0.584 | 0.304 | 0.584 | 0.304 | | |
| 50 % | | **1.31** | 0.551 | 0.292 | 0.152 | 0.292 | 0.152 | | |
| 75 % | | 0.654 | 0.275 | 0.146 | 0.076 | 0.146 | 0.076 | | |
| 90 % | | 0.262 | 0.110 | 0.058 | 0.030 | 0.058 | 0.030 | | |
| None | R2 Stream | **3.46** | **1.46** | 0.773 | 0.402 | 0.773 | 0.402 | | |
| 50 % | | **1.73** | 0.729 | 0.387 | 0.201 | 0.387 | 0.201 | | |
| 75 % | | 0.866 | 0.364 | 0.193 | 0.100 | 0.193 | 0.100 | | |
| 90 % | | 0.346 | 0.146 | 0.077 | 0.040 | 0.077 | 0.040 | | |
| None | R3 Stream | **3.70** | **1.56** | 0.826 | 0.429 | 0.826 | 0.429 | | |
| 50 % | | **1.85** | 0.779 | 0.413 | 0.215 | 0.413 | 0.215 | | |
| 75 % | | 0.925 | 0.389 | 0.207 | 0.107 | 0.207 | 0.107 | | |
| 90 % | | 0.370 | 0.156 | 0.083 | 0.043 | 0.083 | 0.043 | | |
| None | R4 Stream | **2.62** | **1.10** | 0.586 | 0.304 | 0.586 | 0.304 | | |
| 50 % | | **1.31** | 0.552 | 0.293 | 0.152 | 0.293 | 0.152 | | |
| 75 % | | 0.655 | 0.276 | 0.146 | 0.139 | 0.146 | 0.076 | | |
| 90 % | | 0.262 | 0.139 | 0.139 | 0.139 | 0.063 | 0.033 | | |

PEC: predicted environmental concentration
RAC: regulatory acceptable concentration
PEC/RAC ratios above the relevant trigger of 1 are shown in bold

**Table 9.5-10: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in asparagus, garden cress, flower tubers and ornamentals (asparagus, garden cress, flower tubers, ornamentals; modelling use field beans I -- field beans (late) -- 0.2 kg a.s./ha)**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Intended use**<br>**Active substance**<br>**Application rate (g/ha)** | | asparagus, garden cress, flower tubers, ornamentals<br>trifloxystrobin<br>1 x 200 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 | D2 Ditch | 1.06 | 0.347 | 0.184 | 0.096 | 0.184 | 0.096 | | |
| 50 % | | 0.530 | 0.174 | 0.092 | 0.048 | 0.092 | 0.048 | | |
| 75 % | | 0.265 | 0.087 | 0.046 | 0.024 | 0.046 | 0.024 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 90 % | | 0.106 | 0.035 | 0.018 | 0.010 | 0.018 | 0.010 | | |
| None | D2 Stream | 0.989 | 0.416 | 0.221 | 0.115 | 0.221 | 0.115 | | |
| 50 % | | 0.495 | 0.208 | 0.110 | 0.057 | 0.110 | 0.057 | | |
| 75 % | | 0.247 | 0.104 | 0.055 | 0.029 | 0.055 | 0.029 | | |
| 90 % | | 0.099 | 0.042 | 0.022 | 0.012 | 0.022 | 0.012 | | |
| None | D3 Ditch | 1.05 | 0.344 | 0.183 | 0.095 | 0.183 | 0.095 | | |
| 50 % | | 0.525 | 0.172 | 0.091 | 0.048 | 0.091 | 0.048 | | |
| 75 % | | 0.263 | 0.086 | 0.046 | 0.024 | 0.046 | 0.024 | | |
| 90 % | | 0.105 | 0.034 | 0.018 | 0.010 | 0.018 | 0.010 | | |
| None | D4 Pond | 0.042 | 0.038 | 0.027 | 0.018 | 0.027 | 0.018 | | |
| 50 % | | 0.021 | 0.019 | 0.014 | 0.009 | 0.014 | 0.009 | | |
| 75 % | | 0.011 | 0.009 | 0.007 | 0.005 | 0.007 | 0.005 | | |
| 90 % | | 0.004 | 0.004 | 0.003 | 0.002 | 0.003 | 0.002 | | |
| None | D4 Stream | 0.911 | 0.384 | 0.203 | 0.106 | 0.203 | 0.106 | | |
| 50 % | | 0.455 | 0.192 | 0.102 | 0.053 | 0.102 | 0.053 | | |
| 75 % | | 0.228 | 0.096 | 0.051 | 0.026 | 0.051 | 0.026 | | |
| 90 % | | 0.091 | 0.038 | 0.020 | 0.011 | 0.020 | 0.011 | | |
| None | D6 Ditch | 1.05 | 0.346 | 0.183 | 0.095 | 0.183 | 0.095 | | |
| 50 % | | 0.527 | 0.173 | 0.092 | 0.048 | 0.092 | 0.048 | | |
| 75 % | | 0.264 | 0.086 | 0.046 | 0.024 | 0.046 | 0.024 | | |
| 90 % | | 0.105 | 0.035 | 0.018 | 0.010 | 0.018 | 0.010 | | |
| None | D6 Ditch 2nd | 1.05 | 0.344 | 0.182 | 0.095 | 0.182 | 0.095 | | |
| 50 % | | 0.525 | 0.172 | 0.091 | 0.047 | 0.091 | 0.047 | | |
| 75 % | | 0.262 | 0.086 | 0.046 | 0.024 | 0.046 | 0.024 | | |
| 90 % | | 0.105 | 0.034 | 0.018 | 0.010 | 0.018 | 0.010 | | |
| None | R1 Pond | 0.042 | 0.038 | 0.027 | 0.018 | 0.027 | 0.018 | | |
| 50 % | | 0.021 | 0.019 | 0.014 | 0.009 | 0.014 | 0.009 | | |
| 75 % | | 0.011 | 0.009 | 0.007 | 0.005 | 0.007 | 0.005 | | |
| 90 % | | 0.004 | 0.004 | 0.003 | 0.002 | 0.003 | 0.002 | | |
| None | R1 Stream | 0.726 | 0.306 | 0.162 | 0.084 | 0.162 | 0.084 | | |
| 50 % | | 0.363 | 0.153 | 0.081 | 0.042 | 0.081 | 0.042 | | |
| 75 % | | 0.182 | 0.076 | 0.041 | 0.021 | 0.041 | 0.021 | | |
| 90 % | | 0.073 | 0.031 | 0.016 | 0.008 | 0.016 | 0.008 | | |
| None | R2 Stream | 0.973 | 0.410 | 0.217 | 0.113 | 0.217 | 0.113 | | |
| 50 % | | 0.487 | 0.205 | 0.109 | 0.057 | 0.109 | 0.057 | | |
| 75 % | | 0.243 | 0.102 | 0.054 | 0.028 | 0.054 | 0.028 | | |
| 90 % | | 0.097 | 0.041 | 0.022 | 0.011 | 0.022 | 0.011 | | |
| None | R3 Stream | 1.02 | 0.431 | 0.229 | 0.119 | 0.229 | 0.119 | | |
| 50 % | | 0.512 | 0.215 | 0.114 | 0.059 | 0.114 | 0.059 | | |
| 75 % | | 0.256 | 0.108 | 0.057 | 0.030 | 0.057 | 0.030 | | |
| 90 % | | 0.102 | 0.043 | 0.023 | 0.012 | 0.023 | 0.012 | | |
| None | R4 Stream | 0.711 | 0.299 | 0.159 | 0.082 | 0.159 | 0.082 | | |
| 50 % | | 0.355 | 0.150 | 0.079 | 0.041 | 0.079 | 0.041 | | |
| 75 % | | 0.178 | 0.075 | 0.040 | 0.021 | 0.040 | 0.021 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 90 % | | 0.071 | 0.030 | 0.016 | 0.008 | 0.016 | 0.008 | | |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D2 Ditch | **3.84** | **1.26** | 0.667 | 0.347 | 0.667 | 0.347 | | |
| 50 % | | **1.92** | 0.629 | 0.334 | 0.174 | 0.334 | 0.174 | | |
| 75 % | | 0.960 | 0.314 | 0.167 | 0.087 | 0.167 | 0.087 | | |
| 90 % | | 0.384 | 0.126 | 0.067 | 0.035 | 0.067 | 0.035 | | |
| None | D2 Stream | **3.58** | **1.51** | 0.800 | 0.416 | 0.800 | 0.416 | | |
| 50 % | | **1.79** | 0.754 | 0.400 | 0.208 | 0.400 | 0.208 | | |
| 75 % | | 0.896 | 0.377 | 0.200 | 0.104 | 0.200 | 0.104 | | |
| 90 % | | 0.358 | 0.151 | 0.080 | 0.042 | 0.080 | 0.042 | | |
| None | D3 Ditch | **3.81** | **1.25** | 0.662 | 0.344 | 0.662 | 0.344 | | |
| 50 % | | **1.90** | 0.624 | 0.331 | 0.172 | 0.331 | 0.172 | | |
| 75 % | | 0.952 | 0.312 | 0.166 | 0.086 | 0.166 | 0.086 | | |
| 90 % | | 0.381 | 0.125 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | D4 Pond | 0.153 | 0.137 | 0.099 | 0.066 | 0.099 | 0.066 | | |
| 50 % | | 0.076 | 0.068 | 0.049 | 0.033 | 0.049 | 0.033 | | |
| 75 % | | 0.038 | 0.034 | 0.025 | 0.016 | 0.025 | 0.016 | | |
| 90 % | | 0.015 | 0.014 | 0.010 | 0.007 | 0.010 | 0.007 | | |
| None | D4 Stream | **3.30** | **1.39** | 0.737 | 0.383 | 0.737 | 0.383 | | |
| 50 % | | **1.65** | 0.695 | 0.368 | 0.191 | 0.368 | 0.191 | | |
| 75 % | | 0.825 | 0.347 | 0.184 | 0.096 | 0.184 | 0.096 | | |
| 90 % | | 0.330 | 0.139 | 0.074 | 0.038 | 0.074 | 0.038 | | |
| None | D6 Ditch | **3.82** | **1.25** | 0.664 | 0.345 | 0.664 | 0.345 | | |
| 50 % | | **1.91** | 0.626 | 0.332 | 0.172 | 0.332 | 0.172 | | |
| 75 % | | 0.955 | 0.313 | 0.166 | 0.086 | 0.166 | 0.086 | | |
| 90 % | | 0.382 | 0.125 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | D6 Ditch 2nd | **3.80** | **1.25** | 0.661 | 0.343 | 0.661 | 0.343 | | |
| 50 % | | **1.90** | 0.623 | 0.330 | 0.172 | 0.330 | 0.172 | | |
| 75 % | | 0.950 | 0.312 | 0.165 | 0.086 | 0.165 | 0.086 | | |
| 90 % | | 0.380 | 0.125 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | R1 Pond | 0.153 | 0.137 | 0.098 | 0.066 | 0.098 | 0.066 | | |
| 50 % | | 0.076 | 0.068 | 0.049 | 0.033 | 0.049 | 0.033 | | |
| 75 % | | 0.038 | 0.034 | 0.025 | 0.016 | 0.025 | 0.016 | | |
| 90 % | | 0.015 | 0.014 | 0.010 | 0.007 | 0.010 | 0.007 | | |
| None | R1 Stream | **2.63** | **1.11** | 0.587 | 0.305 | 0.587 | 0.305 | | |
| 50 % | | **1.32** | 0.554 | 0.293 | 0.153 | 0.293 | 0.153 | | |
| 75 % | | 0.658 | 0.277 | 0.147 | 0.076 | 0.147 | 0.076 | | |
| 90 % | | 0.263 | 0.111 | 0.059 | 0.030 | 0.059 | 0.030 | | |
| None | R2 Stream | **3.53** | **1.48** | 0.787 | 0.409 | 0.787 | 0.409 | | |
| 50 % | | **1.76** | 0.742 | 0.393 | 0.205 | 0.393 | 0.205 | | |
| 75 % | | 0.882 | 0.371 | 0.197 | 0.102 | 0.197 | 0.102 | | |
| 90 % | | 0.353 | 0.149 | 0.079 | 0.041 | 0.079 | 0.041 | | |
| None | R3 Stream | **3.71** | **1.56** | 0.828 | 0.430 | 0.828 | 0.430 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 50 % | | **1.85** | 0.780 | 0.414 | 0.215 | 0.414 | 0.215 | | |
| 75 % | | 0.927 | 0.390 | 0.207 | 0.108 | 0.207 | 0.108 | | |
| 90 % | | 0.371 | 0.156 | 0.083 | 0.043 | 0.083 | 0.043 | | |
| None | R4 Stream | **2.57** | **1.08** | 0.575 | 0.299 | 0.575 | 0.299 | | |
| 50 % | | **1.29** | 0.542 | 0.287 | 0.149 | 0.287 | 0.149 | | |
| 75 % | | 0.643 | 0.271 | 0.144 | 0.075 | 0.144 | 0.075 | | |
| 90 % | | 0.257 | 0.108 | 0.058 | 0.030 | 0.058 | 0.030 | | |

PEC: predicted environmental concentration
RAC: regulatory acceptable concentration
PEC/RAC ratios above the relevant trigger of 1 are shown in bold

**Table 9.5-11: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in beans and nurseries (beans and nurseries; modelling use field beans II -- field beans II, BBCH 19 -- 2×0.2 kg a.s./ha, 14d int.)**

| **Intended use** | | beans and nurseries | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 2 x 200 g/ha, 14d int. | | | | | | | |
| 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 | D2 Ditch | 1.05 | 0.345 | 0.183 | 0.095 | 0.183 | 0.095 | | |
| 50 % | | 0.526 | 0.172 | 0.091 | 0.048 | 0.091 | 0.048 | | |
| 75 % | | 0.263 | 0.086 | 0.046 | 0.024 | 0.046 | 0.024 | | |
| 90 % | | 0.105 | 0.034 | 0.018 | 0.010 | 0.018 | 0.010 | | |
| None | D2 Stream | 0.876 | 0.369 | 0.196 | 0.102 | 0.196 | 0.102 | | |
| 50 % | | 0.438 | 0.185 | 0.098 | 0.051 | 0.098 | 0.051 | | |
| 75 % | | 0.219 | 0.092 | 0.049 | 0.025 | 0.049 | 0.025 | | |
| 90 % | | 0.088 | 0.037 | 0.020 | 0.010 | 0.020 | 0.010 | | |
| None | D3 Ditch | 1.05 | 0.343 | 0.182 | 0.095 | 0.182 | 0.095 | | |
| 50 % | | 0.524 | 0.172 | 0.091 | 0.047 | 0.091 | 0.047 | | |
| 75 % | | 0.262 | 0.086 | 0.046 | 0.024 | 0.046 | 0.024 | | |
| 90 % | | 0.105 | 0.034 | 0.018 | 0.010 | 0.018 | 0.010 | | |
| None | D4 Pond | *0.057* | *0.051* | *0.036* | *0.024* | *0.036* | *0.024* | | |
| 50 % | | *0.029* | *0.025* | *0.018* | *0.012* | *0.018* | *0.012* | | |
| 75 % | | *0.014* | *0.013* | *0.009* | *0.006* | *0.009* | *0.006* | | |
| 90 % | | *0.006* | *0.005* | *0.004* | *0.002* | *0.004* | *0.002* | | |
| None | D4 Stream | 0.898 | 0.378 | 0.200 | 0.104 | 0.200 | 0.104 | | |
| 50 % | | 0.449 | 0.189 | 0.100 | 0.052 | 0.100 | 0.052 | | |
| 75 % | | 0.224 | 0.095 | 0.050 | 0.026 | 0.050 | 0.026 | | |
| 90 % | | 0.090 | 0.038 | 0.020 | 0.010 | 0.020 | 0.010 | | |
| None | D6 Ditch | 1.03 | 0.339 | 0.180 | 0.093 | 0.180 | 0.093 | | |
| 50 % | | 0.517 | 0.169 | 0.090 | 0.047 | 0.090 | 0.047 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 75 % | | 0.258 | 0.085 | 0.045 | 0.023 | 0.045 | 0.023 | | |
| 90 % | | 0.103 | 0.034 | 0.018 | 0.009 | 0.018 | 0.009 | | |
| None | D6 Ditch 2nd | 1.03 | 0.337 | 0.179 | 0.093 | 0.179 | 0.093 | | |
| 50 % | | 0.515 | 0.169 | 0.089 | 0.047 | 0.089 | 0.047 | | |
| 75 % | | 0.257 | 0.084 | 0.045 | 0.023 | 0.045 | 0.023 | | |
| 90 % | | 0.103 | 0.034 | 0.018 | 0.009 | 0.018 | 0.009 | | |
| None | R1 Pond | *0.049* | *0.043* | *0.031* | *0.020* | *0.031* | *0.020* | | |
| 50 % | | *0.025* | *0.022* | *0.016* | *0.012* | *0.016* | *0.010* | | |
| 75 % | | *0.013* | *0.012* | *0.010* | *0.008* | *0.008* | *0.005* | | |
| 90 % | | *0.008* | *0.007* | *0.006* | *0.005* | *0.004* | *0.002* | | |
| None | R1 Stream | 0.715 | 0.301 | 0.160 | 0.083 | 0.160 | 0.083 | | |
| 50 % | | 0.358 | 0.151 | 0.080 | *0.047* | 0.080 | 0.042 | | |
| 75 % | | 0.179 | 0.075 | *0.047* | *0.047* | 0.040 | 0.021 | | |
| 90 % | | 0.072 | *0.047* | *0.047* | *0.047* | *0.021* | *0.011* | | |
| None | R2 Stream | 0.958 | 0.403 | 0.214 | 0.111 | 0.214 | 0.111 | | |
| 50 % | | 0.479 | 0.202 | 0.107 | 0.056 | 0.107 | 0.056 | | |
| 75 % | | 0.239 | 0.101 | 0.054 | *0.043* | 0.054 | 0.028 | | |
| 90 % | | 0.096 | *0.043* | *0.043* | *0.043* | 0.021 | 0.011 | | |
| None | R3 Stream | 1.02 | 0.430 | 0.228 | 0.119 | 0.228 | 0.119 | | |
| 50 % | | 0.511 | 0.215 | 0.114 | 0.067 | 0.114 | 0.059 | | |
| 75 % | | 0.255 | 0.108 | 0.067 | 0.067 | 0.057 | 0.030 | | |
| 90 % | | 0.102 | 0.067 | 0.067 | 0.067 | 0.030 | 0.016 | | |
| None | R4 Stream | 0.724 | 0.305 | 0.283 | 0.283 | 0.162 | 0.084 | | |
| 50 % | | 0.362 | 0.283 | 0.283 | 0.283 | 0.129 | 0.067 | | |
| 75 % | | 0.283 | 0.283 | 0.283 | 0.283 | 0.129 | 0.067 | | |
| 90 % | | 0.283 | 0.283 | 0.283 | 0.283 | 0.129 | 0.067 | | |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D2 Ditch | **3.81** | **1.25** | 0.662 | 0.344 | 0.662 | 0.344 | | |
| 50 % | | **1.90** | 0.624 | 0.331 | 0.172 | 0.331 | 0.172 | | |
| 75 % | | 0.952 | 0.312 | 0.166 | 0.086 | 0.166 | 0.086 | | |
| 90 % | | 0.381 | 0.125 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | D2 Stream | **3.18** | **1.34** | 0.709 | 0.368 | 0.709 | 0.368 | | |
| 50 % | | **1.59** | 0.668 | 0.354 | 0.184 | 0.354 | 0.184 | | |
| 75 % | | 0.794 | 0.334 | 0.177 | 0.092 | 0.177 | 0.092 | | |
| 90 % | | 0.317 | 0.134 | 0.071 | 0.037 | 0.071 | 0.037 | | |
| None | D3 Ditch | **3.80** | **1.24** | 0.660 | 0.343 | 0.660 | 0.343 | | |
| 50 % | | **1.90** | 0.622 | 0.330 | 0.171 | 0.330 | 0.171 | | |
| 75 % | | 0.949 | 0.311 | 0.165 | 0.086 | 0.165 | 0.086 | | |
| 90 % | | 0.379 | 0.124 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | D4 Pond | 0.208 | 0.184 | 0.131 | 0.086 | 0.131 | 0.086 | | |
| 50 % | | 0.104 | 0.092 | 0.065 | 0.043 | 0.065 | 0.043 | | |
| 75 % | | 0.052 | 0.046 | 0.033 | 0.021 | 0.033 | 0.021 | | |
| 90 % | | 0.021 | 0.018 | 0.013 | 0.009 | 0.013 | 0.009 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| None | D4 Stream | **3.25** | **1.37** | 0.726 | 0.377 | 0.726 | 0.377 | | |
| 50 % | | **1.63** | 0.684 | 0.363 | 0.189 | 0.363 | 0.189 | | |
| 75 % | | 0.813 | 0.342 | 0.182 | 0.094 | 0.182 | 0.094 | | |
| 90 % | | 0.325 | 0.137 | 0.072 | 0.038 | 0.072 | 0.038 | | |
| None | D6 Ditch | **3.74** | **1.23** | 0.650 | 0.338 | 0.650 | 0.338 | | |
| 50 % | | **1.87** | 0.613 | 0.325 | 0.169 | 0.325 | 0.169 | | |
| 75 % | | 0.936 | 0.307 | 0.163 | 0.084 | 0.163 | 0.084 | | |
| 90 % | | 0.374 | 0.123 | 0.065 | 0.034 | 0.065 | 0.034 | | |
| None | D6 Ditch 2nd | **3.73** | **1.22** | 0.648 | 0.337 | 0.648 | 0.337 | | |
| 50 % | | **1.86** | 0.611 | 0.324 | 0.168 | 0.324 | 0.168 | | |
| 75 % | | 0.932 | 0.305 | 0.162 | 0.084 | 0.162 | 0.084 | | |
| 90 % | | 0.373 | 0.122 | 0.065 | 0.034 | 0.065 | 0.034 | | |
| None | R1 Pond | 0.177 | 0.157 | 0.112 | 0.074 | 0.112 | 0.073 | | |
| 50 % | | 0.089 | 0.079 | 0.057 | 0.042 | 0.056 | 0.037 | | |
| 75 % | | 0.048 | 0.044 | 0.035 | 0.028 | 0.028 | 0.018 | | |
| 90 % | | 0.027 | 0.026 | 0.022 | 0.019 | 0.014 | 0.008 | | |
| None | R1 Stream | **2.59** | **1.09** | 0.579 | 0.301 | 0.579 | 0.301 | | |
| 50 % | | **1.30** | 0.546 | 0.289 | 0.171 | 0.289 | 0.150 | | |
| 75 % | | 0.648 | 0.273 | 0.171 | 0.171 | 0.145 | 0.075 | | |
| 90 % | | 0.259 | 0.171 | 0.171 | 0.171 | 0.078 | 0.041 | | |
| None | R2 Stream | **3.47** | **1.46** | 0.775 | 0.403 | 0.775 | 0.403 | | |
| 50 % | | **1.74** | 0.731 | 0.387 | 0.201 | 0.387 | 0.201 | | |
| 75 % | | 0.867 | 0.365 | 0.194 | 0.154 | 0.194 | 0.101 | | |
| 90 % | | 0.347 | 0.154 | 0.154 | 0.154 | 0.078 | 0.040 | | |
| None | R3 Stream | **3.70** | **1.56** | 0.826 | 0.429 | 0.826 | 0.429 | | |
| 50 % | | **1.85** | 0.779 | 0.413 | 0.241 | 0.413 | 0.215 | | |
| 75 % | | 0.925 | 0.389 | 0.241 | 0.241 | 0.207 | 0.107 | | |
| 90 % | | 0.370 | 0.241 | 0.241 | 0.241 | 0.110 | 0.058 | | |
| None | R4 Stream | **2.62** | **1.10** | **1.02** | **1.02** | 0.586 | 0.304 | | |
| 50 % | | **1.31** | **1.02** | **1.02** | **1.02** | 0.466 | 0.244 | | |
| 75 % | | **1.02** | **1.02** | **1.02** | **1.02** | 0.466 | 0.244 | | |
| 90 % | | **1.02** | **1.02** | **1.02** | **1.02** | 0.466 | 0.244 | | |

* 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 9.5-12: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in beans and nurseries (beans and nurseries; modelling use field beans II -- field beans II, BBCH 89 -- 2×0.2 kg a.s./ha, 14d int.)**

| | |
|---|---|
| **Intended use** | beans and nurseries |
| **Active substance** | trifloxystrobin |

| **Application rate (g/ha)** | | 2 x 200 g/ha, 14d int. | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 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 | D2 Ditch | 1.06 | 0.347 | 0.184 | 0.096 | 0.184 | 0.096 | | |
| 50 % | | 0.530 | 0.174 | 0.092 | 0.048 | 0.092 | 0.048 | | |
| 75 % | | 0.265 | 0.087 | 0.046 | 0.024 | 0.046 | 0.024 | | |
| 90 % | | 0.106 | 0.035 | 0.018 | 0.010 | 0.018 | 0.010 | | |
| None | D2 Stream | 0.989 | 0.416 | 0.221 | 0.115 | 0.221 | 0.115 | | |
| 50 % | | 0.495 | 0.208 | 0.110 | 0.057 | 0.110 | 0.057 | | |
| 75 % | | 0.247 | 0.104 | 0.055 | 0.029 | 0.055 | 0.029 | | |
| 90 % | | 0.099 | 0.042 | 0.022 | 0.012 | 0.022 | 0.012 | | |
| None | D3 Ditch | 1.05 | 0.344 | 0.182 | 0.095 | 0.182 | 0.095 | | |
| 50 % | | 0.525 | 0.172 | 0.091 | 0.047 | 0.091 | 0.047 | | |
| 75 % | | 0.262 | 0.086 | 0.046 | 0.024 | 0.046 | 0.024 | | |
| 90 % | | 0.105 | 0.034 | 0.018 | 0.010 | 0.018 | 0.010 | | |
| None | D4 Pond | *0.059* | *0.052* | *0.037* | *0.024* | *0.037* | *0.024* | | |
| 50 % | | *0.029* | *0.026* | *0.019* | *0.012* | *0.019* | *0.012* | | |
| 75 % | | *0.015* | *0.013* | *0.009* | *0.006* | *0.009* | *0.006* | | |
| 90 % | | *0.006* | *0.005* | *0.004* | *0.002* | *0.004* | *0.002* | | |
| None | D4 Stream | 0.946 | 0.399 | 0.211 | 0.110 | 0.211 | 0.110 | | |
| 50 % | | 0.473 | 0.199 | 0.106 | 0.055 | 0.106 | 0.055 | | |
| 75 % | | 0.237 | 0.100 | 0.053 | 0.028 | 0.053 | 0.028 | | |
| 90 % | | 0.095 | 0.040 | 0.021 | 0.011 | 0.021 | 0.011 | | |
| None | D6 Ditch | 1.05 | 0.344 | 0.182 | 0.095 | 0.182 | 0.095 | | |
| 50 % | | 0.525 | 0.172 | 0.091 | 0.047 | 0.091 | 0.047 | | |
| 75 % | | 0.262 | 0.086 | 0.046 | 0.024 | 0.046 | 0.024 | | |
| 90 % | | 0.105 | 0.034 | 0.018 | 0.010 | 0.018 | 0.010 | | |
| None | D6 Ditch 2nd | 1.05 | 0.343 | 0.182 | 0.094 | 0.182 | 0.094 | | |
| 50 % | | 0.523 | 0.171 | 0.091 | 0.047 | 0.091 | 0.047 | | |
| 75 % | | 0.261 | 0.086 | 0.045 | 0.024 | 0.045 | 0.024 | | |
| 90 % | | 0.105 | 0.034 | 0.018 | 0.009 | 0.018 | 0.009 | | |
| None | R1 Pond | *0.059* | *0.053* | *0.038* | *0.026* | *0.036* | *0.024* | | |
| 50 % | | *0.031* | *0.028* | *0.021* | *0.015* | *0.019* | *0.012* | | |
| 75 % | | *0.017* | *0.015* | *0.012* | *0.009* | *0.010* | *0.006* | | |
| 90 % | | *0.009* | *0.008* | *0.007* | 0.006 | *0.005* | *0.003* | | |
| None | R1 Stream | 0.718 | 0.303 | 0.160 | 0.083 | 0.160 | 0.083 | | |
| 50 % | | 0.359 | 0.151 | 0.080 | 0.079 | 0.080 | 0.042 | | |
| 75 % | | 0.180 | 0.079 | 0.079 | 0.079 | 0.040 | 0.021 | | |
| 90 % | | 0.079 | 0.079 | 0.079 | 0.079 | 0.036 | 0.019 | | |
| None | R2 Stream | 0.973 | 0.410 | 0.217 | 0.113 | 0.217 | 0.113 | | |
| 50 % | | 0.487 | 0.205 | 0.109 | 0.057 | 0.109 | 0.057 | | |
| 75 % | | 0.243 | 0.102 | 0.054 | 0.028 | 0.054 | 0.028 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 90 % | | 0.097 | 0.041 | 0.022 | 0.011 | 0.022 | 0.011 | | |
| None | R3 Stream | 1.02 | 0.429 | 0.228 | 0.132 | 0.228 | 0.118 | | |
| 50 % | | 0.509 | 0.215 | 0.132 | 0.132 | 0.114 | 0.059 | | |
| 75 % | | 0.255 | 0.132 | 0.132 | 0.132 | 0.060 | 0.031 | | |
| 90 % | | 0.132 | 0.132 | 0.132 | 0.132 | 0.060 | 0.031 | | |
| None | R4 Stream | 0.711 | 0.356 | 0.356 | 0.356 | 0.161 | 0.085 | | |
| 50 % | | 0.356 | 0.356 | 0.356 | 0.356 | 0.161 | 0.085 | | |
| 75 % | | 0.356 | 0.356 | 0.356 | 0.356 | 0.161 | 0.085 | | |
| 90 % | | 0.356 | 0.356 | 0.356 | 0.356 | 0.161 | 0.085 | | |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D2 Ditch | **3.84** | **1.26** | 0.667 | 0.347 | 0.667 | 0.347 | | |
| 50 % | | **1.92** | 0.629 | 0.334 | 0.174 | 0.334 | 0.174 | | |
| 75 % | | 0.960 | 0.314 | 0.167 | 0.087 | 0.167 | 0.087 | | |
| 90 % | | 0.384 | 0.126 | 0.067 | 0.035 | 0.067 | 0.035 | | |
| None | D2 Stream | **3.58** | **1.51** | 0.800 | 0.416 | 0.800 | 0.416 | | |
| 50 % | | **1.79** | 0.754 | 0.400 | 0.208 | 0.400 | 0.208 | | |
| 75 % | | 0.896 | 0.377 | 0.200 | 0.104 | 0.200 | 0.104 | | |
| 90 % | | 0.358 | 0.151 | 0.080 | 0.042 | 0.080 | 0.042 | | |
| None | D3 Ditch | **3.80** | **1.25** | 0.661 | 0.343 | 0.661 | 0.343 | | |
| 50 % | | **1.90** | 0.623 | 0.330 | 0.172 | 0.330 | 0.172 | | |
| 75 % | | 0.950 | 0.312 | 0.165 | 0.086 | 0.165 | 0.086 | | |
| 90 % | | 0.380 | 0.125 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | D4 Pond | 0.213 | 0.189 | 0.134 | 0.088 | 0.134 | 0.088 | | |
| 50 % | | 0.107 | 0.095 | 0.067 | 0.044 | 0.067 | 0.044 | | |
| 75 % | | 0.053 | 0.047 | 0.034 | 0.022 | 0.034 | 0.022 | | |
| 90 % | | 0.021 | 0.019 | 0.013 | 0.009 | 0.013 | 0.009 | | |
| None | D4 Stream | **3.43** | **1.44** | 0.766 | 0.398 | 0.766 | 0.398 | | |
| 50 % | | **1.71** | 0.722 | 0.383 | 0.199 | 0.383 | 0.199 | | |
| 75 % | | 0.857 | 0.361 | 0.191 | 0.100 | 0.191 | 0.100 | | |
| 90 % | | 0.343 | 0.144 | 0.076 | 0.040 | 0.076 | 0.040 | | |
| None | D6 Ditch | **3.80** | **1.25** | 0.661 | 0.343 | 0.661 | 0.343 | | |
| 50 % | | **1.90** | 0.623 | 0.330 | 0.172 | 0.330 | 0.172 | | |
| 75 % | | 0.951 | 0.312 | 0.165 | 0.086 | 0.165 | 0.086 | | |
| 90 % | | 0.380 | 0.125 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | D6 Ditch 2nd | **3.79** | **1.24** | 0.658 | 0.342 | 0.658 | 0.342 | | |
| 50 % | | **1.89** | 0.621 | 0.329 | 0.171 | 0.329 | 0.171 | | |
| 75 % | | 0.947 | 0.311 | 0.164 | 0.086 | 0.164 | 0.086 | | |
| 90 % | | 0.379 | 0.124 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | R1 Pond | 0.213 | 0.190 | 0.138 | 0.095 | 0.132 | 0.086 | | |
| 50 % | | 0.112 | 0.100 | 0.074 | 0.053 | 0.068 | 0.044 | | |
| 75 % | | 0.061 | 0.056 | 0.043 | 0.032 | 0.036 | 0.023 | | |
| 90 % | | 0.031 | 0.029 | 0.024 | 0.020 | 0.017 | 0.011 | | |
| None | R1 Stream | **2.60** | **1.10** | 0.581 | 0.302 | 0.581 | 0.302 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 50 % | | **1.30** | 0.548 | 0.291 | 0.285 | 0.291 | 0.151 | | |
| 75 % | | 0.651 | 0.285 | 0.285 | 0.285 | 0.145 | 0.075 | | |
| 90 % | | 0.285 | 0.285 | 0.285 | 0.285 | 0.129 | 0.068 | | |
| None | R2 Stream | **3.53** | **1.48** | 0.787 | 0.409 | 0.787 | 0.409 | | |
| 50 % | | **1.76** | 0.742 | 0.393 | 0.205 | 0.393 | 0.205 | | |
| 75 % | | 0.882 | 0.371 | 0.197 | 0.102 | 0.197 | 0.102 | | |
| 90 % | | 0.353 | 0.149 | 0.079 | 0.041 | 0.079 | 0.041 | | |
| None | R3 Stream | **3.69** | **1.55** | 0.824 | 0.478 | 0.824 | 0.428 | | |
| 50 % | | **1.85** | 0.777 | 0.478 | 0.478 | 0.412 | 0.214 | | |
| 75 % | | 0.923 | 0.478 | 0.478 | 0.478 | 0.217 | 0.114 | | |
| 90 % | | 0.478 | 0.478 | 0.478 | 0.478 | 0.217 | 0.114 | | |
| None | R4 Stream | **2.57** | **1.29** | **1.29** | **1.29** | 0.585 | 0.306 | | |
| 50 % | | **1.29** | **1.29** | **1.29** | **1.29** | 0.585 | 0.306 | | |
| 75 % | | **1.29** | **1.29** | **1.29** | **1.29** | 0.585 | 0.306 | | |
| 90 % | | **1.29** | **1.29** | **1.29** | **1.29** | 0.585 | 0.306 | | |

* 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 9.5-13: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in asparagus (asparagus; modelling use field beans III -- field beans III, BBCH 23 -- 2×0.2 kg a.s./ha, 10d int.)**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Intended use** | | asparagus | | | | | | | |
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 2 x 200 g/ha, 10d int. | | | | | | | |
| 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 | D2 Ditch | 1.06 | 0.346 | 0.184 | 0.095 | 0.184 | 0.095 | | |
| 50 % | | 0.528 | 0.173 | 0.092 | 0.048 | 0.092 | 0.048 | | |
| 75 % | | 0.264 | 0.087 | 0.046 | 0.024 | 0.046 | 0.024 | | |
| 90 % | | 0.106 | 0.035 | 0.018 | 0.010 | 0.018 | 0.010 | | |
| None | D2 Stream | 0.935 | 0.394 | 0.209 | 0.108 | 0.209 | 0.108 | | |
| 50 % | | 0.467 | 0.197 | 0.104 | 0.054 | 0.104 | 0.054 | | |
| 75 % | | 0.234 | 0.098 | 0.052 | 0.027 | 0.052 | 0.027 | | |
| 90 % | | 0.094 | 0.039 | 0.021 | 0.011 | 0.021 | 0.011 | | |
| None | D3 Ditch | 1.05 | 0.343 | 0.182 | 0.095 | 0.182 | 0.095 | | |
| 50 % | | 0.524 | 0.172 | 0.091 | 0.047 | 0.091 | 0.047 | | |
| 75 % | | 0.262 | 0.086 | 0.046 | 0.024 | 0.046 | 0.024 | | |
| 90 % | | 0.105 | 0.034 | 0.018 | 0.010 | 0.018 | 0.010 | | |
| None | D4 Pond | *0.061* | *0.054* | *0.039* | *0.025* | *0.039* | *0.025* | | |
| 50 % | | *0.031* | *0.027* | *0.019* | *0.013* | *0.019* | *0.013* | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 75 % | | *0.015* | *0.014* | *0.010* | *0.006* | *0.010* | *0.006* | | |
| 90 % | | *0.006* | *0.005* | *0.004* | *0.003* | *0.004* | *0.003* | | |
| None | D4 Stream | 0.898 | 0.378 | 0.200 | 0.104 | 0.200 | 0.104 | | |
| 50 % | | 0.449 | 0.189 | 0.100 | 0.052 | 0.100 | 0.052 | | |
| 75 % | | 0.224 | 0.095 | 0.050 | 0.026 | 0.050 | 0.026 | | |
| 90 % | | 0.090 | 0.038 | 0.020 | 0.010 | 0.020 | 0.010 | | |
| None | D6 Ditch | 1.03 | 0.339 | 0.180 | 0.093 | 0.180 | 0.093 | | |
| 50 % | | 0.517 | 0.169 | 0.090 | 0.047 | 0.090 | 0.047 | | |
| 75 % | | 0.258 | 0.085 | 0.045 | 0.023 | 0.045 | 0.023 | | |
| 90 % | | 0.103 | 0.034 | 0.018 | 0.009 | 0.018 | 0.009 | | |
| None | D6 Ditch 2nd | 1.03 | 0.339 | 0.180 | 0.093 | 0.180 | 0.093 | | |
| 50 % | | 0.516 | 0.169 | 0.090 | 0.047 | 0.090 | 0.047 | | |
| 75 % | | 0.258 | 0.085 | 0.045 | 0.023 | 0.045 | 0.023 | | |
| 90 % | | 0.103 | 0.034 | 0.018 | 0.009 | 0.018 | 0.009 | | |
| None | R1 Pond | *0.059* | *0.053* | *0.037* | *0.025* | *0.037* | *0.025* | | |
| 50 % | | *0.030* | *0.026* | *0.019* | *0.013* | *0.019* | *0.012* | | |
| 75 % | | *0.015* | *0.014* | *0.011* | *0.008* | *0.009* | *0.006* | | |
| 90 % | | *0.008* | *0.007* | *0.006* | *0.005* | *0.004* | *0.003* | | |
| None | R1 Stream | 0.725 | 0.305 | 0.162 | 0.084 | 0.162 | 0.084 | | |
| 50 % | | 0.363 | 0.153 | 0.081 | *0.049* | 0.081 | 0.042 | | |
| 75 % | | 0.181 | 0.076 | *0.049* | *0.049* | 0.041 | 0.021 | | |
| 90 % | | 0.073 | *0.049* | *0.049* | *0.049* | 0.021 | 0.011 | | |
| None | R2 Stream | 0.958 | 0.403 | 0.214 | 0.111 | 0.214 | 0.111 | | |
| 50 % | | 0.479 | 0.202 | 0.107 | 0.056 | 0.107 | 0.056 | | |
| 75 % | | 0.239 | 0.101 | 0.054 | *0.043* | 0.054 | 0.028 | | |
| 90 % | | 0.096 | *0.043* | *0.043* | *0.043* | 0.021 | 0.011 | | |
| None | R3 Stream | 1.02 | 0.430 | 0.228 | 0.142 | 0.228 | 0.119 | | |
| 50 % | | 0.511 | 0.215 | 0.142 | 0.142 | 0.114 | 0.059 | | |
| 75 % | | 0.255 | 0.142 | 0.142 | 0.142 | 0.065 | 0.034 | | |
| 90 % | | 0.142 | 0.142 | 0.142 | 0.142 | 0.065 | 0.034 | | |
| None | R4 Stream | 0.724 | 0.305 | 0.162 | *0.149* | 0.162 | 0.084 | | |
| 50 % | | 0.362 | 0.152 | *0.149* | *0.149* | 0.081 | 0.042 | | |
| 75 % | | 0.181 | *0.149* | *0.149* | *0.149* | *0.068* | *0.035* | | |
| 90 % | | *0.149* | *0.149* | *0.149* | *0.149* | *0.068* | *0.035* | | |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D2 Ditch | **3.83** | **1.25** | 0.665 | 0.345 | 0.665 | 0.345 | | |
| 50 % | | **1.91** | 0.627 | 0.332 | 0.173 | 0.332 | 0.173 | | |
| 75 % | | 0.956 | 0.313 | 0.166 | 0.086 | 0.166 | 0.086 | | |
| 90 % | | 0.382 | 0.125 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | D2 Stream | **3.39** | **1.43** | 0.756 | 0.393 | 0.756 | 0.393 | | |
| 50 % | | **1.69** | 0.713 | 0.378 | 0.196 | 0.378 | 0.196 | | |
| 75 % | | 0.847 | 0.357 | 0.189 | 0.098 | 0.189 | 0.098 | | |
| 90 % | | 0.339 | 0.143 | 0.076 | 0.039 | 0.076 | 0.039 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| None | D3 Ditch | **3.80** | **1.24** | 0.660 | 0.343 | 0.660 | 0.343 | | |
| 50 % | | **1.90** | 0.622 | 0.330 | 0.171 | 0.330 | 0.171 | | |
| 75 % | | 0.949 | 0.311 | 0.165 | 0.086 | 0.165 | 0.086 | | |
| 90 % | | 0.379 | 0.124 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | D4 Pond | 0.222 | 0.197 | 0.140 | 0.092 | 0.140 | 0.092 | | |
| 50 % | | 0.111 | 0.099 | 0.070 | 0.046 | 0.070 | 0.046 | | |
| 75 % | | 0.055 | 0.049 | 0.035 | 0.023 | 0.035 | 0.023 | | |
| 90 % | | 0.022 | 0.020 | 0.014 | 0.009 | 0.014 | 0.009 | | |
| None | D4 Stream | **3.25** | **1.37** | 0.726 | 0.377 | 0.726 | 0.377 | | |
| 50 % | | **1.63** | 0.684 | 0.363 | 0.189 | 0.363 | 0.189 | | |
| 75 % | | 0.813 | 0.342 | 0.182 | 0.094 | 0.182 | 0.094 | | |
| 90 % | | 0.325 | 0.137 | 0.072 | 0.038 | 0.072 | 0.038 | | |
| None | D6 Ditch | **3.74** | **1.23** | 0.650 | 0.338 | 0.650 | 0.338 | | |
| 50 % | | **1.87** | 0.613 | 0.325 | 0.169 | 0.325 | 0.169 | | |
| 75 % | | 0.936 | 0.307 | 0.163 | 0.084 | 0.163 | 0.084 | | |
| 90 % | | 0.374 | 0.123 | 0.065 | 0.034 | 0.065 | 0.034 | | |
| None | D6 Ditch 2nd | **3.74** | **1.23** | 0.650 | 0.338 | 0.650 | 0.338 | | |
| 50 % | | **1.87** | 0.613 | 0.325 | 0.169 | 0.325 | 0.169 | | |
| 75 % | | 0.936 | 0.307 | 0.163 | 0.084 | 0.163 | 0.084 | | |
| 90 % | | 0.374 | 0.123 | 0.065 | 0.034 | 0.065 | 0.034 | | |
| None | R1 Pond | 0.215 | 0.191 | 0.136 | 0.089 | 0.136 | 0.089 | | |
| 50 % | | 0.108 | 0.096 | 0.068 | 0.046 | 0.068 | 0.045 | | |
| 75 % | | 0.054 | 0.049 | 0.038 | 0.029 | 0.034 | 0.022 | | |
| 90 % | | 0.029 | 0.027 | 0.023 | 0.019 | 0.016 | 0.009 | | |
| None | R1 Stream | **2.63** | **1.11** | 0.587 | 0.305 | 0.587 | 0.305 | | |
| 50 % | | **1.31** | 0.553 | 0.293 | 0.176 | 0.293 | 0.153 | | |
| 75 % | | 0.657 | 0.276 | 0.176 | 0.176 | 0.147 | 0.076 | | |
| 90 % | | 0.263 | 0.176 | 0.176 | 0.176 | 0.078 | 0.041 | | |
| None | R2 Stream | **3.47** | **1.46** | 0.775 | 0.403 | 0.775 | 0.403 | | |
| 50 % | | **1.74** | 0.731 | 0.387 | 0.201 | 0.387 | 0.201 | | |
| 75 % | | 0.867 | 0.365 | 0.194 | 0.154 | 0.194 | 0.101 | | |
| 90 % | | 0.347 | 0.154 | 0.154 | 0.154 | 0.078 | 0.040 | | |
| None | R3 Stream | **3.70** | **1.56** | 0.826 | 0.516 | 0.826 | 0.429 | | |
| 50 % | | **1.85** | 0.779 | 0.516 | 0.516 | 0.413 | 0.215 | | |
| 75 % | | 0.925 | 0.516 | 0.516 | 0.516 | 0.235 | 0.123 | | |
| 90 % | | 0.516 | 0.516 | 0.516 | 0.516 | 0.235 | 0.123 | | |
| None | R4 Stream | **2.62** | **1.10** | 0.586 | 0.540 | 0.586 | 0.304 | | |
| 50 % | | **1.31** | 0.552 | 0.540 | 0.540 | 0.293 | 0.152 | | |
| 75 % | | 0.655 | 0.540 | 0.540 | 0.540 | 0.245 | 0.128 | | |
| 90 % | | 0.540 | 0.540 | 0.540 | 0.540 | 0.245 | 0.128 | | |

* 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 9.5-14: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in asparagus (asparagus; modelling use field beans III -- field beans III, BBCH 95 -- 2×0.2 kg a.s./ha, 10d int.)**

| **Intended use** | | asparagus | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 2 x 200 g/ha, 10d int. | | | | | | | |
| 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 | D2 Ditch | 1.06 | 0.347 | 0.184 | 0.096 | 0.184 | 0.096 | | |
| 50 % | | 0.530 | 0.174 | 0.092 | 0.048 | 0.092 | 0.048 | | |
| 75 % | | 0.265 | 0.087 | 0.046 | 0.024 | 0.046 | 0.024 | | |
| 90 % | | 0.106 | 0.035 | 0.018 | 0.010 | 0.018 | 0.010 | | |
| None | D2 Stream | 0.989 | 0.416 | 0.221 | 0.115 | 0.221 | 0.115 | | |
| 50 % | | 0.495 | 0.208 | 0.110 | 0.057 | 0.110 | 0.057 | | |
| 75 % | | 0.247 | 0.104 | 0.055 | 0.029 | 0.055 | 0.029 | | |
| 90 % | | 0.099 | 0.042 | 0.022 | 0.012 | 0.022 | 0.012 | | |
| None | D3 Ditch | 1.05 | 0.344 | 0.183 | 0.095 | 0.183 | 0.095 | | |
| 50 % | | 0.525 | 0.172 | 0.091 | 0.048 | 0.091 | 0.048 | | |
| 75 % | | 0.263 | 0.086 | 0.046 | 0.024 | 0.046 | 0.024 | | |
| 90 % | | 0.105 | 0.034 | 0.018 | 0.010 | 0.018 | 0.010 | | |
| None | D4 Pond | *0.050* | *0.044* | *0.031* | *0.021* | *0.031* | *0.021* | | |
| 50 % | | *0.025* | *0.022* | *0.016* | *0.010* | *0.016* | *0.010* | | |
| 75 % | | *0.012* | *0.011* | *0.008* | *0.005* | *0.008* | *0.005* | | |
| 90 % | | *0.005* | *0.004* | *0.003* | *0.002* | *0.003* | *0.002* | | |
| None | D4 Stream | 0.949 | 0.400 | 0.212 | 0.110 | 0.212 | 0.110 | | |
| 50 % | | 0.475 | 0.200 | 0.106 | 0.055 | 0.106 | 0.055 | | |
| 75 % | | 0.237 | 0.100 | 0.053 | 0.028 | 0.053 | 0.028 | | |
| 90 % | | 0.095 | 0.040 | 0.021 | 0.011 | 0.021 | 0.011 | | |
| None | D6 Ditch | 1.06 | 0.346 | 0.183 | 0.095 | 0.183 | 0.095 | | |
| 50 % | | 0.527 | 0.173 | 0.092 | 0.048 | 0.092 | 0.048 | | |
| 75 % | | 0.264 | 0.086 | 0.046 | 0.024 | 0.046 | 0.024 | | |
| 90 % | | 0.105 | 0.035 | 0.018 | 0.010 | 0.018 | 0.010 | | |
| None | D6 Ditch 2nd | 1.05 | 0.344 | 0.182 | 0.095 | 0.182 | 0.095 | | |
| 50 % | | 0.525 | 0.172 | 0.091 | 0.047 | 0.091 | 0.047 | | |
| 75 % | | 0.262 | 0.086 | 0.046 | 0.024 | 0.046 | 0.024 | | |
| 90 % | | 0.105 | 0.034 | 0.018 | 0.010 | 0.018 | 0.010 | | |
| None | R1 Pond | *0.053* | *0.047* | *0.033* | *0.022* | *0.033* | *0.022* | | |
| 50 % | | *0.026* | *0.024* | *0.017* | *0.011* | *0.017* | *0.011* | | |
| 75 % | | *0.013* | *0.012* | *0.008* | *0.006* | *0.008* | *0.006* | | |
| 90 % | | *0.005* | *0.005* | *0.003* | *0.002* | *0.003* | *0.002* | | |
| None | R1 Stream | 0.718 | 0.303 | 0.160 | 0.083 | 0.160 | 0.083 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 50 % | | 0.359 | 0.151 | 0.080 | 0.042 | 0.080 | 0.042 | | |
| 75 % | | 0.180 | 0.076 | 0.040 | 0.021 | 0.040 | 0.021 | | |
| 90 % | | 0.072 | 0.030 | 0.016 | 0.008 | 0.016 | 0.008 | | |
| None | R2 Stream | 0.973 | 0.410 | 0.217 | 0.113 | 0.217 | 0.113 | | |
| 50 % | | 0.487 | 0.205 | 0.109 | 0.057 | 0.109 | 0.057 | | |
| 75 % | | 0.243 | 0.102 | 0.054 | 0.028 | 0.054 | 0.028 | | |
| 90 % | | 0.097 | 0.041 | 0.022 | 0.011 | 0.022 | 0.011 | | |
| None | R3 Stream | 1.02 | 0.429 | 0.228 | 0.132 | 0.228 | 0.118 | | |
| 50 % | | 0.509 | 0.215 | 0.132 | 0.132 | 0.114 | 0.059 | | |
| 75 % | | 0.255 | 0.132 | 0.132 | 0.132 | 0.060 | 0.031 | | |
| 90 % | | 0.132 | 0.132 | 0.132 | 0.132 | 0.060 | 0.031 | | |
| None | R4 Stream | 0.711 | 0.299 | *0.272* | *0.272* | 0.159 | 0.082 | | |
| 50 % | | 0.355 | *0.272* | *0.272* | *0.272* | *0.122* | *0.063* | | |
| 75 % | | *0.272* | *0.272* | *0.272* | *0.272* | *0.122* | *0.063* | | |
| 90 % | | *0.272* | *0.272* | *0.272* | *0.272* | *0.122* | *0.063* | | |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D2 Ditch | **3.84** | **1.26** | 0.667 | 0.347 | 0.667 | 0.347 | | |
| 50 % | | **1.92** | 0.629 | 0.334 | 0.174 | 0.334 | 0.174 | | |
| 75 % | | 0.960 | 0.314 | 0.167 | 0.087 | 0.167 | 0.087 | | |
| 90 % | | 0.384 | 0.126 | 0.067 | 0.035 | 0.067 | 0.035 | | |
| None | D2 Stream | **3.58** | **1.51** | 0.800 | 0.416 | 0.800 | 0.416 | | |
| 50 % | | **1.79** | 0.754 | 0.400 | 0.208 | 0.400 | 0.208 | | |
| 75 % | | 0.896 | 0.377 | 0.200 | 0.104 | 0.200 | 0.104 | | |
| 90 % | | 0.358 | 0.151 | 0.080 | 0.042 | 0.080 | 0.042 | | |
| None | D3 Ditch | **3.81** | **1.25** | 0.662 | 0.344 | 0.662 | 0.344 | | |
| 50 % | | **1.90** | 0.624 | 0.331 | 0.172 | 0.331 | 0.172 | | |
| 75 % | | 0.952 | 0.312 | 0.166 | 0.086 | 0.166 | 0.086 | | |
| 90 % | | 0.381 | 0.125 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | D4 Pond | 0.180 | 0.160 | 0.113 | 0.075 | 0.113 | 0.075 | | |
| 50 % | | 0.090 | 0.080 | 0.057 | 0.037 | 0.057 | 0.037 | | |
| 75 % | | 0.045 | 0.040 | 0.028 | 0.018 | 0.028 | 0.018 | | |
| 90 % | | 0.018 | 0.016 | 0.011 | 0.007 | 0.011 | 0.007 | | |
| None | D4 Stream | **3.44** | **1.45** | 0.768 | 0.399 | 0.768 | 0.399 | | |
| 50 % | | **1.72** | 0.724 | 0.384 | 0.200 | 0.384 | 0.200 | | |
| 75 % | | 0.860 | 0.362 | 0.192 | 0.100 | 0.192 | 0.100 | | |
| 90 % | | 0.344 | 0.145 | 0.077 | 0.040 | 0.077 | 0.040 | | |
| None | D6 Ditch | **3.82** | **1.25** | 0.664 | 0.345 | 0.664 | 0.345 | | |
| 50 % | | **1.91** | 0.626 | 0.332 | 0.172 | 0.332 | 0.172 | | |
| 75 % | | 0.955 | 0.313 | 0.166 | 0.086 | 0.166 | 0.086 | | |
| 90 % | | 0.382 | 0.125 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | D6 Ditch 2nd | **3.80** | **1.25** | 0.661 | 0.343 | 0.661 | 0.343 | | |
| 50 % | | **1.90** | 0.623 | 0.330 | 0.172 | 0.330 | 0.172 | | |
| 75 % | | 0.951 | 0.312 | 0.165 | 0.086 | 0.165 | 0.086 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 90 % | | 0.380 | 0.125 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | R1 Pond | 0.192 | 0.170 | 0.121 | 0.079 | 0.121 | 0.079 | | |
| 50 % | | 0.096 | 0.085 | 0.060 | 0.039 | 0.060 | 0.039 | | |
| 75 % | | 0.048 | 0.042 | 0.030 | 0.020 | 0.030 | 0.020 | | |
| 90 % | | 0.019 | 0.017 | 0.012 | 0.008 | 0.012 | 0.008 | | |
| None | R1 Stream | **2.60** | **1.10** | 0.581 | 0.302 | 0.581 | 0.302 | | |
| 50 % | | **1.30** | 0.548 | 0.291 | 0.151 | 0.291 | 0.151 | | |
| 75 % | | 0.651 | 0.274 | 0.145 | 0.075 | 0.145 | 0.075 | | |
| 90 % | | 0.260 | 0.109 | 0.058 | 0.030 | 0.058 | 0.030 | | |
| None | R2 Stream | **3.53** | **1.48** | 0.787 | 0.409 | 0.787 | 0.409 | | |
| 50 % | | **1.76** | 0.742 | 0.393 | 0.205 | 0.393 | 0.205 | | |
| 75 % | | 0.882 | 0.371 | 0.197 | 0.102 | 0.197 | 0.102 | | |
| 90 % | | 0.353 | 0.149 | 0.079 | 0.041 | 0.079 | 0.041 | | |
| None | R3 Stream | **3.69** | **1.55** | 0.824 | 0.478 | 0.824 | 0.428 | | |
| 50 % | | **1.85** | 0.777 | 0.478 | 0.478 | 0.412 | 0.214 | | |
| 75 % | | 0.923 | 0.478 | 0.478 | 0.478 | 0.217 | 0.114 | | |
| 90 % | | 0.478 | 0.478 | 0.478 | 0.478 | 0.217 | 0.114 | | |
| None | R4 Stream | **2.57** | **1.08** | 0.986 | 0.986 | 0.575 | 0.299 | | |
| 50 % | | **1.29** | 0.986 | 0.986 | 0.986 | 0.441 | 0.230 | | |
| 75 % | | 0.986 | 0.986 | 0.986 | 0.986 | 0.441 | 0.230 | | |
| 90 % | | 0.986 | 0.986 | 0.986 | 0.986 | 0.441 | 0.230 | | |

* 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 9.5-15: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in baby leaf crops, beans, garden cress and strawberries (baby leaf crops, beans, garden cress and strawberries; modelling use field beans IV -- field beans IV, BBCH 40 -- 2×0.2 kg a.s./ha, 7d int.)**

| **Intended use** | | baby leaf crops, beans, garden cress and strawberries | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 2 x 200 g/ha, 7d int. | | | | | | | |
| 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 | D2 Ditch | 1.06 | 0.347 | 0.184 | 0.096 | 0.184 | 0.096 | | |
| 50 % | | 0.530 | 0.174 | 0.092 | 0.048 | 0.092 | 0.048 | | |
| 75 % | | 0.265 | 0.087 | 0.046 | 0.024 | 0.046 | 0.024 | | |
| 90 % | | 0.106 | 0.035 | 0.018 | 0.010 | 0.018 | 0.010 | | |
| None | D2 Stream | 0.978 | 0.412 | 0.218 | 0.113 | 0.218 | 0.113 | | |
| 50 % | | 0.489 | 0.206 | 0.109 | 0.057 | 0.109 | 0.057 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 75 % | | 0.244 | 0.103 | 0.055 | 0.028 | 0.055 | 0.028 | | |
| 90 % | | 0.098 | 0.041 | 0.022 | 0.011 | 0.022 | 0.011 | | |
| None | D3 Ditch | 1.05 | 0.343 | 0.182 | 0.095 | 0.182 | 0.095 | | |
| 50 % | | 0.524 | 0.172 | 0.091 | 0.047 | 0.091 | 0.047 | | |
| 75 % | | 0.262 | 0.086 | 0.046 | 0.024 | 0.046 | 0.024 | | |
| 90 % | | 0.105 | 0.034 | 0.018 | 0.010 | 0.018 | 0.010 | | |
| None | D4 Pond | *0.063* | *0.056* | *0.040* | *0.026* | *0.040* | *0.026* | | |
| 50 % | | *0.032* | *0.028* | *0.020* | *0.013* | *0.020* | *0.013* | | |
| 75 % | | *0.016* | *0.014* | *0.010* | *0.007* | *0.010* | *0.007* | | |
| 90 % | | *0.006* | *0.006* | *0.004* | *0.003* | *0.004* | *0.003* | | |
| None | D4 Stream | 0.941 | 0.396 | 0.210 | 0.109 | 0.210 | 0.109 | | |
| 50 % | | 0.471 | 0.198 | 0.105 | 0.055 | 0.105 | 0.055 | | |
| 75 % | | 0.235 | 0.099 | 0.053 | 0.027 | 0.053 | 0.027 | | |
| 90 % | | 0.094 | 0.040 | 0.021 | 0.011 | 0.021 | 0.011 | | |
| None | D6 Ditch | 1.03 | 0.339 | 0.180 | 0.093 | 0.180 | 0.093 | | |
| 50 % | | 0.517 | 0.169 | 0.090 | 0.047 | 0.090 | 0.047 | | |
| 75 % | | 0.258 | 0.085 | 0.045 | 0.023 | 0.045 | 0.023 | | |
| 90 % | | 0.103 | 0.034 | 0.018 | 0.009 | 0.018 | 0.009 | | |
| None | D6 Ditch 2nd | 1.03 | 0.339 | 0.180 | 0.093 | 0.180 | 0.093 | | |
| 50 % | | 0.517 | 0.169 | 0.090 | 0.047 | 0.090 | 0.047 | | |
| 75 % | | 0.258 | 0.085 | 0.045 | 0.023 | 0.045 | 0.023 | | |
| 90 % | | 0.103 | 0.034 | 0.018 | 0.009 | 0.018 | 0.009 | | |
| None | R1 Pond | *0.065* | *0.059* | *0.044* | *0.031* | *0.040* | *0.026* | | |
| 50 % | | *0.036* | *0.033* | *0.026* | *0.020* | *0.022* | *0.014* | | |
| 75 % | | *0.022* | *0.021* | *0.017* | *0.015* | *0.012* | *0.008* | | |
| 90 % | | *0.015* | *0.014* | *0.013* | *0.012* | *0.007* | *0.004* | | |
| None | R1 Stream | 0.726 | 0.306 | 0.162 | 0.104 | 0.162 | 0.084 | | |
| 50 % | | 0.363 | 0.153 | 0.104 | 0.104 | 0.081 | 0.042 | | |
| 75 % | | 0.182 | 0.104 | 0.104 | 0.104 | 0.047 | 0.025 | | |
| 90 % | | 0.104 | 0.104 | 0.104 | 0.104 | 0.047 | 0.025 | | |
| None | R2 Stream | 0.958 | 0.403 | 0.214 | 0.111 | 0.214 | 0.111 | | |
| 50 % | | 0.479 | 0.202 | 0.107 | 0.056 | 0.107 | 0.056 | | |
| 75 % | | 0.239 | 0.101 | 0.054 | *0.043* | 0.054 | 0.028 | | |
| 90 % | | 0.096 | *0.043* | *0.043* | *0.043* | 0.021 | 0.011 | | |
| None | R3 Stream | 1.02 | 0.430 | 0.228 | *0.132* | 0.228 | 0.119 | | |
| 50 % | | 0.511 | 0.215 | *0.132* | *0.132* | 0.114 | 0.059 | | |
| 75 % | | 0.255 | *0.132* | *0.132* | *0.132* | *0.060* | *0.032* | | |
| 90 % | | *0.132* | *0.132* | *0.132* | *0.132* | *0.060* | *0.032* | | |
| None | R4 Stream | 0.724 | *0.510* | *0.510* | *0.510* | *0.231* | *0.121* | | |
| 50 % | | *0.510* | *0.510* | *0.510* | *0.510* | *0.231* | *0.121* | | |
| 75 % | | *0.510* | *0.510* | *0.510* | *0.510* | *0.231* | *0.121* | | |
| 90 % | | *0.510* | *0.510* | *0.510* | *0.510* | *0.231* | *0.121* | | |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| None | D2 Ditch | **3.84** | **1.26** | 0.667 | 0.346 | 0.667 | 0.346 | | |
| 50 % | | **1.92** | 0.629 | 0.333 | 0.173 | 0.333 | 0.173 | | |
| 75 % | | 0.959 | 0.314 | 0.167 | 0.087 | 0.167 | 0.087 | | |
| 90 % | | 0.384 | 0.126 | 0.067 | 0.035 | 0.067 | 0.035 | | |
| None | D2 Stream | **3.54** | **1.49** | 0.791 | 0.411 | 0.791 | 0.411 | | |
| 50 % | | **1.77** | 0.746 | 0.396 | 0.205 | 0.396 | 0.205 | | |
| 75 % | | 0.886 | 0.373 | 0.198 | 0.103 | 0.198 | 0.103 | | |
| 90 % | | 0.354 | 0.149 | 0.079 | 0.041 | 0.079 | 0.041 | | |
| None | D3 Ditch | **3.80** | **1.24** | 0.660 | 0.343 | 0.660 | 0.343 | | |
| 50 % | | **1.90** | 0.622 | 0.330 | 0.171 | 0.330 | 0.171 | | |
| 75 % | | 0.949 | 0.311 | 0.165 | 0.086 | 0.165 | 0.086 | | |
| 90 % | | 0.379 | 0.124 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | D4 Pond | 0.229 | 0.204 | 0.144 | 0.095 | 0.144 | 0.095 | | |
| 50 % | | 0.114 | 0.102 | 0.072 | 0.047 | 0.072 | 0.047 | | |
| 75 % | | 0.057 | 0.051 | 0.036 | 0.024 | 0.036 | 0.024 | | |
| 90 % | | 0.023 | 0.020 | 0.014 | 0.009 | 0.014 | 0.009 | | |
| None | D4 Stream | **3.41** | **1.44** | 0.761 | 0.396 | 0.761 | 0.396 | | |
| 50 % | | **1.71** | 0.718 | 0.381 | 0.198 | 0.381 | 0.198 | | |
| 75 % | | 0.853 | 0.359 | 0.190 | 0.099 | 0.190 | 0.099 | | |
| 90 % | | 0.341 | 0.143 | 0.076 | 0.039 | 0.076 | 0.039 | | |
| None | D6 Ditch | **3.74** | **1.23** | 0.650 | 0.338 | 0.650 | 0.338 | | |
| 50 % | | **1.87** | 0.613 | 0.325 | 0.169 | 0.325 | 0.169 | | |
| 75 % | | 0.936 | 0.307 | 0.163 | 0.084 | 0.163 | 0.084 | | |
| 90 % | | 0.374 | 0.123 | 0.065 | 0.034 | 0.065 | 0.034 | | |
| None | D6 Ditch 2nd | **3.75** | **1.23** | 0.651 | 0.338 | 0.651 | 0.338 | | |
| 50 % | | **1.87** | 0.614 | 0.325 | 0.169 | 0.325 | 0.169 | | |
| 75 % | | 0.936 | 0.307 | 0.163 | 0.084 | 0.163 | 0.084 | | |
| 90 % | | 0.375 | 0.123 | 0.065 | 0.034 | 0.065 | 0.034 | | |
| None | R1 Pond | 0.237 | 0.213 | 0.159 | 0.114 | 0.145 | 0.094 | | |
| 50 % | | 0.132 | 0.120 | 0.093 | 0.072 | 0.078 | 0.050 | | |
| 75 % | | 0.079 | 0.074 | 0.063 | 0.054 | 0.044 | 0.028 | | |
| 90 % | | 0.053 | 0.051 | 0.047 | 0.043 | 0.026 | 0.014 | | |
| None | R1 Stream | **2.63** | **1.11** | 0.587 | 0.377 | 0.587 | 0.305 | | |
| 50 % | | **1.32** | 0.554 | 0.377 | 0.377 | 0.293 | 0.153 | | |
| 75 % | | 0.658 | 0.377 | 0.377 | 0.377 | 0.171 | 0.089 | | |
| 90 % | | 0.377 | 0.377 | 0.377 | 0.377 | 0.171 | 0.089 | | |
| None | R2 Stream | **3.47** | **1.46** | 0.775 | 0.403 | 0.775 | 0.403 | | |
| 50 % | | **1.74** | 0.731 | 0.387 | 0.201 | 0.387 | 0.201 | | |
| 75 % | | 0.867 | 0.365 | 0.194 | 0.157 | 0.194 | 0.101 | | |
| 90 % | | 0.347 | 0.157 | 0.157 | 0.157 | 0.078 | 0.040 | | |
| None | R3 Stream | **3.70** | **1.56** | 0.826 | 0.479 | 0.826 | 0.429 | | |
| 50 % | | **1.85** | 0.779 | 0.479 | 0.479 | 0.413 | 0.215 | | |
| 75 % | | 0.925 | 0.479 | 0.479 | 0.479 | 0.218 | 0.114 | | |
| 90 % | | 0.479 | 0.479 | 0.479 | 0.479 | 0.218 | 0.114 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| None | R4 Stream | **2.62** | **1.85** | **1.85** | **1.85** | 0.838 | 0.438 | | |
| 50 % | | **1.85** | **1.85** | **1.85** | **1.85** | 0.838 | 0.438 | | |
| 75 % | | **1.85** | **1.85** | **1.85** | **1.85** | 0.838 | 0.438 | | |
| 90 % | | **1.85** | **1.85** | **1.85** | **1.85** | 0.838 | 0.438 | | |

* 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 9.5-16: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in baby leaf crops, beans, garden cress and strawberries (baby leaf crops, beans, garden cress and strawberries; modelling use field beans IV -- field beans IV, BBCH 89 -- 2×0.2 kg a.s./ha, 7d int.)**

| **Intended use** | | baby leaf crops, beans, garden cress and strawberries | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 2 x 200 g/ha, 7d int. | | | | | | | |
| 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 | D2 Ditch | *1.44* | *0.454* | *0.235* | *0.120* | *0.235* | *0.120* | | |
| 50 % | | *0.719* | *0.227* | *0.118* | *0.060* | *0.118* | *0.060* | | |
| 75 % | | *0.359* | *0.113* | *0.059* | *0.030* | *0.059* | *0.030* | | |
| 90 % | | *0.143* | *0.045* | *0.023* | *0.012* | *0.023* | *0.012* | | |
| None | D2 Stream | 0.989 | 0.416 | 0.221 | 0.115 | 0.221 | 0.115 | | |
| 50 % | | 0.495 | 0.208 | 0.110 | 0.057 | 0.110 | 0.057 | | |
| 75 % | | 0.247 | 0.104 | 0.055 | 0.029 | 0.055 | 0.029 | | |
| 90 % | | 0.099 | 0.042 | 0.022 | 0.012 | 0.022 | 0.012 | | |
| None | D3 Ditch | 1.05 | 0.344 | 0.182 | 0.095 | 0.182 | 0.095 | | |
| 50 % | | 0.525 | 0.172 | 0.091 | 0.047 | 0.091 | 0.047 | | |
| 75 % | | 0.262 | 0.086 | 0.046 | 0.024 | 0.046 | 0.024 | | |
| 90 % | | 0.105 | 0.034 | 0.018 | 0.010 | 0.018 | 0.010 | | |
| None | D4 Pond | *0.063* | *0.056* | *0.040* | *0.026* | *0.040* | *0.026* | | |
| 50 % | | *0.032* | *0.028* | *0.020* | *0.013* | *0.020* | *0.013* | | |
| 75 % | | *0.016* | *0.014* | *0.010* | *0.007* | *0.010* | *0.007* | | |
| 90 % | | *0.006* | *0.006* | *0.004* | *0.003* | *0.004* | *0.003* | | |
| None | D4 Stream | 0.941 | 0.396 | 0.210 | 0.109 | 0.210 | 0.109 | | |
| 50 % | | 0.471 | 0.198 | 0.105 | 0.055 | 0.105 | 0.055 | | |
| 75 % | | 0.235 | 0.099 | 0.053 | 0.027 | 0.053 | 0.027 | | |
| 90 % | | 0.094 | 0.040 | 0.021 | 0.011 | 0.021 | 0.011 | | |
| None | D6 Ditch | 1.04 | 0.340 | 0.180 | 0.094 | 0.180 | 0.094 | | |
| 50 % | | 0.519 | 0.170 | 0.090 | 0.047 | 0.090 | 0.047 | | |
| 75 % | | 0.260 | 0.085 | 0.045 | 0.023 | 0.045 | 0.023 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 90 % | | 0.104 | 0.034 | 0.018 | 0.009 | 0.018 | 0.009 | | |
| None | D6 Ditch 2nd | 1.04 | 0.342 | 0.182 | 0.094 | 0.182 | 0.094 | | |
| 50 % | | 0.522 | 0.171 | 0.091 | 0.047 | 0.091 | 0.047 | | |
| 75 % | | 0.261 | 0.086 | 0.045 | 0.024 | 0.045 | 0.024 | | |
| 90 % | | 0.104 | 0.034 | 0.018 | 0.009 | 0.018 | 0.009 | | |
| None | R1 Pond | *0.059* | *0.053* | *0.038* | *0.026* | *0.036* | *0.024* | | |
| 50 % | | *0.031* | *0.028* | *0.021* | *0.015* | *0.019* | *0.012* | | |
| 75 % | | *0.017* | *0.015* | *0.012* | *0.009* | *0.010* | *0.006* | | |
| 90 % | | *0.009* | *0.008* | *0.007* | 0.006 | *0.005* | *0.003* | | |
| None | R1 Stream | 0.718 | 0.303 | 0.160 | 0.083 | 0.160 | 0.083 | | |
| 50 % | | 0.359 | 0.151 | 0.080 | 0.079 | 0.080 | 0.042 | | |
| 75 % | | 0.180 | 0.079 | 0.079 | 0.079 | 0.040 | 0.021 | | |
| 90 % | | 0.079 | 0.079 | 0.079 | 0.079 | 0.036 | 0.019 | | |
| None | R2 Stream | 0.973 | 0.410 | 0.217 | 0.113 | 0.217 | 0.113 | | |
| 50 % | | 0.487 | 0.205 | 0.109 | 0.057 | 0.109 | 0.057 | | |
| 75 % | | 0.243 | 0.102 | 0.054 | 0.028 | 0.054 | 0.028 | | |
| 90 % | | 0.097 | 0.041 | 0.022 | 0.011 | 0.022 | 0.011 | | |
| None | R3 Stream | 1.02 | 0.430 | 0.228 | *0.132* | 0.228 | 0.119 | | |
| 50 % | | 0.511 | 0.215 | *0.132* | *0.132* | 0.114 | 0.059 | | |
| 75 % | | 0.255 | *0.132* | *0.132* | *0.132* | *0.060* | *0.032* | | |
| 90 % | | *0.132* | *0.132* | *0.132* | *0.132* | *0.060* | *0.032* | | |
| None | R4 Stream | 0.724 | *0.510* | *0.510* | *0.510* | *0.231* | *0.121* | | |
| 50 % | | *0.510* | *0.510* | *0.510* | *0.510* | *0.231* | *0.121* | | |
| 75 % | | *0.510* | *0.510* | *0.510* | *0.510* | *0.231* | *0.121* | | |
| 90 % | | *0.510* | *0.510* | *0.510* | *0.510* | *0.231* | *0.121* | | |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D2 Ditch | **5.21** | **1.64** | 0.853 | 0.433 | 0.853 | 0.433 | | |
| 50 % | | **2.60** | 0.821 | 0.426 | 0.216 | 0.426 | 0.216 | | |
| 75 % | | **1.30** | 0.410 | 0.213 | 0.108 | 0.213 | 0.108 | | |
| 90 % | | 0.519 | 0.164 | 0.085 | 0.043 | 0.085 | 0.043 | | |
| None | D2 Stream | **3.58** | **1.51** | 0.800 | 0.416 | 0.800 | 0.416 | | |
| 50 % | | **1.79** | 0.754 | 0.400 | 0.208 | 0.400 | 0.208 | | |
| 75 % | | 0.896 | 0.377 | 0.200 | 0.104 | 0.200 | 0.104 | | |
| 90 % | | 0.358 | 0.151 | 0.080 | 0.042 | 0.080 | 0.042 | | |
| None | D3 Ditch | **3.80** | **1.25** | 0.661 | 0.343 | 0.661 | 0.343 | | |
| 50 % | | **1.90** | 0.623 | 0.330 | 0.172 | 0.330 | 0.172 | | |
| 75 % | | 0.950 | 0.312 | 0.165 | 0.086 | 0.165 | 0.086 | | |
| 90 % | | 0.380 | 0.125 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | D4 Pond | 0.229 | 0.204 | 0.144 | 0.095 | 0.144 | 0.095 | | |
| 50 % | | 0.114 | 0.102 | 0.072 | 0.047 | 0.072 | 0.047 | | |
| 75 % | | 0.057 | 0.051 | 0.036 | 0.024 | 0.036 | 0.024 | | |
| 90 % | | 0.023 | 0.020 | 0.014 | 0.009 | 0.014 | 0.009 | | |
| None | D4 Stream | **3.41** | **1.44** | 0.762 | 0.396 | 0.762 | 0.396 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 50 % | | **1.71** | 0.718 | 0.381 | 0.198 | 0.381 | 0.198 | | |
| 75 % | | 0.853 | 0.359 | 0.191 | 0.099 | 0.191 | 0.099 | | |
| 90 % | | 0.341 | 0.143 | 0.076 | 0.039 | 0.076 | 0.039 | | |
| None | D6 Ditch | **3.76** | **1.23** | 0.654 | 0.339 | 0.654 | 0.339 | | |
| 50 % | | **1.88** | 0.616 | 0.327 | 0.170 | 0.327 | 0.170 | | |
| 75 % | | 0.940 | 0.308 | 0.163 | 0.085 | 0.163 | 0.085 | | |
| 90 % | | 0.376 | 0.123 | 0.065 | 0.034 | 0.065 | 0.034 | | |
| None | D6 Ditch 2nd | **3.78** | **1.24** | 0.658 | 0.342 | 0.658 | 0.342 | | |
| 50 % | | **1.89** | 0.620 | 0.329 | 0.171 | 0.329 | 0.171 | | |
| 75 % | | 0.946 | 0.310 | 0.164 | 0.086 | 0.164 | 0.086 | | |
| 90 % | | 0.378 | 0.124 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | R1 Pond | 0.213 | 0.190 | 0.138 | 0.095 | 0.132 | 0.086 | | |
| 50 % | | 0.112 | 0.100 | 0.074 | 0.053 | 0.068 | 0.044 | | |
| 75 % | | 0.061 | 0.056 | 0.043 | 0.032 | 0.036 | 0.023 | | |
| 90 % | | 0.031 | 0.029 | 0.024 | 0.020 | 0.017 | 0.011 | | |
| None | R1 Stream | **2.60** | **1.10** | 0.581 | 0.302 | 0.581 | 0.302 | | |
| 50 % | | **1.30** | 0.548 | 0.291 | 0.285 | 0.291 | 0.151 | | |
| 75 % | | 0.651 | 0.285 | 0.285 | 0.285 | 0.145 | 0.075 | | |
| 90 % | | 0.285 | 0.285 | 0.285 | 0.285 | 0.129 | 0.068 | | |
| None | R2 Stream | **3.53** | **1.48** | 0.787 | 0.409 | 0.787 | 0.409 | | |
| 50 % | | **1.76** | 0.742 | 0.393 | 0.205 | 0.393 | 0.205 | | |
| 75 % | | 0.882 | 0.371 | 0.197 | 0.102 | 0.197 | 0.102 | | |
| 90 % | | 0.353 | 0.149 | 0.079 | 0.041 | 0.079 | 0.041 | | |
| None | R3 Stream | **3.70** | **1.56** | 0.826 | 0.480 | 0.826 | 0.429 | | |
| 50 % | | **1.85** | 0.779 | 0.480 | 0.480 | 0.413 | 0.215 | | |
| 75 % | | 0.925 | 0.480 | 0.480 | 0.480 | 0.218 | 0.114 | | |
| 90 % | | 0.480 | 0.480 | 0.480 | 0.480 | 0.218 | 0.114 | | |
| None | R4 Stream | **2.62** | **1.85** | **1.85** | **1.85** | 0.838 | 0.438 | | |
| 50 % | | **1.85** | **1.85** | **1.85** | **1.85** | 0.838 | 0.438 | | |
| 75 % | | **1.85** | **1.85** | **1.85** | **1.85** | 0.838 | 0.438 | | |
| 90 % | | **1.85** | **1.85** | **1.85** | **1.85** | 0.838 | 0.438 | | |

* 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 9.5-17: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in golf courses (golf courses; modelling use Golf courses -- Grass (Mar) -- 2×0.125 kg a.s./ha, 14d int.)**

| | |
|---|---|
| **Intended use** | golf courses |
| **Active substance** | trifloxystrobin |
| **Application rate (g/ha)** | 2 x 125 g/ha, 14d int. |

| 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 | D1 Ditch | 0.787 | 0.213 | 0.113 | 0.059 | 0.113 | 0.059 | | |
| 50 % | | 0.393 | 0.107 | 0.057 | 0.029 | 0.057 | 0.029 | | |
| 75 % | | 0.197 | 0.053 | 0.028 | 0.015 | 0.028 | 0.015 | | |
| 90 % | | 0.079 | 0.021 | 0.011 | 0.006 | 0.011 | 0.006 | | |
| None | D1 Stream | *0.537* | 0.196 | 0.104 | 0.054 | 0.104 | 0.054 | | |
| 50 % | | *0.269* | 0.098 | 0.052 | 0.027 | 0.052 | 0.027 | | |
| 75 % | | *0.134* | 0.049 | 0.026 | 0.014 | 0.026 | 0.014 | | |
| 90 % | | *0.054* | 0.020 | 0.010 | 0.005 | 0.010 | 0.005 | | |
| None | D2 Ditch | 0.801 | 0.217 | 0.115 | 0.060 | 0.115 | 0.060 | | |
| 50 % | | 0.400 | 0.109 | 0.058 | 0.030 | 0.058 | 0.030 | | |
| 75 % | | 0.200 | 0.054 | 0.029 | 0.015 | 0.029 | 0.015 | | |
| 90 % | | 0.080 | 0.022 | 0.012 | 0.006 | 0.012 | 0.006 | | |
| None | D2 Stream | 0.712 | 0.260 | 0.138 | 0.072 | 0.138 | 0.072 | | |
| 50 % | | 0.356 | 0.130 | 0.069 | 0.036 | 0.069 | 0.036 | | |
| 75 % | | 0.178 | 0.065 | 0.035 | 0.018 | 0.035 | 0.018 | | |
| 90 % | | 0.071 | 0.026 | 0.014 | 0.007 | 0.014 | 0.007 | | |
| None | D3 Ditch | 0.790 | 0.214 | 0.114 | 0.059 | 0.114 | 0.059 | | |
| 50 % | | 0.395 | 0.107 | 0.057 | 0.030 | 0.057 | 0.030 | | |
| 75 % | | 0.197 | 0.054 | 0.028 | 0.015 | 0.028 | 0.015 | | |
| 90 % | | 0.079 | 0.021 | 0.011 | 0.006 | 0.011 | 0.006 | | |
| None | D4 Pond | *0.038* | *0.032* | *0.023* | *0.015* | *0.023* | *0.015* | | |
| 50 % | | *0.019* | *0.016* | *0.011* | *0.008* | *0.011* | *0.008* | | |
| 75 % | | *0.009* | *0.008* | *0.006* | *0.004* | *0.006* | *0.004* | | |
| 90 % | | *0.004* | *0.003* | *0.002* | *0.002* | *0.002* | *0.002* | | |
| None | D4 Stream | 0.637 | 0.233 | 0.123 | 0.064 | 0.123 | 0.064 | | |
| 50 % | | 0.319 | 0.116 | 0.062 | 0.032 | 0.062 | 0.032 | | |
| 75 % | | 0.159 | 0.058 | 0.031 | 0.016 | 0.031 | 0.016 | | |
| 90 % | | 0.064 | 0.023 | 0.012 | 0.006 | 0.012 | 0.006 | | |
| None | D5 Pond | *0.034* | *0.029* | *0.021* | *0.014* | *0.021* | *0.014* | | |
| 50 % | | *0.017* | *0.014* | *0.010* | *0.007* | *0.010* | *0.007* | | |
| 75 % | | *0.008* | *0.007* | *0.005* | *0.003* | *0.005* | *0.003* | | |
| 90 % | | *0.003* | *0.003* | *0.002* | *0.001* | *0.002* | *0.001* | | |
| None | D5 Stream | 0.647 | 0.236 | 0.125 | 0.065 | 0.125 | 0.065 | | |
| 50 % | | 0.323 | 0.118 | 0.063 | 0.033 | 0.063 | 0.033 | | |
| 75 % | | 0.162 | 0.059 | 0.031 | 0.016 | 0.031 | 0.016 | | |
| 90 % | | 0.065 | 0.024 | 0.013 | 0.007 | 0.013 | 0.007 | | |
| None | R2 Stream | 0.688 | 0.252 | 0.133 | 0.069 | 0.133 | 0.069 | | |
| 50 % | | 0.344 | 0.126 | 0.067 | 0.035 | 0.067 | 0.035 | | |
| 75 % | | 0.172 | 0.063 | 0.033 | 0.017 | 0.033 | 0.017 | | |
| 90 % | | 0.069 | 0.025 | 0.013 | 0.007 | 0.013 | 0.007 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| None | R3 Stream | 0.733 | 0.268 | 0.142 | 0.074 | 0.142 | 0.074 | | |
| 50 % | | 0.366 | 0.134 | 0.071 | 0.037 | 0.071 | 0.037 | | |
| 75 % | | 0.183 | 0.067 | 0.036 | 0.018 | 0.036 | 0.018 | | |
| 90 % | | 0.073 | 0.027 | 0.014 | *0.014* | 0.014 | 0.007 | | |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D1 Ditch | **2.85** | 0.772 | 0.409 | 0.213 | 0.409 | 0.213 | | |
| 50 % | | **1.42** | 0.386 | 0.205 | 0.107 | 0.205 | 0.107 | | |
| 75 % | | 0.712 | 0.193 | 0.103 | 0.053 | 0.103 | 0.053 | | |
| 90 % | | 0.285 | 0.077 | 0.041 | 0.021 | 0.041 | 0.021 | | |
| None | D1 Stream | **1.95** | 0.708 | 0.376 | 0.195 | 0.376 | 0.195 | | |
| 50 % | | 0.974 | 0.354 | 0.188 | 0.097 | 0.188 | 0.097 | | |
| 75 % | | 0.487 | 0.177 | 0.094 | 0.049 | 0.094 | 0.049 | | |
| 90 % | | 0.195 | 0.071 | 0.038 | 0.020 | 0.038 | 0.020 | | |
| None | D2 Ditch | **2.90** | 0.786 | 0.417 | 0.217 | 0.417 | 0.217 | | |
| 50 % | | **1.45** | 0.393 | 0.209 | 0.108 | 0.209 | 0.108 | | |
| 75 % | | 0.725 | 0.197 | 0.104 | 0.054 | 0.104 | 0.054 | | |
| 90 % | | 0.290 | 0.079 | 0.042 | 0.022 | 0.042 | 0.022 | | |
| None | D2 Stream | **2.58** | 0.943 | 0.500 | 0.260 | 0.500 | 0.260 | | |
| 50 % | | **1.29** | 0.471 | 0.250 | 0.130 | 0.250 | 0.130 | | |
| 75 % | | 0.645 | 0.236 | 0.125 | 0.065 | 0.125 | 0.065 | | |
| 90 % | | 0.258 | 0.094 | 0.050 | 0.026 | 0.050 | 0.026 | | |
| None | D3 Ditch | **2.86** | 0.775 | 0.411 | 0.214 | 0.411 | 0.214 | | |
| 50 % | | **1.43** | 0.388 | 0.206 | 0.107 | 0.206 | 0.107 | | |
| 75 % | | 0.715 | 0.194 | 0.103 | 0.053 | 0.103 | 0.053 | | |
| 90 % | | 0.286 | 0.078 | 0.041 | 0.021 | 0.041 | 0.021 | | |
| None | D4 Pond | 0.136 | 0.117 | 0.083 | 0.055 | 0.083 | 0.055 | | |
| 50 % | | 0.068 | 0.058 | 0.041 | 0.027 | 0.041 | 0.027 | | |
| 75 % | | 0.034 | 0.029 | 0.021 | 0.014 | 0.021 | 0.014 | | |
| 90 % | | 0.013 | 0.012 | 0.008 | 0.005 | 0.008 | 0.005 | | |
| None | D4 Stream | **2.31** | 0.843 | 0.447 | 0.232 | 0.447 | 0.232 | | |
| 50 % | | **1.15** | 0.422 | 0.224 | 0.116 | 0.224 | 0.116 | | |
| 75 % | | 0.577 | 0.211 | 0.112 | 0.058 | 0.112 | 0.058 | | |
| 90 % | | 0.231 | 0.084 | 0.045 | 0.023 | 0.045 | 0.023 | | |
| None | D5 Pond | 0.122 | 0.105 | 0.074 | 0.049 | 0.074 | 0.049 | | |
| 50 % | | 0.061 | 0.052 | 0.037 | 0.024 | 0.037 | 0.024 | | |
| 75 % | | 0.030 | 0.026 | 0.018 | 0.012 | 0.018 | 0.012 | | |
| 90 % | | 0.012 | 0.011 | 0.007 | 0.005 | 0.007 | 0.005 | | |
| None | D5 Stream | **2.34** | 0.856 | 0.454 | 0.236 | 0.454 | 0.236 | | |
| 50 % | | **1.17** | 0.428 | 0.227 | 0.118 | 0.227 | 0.118 | | |
| 75 % | | 0.586 | 0.214 | 0.113 | 0.059 | 0.113 | 0.059 | | |
| 90 % | | 0.234 | 0.086 | 0.045 | 0.024 | 0.045 | 0.024 | | |
| None | R2 Stream | **2.49** | 0.911 | 0.483 | 0.251 | 0.483 | 0.251 | | |
| 50 % | | **1.25** | 0.456 | 0.242 | 0.126 | 0.242 | 0.126 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 75 % | | 0.624 | 0.228 | 0.121 | 0.063 | 0.121 | 0.063 | | |
| 90 % | | 0.249 | 0.091 | 0.049 | 0.025 | 0.049 | 0.025 | | |
| None | R3 Stream | **2.66** | 0.970 | 0.514 | 0.267 | 0.514 | 0.267 | | |
| 50 % | | **1.33** | 0.485 | 0.257 | 0.134 | 0.257 | 0.134 | | |
| 75 % | | 0.664 | 0.242 | 0.129 | 0.067 | 0.129 | 0.067 | | |
| 90 % | | 0.266 | 0.097 | 0.051 | 0.049 | 0.051 | 0.027 | | |

* 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 9.5-18: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in golf courses (golf courses; modelling use Golf courses -- Grass (Jun) -- 2×0.125 kg a.s./ha, 14d int.)**

| **Intended use** | | golf courses | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 2 x 125 g/ha, 14d int. | | | | | | | |
| 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 | D1 Ditch | *0.969* | *0.250* | *0.130* | *0.066* | *0.130* | *0.066* | | |
| 50 % | | *0.483* | *0.125* | *0.065* | *0.033* | *0.065* | *0.033* | | |
| 75 % | | *0.241* | *0.062* | *0.032* | *0.016* | *0.032* | *0.016* | | |
| 90 % | | *0.096* | *0.025* | *0.013* | *0.007* | *0.013* | *0.007* | | |
| None | D1 Stream | 0.700 | 0.256 | 0.136 | 0.070 | 0.136 | 0.070 | | |
| 50 % | | 0.350 | 0.128 | 0.068 | 0.035 | 0.068 | 0.035 | | |
| 75 % | | 0.175 | 0.064 | 0.034 | 0.018 | 0.034 | 0.018 | | |
| 90 % | | 0.070 | 0.026 | 0.014 | 0.007 | 0.014 | 0.007 | | |
| None | D2 Ditch | *0.980* | *0.253* | *0.131* | *0.067* | *0.131* | *0.067* | | |
| 50 % | | *0.489* | *0.126* | *0.066* | *0.033* | *0.066* | *0.033* | | |
| 75 % | | *0.244* | *0.063* | *0.033* | *0.017* | *0.033* | *0.017* | | |
| 90 % | | *0.097* | *0.025* | *0.013* | *0.007* | *0.013* | *0.007* | | |
| None | D2 Stream | *0.857* | *0.302* | *0.156* | *0.079* | *0.156* | *0.079* | | |
| 50 % | | *0.428* | *0.151* | *0.078* | *0.040* | *0.078* | *0.040* | | |
| 75 % | | *0.213* | *0.075* | *0.039* | *0.020* | *0.039* | *0.020* | | |
| 90 % | | *0.085* | *0.030* | *0.016* | *0.008* | *0.016* | *0.008* | | |
| None | D3 Ditch | 0.795 | 0.215 | 0.114 | 0.059 | 0.114 | 0.059 | | |
| 50 % | | 0.397 | 0.108 | 0.057 | 0.030 | 0.057 | 0.030 | | |
| 75 % | | 0.199 | 0.054 | 0.029 | 0.015 | 0.029 | 0.015 | | |
| 90 % | | 0.079 | 0.022 | 0.011 | 0.006 | 0.011 | 0.006 | | |
| None | D4 Pond | *0.033* | *0.028* | *0.020* | *0.013* | *0.020* | *0.013* | | |
| 50 % | | *0.016* | *0.014* | *0.010* | *0.007* | *0.010* | *0.007* | | |
| 75 % | | *0.008* | *0.007* | *0.005* | *0.003* | *0.005* | *0.003* | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 90 % | | *0.003* | *0.003* | *0.002* | *0.001* | *0.002* | *0.001* | | |
| None | D4 Stream | 0.680 | 0.248 | 0.132 | 0.068 | 0.132 | 0.068 | | |
| 50 % | | 0.340 | 0.124 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| 75 % | | 0.170 | 0.062 | 0.033 | 0.017 | 0.033 | 0.017 | | |
| 90 % | | 0.068 | 0.025 | 0.013 | 0.007 | 0.013 | 0.007 | | |
| None | D5 Pond | *0.038* | *0.032* | *0.023* | *0.015* | *0.023* | *0.015* | | |
| 50 % | | *0.019* | *0.016* | *0.012* | *0.008* | *0.012* | *0.008* | | |
| 75 % | | *0.009* | *0.008* | *0.006* | *0.004* | *0.006* | *0.004* | | |
| 90 % | | *0.004* | *0.003* | *0.002* | *0.002* | *0.002* | *0.002* | | |
| None | D5 Stream | 0.738 | 0.269 | 0.143 | 0.074 | 0.143 | 0.074 | | |
| 50 % | | 0.369 | 0.135 | 0.071 | 0.037 | 0.071 | 0.037 | | |
| 75 % | | 0.184 | 0.067 | 0.036 | 0.019 | 0.036 | 0.019 | | |
| 90 % | | 0.074 | 0.027 | 0.014 | 0.007 | 0.014 | 0.007 | | |
| None | R2 Stream | 0.701 | 0.256 | 0.136 | 0.071 | 0.136 | 0.071 | | |
| 50 % | | 0.350 | 0.128 | 0.068 | 0.035 | 0.068 | 0.035 | | |
| 75 % | | 0.175 | 0.064 | 0.034 | 0.018 | 0.034 | 0.018 | | |
| 90 % | | 0.070 | 0.026 | 0.014 | 0.007 | 0.014 | 0.007 | | |
| None | R3 Stream | 0.737 | 0.269 | 0.143 | 0.074 | 0.143 | 0.074 | | |
| 50 % | | 0.369 | 0.135 | 0.071 | 0.037 | 0.071 | 0.037 | | |
| 75 % | | 0.184 | 0.067 | 0.036 | 0.032 | 0.036 | 0.019 | | |
| 90 % | | 0.074 | 0.032 | 0.032 | 0.032 | 0.014 | 0.008 | | |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D1 Ditch | **3.51** | 0.907 | 0.470 | 0.238 | 0.470 | 0.238 | | |
| 50 % | | **1.75** | 0.453 | 0.235 | 0.119 | 0.235 | 0.119 | | |
| 75 % | | 0.874 | 0.226 | 0.117 | 0.059 | 0.117 | 0.059 | | |
| 90 % | | 0.349 | 0.090 | 0.047 | 0.024 | 0.047 | 0.024 | | |
| None | D1 Stream | **2.53** | 0.926 | 0.491 | 0.255 | 0.491 | 0.255 | | |
| 50 % | | **1.27** | 0.463 | 0.246 | 0.128 | 0.246 | 0.128 | | |
| 75 % | | 0.634 | 0.232 | 0.123 | 0.064 | 0.123 | 0.064 | | |
| 90 % | | 0.253 | 0.093 | 0.049 | 0.025 | 0.049 | 0.025 | | |
| None | D2 Ditch | **3.55** | 0.917 | 0.475 | 0.241 | 0.475 | 0.241 | | |
| 50 % | | **1.77** | 0.458 | 0.237 | 0.120 | 0.237 | 0.120 | | |
| 75 % | | 0.883 | 0.228 | 0.118 | 0.060 | 0.118 | 0.060 | | |
| 90 % | | 0.353 | 0.091 | 0.047 | 0.024 | 0.047 | 0.024 | | |
| None | D2 Stream | **3.11** | **1.09** | 0.567 | 0.288 | 0.567 | 0.288 | | |
| 50 % | | **1.55** | 0.546 | 0.283 | 0.143 | 0.283 | 0.143 | | |
| 75 % | | 0.773 | 0.272 | 0.141 | 0.072 | 0.141 | 0.072 | | |
| 90 % | | 0.308 | 0.109 | 0.056 | 0.029 | 0.056 | 0.029 | | |
| None | D3 Ditch | **2.88** | 0.780 | 0.414 | 0.215 | 0.414 | 0.215 | | |
| 50 % | | **1.44** | 0.390 | 0.207 | 0.108 | 0.207 | 0.108 | | |
| 75 % | | 0.720 | 0.195 | 0.104 | 0.054 | 0.104 | 0.054 | | |
| 90 % | | 0.288 | 0.078 | 0.041 | 0.021 | 0.041 | 0.021 | | |
| None | D4 Pond | 0.118 | 0.102 | 0.072 | 0.047 | 0.072 | 0.047 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 50 % | | 0.059 | 0.051 | 0.036 | 0.024 | 0.036 | 0.024 | | |
| 75 % | | 0.029 | 0.025 | 0.018 | 0.012 | 0.018 | 0.012 | | |
| 90 % | | 0.012 | 0.010 | 0.007 | 0.005 | 0.007 | 0.005 | | |
| None | D4 Stream | **2.46** | 0.900 | 0.477 | 0.248 | 0.477 | 0.248 | | |
| 50 % | | **1.23** | 0.450 | 0.238 | 0.124 | 0.238 | 0.124 | | |
| 75 % | | 0.616 | 0.225 | 0.119 | 0.062 | 0.119 | 0.062 | | |
| 90 % | | 0.246 | 0.090 | 0.048 | 0.025 | 0.048 | 0.025 | | |
| None | D5 Pond | 0.136 | 0.117 | 0.083 | 0.055 | 0.083 | 0.055 | | |
| 50 % | | 0.068 | 0.059 | 0.042 | 0.027 | 0.042 | 0.027 | | |
| 75 % | | 0.034 | 0.029 | 0.021 | 0.014 | 0.021 | 0.014 | | |
| 90 % | | 0.013 | 0.012 | 0.008 | 0.005 | 0.008 | 0.005 | | |
| None | D5 Stream | **2.67** | 0.976 | 0.518 | 0.269 | 0.518 | 0.269 | | |
| 50 % | | **1.34** | 0.488 | 0.259 | 0.134 | 0.259 | 0.134 | | |
| 75 % | | 0.668 | 0.244 | 0.129 | 0.067 | 0.129 | 0.067 | | |
| 90 % | | 0.267 | 0.098 | 0.052 | 0.027 | 0.052 | 0.027 | | |
| None | R2 Stream | **2.54** | 0.928 | 0.492 | 0.255 | 0.492 | 0.255 | | |
| 50 % | | **1.27** | 0.464 | 0.246 | 0.128 | 0.246 | 0.128 | | |
| 75 % | | 0.635 | 0.232 | 0.123 | 0.064 | 0.123 | 0.064 | | |
| 90 % | | 0.254 | 0.093 | 0.049 | 0.026 | 0.049 | 0.026 | | |
| None | R3 Stream | **2.67** | 0.976 | 0.517 | 0.269 | 0.517 | 0.269 | | |
| 50 % | | **1.34** | 0.488 | 0.259 | 0.134 | 0.259 | 0.134 | | |
| 75 % | | 0.668 | 0.244 | 0.129 | 0.115 | 0.129 | 0.067 | | |
| 90 % | | 0.267 | 0.115 | 0.115 | 0.115 | 0.052 | 0.027 | | |

* 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 9.5-19: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in golf courses (golf courses; modelling use Golf courses -- Grass (Sep) -- 2×0.125 kg a.s./ha, 14d int.)**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Intended use** | | golf courses | | | | | | | |
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 2 x 125 g/ha, 14d int. | | | | | | | |
| 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 | D1 Ditch | *0.990* | *0.256* | *0.133* | *0.067* | *0.133* | *0.067* | | |
| 50 % | | *0.494* | *0.128* | *0.066* | *0.034* | *0.066* | *0.034* | | |
| 75 % | | *0.247* | *0.064* | *0.033* | *0.017* | *0.033* | *0.017* | | |
| 90 % | | *0.098* | *0.025* | *0.013* | *0.007* | *0.013* | *0.007* | | |
| None | D1 Stream | 0.700 | 0.256 | 0.136 | 0.070 | 0.136 | 0.070 | | |
| 50 % | | 0.350 | 0.128 | 0.068 | 0.035 | 0.068 | 0.035 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 75 % | | 0.175 | 0.064 | 0.034 | 0.018 | 0.034 | 0.018 | | |
| 90 % | | 0.070 | 0.026 | 0.014 | 0.007 | 0.014 | 0.007 | | |
| None | D2 Ditch | 0.801 | 0.217 | 0.115 | 0.060 | 0.115 | 0.060 | | |
| 50 % | | 0.400 | 0.109 | 0.058 | 0.030 | 0.058 | 0.030 | | |
| 75 % | | 0.200 | 0.054 | 0.029 | 0.015 | 0.029 | 0.015 | | |
| 90 % | | 0.080 | 0.022 | 0.012 | 0.006 | 0.012 | 0.006 | | |
| None | D2 Stream | 0.712 | 0.260 | 0.138 | 0.072 | 0.138 | 0.072 | | |
| 50 % | | 0.356 | 0.130 | 0.069 | 0.036 | 0.069 | 0.036 | | |
| 75 % | | 0.178 | 0.065 | 0.035 | 0.018 | 0.035 | 0.018 | | |
| 90 % | | 0.071 | 0.026 | 0.014 | 0.007 | 0.014 | 0.007 | | |
| None | D3 Ditch | 0.794 | 0.215 | 0.114 | 0.059 | 0.114 | 0.059 | | |
| 50 % | | 0.397 | 0.108 | 0.057 | 0.030 | 0.057 | 0.030 | | |
| 75 % | | 0.198 | 0.054 | 0.029 | 0.015 | 0.029 | 0.015 | | |
| 90 % | | 0.079 | 0.022 | 0.011 | 0.006 | 0.011 | 0.006 | | |
| None | D4 Pond | *0.037* | *0.032* | *0.023* | *0.015* | *0.023* | *0.015* | | |
| 50 % | | *0.019* | *0.016* | *0.011* | *0.007* | *0.011* | *0.007* | | |
| 75 % | | *0.009* | *0.008* | *0.006* | *0.004* | *0.006* | *0.004* | | |
| 90 % | | *0.004* | *0.003* | *0.002* | *0.002* | *0.002* | *0.002* | | |
| None | D4 Stream | 0.684 | 0.250 | 0.132 | 0.069 | 0.132 | 0.069 | | |
| 50 % | | 0.342 | 0.125 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| 75 % | | 0.171 | 0.062 | 0.033 | 0.017 | 0.033 | 0.017 | | |
| 90 % | | 0.068 | 0.025 | 0.013 | 0.007 | 0.013 | 0.007 | | |
| None | D5 Pond | *0.038* | *0.033* | *0.023* | *0.015* | *0.023* | *0.015* | | |
| 50 % | | *0.019* | *0.016* | *0.012* | *0.008* | *0.012* | *0.008* | | |
| 75 % | | *0.010* | *0.008* | *0.006* | *0.004* | *0.006* | *0.004* | | |
| 90 % | | *0.004* | *0.003* | *0.002* | *0.002* | *0.002* | *0.002* | | |
| None | D5 Stream | 0.738 | 0.269 | 0.143 | 0.074 | 0.143 | 0.074 | | |
| 50 % | | 0.369 | 0.135 | 0.071 | 0.037 | 0.071 | 0.037 | | |
| 75 % | | 0.184 | 0.067 | 0.036 | 0.019 | 0.036 | 0.019 | | |
| 90 % | | 0.074 | 0.027 | 0.014 | 0.007 | 0.014 | 0.007 | | |
| None | R2 Stream | 0.701 | 0.256 | 0.136 | 0.071 | 0.136 | 0.071 | | |
| 50 % | | 0.350 | 0.128 | 0.068 | 0.035 | 0.068 | 0.035 | | |
| 75 % | | 0.175 | 0.064 | 0.034 | 0.018 | 0.034 | 0.018 | | |
| 90 % | | 0.070 | 0.026 | *0.017* | *0.017* | 0.014 | 0.007 | | |
| None | R3 Stream | 0.736 | 0.269 | *0.143* | *0.143* | 0.143 | 0.074 | | |
| 50 % | | 0.368 | *0.143* | *0.143* | *0.143* | 0.071 | 0.037 | | |
| 75 % | | 0.184 | *0.143* | *0.143* | *0.143* | *0.065* | *0.034* | | |
| 90 % | | *0.143* | *0.143* | *0.143* | *0.143* | *0.065* | *0.034* | | |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D1 Ditch | **3.59** | 0.927 | 0.480 | 0.244 | 0.480 | 0.244 | | |
| 50 % | | **1.79** | 0.462 | 0.240 | 0.122 | 0.240 | 0.122 | | |
| 75 % | | 0.893 | 0.231 | 0.120 | 0.061 | 0.120 | 0.061 | | |
| 90 % | | 0.356 | 0.092 | 0.048 | 0.024 | 0.048 | 0.024 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| None | D1 Stream | **2.53** | 0.926 | 0.491 | 0.255 | 0.491 | 0.255 | | |
| 50 % | | **1.27** | 0.463 | 0.246 | 0.128 | 0.246 | 0.128 | | |
| 75 % | | 0.634 | 0.232 | 0.123 | 0.064 | 0.123 | 0.064 | | |
| 90 % | | 0.253 | 0.093 | 0.049 | 0.025 | 0.049 | 0.025 | | |
| None | D2 Ditch | **2.90** | 0.786 | 0.417 | 0.217 | 0.417 | 0.217 | | |
| 50 % | | **1.45** | 0.393 | 0.209 | 0.108 | 0.209 | 0.108 | | |
| 75 % | | 0.725 | 0.197 | 0.104 | 0.054 | 0.104 | 0.054 | | |
| 90 % | | 0.290 | 0.079 | 0.042 | 0.022 | 0.042 | 0.022 | | |
| None | D2 Stream | **2.58** | 0.943 | 0.500 | 0.260 | 0.500 | 0.260 | | |
| 50 % | | **1.29** | 0.471 | 0.250 | 0.130 | 0.250 | 0.130 | | |
| 75 % | | 0.645 | 0.236 | 0.125 | 0.065 | 0.125 | 0.065 | | |
| 90 % | | 0.258 | 0.094 | 0.050 | 0.026 | 0.050 | 0.026 | | |
| None | D3 Ditch | **2.87** | 0.779 | 0.413 | 0.215 | 0.413 | 0.215 | | |
| 50 % | | **1.44** | 0.389 | 0.207 | 0.107 | 0.207 | 0.107 | | |
| 75 % | | 0.719 | 0.195 | 0.103 | 0.054 | 0.103 | 0.054 | | |
| 90 % | | 0.287 | 0.078 | 0.041 | 0.021 | 0.041 | 0.021 | | |
| None | D4 Pond | 0.134 | 0.116 | 0.082 | 0.054 | 0.082 | 0.054 | | |
| 50 % | | 0.067 | 0.058 | 0.041 | 0.027 | 0.041 | 0.027 | | |
| 75 % | | 0.033 | 0.029 | 0.020 | 0.013 | 0.020 | 0.013 | | |
| 90 % | | 0.013 | 0.012 | 0.008 | 0.005 | 0.008 | 0.005 | | |
| None | D4 Stream | **2.48** | 0.905 | 0.480 | 0.249 | 0.480 | 0.249 | | |
| 50 % | | **1.24** | 0.453 | 0.240 | 0.125 | 0.240 | 0.125 | | |
| 75 % | | 0.619 | 0.226 | 0.120 | 0.062 | 0.120 | 0.062 | | |
| 90 % | | 0.248 | 0.091 | 0.048 | 0.025 | 0.048 | 0.025 | | |
| None | D5 Pond | 0.139 | 0.119 | 0.084 | 0.055 | 0.084 | 0.055 | | |
| 50 % | | 0.069 | 0.059 | 0.042 | 0.028 | 0.042 | 0.028 | | |
| 75 % | | 0.034 | 0.030 | 0.021 | 0.014 | 0.021 | 0.014 | | |
| 90 % | | 0.014 | 0.012 | 0.008 | 0.005 | 0.008 | 0.005 | | |
| None | D5 Stream | **2.67** | 0.976 | 0.518 | 0.269 | 0.518 | 0.269 | | |
| 50 % | | **1.34** | 0.488 | 0.259 | 0.134 | 0.259 | 0.134 | | |
| 75 % | | 0.668 | 0.244 | 0.129 | 0.067 | 0.129 | 0.067 | | |
| 90 % | | 0.267 | 0.098 | 0.052 | 0.027 | 0.052 | 0.027 | | |
| None | R2 Stream | **2.54** | 0.928 | 0.492 | 0.255 | 0.492 | 0.255 | | |
| 50 % | | **1.27** | 0.464 | 0.246 | 0.128 | 0.246 | 0.128 | | |
| 75 % | | 0.635 | 0.232 | 0.123 | 0.064 | 0.123 | 0.064 | | |
| 90 % | | 0.254 | 0.093 | 0.061 | 0.061 | 0.049 | 0.026 | | |
| None | R3 Stream | **2.67** | 0.974 | 0.519 | 0.519 | 0.517 | 0.268 | | |
| 50 % | | **1.33** | 0.519 | 0.519 | 0.519 | 0.258 | 0.134 | | |
| 75 % | | 0.667 | 0.519 | 0.519 | 0.519 | 0.235 | 0.123 | | |
| 90 % | | 0.519 | 0.519 | 0.519 | 0.519 | 0.235 | 0.123 | | |

* 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 9.5-20: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in golf courses (golf courses; modelling use Golf courses -- Grass (Dec) -- 2×0.125 kg a.s./ha, 14d int.)**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Intended use** | | golf courses | | | | | | | |
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 2 x 125 g/ha, 14d int. | | | | | | | |
| 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 | D1 Ditch | 0.800 | 0.217 | 0.115 | 0.060 | 0.115 | 0.060 | | |
| 50 % | | 0.400 | 0.108 | 0.058 | 0.030 | 0.058 | 0.030 | | |
| 75 % | | 0.200 | 0.054 | 0.029 | 0.015 | 0.029 | 0.015 | | |
| 90 % | | 0.080 | 0.022 | 0.012 | 0.006 | 0.012 | 0.006 | | |
| None | D1 Stream | 0.700 | 0.256 | 0.136 | 0.070 | 0.136 | 0.070 | | |
| 50 % | | 0.350 | 0.128 | 0.068 | 0.035 | 0.068 | 0.035 | | |
| 75 % | | 0.175 | 0.064 | 0.034 | 0.018 | 0.034 | 0.018 | | |
| 90 % | | 0.070 | 0.026 | 0.014 | 0.007 | 0.014 | 0.007 | | |
| None | D2 Ditch | 0.801 | 0.217 | 0.115 | 0.060 | 0.115 | 0.060 | | |
| 50 % | | 0.400 | 0.109 | 0.058 | 0.030 | 0.058 | 0.030 | | |
| 75 % | | 0.200 | 0.054 | 0.029 | 0.015 | 0.029 | 0.015 | | |
| 90 % | | 0.080 | 0.022 | 0.012 | 0.006 | 0.012 | 0.006 | | |
| None | D2 Stream | 0.712 | 0.260 | 0.138 | 0.072 | 0.138 | 0.072 | | |
| 50 % | | 0.356 | 0.130 | 0.069 | 0.036 | 0.069 | 0.036 | | |
| 75 % | | 0.178 | 0.065 | 0.035 | 0.018 | 0.035 | 0.018 | | |
| 90 % | | 0.071 | 0.026 | 0.014 | 0.007 | 0.014 | 0.007 | | |
| None | D3 Ditch | 0.790 | 0.214 | 0.114 | 0.059 | 0.114 | 0.059 | | |
| 50 % | | 0.395 | 0.107 | 0.057 | 0.030 | 0.057 | 0.030 | | |
| 75 % | | 0.197 | 0.054 | 0.028 | 0.015 | 0.028 | 0.015 | | |
| 90 % | | 0.079 | 0.021 | 0.011 | 0.006 | 0.011 | 0.006 | | |
| None | D4 Pond | *0.037* | *0.031* | *0.022* | *0.015* | *0.022* | *0.015* | | |
| 50 % | | *0.018* | *0.016* | *0.011* | *0.007* | *0.011* | *0.007* | | |
| 75 % | | *0.009* | *0.008* | *0.006* | *0.004* | *0.006* | *0.004* | | |
| 90 % | | *0.004* | *0.003* | *0.002* | *0.002* | *0.002* | *0.002* | | |
| None | D4 Stream | 0.684 | 0.250 | 0.132 | 0.069 | 0.132 | 0.069 | | |
| 50 % | | 0.342 | 0.125 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| 75 % | | 0.171 | 0.062 | 0.033 | 0.017 | 0.033 | 0.017 | | |
| 90 % | | 0.068 | 0.025 | 0.013 | 0.007 | 0.013 | 0.007 | | |
| None | D5 Pond | *0.036* | *0.031* | *0.022* | *0.015* | *0.022* | *0.015* | | |
| 50 % | | *0.018* | *0.016* | *0.011* | *0.007* | *0.011* | *0.007* | | |
| 75 % | | *0.009* | *0.008* | *0.006* | *0.004* | *0.006* | *0.004* | | |
| 90 % | | *0.004* | *0.003* | *0.002* | *0.001* | *0.002* | *0.001* | | |
| None | D5 Stream | 0.738 | 0.269 | 0.143 | 0.074 | 0.143 | 0.074 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 50 % | | 0.369 | 0.135 | 0.071 | 0.037 | 0.071 | 0.037 | | |
| 75 % | | 0.184 | 0.067 | 0.036 | 0.019 | 0.036 | 0.019 | | |
| 90 % | | 0.074 | 0.027 | 0.014 | 0.007 | 0.014 | 0.007 | | |
| None | R2 Stream | 0.668 | 0.244 | 0.129 | 0.067 | 0.129 | 0.067 | | |
| 50 % | | 0.334 | 0.122 | 0.065 | 0.034 | 0.065 | 0.034 | | |
| 75 % | | 0.167 | 0.061 | 0.032 | 0.018 | 0.032 | 0.017 | | |
| 90 % | | 0.067 | 0.024 | 0.018 | 0.018 | 0.013 | 0.007 | | |
| None | R3 Stream | 0.729 | 0.266 | 0.141 | 0.073 | 0.141 | 0.073 | | |
| 50 % | | 0.364 | 0.133 | 0.071 | 0.037 | 0.071 | 0.037 | | |
| 75 % | | 0.182 | 0.067 | 0.035 | 0.018 | 0.035 | 0.018 | | |
| 90 % | | 0.073 | 0.027 | 0.014 | 0.007 | 0.014 | 0.007 | | |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D1 Ditch | **2.90** | 0.786 | 0.417 | 0.217 | 0.417 | 0.217 | | |
| 50 % | | **1.45** | 0.393 | 0.208 | 0.108 | 0.208 | 0.108 | | |
| 75 % | | 0.725 | 0.196 | 0.104 | 0.054 | 0.104 | 0.054 | | |
| 90 % | | 0.290 | 0.079 | 0.042 | 0.022 | 0.042 | 0.022 | | |
| None | D1 Stream | **2.53** | 0.926 | 0.491 | 0.255 | 0.491 | 0.255 | | |
| 50 % | | **1.27** | 0.463 | 0.246 | 0.128 | 0.246 | 0.128 | | |
| 75 % | | 0.634 | 0.232 | 0.123 | 0.064 | 0.123 | 0.064 | | |
| 90 % | | 0.253 | 0.093 | 0.049 | 0.025 | 0.049 | 0.025 | | |
| None | D2 Ditch | **2.90** | 0.786 | 0.417 | 0.217 | 0.417 | 0.217 | | |
| 50 % | | **1.45** | 0.393 | 0.209 | 0.108 | 0.209 | 0.108 | | |
| 75 % | | 0.725 | 0.197 | 0.104 | 0.054 | 0.104 | 0.054 | | |
| 90 % | | 0.290 | 0.079 | 0.042 | 0.022 | 0.042 | 0.022 | | |
| None | D2 Stream | **2.58** | 0.943 | 0.500 | 0.260 | 0.500 | 0.260 | | |
| 50 % | | **1.29** | 0.471 | 0.250 | 0.130 | 0.250 | 0.130 | | |
| 75 % | | 0.645 | 0.236 | 0.125 | 0.065 | 0.125 | 0.065 | | |
| 90 % | | 0.258 | 0.094 | 0.050 | 0.026 | 0.050 | 0.026 | | |
| None | D3 Ditch | **2.86** | 0.775 | 0.411 | 0.214 | 0.411 | 0.214 | | |
| 50 % | | **1.43** | 0.388 | 0.206 | 0.107 | 0.206 | 0.107 | | |
| 75 % | | 0.715 | 0.194 | 0.103 | 0.054 | 0.103 | 0.054 | | |
| 90 % | | 0.286 | 0.078 | 0.041 | 0.021 | 0.041 | 0.021 | | |
| None | D4 Pond | 0.133 | 0.114 | 0.081 | 0.053 | 0.081 | 0.053 | | |
| 50 % | | 0.066 | 0.057 | 0.040 | 0.026 | 0.040 | 0.026 | | |
| 75 % | | 0.033 | 0.028 | 0.020 | 0.013 | 0.020 | 0.013 | | |
| 90 % | | 0.013 | 0.011 | 0.008 | 0.005 | 0.008 | 0.005 | | |
| None | D4 Stream | **2.48** | 0.905 | 0.480 | 0.249 | 0.480 | 0.249 | | |
| 50 % | | **1.24** | 0.453 | 0.240 | 0.125 | 0.240 | 0.125 | | |
| 75 % | | 0.619 | 0.226 | 0.120 | 0.062 | 0.120 | 0.062 | | |
| 90 % | | 0.248 | 0.091 | 0.048 | 0.025 | 0.048 | 0.025 | | |
| None | D5 Pond | 0.131 | 0.113 | 0.080 | 0.053 | 0.080 | 0.053 | | |
| 50 % | | 0.066 | 0.056 | 0.040 | 0.026 | 0.040 | 0.026 | | |
| 75 % | | 0.033 | 0.028 | 0.020 | 0.013 | 0.020 | 0.013 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 90 % | | 0.013 | 0.011 | 0.008 | 0.005 | 0.008 | 0.005 | | |
| None | D5 Stream | **2.67** | 0.976 | 0.518 | 0.269 | 0.518 | 0.269 | | |
| 50 % | | **1.34** | 0.488 | 0.259 | 0.134 | 0.259 | 0.134 | | |
| 75 % | | 0.668 | 0.244 | 0.129 | 0.067 | 0.129 | 0.067 | | |
| 90 % | | 0.267 | 0.098 | 0.052 | 0.027 | 0.052 | 0.027 | | |
| None | R2 Stream | **2.42** | 0.884 | 0.468 | 0.243 | 0.468 | 0.243 | | |
| 50 % | | **1.21** | 0.442 | 0.234 | 0.122 | 0.234 | 0.122 | | |
| 75 % | | 0.605 | 0.221 | 0.117 | 0.065 | 0.117 | 0.061 | | |
| 90 % | | 0.242 | 0.088 | 0.065 | 0.065 | 0.047 | 0.024 | | |
| None | R3 Stream | **2.64** | 0.965 | 0.512 | 0.266 | 0.512 | 0.266 | | |
| 50 % | | **1.32** | 0.483 | 0.256 | 0.133 | 0.256 | 0.133 | | |
| 75 % | | 0.660 | 0.241 | 0.128 | 0.066 | 0.128 | 0.066 | | |
| 90 % | | 0.264 | 0.096 | 0.051 | 0.026 | 0.051 | 0.026 | | |

* 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 9.5-21: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in peas (peas; modelling use Legumes I -- BBCH 59 - 89 -- 2×0.2 kg a.s./ha, 7d int.)**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Intended use** | | peas | | | | | | | |
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 2 x 200 g/ha, 7d int. | | | | | | | |
| 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 | 1.05 | 0.343 | 0.182 | 0.095 | 0.182 | 0.095 | | |
| 50 % | | 0.523 | 0.172 | 0.091 | 0.047 | 0.091 | 0.047 | | |
| 75 % | | 0.262 | 0.086 | 0.046 | 0.024 | 0.046 | 0.024 | | |
| 90 % | | 0.105 | 0.034 | 0.018 | 0.010 | 0.018 | 0.010 | | |
| None | D4 Pond | *0.061* | *0.054* | *0.038* | *0.025* | *0.038* | *0.025* | | |
| 50 % | | *0.030* | *0.027* | *0.019* | *0.013* | *0.019* | *0.013* | | |
| 75 % | | *0.015* | *0.014* | *0.010* | *0.006* | *0.010* | *0.006* | | |
| 90 % | | *0.006* | *0.005* | *0.004* | *0.003* | *0.004* | *0.003* | | |
| None | D4 Stream | 0.866 | 0.365 | 0.193 | 0.101 | 0.193 | 0.101 | | |
| 50 % | | 0.433 | 0.182 | 0.097 | 0.050 | 0.097 | 0.050 | | |
| 75 % | | 0.217 | 0.091 | 0.048 | 0.025 | 0.048 | 0.025 | | |
| 90 % | | 0.087 | 0.037 | 0.019 | 0.010 | 0.019 | 0.010 | | |
| None | D5 Pond | *0.061* | *0.054* | *0.038* | *0.025* | *0.038* | *0.025* | | |
| 50 % | | *0.030* | *0.027* | *0.019* | *0.013* | *0.019* | *0.013* | | |
| 75 % | | *0.015* | *0.013* | *0.010* | *0.006* | *0.010* | *0.006* | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 90 % | | *0.006* | *0.005* | *0.004* | *0.003* | *0.004* | *0.003* | | |
| None | D5 Stream | 1.00 | 0.421 | 0.223 | 0.116 | 0.223 | 0.116 | | |
| 50 % | | 0.500 | 0.211 | 0.112 | 0.058 | 0.112 | 0.058 | | |
| 75 % | | 0.250 | 0.105 | 0.056 | 0.029 | 0.056 | 0.029 | | |
| 90 % | | 0.100 | 0.042 | 0.022 | 0.012 | 0.022 | 0.012 | | |
| None | D6 Ditch | 1.04 | 0.342 | 0.181 | 0.094 | 0.181 | 0.094 | | |
| 50 % | | 0.522 | 0.171 | 0.091 | 0.047 | 0.091 | 0.047 | | |
| 75 % | | 0.261 | 0.086 | 0.045 | 0.024 | 0.045 | 0.024 | | |
| 90 % | | 0.104 | 0.034 | 0.018 | 0.009 | 0.018 | 0.009 | | |
| None | R1 Pond | *0.062* | *0.056* | *0.042* | *0.030* | *0.038* | *0.024* | | |
| 50 % | | *0.035* | *0.031* | *0.024* | *0.019* | *0.020* | *0.013* | | |
| 75 % | | *0.021* | *0.020* | *0.017* | *0.015* | *0.012* | *0.007* | | |
| 90 % | | *0.015* | *0.014* | *0.013* | *0.012* | *0.007* | *0.004* | | |
| None | R1 Stream | 0.726 | 0.306 | 0.162 | 0.133 | 0.162 | 0.084 | | |
| 50 % | | 0.363 | 0.153 | 0.133 | 0.133 | 0.081 | 0.042 | | |
| 75 % | | 0.182 | 0.133 | 0.133 | 0.133 | 0.061 | 0.032 | | |
| 90 % | | 0.133 | 0.133 | 0.133 | 0.133 | 0.061 | 0.032 | | |
| None | R2 Stream | 0.971 | 0.409 | 0.217 | 0.113 | 0.217 | 0.113 | | |
| 50 % | | 0.486 | 0.204 | 0.108 | 0.056 | 0.108 | 0.056 | | |
| 75 % | | 0.243 | 0.102 | 0.054 | 0.028 | 0.054 | 0.028 | | |
| 90 % | | 0.097 | 0.041 | 0.022 | *0.020* | 0.022 | 0.011 | | |
| None | R3 Stream | 1.02 | 0.431 | 0.229 | 0.119 | 0.229 | 0.119 | | |
| 50 % | | 0.512 | 0.215 | 0.114 | 0.059 | 0.114 | 0.059 | | |
| 75 % | | 0.256 | 0.108 | 0.057 | 0.030 | 0.057 | 0.030 | | |
| 90 % | | 0.102 | 0.043 | 0.023 | 0.012 | 0.023 | 0.012 | | |
| None | R4 Stream | 0.697 | 0.293 | 0.156 | *0.116* | 0.156 | 0.081 | | |
| 50 % | | 0.348 | 0.147 | *0.116* | *0.116* | 0.078 | 0.040 | | |
| 75 % | | 0.174 | *0.116* | *0.116* | *0.116* | *0.053* | *0.028* | | |
| 90 % | | *0.116* | *0.116* | *0.116* | *0.116* | *0.053* | *0.028* | | |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D3 Ditch | **3.79** | **1.24** | 0.659 | 0.342 | 0.659 | 0.342 | | |
| 50 % | | **1.90** | 0.621 | 0.329 | 0.171 | 0.329 | 0.171 | | |
| 75 % | | 0.948 | 0.311 | 0.165 | 0.086 | 0.165 | 0.086 | | |
| 90 % | | 0.379 | 0.124 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | D4 Pond | 0.221 | 0.196 | 0.139 | 0.091 | 0.139 | 0.091 | | |
| 50 % | | 0.110 | 0.098 | 0.070 | 0.046 | 0.070 | 0.046 | | |
| 75 % | | 0.055 | 0.049 | 0.035 | 0.023 | 0.035 | 0.023 | | |
| 90 % | | 0.022 | 0.020 | 0.014 | 0.009 | 0.014 | 0.009 | | |
| None | D4 Stream | **3.14** | **1.32** | 0.701 | 0.364 | 0.701 | 0.364 | | |
| 50 % | | **1.57** | 0.661 | 0.350 | 0.182 | 0.350 | 0.182 | | |
| 75 % | | 0.784 | 0.330 | 0.175 | 0.091 | 0.175 | 0.091 | | |
| 90 % | | 0.314 | 0.132 | 0.070 | 0.037 | 0.070 | 0.037 | | |
| None | D5 Pond | 0.219 | 0.195 | 0.138 | 0.091 | 0.138 | 0.091 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 50 % | | 0.109 | 0.097 | 0.069 | 0.045 | 0.069 | 0.045 | | |
| 75 % | | 0.055 | 0.049 | 0.034 | 0.023 | 0.034 | 0.023 | | |
| 90 % | | 0.022 | 0.020 | 0.014 | 0.009 | 0.014 | 0.009 | | |
| None | D5 Stream | **3.62** | **1.53** | 0.809 | 0.420 | 0.809 | 0.420 | | |
| 50 % | | **1.81** | 0.763 | 0.405 | 0.210 | 0.405 | 0.210 | | |
| 75 % | | 0.906 | 0.382 | 0.203 | 0.105 | 0.203 | 0.105 | | |
| 90 % | | 0.362 | 0.153 | 0.081 | 0.042 | 0.081 | 0.042 | | |
| None | D6 Ditch | **3.78** | **1.24** | 0.657 | 0.341 | 0.657 | 0.341 | | |
| 50 % | | **1.89** | 0.619 | 0.328 | 0.171 | 0.328 | 0.171 | | |
| 75 % | | 0.945 | 0.310 | 0.164 | 0.086 | 0.164 | 0.086 | | |
| 90 % | | 0.378 | 0.124 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | R1 Pond | 0.224 | 0.203 | 0.151 | 0.108 | 0.136 | 0.088 | | |
| 50 % | | 0.125 | 0.114 | 0.088 | 0.068 | 0.073 | 0.046 | | |
| 75 % | | 0.075 | 0.071 | 0.062 | 0.054 | 0.042 | 0.026 | | |
| 90 % | | 0.053 | 0.051 | 0.048 | 0.045 | 0.025 | 0.014 | | |
| None | R1 Stream | **2.63** | **1.11** | 0.587 | 0.482 | 0.587 | 0.305 | | |
| 50 % | | **1.32** | 0.554 | 0.482 | 0.482 | 0.293 | 0.153 | | |
| 75 % | | 0.658 | 0.482 | 0.482 | 0.482 | 0.220 | 0.115 | | |
| 90 % | | 0.482 | 0.482 | 0.482 | 0.482 | 0.220 | 0.115 | | |
| None | R2 Stream | **3.52** | **1.48** | 0.786 | 0.408 | 0.786 | 0.408 | | |
| 50 % | | **1.76** | 0.741 | 0.393 | 0.204 | 0.393 | 0.204 | | |
| 75 % | | 0.879 | 0.370 | 0.196 | 0.102 | 0.196 | 0.102 | | |
| 90 % | | 0.352 | 0.148 | 0.079 | 0.073 | 0.079 | 0.041 | | |
| None | R3 Stream | **3.71** | **1.56** | 0.828 | 0.430 | 0.828 | 0.430 | | |
| 50 % | | **1.85** | 0.780 | 0.414 | 0.215 | 0.414 | 0.215 | | |
| 75 % | | 0.927 | 0.390 | 0.207 | 0.108 | 0.207 | 0.108 | | |
| 90 % | | 0.371 | 0.156 | 0.083 | 0.043 | 0.083 | 0.043 | | |
| None | R4 Stream | **2.52** | **1.06** | 0.564 | 0.421 | 0.564 | 0.293 | | |
| 50 % | | **1.26** | 0.532 | 0.421 | 0.421 | 0.282 | 0.146 | | |
| 75 % | | 0.631 | 0.421 | 0.421 | 0.421 | 0.191 | 0.100 | | |
| 90 % | | 0.421 | 0.421 | 0.421 | 0.421 | 0.191 | 0.100 | | |

* 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 9.5-22: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in peas (peas; modelling use Legumes II -- BBCH 59 - 79 -- 2×0.2 kg a.s./ha, 14d int.)**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Intended use** | | peas | | | | | | | |
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 2 x 200 g/ha, 14d int. | | | | | | | |
| Nozzle | Vegetated | None | None | None | None | 10 m | 20 m | | |

| reduction | strip (m) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | No spray buffer (m) | 0 m | 5 m | 10 m | 20 m | 10 m | 20 m | | |
| None | D3 Ditch | 1.05 | 0.343 | 0.182 | 0.095 | 0.182 | 0.095 | | |
| 50 % | | 0.523 | 0.172 | 0.091 | 0.047 | 0.091 | 0.047 | | |
| 75 % | | 0.262 | 0.086 | 0.046 | 0.024 | 0.046 | 0.024 | | |
| 90 % | | 0.105 | 0.034 | 0.018 | 0.010 | 0.018 | 0.010 | | |
| None | D4 Pond | *0.058* | *0.052* | *0.037* | *0.024* | *0.037* | *0.024* | | |
| 50 % | | *0.029* | *0.026* | *0.018* | *0.012* | *0.018* | *0.012* | | |
| 75 % | | *0.015* | *0.013* | *0.009* | *0.006* | *0.009* | *0.006* | | |
| 90 % | | *0.006* | *0.005* | *0.004* | *0.002* | *0.004* | *0.002* | | |
| None | D4 Stream | 0.866 | 0.365 | 0.193 | 0.101 | 0.193 | 0.101 | | |
| 50 % | | 0.433 | 0.182 | 0.097 | 0.050 | 0.097 | 0.050 | | |
| 75 % | | 0.217 | 0.091 | 0.048 | 0.025 | 0.048 | 0.025 | | |
| 90 % | | 0.087 | 0.037 | 0.019 | 0.010 | 0.019 | 0.010 | | |
| None | D5 Pond | *0.059* | *0.053* | *0.037* | *0.025* | *0.037* | *0.025* | | |
| 50 % | | *0.030* | *0.026* | *0.019* | *0.012* | *0.019* | *0.012* | | |
| 75 % | | *0.015* | *0.013* | *0.009* | *0.006* | *0.009* | *0.006* | | |
| 90 % | | *0.006* | *0.005* | *0.004* | *0.003* | *0.004* | *0.003* | | |
| None | D5 Stream | 1.00 | 0.421 | 0.223 | 0.116 | 0.223 | 0.116 | | |
| 50 % | | 0.500 | 0.211 | 0.112 | 0.058 | 0.112 | 0.058 | | |
| 75 % | | 0.250 | 0.105 | 0.056 | 0.029 | 0.056 | 0.029 | | |
| 90 % | | 0.100 | 0.042 | 0.022 | 0.012 | 0.022 | 0.012 | | |
| None | D6 Ditch | 1.04 | 0.342 | 0.181 | 0.094 | 0.181 | 0.094 | | |
| 50 % | | 0.522 | 0.171 | 0.091 | 0.047 | 0.091 | 0.047 | | |
| 75 % | | 0.261 | 0.086 | 0.045 | 0.024 | 0.045 | 0.024 | | |
| 90 % | | 0.104 | 0.034 | 0.018 | 0.009 | 0.018 | 0.009 | | |
| None | R1 Pond | *0.062* | *0.056* | *0.042* | *0.030* | *0.038* | *0.024* | | |
| 50 % | | *0.035* | *0.031* | *0.024* | *0.019* | *0.020* | *0.013* | | |
| 75 % | | *0.021* | *0.020* | *0.017* | *0.015* | *0.012* | *0.007* | | |
| 90 % | | *0.015* | *0.014* | *0.013* | *0.012* | *0.007* | *0.004* | | |
| None | R1 Stream | 0.726 | 0.306 | 0.162 | 0.133 | 0.162 | 0.084 | | |
| 50 % | | 0.363 | 0.153 | 0.133 | 0.133 | 0.081 | 0.042 | | |
| 75 % | | 0.182 | 0.133 | 0.133 | 0.133 | 0.061 | 0.032 | | |
| 90 % | | 0.133 | 0.133 | 0.133 | 0.133 | 0.061 | 0.032 | | |
| None | R2 Stream | 0.971 | 0.409 | 0.217 | 0.113 | 0.217 | 0.113 | | |
| 50 % | | 0.486 | 0.204 | 0.108 | *0.066* | 0.108 | 0.056 | | |
| 75 % | | 0.243 | 0.102 | *0.066* | *0.066* | 0.054 | 0.028 | | |
| 90 % | | 0.097 | *0.066* | *0.066* | *0.066* | *0.030* | *0.016* | | |
| None | R3 Stream | 1.02 | 0.431 | 0.229 | 0.119 | 0.229 | 0.119 | | |
| 50 % | | 0.512 | 0.215 | 0.114 | 0.059 | 0.114 | 0.059 | | |
| 75 % | | 0.256 | 0.108 | 0.057 | 0.030 | 0.057 | 0.030 | | |
| 90 % | | 0.102 | 0.043 | 0.023 | 0.012 | 0.023 | 0.012 | | |
| None | R4 Stream | 0.697 | 0.293 | 0.156 | *0.116* | 0.156 | 0.081 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 50 % | | 0.348 | 0.147 | *0.116* | *0.116* | 0.078 | 0.040 | | |
| 75 % | | 0.174 | *0.116* | *0.116* | *0.116* | *0.053* | *0.028* | | |
| 90 % | | *0.116* | *0.116* | *0.116* | *0.116* | *0.053* | *0.028* | | |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D3 Ditch | **3.79** | **1.24** | 0.659 | 0.342 | 0.659 | 0.342 | | |
| 50 % | | **1.90** | 0.621 | 0.329 | 0.171 | 0.329 | 0.171 | | |
| 75 % | | 0.948 | 0.311 | 0.165 | 0.086 | 0.165 | 0.086 | | |
| 90 % | | 0.379 | 0.124 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | D4 Pond | 0.212 | 0.188 | 0.133 | 0.088 | 0.133 | 0.088 | | |
| 50 % | | 0.106 | 0.094 | 0.067 | 0.044 | 0.067 | 0.044 | | |
| 75 % | | 0.053 | 0.047 | 0.033 | 0.022 | 0.033 | 0.022 | | |
| 90 % | | 0.021 | 0.019 | 0.013 | 0.009 | 0.013 | 0.009 | | |
| None | D4 Stream | **3.14** | **1.32** | 0.701 | 0.364 | 0.701 | 0.364 | | |
| 50 % | | **1.57** | 0.661 | 0.350 | 0.182 | 0.350 | 0.182 | | |
| 75 % | | 0.784 | 0.330 | 0.175 | 0.091 | 0.175 | 0.091 | | |
| 90 % | | 0.314 | 0.132 | 0.070 | 0.037 | 0.070 | 0.037 | | |
| None | D5 Pond | 0.215 | 0.191 | 0.136 | 0.089 | 0.136 | 0.089 | | |
| 50 % | | 0.108 | 0.096 | 0.068 | 0.045 | 0.068 | 0.045 | | |
| 75 % | | 0.054 | 0.048 | 0.034 | 0.022 | 0.034 | 0.022 | | |
| 90 % | | 0.021 | 0.019 | 0.013 | 0.009 | 0.013 | 0.009 | | |
| None | D5 Stream | **3.62** | **1.53** | 0.809 | 0.420 | 0.809 | 0.420 | | |
| 50 % | | **1.81** | 0.763 | 0.405 | 0.210 | 0.405 | 0.210 | | |
| 75 % | | 0.906 | 0.382 | 0.203 | 0.105 | 0.203 | 0.105 | | |
| 90 % | | 0.362 | 0.153 | 0.081 | 0.042 | 0.081 | 0.042 | | |
| None | D6 Ditch | **3.78** | **1.24** | 0.657 | 0.341 | 0.657 | 0.341 | | |
| 50 % | | **1.89** | 0.619 | 0.328 | 0.171 | 0.328 | 0.171 | | |
| 75 % | | 0.945 | 0.310 | 0.164 | 0.086 | 0.164 | 0.086 | | |
| 90 % | | 0.378 | 0.124 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | R1 Pond | 0.224 | 0.203 | 0.151 | 0.108 | 0.136 | 0.088 | | |
| 50 % | | 0.125 | 0.114 | 0.088 | 0.068 | 0.073 | 0.046 | | |
| 75 % | | 0.075 | 0.071 | 0.062 | 0.054 | 0.042 | 0.026 | | |
| 90 % | | 0.053 | 0.051 | 0.048 | 0.045 | 0.025 | 0.014 | | |
| None | R1 Stream | **2.63** | **1.11** | 0.587 | 0.482 | 0.587 | 0.305 | | |
| 50 % | | **1.32** | 0.554 | 0.482 | 0.482 | 0.293 | 0.153 | | |
| 75 % | | 0.658 | 0.482 | 0.482 | 0.482 | 0.220 | 0.115 | | |
| 90 % | | 0.482 | 0.482 | 0.482 | 0.482 | 0.220 | 0.115 | | |
| None | R2 Stream | **3.52** | **1.48** | 0.786 | 0.408 | 0.786 | 0.408 | | |
| 50 % | | **1.76** | 0.741 | 0.393 | 0.238 | 0.393 | 0.204 | | |
| 75 % | | 0.879 | 0.370 | 0.238 | 0.238 | 0.196 | 0.102 | | |
| 90 % | | 0.352 | 0.238 | 0.238 | 0.238 | 0.108 | 0.057 | | |
| None | R3 Stream | **3.71** | **1.56** | 0.828 | 0.430 | 0.828 | 0.430 | | |
| 50 % | | **1.85** | 0.780 | 0.414 | 0.215 | 0.414 | 0.215 | | |
| 75 % | | 0.927 | 0.390 | 0.207 | 0.108 | 0.207 | 0.108 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 90 % | | 0.371 | 0.156 | 0.083 | 0.043 | 0.083 | 0.043 | | |
| None | R4 Stream | **2.52** | **1.06** | 0.564 | 0.421 | 0.564 | 0.293 | | |
| 50 % | | **1.26** | 0.532 | 0.421 | 0.421 | 0.282 | 0.146 | | |
| 75 % | | 0.631 | 0.421 | 0.421 | 0.421 | 0.191 | 0.100 | | |
| 90 % | | 0.421 | 0.421 | 0.421 | 0.421 | 0.191 | 0.100 | | |

* 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 9.5-23: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in celeriac (celeriac; modelling use Sugar beets I (June - November) -- BBCH 40-49 -- 2×0.125 kg a.s./ha, 14d int.)**

| **Intended use** | | celeriac | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 2 x 125 g/ha, 14d int. | | | | | | | |
| 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 | 0.655 | 0.214 | 0.114 | 0.059 | 0.114 | 0.059 | | |
| 50 % | | 0.327 | 0.107 | 0.057 | 0.030 | 0.057 | 0.030 | | |
| 75 % | | 0.164 | 0.054 | 0.028 | 0.015 | 0.028 | 0.015 | | |
| 90 % | | 0.065 | 0.021 | 0.011 | 0.006 | 0.011 | 0.006 | | |
| None | D4 Pond | *0.030* | *0.026* | *0.019* | *0.012* | *0.019* | *0.012* | | |
| 50 % | | *0.015* | *0.013* | *0.009* | *0.006* | *0.009* | *0.006* | | |
| 75 % | | *0.007* | *0.007* | *0.005* | *0.003* | *0.005* | *0.003* | | |
| 90 % | | *0.003* | *0.003* | *0.002* | *0.001* | *0.002* | *0.001* | | |
| None | D4 Stream | 0.544 | 0.229 | 0.122 | 0.063 | 0.122 | 0.063 | | |
| 50 % | | 0.272 | 0.115 | 0.061 | 0.032 | 0.061 | 0.032 | | |
| 75 % | | 0.136 | 0.057 | 0.030 | 0.016 | 0.030 | 0.016 | | |
| 90 % | | 0.054 | 0.023 | 0.012 | 0.006 | 0.012 | 0.006 | | |
| None | R1 Pond | *0.037* | *0.033* | *0.024* | *0.016* | *0.023* | *0.015* | | |
| 50 % | | *0.019* | *0.017* | *0.013* | *0.009* | *0.012* | *0.008* | | |
| 75 % | | *0.010* | *0.010* | *0.007* | *0.005* | *0.006* | *0.004* | | |
| 90 % | | *0.005* | *0.005* | *0.004* | 0.003 | *0.003* | *0.002* | | |
| None | R1 Stream | 0.450 | 0.190 | 0.101 | 0.052 | 0.101 | 0.052 | | |
| 50 % | | 0.225 | 0.095 | 0.050 | 0.044 | 0.050 | 0.026 | | |
| 75 % | | 0.113 | 0.047 | 0.044 | 0.044 | 0.025 | 0.013 | | |
| 90 % | | 0.045 | 0.044 | 0.044 | 0.044 | 0.020 | 0.011 | | |
| None | R3 Stream | 0.640 | 0.269 | 0.143 | 0.074 | 0.143 | 0.074 | | |
| 50 % | | 0.320 | 0.135 | 0.071 | 0.037 | 0.071 | 0.037 | | |
| 75 % | | 0.160 | 0.067 | 0.036 | 0.019 | 0.036 | 0.019 | | |
| 90 % | | 0.064 | 0.027 | 0.014 | 0.007 | 0.014 | 0.007 | | |

| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| None | D3 Ditch | **2.37** | 0.777 | 0.412 | 0.214 | 0.412 | 0.214 | | |
| 50 % | | **1.19** | 0.388 | 0.206 | 0.107 | 0.206 | 0.107 | | |
| 75 % | | 0.593 | 0.194 | 0.103 | 0.054 | 0.103 | 0.054 | | |
| 90 % | | 0.237 | 0.078 | 0.041 | 0.021 | 0.041 | 0.021 | | |
| None | D4 Pond | 0.108 | 0.096 | 0.068 | 0.045 | 0.068 | 0.045 | | |
| 50 % | | 0.054 | 0.048 | 0.034 | 0.022 | 0.034 | 0.022 | | |
| 75 % | | 0.027 | 0.024 | 0.017 | 0.011 | 0.017 | 0.011 | | |
| 90 % | | 0.011 | 0.009 | 0.007 | 0.004 | 0.007 | 0.004 | | |
| None | D4 Stream | **1.97** | 0.830 | 0.440 | 0.229 | 0.440 | 0.229 | | |
| 50 % | | 0.986 | 0.415 | 0.220 | 0.114 | 0.220 | 0.114 | | |
| 75 % | | 0.493 | 0.208 | 0.110 | 0.057 | 0.110 | 0.057 | | |
| 90 % | | 0.197 | 0.083 | 0.044 | 0.023 | 0.044 | 0.023 | | |
| None | R1 Pond | 0.132 | 0.118 | 0.086 | 0.059 | 0.082 | 0.054 | | |
| 50 % | | 0.069 | 0.062 | 0.046 | 0.032 | 0.042 | 0.028 | | |
| 75 % | | 0.038 | 0.034 | 0.026 | 0.019 | 0.022 | 0.014 | | |
| 90 % | | 0.019 | 0.017 | 0.014 | 0.012 | 0.011 | 0.007 | | |
| None | R1 Stream | **1.63** | 0.687 | 0.364 | 0.189 | 0.364 | 0.189 | | |
| 50 % | | 0.815 | 0.343 | 0.182 | 0.160 | 0.182 | 0.095 | | |
| 75 % | | 0.408 | 0.172 | 0.160 | 0.160 | 0.091 | 0.047 | | |
| 90 % | | 0.163 | 0.160 | 0.160 | 0.160 | 0.073 | 0.038 | | |
| None | R3 Stream | **2.32** | 0.976 | 0.517 | 0.269 | 0.517 | 0.269 | | |
| 50 % | | **1.16** | 0.488 | 0.259 | 0.134 | 0.259 | 0.134 | | |
| 75 % | | 0.579 | 0.244 | 0.129 | 0.067 | 0.129 | 0.067 | | |
| 90 % | | 0.232 | 0.097 | 0.052 | 0.027 | 0.052 | 0.027 | | |

* 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 9.5-24: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in chicory (chicory; modelling use Sugar beets II -- BBCH 13 - 49, early -- 0.2 kg a.s./ha)**

| **Intended use** | | chicory | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 200 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 | 1.05 | 0.343 | 0.182 | 0.095 | 0.182 | 0.095 | | |
| 50 % | | 0.524 | 0.172 | 0.091 | 0.047 | 0.091 | 0.047 | | |
| 75 % | | 0.262 | 0.086 | 0.046 | 0.024 | 0.046 | 0.024 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 90 % | | 0.105 | 0.034 | 0.018 | 0.010 | 0.018 | 0.010 | | |
| None | D4 Pond | 0.042 | 0.038 | 0.027 | 0.018 | 0.027 | 0.018 | | |
| 50 % | | 0.021 | 0.019 | 0.014 | 0.009 | 0.014 | 0.009 | | |
| 75 % | | 0.011 | 0.009 | 0.007 | 0.005 | 0.007 | 0.005 | | |
| 90 % | | 0.004 | 0.004 | 0.003 | 0.002 | 0.003 | 0.002 | | |
| None | D4 Stream | 0.867 | 0.365 | 0.194 | 0.101 | 0.194 | 0.101 | | |
| 50 % | | 0.434 | 0.183 | 0.097 | 0.050 | 0.097 | 0.050 | | |
| 75 % | | 0.217 | 0.091 | 0.048 | 0.025 | 0.048 | 0.025 | | |
| 90 % | | 0.087 | 0.037 | 0.019 | 0.010 | 0.019 | 0.010 | | |
| None | R1 Pond | 0.042 | 0.038 | 0.027 | 0.018 | 0.027 | 0.018 | | |
| 50 % | | 0.021 | 0.019 | 0.014 | 0.009 | 0.014 | 0.009 | | |
| 75 % | | 0.011 | 0.009 | 0.007 | 0.005 | 0.007 | 0.005 | | |
| 90 % | | 0.004 | 0.004 | 0.003 | 0.002 | 0.003 | 0.002 | | |
| None | R1 Stream | 0.723 | 0.305 | 0.162 | 0.084 | 0.162 | 0.084 | | |
| 50 % | | 0.362 | 0.152 | 0.081 | 0.042 | 0.081 | 0.042 | | |
| 75 % | | 0.181 | 0.076 | 0.040 | 0.021 | 0.040 | 0.021 | | |
| 90 % | | 0.072 | 0.030 | 0.016 | 0.008 | 0.016 | 0.008 | | |
| None | R3 Stream | 1.02 | 0.430 | 0.228 | 0.119 | 0.228 | 0.119 | | |
| 50 % | | 0.511 | 0.215 | 0.114 | 0.059 | 0.114 | 0.059 | | |
| 75 % | | 0.255 | 0.108 | 0.057 | 0.030 | 0.057 | 0.030 | | |
| 90 % | | 0.102 | 0.043 | 0.023 | 0.012 | 0.023 | 0.012 | | |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D3 Ditch | **3.79** | **1.24** | 0.659 | 0.343 | 0.659 | 0.343 | | |
| 50 % | | **1.90** | 0.622 | 0.330 | 0.171 | 0.330 | 0.171 | | |
| 75 % | | 0.949 | 0.311 | 0.165 | 0.086 | 0.165 | 0.086 | | |
| 90 % | | 0.379 | 0.124 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | D4 Pond | 0.153 | 0.137 | 0.098 | 0.066 | 0.098 | 0.066 | | |
| 50 % | | 0.076 | 0.068 | 0.049 | 0.033 | 0.049 | 0.033 | | |
| 75 % | | 0.038 | 0.034 | 0.025 | 0.016 | 0.025 | 0.016 | | |
| 90 % | | 0.015 | 0.014 | 0.010 | 0.007 | 0.010 | 0.007 | | |
| None | D4 Stream | **3.14** | **1.32** | 0.701 | 0.364 | 0.701 | 0.364 | | |
| 50 % | | **1.57** | 0.662 | 0.351 | 0.182 | 0.351 | 0.182 | | |
| 75 % | | 0.786 | 0.331 | 0.175 | 0.091 | 0.175 | 0.091 | | |
| 90 % | | 0.314 | 0.132 | 0.070 | 0.037 | 0.070 | 0.037 | | |
| None | R1 Pond | 0.153 | 0.137 | 0.098 | 0.066 | 0.098 | 0.066 | | |
| 50 % | | 0.076 | 0.068 | 0.049 | 0.033 | 0.049 | 0.033 | | |
| 75 % | | 0.038 | 0.034 | 0.025 | 0.016 | 0.025 | 0.016 | | |
| 90 % | | 0.015 | 0.014 | 0.010 | 0.007 | 0.010 | 0.007 | | |
| None | R1 Stream | **2.62** | **1.10** | 0.585 | 0.304 | 0.585 | 0.304 | | |
| 50 % | | **1.31** | 0.551 | 0.292 | 0.152 | 0.292 | 0.152 | | |
| 75 % | | 0.655 | 0.276 | 0.146 | 0.076 | 0.146 | 0.076 | | |
| 90 % | | 0.262 | 0.110 | 0.058 | 0.030 | 0.058 | 0.030 | | |
| None | R3 Stream | **3.70** | **1.56** | 0.826 | 0.429 | 0.826 | 0.429 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 50 % | | **1.85** | 0.779 | 0.413 | 0.214 | 0.413 | 0.214 | | |
| 75 % | | 0.925 | 0.389 | 0.207 | 0.107 | 0.207 | 0.107 | | |
| 90 % | | 0.370 | 0.156 | 0.083 | 0.043 | 0.083 | 0.043 | | |

PEC: predicted environmental concentration
RAC: regulatory acceptable concentration
PEC/RAC ratios above the relevant trigger of 1 are shown in bold

**Table 9.5-25: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in chicory (chicory; modelling use Sugar beets II -- BBCH 13 - 49, late -- 0.2 kg a.s./ha)**

| **Intended use** | | chicory | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 200 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 | 1.05 | 0.343 | 0.182 | 0.094 | 0.182 | 0.094 | | |
| 50 % | | 0.523 | 0.171 | 0.091 | 0.047 | 0.091 | 0.047 | | |
| 75 % | | 0.261 | 0.086 | 0.045 | 0.024 | 0.045 | 0.024 | | |
| 90 % | | 0.105 | 0.034 | 0.018 | 0.009 | 0.018 | 0.009 | | |
| None | D4 Pond | 0.042 | 0.038 | 0.027 | 0.018 | 0.027 | 0.018 | | |
| 50 % | | 0.021 | 0.019 | 0.014 | 0.009 | 0.014 | 0.009 | | |
| 75 % | | 0.011 | 0.009 | 0.007 | 0.005 | 0.007 | 0.005 | | |
| 90 % | | 0.004 | 0.004 | 0.003 | 0.002 | 0.003 | 0.002 | | |
| None | D4 Stream | 0.915 | 0.385 | 0.204 | 0.106 | 0.204 | 0.106 | | |
| 50 % | | 0.457 | 0.193 | 0.102 | 0.053 | 0.102 | 0.053 | | |
| 75 % | | 0.229 | 0.096 | 0.051 | 0.027 | 0.051 | 0.027 | | |
| 90 % | | 0.092 | 0.039 | 0.020 | 0.011 | 0.020 | 0.011 | | |
| None | R1 Pond | 0.042 | 0.038 | 0.027 | 0.018 | 0.027 | 0.018 | | |
| 50 % | | 0.021 | 0.019 | 0.014 | 0.009 | 0.014 | 0.009 | | |
| 75 % | | 0.011 | 0.009 | 0.007 | 0.005 | 0.007 | 0.005 | | |
| 90 % | | 0.004 | 0.004 | 0.003 | 0.002 | 0.003 | 0.002 | | |
| None | R1 Stream | 0.726 | 0.306 | 0.162 | 0.084 | 0.162 | 0.084 | | |
| 50 % | | 0.363 | 0.153 | 0.081 | 0.042 | 0.081 | 0.042 | | |
| 75 % | | 0.182 | 0.076 | 0.041 | 0.021 | 0.041 | 0.021 | | |
| 90 % | | 0.073 | 0.031 | 0.016 | 0.016 | 0.016 | 0.008 | | |
| None | R3 Stream | 1.02 | 0.431 | 0.229 | 0.119 | 0.229 | 0.119 | | |
| 50 % | | 0.512 | 0.215 | 0.114 | 0.059 | 0.114 | 0.059 | | |
| 75 % | | 0.256 | 0.108 | 0.057 | 0.030 | 0.057 | 0.030 | | |
| 90 % | | 0.102 | 0.043 | 0.023 | 0.012 | 0.023 | 0.012 | | |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D3 Ditch | **3.79** | **1.24** | 0.658 | 0.342 | 0.658 | 0.342 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 50 % | | **1.89** | 0.621 | 0.329 | 0.171 | 0.329 | 0.171 | | |
| 75 % | | 0.947 | 0.311 | 0.164 | 0.086 | 0.164 | 0.086 | | |
| 90 % | | 0.379 | 0.124 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | D4 Pond | 0.153 | 0.137 | 0.099 | 0.066 | 0.099 | 0.066 | | |
| 50 % | | 0.076 | 0.068 | 0.049 | 0.033 | 0.049 | 0.033 | | |
| 75 % | | 0.038 | 0.034 | 0.025 | 0.016 | 0.025 | 0.016 | | |
| 90 % | | 0.015 | 0.014 | 0.010 | 0.007 | 0.010 | 0.007 | | |
| None | D4 Stream | **3.31** | **1.40** | 0.740 | 0.384 | 0.740 | 0.384 | | |
| 50 % | | **1.66** | 0.698 | 0.370 | 0.192 | 0.370 | 0.192 | | |
| 75 % | | 0.829 | 0.349 | 0.185 | 0.096 | 0.185 | 0.096 | | |
| 90 % | | 0.332 | 0.139 | 0.074 | 0.038 | 0.074 | 0.038 | | |
| None | R1 Pond | 0.153 | 0.137 | 0.098 | 0.066 | 0.098 | 0.066 | | |
| 50 % | | 0.076 | 0.068 | 0.049 | 0.033 | 0.049 | 0.033 | | |
| 75 % | | 0.038 | 0.034 | 0.025 | 0.016 | 0.025 | 0.016 | | |
| 90 % | | 0.015 | 0.014 | 0.010 | 0.007 | 0.010 | 0.007 | | |
| None | R1 Stream | **2.63** | **1.11** | 0.587 | 0.305 | 0.587 | 0.305 | | |
| 50 % | | **1.32** | 0.554 | 0.293 | 0.153 | 0.293 | 0.153 | | |
| 75 % | | 0.658 | 0.277 | 0.147 | 0.076 | 0.147 | 0.076 | | |
| 90 % | | 0.263 | 0.111 | 0.059 | 0.058 | 0.059 | 0.030 | | |
| None | R3 Stream | **3.71** | **1.56** | 0.828 | 0.430 | 0.828 | 0.430 | | |
| 50 % | | **1.85** | 0.780 | 0.414 | 0.215 | 0.414 | 0.215 | | |
| 75 % | | 0.927 | 0.390 | 0.207 | 0.108 | 0.207 | 0.108 | | |
| 90 % | | 0.371 | 0.156 | 0.083 | 0.043 | 0.083 | 0.043 | | |

PEC: predicted environmental concentration
RAC: regulatory acceptable concentration
PEC/RAC ratios above the relevant trigger of 1 are shown in bold

**Table 9.5-26: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in flower bulbs (flower bulbs; modelling use VegBulb I -- VegBulb I (early) -- 0.2 kg a.s./ha)**

| **Intended use** | | flower bulbs | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 200 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 | 1.27 | 0.343 | 0.182 | 0.095 | 0.182 | 0.095 | | |
| 50 % | | 0.633 | 0.172 | 0.091 | 0.047 | 0.091 | 0.047 | | |
| 75 % | | 0.316 | 0.086 | 0.046 | 0.024 | 0.046 | 0.024 | | |
| 90 % | | 0.127 | 0.034 | 0.018 | 0.010 | 0.018 | 0.010 | | |
| None | D4 Pond | 0.044 | 0.038 | 0.027 | 0.018 | 0.027 | 0.018 | | |
| 50 % | | 0.022 | 0.019 | 0.014 | 0.009 | 0.014 | 0.009 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 75 % | | 0.011 | 0.009 | 0.007 | 0.005 | 0.007 | 0.005 | | |
| 90 % | | 0.004 | 0.004 | 0.003 | 0.002 | 0.003 | 0.002 | | |
| None | D4 Stream | 0.971 | 0.355 | 0.188 | 0.098 | 0.188 | 0.098 | | |
| 50 % | | 0.486 | 0.177 | 0.094 | 0.049 | 0.094 | 0.049 | | |
| 75 % | | 0.243 | 0.089 | 0.047 | 0.024 | 0.047 | 0.024 | | |
| 90 % | | 0.097 | 0.036 | 0.019 | 0.010 | 0.019 | 0.010 | | |
| None | D6 Ditch | 1.27 | 0.345 | 0.183 | 0.095 | 0.183 | 0.095 | | |
| 50 % | | 0.635 | 0.172 | 0.091 | 0.048 | 0.091 | 0.048 | | |
| 75 % | | 0.318 | 0.086 | 0.046 | 0.024 | 0.046 | 0.024 | | |
| 90 % | | 0.127 | 0.034 | 0.018 | 0.010 | 0.018 | 0.010 | | |
| None | D6 Ditch 2nd | 1.27 | 0.346 | 0.183 | 0.095 | 0.183 | 0.095 | | |
| 50 % | | 0.637 | 0.173 | 0.092 | 0.048 | 0.092 | 0.048 | | |
| 75 % | | 0.319 | 0.086 | 0.046 | 0.024 | 0.046 | 0.024 | | |
| 90 % | | 0.128 | 0.035 | 0.018 | 0.010 | 0.018 | 0.010 | | |
| None | R1 Pond | 0.044 | 0.038 | 0.027 | 0.018 | 0.027 | 0.018 | | |
| 50 % | | 0.022 | 0.019 | 0.014 | 0.009 | 0.014 | 0.009 | | |
| 75 % | | 0.011 | 0.009 | 0.007 | 0.005 | 0.007 | 0.005 | | |
| 90 % | | 0.004 | 0.004 | 0.003 | 0.002 | 0.003 | 0.002 | | |
| None | R1 Stream | 0.820 | 0.300 | 0.159 | 0.083 | 0.159 | 0.083 | | |
| 50 % | | 0.410 | 0.150 | 0.079 | 0.043 | 0.079 | 0.041 | | |
| 75 % | | 0.205 | 0.075 | 0.043 | 0.043 | 0.040 | 0.021 | | |
| 90 % | | 0.082 | 0.043 | 0.043 | 0.043 | 0.018 | 0.009 | | |
| None | R2 Stream | 1.10 | 0.403 | 0.213 | 0.111 | 0.213 | 0.111 | | |
| 50 % | | 0.551 | 0.201 | 0.107 | 0.056 | 0.107 | 0.056 | | |
| 75 % | | 0.275 | 0.101 | 0.053 | 0.028 | 0.053 | 0.028 | | |
| 90 % | | 0.110 | 0.040 | 0.021 | 0.011 | 0.021 | 0.011 | | |
| None | R3 Stream | 1.17 | 0.428 | 0.227 | 0.118 | 0.227 | 0.118 | | |
| 50 % | | 0.585 | 0.214 | 0.113 | 0.059 | 0.113 | 0.059 | | |
| 75 % | | 0.293 | 0.107 | 0.057 | 0.030 | 0.057 | 0.030 | | |
| 90 % | | 0.117 | 0.043 | 0.023 | 0.012 | 0.023 | 0.012 | | |
| None | R4 Stream | 0.829 | 0.303 | 0.161 | 0.136 | 0.161 | 0.083 | | |
| 50 % | | 0.414 | 0.151 | 0.136 | 0.136 | 0.080 | 0.042 | | |
| 75 % | | 0.207 | 0.136 | 0.136 | 0.136 | 0.062 | 0.032 | | |
| 90 % | | 0.136 | 0.136 | 0.136 | 0.136 | 0.062 | 0.032 | | |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D3 Ditch | **4.59** | **1.24** | 0.659 | 0.342 | 0.659 | 0.342 | | |
| 50 % | | **2.29** | 0.622 | 0.330 | 0.171 | 0.330 | 0.171 | | |
| 75 % | | **1.15** | 0.311 | 0.165 | 0.086 | 0.165 | 0.086 | | |
| 90 % | | 0.458 | 0.124 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | D4 Pond | 0.158 | 0.137 | 0.098 | 0.066 | 0.098 | 0.066 | | |
| 50 % | | 0.079 | 0.068 | 0.049 | 0.033 | 0.049 | 0.033 | | |
| 75 % | | 0.039 | 0.034 | 0.025 | 0.016 | 0.025 | 0.016 | | |
| 90 % | | 0.016 | 0.014 | 0.010 | 0.007 | 0.010 | 0.007 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| None | D4 Stream | **3.52** | **1.29** | 0.682 | 0.354 | 0.682 | 0.354 | | |
| 50 % | | **1.76** | 0.643 | 0.341 | 0.177 | 0.341 | 0.177 | | |
| 75 % | | 0.879 | 0.321 | 0.170 | 0.088 | 0.170 | 0.088 | | |
| 90 % | | 0.352 | 0.129 | 0.068 | 0.036 | 0.068 | 0.036 | | |
| None | D6 Ditch | **4.61** | **1.25** | 0.662 | 0.344 | 0.662 | 0.344 | | |
| 50 % | | **2.30** | 0.624 | 0.331 | 0.172 | 0.331 | 0.172 | | |
| 75 % | | **1.15** | 0.312 | 0.166 | 0.086 | 0.166 | 0.086 | | |
| 90 % | | 0.460 | 0.125 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | D6 Ditch 2nd | **4.62** | **1.25** | 0.664 | 0.345 | 0.664 | 0.345 | | |
| 50 % | | **2.31** | 0.626 | 0.332 | 0.172 | 0.332 | 0.172 | | |
| 75 % | | **1.15** | 0.313 | 0.166 | 0.086 | 0.166 | 0.086 | | |
| 90 % | | 0.462 | 0.125 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | R1 Pond | 0.158 | 0.137 | 0.098 | 0.066 | 0.098 | 0.066 | | |
| 50 % | | 0.079 | 0.068 | 0.049 | 0.033 | 0.049 | 0.033 | | |
| 75 % | | 0.039 | 0.034 | 0.025 | 0.016 | 0.025 | 0.016 | | |
| 90 % | | 0.016 | 0.014 | 0.010 | 0.007 | 0.010 | 0.007 | | |
| None | R1 Stream | **2.97** | **1.09** | 0.575 | 0.299 | 0.575 | 0.299 | | |
| 50 % | | **1.48** | 0.542 | 0.288 | 0.155 | 0.288 | 0.150 | | |
| 75 % | | 0.742 | 0.271 | 0.155 | 0.155 | 0.144 | 0.075 | | |
| 90 % | | 0.297 | 0.155 | 0.155 | 0.155 | 0.064 | 0.032 | | |
| None | R2 Stream | **3.99** | **1.46** | 0.773 | 0.402 | 0.773 | 0.402 | | |
| 50 % | | **2.00** | 0.729 | 0.387 | 0.201 | 0.387 | 0.201 | | |
| 75 % | | 0.998 | 0.364 | 0.193 | 0.100 | 0.193 | 0.100 | | |
| 90 % | | 0.399 | 0.146 | 0.077 | 0.040 | 0.077 | 0.040 | | |
| None | R3 Stream | **4.24** | **1.55** | 0.822 | 0.427 | 0.822 | 0.427 | | |
| 50 % | | **2.12** | 0.775 | 0.411 | 0.213 | 0.411 | 0.213 | | |
| 75 % | | **1.06** | 0.387 | 0.205 | 0.107 | 0.205 | 0.107 | | |
| 90 % | | 0.424 | 0.155 | 0.082 | 0.043 | 0.082 | 0.043 | | |
| None | R4 Stream | **3.00** | **1.10** | 0.582 | 0.492 | 0.582 | 0.302 | | |
| 50 % | | **1.50** | 0.549 | 0.492 | 0.492 | 0.291 | 0.151 | | |
| 75 % | | 0.751 | 0.492 | 0.492 | 0.492 | 0.223 | 0.117 | | |
| 90 % | | 0.492 | 0.492 | 0.492 | 0.492 | 0.223 | 0.117 | | |

PEC: predicted environmental concentration
RAC: regulatory acceptable concentration
PEC/RAC ratios above the relevant trigger of 1 are shown in bold

**Table 9.5-27: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in flower bulbs (flower bulbs; modelling use VegBulb I -- VegBulb I (middle) -- 0.2 kg a.s./ha)**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Intended use** | flower bulbs | | | | | | | | |
| **Active substance** | trifloxystrobin | | | | | | | | |
| **Application rate (g/ha)** | 200 g/ha | | | | | | | | |
| Nozzle | Vegetated | None | None | None | None | 10 m | 20 m | | |

| reduction | strip (m) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | No spray buffer (m) | 0 m | 5 m | 10 m | 20 m | 10 m | 20 m | | |
| None | D3 Ditch | 1.26 | 0.343 | 0.182 | 0.095 | 0.182 | 0.095 | | |
| 50 % | | 0.633 | 0.172 | 0.091 | 0.047 | 0.091 | 0.047 | | |
| 75 % | | 0.316 | 0.086 | 0.046 | 0.024 | 0.046 | 0.024 | | |
| 90 % | | 0.127 | 0.034 | 0.018 | 0.010 | 0.018 | 0.010 | | |
| None | D4 Pond | 0.044 | 0.038 | 0.027 | 0.018 | 0.027 | 0.018 | | |
| 50 % | | 0.022 | 0.019 | 0.014 | 0.009 | 0.014 | 0.009 | | |
| 75 % | | 0.011 | 0.009 | 0.007 | 0.005 | 0.007 | 0.005 | | |
| 90 % | | 0.004 | 0.004 | 0.003 | 0.002 | 0.003 | 0.002 | | |
| None | D4 Stream | 0.886 | 0.324 | 0.172 | 0.089 | 0.172 | 0.089 | | |
| 50 % | | 0.443 | 0.162 | 0.086 | 0.045 | 0.086 | 0.045 | | |
| 75 % | | 0.222 | 0.081 | 0.043 | 0.022 | 0.043 | 0.022 | | |
| 90 % | | 0.089 | 0.032 | 0.017 | 0.009 | 0.017 | 0.009 | | |
| None | D6 Ditch | 1.28 | 0.346 | 0.183 | 0.095 | 0.183 | 0.095 | | |
| 50 % | | 0.638 | 0.173 | 0.092 | 0.048 | 0.092 | 0.048 | | |
| 75 % | | 0.319 | 0.087 | 0.046 | 0.024 | 0.046 | 0.024 | | |
| 90 % | | 0.128 | 0.035 | 0.018 | 0.010 | 0.018 | 0.010 | | |
| None | D6 Ditch 2nd | 1.27 | 0.345 | 0.183 | 0.095 | 0.183 | 0.095 | | |
| 50 % | | 0.636 | 0.172 | 0.091 | 0.048 | 0.091 | 0.048 | | |
| 75 % | | 0.318 | 0.086 | 0.046 | 0.024 | 0.046 | 0.024 | | |
| 90 % | | 0.127 | 0.035 | 0.018 | 0.010 | 0.018 | 0.010 | | |
| None | R1 Pond | 0.044 | 0.038 | 0.027 | 0.018 | 0.027 | 0.018 | | |
| 50 % | | 0.022 | 0.019 | 0.014 | 0.009 | 0.014 | 0.009 | | |
| 75 % | | 0.011 | 0.009 | 0.007 | 0.005 | 0.007 | 0.005 | | |
| 90 % | | 0.005 | 0.005 | 0.004 | 0.003 | 0.003 | 0.002 | | |
| None | R1 Stream | 0.821 | 0.300 | 0.159 | 0.083 | 0.159 | 0.083 | | |
| 50 % | | 0.411 | 0.150 | 0.080 | 0.050 | 0.080 | 0.041 | | |
| 75 % | | 0.205 | 0.075 | 0.050 | 0.050 | 0.040 | 0.021 | | |
| 90 % | | 0.082 | 0.050 | 0.050 | 0.050 | 0.023 | 0.012 | | |
| None | R2 Stream | 1.12 | 0.410 | 0.217 | 0.113 | 0.217 | 0.113 | | |
| 50 % | | 0.561 | 0.205 | 0.109 | 0.057 | 0.109 | 0.057 | | |
| 75 % | | 0.280 | 0.102 | 0.054 | 0.028 | 0.054 | 0.028 | | |
| 90 % | | 0.112 | 0.041 | 0.022 | 0.011 | 0.022 | 0.011 | | |
| None | R3 Stream | 1.18 | 0.429 | 0.228 | 0.118 | 0.228 | 0.118 | | |
| 50 % | | 0.587 | 0.215 | 0.114 | 0.082 | 0.114 | 0.059 | | |
| 75 % | | 0.294 | 0.107 | 0.082 | 0.082 | 0.057 | 0.030 | | |
| 90 % | | 0.118 | 0.082 | 0.082 | 0.082 | 0.037 | 0.020 | | |
| None | R4 Stream | 0.808 | 0.295 | 0.156 | 0.081 | 0.156 | 0.081 | | |
| 50 % | | 0.404 | 0.148 | 0.078 | 0.041 | 0.078 | 0.041 | | |
| 75 % | | 0.202 | 0.074 | 0.039 | 0.020 | 0.039 | 0.020 | | |
| 90 % | | 0.081 | 0.030 | 0.016 | 0.008 | 0.016 | 0.008 | | |
| **RAC** | **0.276** | **PEC / RAC ratio** | | | | | | | |

| **(µg/L)** | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| None | D3 Ditch | **4.58** | **1.24** | 0.659 | 0.342 | 0.659 | 0.342 | | |
| 50 % | | **2.29** | 0.621 | 0.330 | 0.171 | 0.330 | 0.171 | | |
| 75 % | | **1.15** | 0.311 | 0.165 | 0.086 | 0.165 | 0.086 | | |
| 90 % | | 0.458 | 0.124 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | D4 Pond | 0.158 | 0.137 | 0.098 | 0.066 | 0.098 | 0.066 | | |
| 50 % | | 0.079 | 0.068 | 0.049 | 0.033 | 0.049 | 0.033 | | |
| 75 % | | 0.039 | 0.034 | 0.025 | 0.016 | 0.025 | 0.016 | | |
| 90 % | | 0.016 | 0.014 | 0.010 | 0.007 | 0.010 | 0.007 | | |
| None | D4 Stream | **3.21** | **1.17** | 0.622 | 0.323 | 0.622 | 0.323 | | |
| 50 % | | **1.60** | 0.586 | 0.311 | 0.162 | 0.311 | 0.162 | | |
| 75 % | | 0.803 | 0.293 | 0.155 | 0.081 | 0.155 | 0.081 | | |
| 90 % | | 0.321 | 0.117 | 0.062 | 0.032 | 0.062 | 0.032 | | |
| None | D6 Ditch | **4.62** | **1.25** | 0.664 | 0.345 | 0.664 | 0.345 | | |
| 50 % | | **2.31** | 0.626 | 0.332 | 0.173 | 0.332 | 0.173 | | |
| 75 % | | **1.16** | 0.313 | 0.166 | 0.086 | 0.166 | 0.086 | | |
| 90 % | | 0.462 | 0.125 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | D6 Ditch 2nd | **4.61** | **1.25** | 0.662 | 0.344 | 0.662 | 0.344 | | |
| 50 % | | **2.30** | 0.624 | 0.331 | 0.172 | 0.331 | 0.172 | | |
| 75 % | | **1.15** | 0.312 | 0.166 | 0.086 | 0.166 | 0.086 | | |
| 90 % | | 0.461 | 0.125 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | R1 Pond | 0.158 | 0.137 | 0.098 | 0.066 | 0.098 | 0.066 | | |
| 50 % | | 0.079 | 0.068 | 0.049 | 0.033 | 0.049 | 0.033 | | |
| 75 % | | 0.039 | 0.034 | 0.026 | 0.019 | 0.025 | 0.016 | | |
| 90 % | | 0.019 | 0.017 | 0.014 | 0.012 | 0.011 | 0.007 | | |
| None | R1 Stream | **2.97** | **1.09** | 0.576 | 0.299 | 0.576 | 0.299 | | |
| 50 % | | **1.49** | 0.543 | 0.288 | 0.182 | 0.288 | 0.150 | | |
| 75 % | | 0.743 | 0.272 | 0.182 | 0.182 | 0.144 | 0.075 | | |
| 90 % | | 0.297 | 0.182 | 0.182 | 0.182 | 0.082 | 0.043 | | |
| None | R2 Stream | **4.07** | **1.48** | 0.787 | 0.409 | 0.787 | 0.409 | | |
| 50 % | | **2.03** | 0.742 | 0.393 | 0.205 | 0.393 | 0.205 | | |
| 75 % | | **1.02** | 0.371 | 0.197 | 0.102 | 0.197 | 0.102 | | |
| 90 % | | 0.406 | 0.149 | 0.079 | 0.041 | 0.079 | 0.041 | | |
| None | R3 Stream | **4.26** | **1.56** | 0.825 | 0.428 | 0.825 | 0.428 | | |
| 50 % | | **2.13** | 0.778 | 0.412 | 0.298 | 0.412 | 0.214 | | |
| 75 % | | **1.06** | 0.389 | 0.298 | 0.298 | 0.206 | 0.107 | | |
| 90 % | | 0.426 | 0.298 | 0.298 | 0.298 | 0.135 | 0.071 | | |
| None | R4 Stream | **2.93** | **1.07** | 0.567 | 0.295 | 0.567 | 0.295 | | |
| 50 % | | **1.46** | 0.534 | 0.283 | 0.147 | 0.283 | 0.147 | | |
| 75 % | | 0.732 | 0.267 | 0.142 | 0.074 | 0.142 | 0.074 | | |
| 90 % | | 0.292 | 0.107 | 0.057 | 0.029 | 0.057 | 0.029 | | |

PEC: predicted environmental concentration
RAC: regulatory acceptable concentration
PEC/RAC ratios above the relevant trigger of 1 are shown in bold

**Table 9.5-28: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in flower bulbs (flower bulbs; modelling use VegBulb I -- VegBulb I (late) -- 0.2 kg a.s./ha)**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Intended use** | | flower bulbs | | | | | | | |
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 200 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 | 1.27 | 0.343 | 0.182 | 0.095 | 0.182 | 0.095 | | |
| 50 % | | 0.633 | 0.172 | 0.091 | 0.047 | 0.091 | 0.047 | | |
| 75 % | | 0.316 | 0.086 | 0.046 | 0.024 | 0.046 | 0.024 | | |
| 90 % | | 0.127 | 0.034 | 0.018 | 0.010 | 0.018 | 0.010 | | |
| None | D4 Pond | 0.044 | 0.038 | 0.027 | 0.018 | 0.027 | 0.018 | | |
| 50 % | | 0.022 | 0.019 | 0.014 | 0.009 | 0.014 | 0.009 | | |
| 75 % | | 0.011 | 0.009 | 0.007 | 0.005 | 0.007 | 0.005 | | |
| 90 % | | 0.004 | 0.004 | 0.003 | 0.002 | 0.003 | 0.002 | | |
| None | D4 Stream | 0.896 | 0.327 | 0.174 | 0.090 | 0.174 | 0.090 | | |
| 50 % | | 0.448 | 0.164 | 0.087 | 0.045 | 0.087 | 0.045 | | |
| 75 % | | 0.224 | 0.082 | 0.043 | 0.023 | 0.043 | 0.023 | | |
| 90 % | | 0.090 | 0.033 | 0.017 | 0.009 | 0.017 | 0.009 | | |
| None | D6 Ditch | 1.28 | 0.346 | 0.183 | 0.095 | 0.183 | 0.095 | | |
| 50 % | | 0.638 | 0.173 | 0.092 | 0.048 | 0.092 | 0.048 | | |
| 75 % | | 0.319 | 0.087 | 0.046 | 0.024 | 0.046 | 0.024 | | |
| 90 % | | 0.128 | 0.035 | 0.018 | 0.010 | 0.018 | 0.010 | | |
| None | D6 Ditch 2nd | 1.27 | 0.345 | 0.183 | 0.095 | 0.183 | 0.095 | | |
| 50 % | | 0.636 | 0.172 | 0.091 | 0.048 | 0.091 | 0.048 | | |
| 75 % | | 0.318 | 0.086 | 0.046 | 0.024 | 0.046 | 0.024 | | |
| 90 % | | 0.127 | 0.035 | 0.018 | 0.010 | 0.018 | 0.010 | | |
| None | R1 Pond | 0.044 | 0.038 | 0.027 | 0.018 | 0.027 | 0.018 | | |
| 50 % | | 0.022 | 0.019 | 0.014 | 0.009 | 0.014 | 0.009 | | |
| 75 % | | 0.011 | 0.009 | 0.007 | 0.005 | 0.007 | 0.005 | | |
| 90 % | | 0.004 | 0.004 | 0.003 | 0.002 | 0.003 | 0.002 | | |
| None | R1 Stream | 0.821 | 0.300 | 0.159 | 0.083 | 0.159 | 0.083 | | |
| 50 % | | 0.411 | 0.150 | 0.080 | 0.041 | 0.080 | 0.041 | | |
| 75 % | | 0.205 | 0.075 | 0.040 | 0.021 | 0.040 | 0.021 | | |
| 90 % | | 0.082 | 0.030 | 0.016 | 0.008 | 0.016 | 0.008 | | |
| None | R2 Stream | 1.12 | 0.410 | 0.217 | 0.113 | 0.217 | 0.113 | | |
| 50 % | | 0.561 | 0.205 | 0.109 | 0.057 | 0.109 | 0.057 | | |
| 75 % | | 0.280 | 0.102 | 0.054 | 0.029 | 0.054 | 0.028 | | |
| 90 % | | 0.112 | 0.041 | 0.029 | 0.029 | 0.022 | 0.011 | | |
| None | R3 Stream | 1.18 | 0.429 | 0.228 | 0.118 | 0.228 | 0.118 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 50 % | | 0.587 | 0.215 | 0.114 | 0.082 | 0.114 | 0.059 | | |
| 75 % | | 0.294 | 0.107 | 0.082 | 0.082 | 0.057 | 0.030 | | |
| 90 % | | 0.118 | 0.082 | 0.082 | 0.082 | 0.037 | 0.020 | | |
| None | R4 Stream | 0.808 | 0.297 | 0.297 | 0.297 | 0.156 | 0.081 | | |
| 50 % | | 0.404 | 0.297 | 0.297 | 0.297 | 0.134 | 0.070 | | |
| 75 % | | 0.297 | 0.297 | 0.297 | 0.297 | 0.134 | 0.070 | | |
| 90 % | | 0.297 | 0.297 | 0.297 | 0.297 | 0.134 | 0.070 | | |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D3 Ditch | **4.59** | **1.24** | 0.659 | 0.342 | 0.659 | 0.342 | | |
| 50 % | | **2.29** | 0.622 | 0.330 | 0.171 | 0.330 | 0.171 | | |
| 75 % | | **1.15** | 0.311 | 0.165 | 0.086 | 0.165 | 0.086 | | |
| 90 % | | 0.458 | 0.124 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | D4 Pond | 0.158 | 0.137 | 0.098 | 0.066 | 0.098 | 0.066 | | |
| 50 % | | 0.079 | 0.068 | 0.049 | 0.033 | 0.049 | 0.033 | | |
| 75 % | | 0.039 | 0.034 | 0.025 | 0.016 | 0.025 | 0.016 | | |
| 90 % | | 0.016 | 0.014 | 0.010 | 0.007 | 0.010 | 0.007 | | |
| None | D4 Stream | **3.25** | **1.19** | 0.629 | 0.327 | 0.629 | 0.327 | | |
| 50 % | | **1.62** | 0.593 | 0.314 | 0.163 | 0.314 | 0.163 | | |
| 75 % | | 0.811 | 0.296 | 0.157 | 0.082 | 0.157 | 0.082 | | |
| 90 % | | 0.325 | 0.118 | 0.063 | 0.033 | 0.063 | 0.033 | | |
| None | D6 Ditch | **4.62** | **1.25** | 0.664 | 0.345 | 0.664 | 0.345 | | |
| 50 % | | **2.31** | 0.626 | 0.332 | 0.173 | 0.332 | 0.173 | | |
| 75 % | | **1.16** | 0.313 | 0.166 | 0.086 | 0.166 | 0.086 | | |
| 90 % | | 0.462 | 0.125 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | D6 Ditch 2nd | **4.61** | **1.25** | 0.662 | 0.344 | 0.662 | 0.344 | | |
| 50 % | | **2.30** | 0.624 | 0.331 | 0.172 | 0.331 | 0.172 | | |
| 75 % | | **1.15** | 0.312 | 0.166 | 0.086 | 0.166 | 0.086 | | |
| 90 % | | 0.461 | 0.125 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | R1 Pond | 0.158 | 0.137 | 0.098 | 0.066 | 0.098 | 0.066 | | |
| 50 % | | 0.079 | 0.068 | 0.049 | 0.033 | 0.049 | 0.033 | | |
| 75 % | | 0.039 | 0.034 | 0.025 | 0.016 | 0.025 | 0.016 | | |
| 90 % | | 0.016 | 0.014 | 0.010 | 0.007 | 0.010 | 0.007 | | |
| None | R1 Stream | **2.97** | **1.09** | 0.576 | 0.299 | 0.576 | 0.299 | | |
| 50 % | | **1.49** | 0.543 | 0.288 | 0.150 | 0.288 | 0.150 | | |
| 75 % | | 0.743 | 0.272 | 0.144 | 0.075 | 0.144 | 0.075 | | |
| 90 % | | 0.297 | 0.109 | 0.058 | 0.030 | 0.058 | 0.030 | | |
| None | R2 Stream | **4.07** | **1.48** | 0.787 | 0.409 | 0.787 | 0.409 | | |
| 50 % | | **2.03** | 0.742 | 0.393 | 0.205 | 0.393 | 0.205 | | |
| 75 % | | **1.02** | 0.371 | 0.197 | 0.103 | 0.197 | 0.102 | | |
| 90 % | | 0.406 | 0.149 | 0.103 | 0.103 | 0.079 | 0.041 | | |
| None | R3 Stream | **4.26** | **1.56** | 0.825 | 0.428 | 0.825 | 0.428 | | |
| 50 % | | **2.13** | 0.778 | 0.412 | 0.298 | 0.412 | 0.214 | | |
| 75 % | | **1.06** | 0.389 | 0.298 | 0.298 | 0.206 | 0.107 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 90 % | | 0.426 | 0.298 | 0.298 | 0.298 | 0.135 | 0.071 | | |
| None | R4 Stream | **2.93** | **1.07** | **1.07** | **1.07** | 0.567 | 0.295 | | |
| 50 % | | **1.46** | **1.07** | **1.07** | **1.07** | 0.486 | 0.254 | | |
| 75 % | | **1.07** | **1.07** | **1.07** | **1.07** | 0.486 | 0.254 | | |
| 90 % | | **1.07** | **1.07** | **1.07** | **1.07** | 0.486 | 0.254 | | |

PEC: predicted environmental concentration
RAC: regulatory acceptable concentration
PEC/RAC ratios above the relevant trigger of 1 are shown in bold

**Table 9.5-29: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in flower bulbs (flower bulbs; modelling use VegBulb II -- VegBulb II (early) -- 5×0.075 kg a.s./ha, 7d int.)**

| **Intended use** | | flower bulbs | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 5 x 75 g/ha, 7d int. | | | | | | | |
| 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 | 0.475 | 0.129 | 0.068 | 0.036 | 0.068 | 0.036 | | |
| 50 % | | 0.237 | 0.064 | 0.034 | 0.018 | 0.034 | 0.018 | | |
| 75 % | | 0.119 | 0.032 | 0.017 | 0.009 | 0.017 | 0.009 | | |
| 90 % | | 0.047 | 0.013 | 0.007 | 0.004 | 0.007 | 0.004 | | |
| None | D4 Pond | *0.030* | *0.026* | *0.018* | *0.012* | *0.018* | *0.012* | | |
| 50 % | | *0.015* | *0.013* | *0.009* | *0.006* | *0.009* | *0.006* | | |
| 75 % | | *0.007* | *0.006* | *0.005* | *0.003* | *0.005* | *0.003* | | |
| 90 % | | *0.003* | *0.003* | *0.002* | *0.001* | *0.002* | *0.001* | | |
| None | D4 Stream | 0.364 | 0.133 | 0.071 | 0.037 | 0.071 | 0.037 | | |
| 50 % | | 0.182 | 0.067 | 0.035 | 0.018 | 0.035 | 0.018 | | |
| 75 % | | 0.091 | 0.033 | 0.018 | 0.009 | 0.018 | 0.009 | | |
| 90 % | | 0.036 | 0.013 | 0.007 | 0.004 | 0.007 | 0.004 | | |
| None | D6 Ditch | 0.476 | 0.129 | 0.069 | 0.036 | 0.069 | 0.036 | | |
| 50 % | | 0.238 | 0.065 | 0.034 | 0.018 | 0.034 | 0.018 | | |
| 75 % | | 0.119 | 0.032 | 0.017 | 0.009 | 0.017 | 0.009 | | |
| 90 % | | 0.048 | 0.013 | 0.007 | 0.004 | 0.007 | 0.004 | | |
| None | D6 Ditch 2nd | 0.478 | 0.130 | 0.069 | 0.036 | 0.069 | 0.036 | | |
| 50 % | | 0.239 | 0.065 | 0.034 | 0.018 | 0.034 | 0.018 | | |
| 75 % | | 0.120 | 0.032 | 0.017 | 0.009 | 0.017 | 0.009 | | |
| 90 % | | 0.048 | 0.013 | 0.007 | 0.004 | 0.007 | 0.004 | | |
| None | R1 Pond | *0.030* | *0.026* | *0.019* | *0.013* | *0.019* | *0.012* | | |
| 50 % | | *0.016* | *0.014* | *0.010* | *0.007* | *0.010* | *0.006* | | |
| 75 % | | *0.008* | *0.007* | *0.006* | *0.004* | *0.005* | *0.003* | | |
| 90 % | | *0.004* | *0.004* | *0.003* | *0.002* | *0.002* | *0.001* | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| None | R1 Stream | 0.307 | 0.112 | 0.060 | 0.031 | 0.060 | 0.031 | | |
| 50 % | | 0.154 | 0.056 | 0.030 | *0.023* | 0.030 | 0.016 | | |
| 75 % | | 0.077 | 0.028 | *0.023* | *0.023* | 0.015 | 0.008 | | |
| 90 % | | 0.031 | *0.023* | *0.023* | *0.023* | *0.010* | *0.005* | | |
| None | R2 Stream | 0.413 | 0.151 | 0.080 | 0.042 | 0.080 | 0.042 | | |
| 50 % | | 0.207 | 0.076 | 0.040 | 0.021 | 0.040 | 0.021 | | |
| 75 % | | 0.103 | 0.038 | 0.020 | *0.015* | 0.020 | 0.010 | | |
| 90 % | | 0.041 | 0.015 | *0.015* | *0.015* | 0.008 | 0.004 | | |
| None | R3 Stream | 0.439 | 0.160 | 0.085 | 0.044 | 0.085 | 0.044 | | |
| 50 % | | 0.220 | 0.080 | 0.043 | *0.042* | 0.043 | 0.022 | | |
| 75 % | | 0.110 | *0.042* | *0.042* | *0.042* | 0.021 | 0.011 | | |
| 90 % | | 0.044 | *0.042* | *0.042* | *0.042* | *0.019* | *0.010* | | |
| None | R4 Stream | 0.311 | *0.116* | *0.116* | *0.116* | 0.060 | 0.031 | | |
| 50 % | | 0.155 | *0.116* | *0.116* | *0.116* | *0.052* | *0.027* | | |
| 75 % | | *0.116* | *0.116* | *0.116* | *0.116* | *0.052* | *0.027* | | |
| 90 % | | *0.116* | *0.116* | *0.116* | *0.116* | *0.052* | *0.027* | | |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D3 Ditch | **1.72** | 0.466 | 0.247 | 0.129 | 0.247 | 0.129 | | |
| 50 % | | 0.859 | 0.233 | 0.124 | 0.064 | 0.124 | 0.064 | | |
| 75 % | | 0.430 | 0.117 | 0.062 | 0.032 | 0.062 | 0.032 | | |
| 90 % | | 0.172 | 0.047 | 0.025 | 0.013 | 0.025 | 0.013 | | |
| None | D4 Pond | 0.108 | 0.093 | 0.067 | 0.044 | 0.067 | 0.044 | | |
| 50 % | | 0.054 | 0.047 | 0.033 | 0.022 | 0.033 | 0.022 | | |
| 75 % | | 0.027 | 0.023 | 0.017 | 0.011 | 0.017 | 0.011 | | |
| 90 % | | 0.011 | 0.009 | 0.007 | 0.004 | 0.007 | 0.004 | | |
| None | D4 Stream | **1.32** | 0.482 | 0.256 | 0.133 | 0.256 | 0.133 | | |
| 50 % | | 0.660 | 0.241 | 0.128 | 0.066 | 0.128 | 0.066 | | |
| 75 % | | 0.330 | 0.121 | 0.064 | 0.033 | 0.064 | 0.033 | | |
| 90 % | | 0.132 | 0.048 | 0.025 | 0.013 | 0.025 | 0.013 | | |
| None | D6 Ditch | **1.73** | 0.468 | 0.248 | 0.129 | 0.248 | 0.129 | | |
| 50 % | | 0.863 | 0.234 | 0.124 | 0.064 | 0.124 | 0.064 | | |
| 75 % | | 0.432 | 0.117 | 0.062 | 0.032 | 0.062 | 0.032 | | |
| 90 % | | 0.172 | 0.047 | 0.025 | 0.013 | 0.025 | 0.013 | | |
| None | D6 Ditch 2nd | **1.73** | 0.470 | 0.249 | 0.129 | 0.249 | 0.129 | | |
| 50 % | | 0.866 | 0.235 | 0.125 | 0.065 | 0.125 | 0.065 | | |
| 75 % | | 0.433 | 0.117 | 0.062 | 0.032 | 0.062 | 0.032 | | |
| 90 % | | 0.173 | 0.047 | 0.025 | 0.013 | 0.025 | 0.013 | | |
| None | R1 Pond | 0.110 | 0.096 | 0.069 | 0.047 | 0.067 | 0.045 | | |
| 50 % | | 0.057 | 0.050 | 0.037 | 0.026 | 0.034 | 0.022 | | |
| 75 % | | 0.030 | 0.027 | 0.020 | 0.015 | 0.018 | 0.012 | | |
| 90 % | | 0.014 | 0.013 | 0.011 | 0.008 | 0.008 | 0.005 | | |
| None | R1 Stream | **1.11** | 0.407 | 0.216 | 0.112 | 0.216 | 0.112 | | |
| 50 % | | 0.557 | 0.203 | 0.108 | 0.082 | 0.108 | 0.056 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 75 % | | 0.279 | 0.102 | 0.082 | 0.082 | 0.054 | 0.028 | | |
| 90 % | | 0.111 | 0.082 | 0.082 | 0.082 | 0.037 | 0.019 | | |
| None | R2 Stream | **1.50** | 0.547 | 0.290 | 0.151 | 0.290 | 0.151 | | |
| 50 % | | 0.748 | 0.274 | 0.145 | 0.075 | 0.145 | 0.075 | | |
| 75 % | | 0.374 | 0.137 | 0.072 | 0.053 | 0.072 | 0.038 | | |
| 90 % | | 0.150 | 0.055 | 0.053 | 0.053 | 0.029 | 0.015 | | |
| None | R3 Stream | **1.59** | 0.581 | 0.308 | 0.160 | 0.308 | 0.160 | | |
| 50 % | | 0.795 | 0.291 | 0.154 | 0.152 | 0.154 | 0.080 | | |
| 75 % | | 0.397 | 0.152 | 0.152 | 0.152 | 0.077 | 0.040 | | |
| 90 % | | 0.159 | 0.152 | 0.152 | 0.152 | 0.069 | 0.036 | | |
| None | R4 Stream | **1.13** | 0.420 | 0.420 | 0.420 | 0.218 | 0.113 | | |
| 50 % | | 0.563 | 0.420 | 0.420 | 0.420 | 0.190 | 0.099 | | |
| 75 % | | 0.420 | 0.420 | 0.420 | 0.420 | 0.190 | 0.099 | | |
| 90 % | | 0.420 | 0.420 | 0.420 | 0.420 | 0.190 | 0.099 | | |

* 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 9.5-30: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in flower bulbs (flower bulbs; modelling use VegBulb II -- VegBulb II (late) -- 5×0.075 kg a.s./ha, 7d int.)**

| **Intended use** | | flower bulbs | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 5 x 75 g/ha, 7d int. | | | | | | | |
| 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 | 0.474 | 0.129 | 0.068 | 0.036 | 0.068 | 0.036 | | |
| 50 % | | 0.237 | 0.064 | 0.034 | 0.018 | 0.034 | 0.018 | | |
| 75 % | | 0.119 | 0.032 | 0.017 | 0.009 | 0.017 | 0.009 | | |
| 90 % | | 0.047 | 0.013 | 0.007 | 0.004 | 0.007 | 0.004 | | |
| None | D4 Pond | *0.031* | *0.027* | *0.019* | *0.013* | *0.019* | *0.013* | | |
| 50 % | | *0.016* | *0.013* | *0.010* | *0.006* | *0.010* | *0.006* | | |
| 75 % | | *0.008* | *0.007* | *0.005* | *0.003* | *0.005* | *0.003* | | |
| 90 % | | *0.003* | *0.003* | *0.002* | *0.001* | *0.002* | *0.001* | | |
| None | D4 Stream | 0.335 | 0.123 | 0.065 | 0.034 | 0.065 | 0.034 | | |
| 50 % | | 0.168 | 0.061 | 0.033 | 0.017 | 0.033 | 0.017 | | |
| 75 % | | 0.084 | 0.031 | 0.016 | 0.008 | 0.016 | 0.008 | | |
| 90 % | | 0.034 | 0.012 | 0.007 | 0.003 | 0.007 | 0.003 | | |
| None | D6 Ditch | 0.478 | 0.130 | 0.069 | 0.036 | 0.069 | 0.036 | | |
| 50 % | | 0.239 | 0.065 | 0.034 | 0.018 | 0.034 | 0.018 | | |
| 75 % | | 0.120 | 0.032 | 0.017 | 0.009 | 0.017 | 0.009 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 90 % | | 0.048 | 0.013 | 0.007 | 0.004 | 0.007 | 0.004 | | |
| None | D6 Ditch 2nd | 0.469 | 0.127 | 0.067 | 0.035 | 0.067 | 0.035 | | |
| 50 % | | 0.234 | 0.064 | 0.034 | 0.018 | 0.034 | 0.018 | | |
| 75 % | | 0.117 | 0.032 | 0.017 | 0.009 | 0.017 | 0.009 | | |
| 90 % | | 0.047 | 0.013 | 0.007 | 0.004 | 0.007 | 0.004 | | |
| None | R1 Pond | *0.031* | *0.027* | *0.020* | *0.014* | *0.019* | *0.012* | | |
| 50 % | | *0.016* | *0.014* | *0.011* | *0.008* | *0.010* | *0.006* | | |
| 75 % | | *0.009* | *0.008* | *0.006* | *0.005* | *0.005* | *0.003* | | |
| 90 % | | *0.005* | *0.004* | *0.004* | *0.003* | *0.003* | *0.002* | | |
| None | R1 Stream | 0.308 | 0.113 | 0.060 | *0.037* | 0.060 | 0.031 | | |
| 50 % | | 0.154 | 0.056 | *0.037* | *0.037* | 0.030 | 0.016 | | |
| 75 % | | 0.077 | *0.037* | *0.037* | *0.037* | *0.016* | *0.009* | | |
| 90 % | | *0.037* | *0.037* | *0.037* | *0.037* | *0.016* | *0.009* | | |
| None | R2 Stream | 0.414 | 0.151 | 0.080 | 0.042 | 0.080 | 0.042 | | |
| 50 % | | 0.207 | 0.076 | 0.040 | 0.021 | 0.040 | 0.021 | | |
| 75 % | | 0.104 | 0.038 | 0.020 | *0.015* | 0.020 | 0.010 | | |
| 90 % | | 0.041 | 0.015 | *0.015* | *0.015* | 0.008 | 0.004 | | |
| None | R3 Stream | 0.441 | 0.161 | 0.086 | 0.044 | 0.086 | 0.044 | | |
| 50 % | | 0.221 | 0.081 | 0.043 | *0.037* | 0.043 | 0.022 | | |
| 75 % | | 0.110 | 0.040 | *0.037* | *0.037* | 0.021 | 0.011 | | |
| 90 % | | 0.044 | *0.037* | *0.037* | *0.037* | *0.017* | *0.009* | | |
| None | R4 Stream | 0.311 | *0.116* | *0.116* | *0.116* | 0.060 | 0.031 | | |
| 50 % | | 0.155 | *0.116* | *0.116* | *0.116* | *0.052* | *0.027* | | |
| 75 % | | *0.116* | *0.116* | *0.116* | *0.116* | *0.052* | *0.027* | | |
| 90 % | | *0.116* | *0.116* | *0.116* | *0.116* | *0.052* | *0.027* | | |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D3 Ditch | **1.72** | 0.466 | 0.247 | 0.129 | 0.247 | 0.129 | | |
| 50 % | | 0.859 | 0.233 | 0.124 | 0.064 | 0.124 | 0.064 | | |
| 75 % | | 0.430 | 0.117 | 0.062 | 0.032 | 0.062 | 0.032 | | |
| 90 % | | 0.172 | 0.047 | 0.025 | 0.013 | 0.025 | 0.013 | | |
| None | D4 Pond | 0.113 | 0.097 | 0.070 | 0.046 | 0.070 | 0.046 | | |
| 50 % | | 0.057 | 0.049 | 0.034 | 0.023 | 0.034 | 0.023 | | |
| 75 % | | 0.028 | 0.024 | 0.017 | 0.012 | 0.017 | 0.012 | | |
| 90 % | | 0.011 | 0.010 | 0.007 | 0.005 | 0.007 | 0.005 | | |
| None | D4 Stream | **1.21** | 0.444 | 0.236 | 0.122 | 0.236 | 0.122 | | |
| 50 % | | 0.607 | 0.222 | 0.118 | 0.061 | 0.118 | 0.061 | | |
| 75 % | | 0.304 | 0.111 | 0.059 | 0.030 | 0.059 | 0.030 | | |
| 90 % | | 0.121 | 0.044 | 0.024 | 0.012 | 0.024 | 0.012 | | |
| None | D6 Ditch | **1.73** | 0.470 | 0.249 | 0.129 | 0.249 | 0.129 | | |
| 50 % | | 0.866 | 0.235 | 0.125 | 0.065 | 0.125 | 0.065 | | |
| 75 % | | 0.433 | 0.117 | 0.062 | 0.032 | 0.062 | 0.032 | | |
| 90 % | | 0.173 | 0.047 | 0.025 | 0.013 | 0.025 | 0.013 | | |
| None | D6 Ditch 2nd | **1.70** | 0.460 | 0.244 | 0.127 | 0.244 | 0.127 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 50 % | | 0.849 | 0.230 | 0.122 | 0.063 | 0.122 | 0.063 | | |
| 75 % | | 0.424 | 0.115 | 0.061 | 0.032 | 0.061 | 0.032 | | |
| 90 % | | 0.170 | 0.046 | 0.024 | 0.013 | 0.024 | 0.013 | | |
| None | R1 Pond | 0.111 | 0.096 | 0.071 | 0.049 | 0.067 | 0.044 | | |
| 50 % | | 0.058 | 0.051 | 0.038 | 0.028 | 0.035 | 0.023 | | |
| 75 % | | 0.033 | 0.029 | 0.022 | 0.017 | 0.018 | 0.012 | | |
| 90 % | | 0.017 | 0.016 | 0.013 | 0.011 | 0.009 | 0.005 | | |
| None | R1 Stream | **1.12** | 0.408 | 0.216 | 0.133 | 0.216 | 0.112 | | |
| 50 % | | 0.558 | 0.204 | 0.133 | 0.133 | 0.108 | 0.056 | | |
| 75 % | | 0.279 | 0.133 | 0.133 | 0.133 | 0.059 | 0.031 | | |
| 90 % | | 0.133 | 0.133 | 0.133 | 0.133 | 0.059 | 0.031 | | |
| None | R2 Stream | **1.50** | 0.548 | 0.291 | 0.151 | 0.291 | 0.151 | | |
| 50 % | | 0.750 | 0.274 | 0.145 | 0.075 | 0.145 | 0.075 | | |
| 75 % | | 0.375 | 0.137 | 0.073 | 0.053 | 0.073 | 0.038 | | |
| 90 % | | 0.150 | 0.055 | 0.053 | 0.053 | 0.029 | 0.015 | | |
| None | R3 Stream | **1.60** | 0.584 | 0.310 | 0.161 | 0.310 | 0.161 | | |
| 50 % | | 0.800 | 0.292 | 0.155 | 0.133 | 0.155 | 0.080 | | |
| 75 % | | 0.400 | 0.146 | 0.133 | 0.133 | 0.078 | 0.040 | | |
| 90 % | | 0.160 | 0.133 | 0.133 | 0.133 | 0.061 | 0.032 | | |
| None | R4 Stream | **1.13** | 0.420 | 0.420 | 0.420 | 0.218 | 0.113 | | |
| 50 % | | 0.563 | 0.420 | 0.420 | 0.420 | 0.190 | 0.099 | | |
| 75 % | | 0.420 | 0.420 | 0.420 | 0.420 | 0.190 | 0.099 | | |
| 90 % | | 0.420 | 0.420 | 0.420 | 0.420 | 0.190 | 0.099 | | |

* 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 9.5-31: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in chokeberry, elderberry, tree nursery (chokeberry, elderberry, tree nursery; modelling use Pome and stone fruit 2x200 g/ha -- BBCH 12-91, early -- 2×0.2 kg a.s./ha, 7d int.)**

| **Intended use** | | chokeberry, elderberry, tree nursery | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 2 x 200 g/ha, 7d int. | | | | | | | |
| 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 | 15.5 | 12.2 | 7.48 | 1.71 | 7.48 | 1.71 | | |
| 50 % | | 7.76 | 6.10 | 3.74 | 0.856 | 3.74 | 0.856 | | |
| 75 % | | 3.88 | 3.05 | 1.87 | 0.428 | 1.87 | 0.428 | | |
| 90 % | | 1.55 | 1.22 | 0.748 | 0.171 | 0.748 | 0.171 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| None | D4 Pond | *1.51* | *1.70* | *0.963* | *0.290* | *0.963* | *0.290* | | |
| 50 % | | *0.755* | *0.847* | *0.481* | *0.145* | *0.481* | *0.145* | | |
| 75 % | | *0.377* | *0.423* | *0.240* | *0.073* | *0.240* | *0.073* | | |
| 90 % | | *0.151* | *0.169* | *0.096* | *0.029* | *0.096* | *0.029* | | |
| None | D4 Stream | 15.8 | 13.6 | 8.34 | 1.91 | 8.34 | 1.91 | | |
| 50 % | | 7.90 | 6.79 | 4.17 | 0.953 | 4.17 | 0.953 | | |
| 75 % | | 3.95 | 3.39 | 2.08 | 0.477 | 2.08 | 0.477 | | |
| 90 % | | 1.58 | 1.36 | 0.834 | 0.191 | 0.834 | 0.191 | | |
| None | D5 Pond | *1.51* | *1.69* | *0.959* | *0.289* | *0.959* | *0.289* | | |
| 50 % | | *0.753* | *0.844* | *0.479* | *0.144* | *0.479* | *0.144* | | |
| 75 % | | *0.376* | *0.422* | *0.240* | *0.072* | *0.240* | *0.072* | | |
| 90 % | | *0.150* | *0.169* | *0.096* | *0.029* | *0.096* | *0.029* | | |
| None | D5 Stream | 16.2 | 13.9 | 8.53 | 1.95 | 8.53 | 1.95 | | |
| 50 % | | 8.08 | 6.94 | 4.26 | 0.975 | 4.26 | 0.975 | | |
| 75 % | | 4.04 | 3.47 | 2.13 | 0.487 | 2.13 | 0.487 | | |
| 90 % | | 1.62 | 1.39 | 0.852 | 0.195 | 0.852 | 0.195 | | |
| None | R1 Pond | *1.51* | *1.69* | *0.959* | *0.289* | *0.959* | *0.289* | | |
| 50 % | | *0.752* | *0.844* | *0.479* | *0.144* | *0.479* | *0.144* | | |
| 75 % | | *0.376* | *0.422* | *0.240* | *0.072* | *0.240* | *0.072* | | |
| 90 % | | *0.150* | *0.169* | *0.096* | *0.029* | *0.096* | *0.029* | | |
| None | R1 Stream | 12.5 | 10.8 | 6.61 | 1.51 | 6.61 | 1.51 | | |
| 50 % | | 6.27 | 5.38 | 3.31 | 0.756 | 3.31 | 0.756 | | |
| 75 % | | 3.13 | 2.69 | 1.65 | 0.378 | 1.65 | 0.378 | | |
| 90 % | | 1.25 | 1.08 | 0.661 | 0.151 | 0.661 | 0.151 | | |
| None | R2 Stream | 16.6 | 14.3 | 8.77 | 2.01 | 8.77 | 2.01 | | |
| 50 % | | 8.31 | 7.14 | 4.39 | 1.00 | 4.39 | 1.00 | | |
| 75 % | | 4.16 | 3.57 | 2.19 | 0.501 | 2.19 | 0.501 | | |
| 90 % | | 1.66 | 1.43 | 0.877 | 0.201 | 0.877 | 0.201 | | |
| None | R3 Stream | 17.7 | 15.2 | 9.36 | 2.14 | 9.36 | 2.14 | | |
| 50 % | | 8.87 | 7.62 | 4.68 | 1.07 | 4.68 | 1.07 | | |
| 75 % | | 4.43 | 3.81 | 2.34 | 0.535 | 2.34 | 0.535 | | |
| 90 % | | 1.77 | 1.52 | 0.935 | 0.214 | 0.935 | 0.214 | | |
| None | R4 Stream | 12.6 | 10.8 | 6.65 | 1.52 | 6.65 | 1.52 | | |
| 50 % | | 6.30 | 5.42 | 3.33 | 0.760 | 3.33 | 0.760 | | |
| 75 % | | 3.15 | 2.71 | 1.66 | 0.380 | 1.66 | 0.380 | | |
| 90 % | | 1.26 | 1.08 | 0.665 | 0.152 | 0.665 | 0.152 | | |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D3 Ditch | **56.2** | **44.2** | **27.1** | **6.20** | **27.1** | **6.20** | | |
| 50 % | | **28.1** | **22.1** | **13.6** | **3.10** | **13.6** | **3.10** | | |
| 75 % | | **14.1** | **11.0** | **6.78** | **1.55** | **6.78** | **1.55** | | |
| 90 % | | **5.62** | **4.42** | **2.71** | 0.620 | **2.71** | 0.620 | | |
| None | D4 Pond | **5.47** | **6.14** | **3.49** | **1.05** | **3.49** | **1.05** | | |
| 50 % | | **2.74** | **3.07** | **1.74** | 0.525 | **1.74** | 0.525 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 75 % | | **1.37** | **1.53** | 0.871 | 0.263 | 0.871 | 0.263 | | |
| 90 % | | 0.546 | 0.613 | 0.348 | 0.105 | 0.348 | 0.105 | | |
| None | D4 Stream | **57.3** | **49.2** | **30.2** | **6.91** | **30.2** | **6.91** | | |
| 50 % | | **28.6** | **24.6** | **15.1** | **3.45** | **15.1** | **3.45** | | |
| 75 % | | **14.3** | **12.3** | **7.55** | **1.73** | **7.55** | **1.73** | | |
| 90 % | | **5.72** | **4.92** | **3.02** | 0.691 | **3.02** | 0.691 | | |
| None | D5 Pond | **5.46** | **6.12** | **3.48** | **1.05** | **3.48** | **1.05** | | |
| 50 % | | **2.73** | **3.06** | **1.74** | 0.523 | **1.74** | 0.523 | | |
| 75 % | | **1.36** | **1.53** | 0.868 | 0.262 | 0.868 | 0.262 | | |
| 90 % | | 0.545 | 0.611 | 0.347 | 0.104 | 0.347 | 0.104 | | |
| None | D5 Stream | **58.6** | **50.3** | **30.9** | **7.06** | **30.9** | **7.06** | | |
| 50 % | | **29.3** | **25.1** | **15.4** | **3.53** | **15.4** | **3.53** | | |
| 75 % | | **14.6** | **12.6** | **7.72** | **1.77** | **7.72** | **1.77** | | |
| 90 % | | **5.86** | **5.03** | **3.09** | 0.706 | **3.09** | 0.706 | | |
| None | R1 Pond | **5.46** | **6.12** | **3.47** | **1.05** | **3.47** | **1.05** | | |
| 50 % | | **2.73** | **3.06** | **1.74** | 0.523 | **1.74** | 0.523 | | |
| 75 % | | **1.36** | **1.53** | 0.868 | 0.262 | 0.868 | 0.262 | | |
| 90 % | | 0.545 | 0.611 | 0.347 | 0.104 | 0.347 | 0.104 | | |
| None | R1 Stream | **45.4** | **39.0** | **24.0** | **5.48** | **24.0** | **5.48** | | |
| 50 % | | **22.7** | **19.5** | **12.0** | **2.74** | **12.0** | **2.74** | | |
| 75 % | | **11.4** | **9.75** | **5.99** | **1.37** | **5.99** | **1.37** | | |
| 90 % | | **4.54** | **3.90** | **2.40** | 0.548 | **2.40** | 0.548 | | |
| None | R2 Stream | **60.3** | **51.8** | **31.8** | **7.27** | **31.8** | **7.27** | | |
| 50 % | | **30.1** | **25.9** | **15.9** | **3.63** | **15.9** | **3.63** | | |
| 75 % | | **15.1** | **12.9** | **7.95** | **1.82** | **7.95** | **1.82** | | |
| 90 % | | **6.03** | **5.17** | **3.18** | 0.726 | **3.18** | 0.726 | | |
| None | R3 Stream | **64.2** | **55.2** | **33.9** | **7.75** | **33.9** | **7.75** | | |
| 50 % | | **32.1** | **27.6** | **16.9** | **3.87** | **16.9** | **3.87** | | |
| 75 % | | **16.1** | **13.8** | **8.47** | **1.94** | **8.47** | **1.94** | | |
| 90 % | | **6.42** | **5.52** | **3.39** | 0.775 | **3.39** | 0.775 | | |
| None | R4 Stream | **45.7** | **39.2** | **24.1** | **5.51** | **24.1** | **5.51** | | |
| 50 % | | **22.8** | **19.6** | **12.1** | **2.75** | **12.1** | **2.75** | | |
| 75 % | | **11.4** | **9.81** | **6.03** | **1.38** | **6.03** | **1.38** | | |
| 90 % | | **4.57** | **3.92** | **2.41** | 0.551 | **2.41** | 0.551 | | |

* 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 9.5-32: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in chokeberry, elderberry, tree nursery (chokeberry, elderberry, tree nursery; modelling use Pome and stone fruit 2x200 g/ha -- BBCH 12-91, late -- 2×0.2 kg a.s./ha, 7d int.)**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Intended use** | | chokeberry, elderberry, tree nursery | | | | | | | |
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 2 x 200 g/ha, 7d int. | | | | | | | |
| 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 | 7.34 | 4.95 | 2.21 | 0.683 | 2.21 | 0.683 | | |
| 50 % | | 3.67 | 2.48 | 1.11 | 0.342 | 1.11 | 0.342 | | |
| 75 % | | 1.84 | 1.24 | 0.553 | 0.171 | 0.553 | 0.171 | | |
| 90 % | | 0.734 | 0.495 | 0.221 | 0.068 | 0.221 | 0.068 | | |
| None | D4 Pond | *0.506* | *0.577* | *0.317* | *0.131* | *0.317* | *0.131* | | |
| 50 % | | *0.253* | *0.289* | *0.159* | *0.066* | *0.159* | *0.066* | | |
| 75 % | | *0.126* | *0.144* | *0.079* | *0.033* | *0.079* | *0.033* | | |
| 90 % | | *0.051* | *0.058* | *0.032* | *0.013* | *0.032* | *0.013* | | |
| None | D4 Stream | 7.20 | 5.62 | 2.51 | 0.774 | 2.51 | 0.774 | | |
| 50 % | | 3.60 | 2.81 | 1.25 | 0.387 | 1.25 | 0.387 | | |
| 75 % | | 1.80 | 1.40 | 0.627 | 0.194 | 0.627 | 0.194 | | |
| 90 % | | 0.720 | 0.562 | 0.251 | 0.077 | 0.251 | 0.077 | | |
| None | D5 Pond | *0.505* | *0.577* | *0.317* | *0.131* | *0.317* | *0.131* | | |
| 50 % | | *0.253* | *0.288* | *0.159* | *0.066* | *0.159* | *0.066* | | |
| 75 % | | *0.126* | *0.144* | *0.079* | *0.033* | *0.079* | *0.033* | | |
| 90 % | | *0.051* | *0.058* | *0.032* | *0.013* | *0.032* | *0.013* | | |
| None | D5 Stream | 7.94 | 6.20 | 2.77 | 0.855 | 2.77 | 0.855 | | |
| 50 % | | 3.97 | 3.10 | 1.39 | 0.427 | 1.39 | 0.427 | | |
| 75 % | | 1.99 | 1.55 | 0.693 | 0.214 | 0.693 | 0.214 | | |
| 90 % | | 0.794 | 0.620 | 0.277 | 0.086 | 0.277 | 0.086 | | |
| None | R1 Pond | *0.445* | *0.508* | *0.279* | *0.115* | *0.279* | *0.115* | | |
| 50 % | | *0.222* | *0.254* | *0.139* | *0.058* | *0.139* | *0.058* | | |
| 75 % | | *0.111* | *0.127* | *0.070* | *0.029* | *0.070* | *0.029* | | |
| 90 % | | *0.044* | *0.051* | *0.028* | *0.012* | *0.028* | *0.012* | | |
| None | R1 Stream | 5.63 | 4.40 | 1.96 | 0.606 | 1.96 | 0.606 | | |
| 50 % | | 2.82 | 2.20 | 0.982 | 0.303 | 0.982 | 0.303 | | |
| 75 % | | 1.41 | 1.10 | 0.491 | 0.152 | 0.491 | 0.152 | | |
| 90 % | | 0.563 | 0.440 | 0.196 | 0.061 | 0.196 | 0.061 | | |
| None | R2 Stream | 7.55 | 5.89 | 2.63 | 0.812 | 2.63 | 0.812 | | |
| 50 % | | 3.78 | 2.95 | 1.32 | 0.406 | 1.32 | 0.406 | | |
| 75 % | | 1.89 | 1.47 | 0.658 | 0.203 | 0.658 | 0.203 | | |
| 90 % | | 0.755 | 0.589 | 0.263 | 0.081 | 0.263 | 0.081 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| None | R3 Stream | 7.94 | 6.20 | 2.77 | 0.854 | 2.77 | 0.854 | | |
| 50 % | | 3.97 | 3.10 | 1.38 | 0.427 | 1.38 | 0.427 | | |
| 75 % | | 1.99 | 1.55 | 0.692 | *0.220* | 0.692 | 0.214 | | |
| 90 % | | 0.794 | 0.620 | 0.277 | *0.220* | 0.277 | 0.085 | | |
| None | R4 Stream | 5.63 | 4.40 | 1.96 | 0.606 | 1.96 | 0.606 | | |
| 50 % | | 2.82 | 2.20 | 0.982 | 0.303 | 0.982 | 0.303 | | |
| 75 % | | 1.41 | 1.10 | 0.491 | 0.152 | 0.491 | 0.152 | | |
| 90 % | | 0.563 | 0.440 | 0.196 | *0.080* | 0.196 | 0.061 | | |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D3 Ditch | **26.6** | **17.9** | **8.02** | **2.47** | **8.02** | **2.47** | | |
| 50 % | | **13.3** | **8.97** | **4.01** | **1.24** | **4.01** | **1.24** | | |
| 75 % | | **6.65** | **4.49** | **2.00** | 0.618 | **2.00** | 0.618 | | |
| 90 % | | **2.66** | **1.79** | 0.802 | 0.247 | 0.802 | 0.247 | | |
| None | D4 Pond | **1.83** | **2.09** | **1.15** | 0.475 | **1.15** | 0.475 | | |
| 50 % | | 0.916 | **1.05** | 0.574 | 0.238 | 0.574 | 0.238 | | |
| 75 % | | 0.458 | 0.522 | 0.287 | 0.119 | 0.287 | 0.119 | | |
| 90 % | | 0.183 | 0.209 | 0.115 | 0.047 | 0.115 | 0.047 | | |
| None | D4 Stream | **26.1** | **20.4** | **9.09** | **2.81** | **9.09** | **2.81** | | |
| 50 % | | **13.0** | **10.2** | **4.55** | **1.40** | **4.55** | **1.40** | | |
| 75 % | | **6.52** | **5.09** | **2.27** | 0.701 | **2.27** | 0.701 | | |
| 90 % | | **2.61** | **2.03** | 0.909 | 0.280 | 0.909 | 0.280 | | |
| None | D5 Pond | **1.83** | **2.09** | **1.15** | 0.475 | **1.15** | 0.475 | | |
| 50 % | | 0.915 | **1.04** | 0.574 | 0.238 | 0.574 | 0.238 | | |
| 75 % | | 0.457 | 0.522 | 0.287 | 0.119 | 0.287 | 0.119 | | |
| 90 % | | 0.183 | 0.209 | 0.115 | 0.047 | 0.115 | 0.047 | | |
| None | D5 Stream | **28.8** | **22.5** | **10.0** | **3.10** | **10.0** | **3.10** | | |
| 50 % | | **14.4** | **11.2** | **5.02** | **1.55** | **5.02** | **1.55** | | |
| 75 % | | **7.20** | **5.62** | **2.51** | 0.774 | **2.51** | 0.774 | | |
| 90 % | | **2.88** | **2.25** | **1.00** | 0.310 | **1.00** | 0.310 | | |
| None | R1 Pond | **1.61** | **1.84** | **1.01** | 0.418 | **1.01** | 0.418 | | |
| 50 % | | 0.805 | 0.918 | 0.505 | 0.209 | 0.505 | 0.209 | | |
| 75 % | | 0.402 | 0.459 | 0.252 | 0.104 | 0.252 | 0.104 | | |
| 90 % | | 0.161 | 0.183 | 0.101 | 0.042 | 0.101 | 0.042 | | |
| None | R1 Stream | **20.4** | **15.9** | **7.12** | **2.20** | **7.12** | **2.20** | | |
| 50 % | | **10.2** | **7.96** | **3.56** | **1.10** | **3.56** | **1.10** | | |
| 75 % | | **5.10** | **3.98** | **1.78** | 0.549 | **1.78** | 0.549 | | |
| 90 % | | **2.04** | **1.59** | 0.712 | 0.220 | 0.712 | 0.220 | | |
| None | R2 Stream | **27.4** | **21.4** | **9.54** | **2.94** | **9.54** | **2.94** | | |
| 50 % | | **13.7** | **10.7** | **4.77** | **1.47** | **4.77** | **1.47** | | |
| 75 % | | **6.84** | **5.34** | **2.38** | 0.736 | **2.38** | 0.736 | | |
| 90 % | | **2.74** | **2.13** | 0.954 | 0.294 | 0.954 | 0.294 | | |
| None | R3 Stream | **28.8** | **22.5** | **10.0** | **3.10** | **10.0** | **3.10** | | |
| 50 % | | **14.4** | **11.2** | **5.01** | **1.55** | **5.01** | **1.55** | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 75 % | | **7.19** | **5.61** | **2.51** | 0.796 | **2.51** | 0.774 | | |
| 90 % | | **2.88** | **2.24** | **1.00** | 0.796 | **1.00** | 0.309 | | |
| None | R4 Stream | **20.4** | **15.9** | **7.12** | **2.20** | **7.12** | **2.20** | | |
| 50 % | | **10.2** | **7.96** | **3.56** | **1.10** | **3.56** | **1.10** | | |
| 75 % | | **5.10** | **3.98** | **1.78** | 0.549 | **1.78** | 0.549 | | |
| 90 % | | **2.04** | **1.59** | 0.711 | 0.288 | 0.711 | 0.220 | | |

* 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 9.5-33: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in elderberry (elderberry; modelling use Pome and stone fruit 2x150 g/ha -- BBCH 15-91, early -- 2×0.15 kg a.s./ha, 14d int.)**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Intended use** | | elderberry | | | | | | | |
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 2 x 150 g/ha, 14d int. | | | | | | | |
| 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 | 11.6 | 9.14 | 5.61 | 1.28 | 5.61 | 1.28 | | |
| 50 % | | 5.82 | 4.57 | 2.81 | 0.642 | 2.81 | 0.642 | | |
| 75 % | | 2.91 | 2.29 | 1.40 | 0.321 | 1.40 | 0.321 | | |
| 90 % | | 1.16 | 0.914 | 0.561 | 0.128 | 0.561 | 0.128 | | |
| None | D4 Pond | *1.06* | *1.19* | *0.674* | *0.203* | *0.674* | *0.203* | | |
| 50 % | | *0.529* | *0.594* | *0.337* | *0.102* | *0.337* | *0.102* | | |
| 75 % | | *0.264* | *0.296* | *0.168* | *0.051* | *0.168* | *0.051* | | |
| 90 % | | *0.106* | *0.118* | *0.067* | *0.020* | *0.067* | *0.020* | | |
| None | D4 Stream | 11.9 | 10.2 | 6.25 | 1.43 | 6.25 | 1.43 | | |
| 50 % | | 5.93 | 5.09 | 3.13 | 0.715 | 3.13 | 0.715 | | |
| 75 % | | 2.96 | 2.55 | 1.56 | 0.357 | 1.56 | 0.357 | | |
| 90 % | | 1.19 | 1.02 | 0.625 | 0.143 | 0.625 | 0.143 | | |
| None | D5 Pond | *0.971* | *1.09* | *0.618* | *0.186* | *0.618* | *0.186* | | |
| 50 % | | *0.485* | *0.544* | *0.309* | *0.093* | *0.309* | *0.093* | | |
| 75 % | | *0.242* | *0.272* | *0.154* | *0.046* | *0.154* | *0.046* | | |
| 90 % | | *0.097* | *0.108* | *0.062* | *0.019* | *0.062* | *0.019* | | |
| None | D5 Stream | 12.1 | 10.4 | 6.40 | 1.46 | 6.40 | 1.46 | | |
| 50 % | | 6.06 | 5.21 | 3.20 | 0.731 | 3.20 | 0.731 | | |
| 75 % | | 3.03 | 2.60 | 1.60 | 0.366 | 1.60 | 0.366 | | |
| 90 % | | 1.21 | 1.04 | 0.639 | 0.146 | 0.639 | 0.146 | | |
| None | R1 Pond | *1.05* | *1.18* | *0.670* | *0.202* | *0.670* | *0.202* | | |
| 50 % | | *0.526* | *0.590* | *0.335* | *0.101* | *0.335* | *0.101* | | |
| 75 % | | *0.263* | *0.295* | *0.167* | *0.050* | *0.167* | *0.050* | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 90 % | | *0.105* | *0.118* | *0.067* | *0.020* | *0.067* | *0.020* | | |
| None | R1 Stream | 9.40 | 8.08 | 4.96 | 1.13 | 4.96 | 1.13 | | |
| 50 % | | 4.70 | 4.04 | 2.48 | 0.567 | 2.48 | 0.567 | | |
| 75 % | | 2.35 | 2.02 | 1.24 | 0.284 | 1.24 | 0.284 | | |
| 90 % | | 0.940 | 0.808 | 0.496 | 0.113 | 0.496 | 0.113 | | |
| None | R2 Stream | 12.5 | 10.7 | 6.58 | 1.50 | 6.58 | 1.50 | | |
| 50 % | | 6.24 | 5.36 | 3.29 | 0.752 | 3.29 | 0.752 | | |
| 75 % | | 3.12 | 2.68 | 1.65 | 0.376 | 1.65 | 0.376 | | |
| 90 % | | 1.25 | 1.07 | 0.658 | 0.150 | 0.658 | 0.150 | | |
| None | R3 Stream | 13.3 | 11.4 | 7.02 | 1.60 | 7.02 | 1.60 | | |
| 50 % | | 6.65 | 5.71 | 3.51 | 0.802 | 3.51 | 0.802 | | |
| 75 % | | 3.33 | 2.86 | 1.75 | 0.401 | 1.75 | 0.401 | | |
| 90 % | | 1.33 | 1.14 | 0.702 | 0.160 | 0.702 | 0.160 | | |
| None | R4 Stream | 9.46 | 8.12 | 4.99 | 1.14 | 4.99 | 1.14 | | |
| 50 % | | 4.73 | 4.06 | 2.50 | 0.570 | 2.50 | 0.570 | | |
| 75 % | | 2.36 | 2.03 | 1.25 | 0.285 | 1.25 | 0.285 | | |
| 90 % | | 0.945 | 0.812 | 0.499 | 0.114 | 0.499 | 0.114 | | |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D3 Ditch | **42.2** | **33.1** | **20.3** | **4.65** | **20.3** | **4.65** | | |
| 50 % | | **21.1** | **16.6** | **10.2** | **2.33** | **10.2** | **2.33** | | |
| 75 % | | **10.5** | **8.28** | **5.08** | **1.16** | **5.08** | **1.16** | | |
| 90 % | | **4.21** | **3.31** | **2.03** | 0.465 | **2.03** | 0.465 | | |
| None | D4 Pond | **3.84** | **4.30** | **2.44** | 0.736 | **2.44** | 0.736 | | |
| 50 % | | **1.92** | **2.15** | **1.22** | 0.368 | **1.22** | 0.368 | | |
| 75 % | | 0.958 | **1.07** | 0.609 | 0.184 | 0.609 | 0.184 | | |
| 90 % | | 0.383 | 0.429 | 0.243 | 0.074 | 0.243 | 0.074 | | |
| None | D4 Stream | **42.9** | **36.9** | **22.7** | **5.18** | **22.7** | **5.18** | | |
| 50 % | | **21.5** | **18.4** | **11.3** | **2.59** | **11.3** | **2.59** | | |
| 75 % | | **10.7** | **9.22** | **5.66** | **1.29** | **5.66** | **1.29** | | |
| 90 % | | **4.29** | **3.69** | **2.27** | 0.518 | **2.27** | 0.518 | | |
| None | D5 Pond | **3.52** | **3.95** | **2.24** | 0.674 | **2.24** | 0.674 | | |
| 50 % | | **1.76** | **1.97** | **1.12** | 0.336 | **1.12** | 0.336 | | |
| 75 % | | 0.877 | 0.984 | 0.558 | 0.168 | 0.558 | 0.168 | | |
| 90 % | | 0.350 | 0.392 | 0.223 | 0.067 | 0.223 | 0.067 | | |
| None | D5 Stream | **43.9** | **37.7** | **23.2** | **5.30** | **23.2** | **5.30** | | |
| 50 % | | **22.0** | **18.9** | **11.6** | **2.65** | **11.6** | **2.65** | | |
| 75 % | | **11.0** | **9.43** | **5.79** | **1.32** | **5.79** | **1.32** | | |
| 90 % | | **4.39** | **3.77** | **2.32** | 0.530 | **2.32** | 0.530 | | |
| None | R1 Pond | **3.81** | **4.28** | **2.43** | 0.731 | **2.43** | 0.731 | | |
| 50 % | | **1.90** | **2.14** | **1.21** | 0.365 | **1.21** | 0.365 | | |
| 75 % | | 0.951 | **1.07** | 0.605 | 0.182 | 0.605 | 0.182 | | |
| 90 % | | 0.380 | 0.426 | 0.242 | 0.073 | 0.242 | 0.073 | | |
| None | R1 Stream | **34.1** | **29.3** | **18.0** | **4.11** | **18.0** | **4.11** | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 50 % | | **17.0** | **14.6** | **8.99** | **2.05** | **8.99** | **2.05** | | |
| 75 % | | **8.51** | **7.32** | **4.49** | **1.03** | **4.49** | **1.03** | | |
| 90 % | | **3.41** | **2.93** | **1.80** | 0.411 | **1.80** | 0.411 | | |
| None | R2 Stream | **45.2** | **38.8** | **23.8** | **5.45** | **23.8** | **5.45** | | |
| 50 % | | **22.6** | **19.4** | **11.9** | **2.72** | **11.9** | **2.72** | | |
| 75 % | | **11.3** | **9.71** | **5.96** | **1.36** | **5.96** | **1.36** | | |
| 90 % | | **4.52** | **3.88** | **2.38** | 0.545 | **2.38** | 0.545 | | |
| None | R3 Stream | **48.2** | **41.4** | **25.4** | **5.81** | **25.4** | **5.81** | | |
| 50 % | | **24.1** | **20.7** | **12.7** | **2.91** | **12.7** | **2.91** | | |
| 75 % | | **12.0** | **10.3** | **6.36** | **1.45** | **6.36** | **1.45** | | |
| 90 % | | **4.82** | **4.14** | **2.54** | 0.581 | **2.54** | 0.581 | | |
| None | R4 Stream | **34.3** | **29.4** | **18.1** | **4.13** | **18.1** | **4.13** | | |
| 50 % | | **17.1** | **14.7** | **9.04** | **2.07** | **9.04** | **2.07** | | |
| 75 % | | **8.57** | **7.36** | **4.52** | **1.03** | **4.52** | **1.03** | | |
| 90 % | | **3.43** | **2.94** | **1.81** | 0.413 | **1.81** | 0.413 | | |

* 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 9.5-34: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in elderberry (elderberry; modelling use Pome and stone fruit 2x150 g/ha -- BBCH 15-91, late -- 2×0.15 kg a.s./ha, 14d int.)**

| **Intended use** | | elderberry | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 2 x 150 g/ha, 14d int. | | | | | | | |
| 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 | 5.51 | 3.72 | 1.66 | 0.512 | 1.66 | 0.512 | | |
| 50 % | | 2.75 | 1.86 | 0.830 | 0.256 | 0.830 | 0.256 | | |
| 75 % | | 1.38 | 0.929 | 0.415 | 0.128 | 0.415 | 0.128 | | |
| 90 % | | 0.551 | 0.372 | 0.166 | 0.051 | 0.166 | 0.051 | | |
| None | D4 Pond | *0.342* | *0.391* | *0.215* | *0.089* | *0.215* | *0.089* | | |
| 50 % | | *0.171* | *0.195* | *0.107* | *0.044* | *0.107* | *0.044* | | |
| 75 % | | *0.085* | *0.097* | *0.054* | *0.022* | *0.054* | *0.022* | | |
| 90 % | | *0.034* | *0.039* | *0.021* | *0.009* | *0.021* | *0.009* | | |
| None | D4 Stream | 5.32 | 4.15 | 1.86 | 0.572 | 1.86 | 0.572 | | |
| 50 % | | 2.66 | 2.08 | 0.927 | 0.286 | 0.927 | 0.286 | | |
| 75 % | | 1.33 | 1.04 | 0.464 | 0.143 | 0.464 | 0.143 | | |
| 90 % | | 0.532 | 0.415 | 0.185 | 0.057 | 0.185 | 0.057 | | |
| None | D5 Pond | *0.354* | *0.405* | *0.222* | *0.092* | *0.222* | *0.092* | | |
| 50 % | | *0.177* | *0.202* | *0.111* | *0.046* | *0.111* | *0.046* | | |
| 75 % | | *0.088* | *0.101* | *0.055* | *0.023* | *0.055* | *0.023* | | |
| 90 % | | *0.035* | *0.040* | *0.022* | *0.009* | *0.022* | *0.009* | | |
| None | D5 Stream | 5.96 | 4.65 | 2.08 | 0.641 | 2.08 | 0.641 | | |
| 50 % | | 2.98 | 2.33 | 1.04 | 0.321 | 1.04 | 0.321 | | |
| 75 % | | 1.49 | 1.16 | 0.519 | 0.160 | 0.519 | 0.160 | | |
| 90 % | | 0.596 | 0.465 | 0.208 | 0.064 | 0.208 | 0.064 | | |
| None | R1 Pond | *0.333* | *0.381* | *0.209* | *0.086* | *0.209* | *0.086* | | |
| 50 % | | *0.167* | *0.190* | *0.104* | *0.043* | *0.104* | *0.043* | | |
| 75 % | | *0.083* | *0.095* | *0.052* | *0.022* | *0.052* | *0.022* | | |
| 90 % | | *0.033* | *0.038* | *0.021* | *0.009* | *0.021* | *0.009* | | |
| None | R1 Stream | 4.23 | 3.30 | 1.47 | 0.455 | 1.47 | 0.455 | | |
| 50 % | | 2.11 | 1.65 | 0.737 | 0.227 | 0.737 | 0.227 | | |
| 75 % | | 1.06 | 0.824 | 0.368 | 0.114 | 0.368 | 0.114 | | |
| 90 % | | 0.423 | 0.330 | 0.147 | 0.046 | 0.147 | 0.046 | | |
| None | R2 Stream | 5.66 | 4.42 | 1.98 | 0.609 | 1.98 | 0.609 | | |
| 50 % | | 2.83 | 2.21 | 0.987 | 0.305 | 0.987 | 0.305 | | |
| 75 % | | 1.42 | 1.11 | 0.494 | 0.152 | 0.494 | 0.152 | | |
| 90 % | | 0.566 | 0.442 | 0.197 | 0.061 | 0.197 | 0.061 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| None | R3 Stream | 5.96 | 4.65 | 2.08 | 0.641 | 2.08 | 0.641 | | |
| 50 % | | 2.98 | 2.32 | 1.04 | 0.320 | 1.04 | 0.320 | | |
| 75 % | | 1.49 | 1.16 | 0.519 | 0.160 | 0.519 | 0.160 | | |
| 90 % | | 0.596 | 0.465 | 0.208 | 0.064 | 0.208 | 0.064 | | |
| None | R4 Stream | 4.22 | 3.30 | 1.47 | 0.455 | 1.47 | 0.455 | | |
| 50 % | | 2.11 | 1.65 | 0.736 | 0.227 | 0.736 | 0.227 | | |
| 75 % | | 1.06 | 0.824 | 0.368 | 0.114 | 0.368 | 0.114 | | |
| 90 % | | 0.422 | 0.330 | 0.147 | *0.093* | 0.147 | 0.046 | | |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D3 Ditch | **19.9** | **13.5** | **6.01** | **1.86** | **6.01** | **1.86** | | |
| 50 % | | **9.97** | **6.73** | **3.01** | 0.928 | **3.01** | 0.928 | | |
| 75 % | | **4.99** | **3.37** | **1.50** | 0.464 | **1.50** | 0.464 | | |
| 90 % | | **1.99** | **1.35** | 0.601 | 0.186 | 0.601 | 0.186 | | |
| None | D4 Pond | **1.24** | **1.42** | 0.778 | 0.321 | 0.778 | 0.321 | | |
| 50 % | | 0.619 | 0.707 | 0.388 | 0.161 | 0.388 | 0.161 | | |
| 75 % | | 0.309 | 0.353 | 0.194 | 0.080 | 0.194 | 0.080 | | |
| 90 % | | 0.124 | 0.141 | 0.078 | 0.032 | 0.078 | 0.032 | | |
| None | D4 Stream | **19.3** | **15.0** | **6.72** | **2.07** | **6.72** | **2.07** | | |
| 50 % | | **9.64** | **7.52** | **3.36** | **1.04** | **3.36** | **1.04** | | |
| 75 % | | **4.82** | **3.76** | **1.68** | 0.518 | **1.68** | 0.518 | | |
| 90 % | | **1.93** | **1.50** | 0.672 | 0.207 | 0.672 | 0.207 | | |
| None | D5 Pond | **1.28** | **1.47** | 0.805 | 0.333 | 0.805 | 0.333 | | |
| 50 % | | 0.641 | 0.732 | 0.402 | 0.166 | 0.402 | 0.166 | | |
| 75 % | | 0.320 | 0.366 | 0.201 | 0.083 | 0.201 | 0.083 | | |
| 90 % | | 0.128 | 0.146 | 0.080 | 0.033 | 0.080 | 0.033 | | |
| None | D5 Stream | **21.6** | **16.8** | **7.53** | **2.32** | **7.53** | **2.32** | | |
| 50 % | | **10.8** | **8.42** | **3.76** | **1.16** | **3.76** | **1.16** | | |
| 75 % | | **5.40** | **4.21** | **1.88** | 0.581 | **1.88** | 0.581 | | |
| 90 % | | **2.16** | **1.68** | 0.753 | 0.232 | 0.753 | 0.232 | | |
| None | R1 Pond | **1.21** | **1.38** | 0.757 | 0.313 | 0.757 | 0.313 | | |
| 50 % | | 0.603 | 0.689 | 0.378 | 0.156 | 0.378 | 0.156 | | |
| 75 % | | 0.301 | 0.344 | 0.189 | 0.078 | 0.189 | 0.078 | | |
| 90 % | | 0.120 | 0.137 | 0.075 | 0.031 | 0.075 | 0.031 | | |
| None | R1 Stream | **15.3** | **11.9** | **5.34** | **1.65** | **5.34** | **1.65** | | |
| 50 % | | **7.66** | **5.97** | **2.67** | 0.824 | **2.67** | 0.824 | | |
| 75 % | | **3.83** | **2.99** | **1.33** | 0.412 | **1.33** | 0.412 | | |
| 90 % | | **1.53** | **1.19** | 0.534 | 0.165 | 0.534 | 0.165 | | |
| None | R2 Stream | **20.5** | **16.0** | **7.16** | **2.21** | **7.16** | **2.21** | | |
| 50 % | | **10.3** | **8.00** | **3.58** | **1.10** | **3.58** | **1.10** | | |
| 75 % | | **5.13** | **4.00** | **1.79** | 0.552 | **1.79** | 0.552 | | |
| 90 % | | **2.05** | **1.60** | 0.715 | 0.221 | 0.715 | 0.221 | | |
| None | R3 Stream | **21.6** | **16.8** | **7.52** | **2.32** | **7.52** | **2.32** | | |
| 50 % | | **10.8** | **8.42** | **3.76** | **1.16** | **3.76** | **1.16** | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 75 % | | **5.39** | **4.21** | **1.88** | 0.580 | **1.88** | 0.580 | | |
| 90 % | | **2.16** | **1.68** | 0.752 | 0.232 | 0.752 | 0.232 | | |
| None | R4 Stream | **15.3** | **11.9** | **5.34** | **1.65** | **5.34** | **1.65** | | |
| 50 % | | **7.65** | **5.97** | **2.67** | 0.824 | **2.67** | 0.824 | | |
| 75 % | | **3.83** | **2.99** | **1.33** | 0.412 | **1.33** | 0.412 | | |
| 90 % | | **1.53** | **1.19** | 0.534 | 0.336 | 0.534 | 0.165 | | |

* 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 9.5-35: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in lettuce, rocket (lettuce, rocket; modelling use Vegetable leafy 2x200 g/ha -- BBCH 12-49, early -- 2×0.2 kg a.s./ha, 7d int.)**

| **Intended use** | | lettuce, rocket | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 2 x 200 g/ha, 7d int. | | | | | | | |
| 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 | 1.26 | 0.343 | 0.182 | 0.095 | 0.182 | 0.095 | | |
| 50 % | | 0.633 | 0.172 | 0.091 | 0.047 | 0.091 | 0.047 | | |
| 75 % | | 0.316 | 0.086 | 0.046 | 0.024 | 0.046 | 0.024 | | |
| 90 % | | 0.127 | 0.034 | 0.018 | 0.010 | 0.018 | 0.010 | | |
| None | D3 Ditch 2nd | 1.27 | 0.343 | 0.182 | 0.095 | 0.182 | 0.095 | | |
| 50 % | | 0.633 | 0.172 | 0.091 | 0.047 | 0.091 | 0.047 | | |
| 75 % | | 0.317 | 0.086 | 0.046 | 0.024 | 0.046 | 0.024 | | |
| 90 % | | 0.127 | 0.034 | 0.018 | 0.010 | 0.018 | 0.010 | | |
| None | D4 Pond | *0.056* | *0.048* | *0.034* | *0.023* | *0.034* | *0.023* | | |
| 50 % | | *0.028* | *0.024* | *0.017* | *0.011* | *0.017* | *0.011* | | |
| 75 % | | *0.014* | *0.012* | *0.009* | *0.006* | *0.009* | *0.006* | | |
| 90 % | | *0.006* | *0.005* | *0.003* | *0.002* | *0.003* | *0.002* | | |
| None | D4 Stream | 1.02 | 0.374 | 0.198 | 0.103 | 0.198 | 0.103 | | |
| 50 % | | 0.511 | 0.187 | 0.099 | 0.052 | 0.099 | 0.052 | | |
| 75 % | | 0.256 | 0.093 | 0.050 | 0.026 | 0.050 | 0.026 | | |
| 90 % | | 0.102 | 0.037 | 0.020 | 0.010 | 0.020 | 0.010 | | |
| None | D6 Ditch | 1.24 | 0.337 | 0.179 | 0.093 | 0.179 | 0.093 | | |
| 50 % | | 0.621 | 0.168 | 0.089 | 0.046 | 0.089 | 0.046 | | |
| 75 % | | 0.311 | 0.084 | 0.045 | 0.023 | 0.045 | 0.023 | | |
| 90 % | | 0.124 | 0.034 | 0.018 | 0.009 | 0.018 | 0.009 | | |
| None | R1 Pond | *0.063* | *0.054* | *0.038* | *0.025* | *0.038* | *0.025* | | |
| 50 % | | *0.032* | *0.027* | *0.019* | *0.013* | *0.019* | *0.013* | | |
| 75 % | | *0.016* | *0.014* | *0.010* | *0.006* | *0.010* | *0.006* | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 90 % | | *0.006* | *0.005* | *0.004* | *0.003* | *0.004* | *0.003* | | |
| None | R1 Pond 2nd | *0.061* | *0.052* | *0.037* | *0.024* | *0.037* | *0.024* | | |
| 50 % | | *0.030* | *0.026* | *0.018* | *0.012* | *0.018* | *0.012* | | |
| 75 % | | *0.015* | *0.013* | *0.009* | *0.006* | *0.009* | *0.006* | | |
| 90 % | | *0.006* | *0.006* | *0.005* | *0.004* | *0.004* | *0.002* | | |
| None | R1 Stream | 0.834 | 0.305 | 0.162 | 0.084 | 0.162 | 0.084 | | |
| 50 % | | 0.417 | 0.152 | 0.081 | 0.042 | 0.081 | 0.042 | | |
| 75 % | | 0.208 | 0.076 | 0.040 | *0.022* | 0.040 | 0.021 | | |
| 90 % | | 0.083 | 0.031 | *0.022* | *0.022* | 0.016 | 0.008 | | |
| None | R1 Stream 2nd | 0.837 | 0.306 | 0.162 | 0.084 | 0.162 | 0.084 | | |
| 50 % | | 0.418 | 0.153 | 0.081 | 0.042 | 0.081 | 0.042 | | |
| 75 % | | 0.209 | 0.076 | 0.041 | *0.036* | 0.041 | 0.021 | | |
| 90 % | | 0.084 | *0.036* | *0.036* | *0.036* | *0.016* | *0.009* | | |
| None | R2 Stream | 1.10 | 0.403 | 0.214 | 0.111 | 0.214 | 0.111 | | |
| 50 % | | 0.551 | 0.201 | 0.107 | 0.056 | 0.107 | 0.056 | | |
| 75 % | | 0.276 | 0.101 | 0.053 | 0.028 | 0.053 | 0.028 | | |
| 90 % | | 0.110 | 0.040 | 0.021 | *0.019* | 0.021 | 0.011 | | |
| None | R2 Stream 2nd | 1.12 | 0.410 | 0.217 | 0.113 | 0.217 | 0.113 | | |
| 50 % | | 0.561 | 0.205 | 0.109 | 0.057 | 0.109 | 0.057 | | |
| 75 % | | 0.280 | 0.102 | 0.054 | 0.028 | 0.054 | 0.028 | | |
| 90 % | | 0.112 | 0.041 | 0.022 | 0.011 | 0.022 | 0.011 | | |
| None | R3 Stream | 1.17 | 0.428 | 0.227 | 0.118 | 0.227 | 0.118 | | |
| 50 % | | 0.586 | 0.214 | 0.114 | 0.059 | 0.114 | 0.059 | | |
| 75 % | | 0.293 | 0.107 | 0.057 | *0.044* | 0.057 | 0.030 | | |
| 90 % | | 0.117 | *0.044* | *0.044* | *0.044* | 0.023 | 0.012 | | |
| None | R3 Stream 2nd | 1.18 | 0.431 | 0.229 | 0.119 | 0.229 | 0.119 | | |
| 50 % | | 0.590 | 0.215 | 0.114 | 0.059 | 0.114 | 0.059 | | |
| 75 % | | 0.295 | 0.108 | 0.057 | 0.030 | 0.057 | 0.030 | | |
| 90 % | | 0.118 | 0.043 | 0.023 | 0.012 | 0.023 | 0.012 | | |
| None | R4 Stream | 0.835 | 0.305 | *0.244* | *0.244* | 0.162 | 0.084 | | |
| 50 % | | 0.418 | *0.244* | *0.244* | *0.244* | *0.111* | *0.058* | | |
| 75 % | | *0.244* | *0.244* | *0.244* | *0.244* | *0.111* | *0.058* | | |
| 90 % | | *0.244* | *0.244* | *0.244* | *0.244* | *0.111* | *0.058* | | |
| None | R4 Stream 2nd | 0.829 | 0.303 | 0.161 | 0.083 | 0.161 | 0.083 | | |
| 50 % | | 0.414 | 0.151 | 0.080 | 0.042 | 0.080 | 0.042 | | |
| 75 % | | 0.207 | 0.076 | 0.040 | 0.021 | 0.040 | 0.021 | | |
| 90 % | | 0.083 | 0.030 | *0.019* | *0.019* | 0.016 | 0.008 | | |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D3 Ditch | **4.58** | **1.24** | 0.659 | 0.342 | 0.659 | 0.342 | | |
| 50 % | | **2.29** | 0.621 | 0.330 | 0.171 | 0.330 | 0.171 | | |
| 75 % | | **1.15** | 0.311 | 0.165 | 0.086 | 0.165 | 0.086 | | |
| 90 % | | 0.458 | 0.124 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | D3 Ditch 2nd | **4.59** | **1.24** | 0.660 | 0.343 | 0.660 | 0.343 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 50 % | | **2.29** | 0.622 | 0.330 | 0.171 | 0.330 | 0.171 | | |
| 75 % | | **1.15** | 0.311 | 0.165 | 0.086 | 0.165 | 0.086 | | |
| 90 % | | 0.459 | 0.124 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | D4 Pond | 0.204 | 0.175 | 0.124 | 0.082 | 0.124 | 0.082 | | |
| 50 % | | 0.102 | 0.087 | 0.062 | 0.041 | 0.062 | 0.041 | | |
| 75 % | | 0.051 | 0.044 | 0.031 | 0.020 | 0.031 | 0.020 | | |
| 90 % | | 0.020 | 0.017 | 0.012 | 0.008 | 0.012 | 0.008 | | |
| None | D4 Stream | **3.71** | **1.35** | 0.718 | 0.373 | 0.718 | 0.373 | | |
| 50 % | | **1.85** | 0.677 | 0.359 | 0.187 | 0.359 | 0.187 | | |
| 75 % | | 0.926 | 0.338 | 0.179 | 0.093 | 0.179 | 0.093 | | |
| 90 % | | 0.370 | 0.136 | 0.072 | 0.037 | 0.072 | 0.037 | | |
| None | D6 Ditch | **4.50** | **1.22** | 0.647 | 0.336 | 0.647 | 0.336 | | |
| 50 % | | **2.25** | 0.610 | 0.324 | 0.168 | 0.324 | 0.168 | | |
| 75 % | | **1.13** | 0.305 | 0.162 | 0.084 | 0.162 | 0.084 | | |
| 90 % | | 0.450 | 0.122 | 0.065 | 0.034 | 0.065 | 0.034 | | |
| None | R1 Pond | 0.228 | 0.196 | 0.139 | 0.091 | 0.139 | 0.091 | | |
| 50 % | | 0.114 | 0.098 | 0.070 | 0.046 | 0.070 | 0.046 | | |
| 75 % | | 0.057 | 0.049 | 0.035 | 0.023 | 0.035 | 0.023 | | |
| 90 % | | 0.023 | 0.020 | 0.014 | 0.010 | 0.014 | 0.009 | | |
| None | R1 Pond 2nd | 0.219 | 0.188 | 0.134 | 0.088 | 0.134 | 0.088 | | |
| 50 % | | 0.109 | 0.094 | 0.067 | 0.044 | 0.067 | 0.044 | | |
| 75 % | | 0.055 | 0.047 | 0.033 | 0.023 | 0.033 | 0.022 | | |
| 90 % | | 0.023 | 0.021 | 0.017 | 0.014 | 0.013 | 0.009 | | |
| None | R1 Stream | **3.02** | **1.10** | 0.586 | 0.304 | 0.586 | 0.304 | | |
| 50 % | | **1.51** | 0.552 | 0.293 | 0.152 | 0.293 | 0.152 | | |
| 75 % | | 0.755 | 0.276 | 0.146 | 0.079 | 0.146 | 0.076 | | |
| 90 % | | 0.302 | 0.111 | 0.079 | 0.079 | 0.059 | 0.030 | | |
| None | R1 Stream 2nd | **3.03** | **1.11** | 0.587 | 0.305 | 0.587 | 0.305 | | |
| 50 % | | **1.52** | 0.554 | 0.293 | 0.153 | 0.293 | 0.153 | | |
| 75 % | | 0.758 | 0.277 | 0.147 | 0.131 | 0.147 | 0.076 | | |
| 90 % | | 0.303 | 0.131 | 0.131 | 0.131 | 0.059 | 0.031 | | |
| None | R2 Stream | **3.99** | **1.46** | 0.774 | 0.402 | 0.774 | 0.402 | | |
| 50 % | | **2.00** | 0.729 | 0.387 | 0.201 | 0.387 | 0.201 | | |
| 75 % | | 0.998 | 0.365 | 0.193 | 0.100 | 0.193 | 0.100 | | |
| 90 % | | 0.399 | 0.146 | 0.078 | 0.068 | 0.078 | 0.040 | | |
| None | R2 Stream 2nd | **4.07** | **1.48** | 0.787 | 0.409 | 0.787 | 0.409 | | |
| 50 % | | **2.03** | 0.742 | 0.393 | 0.205 | 0.393 | 0.205 | | |
| 75 % | | **1.02** | 0.371 | 0.197 | 0.102 | 0.197 | 0.102 | | |
| 90 % | | 0.406 | 0.149 | 0.079 | 0.041 | 0.079 | 0.041 | | |
| None | R3 Stream | **4.25** | **1.55** | 0.822 | 0.427 | 0.822 | 0.427 | | |
| 50 % | | **2.12** | 0.775 | 0.411 | 0.214 | 0.411 | 0.214 | | |
| 75 % | | **1.06** | 0.388 | 0.206 | 0.161 | 0.206 | 0.107 | | |
| 90 % | | 0.424 | 0.161 | 0.161 | 0.161 | 0.082 | 0.043 | | |
| None | R3 Stream | **4.27** | **1.56** | 0.828 | 0.430 | 0.828 | 0.430 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 50 % | 2nd | **2.14** | 0.780 | 0.414 | 0.215 | 0.414 | 0.215 | | |
| 75 % | | **1.07** | 0.390 | 0.207 | 0.108 | 0.207 | 0.108 | | |
| 90 % | | 0.427 | 0.156 | 0.083 | 0.043 | 0.083 | 0.043 | | |
| None | R4 Stream | **3.03** | **1.11** | 0.884 | 0.884 | 0.586 | 0.305 | | |
| 50 % | | **1.51** | 0.884 | 0.884 | 0.884 | 0.402 | 0.211 | | |
| 75 % | | 0.884 | 0.884 | 0.884 | 0.884 | 0.402 | 0.211 | | |
| 90 % | | 0.884 | 0.884 | 0.884 | 0.884 | 0.402 | 0.211 | | |
| None | R4 Stream 2nd | **3.00** | **1.10** | 0.582 | 0.302 | 0.582 | 0.302 | | |
| 50 % | | **1.50** | 0.549 | 0.291 | 0.151 | 0.291 | 0.151 | | |
| 75 % | | 0.751 | 0.274 | 0.146 | 0.076 | 0.146 | 0.076 | | |
| 90 % | | 0.300 | 0.110 | 0.067 | 0.067 | 0.058 | 0.030 | | |

* 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 9.5-36: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in lettuce, rocket (lettuce, rocket; modelling use Vegetable leafy 2x200 g/ha -- BBCH 12-49, late -- 2×0.2 kg a.s./ha, 7d int.)**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Intended use** | | lettuce, rocket | | | | | | | |
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 2 x 200 g/ha, 7d int. | | | | | | | |
| 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 | 1.27 | 0.343 | 0.182 | 0.095 | 0.182 | 0.095 | | |
| 50 % | | 0.633 | 0.172 | 0.091 | 0.047 | 0.091 | 0.047 | | |
| 75 % | | 0.317 | 0.086 | 0.046 | 0.024 | 0.046 | 0.024 | | |
| 90 % | | 0.127 | 0.034 | 0.018 | 0.010 | 0.018 | 0.010 | | |
| None | D3 Ditch 2nd | 1.26 | 0.342 | 0.181 | 0.094 | 0.181 | 0.094 | | |
| 50 % | | 0.630 | 0.171 | 0.091 | 0.047 | 0.091 | 0.047 | | |
| 75 % | | 0.315 | 0.085 | 0.045 | 0.024 | 0.045 | 0.024 | | |
| 90 % | | 0.126 | 0.034 | 0.018 | 0.009 | 0.018 | 0.009 | | |
| None | D4 Pond | *0.060* | *0.052* | *0.037* | *0.024* | *0.037* | *0.024* | | |
| 50 % | | *0.030* | *0.026* | *0.018* | *0.012* | *0.018* | *0.012* | | |
| 75 % | | *0.015* | *0.013* | *0.009* | *0.006* | *0.009* | *0.006* | | |
| 90 % | | *0.006* | *0.005* | *0.004* | *0.002* | *0.004* | *0.002* | | |
| None | D4 Stream | 0.902 | 0.330 | 0.175 | 0.091 | 0.175 | 0.091 | | |
| 50 % | | 0.451 | 0.165 | 0.087 | 0.045 | 0.087 | 0.045 | | |
| 75 % | | 0.225 | 0.082 | 0.044 | 0.023 | 0.044 | 0.023 | | |
| 90 % | | 0.090 | 0.033 | 0.018 | 0.009 | 0.018 | 0.009 | | |
| None | D6 Ditch | 1.24 | 0.335 | 0.178 | 0.092 | 0.178 | 0.092 | | |
| 50 % | | 0.617 | 0.167 | 0.089 | 0.046 | 0.089 | 0.046 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 75 % | | 0.309 | 0.084 | 0.044 | 0.023 | 0.044 | 0.023 | | |
| 90 % | | 0.123 | 0.034 | 0.018 | 0.009 | 0.018 | 0.009 | | |
| None | R1 Pond | *0.055* | *0.048* | *0.035* | *0.026* | *0.033* | *0.022* | | |
| 50 % | | *0.030* | *0.027* | *0.023* | *0.019* | *0.017* | *0.011* | | |
| 75 % | | *0.020* | *0.019* | *0.017* | *0.015* | *0.010* | *0.006* | | |
| 90 % | | *0.015* | *0.014* | *0.014* | *0.013* | *0.007* | *0.004* | | |
| None | R1 Pond 2nd | *0.059* | *0.051* | *0.036* | *0.024* | *0.036* | *0.024* | | |
| 50 % | | *0.029* | *0.025* | *0.018* | *0.012* | *0.018* | *0.012* | | |
| 75 % | | *0.015* | *0.013* | *0.009* | *0.006* | *0.009* | *0.006* | | |
| 90 % | | *0.006* | *0.005* | *0.004* | *0.003* | *0.004* | *0.002* | | |
| None | R1 Stream | 0.837 | 0.306 | 0.162 | *0.118* | 0.162 | 0.084 | | |
| 50 % | | 0.418 | 0.153 | *0.118* | *0.118* | 0.081 | 0.042 | | |
| 75 % | | 0.209 | *0.118* | *0.118* | *0.118* | *0.053* | *0.028* | | |
| 90 % | | *0.118* | *0.118* | *0.118* | *0.118* | *0.053* | *0.028* | | |
| None | R1 Stream 2nd | 0.837 | 0.306 | 0.162 | 0.084 | 0.162 | 0.084 | | |
| 50 % | | 0.418 | 0.153 | 0.081 | *0.063* | 0.081 | 0.042 | | |
| 75 % | | 0.209 | 0.076 | *0.063* | *0.063* | 0.041 | 0.021 | | |
| 90 % | | 0.084 | *0.063* | *0.063* | *0.063* | *0.026* | *0.013* | | |
| None | R2 Stream | 1.12 | 0.410 | 0.217 | 0.113 | 0.217 | 0.113 | | |
| 50 % | | 0.561 | 0.205 | 0.109 | 0.057 | 0.109 | 0.057 | | |
| 75 % | | 0.280 | 0.102 | 0.054 | 0.028 | 0.054 | 0.028 | | |
| 90 % | | 0.112 | 0.041 | 0.022 | *0.019* | 0.022 | 0.011 | | |
| None | R2 Stream 2nd | 1.11 | 0.405 | 0.215 | 0.112 | 0.215 | 0.112 | | |
| 50 % | | 0.554 | 0.203 | 0.107 | 0.064 | 0.107 | 0.056 | | |
| 75 % | | 0.277 | 0.101 | 0.064 | 0.064 | 0.054 | 0.028 | | |
| 90 % | | 0.111 | 0.064 | 0.064 | 0.064 | 0.029 | 0.015 | | |
| None | R3 Stream | 1.18 | 0.431 | 0.228 | 0.119 | 0.228 | 0.119 | | |
| 50 % | | 0.589 | 0.215 | 0.114 | *0.111* | 0.114 | 0.059 | | |
| 75 % | | 0.295 | *0.111* | *0.111* | *0.111* | 0.057 | 0.030 | | |
| 90 % | | 0.118 | *0.111* | *0.111* | *0.111* | *0.051* | *0.026* | | |
| None | R3 Stream 2nd | 1.18 | 0.429 | 0.228 | 0.118 | 0.228 | 0.118 | | |
| 50 % | | 0.587 | 0.215 | 0.114 | 0.059 | 0.114 | 0.059 | | |
| 75 % | | 0.294 | 0.107 | 0.057 | *0.043* | 0.057 | 0.030 | | |
| 90 % | | 0.118 | 0.043 | *0.043* | *0.043* | 0.023 | 0.012 | | |
| None | R4 Stream | 0.835 | *0.351* | *0.351* | *0.351* | 0.162 | 0.084 | | |
| 50 % | | 0.418 | *0.351* | *0.351* | *0.351* | *0.159* | *0.083* | | |
| 75 % | | *0.351* | *0.351* | *0.351* | *0.351* | *0.159* | *0.083* | | |
| 90 % | | *0.351* | *0.351* | *0.351* | *0.351* | *0.159* | *0.083* | | |
| None | R4 Stream 2nd | 0.837 | 0.306 | 0.162 | *0.101* | 0.162 | 0.084 | | |
| 50 % | | 0.418 | 0.153 | *0.101* | *0.101* | 0.081 | 0.042 | | |
| 75 % | | 0.209 | *0.101* | *0.101* | *0.101* | *0.046* | *0.024* | | |
| 90 % | | *0.101* | *0.101* | *0.101* | *0.101* | *0.046* | *0.024* | | |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| None | D3 Ditch | **4.59** | **1.24** | 0.659 | 0.343 | 0.659 | 0.343 | | |
| 50 % | | **2.29** | 0.622 | 0.330 | 0.171 | 0.330 | 0.171 | | |
| 75 % | | **1.15** | 0.311 | 0.165 | 0.086 | 0.165 | 0.086 | | |
| 90 % | | 0.459 | 0.124 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | D3 Ditch 2nd | **4.57** | **1.24** | 0.656 | 0.341 | 0.656 | 0.341 | | |
| 50 % | | **2.28** | 0.618 | 0.328 | 0.171 | 0.328 | 0.171 | | |
| 75 % | | **1.14** | 0.309 | 0.164 | 0.085 | 0.164 | 0.085 | | |
| 90 % | | 0.456 | 0.124 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | D4 Pond | 0.218 | 0.187 | 0.133 | 0.087 | 0.133 | 0.087 | | |
| 50 % | | 0.109 | 0.093 | 0.066 | 0.043 | 0.066 | 0.043 | | |
| 75 % | | 0.054 | 0.047 | 0.033 | 0.022 | 0.033 | 0.022 | | |
| 90 % | | 0.022 | 0.018 | 0.013 | 0.009 | 0.013 | 0.009 | | |
| None | D4 Stream | **3.27** | **1.19** | 0.633 | 0.329 | 0.633 | 0.329 | | |
| 50 % | | **1.63** | 0.597 | 0.316 | 0.164 | 0.316 | 0.164 | | |
| 75 % | | 0.817 | 0.299 | 0.158 | 0.082 | 0.158 | 0.082 | | |
| 90 % | | 0.327 | 0.119 | 0.063 | 0.033 | 0.063 | 0.033 | | |
| None | D6 Ditch | **4.47** | **1.21** | 0.643 | 0.334 | 0.643 | 0.334 | | |
| 50 % | | **2.24** | 0.607 | 0.322 | 0.167 | 0.322 | 0.167 | | |
| 75 % | | **1.12** | 0.303 | 0.161 | 0.084 | 0.161 | 0.084 | | |
| 90 % | | 0.447 | 0.121 | 0.064 | 0.033 | 0.064 | 0.033 | | |
| None | R1 Pond | 0.198 | 0.172 | 0.125 | 0.094 | 0.120 | 0.078 | | |
| 50 % | | 0.108 | 0.098 | 0.082 | 0.067 | 0.062 | 0.040 | | |
| 75 % | | 0.074 | 0.069 | 0.061 | 0.054 | 0.038 | 0.022 | | |
| 90 % | | 0.054 | 0.052 | 0.049 | 0.046 | 0.025 | 0.014 | | |
| None | R1 Pond 2nd | 0.213 | 0.183 | 0.130 | 0.086 | 0.130 | 0.085 | | |
| 50 % | | 0.107 | 0.092 | 0.065 | 0.043 | 0.065 | 0.043 | | |
| 75 % | | 0.053 | 0.046 | 0.033 | 0.022 | 0.033 | 0.021 | | |
| 90 % | | 0.021 | 0.018 | 0.013 | 0.009 | 0.013 | 0.009 | | |
| None | R1 Stream | **3.03** | **1.11** | 0.587 | 0.426 | 0.587 | 0.305 | | |
| 50 % | | **1.52** | 0.554 | 0.426 | 0.426 | 0.293 | 0.153 | | |
| 75 % | | 0.758 | 0.426 | 0.426 | 0.426 | 0.191 | 0.100 | | |
| 90 % | | 0.426 | 0.426 | 0.426 | 0.426 | 0.191 | 0.100 | | |
| None | R1 Stream 2nd | **3.03** | **1.11** | 0.587 | 0.305 | 0.587 | 0.305 | | |
| 50 % | | **1.52** | 0.554 | 0.293 | 0.228 | 0.293 | 0.153 | | |
| 75 % | | 0.758 | 0.277 | 0.228 | 0.228 | 0.147 | 0.076 | | |
| 90 % | | 0.303 | 0.228 | 0.228 | 0.228 | 0.096 | 0.049 | | |
| None | R2 Stream | **4.07** | **1.48** | 0.787 | 0.409 | 0.787 | 0.409 | | |
| 50 % | | **2.03** | 0.742 | 0.393 | 0.205 | 0.393 | 0.205 | | |
| 75 % | | **1.02** | 0.371 | 0.197 | 0.102 | 0.197 | 0.102 | | |
| 90 % | | 0.406 | 0.149 | 0.079 | 0.070 | 0.079 | 0.041 | | |
| None | R2 Stream 2nd | **4.02** | **1.47** | 0.778 | 0.404 | 0.778 | 0.404 | | |
| 50 % | | **2.01** | 0.734 | 0.389 | 0.231 | 0.389 | 0.202 | | |
| 75 % | | **1.00** | 0.367 | 0.231 | 0.231 | 0.195 | 0.101 | | |
| 90 % | | 0.402 | 0.231 | 0.231 | 0.231 | 0.104 | 0.054 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| None | R3 Stream | **4.27** | **1.56** | 0.828 | 0.430 | 0.828 | 0.430 | | |
| 50 % | | **2.14** | 0.780 | 0.414 | 0.403 | 0.414 | 0.215 | | |
| 75 % | | **1.07** | 0.403 | 0.403 | 0.403 | 0.207 | 0.108 | | |
| 90 % | | 0.427 | 0.403 | 0.403 | 0.403 | 0.183 | 0.096 | | |
| None | R3 Stream 2nd | **4.26** | **1.56** | 0.825 | 0.428 | 0.825 | 0.428 | | |
| 50 % | | **2.13** | 0.778 | 0.412 | 0.214 | 0.412 | 0.214 | | |
| 75 % | | **1.06** | 0.389 | 0.206 | 0.155 | 0.206 | 0.107 | | |
| 90 % | | 0.426 | 0.155 | 0.155 | 0.155 | 0.083 | 0.043 | | |
| None | R4 Stream | **3.03** | **1.27** | **1.27** | **1.27** | 0.586 | 0.305 | | |
| 50 % | | **1.51** | **1.27** | **1.27** | **1.27** | 0.576 | 0.301 | | |
| 75 % | | **1.27** | **1.27** | **1.27** | **1.27** | 0.576 | 0.301 | | |
| 90 % | | **1.27** | **1.27** | **1.27** | **1.27** | 0.576 | 0.301 | | |
| None | R4 Stream 2nd | **3.03** | **1.11** | 0.587 | 0.366 | 0.587 | 0.305 | | |
| 50 % | | **1.52** | 0.554 | 0.366 | 0.366 | 0.293 | 0.153 | | |
| 75 % | | 0.758 | 0.366 | 0.366 | 0.366 | 0.167 | 0.087 | | |
| 90 % | | 0.366 | 0.366 | 0.366 | 0.366 | 0.167 | 0.087 | | |

* 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 9.5-37: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in endive, lettuce, radicchio, rocket (endive, lettuce, radicchio, rocket; modelling use Vegetable leafy 1x200 g/ha -- BBCH 12-49, early -- 0.2 kg a.s./ha)**

| **Intended use** | | endive, lettuce, radicchio, rocket | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 200 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 | 1.26 | 0.343 | 0.182 | 0.095 | 0.182 | 0.095 | | |
| 50 % | | 0.633 | 0.172 | 0.091 | 0.047 | 0.091 | 0.047 | | |
| 75 % | | 0.316 | 0.086 | 0.046 | 0.024 | 0.046 | 0.024 | | |
| 90 % | | 0.127 | 0.034 | 0.018 | 0.010 | 0.018 | 0.010 | | |
| None | D3 Ditch 2nd | 1.27 | 0.343 | 0.182 | 0.095 | 0.182 | 0.095 | | |
| 50 % | | 0.633 | 0.172 | 0.091 | 0.047 | 0.091 | 0.047 | | |
| 75 % | | 0.317 | 0.086 | 0.046 | 0.024 | 0.046 | 0.024 | | |
| 90 % | | 0.127 | 0.034 | 0.018 | 0.010 | 0.018 | 0.010 | | |
| None | D4 Pond | 0.044 | 0.038 | 0.027 | 0.018 | 0.027 | 0.018 | | |
| 50 % | | 0.022 | 0.019 | 0.014 | 0.009 | 0.014 | 0.009 | | |
| 75 % | | 0.011 | 0.009 | 0.007 | 0.005 | 0.007 | 0.005 | | |
| 90 % | | 0.004 | 0.004 | 0.003 | 0.002 | 0.003 | 0.002 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| None | D4 Stream | 1.02 | 0.374 | 0.198 | 0.103 | 0.198 | 0.103 | | |
| 50 % | | 0.511 | 0.187 | 0.099 | 0.052 | 0.099 | 0.052 | | |
| 75 % | | 0.256 | 0.093 | 0.050 | 0.026 | 0.050 | 0.026 | | |
| 90 % | | 0.102 | 0.037 | 0.020 | 0.010 | 0.020 | 0.010 | | |
| None | D6 Ditch | 1.24 | 0.337 | 0.179 | 0.093 | 0.179 | 0.093 | | |
| 50 % | | 0.621 | 0.168 | 0.089 | 0.046 | 0.089 | 0.046 | | |
| 75 % | | 0.311 | 0.084 | 0.045 | 0.023 | 0.045 | 0.023 | | |
| 90 % | | 0.124 | 0.034 | 0.018 | 0.009 | 0.018 | 0.009 | | |
| None | R1 Pond | 0.044 | 0.038 | 0.027 | 0.018 | 0.027 | 0.018 | | |
| 50 % | | 0.022 | 0.019 | 0.014 | 0.009 | 0.014 | 0.009 | | |
| 75 % | | 0.011 | 0.009 | 0.007 | 0.005 | 0.007 | 0.005 | | |
| 90 % | | 0.004 | 0.004 | 0.003 | 0.002 | 0.003 | 0.002 | | |
| None | R1 Pond 2nd | 0.044 | 0.038 | 0.027 | 0.018 | 0.027 | 0.018 | | |
| 50 % | | 0.022 | 0.019 | 0.014 | 0.009 | 0.014 | 0.009 | | |
| 75 % | | 0.011 | 0.009 | 0.007 | 0.005 | 0.007 | 0.005 | | |
| 90 % | | 0.004 | 0.004 | 0.003 | 0.002 | 0.003 | 0.002 | | |
| None | R1 Stream | 0.834 | 0.305 | 0.162 | 0.084 | 0.162 | 0.084 | | |
| 50 % | | 0.417 | 0.152 | 0.081 | 0.042 | 0.081 | 0.042 | | |
| 75 % | | 0.208 | 0.076 | 0.040 | 0.021 | 0.040 | 0.021 | | |
| 90 % | | 0.083 | 0.031 | 0.016 | 0.008 | 0.016 | 0.008 | | |
| None | R1 Stream 2nd | 0.837 | 0.306 | 0.162 | 0.084 | 0.162 | 0.084 | | |
| 50 % | | 0.418 | 0.153 | 0.081 | 0.042 | 0.081 | 0.042 | | |
| 75 % | | 0.209 | 0.076 | 0.041 | 0.021 | 0.041 | 0.021 | | |
| 90 % | | 0.084 | 0.031 | 0.016 | 0.008 | 0.016 | 0.008 | | |
| None | R2 Stream | 1.10 | 0.403 | 0.214 | 0.111 | 0.214 | 0.111 | | |
| 50 % | | 0.551 | 0.201 | 0.107 | 0.056 | 0.107 | 0.056 | | |
| 75 % | | 0.276 | 0.101 | 0.053 | 0.028 | 0.053 | 0.028 | | |
| 90 % | | 0.110 | 0.040 | 0.021 | 0.011 | 0.021 | 0.011 | | |
| None | R2 Stream 2nd | 1.12 | 0.410 | 0.217 | 0.113 | 0.217 | 0.113 | | |
| 50 % | | 0.561 | 0.205 | 0.109 | 0.057 | 0.109 | 0.057 | | |
| 75 % | | 0.280 | 0.102 | 0.054 | 0.028 | 0.054 | 0.028 | | |
| 90 % | | 0.112 | 0.041 | 0.022 | 0.011 | 0.022 | 0.011 | | |
| None | R3 Stream | 1.17 | 0.428 | 0.227 | 0.118 | 0.227 | 0.118 | | |
| 50 % | | 0.586 | 0.214 | 0.114 | 0.059 | 0.114 | 0.059 | | |
| 75 % | | 0.293 | 0.107 | 0.057 | 0.030 | 0.057 | 0.030 | | |
| 90 % | | 0.117 | 0.043 | 0.023 | 0.012 | 0.023 | 0.012 | | |
| None | R3 Stream 2nd | 1.18 | 0.431 | 0.229 | 0.119 | 0.229 | 0.119 | | |
| 50 % | | 0.590 | 0.215 | 0.114 | 0.059 | 0.114 | 0.059 | | |
| 75 % | | 0.295 | 0.108 | 0.057 | 0.030 | 0.057 | 0.030 | | |
| 90 % | | 0.118 | 0.043 | 0.023 | 0.012 | 0.023 | 0.012 | | |
| None | R4 Stream | 0.835 | 0.305 | 0.189 | 0.189 | 0.162 | 0.084 | | |
| 50 % | | 0.418 | 0.189 | 0.189 | 0.189 | 0.086 | 0.045 | | |
| 75 % | | 0.209 | 0.189 | 0.189 | 0.189 | 0.086 | 0.045 | | |
| 90 % | | 0.189 | 0.189 | 0.189 | 0.189 | 0.086 | 0.045 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| None | R4 Stream 2nd | 0.829 | 0.303 | 0.161 | 0.083 | 0.161 | 0.083 | | |
| 50 % | | 0.414 | 0.151 | 0.080 | 0.042 | 0.080 | 0.042 | | |
| 75 % | | 0.207 | 0.076 | 0.040 | 0.021 | 0.040 | 0.021 | | |
| 90 % | | 0.083 | 0.030 | 0.016 | 0.015 | 0.016 | 0.008 | | |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D3 Ditch | **4.58** | **1.24** | 0.659 | 0.342 | 0.659 | 0.342 | | |
| 50 % | | **2.29** | 0.621 | 0.330 | 0.171 | 0.330 | 0.171 | | |
| 75 % | | **1.15** | 0.311 | 0.165 | 0.086 | 0.165 | 0.086 | | |
| 90 % | | 0.458 | 0.124 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | D3 Ditch 2nd | **4.59** | **1.24** | 0.660 | 0.343 | 0.660 | 0.343 | | |
| 50 % | | **2.29** | 0.622 | 0.330 | 0.171 | 0.330 | 0.171 | | |
| 75 % | | **1.15** | 0.311 | 0.165 | 0.086 | 0.165 | 0.086 | | |
| 90 % | | 0.459 | 0.124 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | D4 Pond | 0.158 | 0.137 | 0.098 | 0.066 | 0.098 | 0.066 | | |
| 50 % | | 0.079 | 0.068 | 0.049 | 0.033 | 0.049 | 0.033 | | |
| 75 % | | 0.039 | 0.034 | 0.025 | 0.016 | 0.025 | 0.016 | | |
| 90 % | | 0.016 | 0.014 | 0.010 | 0.007 | 0.010 | 0.007 | | |
| None | D4 Stream | **3.71** | **1.35** | 0.718 | 0.373 | 0.718 | 0.373 | | |
| 50 % | | **1.85** | 0.677 | 0.359 | 0.187 | 0.359 | 0.187 | | |
| 75 % | | 0.926 | 0.338 | 0.179 | 0.093 | 0.179 | 0.093 | | |
| 90 % | | 0.370 | 0.136 | 0.072 | 0.037 | 0.072 | 0.037 | | |
| None | D6 Ditch | **4.50** | **1.22** | 0.647 | 0.336 | 0.647 | 0.336 | | |
| 50 % | | **2.25** | 0.610 | 0.324 | 0.168 | 0.324 | 0.168 | | |
| 75 % | | **1.13** | 0.305 | 0.162 | 0.084 | 0.162 | 0.084 | | |
| 90 % | | 0.450 | 0.122 | 0.065 | 0.034 | 0.065 | 0.034 | | |
| None | R1 Pond | 0.158 | 0.137 | 0.098 | 0.066 | 0.098 | 0.066 | | |
| 50 % | | 0.079 | 0.068 | 0.049 | 0.033 | 0.049 | 0.033 | | |
| 75 % | | 0.039 | 0.034 | 0.025 | 0.016 | 0.025 | 0.016 | | |
| 90 % | | 0.016 | 0.014 | 0.010 | 0.007 | 0.010 | 0.007 | | |
| None | R1 Pond 2nd | 0.158 | 0.137 | 0.098 | 0.066 | 0.098 | 0.066 | | |
| 50 % | | 0.079 | 0.068 | 0.049 | 0.033 | 0.049 | 0.033 | | |
| 75 % | | 0.039 | 0.034 | 0.025 | 0.016 | 0.025 | 0.016 | | |
| 90 % | | 0.016 | 0.014 | 0.010 | 0.007 | 0.010 | 0.007 | | |
| None | R1 Stream | **3.02** | **1.10** | 0.586 | 0.304 | 0.586 | 0.304 | | |
| 50 % | | **1.51** | 0.552 | 0.293 | 0.152 | 0.293 | 0.152 | | |
| 75 % | | 0.755 | 0.276 | 0.146 | 0.076 | 0.146 | 0.076 | | |
| 90 % | | 0.302 | 0.111 | 0.059 | 0.030 | 0.059 | 0.030 | | |
| None | R1 Stream 2nd | **3.03** | **1.11** | 0.587 | 0.305 | 0.587 | 0.305 | | |
| 50 % | | **1.52** | 0.554 | 0.293 | 0.153 | 0.293 | 0.153 | | |
| 75 % | | 0.758 | 0.277 | 0.147 | 0.076 | 0.147 | 0.076 | | |
| 90 % | | 0.303 | 0.111 | 0.059 | 0.030 | 0.059 | 0.030 | | |
| None | R2 Stream | **3.99** | **1.46** | 0.774 | 0.402 | 0.774 | 0.402 | | |
| 50 % | | **2.00** | 0.729 | 0.387 | 0.201 | 0.387 | 0.201 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 75 % | | 0.998 | 0.365 | 0.193 | 0.100 | 0.193 | 0.100 | | |
| 90 % | | 0.399 | 0.146 | 0.078 | 0.040 | 0.078 | 0.040 | | |
| None | R2 Stream 2nd | **4.07** | **1.48** | 0.787 | 0.409 | 0.787 | 0.409 | | |
| 50 % | | **2.03** | 0.742 | 0.393 | 0.205 | 0.393 | 0.205 | | |
| 75 % | | **1.02** | 0.371 | 0.197 | 0.102 | 0.197 | 0.102 | | |
| 90 % | | 0.406 | 0.149 | 0.079 | 0.041 | 0.079 | 0.041 | | |
| None | R3 Stream | **4.25** | **1.55** | 0.822 | 0.427 | 0.822 | 0.427 | | |
| 50 % | | **2.12** | 0.775 | 0.411 | 0.214 | 0.411 | 0.214 | | |
| 75 % | | **1.06** | 0.388 | 0.206 | 0.107 | 0.206 | 0.107 | | |
| 90 % | | 0.424 | 0.155 | 0.082 | 0.043 | 0.082 | 0.043 | | |
| None | R3 Stream 2nd | **4.27** | **1.56** | 0.828 | 0.430 | 0.828 | 0.430 | | |
| 50 % | | **2.14** | 0.780 | 0.414 | 0.215 | 0.414 | 0.215 | | |
| 75 % | | **1.07** | 0.390 | 0.207 | 0.108 | 0.207 | 0.108 | | |
| 90 % | | 0.427 | 0.156 | 0.083 | 0.043 | 0.083 | 0.043 | | |
| None | R4 Stream | **3.03** | **1.11** | 0.685 | 0.685 | 0.586 | 0.305 | | |
| 50 % | | **1.51** | 0.685 | 0.685 | 0.685 | 0.312 | 0.163 | | |
| 75 % | | 0.757 | 0.685 | 0.685 | 0.685 | 0.312 | 0.163 | | |
| 90 % | | 0.685 | 0.685 | 0.685 | 0.685 | 0.312 | 0.163 | | |
| None | R4 Stream 2nd | **3.00** | **1.10** | 0.582 | 0.302 | 0.582 | 0.302 | | |
| 50 % | | **1.50** | 0.549 | 0.291 | 0.151 | 0.291 | 0.151 | | |
| 75 % | | 0.751 | 0.274 | 0.146 | 0.076 | 0.146 | 0.076 | | |
| 90 % | | 0.300 | 0.110 | 0.058 | 0.054 | 0.058 | 0.030 | | |

PEC: predicted environmental concentration
RAC: regulatory acceptable concentration
PEC/RAC ratios above the relevant trigger of 1 are shown in bold

**Table 9.5-38: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in endive, lettuce, radicchio, rocket (endive, lettuce, radicchio, rocket; modelling use Vegetable leafy 1x200 g/ha -- BBCH 12-49, late -- 0.2 kg a.s./ha)**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Intended use** | | endive, lettuce, radicchio, rocket | | | | | | | |
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 200 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 | 1.27 | 0.343 | 0.182 | 0.095 | 0.182 | 0.095 | | |
| 50 % | | 0.633 | 0.172 | 0.091 | 0.047 | 0.091 | 0.047 | | |
| 75 % | | 0.317 | 0.086 | 0.046 | 0.024 | 0.046 | 0.024 | | |
| 90 % | | 0.127 | 0.034 | 0.018 | 0.010 | 0.018 | 0.010 | | |
| None | D3 Ditch 2nd | 1.26 | 0.342 | 0.181 | 0.094 | 0.181 | 0.094 | | |
| 50 % | | 0.630 | 0.171 | 0.091 | 0.047 | 0.091 | 0.047 | | |
| 75 % | | 0.315 | 0.085 | 0.045 | 0.024 | 0.045 | 0.024 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 90 % | | 0.126 | 0.034 | 0.018 | 0.009 | 0.018 | 0.009 | | |
| None | D4 Pond | 0.044 | 0.038 | 0.027 | 0.018 | 0.027 | 0.018 | | |
| 50 % | | 0.022 | 0.019 | 0.014 | 0.009 | 0.014 | 0.009 | | |
| 75 % | | 0.011 | 0.009 | 0.007 | 0.005 | 0.007 | 0.005 | | |
| 90 % | | 0.004 | 0.004 | 0.003 | 0.002 | 0.003 | 0.002 | | |
| None | D4 Stream | 0.902 | 0.330 | 0.175 | 0.091 | 0.175 | 0.091 | | |
| 50 % | | 0.451 | 0.165 | 0.087 | 0.045 | 0.087 | 0.045 | | |
| 75 % | | 0.225 | 0.082 | 0.044 | 0.023 | 0.044 | 0.023 | | |
| 90 % | | 0.090 | 0.033 | 0.018 | 0.009 | 0.018 | 0.009 | | |
| None | D6 Ditch | 1.26 | 0.341 | 0.181 | 0.094 | 0.181 | 0.094 | | |
| 50 % | | 0.629 | 0.171 | 0.091 | 0.047 | 0.091 | 0.047 | | |
| 75 % | | 0.315 | 0.085 | 0.045 | 0.024 | 0.045 | 0.024 | | |
| 90 % | | 0.126 | 0.034 | 0.018 | 0.009 | 0.018 | 0.009 | | |
| None | R1 Pond | 0.044 | 0.038 | 0.028 | 0.022 | 0.027 | 0.018 | | |
| 50 % | | 0.025 | 0.023 | 0.019 | 0.016 | 0.014 | 0.009 | | |
| 75 % | | 0.017 | 0.016 | 0.014 | 0.012 | 0.009 | 0.005 | | |
| 90 % | | 0.012 | 0.012 | 0.011 | 0.010 | 0.006 | 0.003 | | |
| None | R1 Pond 2nd | 0.044 | 0.038 | 0.027 | 0.018 | 0.027 | 0.018 | | |
| 50 % | | 0.022 | 0.019 | 0.014 | 0.009 | 0.014 | 0.009 | | |
| 75 % | | 0.011 | 0.009 | 0.007 | 0.005 | 0.007 | 0.005 | | |
| 90 % | | 0.004 | 0.004 | 0.003 | 0.002 | 0.003 | 0.002 | | |
| None | R1 Stream | 0.837 | 0.306 | 0.162 | 0.118 | 0.162 | 0.084 | | |
| 50 % | | 0.418 | 0.153 | 0.118 | 0.118 | 0.081 | 0.042 | | |
| 75 % | | 0.209 | 0.118 | 0.118 | 0.118 | 0.053 | 0.028 | | |
| 90 % | | 0.118 | 0.118 | 0.118 | 0.118 | 0.053 | 0.028 | | |
| None | R1 Stream 2nd | 0.837 | 0.306 | 0.162 | 0.084 | 0.162 | 0.084 | | |
| 50 % | | 0.418 | 0.153 | 0.081 | 0.051 | 0.081 | 0.042 | | |
| 75 % | | 0.209 | 0.076 | 0.051 | 0.051 | 0.041 | 0.021 | | |
| 90 % | | 0.084 | 0.051 | 0.051 | 0.051 | 0.022 | 0.011 | | |
| None | R2 Stream | 1.12 | 0.410 | 0.217 | 0.113 | 0.217 | 0.113 | | |
| 50 % | | 0.561 | 0.205 | 0.109 | 0.057 | 0.109 | 0.057 | | |
| 75 % | | 0.280 | 0.102 | 0.054 | 0.028 | 0.054 | 0.028 | | |
| 90 % | | 0.112 | 0.041 | 0.022 | 0.011 | 0.022 | 0.011 | | |
| None | R2 Stream 2nd | 1.11 | 0.405 | 0.215 | 0.112 | 0.215 | 0.112 | | |
| 50 % | | 0.554 | 0.203 | 0.107 | 0.056 | 0.107 | 0.056 | | |
| 75 % | | 0.277 | 0.101 | 0.054 | 0.038 | 0.054 | 0.028 | | |
| 90 % | | 0.111 | 0.041 | 0.038 | 0.038 | 0.022 | 0.011 | | |
| None | R3 Stream | 1.18 | 0.431 | 0.228 | 0.119 | 0.228 | 0.119 | | |
| 50 % | | 0.589 | 0.215 | 0.114 | 0.059 | 0.114 | 0.059 | | |
| 75 % | | 0.295 | 0.108 | 0.057 | 0.030 | 0.057 | 0.030 | | |
| 90 % | | 0.118 | 0.043 | 0.023 | 0.012 | 0.023 | 0.012 | | |
| None | R3 Stream 2nd | 1.18 | 0.429 | 0.228 | 0.118 | 0.228 | 0.118 | | |
| 50 % | | 0.587 | 0.215 | 0.114 | 0.059 | 0.114 | 0.059 | | |
| 75 % | | 0.294 | 0.107 | 0.057 | 0.043 | 0.057 | 0.030 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 90 % | | 0.118 | 0.043 | 0.043 | 0.043 | 0.023 | 0.012 | | |
| None | R4 Stream | 0.835 | 0.354 | 0.354 | 0.354 | 0.162 | 0.084 | | |
| 50 % | | 0.418 | 0.354 | 0.354 | 0.354 | 0.161 | 0.084 | | |
| 75 % | | 0.354 | 0.354 | 0.354 | 0.354 | 0.161 | 0.084 | | |
| 90 % | | 0.354 | 0.354 | 0.354 | 0.354 | 0.161 | 0.084 | | |
| None | R4 Stream 2nd | 0.837 | 0.306 | 0.162 | 0.084 | 0.162 | 0.084 | | |
| 50 % | | 0.418 | 0.153 | 0.081 | 0.067 | 0.081 | 0.042 | | |
| 75 % | | 0.209 | 0.076 | 0.067 | 0.067 | 0.041 | 0.021 | | |
| 90 % | | 0.084 | 0.067 | 0.067 | 0.067 | 0.031 | 0.016 | | |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D3 Ditch | **4.59** | **1.24** | 0.659 | 0.343 | 0.659 | 0.343 | | |
| 50 % | | **2.29** | 0.622 | 0.330 | 0.171 | 0.330 | 0.171 | | |
| 75 % | | **1.15** | 0.311 | 0.165 | 0.086 | 0.165 | 0.086 | | |
| 90 % | | 0.459 | 0.124 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | D3 Ditch 2nd | **4.57** | **1.24** | 0.656 | 0.341 | 0.656 | 0.341 | | |
| 50 % | | **2.28** | 0.618 | 0.328 | 0.171 | 0.328 | 0.171 | | |
| 75 % | | **1.14** | 0.309 | 0.164 | 0.085 | 0.164 | 0.085 | | |
| 90 % | | 0.456 | 0.124 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | D4 Pond | 0.158 | 0.137 | 0.098 | 0.066 | 0.098 | 0.066 | | |
| 50 % | | 0.079 | 0.068 | 0.049 | 0.033 | 0.049 | 0.033 | | |
| 75 % | | 0.039 | 0.034 | 0.025 | 0.016 | 0.025 | 0.016 | | |
| 90 % | | 0.016 | 0.014 | 0.010 | 0.007 | 0.010 | 0.007 | | |
| None | D4 Stream | **3.27** | **1.19** | 0.633 | 0.329 | 0.633 | 0.329 | | |
| 50 % | | **1.63** | 0.597 | 0.316 | 0.164 | 0.316 | 0.164 | | |
| 75 % | | 0.817 | 0.299 | 0.158 | 0.082 | 0.158 | 0.082 | | |
| 90 % | | 0.327 | 0.119 | 0.063 | 0.033 | 0.063 | 0.033 | | |
| None | D6 Ditch | **4.56** | **1.24** | 0.655 | 0.341 | 0.655 | 0.341 | | |
| 50 % | | **2.28** | 0.618 | 0.328 | 0.170 | 0.328 | 0.170 | | |
| 75 % | | **1.14** | 0.309 | 0.164 | 0.085 | 0.164 | 0.085 | | |
| 90 % | | 0.456 | 0.124 | 0.066 | 0.034 | 0.066 | 0.034 | | |
| None | R1 Pond | 0.158 | 0.137 | 0.103 | 0.079 | 0.098 | 0.066 | | |
| 50 % | | 0.089 | 0.082 | 0.068 | 0.056 | 0.049 | 0.033 | | |
| 75 % | | 0.061 | 0.057 | 0.050 | 0.045 | 0.031 | 0.019 | | |
| 90 % | | 0.044 | 0.043 | 0.040 | 0.038 | 0.021 | 0.012 | | |
| None | R1 Pond 2nd | 0.158 | 0.137 | 0.098 | 0.066 | 0.098 | 0.066 | | |
| 50 % | | 0.079 | 0.068 | 0.049 | 0.033 | 0.049 | 0.033 | | |
| 75 % | | 0.039 | 0.034 | 0.025 | 0.016 | 0.025 | 0.016 | | |
| 90 % | | 0.016 | 0.014 | 0.010 | 0.007 | 0.010 | 0.007 | | |
| None | R1 Stream | **3.03** | **1.11** | 0.587 | 0.426 | 0.587 | 0.305 | | |
| 50 % | | **1.52** | 0.554 | 0.426 | 0.426 | 0.293 | 0.153 | | |
| 75 % | | 0.758 | 0.426 | 0.426 | 0.426 | 0.191 | 0.100 | | |
| 90 % | | 0.426 | 0.426 | 0.426 | 0.426 | 0.191 | 0.100 | | |
| None | R1 Stream | **3.03** | **1.11** | 0.587 | 0.305 | 0.587 | 0.305 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 50 % | 2nd | **1.52** | 0.554 | 0.293 | 0.185 | 0.293 | 0.153 | | |
| 75 % | | 0.758 | 0.277 | 0.185 | 0.185 | 0.147 | 0.076 | | |
| 90 % | | 0.303 | 0.185 | 0.185 | 0.185 | 0.078 | 0.039 | | |
| None | R2 Stream | **4.07** | **1.48** | 0.787 | 0.409 | 0.787 | 0.409 | | |
| 50 % | | **2.03** | 0.742 | 0.393 | 0.205 | 0.393 | 0.205 | | |
| 75 % | | **1.02** | 0.371 | 0.197 | 0.102 | 0.197 | 0.102 | | |
| 90 % | | 0.406 | 0.149 | 0.079 | 0.041 | 0.079 | 0.041 | | |
| None | R2 Stream 2nd | **4.02** | **1.47** | 0.778 | 0.404 | 0.778 | 0.404 | | |
| 50 % | | **2.01** | 0.734 | 0.389 | 0.202 | 0.389 | 0.202 | | |
| 75 % | | **1.00** | 0.367 | 0.195 | 0.136 | 0.195 | 0.101 | | |
| 90 % | | 0.402 | 0.147 | 0.136 | 0.136 | 0.078 | 0.041 | | |
| None | R3 Stream | **4.27** | **1.56** | 0.828 | 0.430 | 0.828 | 0.430 | | |
| 50 % | | **2.14** | 0.780 | 0.414 | 0.215 | 0.414 | 0.215 | | |
| 75 % | | **1.07** | 0.390 | 0.207 | 0.108 | 0.207 | 0.108 | | |
| 90 % | | 0.427 | 0.156 | 0.083 | 0.043 | 0.083 | 0.043 | | |
| None | R3 Stream 2nd | **4.26** | **1.56** | 0.825 | 0.428 | 0.825 | 0.428 | | |
| 50 % | | **2.13** | 0.778 | 0.412 | 0.214 | 0.412 | 0.214 | | |
| 75 % | | **1.06** | 0.389 | 0.206 | 0.155 | 0.206 | 0.107 | | |
| 90 % | | 0.426 | 0.155 | 0.155 | 0.155 | 0.083 | 0.043 | | |
| None | R4 Stream | **3.03** | **1.28** | **1.28** | **1.28** | 0.586 | 0.305 | | |
| 50 % | | **1.51** | **1.28** | **1.28** | **1.28** | 0.583 | 0.305 | | |
| 75 % | | **1.28** | **1.28** | **1.28** | **1.28** | 0.583 | 0.305 | | |
| 90 % | | **1.28** | **1.28** | **1.28** | **1.28** | 0.583 | 0.305 | | |
| None | R4 Stream 2nd | **3.03** | **1.11** | 0.587 | 0.305 | 0.587 | 0.305 | | |
| 50 % | | **1.52** | 0.554 | 0.293 | 0.243 | 0.293 | 0.153 | | |
| 75 % | | 0.758 | 0.277 | 0.243 | 0.243 | 0.147 | 0.076 | | |
| 90 % | | 0.303 | 0.243 | 0.243 | 0.243 | 0.111 | 0.058 | | |

PEC: predicted environmental concentration
RAC: regulatory acceptable concentration
PEC/RAC ratios above the relevant trigger of 1 are shown in bold

**Table 9.5-39: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in chokeberry, elderberry, tree nursery (chokeberry, elderberry, tree nursery; modelling use Pome and stone fruit 2x200 g/ha -- BBCH 12-91, early -- 2×0.2 kg a.s./ha, 7d int.)**

| **Intended use** | | chokeberry, elderberry, tree nursery | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 2 x 200 g/ha, 7d int. | | | | | | | |
| Nozzle reduction | Vegetated strip (m) | None | None | | | | | | |
| | No spray buffer (m) | 30 m | 50 m | | | | | | |
| None | D3 Ditch | 0.655 | 0.193 | | | | | | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 50 % | | 0.327 | 0.097 | | | | | | | | |
| 75 % | | 0.164 | 0.048 | | | | | | | | |
| 90 % | | 0.065 | 0.019 | | | | | | | | |
| None | D4 Pond | *0.128* | *0.043* | | | | | | | | |
| 50 % | | *0.064* | *0.022* | | | | | | | | |
| 75 % | | *0.032* | *0.011* | | | | | | | | |
| 90 % | | *0.013* | *0.004* | | | | | | | | |
| None | D4 Stream | 0.729 | 0.215 | | | | | | | | |
| 50 % | | 0.365 | 0.108 | | | | | | | | |
| 75 % | | 0.182 | 0.054 | | | | | | | | |
| 90 % | | 0.073 | 0.022 | | | | | | | | |
| None | D5 Pond | *0.128* | *0.043* | | | | | | | | |
| 50 % | | *0.064* | *0.021* | | | | | | | | |
| 75 % | | *0.032* | *0.011* | | | | | | | | |
| 90 % | | *0.013* | *0.004* | | | | | | | | |
| None | D5 Stream | 0.745 | 0.220 | | | | | | | | |
| 50 % | | 0.373 | 0.110 | | | | | | | | |
| 75 % | | 0.186 | 0.055 | | | | | | | | |
| 90 % | | 0.075 | 0.022 | | | | | | | | |
| None | R1 Pond | *0.128* | *0.043* | | | | | | | | |
| 50 % | | *0.064* | *0.021* | | | | | | | | |
| 75 % | | *0.032* | *0.011* | | | | | | | | |
| 90 % | | *0.013* | *0.004* | | | | | | | | |
| None | R1 Stream | 0.578 | 0.171 | | | | | | | | |
| 50 % | | 0.289 | 0.085 | | | | | | | | |
| 75 % | | 0.145 | 0.043 | | | | | | | | |
| 90 % | | 0.058 | 0.017 | | | | | | | | |
| None | R2 Stream | 0.767 | 0.227 | | | | | | | | |
| 50 % | | 0.384 | 0.113 | | | | | | | | |
| 75 % | | 0.192 | 0.057 | | | | | | | | |
| 90 % | | 0.077 | 0.023 | | | | | | | | |
| None | R3 Stream | 0.818 | 0.242 | | | | | | | | |
| 50 % | | 0.409 | 0.121 | | | | | | | | |
| 75 % | | 0.205 | 0.060 | | | | | | | | |
| 90 % | | 0.082 | 0.032 | | | | | | | | |
| None | R4 Stream | 0.582 | 0.172 | | | | | | | | |
| 50 % | | 0.291 | *0.093* | | | | | | | | |
| 75 % | | 0.145 | *0.093* | | | | | | | | |
| 90 % | | *0.093* | *0.093* | | | | | | | | |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | | | |
| None | D3 Ditch | **2.37** | 0.700 | | | | | | | | |
| 50 % | | **1.19** | 0.350 | | | | | | | | |
| 75 % | | 0.593 | 0.175 | | | | | | | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 90 % | | 0.237 | 0.070 | | | | | | |
| None | D4 Pond | 0.465 | 0.156 | | | | | | |
| 50 % | | 0.232 | 0.078 | | | | | | |
| 75 % | | 0.116 | 0.039 | | | | | | |
| 90 % | | 0.046 | 0.016 | | | | | | |
| None | D4 Stream | **2.64** | 0.780 | | | | | | |
| 50 % | | **1.32** | 0.390 | | | | | | |
| 75 % | | 0.660 | 0.195 | | | | | | |
| 90 % | | 0.264 | 0.078 | | | | | | |
| None | D5 Pond | 0.463 | 0.155 | | | | | | |
| 50 % | | 0.231 | 0.078 | | | | | | |
| 75 % | | 0.116 | 0.039 | | | | | | |
| 90 % | | 0.046 | 0.016 | | | | | | |
| None | D5 Stream | **2.70** | 0.797 | | | | | | |
| 50 % | | **1.35** | 0.399 | | | | | | |
| 75 % | | 0.675 | 0.199 | | | | | | |
| 90 % | | 0.270 | 0.080 | | | | | | |
| None | R1 Pond | 0.463 | 0.155 | | | | | | |
| 50 % | | 0.231 | 0.078 | | | | | | |
| 75 % | | 0.116 | 0.039 | | | | | | |
| 90 % | | 0.046 | 0.016 | | | | | | |
| None | R1 Stream | **2.09** | 0.618 | | | | | | |
| 50 % | | **1.05** | 0.309 | | | | | | |
| 75 % | | 0.524 | 0.155 | | | | | | |
| 90 % | | 0.209 | 0.062 | | | | | | |
| None | R2 Stream | **2.78** | 0.821 | | | | | | |
| 50 % | | **1.39** | 0.410 | | | | | | |
| 75 % | | 0.695 | 0.205 | | | | | | |
| 90 % | | 0.278 | 0.082 | | | | | | |
| None | R3 Stream | **2.96** | 0.875 | | | | | | |
| 50 % | | **1.48** | 0.438 | | | | | | |
| 75 % | | 0.741 | 0.219 | | | | | | |
| 90 % | | 0.296 | 0.116 | | | | | | |
| None | R4 Stream | **2.11** | 0.622 | | | | | | |
| 50 % | | **1.05** | 0.336 | | | | | | |
| 75 % | | 0.527 | 0.336 | | | | | | |
| 90 % | | 0.336 | 0.336 | | | | | | |

* 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 9.5-40: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in chokeberry, elderberry, tree nursery (chokeberry, elderberry, tree nursery; modelling use Pome and stone fruit 2x200 g/ha -- BBCH 12-91, late -- 2×0.2 kg a.s./ha, 7d int.)**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Intended use** | | chokeberry, elderberry, tree nursery | | | | | | | |
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 2 x 200 g/ha, 7d int. | | | | | | | |
| Nozzle reduction | Vegetated strip (m) | None | None | | | | | | |
| | No spray buffer (m) | 30 m | 50 m | | | | | | |
| None | D3 Ditch | 0.339 | 0.140 | | | | | | |
| 50 % | | 0.170 | 0.070 | | | | | | |
| 75 % | | 0.085 | 0.035 | | | | | | |
| 90 % | | 0.034 | 0.014 | | | | | | |
| None | D4 Pond | *0.074* | *0.034* | | | | | | |
| 50 % | | *0.037* | *0.017* | | | | | | |
| 75 % | | *0.019* | *0.009* | | | | | | |
| 90 % | | *0.007* | *0.003* | | | | | | |
| None | D4 Stream | 0.385 | 0.158 | | | | | | |
| 50 % | | 0.192 | 0.079 | | | | | | |
| 75 % | | 0.096 | 0.040 | | | | | | |
| 90 % | | 0.039 | 0.016 | | | | | | |
| None | D5 Pond | *0.074* | *0.034* | | | | | | |
| 50 % | | *0.037* | *0.017* | | | | | | |
| 75 % | | *0.019* | *0.009* | | | | | | |
| 90 % | | *0.007* | *0.003* | | | | | | |
| None | D5 Stream | 0.425 | 0.175 | | | | | | |
| 50 % | | 0.212 | 0.087 | | | | | | |
| 75 % | | 0.106 | 0.044 | | | | | | |
| 90 % | | 0.043 | 0.018 | | | | | | |
| None | R1 Pond | *0.065* | *0.030* | | | | | | |
| 50 % | | *0.033* | *0.015* | | | | | | |
| 75 % | | *0.016* | *0.008* | | | | | | |
| 90 % | | *0.007* | *0.003* | | | | | | |
| None | R1 Stream | 0.301 | 0.124 | | | | | | |
| 50 % | | 0.151 | 0.062 | | | | | | |
| 75 % | | 0.075 | 0.031 | | | | | | |
| 90 % | | 0.030 | 0.012 | | | | | | |
| None | R2 Stream | 0.404 | 0.166 | | | | | | |
| 50 % | | 0.202 | 0.083 | | | | | | |
| 75 % | | 0.101 | 0.042 | | | | | | |
| 90 % | | 0.040 | 0.017 | | | | | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| None | R3 Stream | 0.424 | *0.220* | | | | | | |
| 50 % | | *0.220* | *0.220* | | | | | | |
| 75 % | | *0.220* | *0.220* | | | | | | |
| 90 % | | *0.220* | *0.220* | | | | | | |
| None | R4 Stream | 0.301 | 0.124 | | | | | | |
| 50 % | | 0.151 | *0.080* | | | | | | |
| 75 % | | *0.080* | *0.080* | | | | | | |
| 90 % | | *0.080* | *0.080* | | | | | | |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D3 Ditch | **1.23** | 0.506 | | | | | | |
| 50 % | | 0.614 | 0.253 | | | | | | |
| 75 % | | 0.307 | 0.126 | | | | | | |
| 90 % | | 0.123 | 0.051 | | | | | | |
| None | D4 Pond | 0.268 | 0.124 | | | | | | |
| 50 % | | 0.134 | 0.062 | | | | | | |
| 75 % | | 0.067 | 0.031 | | | | | | |
| 90 % | | 0.027 | 0.012 | | | | | | |
| None | D4 Stream | **1.39** | 0.574 | | | | | | |
| 50 % | | 0.697 | 0.287 | | | | | | |
| 75 % | | 0.349 | 0.143 | | | | | | |
| 90 % | | 0.139 | 0.058 | | | | | | |
| None | D5 Pond | 0.268 | 0.124 | | | | | | |
| 50 % | | 0.134 | 0.062 | | | | | | |
| 75 % | | 0.067 | 0.031 | | | | | | |
| 90 % | | 0.027 | 0.012 | | | | | | |
| None | D5 Stream | **1.54** | 0.633 | | | | | | |
| 50 % | | 0.769 | 0.317 | | | | | | |
| 75 % | | 0.385 | 0.158 | | | | | | |
| 90 % | | 0.154 | 0.063 | | | | | | |
| None | R1 Pond | 0.236 | 0.108 | | | | | | |
| 50 % | | 0.118 | 0.054 | | | | | | |
| 75 % | | 0.059 | 0.027 | | | | | | |
| 90 % | | 0.024 | 0.011 | | | | | | |
| None | R1 Stream | **1.09** | 0.449 | | | | | | |
| 50 % | | 0.545 | 0.225 | | | | | | |
| 75 % | | 0.273 | 0.112 | | | | | | |
| 90 % | | 0.109 | 0.045 | | | | | | |
| None | R2 Stream | **1.46** | 0.602 | | | | | | |
| 50 % | | 0.731 | 0.301 | | | | | | |
| 75 % | | 0.366 | 0.150 | | | | | | |
| 90 % | | 0.146 | 0.060 | | | | | | |
| None | R3 Stream | **1.54** | 0.796 | | | | | | |
| 50 % | | 0.796 | 0.796 | | | | | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 75 % | | 0.796 | 0.796 | | | | | | |
| 90 % | | 0.796 | 0.796 | | | | | | |
| None | R4 Stream | **1.09** | 0.449 | | | | | | |
| 50 % | | 0.545 | 0.288 | | | | | | |
| 75 % | | 0.288 | 0.288 | | | | | | |
| 90 % | | 0.288 | 0.288 | | | | | | |

* 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 9.5-41: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in elderberry (elderberry; modelling use Pome and stone fruit 2x150 g/ha -- BBCH 15-91, early -- 2×0.15 kg a.s./ha, 14d int.)**

| **Intended use** | | elderberry | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 2 x 150 g/ha, 14d int. | | | | | | | |
| Nozzle reduction | Vegetated strip (m) | None | None | | | | | | |
| | No spray buffer (m) | 30 m | 50 m | | | | | | |
| None | D3 Ditch | 0.491 | 0.145 | | | | | | |
| 50 % | | 0.245 | 0.073 | | | | | | |
| 75 % | | 0.123 | 0.036 | | | | | | |
| 90 % | | 0.049 | 0.015 | | | | | | |
| None | D4 Pond | *0.090* | *0.030* | | | | | | |
| 50 % | | *0.045* | *0.015* | | | | | | |
| 75 % | | *0.022* | *0.008* | | | | | | |
| 90 % | | *0.009* | *0.003* | | | | | | |
| None | D4 Stream | 0.547 | 0.161 | | | | | | |
| 50 % | | 0.273 | 0.081 | | | | | | |
| 75 % | | 0.137 | 0.040 | | | | | | |
| 90 % | | 0.055 | 0.016 | | | | | | |
| None | D5 Pond | *0.082* | *0.028* | | | | | | |
| 50 % | | *0.041* | *0.014* | | | | | | |
| 75 % | | *0.021* | *0.007* | | | | | | |
| 90 % | | *0.008* | *0.003* | | | | | | |
| None | D5 Stream | 0.559 | 0.165 | | | | | | |
| 50 % | | 0.279 | 0.083 | | | | | | |
| 75 % | | 0.140 | 0.041 | | | | | | |
| 90 % | | 0.056 | 0.017 | | | | | | |
| None | R1 Pond | *0.089* | *0.030* | | | | | | |
| 50 % | | *0.045* | *0.015* | | | | | | |
| 75 % | | *0.022* | *0.008* | | | | | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 90 % | | *0.009* | *0.003* | | | | | | |
| None | R1 Stream | 0.434 | 0.128 | | | | | | |
| 50 % | | 0.217 | 0.064 | | | | | | |
| 75 % | | 0.108 | 0.032 | | | | | | |
| 90 % | | 0.043 | 0.013 | | | | | | |
| None | R2 Stream | 0.575 | 0.170 | | | | | | |
| 50 % | | 0.288 | 0.085 | | | | | | |
| 75 % | | 0.144 | 0.043 | | | | | | |
| 90 % | | 0.058 | 0.017 | | | | | | |
| None | R3 Stream | 0.613 | 0.181 | | | | | | |
| 50 % | | 0.307 | 0.091 | | | | | | |
| 75 % | | 0.153 | 0.045 | | | | | | |
| 90 % | | 0.061 | 0.024 | | | | | | |
| None | R4 Stream | 0.436 | 0.129 | | | | | | |
| 50 % | | 0.218 | *0.098* | | | | | | |
| 75 % | | 0.109 | *0.098* | | | | | | |
| 90 % | | *0.098* | *0.098* | | | | | | |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D3 Ditch | **1.78** | 0.525 | | | | | | |
| 50 % | | 0.889 | 0.263 | | | | | | |
| 75 % | | 0.445 | 0.131 | | | | | | |
| 90 % | | 0.178 | 0.053 | | | | | | |
| None | D4 Pond | 0.325 | 0.109 | | | | | | |
| 50 % | | 0.162 | 0.054 | | | | | | |
| 75 % | | 0.081 | 0.027 | | | | | | |
| 90 % | | 0.032 | 0.011 | | | | | | |
| None | D4 Stream | **1.98** | 0.585 | | | | | | |
| 50 % | | 0.990 | 0.292 | | | | | | |
| 75 % | | 0.495 | 0.146 | | | | | | |
| 90 % | | 0.198 | 0.058 | | | | | | |
| None | D5 Pond | 0.297 | 0.100 | | | | | | |
| 50 % | | 0.149 | 0.050 | | | | | | |
| 75 % | | 0.074 | 0.025 | | | | | | |
| 90 % | | 0.030 | 0.010 | | | | | | |
| None | D5 Stream | **2.02** | 0.598 | | | | | | |
| 50 % | | **1.01** | 0.299 | | | | | | |
| 75 % | | 0.506 | 0.150 | | | | | | |
| 90 % | | 0.203 | 0.060 | | | | | | |
| None | R1 Pond | 0.323 | 0.108 | | | | | | |
| 50 % | | 0.161 | 0.054 | | | | | | |
| 75 % | | 0.080 | 0.027 | | | | | | |
| 90 % | | 0.032 | 0.011 | | | | | | |
| None | R1 Stream | **1.57** | 0.464 | | | | | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 50 % | | 0.785 | 0.232 | | | | | | |
| 75 % | | 0.393 | 0.116 | | | | | | |
| 90 % | | 0.157 | 0.046 | | | | | | |
| None | R2 Stream | **2.08** | 0.616 | | | | | | |
| 50 % | | **1.04** | 0.308 | | | | | | |
| 75 % | | 0.521 | 0.154 | | | | | | |
| 90 % | | 0.208 | 0.062 | | | | | | |
| None | R3 Stream | **2.22** | 0.656 | | | | | | |
| 50 % | | **1.11** | 0.328 | | | | | | |
| 75 % | | 0.555 | 0.164 | | | | | | |
| 90 % | | 0.222 | 0.086 | | | | | | |
| None | R4 Stream | **1.58** | 0.467 | | | | | | |
| 50 % | | 0.790 | 0.353 | | | | | | |
| 75 % | | 0.395 | 0.353 | | | | | | |
| 90 % | | 0.353 | 0.353 | | | | | | |

* 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 9.5-42: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in elderberry (elderberry; modelling use Pome and stone fruit 2x150 g/ha -- BBCH 15-91, late -- 2×0.15 kg a.s./ha, 14d int.)**

| **Intended use** | | elderberry | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 2 x 150 g/ha, 14d int. | | | | | | | |
| Nozzle reduction | Vegetated strip (m) | None | None | | | | | | |
| | No spray buffer (m) | 30 m | 50 m | | | | | | |
| None | D3 Ditch | 0.255 | 0.105 | | | | | | |
| 50 % | | 0.127 | 0.052 | | | | | | |
| 75 % | | 0.064 | 0.026 | | | | | | |
| 90 % | | 0.025 | 0.011 | | | | | | |
| None | D4 Pond | *0.050* | *0.023* | | | | | | |
| 50 % | | *0.025* | *0.012* | | | | | | |
| 75 % | | *0.013* | *0.006* | | | | | | |
| 90 % | | *0.005* | *0.002* | | | | | | |
| None | D4 Stream | 0.284 | 0.117 | | | | | | |
| 50 % | | 0.142 | 0.059 | | | | | | |
| 75 % | | 0.071 | 0.029 | | | | | | |
| 90 % | | 0.028 | 0.012 | | | | | | |
| None | D5 Pond | *0.052* | *0.024* | | | | | | |
| 50 % | | *0.026* | *0.012* | | | | | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 75 % | | *0.013* | *0.006* | | | | | | |
| 90 % | | *0.005* | *0.002* | | | | | | |
| None | D5 Stream | 0.319 | 0.131 | | | | | | |
| 50 % | | 0.159 | 0.066 | | | | | | |
| 75 % | | 0.080 | 0.033 | | | | | | |
| 90 % | | 0.032 | 0.013 | | | | | | |
| None | R1 Pond | *0.049* | *0.022* | | | | | | |
| 50 % | | *0.024* | *0.011* | | | | | | |
| 75 % | | *0.012* | *0.006* | | | | | | |
| 90 % | | *0.005* | *0.002* | | | | | | |
| None | R1 Stream | 0.226 | 0.093 | | | | | | |
| 50 % | | 0.113 | 0.047 | | | | | | |
| 75 % | | 0.057 | 0.023 | | | | | | |
| 90 % | | 0.023 | 0.009 | | | | | | |
| None | R2 Stream | 0.303 | 0.125 | | | | | | |
| 50 % | | 0.151 | 0.062 | | | | | | |
| 75 % | | 0.076 | 0.031 | | | | | | |
| 90 % | | 0.030 | 0.012 | | | | | | |
| None | R3 Stream | 0.318 | 0.131 | | | | | | |
| 50 % | | 0.159 | 0.066 | | | | | | |
| 75 % | | 0.080 | 0.037 | | | | | | |
| 90 % | | 0.037 | 0.037 | | | | | | |
| None | R4 Stream | 0.226 | 0.093 | | | | | | |
| 50 % | | 0.113 | *0.093* | | | | | | |
| 75 % | | *0.093* | *0.093* | | | | | | |
| 90 % | | *0.093* | *0.093* | | | | | | |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D3 Ditch | 0.922 | 0.379 | | | | | | |
| 50 % | | 0.461 | 0.190 | | | | | | |
| 75 % | | 0.230 | 0.095 | | | | | | |
| 90 % | | 0.092 | 0.038 | | | | | | |
| None | D4 Pond | 0.182 | 0.083 | | | | | | |
| 50 % | | 0.091 | 0.042 | | | | | | |
| 75 % | | 0.045 | 0.021 | | | | | | |
| 90 % | | 0.018 | 0.008 | | | | | | |
| None | D4 Stream | **1.03** | 0.424 | | | | | | |
| 50 % | | 0.515 | 0.212 | | | | | | |
| 75 % | | 0.258 | 0.106 | | | | | | |
| 90 % | | 0.103 | 0.042 | | | | | | |
| None | D5 Pond | 0.188 | 0.087 | | | | | | |
| 50 % | | 0.094 | 0.043 | | | | | | |
| 75 % | | 0.047 | 0.022 | | | | | | |
| 90 % | | 0.019 | 0.009 | | | | | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| None | D5 Stream | **1.15** | 0.475 | | | | | | |
| 50 % | | 0.577 | 0.238 | | | | | | |
| 75 % | | 0.288 | 0.119 | | | | | | |
| 90 % | | 0.115 | 0.047 | | | | | | |
| None | R1 Pond | 0.177 | 0.081 | | | | | | |
| 50 % | | 0.088 | 0.041 | | | | | | |
| 75 % | | 0.044 | 0.020 | | | | | | |
| 90 % | | 0.018 | 0.008 | | | | | | |
| None | R1 Stream | 0.818 | 0.337 | | | | | | |
| 50 % | | 0.409 | 0.168 | | | | | | |
| 75 % | | 0.205 | 0.084 | | | | | | |
| 90 % | | 0.082 | 0.034 | | | | | | |
| None | R2 Stream | **1.10** | 0.451 | | | | | | |
| 50 % | | 0.548 | 0.226 | | | | | | |
| 75 % | | 0.274 | 0.113 | | | | | | |
| 90 % | | 0.110 | 0.045 | | | | | | |
| None | R3 Stream | **1.15** | 0.475 | | | | | | |
| 50 % | | 0.576 | 0.237 | | | | | | |
| 75 % | | 0.288 | 0.135 | | | | | | |
| 90 % | | 0.135 | 0.135 | | | | | | |
| None | R4 Stream | 0.818 | 0.337 | | | | | | |
| 50 % | | 0.409 | 0.336 | | | | | | |
| 75 % | | 0.336 | 0.336 | | | | | | |
| 90 % | | 0.336 | 0.336 | | | | | | |

* 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 9.5-43: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in tobacco (tobacco; modelling use Tobacco -- BBCH 11 - 39 -- 0.2 kg a.s./ha)**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Intended use** | | tobacco | | | | | | | |
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 200 g/ha | | | | | | | |
| Nozzle reduction | Vegetated strip (m) | None | None | None | None | None | None | 10 m | 20 m |
| | No spray buffer (m) | 0 m | 5 m | 10 m | 20 m | 30 m | 50 m | 10 m | 20 m |
| None | R3 Stream | 0.942 | 0.431 | 0.229 | 0.119 | 0.081 | 0.049 | 0.229 | 0.119 |
| 50 % | | 0.471 | 0.215 | 0.114 | 0.059 | 0.040 | 0.025 | 0.114 | 0.059 |
| 75 % | | 0.235 | 0.108 | 0.057 | 0.030 | 0.020 | 0.012 | 0.057 | 0.030 |
| 90 % | | 0.094 | 0.043 | 0.023 | 0.012 | 0.008 | 0.005 | 0.023 | 0.012 |

| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| None | R3 Stream | **3.41** | **1.56** | 0.828 | 0.430 | 0.292 | 0.178 | 0.828 | 0.430 |
| 50 % | | **1.71** | 0.780 | 0.414 | 0.215 | 0.146 | 0.089 | 0.414 | 0.215 |
| 75 % | | 0.853 | 0.390 | 0.207 | 0.108 | 0.073 | 0.045 | 0.207 | 0.108 |
| 90 % | | 0.341 | 0.156 | 0.083 | 0.043 | 0.029 | 0.018 | 0.083 | 0.043 |

PEC: predicted environmental concentration
RAC: regulatory acceptable concentration
PEC/RAC ratios above the relevant trigger of 1 are shown in bold

**Table 9.5-44: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in hops (hops; modelling use Hops -- BBCH 37 - 79, early -- 2×0.15 kg a.s./ha, 14d int.)**

| **Intended use** | | hops | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 2 x 150 g/ha, 14d int. | | | | | | | |
| Nozzle reduction | Vegetated strip (m) | None | None | None | None | None | None | 10 m | 20 m |
| | No spray buffer (m) | 0 m | 5 m | 10 m | 20 m | 30 m | 50 m | 10 m | 20 m |
| None | R1 Pond | *0.466* | *0.535* | *0.286* | *0.088* | *0.038* | *0.012* | *0.286* | *0.087* |
| 50 % | | *0.233* | *0.268* | *0.143* | *0.044* | *0.019* | *0.007* | *0.143* | *0.044* |
| 75 % | | *0.117* | *0.134* | *0.072* | *0.023* | *0.010* | *0.004* | *0.072* | *0.022* |
| 90 % | | *0.047* | *0.054* | *0.029* | *0.010* | *0.005* | *0.002* | *0.029* | *0.009* |
| None | R1 Stream | 5.64 | 4.61 | 2.40 | 0.722 | 0.234 | 0.056 | 2.40 | 0.722 |
| 50 % | | 2.82 | 2.30 | 1.20 | 0.361 | 0.117 | 0.028 | 1.20 | 0.361 |
| 75 % | | 1.41 | 1.15 | 0.600 | 0.180 | 0.059 | 0.014 | 0.600 | 0.180 |
| 90 % | | 0.564 | 0.460 | 0.240 | 0.072 | 0.023 | 0.014 | 0.240 | 0.072 |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | R1 Pond | **1.69** | **1.94** | **1.04** | 0.318 | 0.136 | 0.045 | **1.04** | 0.316 |
| 50 % | | 0.845 | 0.970 | 0.519 | 0.160 | 0.070 | 0.024 | 0.519 | 0.158 |
| 75 % | | 0.424 | 0.486 | 0.261 | 0.082 | 0.036 | 0.014 | 0.260 | 0.079 |
| 90 % | | 0.171 | 0.196 | 0.106 | 0.034 | 0.016 | 0.007 | 0.105 | 0.032 |
| None | R1 Stream | **20.4** | **16.7** | **8.70** | **2.62** | 0.847 | 0.203 | **8.70** | **2.62** |
| 50 % | | **10.2** | **8.34** | **4.35** | **1.31** | 0.424 | 0.101 | **4.35** | **1.31** |
| 75 % | | **5.11** | **4.17** | **2.17** | 0.654 | 0.212 | 0.052 | **2.17** | 0.654 |
| 90 % | | **2.04** | **1.67** | 0.870 | 0.262 | 0.085 | 0.052 | 0.870 | 0.262 |

* 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 9.5-45: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in hops (hops; modelling use Hops -- BBCH 37 - 79, late -- 2×0.15 kg a.s./ha, 14d int.)**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Intended use** | | hops | | | | | | | |
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 2 x 150 g/ha, 14d int. | | | | | | | |
| Nozzle reduction | Vegetated strip (m) | None | None | None | None | None | None | 10 m | 20 m |
| | No spray buffer (m) | 0 m | 5 m | 10 m | 20 m | 30 m | 50 m | 10 m | 20 m |
| None | R1 Pond | *0.430* | *0.494* | *0.264* | *0.080* | *0.034* | *0.011* | *0.264* | *0.080* |
| 50 % | | *0.215* | *0.247* | *0.132* | *0.040* | *0.017* | *0.005* | *0.132* | *0.040* |
| 75 % | | *0.107* | *0.123* | *0.066* | *0.020* | *0.008* | *0.003* | *0.066* | *0.020* |
| 90 % | | *0.043* | *0.049* | *0.026* | *0.008* | *0.003* | *0.001* | *0.026* | *0.008* |
| None | R1 Stream | 5.52 | 4.50 | 2.35 | 0.706 | 0.229 | 0.055 | 2.35 | 0.706 |
| 50 % | | 2.76 | 2.25 | 1.17 | 0.353 | 0.114 | 0.027 | 1.17 | 0.353 |
| 75 % | | 1.38 | 1.13 | 0.587 | 0.176 | 0.057 | 0.014 | 0.587 | 0.176 |
| 90 % | | 0.551 | 0.450 | 0.235 | 0.071 | 0.023 | 0.006 | 0.235 | 0.071 |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | R1 Pond | **1.56** | **1.79** | 0.955 | 0.290 | 0.122 | 0.039 | 0.955 | 0.290 |
| 50 % | | 0.778 | 0.893 | 0.477 | 0.145 | 0.061 | 0.019 | 0.477 | 0.145 |
| 75 % | | 0.388 | 0.446 | 0.238 | 0.072 | 0.030 | 0.010 | 0.238 | 0.072 |
| 90 % | | 0.155 | 0.178 | 0.095 | 0.029 | 0.012 | 0.004 | 0.095 | 0.029 |
| None | R1 Stream | **20.0** | **16.3** | **8.50** | **2.56** | 0.828 | 0.198 | **8.50** | **2.56** |
| 50 % | | **9.99** | **8.16** | **4.25** | **1.28** | 0.414 | 0.099 | **4.25** | **1.28** |
| 75 % | | **5.00** | **4.08** | **2.13** | 0.639 | 0.207 | 0.050 | **2.13** | 0.639 |
| 90 % | | **2.00** | **1.63** | 0.850 | 0.256 | 0.083 | 0.020 | 0.850 | 0.256 |

* 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 9.5-46: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in berries (berries; modelling use vines I -- early, BBCH 15 -- 2×0.15 kg a.s./ha, 7d int.)**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Intended use** | | berries | | | | | | | |
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 2 x 150 g/ha, 7d int. | | | | | | | |
| Nozzle reduction | Vegetated strip (m) | None | None | None | None | None | None | 10 m | 20 m |
| | No spray | 0 m | 5 m | 10 m | 20 m | 30 m | 50 m | 10 m | 20 m |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | buffer (m) | | | | | | | | |
| None | D6 Ditch | 2.52 | 1.52 | 0.551 | 0.193 | 0.104 | 0.047 | 0.551 | 0.193 |
| 50 % | | 1.26 | 0.762 | 0.276 | 0.097 | 0.052 | 0.024 | 0.276 | 0.097 |
| 75 % | | 0.630 | 0.381 | 0.138 | 0.048 | 0.026 | 0.012 | 0.138 | 0.048 |
| 90 % | | 0.252 | 0.152 | 0.055 | 0.019 | 0.010 | 0.005 | 0.055 | 0.019 |
| None | R1 Pond | *0.140* | *0.163* | *0.089* | *0.045* | *0.028* | *0.015* | *0.089* | *0.045* |
| 50 % | | *0.070* | *0.082* | *0.045* | *0.022* | *0.014* | *0.008* | *0.045* | *0.022* |
| 75 % | | *0.035* | *0.041* | *0.022* | *0.011* | *0.007* | *0.004* | *0.022* | *0.011* |
| 90 % | | *0.014* | *0.016* | *0.009* | *0.004* | *0.003* | *0.002* | *0.009* | *0.004* |
| None | R1 Stream | 1.87 | 1.36 | 0.492 | 0.173 | 0.093 | 0.042 | 0.492 | 0.173 |
| 50 % | | 0.933 | 0.680 | 0.246 | 0.086 | 0.046 | 0.021 | 0.246 | 0.086 |
| 75 % | | 0.467 | 0.340 | 0.123 | 0.043 | 0.023 | 0.011 | 0.123 | 0.043 |
| 90 % | | 0.187 | 0.136 | 0.049 | 0.017 | 0.009 | *0.005* | 0.049 | 0.017 |
| None | R2 Stream | 2.48 | 1.81 | 0.654 | 0.229 | 0.123 | 0.056 | 0.654 | 0.229 |
| 50 % | | 1.24 | 0.903 | 0.327 | 0.115 | 0.062 | 0.028 | 0.327 | 0.115 |
| 75 % | | 0.620 | 0.452 | 0.164 | 0.057 | 0.031 | 0.014 | 0.164 | 0.057 |
| 90 % | | 0.248 | 0.181 | 0.065 | 0.023 | 0.012 | 0.006 | 0.065 | 0.023 |
| None | R3 Stream | 2.64 | 1.92 | 0.697 | 0.244 | 0.131 | 0.060 | 0.697 | 0.244 |
| 50 % | | 1.32 | 0.962 | 0.348 | 0.122 | 0.066 | 0.030 | 0.348 | 0.122 |
| 75 % | | 0.660 | 0.481 | 0.174 | 0.061 | 0.033 | 0.015 | 0.174 | 0.061 |
| 90 % | | 0.264 | 0.192 | 0.070 | 0.024 | 0.013 | 0.006 | 0.070 | 0.024 |
| None | R4 Stream | 1.88 | 1.37 | 0.496 | 0.174 | 0.093 | 0.043 | 0.496 | 0.174 |
| 50 % | | 0.940 | 0.685 | 0.248 | 0.087 | 0.047 | *0.035* | 0.248 | 0.087 |
| 75 % | | 0.470 | 0.342 | 0.124 | 0.044 | *0.035* | *0.035* | 0.124 | 0.044 |
| 90 % | | 0.188 | 0.137 | 0.050 | *0.035* | *0.035* | *0.035* | 0.050 | 0.017 |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D6 Ditch | **9.13** | **5.52** | **2.00** | 0.701 | 0.376 | 0.171 | **2.00** | 0.701 |
| 50 % | | **4.56** | **2.76** | 0.999 | 0.350 | 0.188 | 0.086 | 0.999 | 0.350 |
| 75 % | | **2.28** | **1.38** | 0.500 | 0.175 | 0.094 | 0.043 | 0.500 | 0.175 |
| 90 % | | 0.912 | 0.552 | 0.200 | 0.070 | 0.038 | 0.017 | 0.200 | 0.070 |
| None | R1 Pond | 0.509 | 0.592 | 0.324 | 0.162 | 0.103 | 0.055 | 0.324 | 0.162 |
| 50 % | | 0.254 | 0.296 | 0.162 | 0.081 | 0.051 | 0.028 | 0.162 | 0.081 |
| 75 % | | 0.127 | 0.148 | 0.081 | 0.040 | 0.026 | 0.014 | 0.081 | 0.040 |
| 90 % | | 0.051 | 0.059 | 0.032 | 0.016 | 0.010 | 0.005 | 0.032 | 0.016 |
| None | R1 Stream | **6.76** | **4.93** | **1.78** | 0.626 | 0.336 | 0.153 | **1.78** | 0.626 |
| 50 % | | **3.38** | **2.46** | 0.892 | 0.313 | 0.168 | 0.076 | 0.892 | 0.313 |
| 75 % | | **1.69** | **1.23** | 0.446 | 0.157 | 0.084 | 0.038 | 0.446 | 0.157 |
| 90 % | | 0.676 | 0.492 | 0.178 | 0.063 | 0.034 | 0.018 | 0.178 | 0.063 |
| None | R2 Stream | **8.99** | **6.54** | **2.37** | 0.831 | 0.446 | 0.203 | **2.37** | 0.831 |
| 50 % | | **4.49** | **3.27** | **1.19** | 0.416 | 0.223 | 0.101 | **1.19** | 0.416 |
| 75 % | | **2.25** | **1.64** | 0.592 | 0.208 | 0.112 | 0.051 | 0.592 | 0.208 |
| 90 % | | 0.898 | 0.654 | 0.237 | 0.083 | 0.045 | 0.020 | 0.237 | 0.083 |
| None | R3 Stream | **9.57** | **6.97** | **2.52** | 0.885 | 0.475 | 0.216 | **2.52** | 0.885 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 50 % | | **4.78** | **3.48** | **1.26** | 0.443 | 0.238 | 0.108 | **1.26** | 0.443 |
| 75 % | | **2.39** | **1.74** | 0.631 | 0.221 | 0.119 | 0.054 | 0.631 | 0.221 |
| 90 % | | 0.957 | 0.697 | 0.253 | 0.088 | 0.047 | 0.022 | 0.253 | 0.088 |
| None | R4 Stream | **6.82** | **4.96** | **1.80** | 0.630 | 0.338 | 0.154 | **1.80** | 0.630 |
| 50 % | | **3.41** | **2.48** | 0.899 | 0.315 | 0.169 | 0.128 | 0.899 | 0.315 |
| 75 % | | **1.70** | **1.24** | 0.449 | 0.158 | 0.128 | 0.128 | 0.449 | 0.158 |
| 90 % | | 0.681 | 0.496 | 0.180 | 0.128 | 0.128 | 0.128 | 0.180 | 0.063 |

* 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 9.5-47: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in berries (berries; modelling use vines I -- middle, BBCH 65 -- 2×0.15 kg a.s./ha, 7d int.)**

| **Intended use** | | berries | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 2 x 150 g/ha, 7d int. | | | | | | | |
| Nozzle reduction | Vegetated strip (m) | None | None | None | None | None | None | 10 m | 20 m |
| | No spray buffer (m) | 0 m | 5 m | 10 m | 20 m | 30 m | 50 m | 10 m | 20 m |
| None | D6 Ditch | *2.61* | *1.57* | *0.564* | 0.197 | 0.106 | 0.048 | *0.564* | 0.197 |
| 50 % | | *1.31* | *0.786* | *0.282* | 0.099 | 0.053 | 0.024 | *0.282* | 0.099 |
| 75 % | | *0.652* | *0.393* | *0.141* | 0.049 | 0.027 | 0.012 | *0.141* | 0.049 |
| 90 % | | *0.261* | *0.157* | *0.056* | 0.020 | 0.011 | 0.005 | *0.056* | 0.020 |
| None | R1 Pond | *0.137* | *0.159* | *0.088* | *0.045* | *0.029* | *0.016* | *0.087* | *0.043* |
| 50 % | | *0.069* | *0.080* | *0.045* | *0.023* | *0.015* | *0.009* | *0.044* | *0.022* |
| 75 % | | *0.035* | *0.041* | *0.023* | *0.012* | *0.008* | *0.005* | *0.022* | *0.011* |
| 90 % | | *0.015* | *0.017* | *0.010* | *0.006* | *0.004* | *0.003* | *0.009* | *0.005* |
| None | R1 Stream | 1.88 | 1.37 | 0.496 | 0.174 | 0.093 | 0.042 | 0.496 | 0.174 |
| 50 % | | 0.939 | 0.684 | 0.248 | 0.087 | 0.047 | *0.029* | 0.248 | 0.087 |
| 75 % | | 0.470 | 0.342 | 0.124 | 0.044 | *0.029* | *0.029* | 0.124 | 0.044 |
| 90 % | | 0.188 | 0.137 | 0.050 | *0.029* | *0.029* | *0.029* | 0.050 | 0.017 |
| None | R2 Stream | 2.53 | 1.84 | 0.666 | 0.234 | 0.126 | 0.057 | 0.666 | 0.234 |
| 50 % | | 1.26 | 0.920 | 0.333 | 0.117 | 0.063 | 0.029 | 0.333 | 0.117 |
| 75 % | | 0.631 | 0.460 | 0.167 | 0.058 | 0.031 | 0.014 | 0.167 | 0.058 |
| 90 % | | 0.253 | 0.184 | 0.067 | 0.023 | 0.013 | 0.006 | 0.067 | 0.023 |
| None | R3 Stream | 2.66 | 1.94 | 0.701 | 0.246 | 0.132 | 0.060 | 0.701 | 0.246 |
| 50 % | | 1.33 | 0.967 | 0.350 | 0.123 | 0.066 | 0.030 | 0.350 | 0.123 |
| 75 % | | 0.664 | 0.484 | 0.175 | 0.061 | 0.033 | 0.015 | 0.175 | 0.061 |
| 90 % | | 0.266 | 0.193 | 0.070 | 0.025 | 0.013 | *0.009* | 0.070 | 0.025 |
| None | R4 Stream | 1.88 | 1.37 | 0.497 | 0.174 | 0.094 | 0.043 | 0.497 | 0.174 |
| 50 % | | 0.942 | 0.686 | 0.249 | 0.087 | 0.047 | 0.021 | 0.249 | 0.087 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 75 % | | 0.471 | 0.343 | 0.124 | 0.044 | 0.023 | 0.011 | 0.124 | 0.044 |
| 90 % | | 0.188 | 0.137 | 0.050 | 0.017 | 0.009 | *0.006* | 0.050 | 0.017 |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D6 Ditch | **9.47** | **5.70** | **2.04** | 0.715 | 0.384 | 0.174 | **2.04** | 0.715 |
| 50 % | | **4.73** | **2.85** | **1.02** | 0.357 | 0.192 | 0.087 | **1.02** | 0.357 |
| 75 % | | **2.36** | **1.42** | 0.510 | 0.179 | 0.096 | 0.043 | 0.510 | 0.179 |
| 90 % | | 0.944 | 0.568 | 0.204 | 0.071 | 0.038 | 0.017 | 0.204 | 0.071 |
| None | R1 Pond | 0.495 | 0.575 | 0.317 | 0.161 | 0.104 | 0.059 | 0.314 | 0.157 |
| 50 % | | 0.250 | 0.290 | 0.161 | 0.083 | 0.055 | 0.032 | 0.158 | 0.079 |
| 75 % | | 0.128 | 0.148 | 0.083 | 0.045 | 0.030 | 0.019 | 0.080 | 0.040 |
| 90 % | | 0.054 | 0.063 | 0.037 | 0.021 | 0.016 | 0.011 | 0.033 | 0.017 |
| None | R1 Stream | **6.81** | **4.96** | **1.80** | 0.630 | 0.338 | 0.154 | **1.80** | 0.630 |
| 50 % | | **3.40** | **2.48** | 0.898 | 0.315 | 0.169 | 0.105 | 0.898 | 0.315 |
| 75 % | | **1.70** | **1.24** | 0.449 | 0.158 | 0.105 | 0.105 | 0.449 | 0.158 |
| 90 % | | 0.680 | 0.496 | 0.180 | 0.105 | 0.105 | 0.105 | 0.180 | 0.063 |
| None | R2 Stream | **9.15** | **6.67** | **2.41** | 0.847 | 0.455 | 0.207 | **2.41** | 0.847 |
| 50 % | | **4.58** | **3.33** | **1.21** | 0.423 | 0.228 | 0.103 | **1.21** | 0.423 |
| 75 % | | **2.29** | **1.67** | 0.604 | 0.212 | 0.114 | 0.051 | 0.604 | 0.212 |
| 90 % | | 0.915 | 0.667 | 0.241 | 0.085 | 0.045 | 0.021 | 0.241 | 0.085 |
| None | R3 Stream | **9.62** | **7.01** | **2.54** | 0.890 | 0.478 | 0.217 | **2.54** | 0.890 |
| 50 % | | **4.81** | **3.50** | **1.27** | 0.445 | 0.239 | 0.109 | **1.27** | 0.445 |
| 75 % | | **2.41** | **1.75** | 0.635 | 0.222 | 0.120 | 0.054 | 0.635 | 0.222 |
| 90 % | | 0.962 | 0.701 | 0.254 | 0.089 | 0.048 | 0.034 | 0.254 | 0.089 |
| None | R4 Stream | **6.83** | **4.97** | **1.80** | 0.632 | 0.339 | 0.154 | **1.80** | 0.632 |
| 50 % | | **3.41** | **2.49** | 0.900 | 0.316 | 0.170 | 0.077 | 0.900 | 0.316 |
| 75 % | | **1.71** | **1.24** | 0.450 | 0.158 | 0.085 | 0.038 | 0.450 | 0.158 |
| 90 % | | 0.682 | 0.497 | 0.180 | 0.063 | 0.034 | 0.020 | 0.180 | 0.063 |

* 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 9.5-48: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in berries (berries; modelling use vines I -- late, BBCH 89 -- 2×0.15 kg a.s./ha, 7d int.)**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Intended use** | | berries | | | | | | | |
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 2 x 150 g/ha, 7d int. | | | | | | | |
| Nozzle reduction | Vegetated strip (m) | None | None | None | None | None | None | 10 m | 20 m |
| | No spray buffer (m) | 0 m | 5 m | 10 m | 20 m | 30 m | 50 m | 10 m | 20 m |
| None | D6 Ditch | *3.09* | *1.86* | *0.667* | *0.231* | *0.124* | *0.056* | *0.667* | *0.231* |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 50 % | | *1.54* | *0.928* | *0.333* | *0.116* | *0.062* | *0.028* | *0.333* | *0.116* |
| 75 % | | *0.771* | *0.464* | *0.166* | *0.058* | *0.031* | *0.014* | *0.166* | *0.058* |
| 90 % | | *0.308* | *0.185* | *0.066* | *0.023* | *0.012* | *0.006* | *0.066* | *0.023* |
| None | R1 Pond | *0.129* | *0.150* | *0.082* | *0.041* | *0.026* | *0.014* | *0.082* | *0.041* |
| 50 % | | *0.064* | *0.075* | *0.041* | *0.020* | *0.013* | *0.007* | *0.041* | *0.020* |
| 75 % | | *0.032* | *0.037* | *0.020* | *0.010* | *0.007* | *0.004* | *0.020* | *0.010* |
| 90 % | | *0.013* | *0.015* | *0.008* | *0.004* | *0.003* | *0.001* | *0.008* | *0.004* |
| None | R1 Stream | 1.88 | 1.37 | 0.497 | 0.174 | 0.094 | 0.043 | 0.497 | 0.174 |
| 50 % | | 0.942 | 0.686 | 0.249 | 0.087 | 0.047 | 0.021 | 0.249 | 0.087 |
| 75 % | | 0.471 | 0.343 | 0.124 | 0.044 | 0.023 | 0.011 | 0.124 | 0.044 |
| 90 % | | 0.188 | 0.137 | 0.050 | 0.017 | 0.009 | 0.004 | 0.050 | 0.017 |
| None | R2 Stream | 2.53 | 1.84 | 0.666 | 0.234 | 0.126 | 0.057 | 0.666 | 0.234 |
| 50 % | | 1.26 | 0.920 | 0.333 | 0.117 | 0.063 | 0.029 | 0.333 | 0.117 |
| 75 % | | 0.631 | 0.460 | 0.167 | 0.058 | 0.031 | 0.014 | 0.167 | 0.058 |
| 90 % | | 0.253 | 0.184 | 0.067 | 0.023 | 0.013 | 0.006 | 0.067 | 0.023 |
| None | R3 Stream | 2.66 | 1.94 | 0.701 | 0.246 | 0.132 | 0.060 | 0.701 | 0.246 |
| 50 % | | 1.33 | 0.967 | 0.350 | 0.123 | 0.066 | 0.030 | 0.350 | 0.123 |
| 75 % | | 0.664 | 0.484 | 0.175 | 0.061 | 0.033 | 0.015 | 0.175 | 0.061 |
| 90 % | | 0.266 | 0.193 | 0.070 | 0.025 | 0.013 | 0.007 | 0.070 | 0.025 |
| None | R4 Stream | 1.88 | 1.37 | 0.497 | 0.174 | *0.143* | *0.143* | 0.497 | 0.174 |
| 50 % | | 0.942 | 0.686 | 0.249 | *0.143* | *0.143* | *0.143* | 0.249 | 0.087 |
| 75 % | | 0.471 | 0.343 | *0.143* | *0.143* | *0.143* | *0.143* | 0.124 | 0.044 |
| 90 % | | 0.188 | *0.143* | *0.143* | *0.143* | *0.143* | *0.143* | *0.064* | *0.033* |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D6 Ditch | **11.2** | **6.74** | **2.41** | 0.838 | 0.447 | 0.202 | **2.41** | 0.838 |
| 50 % | | **5.59** | **3.36** | **1.21** | 0.419 | 0.224 | 0.101 | **1.21** | 0.419 |
| 75 % | | **2.79** | **1.68** | 0.603 | 0.209 | 0.112 | 0.050 | 0.603 | 0.209 |
| 90 % | | **1.12** | 0.671 | 0.241 | 0.084 | 0.045 | 0.020 | 0.241 | 0.084 |
| None | R1 Pond | 0.466 | 0.542 | 0.296 | 0.148 | 0.094 | 0.050 | 0.296 | 0.148 |
| 50 % | | 0.233 | 0.271 | 0.148 | 0.074 | 0.047 | 0.025 | 0.148 | 0.074 |
| 75 % | | 0.116 | 0.135 | 0.074 | 0.037 | 0.024 | 0.013 | 0.074 | 0.037 |
| 90 % | | 0.046 | 0.054 | 0.029 | 0.015 | 0.009 | 0.005 | 0.029 | 0.015 |
| None | R1 Stream | **6.83** | **4.97** | **1.80** | 0.632 | 0.339 | 0.154 | **1.80** | 0.632 |
| 50 % | | **3.41** | **2.49** | 0.900 | 0.316 | 0.170 | 0.077 | 0.900 | 0.316 |
| 75 % | | **1.71** | **1.24** | 0.450 | 0.158 | 0.085 | 0.038 | 0.450 | 0.158 |
| 90 % | | 0.683 | 0.497 | 0.180 | 0.063 | 0.034 | 0.016 | 0.180 | 0.063 |
| None | R2 Stream | **9.15** | **6.67** | **2.41** | 0.847 | 0.455 | 0.207 | **2.41** | 0.847 |
| 50 % | | **4.58** | **3.33** | **1.21** | 0.423 | 0.228 | 0.103 | **1.21** | 0.423 |
| 75 % | | **2.29** | **1.67** | 0.604 | 0.212 | 0.114 | 0.051 | 0.604 | 0.212 |
| 90 % | | 0.915 | 0.667 | 0.241 | 0.085 | 0.045 | 0.021 | 0.241 | 0.085 |
| None | R3 Stream | **9.62** | **7.01** | **2.54** | 0.890 | 0.478 | 0.217 | **2.54** | 0.890 |
| 50 % | | **4.81** | **3.50** | **1.27** | 0.445 | 0.239 | 0.109 | **1.27** | 0.445 |
| 75 % | | **2.41** | **1.75** | 0.635 | 0.222 | 0.120 | 0.054 | 0.635 | 0.222 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 90 % | | 0.962 | 0.701 | 0.254 | 0.089 | 0.048 | 0.026 | 0.254 | 0.089 |
| None | R4 Stream | **6.83** | **4.97** | **1.80** | 0.632 | 0.519 | 0.519 | **1.80** | 0.632 |
| 50 % | | **3.41** | **2.49** | 0.900 | 0.519 | 0.519 | 0.519 | 0.900 | 0.316 |
| 75 % | | **1.71** | **1.24** | 0.519 | 0.519 | 0.519 | 0.519 | 0.450 | 0.158 |
| 90 % | | 0.682 | 0.519 | 0.519 | 0.519 | 0.519 | 0.519 | 0.232 | 0.121 |

* 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 9.5-49: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in berries (berries; modelling use vines II -- early, BBCH 15 -- 2×0.2 kg a.s./ha, 7d int.)**

| **Intended use** | | berries | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 2 x 200 g/ha, 7d int. | | | | | | | |
| Nozzle reduction | Vegetated strip (m) | None | None | None | None | None | None | 10 m | 20 m |
| | No spray buffer (m) | 0 m | 5 m | 10 m | 20 m | 30 m | 50 m | 10 m | 20 m |
| None | D6 Ditch | 3.36 | 2.03 | 0.736 | 0.258 | 0.139 | 0.063 | 0.736 | 0.258 |
| 50 % | | 1.68 | 1.01 | 0.368 | 0.129 | 0.069 | 0.032 | 0.368 | 0.129 |
| 75 % | | 0.840 | 0.508 | 0.184 | 0.065 | 0.035 | 0.016 | 0.184 | 0.065 |
| 90 % | | 0.336 | 0.203 | 0.074 | 0.026 | 0.014 | 0.006 | 0.074 | 0.026 |
| None | R1 Pond | *0.187* | *0.218* | *0.119* | *0.060* | *0.038* | *0.020* | *0.119* | *0.060* |
| 50 % | | *0.094* | *0.109* | *0.060* | *0.030* | *0.019* | *0.010* | *0.060* | *0.030* |
| 75 % | | *0.047* | *0.054* | *0.030* | *0.015* | *0.009* | *0.005* | *0.030* | *0.015* |
| 90 % | | *0.019* | *0.022* | *0.012* | *0.006* | *0.004* | *0.002* | *0.012* | *0.006* |
| None | R1 Stream | 2.49 | 1.81 | 0.657 | 0.230 | 0.124 | 0.056 | 0.657 | 0.230 |
| 50 % | | 1.24 | 0.907 | 0.328 | 0.115 | 0.062 | 0.028 | 0.328 | 0.115 |
| 75 % | | 0.622 | 0.453 | 0.164 | 0.058 | 0.031 | 0.014 | 0.164 | 0.058 |
| 90 % | | 0.249 | 0.181 | 0.066 | 0.023 | 0.012 | *0.007* | 0.066 | 0.023 |
| None | R2 Stream | 3.31 | 2.41 | 0.872 | 0.306 | 0.164 | 0.075 | 0.872 | 0.306 |
| 50 % | | 1.65 | 1.20 | 0.436 | 0.153 | 0.082 | 0.037 | 0.436 | 0.153 |
| 75 % | | 0.826 | 0.602 | 0.218 | 0.077 | 0.041 | 0.019 | 0.218 | 0.077 |
| 90 % | | 0.330 | 0.241 | 0.087 | 0.031 | 0.016 | 0.008 | 0.087 | 0.031 |
| None | R3 Stream | 3.52 | 2.57 | 0.929 | 0.326 | 0.175 | 0.080 | 0.929 | 0.326 |
| 50 % | | 1.76 | 1.28 | 0.465 | 0.163 | 0.088 | 0.040 | 0.465 | 0.163 |
| 75 % | | 0.880 | 0.641 | 0.232 | 0.081 | 0.044 | 0.020 | 0.232 | 0.081 |
| 90 % | | 0.352 | 0.257 | 0.093 | 0.033 | 0.018 | 0.008 | 0.093 | 0.033 |
| None | R4 Stream | 2.51 | 1.83 | 0.662 | 0.232 | 0.125 | 0.057 | 0.662 | 0.232 |
| 50 % | | 1.25 | 0.913 | 0.331 | 0.116 | 0.062 | *0.048* | 0.331 | 0.116 |
| 75 % | | 0.627 | 0.457 | 0.165 | 0.058 | *0.048* | *0.048* | 0.165 | 0.058 |
| 90 % | | 0.251 | 0.183 | 0.066 | *0.048* | *0.048* | *0.048* | 0.066 | 0.023 |

| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| None | D6 Ditch | **12.2** | **7.36** | **2.66** | 0.934 | 0.502 | 0.228 | **2.66** | 0.934 |
| 50 % | | **6.09** | **3.68** | **1.33** | 0.467 | 0.251 | 0.114 | **1.33** | 0.467 |
| 75 % | | **3.04** | **1.84** | 0.666 | 0.234 | 0.125 | 0.057 | 0.666 | 0.234 |
| 90 % | | **1.22** | 0.736 | 0.266 | 0.093 | 0.050 | 0.023 | 0.266 | 0.093 |
| None | R1 Pond | 0.679 | 0.789 | 0.432 | 0.216 | 0.137 | 0.074 | 0.432 | 0.216 |
| 50 % | | 0.339 | 0.394 | 0.216 | 0.108 | 0.068 | 0.037 | 0.216 | 0.108 |
| 75 % | | 0.169 | 0.197 | 0.108 | 0.054 | 0.034 | 0.018 | 0.108 | 0.054 |
| 90 % | | 0.068 | 0.079 | 0.043 | 0.021 | 0.014 | 0.007 | 0.043 | 0.021 |
| None | R1 Stream | **9.01** | **6.57** | **2.38** | 0.834 | 0.448 | 0.204 | **2.38** | 0.834 |
| 50 % | | **4.51** | **3.28** | **1.19** | 0.417 | 0.224 | 0.102 | **1.19** | 0.417 |
| 75 % | | **2.25** | **1.64** | 0.595 | 0.209 | 0.112 | 0.051 | 0.595 | 0.209 |
| 90 % | | 0.901 | 0.657 | 0.238 | 0.083 | 0.045 | 0.025 | 0.238 | 0.083 |
| None | R2 Stream | **12.0** | **8.73** | **3.16** | **1.11** | 0.595 | 0.270 | **3.16** | **1.11** |
| 50 % | | **5.99** | **4.36** | **1.58** | 0.554 | 0.298 | 0.135 | **1.58** | 0.554 |
| 75 % | | **2.99** | **2.18** | 0.790 | 0.277 | 0.149 | 0.068 | 0.790 | 0.277 |
| 90 % | | **1.20** | 0.872 | 0.316 | 0.111 | 0.059 | 0.027 | 0.316 | 0.111 |
| None | R3 Stream | **12.8** | **9.29** | **3.37** | **1.18** | 0.634 | 0.288 | **3.37** | **1.18** |
| 50 % | | **6.38** | **4.64** | **1.68** | 0.590 | 0.317 | 0.144 | **1.68** | 0.590 |
| 75 % | | **3.19** | **2.32** | 0.841 | 0.295 | 0.158 | 0.072 | 0.841 | 0.295 |
| 90 % | | **1.27** | 0.929 | 0.337 | 0.118 | 0.063 | 0.029 | 0.337 | 0.118 |
| None | R4 Stream | **9.08** | **6.62** | **2.40** | 0.841 | 0.451 | 0.205 | **2.40** | 0.841 |
| 50 % | | **4.54** | **3.31** | **1.20** | 0.420 | 0.226 | 0.172 | **1.20** | 0.420 |
| 75 % | | **2.27** | **1.65** | 0.599 | 0.210 | 0.172 | 0.172 | 0.599 | 0.210 |
| 90 % | | 0.908 | 0.662 | 0.239 | 0.172 | 0.172 | 0.172 | 0.239 | 0.084 |

* 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 9.5-50: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in berries (berries; modelling use vines II -- middle, BBCH 65 -- 2×0.2 kg a.s./ha, 7d int.)**

| **Intended use** | | berries | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 2 x 200 g/ha, 7d int. | | | | | | | |
| Nozzle reduction | Vegetated strip (m) | None | None | None | None | None | None | 10 m | 20 m |
| | No spray buffer (m) | 0 m | 5 m | 10 m | 20 m | 30 m | 50 m | 10 m | 20 m |
| None | D6 Ditch | *3.49* | *2.10* | *0.752* | 0.263 | 0.141 | 0.064 | *0.752* | 0.263 |
| 50 % | | *1.74* | *1.05* | *0.376* | 0.132 | 0.071 | 0.032 | *0.376* | 0.132 |
| 75 % | | *0.870* | *0.524* | *0.188* | 0.066 | 0.035 | 0.016 | *0.188* | 0.066 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 90 % | | *0.348* | *0.209* | 0.075 | 0.026 | 0.014 | 0.006 | 0.075 | 0.026 |
| None | R1 Pond | *0.182* | *0.212* | *0.117* | *0.059* | *0.039* | *0.022* | *0.116* | *0.058* |
| 50 % | | *0.092* | *0.107* | *0.059* | *0.031* | *0.020* | *0.012* | *0.058* | *0.029* |
| 75 % | | *0.047* | *0.055* | *0.031* | *0.016* | *0.011* | *0.007* | *0.030* | *0.015* |
| 90 % | | *0.020* | *0.023* | *0.014* | *0.008* | *0.006* | *0.004* | *0.012* | *0.006* |
| None | R1 Stream | 2.50 | 1.83 | 0.661 | 0.232 | 0.124 | 0.057 | 0.661 | 0.232 |
| 50 % | | 1.25 | 0.912 | 0.330 | 0.116 | 0.062 | *0.039* | 0.330 | 0.116 |
| 75 % | | 0.626 | 0.456 | 0.165 | 0.058 | *0.039* | *0.039* | 0.165 | 0.058 |
| 90 % | | 0.250 | 0.182 | 0.066 | *0.039* | *0.039* | *0.039* | 0.066 | 0.023 |
| None | R2 Stream | 3.37 | 2.45 | 0.889 | 0.312 | 0.167 | 0.076 | 0.889 | 0.312 |
| 50 % | | 1.68 | 1.23 | 0.444 | 0.156 | 0.084 | 0.038 | 0.444 | 0.156 |
| 75 % | | 0.842 | 0.613 | 0.222 | 0.078 | 0.042 | 0.019 | 0.222 | 0.078 |
| 90 % | | 0.337 | 0.245 | 0.089 | 0.031 | 0.017 | 0.008 | 0.089 | 0.031 |
| None | R3 Stream | 3.54 | 2.58 | 0.934 | 0.328 | 0.176 | 0.080 | 0.934 | 0.328 |
| 50 % | | 1.77 | 1.29 | 0.467 | 0.164 | 0.088 | 0.040 | 0.467 | 0.164 |
| 75 % | | 0.885 | 0.645 | 0.234 | 0.082 | 0.044 | 0.020 | 0.234 | 0.082 |
| 90 % | | 0.354 | 0.258 | 0.093 | 0.033 | 0.018 | *0.013* | 0.093 | 0.033 |
| None | R4 Stream | 2.51 | 1.83 | 0.663 | 0.232 | 0.125 | 0.057 | 0.663 | 0.232 |
| 50 % | | 1.25 | 0.915 | 0.331 | 0.116 | 0.062 | 0.028 | 0.331 | 0.116 |
| 75 % | | 0.628 | 0.458 | 0.166 | 0.058 | 0.031 | 0.014 | 0.166 | 0.058 |
| 90 % | | 0.251 | 0.183 | 0.066 | 0.023 | 0.013 | *0.008* | 0.066 | 0.023 |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D6 Ditch | **12.6** | **7.60** | **2.73** | 0.953 | 0.512 | 0.233 | **2.73** | 0.953 |
| 50 % | | **6.31** | **3.80** | **1.36** | 0.476 | 0.256 | 0.116 | **1.36** | 0.476 |
| 75 % | | **3.15** | **1.90** | 0.680 | 0.238 | 0.128 | 0.058 | 0.680 | 0.238 |
| 90 % | | **1.26** | 0.758 | 0.272 | 0.095 | 0.051 | 0.023 | 0.272 | 0.095 |
| None | R1 Pond | 0.661 | 0.767 | 0.423 | 0.215 | 0.139 | 0.078 | 0.420 | 0.210 |
| 50 % | | 0.334 | 0.387 | 0.215 | 0.111 | 0.074 | 0.043 | 0.211 | 0.105 |
| 75 % | | 0.171 | 0.197 | 0.111 | 0.059 | 0.041 | 0.025 | 0.107 | 0.054 |
| 90 % | | 0.073 | 0.083 | 0.049 | 0.028 | 0.021 | 0.015 | 0.045 | 0.022 |
| None | R1 Stream | **9.07** | **6.61** | **2.39** | 0.840 | 0.451 | 0.205 | **2.39** | 0.840 |
| 50 % | | **4.54** | **3.31** | **1.20** | 0.420 | 0.225 | 0.141 | **1.20** | 0.420 |
| 75 % | | **2.27** | **1.65** | 0.599 | 0.210 | 0.141 | 0.141 | 0.599 | 0.210 |
| 90 % | | 0.907 | 0.661 | 0.239 | 0.141 | 0.141 | 0.141 | 0.239 | 0.084 |
| None | R2 Stream | **12.2** | **8.89** | **3.22** | **1.13** | 0.606 | 0.275 | **3.22** | **1.13** |
| 50 % | | **6.10** | **4.45** | **1.61** | 0.564 | 0.303 | 0.138 | **1.61** | 0.564 |
| 75 % | | **3.05** | **2.22** | 0.805 | 0.282 | 0.151 | 0.069 | 0.805 | 0.282 |
| 90 % | | **1.22** | 0.889 | 0.322 | 0.113 | 0.061 | 0.028 | 0.322 | 0.113 |
| None | R3 Stream | **12.8** | **9.35** | **3.39** | **1.19** | 0.637 | 0.289 | **3.39** | **1.19** |
| 50 % | | **6.41** | **4.67** | **1.69** | 0.593 | 0.319 | 0.145 | **1.69** | 0.593 |
| 75 % | | **3.21** | **2.34** | 0.846 | 0.297 | 0.159 | 0.072 | 0.846 | 0.297 |
| 90 % | | **1.28** | 0.934 | 0.338 | 0.119 | 0.064 | 0.046 | 0.338 | 0.119 |
| None | R4 Stream | **9.10** | **6.63** | **2.40** | 0.842 | 0.452 | 0.205 | **2.40** | 0.842 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 50 % | | **4.55** | **3.32** | **1.20** | 0.421 | 0.226 | 0.103 | **1.20** | 0.421 |
| 75 % | | **2.27** | **1.66** | 0.600 | 0.211 | 0.113 | 0.051 | 0.600 | 0.211 |
| 90 % | | 0.909 | 0.663 | 0.240 | 0.084 | 0.045 | 0.027 | 0.240 | 0.084 |

* 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 9.5-51: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in berries (berries; modelling use vines II -- late, BBCH 89 -- 2×0.2 kg a.s./ha, 7d int.)**

| **Intended use** | | berries | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 2 x 200 g/ha, 7d int. | | | | | | | |
| Nozzle reduction | Vegetated strip (m) | None | None | None | None | None | None | 10 m | 20 m |
| | No spray buffer (m) | 0 m | 5 m | 10 m | 20 m | 30 m | 50 m | 10 m | 20 m |
| None | D6 Ditch | *4.12* | *2.48* | *0.889* | *0.309* | *0.165* | *0.074* | *0.889* | *0.309* |
| 50 % | | *2.06* | *1.24* | *0.444* | *0.154* | *0.082* | *0.037* | *0.444* | *0.154* |
| 75 % | | *1.03* | *0.619* | *0.222* | *0.077* | *0.041* | *0.019* | *0.222* | *0.077* |
| 90 % | | *0.411* | *0.247* | *0.089* | *0.031* | *0.016* | *0.007* | *0.089* | *0.031* |
| None | R1 Pond | *0.172* | *0.200* | *0.109* | *0.055* | *0.035* | *0.019* | *0.109* | *0.055* |
| 50 % | | *0.086* | *0.100* | *0.055* | *0.027* | *0.017* | *0.009* | *0.055* | *0.027* |
| 75 % | | *0.043* | *0.050* | *0.027* | *0.014* | *0.009* | *0.005* | *0.027* | *0.014* |
| 90 % | | *0.017* | *0.020* | *0.011* | *0.005* | *0.003* | *0.002* | *0.011* | *0.005* |
| None | R1 Stream | 2.51 | 1.83 | 0.663 | 0.233 | 0.125 | 0.057 | 0.663 | 0.233 |
| 50 % | | 1.26 | 0.915 | 0.331 | 0.116 | 0.062 | 0.028 | 0.331 | 0.116 |
| 75 % | | 0.628 | 0.458 | 0.166 | 0.058 | 0.031 | 0.014 | 0.166 | 0.058 |
| 90 % | | 0.251 | 0.183 | 0.066 | 0.023 | 0.013 | 0.006 | 0.066 | 0.023 |
| None | R2 Stream | 3.37 | 2.45 | 0.889 | 0.312 | 0.167 | 0.076 | 0.889 | 0.312 |
| 50 % | | 1.68 | 1.23 | 0.444 | 0.156 | 0.084 | 0.038 | 0.444 | 0.156 |
| 75 % | | 0.842 | 0.613 | 0.222 | 0.078 | 0.042 | 0.019 | 0.222 | 0.078 |
| 90 % | | 0.337 | 0.245 | 0.089 | 0.031 | 0.017 | 0.008 | 0.089 | 0.031 |
| None | R3 Stream | 3.54 | 2.58 | 0.934 | 0.328 | 0.176 | 0.080 | 0.934 | 0.328 |
| 50 % | | 1.77 | 1.29 | 0.467 | 0.164 | 0.088 | 0.040 | 0.467 | 0.164 |
| 75 % | | 0.885 | 0.645 | 0.234 | 0.082 | 0.044 | 0.020 | 0.234 | 0.082 |
| 90 % | | 0.354 | 0.258 | 0.093 | 0.033 | 0.018 | 0.010 | 0.093 | 0.033 |
| None | R4 Stream | 2.51 | 1.83 | 0.663 | 0.232 | *0.193* | *0.193* | 0.663 | 0.232 |
| 50 % | | 1.25 | 0.915 | 0.331 | *0.193* | *0.193* | *0.193* | 0.331 | 0.116 |
| 75 % | | 0.628 | 0.458 | *0.193* | *0.193* | *0.193* | *0.193* | 0.166 | 0.058 |
| 90 % | | 0.251 | *0.193* | *0.193* | *0.193* | *0.193* | *0.193* | *0.087* | *0.045* |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| None | D6 Ditch | **14.9** | **8.99** | **3.22** | **1.12** | 0.597 | 0.269 | **3.22** | **1.12** |
| 50 % | | **7.46** | **4.49** | **1.61** | 0.559 | 0.298 | 0.134 | **1.61** | 0.559 |
| 75 % | | **3.72** | **2.24** | 0.804 | 0.279 | 0.149 | 0.067 | 0.804 | 0.279 |
| 90 % | | **1.49** | 0.895 | 0.321 | 0.112 | 0.059 | 0.027 | 0.321 | 0.112 |
| None | R1 Pond | 0.622 | 0.724 | 0.395 | 0.197 | 0.125 | 0.067 | 0.395 | 0.197 |
| 50 % | | 0.311 | 0.361 | 0.197 | 0.099 | 0.063 | 0.034 | 0.197 | 0.099 |
| 75 % | | 0.155 | 0.180 | 0.099 | 0.049 | 0.031 | 0.017 | 0.099 | 0.049 |
| 90 % | | 0.062 | 0.072 | 0.039 | 0.020 | 0.012 | 0.007 | 0.039 | 0.020 |
| None | R1 Stream | **9.10** | **6.63** | **2.40** | 0.842 | 0.452 | 0.205 | **2.40** | 0.842 |
| 50 % | | **4.55** | **3.32** | **1.20** | 0.421 | 0.226 | 0.103 | **1.20** | 0.421 |
| 75 % | | **2.27** | **1.66** | 0.600 | 0.211 | 0.113 | 0.051 | 0.600 | 0.211 |
| 90 % | | 0.910 | 0.663 | 0.240 | 0.084 | 0.045 | 0.021 | 0.240 | 0.084 |
| None | R2 Stream | **12.2** | **8.89** | **3.22** | **1.13** | 0.606 | 0.275 | **3.22** | **1.13** |
| 50 % | | **6.10** | **4.45** | **1.61** | 0.564 | 0.303 | 0.138 | **1.61** | 0.564 |
| 75 % | | **3.05** | **2.22** | 0.805 | 0.282 | 0.151 | 0.069 | 0.805 | 0.282 |
| 90 % | | **1.22** | 0.889 | 0.322 | 0.113 | 0.061 | 0.028 | 0.322 | 0.113 |
| None | R3 Stream | **12.8** | **9.35** | **3.39** | **1.19** | 0.637 | 0.289 | **3.39** | **1.19** |
| 50 % | | **6.41** | **4.67** | **1.69** | 0.593 | 0.319 | 0.145 | **1.69** | 0.593 |
| 75 % | | **3.21** | **2.34** | 0.846 | 0.297 | 0.159 | 0.072 | 0.846 | 0.297 |
| 90 % | | **1.28** | 0.934 | 0.338 | 0.119 | 0.064 | 0.034 | 0.338 | 0.119 |
| None | R4 Stream | **9.10** | **6.63** | **2.40** | 0.842 | 0.700 | 0.700 | **2.40** | 0.842 |
| 50 % | | **4.55** | **3.32** | **1.20** | 0.700 | 0.700 | 0.700 | **1.20** | 0.421 |
| 75 % | | **2.27** | **1.66** | 0.700 | 0.700 | 0.700 | 0.700 | 0.600 | 0.211 |
| 90 % | | 0.909 | 0.700 | 0.700 | 0.700 | 0.700 | 0.700 | 0.313 | 0.163 |

* 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 9.5-52: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in berries (berries; modelling use vines III -- early, BBCH 15 -- 2×0.15 kg a.s./ha, 14d int.)**

| **Intended use** | | berries | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 2 x 150 g/ha, 14d int. | | | | | | | |
| Nozzle reduction | Vegetated strip (m) | None | None | None | None | None | None | 10 m | 20 m |
| | No spray buffer (m) | 0 m | 5 m | 10 m | 20 m | 30 m | 50 m | 10 m | 20 m |
| None | D6 Ditch | 2.52 | 1.52 | 0.551 | 0.193 | 0.104 | 0.047 | 0.551 | 0.193 |
| 50 % | | 1.26 | 0.762 | 0.276 | 0.097 | 0.052 | 0.024 | 0.276 | 0.097 |
| 75 % | | 0.630 | 0.381 | 0.138 | 0.048 | 0.026 | 0.012 | 0.138 | 0.048 |
| 90 % | | 0.252 | 0.152 | 0.055 | 0.019 | 0.010 | 0.005 | 0.055 | 0.019 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| None | R1 Pond | *0.132* | *0.154* | *0.084* | *0.042* | *0.027* | *0.014* | *0.084* | *0.042* |
| 50 % | | *0.066* | *0.077* | *0.042* | *0.021* | *0.013* | *0.007* | *0.042* | *0.021* |
| 75 % | | *0.033* | *0.038* | *0.021* | *0.011* | *0.007* | *0.004* | *0.021* | *0.011* |
| 90 % | | *0.013* | *0.015* | *0.008* | *0.004* | *0.003* | *0.001* | *0.008* | *0.004* |
| None | R1 Stream | 1.87 | 1.36 | 0.492 | 0.173 | 0.093 | 0.042 | 0.492 | 0.173 |
| 50 % | | 0.933 | 0.680 | 0.246 | 0.086 | 0.046 | *0.023* | 0.246 | 0.086 |
| 75 % | | 0.467 | 0.340 | 0.123 | 0.043 | 0.023 | *0.023* | 0.123 | 0.043 |
| 90 % | | 0.187 | 0.136 | 0.049 | *0.023* | *0.023* | *0.023* | 0.049 | 0.017 |
| None | R2 Stream | 2.48 | 1.81 | 0.654 | 0.229 | 0.123 | 0.056 | 0.654 | 0.229 |
| 50 % | | 1.24 | 0.903 | 0.327 | 0.115 | 0.062 | 0.028 | 0.327 | 0.115 |
| 75 % | | 0.620 | 0.452 | 0.164 | 0.057 | 0.031 | 0.014 | 0.164 | 0.057 |
| 90 % | | 0.248 | 0.181 | 0.065 | 0.023 | 0.012 | 0.006 | 0.065 | 0.023 |
| None | R3 Stream | 2.64 | 1.92 | 0.697 | 0.244 | 0.131 | 0.060 | 0.697 | 0.244 |
| 50 % | | 1.32 | 0.962 | 0.348 | 0.122 | 0.066 | 0.030 | 0.348 | 0.122 |
| 75 % | | 0.660 | 0.481 | 0.174 | 0.061 | 0.033 | 0.015 | 0.174 | 0.061 |
| 90 % | | 0.264 | 0.192 | 0.070 | 0.024 | 0.013 | 0.006 | 0.070 | 0.024 |
| None | R4 Stream | 1.88 | 1.37 | 0.496 | 0.174 | 0.093 | *0.074* | 0.496 | 0.174 |
| 50 % | | 0.940 | 0.685 | 0.248 | 0.087 | *0.074* | *0.074* | 0.248 | 0.087 |
| 75 % | | 0.470 | 0.342 | 0.124 | *0.074* | *0.074* | *0.074* | 0.124 | 0.044 |
| 90 % | | 0.188 | 0.137 | *0.074* | *0.074* | *0.074* | *0.074* | 0.050 | 0.017 |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D6 Ditch | **9.13** | **5.52** | **2.00** | 0.701 | 0.376 | 0.171 | **2.00** | 0.701 |
| 50 % | | **4.56** | **2.76** | 0.999 | 0.350 | 0.188 | 0.086 | 0.999 | 0.350 |
| 75 % | | **2.28** | **1.38** | 0.500 | 0.175 | 0.094 | 0.043 | 0.500 | 0.175 |
| 90 % | | 0.912 | 0.552 | 0.200 | 0.070 | 0.038 | 0.017 | 0.200 | 0.070 |
| None | R1 Pond | 0.479 | 0.558 | 0.305 | 0.152 | 0.097 | 0.052 | 0.305 | 0.152 |
| 50 % | | 0.239 | 0.279 | 0.152 | 0.076 | 0.048 | 0.026 | 0.152 | 0.076 |
| 75 % | | 0.120 | 0.139 | 0.076 | 0.038 | 0.024 | 0.013 | 0.076 | 0.038 |
| 90 % | | 0.048 | 0.055 | 0.030 | 0.015 | 0.010 | 0.005 | 0.030 | 0.015 |
| None | R1 Stream | **6.76** | **4.93** | **1.78** | 0.626 | 0.336 | 0.153 | **1.78** | 0.626 |
| 50 % | | **3.38** | **2.46** | 0.892 | 0.313 | 0.168 | 0.082 | 0.892 | 0.313 |
| 75 % | | **1.69** | **1.23** | 0.446 | 0.157 | 0.084 | 0.082 | 0.446 | 0.157 |
| 90 % | | 0.676 | 0.492 | 0.178 | 0.082 | 0.082 | 0.082 | 0.178 | 0.063 |
| None | R2 Stream | **8.99** | **6.54** | **2.37** | 0.831 | 0.446 | 0.203 | **2.37** | 0.831 |
| 50 % | | **4.49** | **3.27** | **1.19** | 0.416 | 0.223 | 0.101 | **1.19** | 0.416 |
| 75 % | | **2.25** | **1.64** | 0.592 | 0.208 | 0.112 | 0.051 | 0.592 | 0.208 |
| 90 % | | 0.898 | 0.654 | 0.237 | 0.083 | 0.045 | 0.020 | 0.237 | 0.083 |
| None | R3 Stream | **9.57** | **6.97** | **2.52** | 0.885 | 0.475 | 0.216 | **2.52** | 0.885 |
| 50 % | | **4.78** | **3.48** | **1.26** | 0.443 | 0.238 | 0.108 | **1.26** | 0.443 |
| 75 % | | **2.39** | **1.74** | 0.631 | 0.221 | 0.119 | 0.054 | 0.631 | 0.221 |
| 90 % | | 0.957 | 0.697 | 0.253 | 0.088 | 0.047 | 0.022 | 0.253 | 0.088 |
| None | R4 Stream | **6.82** | **4.96** | **1.80** | 0.630 | 0.338 | 0.268 | **1.80** | 0.630 |
| 50 % | | **3.41** | **2.48** | 0.899 | 0.315 | 0.268 | 0.268 | 0.899 | 0.315 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 75 % | | **1.70** | **1.24** | 0.449 | 0.268 | 0.268 | 0.268 | 0.449 | 0.158 |
| 90 % | | 0.681 | 0.496 | 0.268 | 0.268 | 0.268 | 0.268 | 0.180 | 0.063 |

* 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 9.5-53: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in berries (berries; modelling use vines III -- middle, BBCH 65 -- 2×0.15 kg a.s./ha, 14d int.)**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Intended use** | | berries | | | | | | | |
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 2 x 150 g/ha, 14d int. | | | | | | | |
| Nozzle reduction | Vegetated strip (m) | None | None | None | None | None | None | 10 m | 20 m |
| | No spray buffer (m) | 0 m | 5 m | 10 m | 20 m | 30 m | 50 m | 10 m | 20 m |
| None | D6 Ditch | 2.57 | 1.55 | 0.562 | 0.197 | 0.106 | 0.048 | 0.562 | 0.197 |
| 50 % | | 1.28 | 0.777 | 0.281 | 0.099 | 0.053 | 0.024 | 0.281 | 0.099 |
| 75 % | | 0.642 | 0.388 | 0.141 | 0.049 | 0.027 | 0.012 | 0.141 | 0.049 |
| 90 % | | 0.257 | 0.155 | 0.056 | 0.020 | 0.011 | 0.005 | 0.056 | 0.020 |
| None | R1 Pond | *0.134* | *0.155* | *0.086* | *0.044* | *0.028* | *0.016* | *0.085* | *0.042* |
| 50 % | | *0.068* | *0.078* | *0.044* | *0.023* | *0.015* | *0.009* | *0.043* | *0.021* |
| 75 % | | *0.035* | *0.040* | *0.023* | *0.012* | *0.008* | *0.005* | *0.022* | *0.011* |
| 90 % | | *0.015* | *0.017* | *0.010* | *0.006* | *0.004* | *0.003* | *0.009* | *0.005* |
| None | R1 Stream | 1.88 | 1.37 | 0.496 | 0.174 | 0.093 | 0.042 | 0.496 | 0.174 |
| 50 % | | 0.939 | 0.684 | 0.248 | 0.087 | 0.047 | *0.034* | 0.248 | 0.087 |
| 75 % | | 0.470 | 0.342 | 0.124 | 0.044 | *0.034* | *0.034* | 0.124 | 0.044 |
| 90 % | | 0.188 | 0.137 | 0.050 | *0.034* | *0.034* | *0.034* | 0.050 | 0.017 |
| None | R2 Stream | 2.53 | 1.84 | 0.666 | 0.234 | 0.126 | 0.057 | 0.666 | 0.234 |
| 50 % | | 1.26 | 0.920 | 0.333 | 0.117 | 0.063 | 0.029 | 0.333 | 0.117 |
| 75 % | | 0.631 | 0.460 | 0.167 | 0.058 | 0.031 | 0.014 | 0.167 | 0.058 |
| 90 % | | 0.253 | 0.184 | 0.067 | 0.023 | 0.013 | 0.006 | 0.067 | 0.023 |
| None | R3 Stream | 2.66 | 1.94 | 0.701 | 0.246 | 0.132 | 0.060 | 0.701 | 0.246 |
| 50 % | | 1.33 | 0.967 | 0.350 | 0.123 | 0.066 | 0.030 | 0.350 | 0.123 |
| 75 % | | 0.664 | 0.484 | 0.175 | 0.061 | 0.033 | *0.021* | 0.175 | 0.061 |
| 90 % | | 0.266 | 0.193 | 0.070 | 0.025 | *0.021* | *0.021* | 0.070 | 0.025 |
| None | R4 Stream | 1.88 | 1.37 | 0.497 | 0.174 | 0.094 | 0.043 | 0.497 | 0.174 |
| 50 % | | 0.942 | 0.686 | 0.249 | 0.087 | 0.047 | 0.021 | 0.249 | 0.087 |
| 75 % | | 0.471 | 0.343 | 0.124 | 0.044 | 0.023 | *0.021* | 0.124 | 0.044 |
| 90 % | | 0.188 | 0.137 | 0.050 | *0.021* | *0.021* | *0.021* | 0.050 | 0.017 |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D6 Ditch | **9.31** | **5.63** | **2.04** | 0.715 | 0.384 | 0.174 | **2.04** | 0.715 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 50 % | | **4.65** | **2.81** | **1.02** | 0.357 | 0.192 | 0.087 | **1.02** | 0.357 |
| 75 % | | **2.33** | **1.41** | 0.509 | 0.179 | 0.096 | 0.043 | 0.509 | 0.179 |
| 90 % | | 0.931 | 0.563 | 0.204 | 0.071 | 0.038 | 0.017 | 0.204 | 0.071 |
| None | R1 Pond | 0.484 | 0.562 | 0.310 | 0.158 | 0.102 | 0.057 | 0.308 | 0.154 |
| 50 % | | 0.245 | 0.284 | 0.158 | 0.082 | 0.054 | 0.031 | 0.155 | 0.078 |
| 75 % | | 0.125 | 0.144 | 0.082 | 0.043 | 0.029 | 0.018 | 0.078 | 0.039 |
| 90 % | | 0.053 | 0.061 | 0.036 | 0.021 | 0.015 | 0.011 | 0.033 | 0.016 |
| None | R1 Stream | **6.81** | **4.96** | **1.80** | 0.630 | 0.338 | 0.154 | **1.80** | 0.630 |
| 50 % | | **3.40** | **2.48** | 0.898 | 0.315 | 0.169 | 0.121 | 0.898 | 0.315 |
| 75 % | | **1.70** | **1.24** | 0.449 | 0.158 | 0.121 | 0.121 | 0.449 | 0.158 |
| 90 % | | 0.680 | 0.496 | 0.180 | 0.121 | 0.121 | 0.121 | 0.180 | 0.063 |
| None | R2 Stream | **9.15** | **6.67** | **2.41** | 0.847 | 0.455 | 0.207 | **2.41** | 0.847 |
| 50 % | | **4.58** | **3.33** | **1.21** | 0.423 | 0.228 | 0.103 | **1.21** | 0.423 |
| 75 % | | **2.29** | **1.67** | 0.604 | 0.212 | 0.114 | 0.051 | 0.604 | 0.212 |
| 90 % | | 0.915 | 0.667 | 0.241 | 0.085 | 0.045 | 0.021 | 0.241 | 0.085 |
| None | R3 Stream | **9.62** | **7.01** | **2.54** | 0.890 | 0.478 | 0.217 | **2.54** | 0.890 |
| 50 % | | **4.81** | **3.50** | **1.27** | 0.445 | 0.239 | 0.109 | **1.27** | 0.445 |
| 75 % | | **2.41** | **1.75** | 0.635 | 0.222 | 0.120 | 0.075 | 0.635 | 0.222 |
| 90 % | | 0.962 | 0.701 | 0.254 | 0.089 | 0.075 | 0.075 | 0.254 | 0.089 |
| None | R4 Stream | **6.83** | **4.97** | **1.80** | 0.632 | 0.339 | 0.154 | **1.80** | 0.632 |
| 50 % | | **3.41** | **2.49** | 0.900 | 0.316 | 0.170 | 0.077 | 0.900 | 0.316 |
| 75 % | | **1.71** | **1.24** | 0.450 | 0.158 | 0.085 | 0.075 | 0.450 | 0.158 |
| 90 % | | 0.682 | 0.497 | 0.180 | 0.075 | 0.075 | 0.075 | 0.180 | 0.063 |

* 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 9.5-54: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in berries (berries; modelling use vines III -- late, BBCH 89 -- 2×0.15 kg a.s./ha, 14d int.)**

| **Intended use** | | berries | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 2 x 150 g/ha, 14d int. | | | | | | | |
| Nozzle reduction | Vegetated strip (m) | None | None | None | None | None | None | 10 m | 20 m |
| | No spray buffer (m) | 0 m | 5 m | 10 m | 20 m | 30 m | 50 m | 10 m | 20 m |
| None | D6 Ditch | 2.57 | 1.55 | 0.562 | 0.197 | 0.106 | 0.048 | 0.562 | 0.197 |
| 50 % | | 1.28 | 0.777 | 0.281 | 0.099 | 0.053 | 0.024 | 0.281 | 0.099 |
| 75 % | | 0.642 | 0.388 | 0.141 | 0.049 | 0.027 | 0.012 | 0.141 | 0.049 |
| 90 % | | 0.257 | 0.155 | 0.056 | 0.020 | 0.011 | 0.005 | 0.056 | 0.020 |
| None | R1 Pond | *0.129* | *0.150* | *0.082* | *0.041* | *0.026* | *0.014* | *0.082* | *0.041* |
| 50 % | | *0.064* | *0.075* | *0.041* | *0.020* | *0.013* | *0.007* | *0.041* | *0.020* |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 75 % | | *0.032* | *0.037* | *0.020* | *0.010* | *0.007* | *0.004* | *0.020* | *0.010* |
| 90 % | | *0.013* | *0.015* | *0.008* | *0.004* | *0.003* | *0.001* | *0.008* | *0.004* |
| None | R1 Stream | 1.88 | 1.37 | 0.497 | 0.174 | 0.094 | 0.043 | 0.497 | 0.174 |
| 50 % | | 0.942 | 0.686 | 0.249 | 0.087 | 0.047 | 0.021 | 0.249 | 0.087 |
| 75 % | | 0.471 | 0.343 | 0.124 | 0.044 | 0.023 | 0.011 | 0.124 | 0.044 |
| 90 % | | 0.188 | 0.137 | 0.050 | 0.017 | 0.009 | 0.004 | 0.050 | 0.017 |
| None | R2 Stream | 2.53 | 1.84 | 0.666 | 0.234 | 0.126 | 0.057 | 0.666 | 0.234 |
| 50 % | | 1.26 | 0.920 | 0.333 | 0.117 | 0.063 | 0.029 | 0.333 | 0.117 |
| 75 % | | 0.631 | 0.460 | 0.167 | 0.058 | 0.031 | 0.014 | 0.167 | 0.058 |
| 90 % | | 0.253 | 0.184 | 0.067 | 0.023 | 0.013 | 0.006 | 0.067 | 0.023 |
| None | R3 Stream | 2.66 | 1.94 | 0.701 | 0.246 | *0.185* | *0.185* | 0.701 | 0.246 |
| 50 % | | 1.33 | 0.967 | 0.350 | *0.185* | *0.185* | *0.185* | 0.350 | 0.123 |
| 75 % | | 0.664 | 0.484 | *0.185* | *0.185* | *0.185* | *0.185* | 0.175 | 0.061 |
| 90 % | | 0.266 | 0.193 | *0.185* | *0.185* | *0.185* | *0.185* | *0.084* | *0.044* |
| None | R4 Stream | 1.88 | 1.37 | 0.497 | 0.174 | 0.094 | 0.043 | 0.497 | 0.174 |
| 50 % | | 0.942 | 0.686 | 0.249 | 0.087 | 0.047 | *0.038* | 0.249 | 0.087 |
| 75 % | | 0.471 | 0.343 | 0.124 | 0.044 | *0.038* | *0.038* | 0.124 | 0.044 |
| 90 % | | 0.188 | 0.137 | 0.050 | *0.038* | *0.038* | *0.038* | 0.050 | 0.017 |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D6 Ditch | **9.31** | **5.63** | **2.04** | 0.715 | 0.384 | 0.174 | **2.04** | 0.715 |
| 50 % | | **4.65** | **2.81** | **1.02** | 0.357 | 0.192 | 0.087 | **1.02** | 0.357 |
| 75 % | | **2.33** | **1.41** | 0.509 | 0.179 | 0.096 | 0.043 | 0.509 | 0.179 |
| 90 % | | 0.931 | 0.563 | 0.204 | 0.071 | 0.038 | 0.017 | 0.204 | 0.071 |
| None | R1 Pond | 0.466 | 0.542 | 0.296 | 0.148 | 0.094 | 0.050 | 0.296 | 0.148 |
| 50 % | | 0.233 | 0.271 | 0.148 | 0.074 | 0.047 | 0.025 | 0.148 | 0.074 |
| 75 % | | 0.116 | 0.135 | 0.074 | 0.037 | 0.024 | 0.013 | 0.074 | 0.037 |
| 90 % | | 0.046 | 0.054 | 0.029 | 0.015 | 0.009 | 0.005 | 0.029 | 0.015 |
| None | R1 Stream | **6.83** | **4.97** | **1.80** | 0.632 | 0.339 | 0.154 | **1.80** | 0.632 |
| 50 % | | **3.41** | **2.49** | 0.900 | 0.316 | 0.170 | 0.077 | 0.900 | 0.316 |
| 75 % | | **1.71** | **1.24** | 0.450 | 0.158 | 0.085 | 0.038 | 0.450 | 0.158 |
| 90 % | | 0.683 | 0.497 | 0.180 | 0.063 | 0.034 | 0.016 | 0.180 | 0.063 |
| None | R2 Stream | **9.15** | **6.67** | **2.41** | 0.847 | 0.455 | 0.207 | **2.41** | 0.847 |
| 50 % | | **4.58** | **3.33** | **1.21** | 0.423 | 0.228 | 0.103 | **1.21** | 0.423 |
| 75 % | | **2.29** | **1.67** | 0.604 | 0.212 | 0.114 | 0.051 | 0.604 | 0.212 |
| 90 % | | 0.915 | 0.667 | 0.241 | 0.085 | 0.045 | 0.021 | 0.241 | 0.085 |
| None | R3 Stream | **9.62** | **7.01** | **2.54** | 0.890 | 0.668 | 0.668 | **2.54** | 0.890 |
| 50 % | | **4.81** | **3.50** | **1.27** | 0.668 | 0.668 | 0.668 | **1.27** | 0.445 |
| 75 % | | **2.41** | **1.75** | 0.668 | 0.668 | 0.668 | 0.668 | 0.635 | 0.222 |
| 90 % | | 0.962 | 0.701 | 0.668 | 0.668 | 0.668 | 0.668 | 0.304 | 0.159 |
| None | R4 Stream | **6.83** | **4.97** | **1.80** | 0.632 | 0.339 | 0.154 | **1.80** | 0.632 |
| 50 % | | **3.41** | **2.49** | 0.900 | 0.316 | 0.170 | 0.138 | 0.900 | 0.316 |
| 75 % | | **1.71** | **1.24** | 0.450 | 0.158 | 0.138 | 0.138 | 0.450 | 0.158 |
| 90 % | | 0.682 | 0.497 | 0.180 | 0.138 | 0.138 | 0.138 | 0.180 | 0.063 |

* 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 9.5-55: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in berries (berries; modelling use vines IV -- early, BBCH 15 -- 2×0.2 kg a.s./ha, 14d int.)**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Intended use** | | berries | | | | | | | |
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 2 x 200 g/ha, 14d int. | | | | | | | |
| Nozzle reduction | Vegetated strip (m) | None | None | None | None | None | None | 10 m | 20 m |
| | No spray buffer (m) | 0 m | 5 m | 10 m | 20 m | 30 m | 50 m | 10 m | 20 m |
| None | D6 Ditch | 3.36 | 2.03 | 0.736 | 0.258 | 0.139 | 0.063 | 0.736 | 0.258 |
| 50 % | | 1.68 | 1.01 | 0.368 | 0.129 | 0.069 | 0.032 | 0.368 | 0.129 |
| 75 % | | 0.840 | 0.508 | 0.184 | 0.065 | 0.035 | 0.016 | 0.184 | 0.065 |
| 90 % | | 0.336 | 0.203 | 0.074 | 0.026 | 0.014 | 0.006 | 0.074 | 0.026 |
| None | R1 Pond | *0.177* | *0.205* | *0.112* | *0.056* | *0.036* | *0.019* | *0.112* | *0.056* |
| 50 % | | *0.088* | *0.103* | *0.056* | *0.028* | *0.018* | *0.010* | *0.056* | *0.028* |
| 75 % | | *0.044* | *0.051* | *0.028* | *0.014* | *0.009* | *0.005* | *0.028* | *0.014* |
| 90 % | | *0.018* | *0.021* | *0.011* | *0.006* | *0.004* | *0.002* | *0.011* | *0.006* |
| None | R1 Stream | 2.49 | 1.81 | 0.657 | 0.230 | 0.124 | 0.056 | 0.657 | 0.230 |
| 50 % | | 1.24 | 0.907 | 0.328 | 0.115 | 0.062 | *0.031* | 0.328 | 0.115 |
| 75 % | | 0.622 | 0.453 | 0.164 | 0.058 | 0.031 | *0.031* | 0.164 | 0.058 |
| 90 % | | 0.249 | 0.181 | 0.066 | *0.031* | *0.031* | *0.031* | 0.066 | 0.023 |
| None | R2 Stream | 3.31 | 2.41 | 0.872 | 0.306 | 0.164 | 0.075 | 0.872 | 0.306 |
| 50 % | | 1.65 | 1.20 | 0.436 | 0.153 | 0.082 | 0.037 | 0.436 | 0.153 |
| 75 % | | 0.826 | 0.602 | 0.218 | 0.077 | 0.041 | 0.019 | 0.218 | 0.077 |
| 90 % | | 0.330 | 0.241 | 0.087 | 0.031 | 0.016 | 0.008 | 0.087 | 0.031 |
| None | R3 Stream | 3.52 | 2.57 | 0.929 | 0.326 | 0.175 | 0.080 | 0.929 | 0.326 |
| 50 % | | 1.76 | 1.28 | 0.465 | 0.163 | 0.088 | 0.040 | 0.465 | 0.163 |
| 75 % | | 0.880 | 0.641 | 0.232 | 0.081 | 0.044 | 0.020 | 0.232 | 0.081 |
| 90 % | | 0.352 | 0.257 | 0.093 | 0.033 | 0.018 | 0.008 | 0.093 | 0.033 |
| None | R4 Stream | 2.51 | 1.83 | 0.662 | 0.232 | 0.125 | *0.100* | 0.662 | 0.232 |
| 50 % | | 1.25 | 0.913 | 0.331 | 0.116 | *0.100* | *0.100* | 0.331 | 0.116 |
| 75 % | | 0.627 | 0.457 | 0.165 | *0.100* | *0.100* | *0.100* | 0.165 | 0.058 |
| 90 % | | 0.251 | 0.183 | *0.100* | *0.100* | *0.100* | *0.100* | 0.066 | 0.023 |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D6 Ditch | **12.2** | **7.36** | **2.66** | 0.934 | 0.502 | 0.228 | **2.66** | 0.934 |
| 50 % | | **6.09** | **3.68** | **1.33** | 0.467 | 0.251 | 0.114 | **1.33** | 0.467 |
| 75 % | | **3.04** | **1.84** | 0.666 | 0.234 | 0.125 | 0.057 | 0.666 | 0.234 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 90 % | | **1.22** | 0.736 | 0.266 | 0.093 | 0.050 | 0.023 | 0.266 | 0.093 |
| None | R1 Pond | 0.639 | 0.744 | 0.407 | 0.203 | 0.129 | 0.069 | 0.407 | 0.203 |
| 50 % | | 0.319 | 0.372 | 0.203 | 0.101 | 0.064 | 0.034 | 0.203 | 0.101 |
| 75 % | | 0.159 | 0.186 | 0.101 | 0.051 | 0.032 | 0.017 | 0.101 | 0.051 |
| 90 % | | 0.064 | 0.074 | 0.041 | 0.020 | 0.013 | 0.007 | 0.041 | 0.020 |
| None | R1 Stream | **9.01** | **6.57** | **2.38** | 0.834 | 0.448 | 0.204 | **2.38** | 0.834 |
| 50 % | | **4.51** | **3.28** | **1.19** | 0.417 | 0.224 | 0.111 | **1.19** | 0.417 |
| 75 % | | **2.25** | **1.64** | 0.595 | 0.209 | 0.112 | 0.111 | 0.595 | 0.209 |
| 90 % | | 0.901 | 0.657 | 0.238 | 0.111 | 0.111 | 0.111 | 0.238 | 0.083 |
| None | R2 Stream | **12.0** | **8.73** | **3.16** | **1.11** | 0.595 | 0.270 | **3.16** | **1.11** |
| 50 % | | **5.99** | **4.36** | **1.58** | 0.554 | 0.298 | 0.135 | **1.58** | 0.554 |
| 75 % | | **2.99** | **2.18** | 0.790 | 0.277 | 0.149 | 0.068 | 0.790 | 0.277 |
| 90 % | | **1.20** | 0.872 | 0.316 | 0.111 | 0.059 | 0.027 | 0.316 | 0.111 |
| None | R3 Stream | **12.8** | **9.29** | **3.37** | **1.18** | 0.634 | 0.288 | **3.37** | **1.18** |
| 50 % | | **6.38** | **4.64** | **1.68** | 0.590 | 0.317 | 0.144 | **1.68** | 0.590 |
| 75 % | | **3.19** | **2.32** | 0.841 | 0.295 | 0.158 | 0.072 | 0.841 | 0.295 |
| 90 % | | **1.27** | 0.929 | 0.337 | 0.118 | 0.063 | 0.029 | 0.337 | 0.118 |
| None | R4 Stream | **9.08** | **6.62** | **2.40** | 0.841 | 0.451 | 0.361 | **2.40** | 0.841 |
| 50 % | | **4.54** | **3.31** | **1.20** | 0.420 | 0.361 | 0.361 | **1.20** | 0.420 |
| 75 % | | **2.27** | **1.65** | 0.599 | 0.361 | 0.361 | 0.361 | 0.599 | 0.210 |
| 90 % | | 0.908 | 0.662 | 0.361 | 0.361 | 0.361 | 0.361 | 0.239 | 0.084 |

* 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 9.5-56: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in berries (berries; modelling use vines IV -- middle, BBCH 65 -- 2×0.2 kg a.s./ha, 14d int.)**

| | |
|---|---|
| **Intended use** | berries |
| **Active substance** | trifloxystrobin |
| **Application rate (g/ha)** | 2 x 200 g/ha, 14d int. |

| Nozzle reduction | Vegetated strip (m) | None | None | None | None | None | None | 10 m | 20 m |
|---|---|---|---|---|---|---|---|---|---|
| | No spray buffer (m) | 0 m | 5 m | 10 m | 20 m | 30 m | 50 m | 10 m | 20 m |
| None | D6 Ditch | 3.43 | 2.07 | 0.750 | 0.263 | 0.141 | 0.064 | 0.750 | 0.263 |
| 50 % | | 1.71 | 1.03 | 0.375 | 0.132 | 0.071 | 0.032 | 0.375 | 0.132 |
| 75 % | | 0.857 | 0.518 | 0.188 | 0.066 | 0.035 | 0.016 | 0.188 | 0.066 |
| 90 % | | 0.343 | 0.207 | 0.075 | 0.026 | 0.014 | 0.006 | 0.075 | 0.026 |
| None | R1 Pond | *0.178* | *0.207* | *0.114* | *0.058* | *0.038* | *0.021* | *0.113* | *0.057* |
| 50 % | | *0.090* | *0.104* | *0.058* | *0.030* | *0.020* | *0.012* | *0.057* | *0.029* |
| 75 % | | *0.046* | *0.053* | *0.030* | *0.016* | *0.011* | *0.007* | *0.029* | *0.014* |
| 90 % | | *0.020* | *0.023* | *0.013* | *0.008* | *0.006* | *0.004* | *0.012* | *0.006* |
| None | R1 Stream | 2.50 | 1.83 | 0.661 | 0.232 | 0.124 | 0.057 | 0.661 | 0.232 |
| 50 % | | 1.25 | 0.912 | 0.330 | 0.116 | 0.062 | *0.045* | 0.330 | 0.116 |
| 75 % | | 0.626 | 0.456 | 0.165 | 0.058 | *0.045* | *0.045* | 0.165 | 0.058 |
| 90 % | | 0.250 | 0.182 | 0.066 | *0.045* | *0.045* | *0.045* | 0.066 | 0.023 |
| None | R2 Stream | 3.37 | 2.45 | 0.889 | 0.312 | 0.167 | 0.076 | 0.889 | 0.312 |
| 50 % | | 1.68 | 1.23 | 0.444 | 0.156 | 0.084 | 0.038 | 0.444 | 0.156 |
| 75 % | | 0.842 | 0.613 | 0.222 | 0.078 | 0.042 | 0.019 | 0.222 | 0.078 |
| 90 % | | 0.337 | 0.245 | 0.089 | 0.031 | 0.017 | 0.008 | 0.089 | 0.031 |
| None | R3 Stream | 3.54 | 2.58 | 0.934 | 0.328 | 0.176 | 0.080 | 0.934 | 0.328 |
| 50 % | | 1.77 | 1.29 | 0.467 | 0.164 | 0.088 | 0.040 | 0.467 | 0.164 |
| 75 % | | 0.885 | 0.645 | 0.234 | 0.082 | 0.044 | *0.028* | 0.234 | 0.082 |
| 90 % | | 0.354 | 0.258 | 0.093 | 0.033 | *0.028* | *0.028* | 0.093 | 0.033 |
| None | R4 Stream | 2.51 | 1.83 | 0.663 | 0.232 | 0.125 | 0.057 | 0.663 | 0.232 |
| 50 % | | 1.25 | 0.915 | 0.331 | 0.116 | 0.062 | 0.028 | 0.331 | 0.116 |
| 75 % | | 0.628 | 0.458 | 0.166 | 0.058 | 0.031 | *0.028* | 0.166 | 0.058 |
| 90 % | | 0.251 | 0.183 | 0.066 | *0.028* | *0.028* | *0.028* | 0.066 | 0.023 |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D6 Ditch | **12.4** | **7.50** | **2.72** | 0.953 | 0.512 | 0.233 | **2.72** | 0.953 |
| 50 % | | **6.21** | **3.75** | **1.36** | 0.476 | 0.256 | 0.116 | **1.36** | 0.476 |
| 75 % | | **3.10** | **1.88** | 0.679 | 0.238 | 0.128 | 0.058 | 0.679 | 0.238 |
| 90 % | | **1.24** | 0.750 | 0.272 | 0.095 | 0.051 | 0.023 | 0.272 | 0.095 |
| None | R1 Pond | 0.646 | 0.750 | 0.413 | 0.210 | 0.136 | 0.076 | 0.410 | 0.205 |
| 50 % | | 0.326 | 0.378 | 0.210 | 0.109 | 0.072 | 0.042 | 0.207 | 0.103 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 75 % | | 0.167 | 0.193 | 0.109 | 0.058 | 0.039 | 0.025 | 0.105 | 0.052 |
| 90 % | | 0.071 | 0.082 | 0.048 | 0.028 | 0.020 | 0.014 | 0.043 | 0.022 |
| None | R1 Stream | **9.07** | **6.61** | **2.39** | 0.840 | 0.451 | 0.205 | **2.39** | 0.840 |
| 50 % | | **4.54** | **3.31** | **1.20** | 0.420 | 0.225 | 0.164 | **1.20** | 0.420 |
| 75 % | | **2.27** | **1.65** | 0.599 | 0.210 | 0.164 | 0.164 | 0.599 | 0.210 |
| 90 % | | 0.907 | 0.661 | 0.239 | 0.164 | 0.164 | 0.164 | 0.239 | 0.084 |
| None | R2 Stream | **12.2** | **8.89** | **3.22** | **1.13** | 0.606 | 0.275 | **3.22** | **1.13** |
| 50 % | | **6.10** | **4.45** | **1.61** | 0.564 | 0.303 | 0.138 | **1.61** | 0.564 |
| 75 % | | **3.05** | **2.22** | 0.805 | 0.282 | 0.151 | 0.069 | 0.805 | 0.282 |
| 90 % | | **1.22** | 0.889 | 0.322 | 0.113 | 0.061 | 0.028 | 0.322 | 0.113 |
| None | R3 Stream | **12.8** | **9.35** | **3.39** | **1.19** | 0.637 | 0.289 | **3.39** | **1.19** |
| 50 % | | **6.41** | **4.67** | **1.69** | 0.593 | 0.319 | 0.145 | **1.69** | 0.593 |
| 75 % | | **3.21** | **2.34** | 0.846 | 0.297 | 0.159 | 0.101 | 0.846 | 0.297 |
| 90 % | | **1.28** | 0.934 | 0.338 | 0.119 | 0.101 | 0.101 | 0.338 | 0.119 |
| None | R4 Stream | **9.10** | **6.63** | **2.40** | 0.842 | 0.452 | 0.205 | **2.40** | 0.842 |
| 50 % | | **4.55** | **3.32** | **1.20** | 0.421 | 0.226 | 0.103 | **1.20** | 0.421 |
| 75 % | | **2.27** | **1.66** | 0.600 | 0.211 | 0.113 | 0.100 | 0.600 | 0.211 |
| 90 % | | 0.909 | 0.663 | 0.240 | 0.100 | 0.100 | 0.100 | 0.240 | 0.084 |

* 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 9.5-57: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in berries (berries; modelling use vines IV -- late, BBCH 89 -- 2×0.2 kg a.s./ha, 14d int.)**

| **Intended use** | | berries | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 2 x 200 g/ha, 14d int. | | | | | | | |
| Nozzle reduction | Vegetated strip (m) | None | None | None | None | None | None | 10 m | 20 m |
| | No spray buffer (m) | 0 m | 5 m | 10 m | 20 m | 30 m | 50 m | 10 m | 20 m |
| None | D6 Ditch | 3.43 | 2.07 | 0.750 | 0.263 | 0.141 | 0.064 | 0.750 | 0.263 |
| 50 % | | 1.71 | 1.03 | 0.375 | 0.132 | 0.071 | 0.032 | 0.375 | 0.132 |
| 75 % | | 0.857 | 0.518 | 0.188 | 0.066 | 0.035 | 0.016 | 0.188 | 0.066 |
| 90 % | | 0.343 | 0.207 | 0.075 | 0.026 | 0.014 | 0.006 | 0.075 | 0.026 |
| None | R1 Pond | *0.172* | *0.200* | *0.109* | *0.055* | *0.035* | *0.019* | *0.109* | *0.055* |
| 50 % | | *0.086* | *0.100* | *0.055* | *0.027* | *0.017* | *0.009* | *0.055* | *0.027* |
| 75 % | | *0.043* | *0.050* | *0.027* | *0.014* | *0.009* | *0.005* | *0.027* | *0.014* |
| 90 % | | *0.017* | *0.020* | *0.011* | *0.005* | *0.003* | *0.002* | *0.011* | *0.005* |
| None | R1 Stream | 2.51 | 1.83 | 0.663 | 0.233 | 0.125 | 0.057 | 0.663 | 0.233 |
| 50 % | | 1.26 | 0.915 | 0.331 | 0.116 | 0.062 | 0.028 | 0.331 | 0.116 |
| 75 % | | 0.628 | 0.458 | 0.166 | 0.058 | 0.031 | 0.014 | 0.166 | 0.058 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 90 % | | 0.251 | 0.183 | 0.066 | 0.023 | 0.013 | 0.006 | 0.066 | 0.023 |
| None | R2 Stream | 3.37 | 2.45 | 0.889 | 0.312 | 0.167 | 0.076 | 0.889 | 0.312 |
| 50 % | | 1.68 | 1.23 | 0.444 | 0.156 | 0.084 | 0.038 | 0.444 | 0.156 |
| 75 % | | 0.842 | 0.613 | 0.222 | 0.078 | 0.042 | 0.019 | 0.222 | 0.078 |
| 90 % | | 0.337 | 0.245 | 0.089 | 0.031 | 0.017 | 0.008 | 0.089 | 0.031 |
| None | R3 Stream | 3.54 | 2.58 | 0.934 | 0.328 | 0.176 | 0.080 | 0.934 | 0.328 |
| 50 % | | 1.77 | 1.29 | 0.467 | 0.164 | 0.088 | 0.040 | 0.467 | 0.164 |
| 75 % | | 0.885 | 0.645 | 0.234 | 0.082 | 0.044 | 0.020 | 0.234 | 0.082 |
| 90 % | | 0.354 | 0.258 | 0.093 | 0.033 | 0.018 | 0.010 | 0.093 | 0.033 |
| None | R4 Stream | 2.51 | 1.83 | 0.663 | 0.232 | 0.125 | *0.062* | 0.663 | 0.232 |
| 50 % | | 1.25 | 0.915 | 0.331 | 0.116 | 0.062 | *0.062* | 0.331 | 0.116 |
| 75 % | | 0.628 | 0.458 | 0.166 | *0.062* | *0.062* | *0.062* | 0.166 | 0.058 |
| 90 % | | 0.251 | 0.183 | 0.066 | *0.062* | *0.062* | *0.062* | 0.066 | 0.023 |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D6 Ditch | **12.4** | **7.50** | **2.72** | 0.953 | 0.512 | 0.233 | **2.72** | 0.953 |
| 50 % | | **6.21** | **3.75** | **1.36** | 0.476 | 0.256 | 0.116 | **1.36** | 0.476 |
| 75 % | | **3.10** | **1.88** | 0.679 | 0.238 | 0.128 | 0.058 | 0.679 | 0.238 |
| 90 % | | **1.24** | 0.750 | 0.272 | 0.095 | 0.051 | 0.023 | 0.272 | 0.095 |
| None | R1 Pond | 0.622 | 0.724 | 0.395 | 0.197 | 0.125 | 0.067 | 0.395 | 0.197 |
| 50 % | | 0.311 | 0.361 | 0.197 | 0.099 | 0.063 | 0.034 | 0.197 | 0.099 |
| 75 % | | 0.155 | 0.180 | 0.099 | 0.049 | 0.031 | 0.017 | 0.099 | 0.049 |
| 90 % | | 0.062 | 0.072 | 0.039 | 0.020 | 0.012 | 0.007 | 0.039 | 0.020 |
| None | R1 Stream | **9.10** | **6.63** | **2.40** | 0.842 | 0.452 | 0.205 | **2.40** | 0.842 |
| 50 % | | **4.55** | **3.32** | **1.20** | 0.421 | 0.226 | 0.103 | **1.20** | 0.421 |
| 75 % | | **2.27** | **1.66** | 0.600 | 0.211 | 0.113 | 0.051 | 0.600 | 0.211 |
| 90 % | | 0.910 | 0.663 | 0.240 | 0.084 | 0.045 | 0.021 | 0.240 | 0.084 |
| None | R2 Stream | **12.2** | **8.89** | **3.22** | **1.13** | 0.606 | 0.275 | **3.22** | **1.13** |
| 50 % | | **6.10** | **4.45** | **1.61** | 0.564 | 0.303 | 0.138 | **1.61** | 0.564 |
| 75 % | | **3.05** | **2.22** | 0.805 | 0.282 | 0.151 | 0.069 | 0.805 | 0.282 |
| 90 % | | **1.22** | 0.889 | 0.322 | 0.113 | 0.061 | 0.028 | 0.322 | 0.113 |
| None | R3 Stream | **12.8** | **9.35** | **3.39** | **1.19** | 0.637 | 0.289 | **3.39** | **1.19** |
| 50 % | | **6.41** | **4.67** | **1.69** | 0.593 | 0.319 | 0.145 | **1.69** | 0.593 |
| 75 % | | **3.21** | **2.34** | 0.846 | 0.297 | 0.159 | 0.072 | 0.846 | 0.297 |
| 90 % | | **1.28** | 0.934 | 0.338 | 0.119 | 0.064 | 0.034 | 0.338 | 0.119 |
| None | R4 Stream | **9.10** | **6.63** | **2.40** | 0.842 | 0.452 | 0.223 | **2.40** | 0.842 |
| 50 % | | **4.55** | **3.32** | **1.20** | 0.421 | 0.226 | 0.223 | **1.20** | 0.421 |
| 75 % | | **2.27** | **1.66** | 0.600 | 0.223 | 0.223 | 0.223 | 0.600 | 0.211 |
| 90 % | | 0.909 | 0.663 | 0.240 | 0.223 | 0.223 | 0.223 | 0.240 | 0.084 |

* 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 9.5-58: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in berries (berries; modelling use vines V -- BBCH 40-69 -- 2×0.15 kg a.s./ha, 21d int.)**

| **Intended use** | | berries | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 2 x 150 g/ha, 21d int. | | | | | | | |
| Nozzle reduction | Vegetated strip (m) | None | None | None | None | None | None | 10 m | 20 m |
| | No spray buffer (m) | 0 m | 5 m | 10 m | 20 m | 30 m | 50 m | 10 m | 20 m |
| None | D6 Ditch | 2.56 | 1.55 | 0.560 | 0.197 | 0.106 | 0.048 | 0.560 | 0.197 |
| 50 % | | 1.28 | 0.774 | 0.280 | 0.098 | 0.053 | 0.024 | 0.280 | 0.098 |
| 75 % | | 0.640 | 0.387 | 0.140 | 0.049 | 0.026 | 0.012 | 0.140 | 0.049 |
| 90 % | | 0.256 | 0.155 | 0.056 | 0.020 | 0.011 | 0.005 | 0.056 | 0.020 |
| None | R1 Pond | *0.124* | *0.144* | *0.079* | *0.040* | *0.025* | *0.014* | *0.079* | *0.039* |
| 50 % | | *0.062* | *0.072* | *0.040* | *0.020* | *0.013* | *0.007* | *0.039* | *0.020* |
| 75 % | | *0.031* | *0.036* | *0.020* | *0.010* | *0.007* | *0.004* | *0.020* | *0.010* |
| 90 % | | *0.013* | *0.015* | *0.008* | *0.004* | *0.003* | *0.002* | *0.008* | *0.004* |
| None | R1 Stream | 1.88 | 1.37 | 0.496 | 0.174 | 0.093 | 0.042 | 0.496 | 0.174 |
| 50 % | | 0.940 | 0.685 | 0.248 | 0.087 | 0.047 | 0.032 | 0.248 | 0.087 |
| 75 % | | 0.470 | 0.342 | 0.124 | 0.044 | 0.032 | 0.032 | 0.124 | 0.044 |
| 90 % | | 0.188 | 0.137 | 0.050 | 0.032 | 0.032 | 0.032 | 0.050 | 0.017 |
| None | R2 Stream | 2.52 | 1.83 | 0.664 | 0.233 | 0.125 | 0.057 | 0.664 | 0.233 |
| 50 % | | 1.26 | 0.917 | 0.332 | 0.116 | 0.063 | 0.028 | 0.332 | 0.116 |
| 75 % | | 0.629 | 0.458 | 0.166 | 0.058 | 0.031 | 0.014 | 0.166 | 0.058 |
| 90 % | | 0.252 | 0.183 | 0.066 | 0.023 | 0.013 | 0.006 | 0.066 | 0.023 |
| None | R3 Stream | 2.66 | 1.94 | 0.701 | 0.246 | 0.132 | 0.060 | 0.701 | 0.246 |
| 50 % | | 1.33 | 0.967 | 0.350 | 0.123 | 0.066 | 0.030 | 0.350 | 0.123 |
| 75 % | | 0.664 | 0.484 | 0.175 | 0.061 | 0.033 | 0.015 | 0.175 | 0.061 |
| 90 % | | 0.266 | 0.193 | 0.070 | 0.025 | 0.013 | 0.006 | 0.070 | 0.025 |
| None | R4 Stream | 1.85 | 1.35 | 0.488 | 0.171 | 0.092 | 0.042 | 0.488 | 0.171 |
| 50 % | | 0.924 | 0.673 | 0.244 | 0.086 | 0.046 | 0.027 | 0.244 | 0.086 |
| 75 % | | 0.462 | 0.337 | 0.122 | 0.043 | 0.027 | 0.027 | 0.122 | 0.043 |
| 90 % | | 0.185 | 0.135 | 0.049 | 0.027 | 0.027 | 0.027 | 0.049 | 0.017 |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D6 Ditch | **9.27** | **5.61** | **2.03** | 0.712 | 0.382 | 0.174 | **2.03** | 0.712 |
| 50 % | | **4.63** | **2.80** | **1.01** | 0.356 | 0.191 | 0.087 | **1.01** | 0.356 |
| 75 % | | **2.32** | **1.40** | 0.507 | 0.178 | 0.096 | 0.043 | 0.507 | 0.178 |
| 90 % | | 0.927 | 0.561 | 0.203 | 0.071 | 0.038 | 0.017 | 0.203 | 0.071 |
| None | R1 Pond | 0.449 | 0.522 | 0.286 | 0.143 | 0.091 | 0.049 | 0.285 | 0.142 |
| 50 % | | 0.225 | 0.261 | 0.143 | 0.072 | 0.046 | 0.025 | 0.143 | 0.071 |
| 75 % | | 0.113 | 0.131 | 0.072 | 0.037 | 0.024 | 0.013 | 0.071 | 0.036 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 90 % | | 0.046 | 0.053 | 0.029 | 0.015 | 0.010 | 0.006 | 0.029 | 0.014 |
| None | R1 Stream | **6.81** | **4.96** | **1.80** | 0.630 | 0.338 | 0.154 | **1.80** | 0.630 |
| 50 % | | **3.41** | **2.48** | 0.898 | 0.315 | 0.169 | 0.117 | 0.898 | 0.315 |
| 75 % | | **1.70** | **1.24** | 0.449 | 0.158 | 0.117 | 0.117 | 0.449 | 0.158 |
| 90 % | | 0.681 | 0.496 | 0.180 | 0.117 | 0.117 | 0.117 | 0.180 | 0.063 |
| None | R2 Stream | **9.12** | **6.64** | **2.41** | 0.843 | 0.453 | 0.206 | **2.41** | 0.843 |
| 50 % | | **4.56** | **3.32** | **1.20** | 0.422 | 0.226 | 0.103 | **1.20** | 0.422 |
| 75 % | | **2.28** | **1.66** | 0.601 | 0.211 | 0.113 | 0.051 | 0.601 | 0.211 |
| 90 % | | 0.912 | 0.664 | 0.241 | 0.084 | 0.045 | 0.021 | 0.241 | 0.084 |
| None | R3 Stream | **9.62** | **7.01** | **2.54** | 0.890 | 0.478 | 0.217 | **2.54** | 0.890 |
| 50 % | | **4.81** | **3.50** | **1.27** | 0.445 | 0.239 | 0.109 | **1.27** | 0.445 |
| 75 % | | **2.41** | **1.75** | 0.635 | 0.222 | 0.120 | 0.054 | 0.635 | 0.222 |
| 90 % | | 0.962 | 0.701 | 0.254 | 0.089 | 0.048 | 0.022 | 0.254 | 0.089 |
| None | R4 Stream | **6.70** | **4.88** | **1.77** | 0.620 | 0.333 | 0.151 | **1.77** | 0.620 |
| 50 % | | **3.35** | **2.44** | 0.883 | 0.310 | 0.166 | 0.099 | 0.883 | 0.310 |
| 75 % | | **1.67** | **1.22** | 0.442 | 0.155 | 0.099 | 0.099 | 0.442 | 0.155 |
| 90 % | | 0.670 | 0.488 | 0.176 | 0.099 | 0.099 | 0.099 | 0.176 | 0.062 |

* 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 9.5-59: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in grapes (grapes; modelling use vines VI -- early, BBCH 15 -- 2×0.05 kg a.s./ha, 14d int.)**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Intended use** | | grapes | | | | | | | |
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 2 x 50 g/ha, 14d int. | | | | | | | |
| 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 | D6 Ditch | 0.840 | 0.508 | 0.184 | 0.065 | 0.184 | 0.065 | | |
| 50 % | | 0.420 | 0.254 | 0.092 | 0.032 | 0.092 | 0.032 | | |
| 75 % | | 0.210 | 0.127 | 0.046 | 0.016 | 0.046 | 0.016 | | |
| 90 % | | 0.084 | 0.051 | 0.018 | 0.007 | 0.018 | 0.007 | | |
| None | R1 Pond | *0.044* | *0.051* | *0.028* | *0.014* | *0.028* | *0.014* | | |
| 50 % | | *0.022* | *0.026* | *0.014* | *0.007* | *0.014* | *0.007* | | |
| 75 % | | *0.011* | *0.013* | *0.007* | *0.004* | *0.007* | *0.004* | | |
| 90 % | | *0.004* | *0.005* | *0.003* | *0.001* | *0.003* | *0.001* | | |
| None | R1 Stream | 0.622 | 0.453 | 0.164 | 0.058 | 0.164 | 0.058 | | |
| 50 % | | 0.311 | 0.227 | 0.082 | 0.029 | 0.082 | 0.029 | | |
| 75 % | | 0.156 | 0.113 | 0.041 | 0.014 | 0.041 | 0.014 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 90 % | | 0.062 | 0.045 | 0.016 | *0.007* | 0.016 | 0.006 | | |
| None | R2 Stream | 0.827 | 0.602 | 0.218 | 0.077 | 0.218 | 0.077 | | |
| 50 % | | 0.413 | 0.301 | 0.109 | 0.038 | 0.109 | 0.038 | | |
| 75 % | | 0.207 | 0.151 | 0.055 | 0.019 | 0.055 | 0.019 | | |
| 90 % | | 0.083 | 0.060 | 0.022 | 0.008 | 0.022 | 0.008 | | |
| None | R3 Stream | 0.880 | 0.641 | 0.232 | 0.081 | 0.232 | 0.081 | | |
| 50 % | | 0.440 | 0.321 | 0.116 | 0.041 | 0.116 | 0.041 | | |
| 75 % | | 0.220 | 0.160 | 0.058 | 0.020 | 0.058 | 0.020 | | |
| 90 % | | 0.088 | 0.064 | 0.023 | 0.008 | 0.023 | 0.008 | | |
| None | R4 Stream | 0.627 | 0.457 | 0.165 | 0.058 | 0.165 | 0.058 | | |
| 50 % | | 0.313 | 0.228 | 0.083 | 0.029 | 0.083 | 0.029 | | |
| 75 % | | 0.157 | 0.114 | 0.041 | *0.024* | 0.041 | 0.015 | | |
| 90 % | | 0.063 | 0.046 | *0.024* | *0.024* | 0.017 | 0.006 | | |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D6 Ditch | **3.04** | **1.84** | 0.666 | 0.234 | 0.666 | 0.234 | | |
| 50 % | | **1.52** | 0.920 | 0.333 | 0.117 | 0.333 | 0.117 | | |
| 75 % | | 0.761 | 0.460 | 0.167 | 0.058 | 0.167 | 0.058 | | |
| 90 % | | 0.304 | 0.184 | 0.067 | 0.024 | 0.067 | 0.024 | | |
| None | R1 Pond | 0.159 | 0.186 | 0.101 | 0.051 | 0.101 | 0.051 | | |
| 50 % | | 0.080 | 0.093 | 0.051 | 0.025 | 0.051 | 0.025 | | |
| 75 % | | 0.040 | 0.046 | 0.025 | 0.013 | 0.025 | 0.013 | | |
| 90 % | | 0.016 | 0.018 | 0.010 | 0.005 | 0.010 | 0.005 | | |
| None | R1 Stream | **2.25** | **1.64** | 0.595 | 0.209 | 0.595 | 0.209 | | |
| 50 % | | **1.13** | 0.821 | 0.297 | 0.104 | 0.297 | 0.104 | | |
| 75 % | | 0.563 | 0.411 | 0.149 | 0.052 | 0.149 | 0.052 | | |
| 90 % | | 0.225 | 0.164 | 0.059 | 0.026 | 0.059 | 0.021 | | |
| None | R2 Stream | **2.99** | **2.18** | 0.790 | 0.277 | 0.790 | 0.277 | | |
| 50 % | | **1.50** | **1.09** | 0.395 | 0.138 | 0.395 | 0.138 | | |
| 75 % | | 0.749 | 0.545 | 0.197 | 0.069 | 0.197 | 0.069 | | |
| 90 % | | 0.299 | 0.218 | 0.079 | 0.028 | 0.079 | 0.028 | | |
| None | R3 Stream | **3.19** | **2.32** | 0.841 | 0.295 | 0.841 | 0.295 | | |
| 50 % | | **1.59** | **1.16** | 0.421 | 0.147 | 0.421 | 0.147 | | |
| 75 % | | 0.797 | 0.581 | 0.210 | 0.074 | 0.210 | 0.074 | | |
| 90 % | | 0.319 | 0.232 | 0.084 | 0.029 | 0.084 | 0.029 | | |
| None | R4 Stream | **2.27** | **1.65** | 0.599 | 0.210 | 0.599 | 0.210 | | |
| 50 % | | **1.14** | 0.827 | 0.300 | 0.105 | 0.300 | 0.105 | | |
| 75 % | | 0.568 | 0.414 | 0.150 | 0.086 | 0.150 | 0.053 | | |
| 90 % | | 0.227 | 0.166 | 0.086 | 0.086 | 0.060 | 0.021 | | |

* 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 9.5-60:** **Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in grapes (grapes; modelling use vines VI -- middle, BBCH 65 -- 2×0.05 kg a.s./ha, 14d int.)**

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Intended use** | | grapes | | | | | | | |
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 2 x 50 g/ha, 14d int. | | | | | | | |
| 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 | D6 Ditch | 0.856 | 0.518 | 0.188 | 0.066 | 0.188 | 0.066 | | |
| 50 % | | 0.428 | 0.259 | 0.094 | 0.033 | 0.094 | 0.033 | | |
| 75 % | | 0.214 | 0.129 | 0.047 | 0.017 | 0.047 | 0.017 | | |
| 90 % | | 0.086 | 0.052 | 0.019 | 0.007 | 0.019 | 0.007 | | |
| None | R1 Pond | *0.045* | *0.052* | *0.028* | *0.015* | *0.028* | *0.014* | | |
| 50 % | | *0.023* | *0.026* | *0.015* | *0.008* | *0.014* | *0.007* | | |
| 75 % | | *0.011* | *0.013* | *0.008* | *0.004* | *0.007* | *0.004* | | |
| 90 % | | *0.005* | *0.006* | *0.003* | *0.002* | *0.003* | *0.002* | | |
| None | R1 Stream | 0.626 | 0.456 | 0.165 | 0.058 | 0.165 | 0.058 | | |
| 50 % | | 0.313 | 0.228 | 0.083 | 0.029 | 0.083 | 0.029 | | |
| 75 % | | 0.157 | 0.114 | 0.041 | 0.015 | 0.041 | 0.015 | | |
| 90 % | | 0.063 | 0.046 | 0.017 | *0.011* | 0.017 | 0.006 | | |
| None | R2 Stream | 0.842 | 0.613 | 0.222 | 0.078 | 0.222 | 0.078 | | |
| 50 % | | 0.421 | 0.307 | 0.111 | 0.039 | 0.111 | 0.039 | | |
| 75 % | | 0.210 | 0.153 | 0.056 | 0.020 | 0.056 | 0.020 | | |
| 90 % | | 0.084 | 0.061 | 0.022 | 0.008 | 0.022 | 0.008 | | |
| None | R3 Stream | 0.885 | 0.645 | 0.234 | 0.082 | 0.234 | 0.082 | | |
| 50 % | | 0.443 | 0.323 | 0.117 | 0.041 | 0.117 | 0.041 | | |
| 75 % | | 0.221 | 0.161 | 0.058 | 0.021 | 0.058 | 0.021 | | |
| 90 % | | 0.089 | 0.065 | 0.023 | 0.008 | 0.023 | 0.008 | | |
| None | R4 Stream | 0.628 | 0.458 | 0.166 | 0.058 | 0.166 | 0.058 | | |
| 50 % | | 0.314 | 0.229 | 0.083 | 0.029 | 0.083 | 0.029 | | |
| 75 % | | 0.157 | 0.114 | 0.041 | 0.015 | 0.041 | 0.015 | | |
| 90 % | | 0.063 | 0.046 | 0.017 | *0.007* | 0.017 | 0.006 | | |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D6 Ditch | **3.10** | **1.88** | 0.679 | 0.238 | 0.679 | 0.238 | | |
| 50 % | | **1.55** | 0.938 | 0.339 | 0.119 | 0.339 | 0.119 | | |
| 75 % | | 0.776 | 0.469 | 0.170 | 0.060 | 0.170 | 0.060 | | |
| 90 % | | 0.310 | 0.188 | 0.068 | 0.024 | 0.068 | 0.024 | | |
| None | R1 Pond | 0.161 | 0.187 | 0.103 | 0.053 | 0.102 | 0.051 | | |
| 50 % | | 0.082 | 0.094 | 0.053 | 0.027 | 0.051 | 0.026 | | |
| 75 % | | 0.041 | 0.048 | 0.027 | 0.014 | 0.026 | 0.013 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 90 % | | 0.018 | 0.020 | 0.012 | 0.007 | 0.011 | 0.005 | | |
| None | R1 Stream | **2.27** | **1.65** | 0.599 | 0.210 | 0.599 | 0.210 | | |
| 50 % | | **1.13** | 0.826 | 0.299 | 0.105 | 0.299 | 0.105 | | |
| 75 % | | 0.567 | 0.413 | 0.150 | 0.053 | 0.150 | 0.053 | | |
| 90 % | | 0.227 | 0.165 | 0.060 | 0.039 | 0.060 | 0.021 | | |
| None | R2 Stream | **3.05** | **2.22** | 0.805 | 0.282 | 0.805 | 0.282 | | |
| 50 % | | **1.53** | **1.11** | 0.403 | 0.141 | 0.403 | 0.141 | | |
| 75 % | | 0.762 | 0.555 | 0.201 | 0.071 | 0.201 | 0.071 | | |
| 90 % | | 0.305 | 0.222 | 0.080 | 0.028 | 0.080 | 0.028 | | |
| None | R3 Stream | **3.21** | **2.34** | 0.846 | 0.297 | 0.846 | 0.297 | | |
| 50 % | | **1.60** | **1.17** | 0.423 | 0.149 | 0.423 | 0.149 | | |
| 75 % | | 0.802 | 0.584 | 0.212 | 0.074 | 0.212 | 0.074 | | |
| 90 % | | 0.321 | 0.234 | 0.085 | 0.030 | 0.085 | 0.030 | | |
| None | R4 Stream | **2.28** | **1.66** | 0.600 | 0.211 | 0.600 | 0.211 | | |
| 50 % | | **1.14** | 0.829 | 0.300 | 0.105 | 0.300 | 0.105 | | |
| 75 % | | 0.569 | 0.414 | 0.150 | 0.053 | 0.150 | 0.053 | | |
| 90 % | | 0.228 | 0.166 | 0.060 | 0.024 | 0.060 | 0.021 | | |

* 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 9.5-61: Aquatic organisms: PECsw calculation and acceptability of risk (PEC/RAC < 1) for trifloxystrobin based on FOCUS Step 4 calculations and toxicity data for invertebrates prolonged with mitigation of spray drift and run-off for the use of FLU+TFS SC 500 in grapes (grapes; modelling use vines VI -- late, BBCH 85 -- 2×0.05 kg a.s./ha, 14d int.)**

| **Intended use** | | grapes | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Active substance** | | trifloxystrobin | | | | | | | |
| **Application rate (g/ha)** | | 2 x 50 g/ha, 14d int. | | | | | | | |
| 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 | D6 Ditch | 0.856 | 0.518 | 0.188 | 0.066 | 0.188 | 0.066 | | |
| 50 % | | 0.428 | 0.259 | 0.094 | 0.033 | 0.094 | 0.033 | | |
| 75 % | | 0.214 | 0.129 | 0.047 | 0.017 | 0.047 | 0.017 | | |
| 90 % | | 0.086 | 0.052 | 0.019 | 0.007 | 0.019 | 0.007 | | |
| None | R1 Pond | *0.039* | *0.046* | *0.025* | *0.012* | *0.025* | *0.012* | | |
| 50 % | | *0.020* | *0.023* | *0.012* | *0.006* | *0.012* | *0.006* | | |
| 75 % | | *0.010* | *0.011* | *0.006* | *0.003* | *0.006* | *0.003* | | |
| 90 % | | *0.004* | *0.005* | *0.003* | *0.001* | *0.003* | *0.001* | | |
| None | R1 Stream | 0.628 | 0.458 | 0.166 | 0.058 | 0.166 | 0.058 | | |
| 50 % | | 0.314 | 0.229 | 0.083 | 0.029 | 0.083 | 0.029 | | |
| 75 % | | 0.157 | 0.114 | 0.041 | 0.015 | 0.041 | 0.015 | | |
| 90 % | | 0.063 | 0.046 | 0.017 | 0.006 | 0.017 | 0.006 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| None | R2 Stream | 0.842 | 0.613 | 0.222 | 0.078 | 0.222 | 0.078 | | |
| 50 % | | 0.421 | 0.307 | 0.111 | 0.039 | 0.111 | 0.039 | | |
| 75 % | | 0.210 | 0.153 | 0.056 | 0.020 | 0.056 | 0.020 | | |
| 90 % | | 0.084 | 0.061 | 0.022 | 0.008 | 0.022 | 0.008 | | |
| None | R3 Stream | 0.885 | 0.645 | 0.234 | 0.082 | 0.234 | 0.082 | | |
| 50 % | | 0.443 | 0.323 | 0.117 | 0.041 | 0.117 | 0.041 | | |
| 75 % | | 0.221 | 0.161 | 0.058 | 0.021 | 0.058 | 0.021 | | |
| 90 % | | 0.089 | 0.065 | 0.023 | 0.012 | 0.023 | 0.008 | | |
| None | R4 Stream | 0.628 | 0.458 | 0.166 | 0.058 | 0.166 | 0.058 | | |
| 50 % | | 0.314 | 0.229 | 0.083 | 0.029 | 0.083 | 0.029 | | |
| 75 % | | 0.157 | 0.114 | 0.041 | 0.015 | 0.041 | 0.015 | | |
| 90 % | | 0.063 | 0.046 | 0.017 | *0.012* | 0.017 | 0.006 | | |
| **RAC (µg/L)** | **0.276** | **PEC / RAC ratio** | | | | | | | |
| None | D6 Ditch | **3.10** | **1.88** | 0.679 | 0.238 | 0.679 | 0.238 | | |
| 50 % | | **1.55** | 0.938 | 0.339 | 0.119 | 0.339 | 0.119 | | |
| 75 % | | 0.776 | 0.469 | 0.170 | 0.060 | 0.170 | 0.060 | | |
| 90 % | | 0.310 | 0.188 | 0.068 | 0.024 | 0.068 | 0.024 | | |
| None | R1 Pond | 0.142 | 0.165 | 0.090 | 0.045 | 0.090 | 0.045 | | |
| 50 % | | 0.071 | 0.083 | 0.045 | 0.022 | 0.045 | 0.022 | | |
| 75 % | | 0.036 | 0.041 | 0.022 | 0.011 | 0.022 | 0.011 | | |
| 90 % | | 0.014 | 0.016 | 0.009 | 0.004 | 0.009 | 0.004 | | |
| None | R1 Stream | **2.28** | **1.66** | 0.600 | 0.211 | 0.600 | 0.211 | | |
| 50 % | | **1.14** | 0.829 | 0.300 | 0.105 | 0.300 | 0.105 | | |
| 75 % | | 0.569 | 0.414 | 0.150 | 0.053 | 0.150 | 0.053 | | |
| 90 % | | 0.228 | 0.166 | 0.060 | 0.021 | 0.060 | 0.021 | | |
| None | R2 Stream | **3.05** | **2.22** | 0.805 | 0.282 | 0.805 | 0.282 | | |
| 50 % | | **1.53** | **1.11** | 0.403 | 0.141 | 0.403 | 0.141 | | |
| 75 % | | 0.762 | 0.555 | 0.201 | 0.071 | 0.201 | 0.071 | | |
| 90 % | | 0.305 | 0.222 | 0.080 | 0.028 | 0.080 | 0.028 | | |
| None | R3 Stream | **3.21** | **2.34** | 0.846 | 0.297 | 0.846 | 0.297 | | |
| 50 % | | **1.60** | **1.17** | 0.423 | 0.149 | 0.423 | 0.149 | | |
| 75 % | | 0.802 | 0.584 | 0.212 | 0.074 | 0.212 | 0.074 | | |
| 90 % | | 0.321 | 0.234 | 0.085 | 0.043 | 0.085 | 0.030 | | |
| None | R4 Stream | **2.28** | **1.66** | 0.600 | 0.211 | 0.600 | 0.211 | | |
| 50 % | | **1.14** | 0.829 | 0.300 | 0.105 | 0.300 | 0.105 | | |
| 75 % | | 0.569 | 0.414 | 0.150 | 0.053 | 0.150 | 0.053 | | |
| 90 % | | 0.228 | 0.166 | 0.060 | 0.044 | 0.060 | 0.021 | | |

* 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

**Trifloxystrobin metabolites**

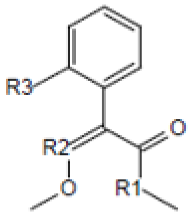
The following tables present the risk assessments for trifloxystrobin metabolites based on Focus Step 1 to 3 $PEC_{sw}$ and also include some refinement options when necessary as explained below.

According to the LoEP, the following metabolites require further assessment for surface water: CGA 357261, CGA 321113, CGA 373466, CGA 381318, NOA 413161, NOA 413163, CGA 357276, NOA 409480, CGA 357262, CGA 107170.

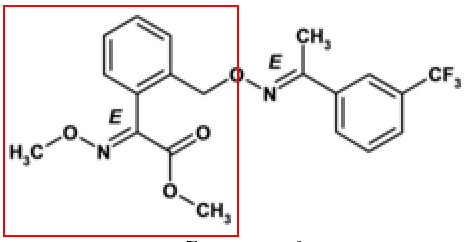
The approach for metabolite risk assessment refers to part 10.2.4 decision scheme of the Aquatic Guidance Document (EFSA:3290 (2013)). The decision scheme is followed step by step.

**Step 1:** None of the studies with the active substance is adequate for assessing the potential effect of the metabolites: ⇨ step 3.

**Step 3:** As mentioned in the Aquatic Guidance Document, toxophores for major classes of PPP have been identified (Sinclair, 2009; M-551653-01-1, Appendix 2), for strobilurins, it is:




strobilurin analogue




Trifloxystrobin

On this basis, it is considered that metabolites CGA 357261 and CGA 357262 still contain the toxophore (⇨ step 4). The other metabolites (CGA 373466, CGA 321113, CGA 381318, CGA 357276, CGA 107170, NOA 413161, NOA 413163 and NOA 409480) have lost the toxophore (⇨ step 6).

**Step 4:** Identify the species or taxonomic group determining the lowest tier 1 RACsw,ac for the active substance. Is the acute metabolite $L(E)C_{50}$ > 10 times the a.s. $L(E)C_{50}$ (on a molar basis)?
Trifloxystrobin $E(L)C_{50}$ for fish, daphnia and algae are very similar, therefore it is proposed that the comparison is made for these 3 taxonomic groups, when possible. The active substance and the 2 metabolites CGA 357261 and CGA 357262 have the same molecular weight so a direct comparison of the endpoints is possible.

This approach shows that the lowest factor is 60 between parent and CGA 357261 (acute fish toxicity ratio) and it is greater than 100 for CGA 357262 for all 3 taxonomic groups (⇨ step 6).

| | Species | Endpoint | Ratio TFS/Metabolite |
|---|---|---|---|
| **Trifloxystrobin** | Acute fish (*O. mykiss*) | 0.015 mg a.s./L | - |
| **CGA 357261** | Acute fish (*O. mykiss*) | 0.9 mg p.m./L | 60 |
| **CGA 357262** | Acute fish (*O. mykiss*) | 5.51 mg p.m./L | 367 |

**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.

**As a conclusion**: For all metabolites, except CGA 381318 (see paragraph below), the first step of the risk assessment will address all taxonomic groups with parent endpoints when no study was performed with the metabolite. For metabolite CGA 381318 no test data are available. This metabolite is a stereoisomer of CGA 373466. Therefore, as a refinement option it is proposed to use the data set of the latter rather than parent data. This is still a conservative assumption because a decrease of toxicity is observed from isomer EE (parent) to EZ (CGA 357261) to ZZ (CGA 357262). CGA 381318 is the ZZ isomer of CGA 357466 which has very limited effects on aquatic organisms:

| Metabolite | Type of organisms | Acute endpoint (mg/L) | NOEC (mg/L) |
|---|---|---|---|
| CGA 381318 | Fish | 200 (read across) | > 2 (read across) |
| | *Daphnia magna* | 100 (read across) | > 2 (read across) |
| | *D. subspicatus* | - | 100 (read across) |

**<u>Refinement options for chronic risk assessment of metabolites</u>**

The tier 1 risk assessment is based on parent endpoints as explained previously. According to the aquatic guidance document, non-testing approaches can be applied to metabolites without the toxophore of the parent. The availability of QSAR for fish and daphnia chronic endpoints of trifloxystrobin metabolites has been checked; it was concluded that the properties of these metabolites would not be accurately reflected by models due to their complex chiral structures.

Alternatively, it is proposed to apply a simple acute to chronic ratio (ACR) approach. The ratios to be applied on acute fish endpoints are based on the most recent publications of Kienzler et al. (2017) and May et al. (2016), for daphnia, the publication of May et al. (2016) and Ahlers et al. (2006) were used. Other older works were also considered but not taken into account because of different approaches used in the evaluation and/or more limited data sets.

**ACR for fish:**

Both publications present calculations of the ACR based on the mode of action of the chemical of interest on fish. All trifloxystrobin metabolites belong to MoA 5 (according to the modified Verhaar scheme classification tool of ToxTree), i.e. "not possible to classify". As a conservative approach, the 90$^{th}$ percentile of the ACR is used in this assessment. The different ACR are presented in the table below.

| ACR type | ACR value (90$^{th}$ percentile) | Number of values considered to derive the ACR | Reference |
|---|---|---|---|
| Chemicals and pesticides, all fish species and test types | 102.4 | 192 | Appendix 2<br>May et al, 2016<br>M-634484-01-1 |
| Chemicals, all fish species and test types | 68.0 | 122 | |
| Pesticides, all fish species and test types | 120.1 | 70 | |
| Based on ELS studies only, for chemicals, different species included | 96.6 | 99 | |
| Based on ELS studies only, for chemicals, same species only | 63.5 | 63 | |

| | | | |
|---|---|---|---|
| For substances with MoA 5, all fish species and test types | 39.1 | 30 | |
| Organic chemicals (including pesticides) | 70.9<br>92.9% have an ACR < 100 | 240 | Appendix 2<br>Kienzler et al, 2017<br>M-632126-01-1 |
| Organic chemicals (including pesticides) with MoA 5 | Not reported<br>94.4% have an ACR < 100 | 54 | |

Trifloxystrobin metabolites are not considered as pesticides because they have lost the toxophore of the parent therefore ACR based on pesticides only are not considered further. Based on the remaining ACR, it is proposed to select an ACR of 100 because it will be protective for 94.4% of organic chemicals with a MoA 5 and it is very similar to the ACR of 96.6 based on ELS only tests which is the required test for chronic assessment of pesticides.

**ACR for daphnia:**

Less ACR types are available for daphnia because the data set is based on one species and one chronic test type only, the 21-d daphnia reproduction test.

| ACR type | ACR value (90th percentile) | Number of values considered to derive the ACR | Reference |
|---|---|---|---|
| Chemicals and pesticides | 76.5 | 199 | Appendix 2<br>May et al, 2016<br>M-634484-01-1 |
| Chemicals | 50.2 | 130 | |
| Pesticides | 109.4 | 69 | |
| Industrial chemicals | 41.5 | 102 | Appendix 2<br>Ahlers et al, 2006<br>M-634467-01-1 |

An ACR of 50 is proposed for daphnia because trifloxystrobin metabolites are not considered as pesticides.

For metabolite NOA 408480, the ACR for chronic invertebrates is based on the ACR of the metabolite CGA 357276 because both metabolites display a nitrile group. The ACR for CGA 357276 is 200 (0.514/0.00259) so the NOEC for NOA 408480 is 0.011 mg/L (2.25/200).

The following table summarizes the relevant endpoints for the chronic risk assessment of trifloxystrobin metabolites.

**ACR based endpoints used for chronic risk assessment of metabolites:**

| Metabolite | Type of organisms | Acute endpoint (mg/L) | ACR | ACR based NOEC (mg/L) |
|---|---|---|---|---|
| NOA 413161 | Fish | > 100 | 100 | > 1 |
| | *Daphnia magna* | > 100 | 50 | > 2 |
| CGA 357261 | Fish | 0.9 | 100 | 0.009 |
| CGA 373466 | Fish | > 200 | 100 | > 2 |
| | *Daphnia magna* | > 100 | 50 | > 2 |
| NOA 413163 | Fish | > 100 | 100 | > 1 |
| | *Daphnia magna* | > 100 | 50 | > 2 |
| CGA 357262 | Fish | > 5.51 | 100 | > 0.0551 |
| | *Daphnia magna* | > 2.24 | 50 | > 0.0448 |
| CGA 107170 | Fish | 13.6 | 100 | 0.136 |
| | *Daphnia magna* | 10.7 | 50 | 0.214 |
| CGA 357276 | Fish | 0.983 | 100 | 0.00983 |
| NOA 409480 | *Daphnia magna* | 2.25 | 200 | 0.011 |

The risk assessment for trifloxystrobin is considered to provide a risk envelope for the metabolites. To present the risk assessment for the ten metabolites in a clearly arranged way, only the worst-case FOCUS step 1/2 exposure scenario is presented for each of the metabolites. In case this risk assessment fails, the complete risk assessment using FOCUS step 3 PEC values is presented.

**zRMS comment:**

In Registratio Report for ppp Twist the zRMS-FR ( available on Circa Platform) provided the following conclusion of the risk assessment for TFS metabolites:
zRMS FR:
„zRMS agrees that the toxophore is still present for CGA 357261 and CGA 357262 and is lost for CGA 357276, CGA 107170 and NOA 409480. However, the loss of the toxophore for CGA 321113, NOA 413161, CGA 373466, NOA 413163 and CGA 381318 is questionable given the high structural similarity of these metabolites to trifloxystrobin and to the strobilurin analogue toxophore presented above. Nevertheless, except **for CGA 381318** for which no toxicity data is available, toxicity data for these metabolites show lower toxicities on sensitive species compared to parent/active substance or even to metabolites that had lost the toxophore. For CGA 381318 for which no toxicity data is available, considering that it is an intermediate metabolite between CGA 357262 and NOA 409 480 and/or an isomer of CGA 373466, three metabolites for wich lower toxicities compared to parent/active substance were measured, an increase of toxicity seems unlikely.
Overall, considering all metabolites data, the lowest toxicity factor calculated is 26 between parent/active substance and CGA 357276 on a molar basis (based on acute daphnia endpoints). Therefore, it is zRMS opinion that given the overall lower toxicity of metabolites compared to parent trifloxydtrobin, the acute and chronic risk assessment for trifloxystrobin metabolites can be considered covered by the risk assessment conducted for the active substance''.
Nevertheless, for transparency and in case that some MS would accept the applicant 's proposal as a refinement, the risk assessment initially presented by applicant for metabolites is presented is presented below:

**FOCUS Step 1/2 risk assessment**

### 9.5.2.1 Metabolite CGA 321113

**Table 9.5-62: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 321113 for each organism group based on FOCUS Steps 1, 2 calculations for the use of FLU+TFS SC 500 in chokeberry, elderberry and tree nursery (chokeberry, elderberry, tree nursery; modelling use Pome and stone fruit 2x200 g/ha -- BBCH 12-91, early -- 2×200g a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Sed. dwell. prolonged** | **Algae** | | **Sed. dwell. prolonged** | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Chironomus riparius*** | ***Pseudokirchneriella subcapitata*** | | ***Lumbriculus variegatus*** | | |
| **Endpoint**<br><br>**(µg/L)** | | **$LC_{50}$**<br><br>**> 106000** | **NOEC**<br><br>**> 100000** | **$EC_{50}$**<br><br>**38000** | **NOEC**<br><br>**9920** | **NOEC**<br><br>**25000** | **$E_rC_{50}$**<br><br>**> 100000** | | **NOEC**<br><br>**98400 (µg/kg)** | | |
| **AF** | | **100** | **10** | **100** | **10** | **10** | **10** | | **10** | | |
| **RAC (µg/L)** | | **> 1060** | **> 10000** | **380** | **992** | **2500** | **> 10000** | | **9840 (µg/kg)** | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | **PEC $_{gl-max}$ (µg/kg)** | | | |
| **Step 1** | | | | | | | | | | | |
| - - | 257 | 0.242 | 0.026 | 0.676 | 0.259 | 0.103 | 0.026 | 292 | 0.030 | | |
| **Step 2** | | | | | | | | | | | |
| Northern Europe Mar. - May(Spring | 45.0 | 0.042 | 0.004 | 0.118 | 0.045 | 0.018 | 0.004 | 50.6 | 0.005 | | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| ) | | | | | | | | | | | |
| Southern Europe Mar. - May(Spring ) | 60.5 | 0.057 | 0.006 | 0.159 | 0.061 | 0.024 | 0.006 | 68.7 | 0.007 | | |

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

### 9.5.2.2 Metabolite NOA 413161

**Table 9.5-63: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for NOA 413161 for each organism group based on FOCUS Steps 1, 2 calculations for the use of FLU+TFS SC 500 in flower bulbs (flower bulbs; modelling use VegBulb II -- VegBulb II (Aut) -- 5×75g a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ > 100000** | **NOEC (parent) 4.3** | **NOEC (ACR) > 1000** | **$EC_{50}$ > 100000** | **NOEC (parent) 2.76** | **NOEC (ACR) > 2000** | **$E_rC_{50}/E_yC_{50}$ > 100000** | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | **10** | | | |
| **RAC (µg/L)** | | **> 1000** | **0.43** | **> 100** | **> 1000** | **0.276** | **> 200** | **> 10000** | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 1** | | | | | | | | | | | |
| - - | 17.6 | 0.018 | **40.9** | 0.176 | 0.018 | **63.7** | 0.088 | 0.002 | | | |
| **Step 2** | | | | | | | | | | | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Northern Europe Oct. - Feb.(Autumn) | 5.70 | 0.006 | **13.3** | 0.057 | 0.006 | **20.7** | 0.029 | 0.001 | | | |
| Southern Europe Oct. - Feb.(Autumn) | 4.56 | 0.005 | **10.6** | 0.046 | 0.005 | **16.5** | 0.023 | <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

### 9.5.2.3 Metabolite NOA 413161

**Table 9.5-64: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for NOA 413161 for each organism group based on FOCUS Steps 1, 2 calculations for the use of FLU+TFS SC 500 in chokeberry, elderberry and tree nursery (chokeberry, elderberry, tree nursery; modelling use Pome and stone fruit 2x200 g/ha -- BBCH 12-91, early -- 2×200g a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ > 100000** | **NOEC (parent) 4.3** | **NOEC (ACR) > 1000** | **$EC_{50}$ > 100000** | **NOEC (parent) 2.76** | **NOEC (ACR) > 2000** | **$E_rC_{50}$/$E_yC_{50}$ > 100000** | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | **10** | | | |
| **RAC (µg/L)** | | **> 1000** | **0.43** | **> 100** | **> 1000** | **0.276** | **> 200** | **> 10000** | | | |
| **FOCUS Scenario** | **$PEC_{gl\text{-}max}$ (µg/L)** | | | | | | | | | | |
| **Step 1** | | | | | | | | | | | |
| - - | 18.8 | 0.019 | **43.6** | 0.188 | 0.019 | **68.0** | 0.094 | 0.002 | | | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Step 2** | | | | | | | | | | | |
| Northern Europe Mar. - May(Spring) | 2.60 | 0.003 | **6.06** | 0.026 | 0.003 | **9.44** | 0.013 | <0.001 | | | |
| Southern Europe Mar. - May(Spring) | 5.21 | 0.005 | **12.1** | 0.052 | 0.005 | **18.9** | 0.026 | 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

### 9.5.2.4 Metabolite CGA 357261

**Table 9.5-65: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357261 for each organism group based on FOCUS Steps 1, 2 calculations for the use of FLU+TFS SC 500 in chokeberry, elderberry and tree nursery (chokeberry, elderberry, tree nursery; modelling use Pome and stone fruit 2x200 g/ha -- BBCH 12-91, early -- 2×200g a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Desmodesmus subspicatus*** | | | | |
| **Endpoint**<br><br>**(µg/L)** | | **$LC_{50}$**<br><br>**900** | **NOEC (parent)**<br><br>**4.3** | **NOEC (ACR)**<br><br>**9** | **$EC_{50}$**<br><br>**> 2660** | **NOEC**<br><br>**101** | **$E_rC_{50}/E_yC_{50}$**<br><br>**> 2720** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9** | **0.43** | **0.9** | **> 26.6** | **10.1** | **> 272** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 1** | | | | | | | | | | | |
| - - | 32.6 | **3.62** | **75.8** | **36.2** | **1.23** | **3.23** | 0.120 | | | | |
| **Step 2** | | | | | | | | | | | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Northern Europe Mar. - May(Spring) | 14.9 | **1.65** | **34.6** | **16.5** | 0.559 | **1.47** | 0.055 | | | | |
| Southern Europe Mar. - May(Spring) | 14.9 | **1.65** | **34.6** | **16.5** | 0.559 | **1.47** | 0.055 | | | | |

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

### 9.5.2.5 Metabolite CGA 373466

**Table 9.5-66: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 373466 for each organism group based on FOCUS Steps 1, 2 calculations for the use of FLU+TFS SC 500 in chokeberry, elderberry and tree nursery (chokeberry, elderberry, tree nursery; modelling use Pome and stone fruit 2x200 g/ha -- BBCH 12-91, early -- 2×200g a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Desmodesmus subspicatus*** | | | |
| **Endpoint** <br> **(µg/L)** | | **$LC_{50}$** <br> **> 200000** | **NOEC (parent)** <br> **4.3** | **NOEC (ACR)** <br> **> 2000** | **$EC_{50}$** <br> **> 100000** | **NOEC (parent)** <br> **2.76** | **NOEC (ACR)** <br> **> 2000** | **$E_rC_{50}/E_yC_{50}$** <br> **> 100000** | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | **10** | | | |
| **RAC (µg/L)** | | **> 2000** | **0.43** | **> 200** | **> 1000** | **0.276** | **> 200** | **> 10000** | | | |
| **FOCUS Scenario** | **PEC $_{gl\text{-}max}$ (µg/L)** | | | | | | | | | | |
| **Step 1** | | | | | | | | | | | |
| - - | 118 | 0.059 | **274** | 0.589 | 0.118 | **427** | 0.589 | 0.012 | | | |
| **Step 2** | | | | | | | | | | | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Northern Europe Mar. - May(Spring) | 19.9 | 0.010 | **46.2** | 0.099 | 0.020 | **71.9** | 0.099 | 0.002 | | | |
| Southern Europe Mar. - May(Spring) | 26.2 | 0.013 | **60.9** | 0.131 | 0.026 | **94.9** | 0.131 | 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

### 9.5.2.6 Metabolite NOA 413163

**Table 9.5-67: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for NOA 413163 for each organism group based on FOCUS Steps 1, 2 calculations for the use of FLU+TFS SC 500 in flower bulbs (flower bulbs; modelling use VegBulb II -- VegBulb II (Aut) -- 5×75g a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | |
| **Endpoint** (µg/L) | | **$LC_{50}$** > 100000 | **NOEC (parent)** 4.3 | **NOEC (ACR)** > 1000 | **$EC_{50}$** > 100000 | **NOEC (parent)** 2.76 | **NOEC (ACR)** > 2000 | **$E_rC_{50}$/$E_yC_{50}$** > 100000 | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | **10** | | | |
| **RAC (µg/L)** | | **> 1000** | **0.43** | **> 100** | **> 1000** | **0.276** | **> 200** | **> 10000** | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 1** | | | | | | | | | | | |
| - - | 7.73 | 0.008 | **18.0** | 0.077 | 0.008 | **28.0** | 0.039 | 0.001 | | | |
| **Step 2** | | | | | | | | | | | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Northern Europe Oct. - Feb.(Autumn) | 2.61 | 0.003 | **6.08** | 0.026 | 0.003 | **9.47** | 0.013 | <0.001 | | | |
| Southern Europe Oct. - Feb.(Autumn) | 2.09 | 0.002 | **4.86** | 0.021 | 0.002 | **7.58** | 0.010 | <0.001 | | | |

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

### 9.5.2.7 Metabolite NOA 413163

**Table 9.5-68: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for NOA 413163 for each organism group based on FOCUS Steps 1, 2 calculations for the use of FLU+TFS SC 500 in chokeberry, elderberry and tree nursery (chokeberry, elderberry, tree nursery; modelling use Pome and stone fruit 2x200 g/ha -- BBCH 12-91, early -- 2×200g a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ > 100000** | **NOEC (parent) 4.3** | **NOEC (ACR) > 1000** | **$EC_{50}$ > 100000** | **NOEC (parent) 2.76** | **NOEC (ACR) > 2000** | **$E_rC_{50}$/$E_yC_{50}$ > 100000** | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | **10** | | | |
| **RAC (µg/L)** | | **> 1000** | **0.43** | **> 100** | **> 1000** | **0.276** | **> 200** | **> 10000** | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 1** | | | | | | | | | | | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| - - | 8.25 | 0.008 | **19.2** | 0.082 | 0.008 | **29.9** | 0.041 | 0.001 | | | |
| **Step 2** | | | | | | | | | | | |
| Northern Europe Mar. - May(Spring) | 1.17 | 0.001 | **2.71** | 0.012 | 0.001 | **4.23** | 0.006 | <0.001 | | | |
| Southern Europe Mar. - May(Spring) | 2.33 | 0.002 | **5.43** | 0.023 | 0.002 | **8.45** | 0.012 | <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

### 9.5.2.8 Metabolite CGA 357262

**Table 9.5-69: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357262 for each organism group based on FOCUS Steps 1, 2 calculations for the use of FLU+TFS SC 500 in chokeberry, elderberry and tree nursery (chokeberry, elderberry, tree nursery; modelling use Pome and stone fruit 2x200 g/ha -- BBCH 12-91, early -- 2×200g a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | |
| **Endpoint**<br><br>**(µg/L)** | | **$LC_{50}$**<br><br>**> 5510** | **NOEC (parent)**<br><br>**4.3** | **NOEC (ACR)**<br><br>**> 55.1** | **$EC_{50}$**<br><br>**> 2240** | **NOEC (parent)**<br><br>**2.76** | **NOEC (ACR)**<br><br>**> 44.8** | **$E_rC_{50}$/$E_yC_{50}$**<br><br>**> 2650** | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | **10** | | | |
| **RAC (µg/L)** | | **> 55.1** | **0.43** | **> 5.51** | **> 22.4** | **0.276** | **> 4.48** | **> 265** | | | |
| **FOCUS Scenario** | **$PEC_{gl\text{-}max}$ (µg/L)** | | | | | | | | | | |
| **Step 1** | | | | | | | | | | | |
| - - | 3.93 | 0.071 | **9.14** | 0.714 | 0.176 | **14.2** | 0.878 | 0.015 | | | |

| **Step 2** | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Northern Europe Mar. - May(Spring) | 3.43 | 0.062 | **7.98** | 0.623 | 0.153 | **12.4** | 0.766 | 0.013 | | | |
| Southern Europe Mar. - May(Spring) | 3.43 | 0.062 | **7.98** | 0.623 | 0.153 | **12.4** | 0.766 | 0.013 | | | |

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

### 9.5.2.9 Metabolite CGA 107170

**Table 9.5-70: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 107170 for each organism group based on FOCUS Steps 1, 2 calculations for the use of FLU+TFS SC 500 in chokeberry, elderberry and tree nursery (chokeberry, elderberry, tree nursery; modelling use Pome and stone fruit 2x200 g/ha -- BBCH 12-91, early -- 2×200g a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Desmodesmus subspicatus*** | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 13600** | **NOEC (parent) 4.3** | **NOEC (ACR) 136** | **$EC_{50}$ 10700** | **NOEC (parent) 2.76** | **NOEC (ACR) 214** | **$E_rC_{50}/E_yC_{50}$ 13900** | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | **10** | | | |
| **RAC (µg/L)** | | **136** | **0.43** | **13.6** | **107** | **0.276** | **21.4** | **1390** | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 1** | | | | | | | | | | | |
| - - | 41.3 | 0.304 | **96.1** | **3.04** | 0.386 | **150** | **1.93** | 0.030 | | | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Step 2** | | | | | | | | | | | |
| Northern Europe Mar. - May(Spring) | 8.15 | 0.060 | **18.9** | 0.599 | 0.076 | **29.5** | 0.381 | 0.006 | | | |
| Southern Europe Mar. - May(Spring) | 8.15 | 0.060 | **18.9** | 0.599 | 0.076 | **29.5** | 0.381 | 0.006 | | | |

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

### 9.5.2.10 Metabolite NOA 409480

**Table 9.5-71: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for NOA 409480 for each organism group based on FOCUS Steps 1, 2 calculations for the use of FLU+TFS SC 500 in flower bulbs (flower bulbs; modelling use VegBulb II -- VegBulb II (Aut) -- 5×75g a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 1920** | **NOEC (parent) 4.3** | **$EC_{50}$ 2250** | **NOEC (parent) 2.76** | **NOEC (ACR) 11** | **$E_rC_{50}$/$E_yC_{50}$ > 2020** | | | | |
| **AF** | | **100** | **10** | **100** | **10** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **19.2** | **0.43** | **22.5** | **0.276** | **1.1** | **> 202** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 1** | | | | | | | | | | | |
| - - | 2.19 | 0.114 | **5.10** | 0.097 | **7.95** | **1.99** | 0.011 | | | | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Step 2** | | | | | | | | | | | |
| Northern Europe Oct. - Feb.(Autumn) | 0.746 | 0.039 | **1.73** | 0.033 | **2.70** | 0.678 | 0.004 | | | | |
| Southern Europe Oct. - Feb.(Autumn) | 0.597 | 0.031 | **1.39** | 0.027 | **2.16** | 0.543 | 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

### 9.5.2.11 Metabolite NOA 409480

**Table 9.5-72: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for NOA 409480 for each organism group based on FOCUS Steps 1, 2 calculations for the use of FLU+TFS SC 500 in chokeberry, elderberry and tree nursery (chokeberry, elderberry, tree nursery; modelling use Pome and stone fruit 2x200 g/ha -- BBCH 12-91, early -- 2×200g a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 1920** | **NOEC (parent) 4.3** | **$EC_{50}$ 2250** | **NOEC (parent) 2.76** | **NOEC (ACR) 11** | **$E_rC_{50}/E_yC_{50}$ > 2020** | | | | |
| **AF** | | **100** | **10** | **100** | **10** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **19.2** | **0.43** | **22.5** | **0.276** | **1.1** | **> 202** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 1** | | | | | | | | | | | |
| - - | 2.34 | 0.122 | **5.44** | 0.104 | **8.48** | **2.13** | 0.012 | | | | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Step 2 | | | | | | | | | | | |
| Northern Europe Mar. - May(Spring) | 0.332 | 0.017 | 0.772 | 0.015 | **1.20** | 0.302 | 0.002 | | | | |
| Southern Europe Mar. - May(Spring) | 0.664 | 0.035 | **1.54** | 0.030 | **2.41** | 0.604 | 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

### 9.5.2.12 Metabolite CGA 357276

**Table 9.5-73: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357276 for each organism group based on FOCUS Steps 1, 2 calculations for the use of FLU+TFS SC 500 in chokeberry, elderberry and tree nursery (chokeberry, elderberry, tree nursery; modelling use Pome and stone fruit 2x200 g/ha -- BBCH 12-91, early -- 2×200g a.s./ha, 7d int.)**

| Group | | Fish acute | Fish prolonged | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Test species | | *Oncorhynchus mykiss* | *Oncorhynchus mykiss* | *Fish prolonged* | *Daphnia magna* | *Daphnia magna* | *Pseudokirchneriella subcapitata* | | | | |
| Endpoint<br><br>(µg/L) | | $LC_{50}$<br><br>983 | NOEC (parent)<br><br>4.3 | NOEC (ACR)<br><br>9.83 | $EC_{50}$<br><br>514 | NOEC<br><br>2.59 | $E_rC_{50}/E_yC_{50}$<br><br>> 5880 | | | | |
| AF | | 100 | 10 | 10 | 100 | 10 | 10 | | | | |
| RAC (µg/L) | | 9.83 | 0.43 | 0.983 | 5.14 | 0.259 | > 588 | | | | |
| FOCUS Scenario | PEC $_{gl-max}$ (µg/L) | | | | | | | | | | |
| Step 1 | | | | | | | | | | | |
| - - | 4.57 | 0.465 | **10.6** | **4.65** | 0.889 | **17.6** | 0.008 | | | | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Step 2** | | | | | | | | | | | |
| Northern Europe Mar. - May(Spring) | 1.58 | 0.161 | **3.67** | **1.61** | 0.307 | **6.09** | 0.003 | | | | |
| Southern Europe Mar. - May(Spring) | 1.58 | 0.161 | **3.67** | **1.61** | 0.307 | **6.09** | 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

### 9.5.2.13 Metabolite CGA 381318

**Table 9.5-74: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 381318 for each organism group based on FOCUS Steps 1, 2 calculations for the use of FLU+TFS SC 500 in chokeberry, elderberry and tree nursery (chokeberry, elderberry, tree nursery; modelling use Pome and stone fruit 2x200 g/ha -- BBCH 12-91, early -- 2×200g a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Desmodesmus subspicatus*** | | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ (read across) > 200000** | **NOEC (read across) > 2000** | **$EC_{50}$ (read across) > 100000** | **NOEC (read across) > 2000** | **$E_rC_{50}$/$E_yC_{50}$ (read across) > 100000** | | | | | |
| **AF** | | **100** | **10** | **100** | **10** | **10** | | | | | |
| **RAC (µg/L)** | | **> 2000** | **> 200** | **> 1000** | **> 200** | **> 10000** | | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 1** | | | | | | | | | | | |
| - - | 7.24 | 0.004 | 0.036 | 0.007 | 0.036 | 0.001 | | | | | |
| **Step 2** | | | | | | | | | | | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Northern Europe Mar. - May(Spring) | 0.894 | <0.001 | 0.004 | 0.001 | 0.004 | <0.001 | | | | | |
| Southern Europe Mar. - May(Spring) | 1.79 | 0.001 | 0.009 | 0.002 | 0.009 | <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

### 9.5.2.14 Metabolite CGA 381318

**Table 9.5-75: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 381318 for each organism group based on FOCUS Steps 1, 2 calculations for the use of FLU+TFS SC 500 in flower bulbs (flower bulbs; modelling use VegBulb II -- VegBulb II (Aut) -- 5×75g a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Desmodesmus subspicatus*** | | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ (read across) > 200000** | **NOEC (read across) > 2000** | **$EC_{50}$ (read across) > 100000** | **NOEC (read across) > 2000** | **$E_rC_{50}/E_yC_{50}$ (read across) > 100000** | | | | | |
| **AF** | | **100** | **10** | **100** | **10** | **10** | | | | | |
| **RAC (µg/L)** | | **> 2000** | **> 200** | **> 1000** | **> 200** | **> 10000** | | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 1** | | | | | | | | | | | |
| - - | 6.79 | 0.003 | 0.034 | 0.007 | 0.034 | 0.001 | | | | | |
| **Step 2** | | | | | | | | | | | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Northern Europe Oct. - Feb.(Autumn) | 1.71 | 0.001 | 0.009 | 0.002 | 0.009 | <0.001 | | | | | |
| Southern Europe Oct. - Feb.(Autumn) | 1.37 | 0.001 | 0.007 | 0.001 | 0.007 | <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

**FOCUS Step 3 risk assessment**

### 9.5.2.15 Metabolite CGA 357261

**Table 9.5-76: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357261 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in asparagus, garden cress, flower tubers and ornamentals (asparagus, garden cress, flower tubers, ornamentals; modelling use field beans I -- field beans (early) -- 0.2 kg a.s./ha)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Desmodesmus subspicatus*** | | | | |
| **Endpoint**<br>**(µg/L)** | | **$LC_{50}$**<br>**900** | **NOEC (parent)**<br>**4.3** | **NOEC (ACR)**<br>**9** | **$EC_{50}$**<br>**> 2660** | **NOEC**<br>**101** | **$E_rC_{50}/E_yC_{50}$**<br>**> 2720** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9** | **0.43** | **0.9** | **> 26.6** | **10.1** | **> 272** | | | | |
| **FOCUS Scenario** | **PEC $_{gl\text{-}max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D2/Ditch | 0.016 | 0.002 | 0.037 | 0.018 | 0.001 | 0.002 | <0.001 | | | | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| D2/Stream | 0.003 | <0.001 | 0.007 | 0.003 | <0.001 | <0.001 | <0.001 | | | | |
| D3/Ditch | 0.010 | 0.001 | 0.023 | 0.011 | <0.001 | 0.001 | <0.001 | | | | |
| D4/Pond | 0.018 | 0.002 | 0.042 | 0.020 | 0.001 | 0.002 | <0.001 | | | | |
| D4/Stream | <0.001 | <0.001 | <0.002 | <0.001 | <0.001 | <0.001 | <0.001 | | | | |
| D6/Ditch | 0.003 | <0.001 | 0.007 | 0.003 | <0.001 | <0.001 | <0.001 | | | | |
| D6/Ditch 2nd | 0.002 | <0.001 | 0.005 | 0.002 | <0.001 | <0.001 | <0.001 | | | | |
| R1/Pond | 0.015 | 0.002 | 0.035 | 0.017 | 0.001 | 0.001 | <0.001 | | | | |
| R1/Stream | 0.004 | <0.001 | 0.009 | 0.004 | <0.001 | <0.001 | <0.001 | | | | |
| R2/Stream | 0.021 | 0.002 | 0.049 | 0.023 | 0.001 | 0.002 | <0.001 | | | | |
| R3/Stream | 0.011 | 0.001 | 0.026 | 0.012 | <0.001 | 0.001 | <0.001 | | | | |
| R4/Stream | 0.057 | 0.006 | 0.133 | 0.063 | 0.002 | 0.006 | <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 9.5-77: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357261 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in asparagus, garden cress, flower tubers and ornamentals (asparagus, garden cress, flower tubers, ornamentals; modelling use field beans I -- field beans (late) -- 0.2 kg a.s./ha)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Desmodesmus subspicatus*** | | | | |
| **Endpoint**<br><br>**(µg/L)** | | **$LC_{50}$**<br><br>**900** | **NOEC (parent)**<br><br>**4.3** | **NOEC (ACR)**<br><br>**9** | **$EC_{50}$**<br><br>**> 2660** | **NOEC**<br><br>**101** | **$E_rC_{50}$/$E_yC_{50}$**<br><br>**> 2720** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9** | **0.43** | **0.9** | **> 26.6** | **10.1** | **> 272** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D2/Ditch | 0.187 | 0.021 | 0.435 | 0.208 | 0.007 | 0.019 | 0.001 | | | | |
| D2/Stream | 0.177 | 0.020 | 0.412 | 0.197 | 0.007 | 0.018 | 0.001 | | | | |
| D3/Ditch | 0.026 | 0.003 | 0.060 | 0.029 | 0.001 | 0.003 | <0.001 | | | | |
| D4/Pond | 0.016 | 0.002 | 0.037 | 0.018 | 0.001 | 0.002 | <0.001 | | | | |
| D4/Stream | <0.001 | <0.001 | <0.002 | <0.001 | <0.001 | <0.001 | <0.001 | | | | |
| D6/Ditch | 0.113 | 0.013 | 0.263 | 0.126 | 0.004 | 0.011 | <0.001 | | | | |
| D6/Ditch 2nd | 0.023 | 0.003 | 0.053 | 0.026 | 0.001 | 0.002 | <0.001 | | | | |
| R1/Pond | 0.015 | 0.002 | 0.035 | 0.017 | 0.001 | 0.001 | <0.001 | | | | |
| R1/Stream | <0.001 | <0.001 | <0.002 | <0.001 | <0.001 | <0.001 | <0.001 | | | | |
| R2/Stream | <0.001 | <0.001 | <0.002 | <0.001 | <0.001 | <0.001 | <0.001 | | | | |
| R3/Stream | 0.001 | <0.001 | 0.002 | 0.001 | <0.001 | <0.001 | <0.001 | | | | |
| R4/Stream | <0.001 | <0.001 | <0.002 | <0.001 | <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

**Table 9.5-78: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357261 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in beans and nurseries (beans and nurseries; modelling use field beans II -- field beans II, BBCH 19 -- 2×0.2 kg a.s./ha, 14d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Desmodesmus subspicatus*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 900** | **NOEC (parent) 4.3** | **NOEC (ACR) 9** | **$EC_{50}$ > 2660** | **NOEC 101** | **$E_rC_{50}/E_yC_{50}$ > 2720** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9** | **0.43** | **0.9** | **> 26.6** | **10.1** | **> 272** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D2/Ditch | 0.099 | 0.011 | 0.230 | 0.110 | 0.004 | 0.010 | <0.001 | | | | |
| D2/Stream | 0.043 | 0.005 | 0.100 | 0.048 | 0.002 | 0.004 | <0.001 | | | | |
| D3/Ditch | 0.011 | 0.001 | 0.026 | 0.012 | <0.001 | 0.001 | <0.001 | | | | |
| D4/Pond | 0.028 | 0.003 | 0.065 | 0.031 | 0.001 | 0.003 | <0.001 | | | | |
| D4/Stream | <0.001 | <0.001 | <0.002 | <0.001 | <0.001 | <0.001 | <0.001 | | | | |
| D6/Ditch | 0.158 | 0.018 | 0.367 | 0.176 | 0.006 | 0.016 | 0.001 | | | | |
| D6/Ditch 2nd | 0.008 | 0.001 | 0.019 | 0.009 | <0.001 | 0.001 | <0.001 | | | | |
| R1/Pond | 0.026 | 0.003 | 0.060 | 0.029 | 0.001 | 0.003 | <0.001 | | | | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| R1/Stream | 0.027 | 0.003 | 0.063 | 0.030 | 0.001 | 0.003 | <0.001 | | | | |
| R2/Stream | 0.068 | 0.008 | 0.158 | 0.076 | 0.003 | 0.007 | <0.001 | | | | |
| R3/Stream | 0.504 | 0.056 | **1.17** | 0.560 | 0.019 | 0.050 | 0.002 | | | | |
| R4/Stream | 1.03 | 0.114 | **2.39** | **1.14*** | 0.039 | 0.102 | 0.004 | | | | |

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

*** R4 not relevant in member states with registered uses of this use group**

**Table 9.5-79: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357261 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in beans and nurseries (beans and nurseries; modelling use field beans II -- field beans II, BBCH 89 -- 2×0.2 kg a.s./ha, 14d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Desmodesmus subspicatus*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$** **900** | **NOEC (parent)** **4.3** | **NOEC (ACR)** **9** | **$EC_{50}$** **> 2660** | **NOEC** **101** | **$E_rC_{50}/E_yC_{50}$** **> 2720** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9** | **0.43** | **0.9** | **> 26.6** | **10.1** | **> 272** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D2/Ditch | 0.374 | 0.042 | 0.870 | 0.416 | 0.014 | 0.037 | 0.001 | | | | |
| D2/Stream | 0.167 | 0.019 | 0.388 | 0.186 | 0.006 | 0.017 | 0.001 | | | | |
| D3/Ditch | 0.023 | 0.003 | 0.053 | 0.026 | 0.001 | 0.002 | <0.001 | | | | |
| D4/Pond | 0.031 | 0.003 | 0.072 | 0.034 | 0.001 | 0.003 | <0.001 | | | | |
| D4/Stream | <0.001 | <0.001 | <0.002 | <0.001 | <0.001 | <0.001 | <0.001 | | | | |
| D6/Ditch | 0.056 | 0.006 | 0.130 | 0.062 | 0.002 | 0.006 | <0.001 | | | | |
| D6/Ditch 2nd | 0.026 | 0.003 | 0.060 | 0.029 | 0.001 | 0.003 | <0.001 | | | | |
| R1/Pond | 0.031 | 0.003 | 0.072 | 0.034 | 0.001 | 0.003 | <0.001 | | | | |
| R1/Stream | 0.100 | 0.011 | 0.233 | 0.111 | 0.004 | 0.010 | <0.001 | | | | |
| R2/Stream | <0.001 | <0.001 | <0.002 | <0.001 | <0.001 | <0.001 | <0.001 | | | | |
| R3/Stream | 0.179 | 0.020 | 0.416 | 0.199 | 0.007 | 0.018 | 0.001 | | | | |
| R4/Stream | 0.452 | 0.050 | **1.05** | 0.502 | 0.017 | 0.045 | 0.002 | | | | |

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 9.5-80: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357261 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in asparagus (asparagus; modelling use field beans III -- field beans III, BBCH 23 -- 2×0.2 kg a.s./ha, 10d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Desmodesmus subspicatus*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 900** | **NOEC (parent) 4.3** | **NOEC (ACR) 9** | **$EC_{50}$ > 2660** | **NOEC 101** | **$E_rC_{50}/E_yC_{50}$ > 2720** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9** | **0.43** | **0.9** | **> 26.6** | **10.1** | **> 272** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D2/Ditch | 0.101 | 0.011 | 0.235 | 0.112 | 0.004 | 0.010 | <0.001 | | | | |
| D2/Stream | 0.069 | 0.008 | 0.160 | 0.077 | 0.003 | 0.007 | <0.001 | | | | |
| D3/Ditch | 0.014 | 0.002 | 0.033 | 0.016 | 0.001 | 0.001 | <0.001 | | | | |
| D4/Pond | 0.033 | 0.004 | 0.077 | 0.037 | 0.001 | 0.003 | <0.001 | | | | |
| D4/Stream | <0.001 | <0.001 | <0.002 | <0.001 | <0.001 | <0.001 | <0.001 | | | | |
| D6/Ditch | 0.032 | 0.004 | 0.074 | 0.036 | 0.001 | 0.003 | <0.001 | | | | |
| D6/Ditch 2nd | 0.009 | 0.001 | 0.021 | 0.010 | <0.001 | 0.001 | <0.001 | | | | |
| R1/Pond | 0.030 | 0.003 | 0.070 | 0.033 | 0.001 | 0.003 | <0.001 | | | | |
| R1/Stream | 0.075 | 0.008 | 0.174 | 0.083 | 0.003 | 0.007 | <0.001 | | | | |
| R2/Stream | 0.068 | 0.008 | 0.158 | 0.076 | 0.003 | 0.007 | <0.001 | | | | |
| R3/Stream | 0.202 | 0.022 | 0.470 | 0.224 | 0.008 | 0.020 | 0.001 | | | | |
| R4/Stream | 0.198 | 0.022 | 0.460 | 0.220 | 0.007 | 0.020 | 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 9.5-81: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357261 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in asparagus (asparagus; modelling use field beans III -- field beans III, BBCH 95 -- 2×0.2 kg a.s./ha, 10d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Desmodesmus subspicatus*** | | | | |
| **Endpoint**<br><br>**(µg/L)** | | **$LC_{50}$**<br><br>**900** | **NOEC (parent)**<br><br>**4.3** | **NOEC (ACR)**<br><br>**9** | **$EC_{50}$**<br><br>**> 2660** | **NOEC**<br><br>**101** | **$E_rC_{50}/E_yC_{50}$**<br><br>**> 2720** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9** | **0.43** | **0.9** | **> 26.6** | **10.1** | **> 272** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D2/Ditch | 0.264 | 0.029 | 0.614 | 0.293 | 0.010 | 0.026 | 0.001 | | | | |
| D2/Stream | 0.229 | 0.025 | 0.533 | 0.254 | 0.009 | 0.023 | 0.001 | | | | |
| D3/Ditch | 0.026 | 0.003 | 0.060 | 0.029 | 0.001 | 0.003 | <0.001 | | | | |
| D4/Pond | 0.028 | 0.003 | 0.065 | 0.031 | 0.001 | 0.003 | <0.001 | | | | |
| D4/Stream | <0.001 | <0.001 | <0.002 | <0.001 | <0.001 | <0.001 | <0.001 | | | | |
| D6/Ditch | 0.116 | 0.013 | 0.270 | 0.129 | 0.004 | 0.011 | <0.001 | | | | |
| D6/Ditch 2nd | 0.039 | 0.004 | 0.091 | 0.043 | 0.001 | 0.004 | <0.001 | | | | |
| R1/Pond | 0.025 | 0.003 | 0.058 | 0.028 | 0.001 | 0.002 | <0.001 | | | | |
| R1/Stream | <0.001 | <0.001 | <0.002 | <0.001 | <0.001 | <0.001 | <0.001 | | | | |
| R2/Stream | <0.001 | <0.001 | <0.002 | <0.001 | <0.001 | <0.001 | <0.001 | | | | |
| R3/Stream | 0.179 | 0.020 | 0.416 | 0.199 | 0.007 | 0.018 | 0.001 | | | | |
| R4/Stream | 0.363 | 0.040 | 0.844 | 0.403 | 0.014 | 0.036 | 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 9.5-82: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357261 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in baby leaf crops, beans, garden cress and strawberries (baby leaf crops, beans, garden cress, strawberries; modelling use field beans IV -- field beans IV, BBCH 40 -- 2×0.2 kg a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Desmodesmus subspicatus*** | | | | |
| **Endpoint**<br>**(µg/L)** | | **$LC_{50}$**<br>**900** | **NOEC (parent)**<br>**4.3** | **NOEC (ACR)**<br>**9** | **$EC_{50}$**<br>**> 2660** | **NOEC**<br>**101** | **$E_rC_{50}/E_yC_{50}$**<br>**> 2720** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9** | **0.43** | **0.9** | **> 26.6** | **10.1** | **> 272** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D2/Ditch | 0.110 | 0.012 | 0.256 | 0.122 | 0.004 | 0.011 | <0.001 | | | | |
| D2/Stream | 0.080 | 0.009 | 0.186 | 0.089 | 0.003 | 0.008 | <0.001 | | | | |
| D3/Ditch | 0.014 | 0.002 | 0.033 | 0.016 | 0.001 | 0.001 | <0.001 | | | | |
| D4/Pond | 0.032 | 0.004 | 0.074 | 0.036 | 0.001 | 0.003 | <0.001 | | | | |
| D4/Stream | <0.001 | <0.001 | <0.002 | <0.001 | <0.001 | <0.001 | <0.001 | | | | |
| D6/Ditch | 0.032 | 0.004 | 0.074 | 0.036 | 0.001 | 0.003 | <0.001 | | | | |
| D6/Ditch 2nd | 0.010 | 0.001 | 0.023 | 0.011 | <0.001 | 0.001 | <0.001 | | | | |
| R1/Pond | 0.042 | 0.005 | 0.098 | 0.047 | 0.002 | 0.004 | <0.001 | | | | |
| R1/Stream | 0.141 | 0.016 | 0.328 | 0.157 | 0.005 | 0.014 | 0.001 | | | | |
| R2/Stream | 0.069 | 0.008 | 0.160 | 0.077 | 0.003 | 0.007 | <0.001 | | | | |
| R3/Stream | 0.179 | 0.020 | 0.416 | 0.199 | 0.007 | 0.018 | 0.001 | | | | |
| R4/Stream | 0.641 | 0.071 | **1.49** | 0.712 | 0.024 | 0.063 | 0.002 | | | | |

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 9.5-83: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357261 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in baby leaf crops, beans, garden cress and strawberries (baby leaf crops, beans, garden cress, strawberries; modelling use field beans IV -- field beans IV, BBCH 89 -- 2×0.2 kg a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Desmodesmus subspicatus*** | | | | |
| **Endpoint**<br><br>**(µg/L)** | | **$LC_{50}$**<br><br>**900** | **NOEC (parent)**<br><br>**4.3** | **NOEC (ACR)**<br><br>**9** | **$EC_{50}$**<br><br>**> 2660** | **NOEC**<br><br>**101** | **$E_rC_{50}/E_yC_{50}$**<br><br>**> 2720** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9** | **0.43** | **0.9** | **> 26.6** | **10.1** | **> 272** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D2/Ditch | 0.555 | 0.062 | **1.29** | 0.617 | 0.021 | 0.055 | 0.002 | | | | |
| D2/Stream | 0.300 | 0.033 | 0.698 | 0.333 | 0.011 | 0.030 | 0.001 | | | | |
| D3/Ditch | 0.021 | 0.002 | 0.049 | 0.023 | 0.001 | 0.002 | <0.001 | | | | |
| D4/Pond | 0.032 | 0.004 | 0.074 | 0.036 | 0.001 | 0.003 | <0.001 | | | | |
| D4/Stream | <0.001 | <0.001 | <0.002 | <0.001 | <0.001 | <0.001 | <0.001 | | | | |
| D6/Ditch | 0.033 | 0.004 | 0.077 | 0.037 | 0.001 | 0.003 | <0.001 | | | | |
| D6/Ditch 2nd | 0.012 | 0.001 | 0.028 | 0.013 | <0.001 | 0.001 | <0.001 | | | | |
| R1/Pond | 0.031 | 0.003 | 0.072 | 0.034 | 0.001 | 0.003 | <0.001 | | | | |
| R1/Stream | 0.100 | 0.011 | 0.233 | 0.111 | 0.004 | 0.010 | <0.001 | | | | |
| R2/Stream | <0.001 | <0.001 | <0.002 | <0.001 | <0.001 | <0.001 | <0.001 | | | | |
| R3/Stream | 0.180 | 0.020 | 0.419 | 0.200 | 0.007 | 0.018 | 0.001 | | | | |
| R4/Stream | 0.641 | 0.071 | **1.49** | 0.712 | 0.024 | 0.063 | 0.002 | | | | |

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 9.5-84: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357261 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in golf courses (golf courses; modelling use Golf courses -- Grass (Mar) -- 2×0.125 kg a.s./ha, 14d int.)**

| Group | | Fish acute | Fish prolonged | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Test species | | *Oncorhynchus mykiss* | *Oncorhynchus mykiss* | *Fish prolonged* | *Daphnia magna* | *Daphnia magna* | *Desmodesmus subspicatus* | | | | |
| Endpoint (µg/L) | | $LC_{50}$ 900 | NOEC (parent) 4.3 | NOEC (ACR) 9 | $EC_{50}$ > 2660 | NOEC 101 | $E_rC_{50}/E_yC_{50}$ > 2720 | | | | |
| AF | | 100 | 10 | 10 | 100 | 10 | 10 | | | | |
| RAC (µg/L) | | 9 | 0.43 | 0.9 | > 26.6 | 10.1 | > 272 | | | | |
| FOCUS Scenario | $PEC_{gl\text{-}max}$ (µg/L) | | | | | | | | | | |
| Step 3 | | | | | | | | | | | |
| D1/Ditch | 0.017 | 0.002 | 0.040 | 0.019 | 0.001 | 0.002 | <0.001 | | | | |
| D1/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <<0.001 | <<0.001 | | | | |
| D2/Ditch | 0.104 | 0.012 | 0.242 | 0.116 | 0.004 | 0.010 | <0.001 | | | | |
| D2/Stream | 0.094 | 0.010 | 0.219 | 0.104 | 0.004 | 0.009 | <0.001 | | | | |
| D3/Ditch | 0.003 | <0.001 | 0.007 | 0.003 | <0.001 | <0.001 | <0.001 | | | | |
| D4/Pond | 0.017 | 0.002 | 0.040 | 0.019 | 0.001 | 0.002 | <0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <<0.001 | <<0.001 | | | | |
| D5/Pond | 0.022 | 0.002 | 0.051 | 0.024 | 0.001 | 0.002 | <0.001 | | | | |
| D5/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <<0.001 | <<0.001 | | | | |
| R2/Stream | 0.009 | 0.001 | 0.021 | 0.010 | <0.001 | 0.001 | <0.001 | | | | |
| R3/Stream | 0.020 | 0.002 | 0.047 | 0.022 | 0.001 | 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

~~**Table 9.5-85: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357261 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in golf courses (golf courses; modelling use Golf courses – Grass (Jun) – 2×0.125 kg a.s./ha, 14d int.)**~~

| ~~Group~~ | | ~~Fish acute~~ | ~~Fish prolonged~~ | ~~Fish prolonged~~ | ~~Inverteb. acute~~ | ~~Inverteb. prolonged~~ | ~~Algae~~ | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| ~~Test species~~ | | ~~*Oncorhynchus mykiss*~~ | ~~*Oncorhynchus mykiss*~~ | ~~*Fish prolonged*~~ | ~~*Daphnia magna*~~ | ~~*Daphnia magna*~~ | ~~*Desmodesmus subspicatus*~~ | | | | |
| ~~Endpoint (µg/L)~~ | | ~~$LC_{50}$ 900~~ | ~~NOEC (parent) 4.3~~ | ~~NOEC (ACR) 9~~ | ~~$EC_{50}$ > 2660~~ | ~~NOEC 101~~ | ~~$E_rC_{50}/E_yC_{50}$ > 2720~~ | | | | |
| ~~AF~~ | | ~~100~~ | ~~10~~ | ~~10~~ | ~~100~~ | ~~10~~ | ~~10~~ | | | | |
| ~~RAC (µg/L)~~ | | ~~9~~ | ~~0.43~~ | ~~0.9~~ | ~~> 26.6~~ | ~~10.1~~ | ~~> 272~~ | | | | |
| ~~FOCUS Scenario~~ | ~~$PEC_{gl-max}$ (µg/L)~~ | | | | | | | | | | |
| ~~Step 3~~ | | | | | | | | | | | |
| ~~D1/Ditch~~ | ~~0.574~~ | ~~0.064~~ | ~~**1.33**~~ | ~~0.638~~ | ~~0.022~~ | ~~0.057~~ | ~~0.002~~ | | | | |
| ~~D1/Stream~~ | ~~0.004~~ | ~~<0.001~~ | ~~0.009~~ | ~~0.004~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ | | | | |
| ~~D2/Ditch~~ | ~~0.773~~ | ~~0.086~~ | ~~**1.80**~~ | ~~0.859~~ | ~~0.029~~ | ~~0.077~~ | ~~0.003~~ | | | | |
| ~~D2/Stream~~ | ~~0.519~~ | ~~0.058~~ | ~~**1.21**~~ | ~~0.577~~ | ~~0.020~~ | ~~0.051~~ | ~~0.002~~ | | | | |
| ~~D3/Ditch~~ | ~~0.025~~ | ~~0.003~~ | ~~0.058~~ | ~~0.028~~ | ~~0.001~~ | ~~0.002~~ | ~~<0.001~~ | | | | |
| ~~D4/Pond~~ | ~~0.021~~ | ~~0.002~~ | ~~0.049~~ | ~~0.023~~ | ~~0.001~~ | ~~0.002~~ | ~~<0.001~~ | | | | |
| ~~D4/Stream~~ | ~~<0.001~~ | ~~<<0.001~~ | ~~<0.002~~ | ~~<0.001~~ | ~~<<0.001~~ | ~~<<0.001~~ | ~~<<0.001~~ | | | | |
| ~~D5/Pond~~ | ~~0.024~~ | ~~0.003~~ | ~~0.056~~ | ~~0.027~~ | ~~0.001~~ | ~~0.002~~ | ~~<0.001~~ | | | | |
| ~~D5/Stream~~ | ~~<0.001~~ | ~~<<0.001~~ | ~~<0.002~~ | ~~<0.001~~ | ~~<<0.001~~ | ~~<<0.001~~ | ~~<<0.001~~ | | | | |
| ~~R2/Stream~~ | ~~<0.001~~ | ~~<<0.001~~ | ~~<0.002~~ | ~~<0.001~~ | ~~<<0.001~~ | ~~<<0.001~~ | ~~<<0.001~~ | | | | |
| ~~R3/Stream~~ | ~~0.027~~ | ~~0.003~~ | ~~0.063~~ | ~~0.030~~ | ~~0.001~~ | ~~0.003~~ | ~~<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 9.5-86: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357261 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in golf courses (golf courses; modelling use Golf courses – Grass (Sep) – 2×0.125 kg a.s./ha, 14d int.)**

| Group | | Fish acute | Fish prolonged | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Test species | | *Oncorhynchus mykiss* | *Oncorhynchus mykiss* | *Fish prolonged* | *Daphnia magna* | *Daphnia magna* | *Desmodesmus subspicatus* | | | | |
| Endpoint<br>(µg/L) | | $LC_{50}$<br>900 | NOEC (parent)<br>4.3 | NOEC (ACR)<br>9 | $EC_{50}$<br>> 2660 | NOEC<br>101 | $E_rC_{50}/E_yC_{50}$<br>> 2720 | | | | |
| AF | | 100 | 10 | 10 | 100 | 10 | 10 | | | | |
| RAC (µg/L) | | 9 | 0.43 | 0.9 | > 26.6 | 10.1 | > 272 | | | | |
| FOCUS Scenario | $PEC_{gl\text{-}max}$ (µg/L) | | | | | | | | | | |
| Step 3 | | | | | | | | | | | |
| D1/Ditch | 0.492 | 0.055 | **1.14** | 0.547 | 0.018 | 0.049 | 0.002 | | | | |
| D1/Stream | 0.003 | <0.001 | 0.007 | 0.003 | <0.001 | <0.001 | <0.001 | | | | |
| D2/Ditch | 0.547 | 0.061 | **1.27** | 0.608 | 0.021 | 0.054 | 0.002 | | | | |
| D2/Stream | 0.338 | 0.038 | 0.786 | 0.376 | 0.013 | 0.033 | 0.001 | | | | |
| D3/Ditch | 0.013 | 0.001 | 0.030 | 0.014 | <0.001 | 0.001 | <0.001 | | | | |
| D4/Pond | 0.019 | 0.002 | 0.044 | 0.021 | 0.001 | 0.002 | <0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <<0.001 | <<0.001 | | | | |
| D5/Pond | 0.022 | 0.002 | 0.051 | 0.024 | 0.001 | 0.002 | <0.001 | | | | |
| D5/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <<0.001 | <<0.001 | | | | |
| R2/Stream | 0.029 | 0.003 | 0.067 | 0.032 | 0.001 | 0.003 | <0.001 | | | | |
| R3/Stream | 0.196 | 0.022 | 0.456 | 0.218 | 0.007 | 0.019 | 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 9.5-87: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357261 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in golf courses (golf courses; modelling use Golf courses – Grass (Dec) – 2×0.125 kg a.s./ha, 14d int.)**~~

| ~~Group~~ | | ~~Fish acute~~ | ~~Fish prolonged~~ | ~~Fish prolonged~~ | ~~Inverteb. acute~~ | ~~Inverteb. prolonged~~ | ~~Algae~~ | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| ~~Test species~~ | | ~~*Oncorhynchus mykiss*~~ | ~~*Oncorhynchus mykiss*~~ | ~~*Fish prolonged*~~ | ~~*Daphnia magna*~~ | ~~*Daphnia magna*~~ | ~~*Desmodesmus subspicatus*~~ | | | | |
| ~~Endpoint (µg/L)~~ | | ~~$LC_{50}$ 900~~ | ~~NOEC (parent) 4.3~~ | ~~NOEC (ACR) 9~~ | ~~$EC_{50}$ > 2660~~ | ~~NOEC 101~~ | ~~$E_rC_{50}/E_yC_{50}$ > 2720~~ | | | | |
| ~~AF~~ | | ~~100~~ | ~~10~~ | ~~10~~ | ~~100~~ | ~~10~~ | ~~10~~ | | | | |
| ~~RAC (µg/L)~~ | | ~~9~~ | ~~0.43~~ | ~~0.9~~ | ~~> 26.6~~ | ~~10.1~~ | ~~> 272~~ | | | | |
| ~~FOCUS Scenario~~ | ~~PEC $_{gl-max}$ (µg/L)~~ | | | | | | | | | | |
| ~~Step 3~~ | | | | | | | | | | | |
| ~~D1/Ditch~~ | ~~0.069~~ | ~~0.008~~ | ~~0.160~~ | ~~0.077~~ | ~~0.003~~ | ~~0.007~~ | ~~<0.001~~ | | | | |
| ~~D1/Stream~~ | ~~0.001~~ | ~~<0.001~~ | ~~0.002~~ | ~~0.001~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ | | | | |
| ~~D2/Ditch~~ | ~~0.088~~ | ~~0.010~~ | ~~0.205~~ | ~~0.098~~ | ~~0.003~~ | ~~0.009~~ | ~~<0.001~~ | | | | |
| ~~D2/Stream~~ | ~~0.030~~ | ~~0.003~~ | ~~0.070~~ | ~~0.033~~ | ~~0.001~~ | ~~0.003~~ | ~~<0.001~~ | | | | |
| ~~D3/Ditch~~ | ~~0.002~~ | ~~<0.001~~ | ~~0.005~~ | ~~0.002~~ | ~~<0.001~~ | ~~<0.001~~ | ~~<0.001~~ | | | | |
| ~~D4/Pond~~ | ~~0.015~~ | ~~0.002~~ | ~~0.035~~ | ~~0.017~~ | ~~0.001~~ | ~~0.001~~ | ~~<0.001~~ | | | | |
| ~~D4/Stream~~ | ~~<0.001~~ | ~~<<0.001~~ | ~~<0.002~~ | ~~<0.001~~ | ~~<<0.001~~ | ~~<<0.001~~ | ~~<<0.001~~ | | | | |
| ~~D5/Pond~~ | ~~0.013~~ | ~~0.001~~ | ~~0.030~~ | ~~0.014~~ | ~~<0.001~~ | ~~0.001~~ | ~~<0.001~~ | | | | |
| ~~D5/Stream~~ | ~~<0.001~~ | ~~<<0.001~~ | ~~<0.002~~ | ~~<0.001~~ | ~~<<0.001~~ | ~~<<0.001~~ | ~~<<0.001~~ | | | | |
| ~~R2/Stream~~ | ~~0.032~~ | ~~0.004~~ | ~~0.074~~ | ~~0.036~~ | ~~0.001~~ | ~~0.003~~ | ~~<0.001~~ | | | | |
| ~~R3/Stream~~ | ~~<0.001~~ | ~~<<0.001~~ | ~~<0.002~~ | ~~<0.001~~ | ~~<<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~~

**Table 9.5-88: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357261 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in peas (peas; modelling use Legumes, BBCH 59 - 89 -- 2×0.2 kg a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Desmodesmus subspicatus*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 900** | **NOEC (parent) 4.3** | **NOEC (ACR) 9** | **$EC_{50}$ > 2660** | **NOEC 101** | **$E_rC_{50}$/$E_yC_{50}$ > 2720** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9** | **0.43** | **0.9** | **> 26.6** | **10.1** | **> 272** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D3/Ditch | 0.011 | 0.001 | 0.026 | 0.012 | <0.001 | 0.001 | <0.001 | | | | |
| D4/Pond | 0.026 | 0.003 | 0.060 | 0.029 | 0.001 | 0.003 | <0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <<0.001 | <<0.001 | | | | |
| D5/Pond | 0.037 | 0.004 | 0.086 | 0.041 | 0.001 | 0.004 | <0.001 | | | | |
| D5/Stream | 0.001 | <0.001 | 0.002 | 0.001 | <0.001 | <0.001 | <0.001 | | | | |
| D6/Ditch | 0.006 | 0.001 | 0.014 | 0.007 | <0.001 | 0.001 | <0.001 | | | | |
| R1/Pond | 0.045 | 0.005 | 0.105 | 0.050 | 0.002 | 0.004 | <0.001 | | | | |
| R1/Stream | 0.187 | 0.021 | 0.435 | 0.208 | 0.007 | 0.019 | 0.001 | | | | |
| R2/Stream | 0.030 | 0.003 | 0.070 | 0.033 | 0.001 | 0.003 | <0.001 | | | | |
| R3/Stream | 0.002 | <0.001 | 0.005 | 0.002 | <0.001 | <0.001 | <0.001 | | | | |
| R4/Stream | 0.086 | 0.010 | 0.200 | 0.096 | 0.003 | 0.009 | <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 9.5-89: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357261 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in peas (peas; modelling use Legumes, BBCH 59 - 79 -- 2×0.2 kg a.s./ha, 14d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Desmodesmus subspicatus*** | | | | |
| **Endpoint**<br><br>**(µg/L)** | | **$LC_{50}$**<br><br>**900** | **NOEC (parent)**<br><br>**4.3** | **NOEC (ACR)**<br><br>**9** | **$EC_{50}$**<br><br>**> 2660** | **NOEC**<br><br>**101** | **$E_rC_{50}/E_yC_{50}$**<br><br>**> 2720** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9** | **0.43** | **0.9** | **> 26.6** | **10.1** | **> 272** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D3/Ditch | 0.014 | 0.002 | 0.033 | 0.016 | 0.001 | 0.001 | <0.001 | | | | |
| D4/Pond | 0.026 | 0.003 | 0.060 | 0.029 | 0.001 | 0.003 | <0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <<0.001 | <<0.001 | | | | |
| D5/Pond | 0.037 | 0.004 | 0.086 | 0.041 | 0.001 | 0.004 | <0.001 | | | | |
| D5/Stream | 0.001 | <0.001 | 0.002 | 0.001 | <0.001 | <0.001 | <0.001 | | | | |
| D6/Ditch | 0.006 | 0.001 | 0.014 | 0.007 | <0.001 | 0.001 | <0.001 | | | | |
| R1/Pond | 0.045 | 0.005 | 0.105 | 0.050 | 0.002 | 0.004 | <0.001 | | | | |
| R1/Stream | 0.187 | 0.021 | 0.435 | 0.208 | 0.007 | 0.019 | 0.001 | | | | |
| R2/Stream | 0.096 | 0.011 | 0.223 | 0.107 | 0.004 | 0.010 | <0.001 | | | | |
| R3/Stream | 0.002 | <0.001 | 0.005 | 0.002 | <0.001 | <0.001 | <0.001 | | | | |
| R4/Stream | 0.086 | 0.010 | 0.200 | 0.096 | 0.003 | 0.009 | <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 9.5-90: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357261 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in celeriac (celeriac; modelling use Sugar beets, BBCH 40 - 49 (June - November) -- 2×0.125 kg a.s./ha, 14d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Desmodesmus subspicatus*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 900** | **NOEC (parent) 4.3** | **NOEC (ACR) 9** | **$EC_{50}$ > 2660** | **NOEC 101** | **$E_rC_{50}/E_yC_{50}$ > 2720** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9** | **0.43** | **0.9** | **> 26.6** | **10.1** | **> 272** | | | | |
| **FOCUS Scenario** | **PEC $_{gl\text{-}max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D3/Ditch | 0.009 | 0.001 | 0.021 | 0.010 | <0.001 | 0.001 | <0.001 | | | | |
| D4/Pond | 0.017 | 0.002 | 0.040 | 0.019 | 0.001 | 0.002 | <0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <<0.001 | <<0.001 | | | | |
| R1/Pond | 0.019 | 0.002 | 0.044 | 0.021 | 0.001 | 0.002 | <0.001 | | | | |
| R1/Stream | 0.053 | 0.006 | 0.123 | 0.059 | 0.002 | 0.005 | <0.001 | | | | |
| R3/Stream | 0.002 | <0.001 | 0.005 | 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

**Table 9.5-91: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357261 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in chicory (chicory; modelling use Sugar beets, BBCH 13 - 49, early -- 0.2 kg a.s./ha)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Desmodesmus subspicatus*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 900** | **NOEC (parent) 4.3** | **NOEC (ACR) 9** | **$EC_{50}$ > 2660** | **NOEC 101** | **$E_rC_{50}$/$E_yC_{50}$ > 2720** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9** | **0.43** | **0.9** | **> 26.6** | **10.1** | **> 272** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D3/Ditch | 0.010 | 0.001 | 0.023 | 0.011 | <0.001 | 0.001 | <0.001 | | | | |
| D4/Pond | 0.016 | 0.002 | 0.037 | 0.018 | 0.001 | 0.002 | <0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <<0.001 | <<0.001 | | | | |
| R1/Pond | 0.016 | 0.002 | 0.037 | 0.018 | 0.001 | 0.002 | <0.001 | | | | |
| R1/Stream | 0.006 | 0.001 | 0.014 | 0.007 | <0.001 | 0.001 | <0.001 | | | | |
| R3/Stream | 0.014 | 0.002 | 0.033 | 0.016 | 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

**Table 9.5-92: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357261 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in chicory (chicory; modelling use Sugar beets, BBCH 13 - 49, late -- 0.2 kg a.s./ha)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Desmodesmus subspicatus*** | | | | |
| **Endpoint**<br><br>**(µg/L)** | | **$LC_{50}$**<br><br>**900** | **NOEC (parent)**<br><br>**4.3** | **NOEC (ACR)**<br><br>**9** | **$EC_{50}$**<br><br>**> 2660** | **NOEC**<br><br>**101** | **$E_rC_{50}/E_yC_{50}$**<br><br>**> 2720** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9** | **0.43** | **0.9** | **> 26.6** | **10.1** | **> 272** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D3/Ditch | 0.007 | 0.001 | 0.016 | 0.008 | <0.001 | 0.001 | <0.001 | | | | |
| D4/Pond | 0.015 | 0.002 | 0.035 | 0.017 | 0.001 | 0.001 | <0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <<0.001 | <<0.001 | | | | |
| R1/Pond | 0.014 | 0.002 | 0.033 | 0.016 | 0.001 | 0.001 | <0.001 | | | | |
| R1/Stream | 0.036 | 0.004 | 0.084 | 0.040 | 0.001 | 0.004 | <0.001 | | | | |
| R3/Stream | 0.002 | <0.001 | 0.005 | 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

**Table 9.5-93: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357261 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in flower bulbs (flower bulbs; modelling use VegBulb I -- VegBulb I (early) -- 0.2 kg a.s./ha)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Desmodesmus subspicatus*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 900** | **NOEC (parent) 4.3** | **NOEC (ACR) 9** | **$EC_{50}$ > 2660** | **NOEC 101** | **$E_rC_{50}/E_yC_{50}$ > 2720** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9** | **0.43** | **0.9** | **> 26.6** | **10.1** | **> 272** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D3/Ditch | 0.011 | 0.001 | 0.026 | 0.012 | <0.001 | 0.001 | <0.001 | | | | |
| D4/Pond | 0.016 | 0.002 | 0.037 | 0.018 | 0.001 | 0.002 | <0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <<0.001 | <<0.001 | | | | |
| D6/Ditch | 0.049 | 0.005 | 0.114 | 0.054 | 0.002 | 0.005 | <0.001 | | | | |
| D6/Ditch 2nd | 0.093 | 0.010 | 0.216 | 0.103 | 0.003 | 0.009 | <0.001 | | | | |
| R1/Pond | 0.017 | 0.002 | 0.040 | 0.019 | 0.001 | 0.002 | <0.001 | | | | |
| R1/Stream | 0.104 | 0.012 | 0.242 | 0.116 | 0.004 | 0.010 | <0.001 | | | | |
| R2/Stream | 0.020 | 0.002 | 0.047 | 0.022 | 0.001 | 0.002 | <0.001 | | | | |
| R3/Stream | 0.009 | 0.001 | 0.021 | 0.010 | <0.001 | 0.001 | <0.001 | | | | |
| R4/Stream | 0.205 | 0.023 | 0.477 | 0.228 | 0.008 | 0.020 | 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 9.5-94: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357261 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in flower bulbs (flower bulbs; modelling use VegBulb I -- VegBulb I (middle) -- 0.2 kg a.s./ha)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Desmodesmus subspicatus*** | | | | |
| **Endpoint** (µg/L) | | **$LC_{50}$** 900 | **NOEC (parent)** 4.3 | **NOEC (ACR)** 9 | **$EC_{50}$** > 2660 | **NOEC** 101 | **$E_rC_{50}/E_yC_{50}$** > 2720 | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9** | **0.43** | **0.9** | **> 26.6** | **10.1** | **> 272** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D3/Ditch | 0.013 | 0.001 | 0.030 | 0.014 | <0.001 | 0.001 | <0.001 | | | | |
| D4/Pond | 0.014 | 0.002 | 0.033 | 0.016 | 0.001 | 0.001 | <0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <<0.001 | <<0.001 | | | | |
| D6/Ditch | 0.228 | 0.025 | 0.530 | 0.253 | 0.009 | 0.023 | 0.001 | | | | |
| D6/Ditch 2nd | 0.029 | 0.003 | 0.067 | 0.032 | 0.001 | 0.003 | <0.001 | | | | |
| R1/Pond | 0.019 | 0.002 | 0.044 | 0.021 | 0.001 | 0.002 | <0.001 | | | | |
| R1/Stream | 0.061 | 0.007 | 0.142 | 0.068 | 0.002 | 0.006 | <0.001 | | | | |
| R2/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <<0.001 | <<0.001 | | | | |
| R3/Stream | 0.108 | 0.012 | 0.251 | 0.120 | 0.004 | 0.011 | <0.001 | | | | |
| R4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<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

**Table 9.5-95: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357261 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in flower bulbs (flower bulbs; modelling use VegBulb I -- VegBulb I (late) -- 0.2 kg a.s./ha)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Desmodesmus subspicatus*** | | | | |
| **Endpoint**<br><br>**(µg/L)** | | **$LC_{50}$**<br><br>**900** | **NOEC (parent)**<br><br>**4.3** | **NOEC (ACR)**<br><br>**9** | **$EC_{50}$**<br><br>**> 2660** | **NOEC**<br><br>**101** | **$E_rC_{50}/E_yC_{50}$**<br><br>**> 2720** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9** | **0.43** | **0.9** | **> 26.6** | **10.1** | **> 272** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D3/Ditch | 0.014 | 0.002 | 0.033 | 0.016 | 0.001 | 0.001 | <0.001 | | | | |
| D4/Pond | 0.016 | 0.002 | 0.037 | 0.018 | 0.001 | 0.002 | <0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <<0.001 | <<0.001 | | | | |
| D6/Ditch | 0.228 | 0.025 | 0.530 | 0.253 | 0.009 | 0.023 | 0.001 | | | | |
| D6/Ditch 2nd | 0.029 | 0.003 | 0.067 | 0.032 | 0.001 | 0.003 | <0.001 | | | | |
| R1/Pond | 0.017 | 0.002 | 0.040 | 0.019 | 0.001 | 0.002 | <0.001 | | | | |
| R1/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <<0.001 | <<0.001 | | | | |
| R2/Stream | 0.045 | 0.005 | 0.105 | 0.050 | 0.002 | 0.004 | <0.001 | | | | |
| R3/Stream | 0.108 | 0.012 | 0.251 | 0.120 | 0.004 | 0.011 | <0.001 | | | | |
| R4/Stream | 0.388 | 0.043 | 0.902 | 0.431 | 0.015 | 0.038 | 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 9.5-96: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357261 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in flower bulbs (flower bulbs; modelling use VegBulb II -- VegBulb II (early) -- 5×0.075 kg a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Desmodesmus subspicatus*** | | | | |
| **Endpoint**<br><br>**(µg/L)** | | **$LC_{50}$**<br><br>**900** | **NOEC (parent)**<br><br>**4.3** | **NOEC (ACR)**<br><br>**9** | **$EC_{50}$**<br><br>**> 2660** | **NOEC**<br><br>**101** | **$E_rC_{50}/E_yC_{50}$**<br><br>**> 2720** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9** | **0.43** | **0.9** | **> 26.6** | **10.1** | **> 272** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D3/Ditch | 0.004 | <0.001 | 0.009 | 0.004 | <0.001 | <0.001 | <0.001 | | | | |
| D4/Pond | 0.017 | 0.002 | 0.040 | 0.019 | 0.001 | 0.002 | <0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <<0.001 | <<0.001 | | | | |
| D6/Ditch | 0.089 | 0.010 | 0.207 | 0.099 | 0.003 | 0.009 | <0.001 | | | | |
| D6/Ditch 2nd | 0.035 | 0.004 | 0.081 | 0.039 | 0.001 | 0.003 | <0.001 | | | | |
| R1/Pond | 0.021 | 0.002 | 0.049 | 0.023 | 0.001 | 0.002 | <0.001 | | | | |
| R1/Stream | 0.039 | 0.004 | 0.091 | 0.043 | 0.001 | 0.004 | <0.001 | | | | |
| R2/Stream | 0.028 | 0.003 | 0.065 | 0.031 | 0.001 | 0.003 | <0.001 | | | | |
| R3/Stream | 0.102 | 0.011 | 0.237 | 0.113 | 0.004 | 0.010 | <0.001 | | | | |
| R4/Stream | 0.156 | 0.017 | 0.363 | 0.173 | 0.006 | 0.015 | 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 9.5-97: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357261 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in flower bulbs (flower bulbs; modelling use VegBulb II -- VegBulb II (late) -- 5×0.075 kg a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Desmodesmus subspicatus*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 900** | **NOEC (parent) 4.3** | **NOEC (ACR) 9** | **$EC_{50}$ > 2660** | **NOEC 101** | **$E_rC_{50}/E_yC_{50}$ > 2720** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9** | **0.43** | **0.9** | **> 26.6** | **10.1** | **> 272** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D3/Ditch | 0.005 | 0.001 | 0.012 | 0.006 | <0.001 | <0.001 | <0.001 | | | | |
| D4/Pond | 0.018 | 0.002 | 0.042 | 0.020 | 0.001 | 0.002 | <0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <<0.001 | <<0.001 | | | | |
| D6/Ditch | 0.097 | 0.011 | 0.226 | 0.108 | 0.004 | 0.010 | <0.001 | | | | |
| D6/Ditch 2nd | 0.013 | 0.001 | 0.030 | 0.014 | <0.001 | 0.001 | <0.001 | | | | |
| R1/Pond | 0.022 | 0.002 | 0.051 | 0.024 | 0.001 | 0.002 | <0.001 | | | | |
| R1/Stream | 0.052 | 0.006 | 0.121 | 0.058 | 0.002 | 0.005 | <0.001 | | | | |
| R2/Stream | 0.028 | 0.003 | 0.065 | 0.031 | 0.001 | 0.003 | <0.001 | | | | |
| R3/Stream | 0.053 | 0.006 | 0.123 | 0.059 | 0.002 | 0.005 | <0.001 | | | | |
| R4/Stream | 0.156 | 0.017 | 0.363 | 0.173 | 0.006 | 0.015 | 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 9.5-98: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357261 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in chokeberry, elderberry and tree nursery (chokeberry, elderberry, tree nursery; modelling use Pome and stone fruit 2x200 g/ha -- BBCH 12-91, early -- 2×0.2 kg a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Desmodesmus subspicatus*** | | | | |
| **Endpoint**<br><br>**(µg/L)** | | **$LC_{50}$**<br><br>**900** | **NOEC (parent)**<br><br>**4.3** | **NOEC (ACR)**<br><br>**9** | **$EC_{50}$**<br><br>**> 2660** | **NOEC**<br><br>**101** | **$E_rC_{50}/E_yC_{50}$**<br><br>**> 2720** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9** | **0.43** | **0.9** | **> 26.6** | **10.1** | **> 272** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D3/Ditch | 0.161 | 0.018 | 0.374 | 0.179 | 0.006 | 0.016 | 0.001 | | | | |
| D4/Pond | 0.771 | 0.086 | **1.79** | 0.857 | 0.029 | 0.076 | 0.003 | | | | |
| D4/Stream | 0.005 | 0.001 | 0.012 | 0.006 | <0.001 | <0.001 | <0.001 | | | | |
| D5/Pond | 0.830 | 0.092 | **1.93** | 0.922 | 0.031 | 0.082 | 0.003 | | | | |
| D5/Stream | 0.008 | 0.001 | 0.019 | 0.009 | <0.001 | 0.001 | <0.001 | | | | |
| R1/Pond | 0.605 | 0.067 | **1.41** | 0.672 | 0.023 | 0.060 | 0.002 | | | | |
| R1/Stream | 0.002 | <0.001 | 0.005 | 0.002 | <0.001 | <0.001 | <0.001 | | | | |
| R2/Stream | 0.003 | <0.001 | 0.007 | 0.003 | <0.001 | <0.001 | <0.001 | | | | |
| R3/Stream | 0.046 | 0.005 | 0.107 | 0.051 | 0.002 | 0.005 | <0.001 | | | | |
| R4/Stream | 0.121 | 0.013 | 0.281 | 0.134 | 0.005 | 0.012 | <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 9.5-99: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357261 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in chokeberry, elderberry and tree nursery (chokeberry, elderberry, tree nursery; modelling use Pome and stone fruit 2x200 g/ha -- BBCH 12-91, late -- 2×0.2 kg a.s./ha, 7d int.)**

| Group | | Fish acute | Fish prolonged | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Test species | | *Oncorhynchus mykiss* | *Oncorhynchus mykiss* | *Fish prolonged* | *Daphnia magna* | *Daphnia magna* | *Desmodesmus subspicatus* | | | | |
| Endpoint<br>(µg/L) | | $LC_{50}$<br>900 | NOEC (parent)<br>4.3 | NOEC (ACR)<br>9 | $EC_{50}$<br>> 2660 | NOEC<br>101 | $E_rC_{50}/E_yC_{50}$<br>> 2720 | | | | |
| AF | | 100 | 10 | 10 | 100 | 10 | 10 | | | | |
| RAC (µg/L) | | 9 | 0.43 | 0.9 | > 26.6 | 10.1 | > 272 | | | | |
| FOCUS Scenario | PEC $_{gl-max}$ (µg/L) | | | | | | | | | | |
| Step 3 | | | | | | | | | | | |
| D3/Ditch | 0.150 | 0.017 | 0.349 | 0.167 | 0.006 | 0.015 | 0.001 | | | | |
| D4/Pond | 0.183 | 0.020 | 0.426 | 0.203 | 0.007 | 0.018 | 0.001 | | | | |
| D4/Stream | 0.003 | <0.001 | 0.007 | 0.003 | <0.001 | <0.001 | <0.001 | | | | |
| D5/Pond | 0.275 | 0.031 | 0.640 | 0.306 | 0.010 | 0.027 | 0.001 | | | | |
| D5/Stream | 0.010 | 0.001 | 0.023 | 0.011 | <0.001 | 0.001 | <0.001 | | | | |
| R1/Pond | 0.168 | 0.019 | 0.391 | 0.187 | 0.006 | 0.017 | 0.001 | | | | |
| R1/Stream | 0.001 | <0.001 | 0.002 | 0.001 | <0.001 | <0.001 | <0.001 | | | | |
| R2/Stream | 0.001 | <0.001 | 0.002 | 0.001 | <0.001 | <0.001 | <0.001 | | | | |
| R3/Stream | 0.305 | 0.034 | 0.709 | 0.339 | 0.011 | 0.030 | 0.001 | | | | |
| R4/Stream | 0.076 | 0.008 | 0.177 | 0.084 | 0.003 | 0.008 | <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 9.5-100: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357261 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in lettuce, rocket (lettuce, rocket; modelling use Vegetable leafy 2x200 g/ha -- BBCH 12-49, early -- 2×0.2 kg a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Desmodesmus subspicatus*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$** 900 | **NOEC (parent)** 4.3 | **NOEC (ACR)** 9 | **$EC_{50}$** > 2660 | **NOEC** 101 | **$E_rC_{50}$/$E_yC_{50}$** > 2720 | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9** | **0.43** | **0.9** | **> 26.6** | **10.1** | **> 272** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D3/Ditch | 0.011 | 0.001 | 0.026 | 0.012 | <0.001 | 0.001 | <0.001 | | | | |
| D3/Ditch 2nd | 0.016 | 0.002 | 0.037 | 0.018 | 0.001 | 0.002 | <0.001 | | | | |
| D4/Pond | 0.026 | 0.003 | 0.060 | 0.029 | 0.001 | 0.003 | <0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <<0.001 | <<0.001 | | | | |
| D6/Ditch | 0.003 | <0.001 | 0.007 | 0.003 | <0.001 | <0.001 | <0.001 | | | | |
| R1/Pond | 0.028 | 0.003 | 0.065 | 0.031 | 0.001 | 0.003 | <0.001 | | | | |
| R1/Pond 2nd | 0.028 | 0.003 | 0.065 | 0.031 | 0.001 | 0.003 | <0.001 | | | | |
| R1/Stream | 0.034 | 0.004 | 0.079 | 0.038 | 0.001 | 0.003 | <0.001 | | | | |
| R1/Stream 2nd | 0.050 | 0.006 | 0.116 | 0.056 | 0.002 | 0.005 | <0.001 | | | | |
| R2/Stream | 0.034 | 0.004 | 0.079 | 0.038 | 0.001 | 0.003 | <0.001 | | | | |
| R2/Stream 2nd | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <<0.001 | <<0.001 | | | | |
| R3/Stream | 0.065 | 0.007 | 0.151 | 0.072 | 0.002 | 0.006 | <0.001 | | | | |
| R3/Stream 2nd | 0.002 | <0.001 | 0.005 | 0.002 | <0.001 | <0.001 | <0.001 | | | | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| R4/Stream | 0.312 | 0.035 | 0.726 | 0.347 | 0.012 | 0.031 | 0.001 | | | | |
| R4/Stream 2nd | 0.008 | 0.001 | 0.019 | 0.009 | <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

**Table 9.5-101: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357261 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in lettuce, rocket (lettuce, rocket; modelling use Vegetable leafy 2x200 g/ha -- BBCH 12-49, late -- 2×0.2 kg a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Desmodesmus subspicatus*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 900** | **NOEC (parent) 4.3** | **NOEC (ACR) 9** | **$EC_{50}$ > 2660** | **NOEC 101** | **$E_rC_{50}/E_yC_{50}$ > 2720** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9** | **0.43** | **0.9** | **> 26.6** | **10.1** | **> 272** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D3/Ditch | 0.013 | 0.001 | 0.030 | 0.014 | <0.001 | 0.001 | <0.001 | | | | |
| D3/Ditch 2nd | 0.006 | 0.001 | 0.014 | 0.007 | <0.001 | 0.001 | <0.001 | | | | |
| D4/Pond | 0.026 | 0.003 | 0.060 | 0.029 | 0.001 | 0.003 | <0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <<0.001 | <<0.001 | | | | |
| D6/Ditch | 0.234 | 0.026 | 0.544 | 0.260 | 0.009 | 0.023 | 0.001 | | | | |
| R1/Pond | 0.044 | 0.005 | 0.102 | 0.049 | 0.002 | 0.004 | <0.001 | | | | |
| R1/Pond 2nd | 0.023 | 0.003 | 0.053 | 0.026 | 0.001 | 0.002 | <0.001 | | | | |
| R1/Stream | 0.161 | 0.018 | 0.374 | 0.179 | 0.006 | 0.016 | 0.001 | | | | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| R1/Stream 2nd | 0.152 | 0.017 | 0.353 | 0.169 | 0.006 | 0.015 | 0.001 | | | | |
| R2/Stream | 0.028 | 0.003 | 0.065 | 0.031 | 0.001 | 0.003 | <0.001 | | | | |
| R2/Stream 2nd | 0.103 | 0.011 | 0.240 | 0.114 | 0.004 | 0.010 | <0.001 | | | | |
| R3/Stream | 0.136 | 0.015 | 0.316 | 0.151 | 0.005 | 0.013 | 0.001 | | | | |
| R3/Stream 2nd | 0.030 | 0.003 | 0.070 | 0.033 | 0.001 | 0.003 | <0.001 | | | | |
| R4/Stream | 0.464 | 0.052 | **1.08** | 0.516 | 0.017 | 0.046 | 0.002 | | | | |
| R4/Stream 2nd | 0.077 | 0.009 | 0.179 | 0.086 | 0.003 | 0.008 | <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 9.5-102: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357261 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in tobacco (tobacco; modelling use Tobacco -- BBCH 11 - 39 -- 0.2 kg a.s./ha)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Desmodesmus subspicatus*** | | | | |
| **Endpoint**<br><br>**(µg/L)** | | **$LC_{50}$**<br><br>**900** | **NOEC (parent)**<br><br>**4.3** | **NOEC (ACR)**<br><br>**9** | **$EC_{50}$**<br><br>**> 2660** | **NOEC**<br><br>**101** | **$E_rC_{50}/E_yC_{50}$**<br><br>**> 2720** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9** | **0.43** | **0.9** | **> 26.6** | **10.1** | **> 272** | | | | |
| **FOCUS Scenario** | **PEC $_{gl\text{-}max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| R3/Stream | 0.001 | <0.001 | 0.002 | 0.001 | <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

**Table 9.5-103: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357261 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in hops (hops; modelling use Hops -- BBCH 37 - 79, early -- 2×0.15 kg a.s./ha, 14d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Desmodesmus subspicatus*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 900** | **NOEC (parent) 4.3** | **NOEC (ACR) 9** | **$EC_{50}$ > 2660** | **NOEC 101** | **$E_rC_{50}/E_yC_{50}$ > 2720** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9** | **0.43** | **0.9** | **> 26.6** | **10.1** | **> 272** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| R1/Pond | 0.211 | 0.023 | 0.491 | 0.234 | 0.008 | 0.021 | 0.001 | | | | |
| R1/Stream | 0.025 | 0.003 | 0.058 | 0.028 | 0.001 | 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

**Table 9.5-104: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357261 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in hops (hops; modelling use Hops -- BBCH 37 - 79, late -- 2×0.15 kg a.s./ha, 14d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Desmodesmus subspicatus*** | | | | |
| **Endpoint**<br><br>**(µg/L)** | | **$LC_{50}$**<br><br>**900** | **NOEC (parent)**<br><br>**4.3** | **NOEC (ACR)**<br><br>**9** | **$EC_{50}$**<br><br>**> 2660** | **NOEC**<br><br>**101** | **$E_rC_{50}/E_yC_{50}$**<br><br>**> 2720** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9** | **0.43** | **0.9** | **> 26.6** | **10.1** | **> 272** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| R1/Pond | 0.202 | 0.022 | 0.470 | 0.224 | 0.008 | 0.020 | 0.001 | | | | |
| R1/Stream | 0.001 | <0.001 | 0.002 | 0.001 | <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

**Table 9.5-105: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357261 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in berries (berries; modelling use Vines II -- early, BBCH 15 -- 2×0.2 kg a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Desmodesmus subspicatus*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 900** | **NOEC (parent) 4.3** | **NOEC (ACR) 9** | **$EC_{50}$ > 2660** | **NOEC 101** | **$E_rC_{50}$/$E_yC_{50}$ > 2720** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9** | **0.43** | **0.9** | **> 26.6** | **10.1** | **> 272** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D6/Ditch | 0.050 | 0.006 | 0.116 | 0.056 | 0.002 | 0.005 | <0.001 | | | | |
| R1/Pond | 0.079 | 0.009 | 0.184 | 0.088 | 0.003 | 0.008 | <0.001 | | | | |
| R1/Stream | 0.011 | 0.001 | 0.026 | 0.012 | <0.001 | 0.001 | <0.001 | | | | |
| R2/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <<0.001 | <<0.001 | | | | |
| R3/Stream | 0.002 | <0.001 | 0.005 | 0.002 | <0.001 | <0.001 | <0.001 | | | | |
| R4/Stream | 0.076 | 0.008 | 0.177 | 0.084 | 0.003 | 0.008 | <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 9.5-106: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357261 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in berries (berries; modelling use Vines II -- middle, BBCH 65 -- 2×0.2 kg a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Desmodesmus subspicatus*** | | | | |
| **Endpoint** <br> **(µg/L)** | | **$LC_{50}$** <br> **900** | **NOEC (parent)** <br> **4.3** | **NOEC (ACR)** <br> **9** | **$EC_{50}$** <br> **> 2660** | **NOEC** <br> **101** | **$E_rC_{50}/E_yC_{50}$** <br> **> 2720** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9** | **0.43** | **0.9** | **> 26.6** | **10.1** | **> 272** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D6/Ditch | 0.599 | 0.067 | **1.39** | 0.666 | 0.023 | 0.059 | 0.002 | | | | |
| R1/Pond | 0.083 | 0.009 | 0.193 | 0.092 | 0.003 | 0.008 | <0.001 | | | | |
| R1/Stream | 0.055 | 0.006 | 0.128 | 0.061 | 0.002 | 0.005 | <0.001 | | | | |
| R2/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <<0.001 | <<0.001 | | | | |
| R3/Stream | 0.016 | 0.002 | 0.037 | 0.018 | 0.001 | 0.002 | <0.001 | | | | |
| R4/Stream | 0.012 | 0.001 | 0.028 | 0.013 | <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

**Table 9.5-107: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357261 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in berries (berries; modelling use Vines II -- late, BBCH 89 -- 2×0.2 kg a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Desmodesmus subspicatus*** | | | | |
| **Endpoint**<br><br>**(µg/L)** | | **$LC_{50}$**<br><br>**900** | **NOEC (parent)**<br><br>**4.3** | **NOEC (ACR)**<br><br>**9** | **$EC_{50}$**<br><br>**> 2660** | **NOEC**<br><br>**101** | **$E_rC_{50}/E_yC_{50}$**<br><br>**> 2720** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9** | **0.43** | **0.9** | **> 26.6** | **10.1** | **> 272** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D6/Ditch | 0.665 | 0.074 | **1.55** | 0.739 | 0.025 | 0.066 | 0.002 | | | | |
| R1/Pond | 0.065 | 0.007 | 0.151 | 0.072 | 0.002 | 0.006 | <0.001 | | | | |
| R1/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <<0.001 | <<0.001 | | | | |
| R2/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <<0.001 | <<0.001 | | | | |
| R3/Stream | 0.014 | 0.002 | 0.033 | 0.016 | 0.001 | 0.001 | <0.001 | | | | |
| R4/Stream | 0.171 | 0.019 | 0.398 | 0.190 | 0.006 | 0.017 | 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 9.5-108: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357261 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in grapes (grapes; modelling use vines VI -- early, BBCH 15 -- 2×0.05 kg a.s./ha, 14d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Desmodesmus subspicatus*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 900** | **NOEC (parent) 4.3** | **NOEC (ACR) 9** | **$EC_{50}$ > 2660** | **NOEC 101** | **$E_rC_{50}/E_yC_{50}$ > 2720** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9** | **0.43** | **0.9** | **> 26.6** | **10.1** | **> 272** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D6/Ditch | 0.013 | 0.001 | 0.030 | 0.014 | <0.001 | 0.001 | <0.001 | | | | |
| R1/Pond | 0.020 | 0.002 | 0.047 | 0.022 | 0.001 | 0.002 | <0.001 | | | | |
| R1/Stream | 0.012 | 0.001 | 0.028 | 0.013 | <0.001 | 0.001 | <0.001 | | | | |
| R2/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <<0.001 | <<0.001 | | | | |
| R3/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <<0.001 | <<0.001 | | | | |
| R4/Stream | 0.042 | 0.005 | 0.098 | 0.047 | 0.002 | 0.004 | <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 9.5-109: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357261 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in grapes (grapes; modelling use vines VI -- middle, BBCH 65 -- 2×0.05 kg a.s./ha, 14d int.)**

| Group | | Fish acute | Fish prolonged | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Test species | | *Oncorhynchus mykiss* | *Oncorhynchus mykiss* | *Fish prolonged* | *Daphnia magna* | *Daphnia magna* | *Desmodesmus subspicatus* | | | | |
| Endpoint<br><br>(µg/L) | | $LC_{50}$<br><br>900 | NOEC (parent)<br><br>4.3 | NOEC (ACR)<br><br>9 | $EC_{50}$<br><br>> 2660 | NOEC<br><br>101 | $E_rC_{50}/E_yC_{50}$<br><br>> 2720 | | | | |
| AF | | 100 | 10 | 10 | 100 | 10 | 10 | | | | |
| RAC (µg/L) | | 9 | 0.43 | 0.9 | > 26.6 | 10.1 | > 272 | | | | |
| FOCUS Scenario | PEC $_{gl\text{-}max}$ (µg/L) | | | | | | | | | | |
| Step 3 | | | | | | | | | | | |
| D6/Ditch | 0.133 | 0.015 | 0.309 | 0.148 | 0.005 | 0.013 | <0.001 | | | | |
| R1/Pond | 0.021 | 0.002 | 0.049 | 0.023 | 0.001 | 0.002 | <0.001 | | | | |
| R1/Stream | 0.014 | 0.002 | 0.033 | 0.016 | 0.001 | 0.001 | <0.001 | | | | |
| R2/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <<0.001 | <<0.001 | | | | |
| R3/Stream | 0.009 | 0.001 | 0.021 | 0.010 | <0.001 | 0.001 | <0.001 | | | | |
| R4/Stream | 0.011 | 0.001 | 0.026 | 0.012 | <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

**Table 9.5-110: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357261 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in grapes (grapes; modelling use vines VI -- late, BBCH 85 -- 2×0.05 kg a.s./ha, 14d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Desmodesmus subspicatus*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 900** | **NOEC (parent) 4.3** | **NOEC (ACR) 9** | **$EC_{50}$ > 2660** | **NOEC 101** | **$E_rC_{50}/E_yC_{50}$ > 2720** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9** | **0.43** | **0.9** | **> 26.6** | **10.1** | **> 272** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D6/Ditch | 0.159 | 0.018 | 0.370 | 0.177 | 0.006 | 0.016 | 0.001 | | | | |
| R1/Pond | 0.018 | 0.002 | 0.042 | 0.020 | 0.001 | 0.002 | <0.001 | | | | |
| R1/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <<0.001 | <<0.001 | | | | |
| R2/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <<0.001 | <<0.001 | | | | |
| R3/Stream | 0.010 | 0.001 | 0.023 | 0.011 | <0.001 | 0.001 | <0.001 | | | | |
| R4/Stream | 0.016 | 0.002 | 0.037 | 0.018 | 0.001 | 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

All RQ are below the trigger of 1 except for the use in beans and nurseries (2×0.2 kg a.s./ha, 14 d interval) for FOCUS scenario R4 for fish prolonged. **However, as FOCUS scenario R4 is not relevant for the member states considered in this submission, a further risk assessment is not needed.**

### 9.5.2.16 Metabolite NOA 409480

**Table 9.5-111: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for NOA 409480 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in asparagus, garden cress, flower tubers and ornamentals (asparagus, garden cress, flower tubers, ornamentals; modelling use field beans I -- field beans (early) -- 0.2 kg a.s./ha)**

| Group | | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Inverteb. prolonged | Algae | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Test species | | *Oncorhynchus mykiss* | *Oncorhynchus mykiss* | *Daphnia magna* | *Daphnia magna* | *Daphnia magna* | *Pseudokirchneriella subcapitata* | | | | |
| Endpoint (µg/L) | | $LC_{50}$ 1920 | NOEC (parent) 4.3 | $EC_{50}$ 2250 | NOEC (parent) 2.76 | NOEC (ACR) 11 | $E_rC_{50}/E_yC_{50}$ > 2020 | | | | |
| AF | | 100 | 10 | 100 | 10 | 10 | 10 | | | | |
| RAC (µg/L) | | 19.2 | 0.43 | 22.5 | 0.276 | 1.1 | > 202 | | | | |
| FOCUS Scenario | PEC $_{gl\text{-}max}$ (µg/L) | | | | | | | | | | |
| Step 3 | | | | | | | | | | | |
| D2/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D2/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D3/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Pond | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D6/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D6/Ditch 2nd | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R1/Pond | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R1/Stream | 0.006 | <0.001 | 0.014 | <0.001 | 0.022 | 0.005 | <0.001 | | | | |
| R2/Stream | 0.002 | <0.001 | 0.005 | <0.001 | 0.007 | 0.002 | <0.001 | | | | |
| R3/Stream | 0.007 | <0.001 | 0.016 | <0.001 | 0.025 | 0.006 | <0.001 | | | | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| R4/Stream | 0.012 | 0.001 | 0.028 | 0.001 | 0.043 | 0.011 | <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 9.5-112: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for NOA 409480 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in asparagus, garden cress, flower tubers and ornamentals (asparagus, garden cress, flower tubers, ornamentals; modelling use field beans I -- field beans (late) -- 0.2 kg a.s./ha)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 1920** | **NOEC (parent) 4.3** | **$EC_{50}$ 2250** | **NOEC (parent) 2.76** | **NOEC (ACR) 11** | **$E_rC_{50}$/$E_yC_{50}$ > 2020** | | | | |
| **AF** | | **100** | **10** | **100** | **10** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **19.2** | **0.43** | **22.5** | **0.276** | **1.1** | **> 202** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D2/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D2/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D3/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Pond | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D6/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D6/Ditch 2nd | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R1/Pond | 0.002 | <0.001 | 0.005 | <0.001 | 0.007 | 0.002 | <0.001 | | | | |
| R1/Stream | 0.004 | <0.001 | 0.009 | <0.001 | 0.014 | 0.004 | <0.001 | | | | |
| R2/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R3/Stream | 0.002 | <0.001 | 0.005 | <0.001 | 0.007 | 0.002 | <0.001 | | | | |
| R4/Stream | 0.001 | <0.001 | 0.002 | <0.001 | 0.004 | 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 9.5-113: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for NOA 409480 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in beans and nurseries (beans and nurseries; modelling use field beans II -- field beans II, BBCH 19 -- 2×0.2 kg a.s./ha, 14d int.)**

| Group | | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Inverteb. prolonged | Algae | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Test species | | *Oncorhynchus mykiss* | *Oncorhynchus mykiss* | *Daphnia magna* | *Daphnia magna* | *Daphnia magna* | *Pseudokirchneriella subcapitata* | | | | |
| Endpoint (µg/L) | | $LC_{50}$ 1920 | NOEC (parent) 4.3 | $EC_{50}$ 2250 | NOEC (parent) 2.76 | NOEC (ACR) 11 | $E_rC_{50}/E_yC_{50}$ > 2020 | | | | |
| AF | | 100 | 10 | 100 | 10 | 10 | 10 | | | | |
| RAC (µg/L) | | 19.2 | 0.43 | 22.5 | 0.276 | 1.1 | > 202 | | | | |
| FOCUS Scenario | PEC $_{gl-max}$ (µg/L) | | | | | | | | | | |
| Step 3 | | | | | | | | | | | |
| D2/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D2/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D3/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Pond | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D6/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D6/Ditch 2nd | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R1/Pond | 0.001 | <0.001 | 0.002 | <0.001 | 0.004 | 0.001 | <0.001 | | | | |
| R1/Stream | 0.010 | 0.001 | 0.023 | <0.001 | 0.036 | 0.009 | <0.001 | | | | |
| R2/Stream | 0.002 | <0.001 | 0.005 | <0.001 | 0.007 | 0.002 | <0.001 | | | | |
| R3/Stream | 0.010 | 0.001 | 0.023 | <0.001 | 0.036 | 0.009 | <0.001 | | | | |
| R4/Stream | 0.017 | 0.001 | 0.040 | 0.001 | 0.062 | 0.015 | <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 9.5-114: Aquatic organisms: accepttTwistability of risk (PEC/RAC < 1) for NOA 409480 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in beans and nurseries (beans and nurseries; modelling use field beans II -- field beans II, BBCH 89 -- 2×0.2 kg a.s./ha, 14d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 1920** | **NOEC (parent) 4.3** | **$EC_{50}$ 2250** | **NOEC (parent) 2.76** | **NOEC (ACR) 11** | **$E_rC_{50}/E_yC_{50}$ > 2020** | | | | |
| **AF** | | **100** | **10** | **100** | **10** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **19.2** | **0.43** | **22.5** | **0.276** | **1.1** | **> 202** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D2/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D2/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D3/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Pond | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D6/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D6/Ditch 2nd | 0.001 | <0.001 | 0.002 | <0.001 | 0.004 | 0.001 | <0.001 | | | | |
| R1/Pond | 0.002 | <0.001 | 0.005 | <0.001 | 0.007 | 0.002 | <0.001 | | | | |
| R1/Stream | 0.005 | <0.001 | 0.012 | <0.001 | 0.018 | 0.005 | <0.001 | | | | |
| R2/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R3/Stream | 0.004 | <0.001 | 0.009 | <0.001 | 0.014 | 0.004 | <0.001 | | | | |
| R4/Stream | 0.010 | 0.001 | 0.023 | <0.001 | 0.036 | 0.009 | <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 9.5-115: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for NOA 409480 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in asparagus (asparagus; modelling use field beans III -- field beans III, BBCH 23 -- 2×0.2 kg a.s./ha, 10d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 1920** | **NOEC (parent) 4.3** | **$EC_{50}$ 2250** | **NOEC (parent) 2.76** | **NOEC (ACR) 11** | **$E_rC_{50}$/$E_yC_{50}$ > 2020** | | | | |
| **AF** | | **100** | **10** | **100** | **10** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **19.2** | **0.43** | **22.5** | **0.276** | **1.1** | **> 202** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D2/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D2/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D3/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Pond | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D6/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D6/Ditch 2nd | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R1/Pond | 0.001 | <0.001 | 0.002 | <0.001 | 0.004 | 0.001 | <0.001 | | | | |
| R1/Stream | 0.010 | 0.001 | 0.023 | <0.001 | 0.036 | 0.009 | <0.001 | | | | |
| R2/Stream | 0.002 | <0.001 | 0.005 | <0.001 | 0.007 | 0.002 | <0.001 | | | | |
| R3/Stream | 0.010 | 0.001 | 0.023 | <0.001 | 0.036 | 0.009 | <0.001 | | | | |
| R4/Stream | 0.016 | 0.001 | 0.037 | 0.001 | 0.058 | 0.015 | <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 9.5-116: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for NOA 409480 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in asparagus (asparagus; modelling use field beans III -- field beans III, BBCH 95 -- 2×0.2 kg a.s./ha, 10d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 1920** | **NOEC (parent) 4.3** | **$EC_{50}$ 2250** | **NOEC (parent) 2.76** | **NOEC (ACR) 11** | **$E_rC_{50}$/$E_yC_{50}$ > 2020** | | | | |
| **AF** | | **100** | **10** | **100** | **10** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **19.2** | **0.43** | **22.5** | **0.276** | **1.1** | **> 202** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D2/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D2/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D3/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Pond | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D6/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D6/Ditch 2nd | 0.001 | <0.001 | 0.002 | <0.001 | 0.004 | 0.001 | <0.001 | | | | |
| R1/Pond | 0.003 | <0.001 | 0.007 | <0.001 | 0.011 | 0.003 | <0.001 | | | | |
| R1/Stream | 0.007 | <0.001 | 0.016 | <0.001 | 0.025 | 0.006 | <0.001 | | | | |
| R2/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R3/Stream | 0.004 | <0.001 | 0.009 | <0.001 | 0.014 | 0.004 | <0.001 | | | | |
| R4/Stream | 0.007 | <0.001 | 0.016 | <0.001 | 0.025 | 0.006 | <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 9.5-117: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for NOA 409480 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in baby leaf crops, beans, garden cress and strawberries (baby leaf crops, beans, garden cress, strawberries; modelling use field beans IV -- field beans IV, BBCH 40 -- 2×0.2 kg a.s./ha, 7d int.)**

| Group | | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Inverteb. prolonged | Algae | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Test species | | *Oncorhynchus mykiss* | *Oncorhynchus mykiss* | *Daphnia magna* | *Daphnia magna* | *Daphnia magna* | *Pseudokirchneriella subcapitata* | | | | |
| Endpoint (µg/L) | | $LC_{50}$ 1920 | NOEC (parent) 4.3 | $EC_{50}$ 2250 | NOEC (parent) 2.76 | NOEC (ACR) 11 | $E_rC_{50}/E_yC_{50}$ > 2020 | | | | |
| AF | | 100 | 10 | 100 | 10 | 10 | 10 | | | | |
| RAC (µg/L) | | 19.2 | 0.43 | 22.5 | 0.276 | 1.1 | > 202 | | | | |
| FOCUS Scenario | PEC $_{gl-max}$ (µg/L) | | | | | | | | | | |
| Step 3 | | | | | | | | | | | |
| D2/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D2/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D3/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Pond | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D6/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D6/Ditch 2nd | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R1/Pond | 0.002 | <0.001 | 0.005 | <0.001 | 0.007 | 0.002 | <0.001 | | | | |
| R1/Stream | 0.010 | 0.001 | 0.023 | <0.001 | 0.036 | 0.009 | <0.001 | | | | |
| R2/Stream | 0.003 | <0.001 | 0.007 | <0.001 | 0.011 | 0.003 | <0.001 | | | | |
| R3/Stream | 0.008 | <0.001 | 0.019 | <0.001 | 0.029 | 0.007 | <0.001 | | | | |
| R4/Stream | 0.019 | 0.001 | 0.044 | 0.001 | 0.069 | 0.017 | <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 9.5-118: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for NOA 409480 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in baby leaf crops, beans, garden cress and strawberries (baby leaf crops, beans, garden cress, strawberries; modelling use field beans IV -- field beans IV, BBCH 89 -- 2×0.2 kg a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 1920** | **NOEC (parent) 4.3** | **$EC_{50}$ 2250** | **NOEC (parent) 2.76** | **NOEC (ACR) 11** | **$E_rC_{50}/E_yC_{50}$ > 2020** | | | | |
| **AF** | | **100** | **10** | **100** | **10** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **19.2** | **0.43** | **22.5** | **0.276** | **1.1** | **> 202** | | | | |
| **FOCUS Scenario** | **PEC $_{gl\text{-}max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D2/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D2/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D3/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Pond | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D6/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D6/Ditch 2nd | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R1/Pond | 0.002 | <0.001 | 0.005 | <0.001 | 0.007 | 0.002 | <0.001 | | | | |
| R1/Stream | 0.005 | <0.001 | 0.012 | <0.001 | 0.018 | 0.005 | <0.001 | | | | |
| R2/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| R3/Stream | 0.009 | <0.001 | 0.021 | <0.001 | 0.033 | 0.008 | <0.001 | | | | |
| R4/Stream | 0.019 | 0.001 | 0.044 | 0.001 | 0.069 | 0.017 | <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 9.5-119: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for NOA 409480 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in golf courses (golf courses; modelling use Golf courses -- Grass (Mar) -- 2×0.125 kg a.s./ha, 14d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 1920** | **NOEC (parent) 4.3** | **$EC_{50}$ 2250** | **NOEC (parent) 2.76** | **NOEC (ACR) 11** | **$E_rC_{50}/E_yC_{50}$ > 2020** | | | | |
| **AF** | | **100** | **10** | **100** | **10** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **19.2** | **0.43** | **22.5** | **0.276** | **1.1** | **> 202** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D1/Ditch | <0.001 | <0.001 | <0.002 | <0.001 | <0.004 | <0.001 | <0.001 | | | | |
| D1/Stream | <0.001 | <0.001 | <0.002 | <0.001 | <0.004 | <0.001 | <0.001 | | | | |
| D2/Ditch | <0.001 | <0.001 | <0.002 | <0.001 | <0.004 | <0.001 | <0.001 | | | | |
| D2/Stream | <0.001 | <0.001 | <0.002 | <0.001 | <0.004 | <0.001 | <0.001 | | | | |
| D3/Ditch | <0.001 | <0.001 | <0.002 | <0.001 | <0.004 | <0.001 | <0.001 | | | | |
| D4/Pond | <0.001 | <0.001 | <0.002 | <0.001 | <0.004 | <0.001 | <0.001 | | | | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| D4/Stream | <0.001 | <0.001 | <0.002 | <0.001 | <0.004 | <0.001 | <0.001 | | | | |
| D5/Pond | <0.001 | <0.001 | <0.002 | <0.001 | <0.004 | <0.001 | <0.001 | | | | |
| D5/Stream | <0.001 | <0.001 | <0.002 | <0.001 | <0.004 | <0.001 | <0.001 | | | | |
| R2/Stream | 0.001 | <0.001 | 0.002 | <0.001 | 0.004 | 0.001 | <0.001 | | | | |
| R3/Stream | 0.004 | <0.001 | 0.009 | <0.001 | 0.014 | 0.004 | <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 9.5-120: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for NOA 409480 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in golf courses (golf courses; modelling use Golf courses -- Grass (Jun) -- 2×0.125 kg a.s./ha, 14d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 1920** | **NOEC (parent) 4.3** | **$EC_{50}$ 2250** | **NOEC (parent) 2.76** | **NOEC (ACR) 11** | **$E_rC_{50}/E_yC_{50}$ > 2020** | | | | |
| **AF** | | **100** | **10** | **100** | **10** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **19.2** | **0.43** | **22.5** | **0.276** | **1.1** | **> 202** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D1/Ditch | <0.001 | <0.001 | <0.002 | <0.001 | <0.004 | <0.001 | <0.001 | | | | |
| D1/Stream | <0.001 | <0.001 | <0.002 | <0.001 | <0.004 | <0.001 | <0.001 | | | | |
| D2/Ditch | <0.001 | <0.001 | <0.002 | <0.001 | <0.004 | <0.001 | <0.001 | | | | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| D2/Stream | <0.001 | <0.001 | <0.002 | <0.001 | <0.004 | <0.001 | <0.001 | | | | |
| D3/Ditch | <0.001 | <0.001 | <0.002 | <0.001 | <0.004 | <0.001 | <0.001 | | | | |
| D4/Pond | <0.001 | <0.001 | <0.002 | <0.001 | <0.004 | <0.001 | <0.001 | | | | |
| D4/Stream | <0.001 | <0.001 | <0.002 | <0.001 | <0.004 | <0.001 | <0.001 | | | | |
| D5/Pond | <0.001 | <0.001 | <0.002 | <0.001 | <0.004 | <0.001 | <0.001 | | | | |
| D5/Stream | <0.001 | <0.001 | <0.002 | <0.001 | <0.004 | <0.001 | <0.001 | | | | |
| R2/Stream | <0.001 | <0.001 | <0.002 | <0.001 | <0.004 | <0.001 | <0.001 | | | | |
| R3/Stream | 0.002 | <0.001 | 0.005 | <0.001 | 0.007 | 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

**Table 9.5-121: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for NOA 409480 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in golf courses (golf courses; modelling use Golf courses -- Grass (Sep) -- 2×0.125 kg a.s./ha, 14d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint**<br><br>**(µg/L)** | | **$LC_{50}$**<br><br>**1920** | **NOEC (parent)**<br><br>**4.3** | **$EC_{50}$**<br><br>**2250** | **NOEC (parent)**<br><br>**2.76** | **NOEC (ACR)**<br><br>**11** | **$E_rC_{50}/E_yC_{50}$**<br><br>**> 2020** | | | | |
| **AF** | | **100** | **10** | **100** | **10** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **19.2** | **0.43** | **22.5** | **0.276** | **1.1** | **> 202** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D1/Ditch | <0.001 | <0.001 | <0.002 | <0.001 | <0.004 | <0.001 | <0.001 | | | | |
| D1/Stream | <0.001 | <0.001 | <0.002 | <0.001 | <0.004 | <0.001 | <0.001 | | | | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| D2/Ditch | <0.001 | <0.001 | <0.002 | <0.001 | <0.004 | <0.001 | <0.001 | | | | |
| D2/Stream | <0.001 | <0.001 | <0.002 | <0.001 | <0.004 | <0.001 | <0.001 | | | | |
| D3/Ditch | <0.001 | <0.001 | <0.002 | <0.001 | <0.004 | <0.001 | <0.001 | | | | |
| D4/Pond | <0.001 | <0.001 | <0.002 | <0.001 | <0.004 | <0.001 | <0.001 | | | | |
| D4/Stream | <0.001 | <0.001 | <0.002 | <0.001 | <0.004 | <0.001 | <0.001 | | | | |
| D5/Pond | <0.001 | <0.001 | <0.002 | <0.001 | <0.004 | <0.001 | <0.001 | | | | |
| D5/Stream | <0.001 | <0.001 | <0.002 | <0.001 | <0.004 | <0.001 | <0.001 | | | | |
| R2/Stream | 0.001 | <0.001 | 0.002 | <0.001 | 0.004 | 0.001 | <0.001 | | | | |
| R3/Stream | 0.006 | <0.001 | 0.014 | <0.001 | 0.022 | 0.005 | <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 9.5-122: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for NOA 409480 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in golf courses (golf courses; modelling use Golf courses -- Grass (Dec) -- 2×0.125 kg a.s./ha, 14d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 1920** | **NOEC (parent) 4.3** | **$EC_{50}$ 2250** | **NOEC (parent) 2.76** | **NOEC (ACR) 11** | **$E_rC_{50}$/$E_yC_{50}$ > 2020** | | | | |
| **AF** | | **100** | **10** | **100** | **10** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **19.2** | **0.43** | **22.5** | **0.276** | **1.1** | **> 202** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D1/Ditch | <0.001 | <0.001 | <0.002 | <0.001 | <0.004 | <0.001 | <0.001 | | | | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| D1/Stream | <0.001 | <0.001 | <0.002 | <0.001 | <0.004 | <0.001 | <0.001 | | | | |
| D2/Ditch | <0.001 | <0.001 | <0.002 | <0.001 | <0.004 | <0.001 | <0.001 | | | | |
| D2/Stream | <0.001 | <0.001 | <0.002 | <0.001 | <0.004 | <0.001 | <0.001 | | | | |
| D3/Ditch | <0.001 | <0.001 | <0.002 | <0.001 | <0.004 | <0.001 | <0.001 | | | | |
| D4/Pond | <0.001 | <0.001 | <0.002 | <0.001 | <0.004 | <0.001 | <0.001 | | | | |
| D4/Stream | <0.001 | <0.001 | <0.002 | <0.001 | <0.004 | <0.001 | <0.001 | | | | |
| D5/Pond | <0.001 | <0.001 | <0.002 | <0.001 | <0.004 | <0.001 | <0.001 | | | | |
| D5/Stream | <0.001 | <0.001 | <0.002 | <0.001 | <0.004 | <0.001 | <0.001 | | | | |
| R2/Stream | 0.002 | <0.001 | 0.005 | <0.001 | 0.007 | 0.002 | <0.001 | | | | |
| R3/Stream | <0.001 | <0.001 | <0.002 | <0.001 | <0.004 | <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 9.5-123: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for NOA 409480 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in peas (peas; modelling use Legumes I, BBCH 59 - 89 -- 2×0.2 kg a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 1920** | **NOEC (parent) 4.3** | **$EC_{50}$ 2250** | **NOEC (parent) 2.76** | **NOEC (ACR) 11** | **$E_rC_{50}/E_yC_{50}$ > 2020** | | | | |
| **AF** | | **100** | **10** | **100** | **10** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **19.2** | **0.43** | **22.5** | **0.276** | **1.1** | **> 202** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D3/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Pond | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D5/Pond | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D5/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D6/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R1/Pond | 0.002 | <0.001 | 0.005 | <0.001 | 0.007 | 0.002 | <0.001 | | | | |
| R1/Stream | 0.010 | 0.001 | 0.023 | <0.001 | 0.036 | 0.009 | <0.001 | | | | |
| R2/Stream | 0.002 | <0.001 | 0.005 | <0.001 | 0.007 | 0.002 | <0.001 | | | | |
| R3/Stream | 0.004 | <0.001 | 0.009 | <0.001 | 0.014 | 0.004 | <0.001 | | | | |
| R4/Stream | 0.015 | 0.001 | 0.035 | 0.001 | 0.054 | 0.014 | <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 9.5-124: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for NOA 409480 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in peas (peas; modelling use Legumes II, BBCH 59 - 79 -- 2×0.2 kg a.s./ha, 14d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 1920** | **NOEC (parent) 4.3** | **$EC_{50}$ 2250** | **NOEC (parent) 2.76** | **NOEC (ACR) 11** | **$E_rC_{50}$/$E_yC_{50}$ > 2020** | | | | |
| **AF** | | **100** | **10** | **100** | **10** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **19.2** | **0.43** | **22.5** | **0.276** | **1.1** | **> 202** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D3/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Pond | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D5/Pond | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D5/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D6/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R1/Pond | 0.002 | <0.001 | 0.005 | <0.001 | 0.007 | 0.002 | <0.001 | | | | |
| R1/Stream | 0.010 | 0.001 | 0.023 | <0.001 | 0.036 | 0.009 | <0.001 | | | | |
| R2/Stream | 0.002 | <0.001 | 0.005 | <0.001 | 0.007 | 0.002 | <0.001 | | | | |
| R3/Stream | 0.004 | <0.001 | 0.009 | <0.001 | 0.014 | 0.004 | <0.001 | | | | |
| R4/Stream | 0.015 | 0.001 | 0.035 | 0.001 | 0.054 | 0.014 | <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 9.5-125: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for NOA 409480 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in celeriac (celeriac; modelling use Sugar beets I, BBCH 40 - 49 (early) -- 2×0.125 kg a.s./ha, 14d int.)**

| Group | | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Inverteb. prolonged | Algae | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Test species | | *Oncorhynchus mykiss* | *Oncorhynchus mykiss* | *Daphnia magna* | *Daphnia magna* | *Daphnia magna* | *Pseudokirchneriella subcapitata* | | | | |
| Endpoint (µg/L) | | $LC_{50}$ 1920 | NOEC (parent) 4.3 | $EC_{50}$ 2250 | NOEC (parent) 2.76 | NOEC (ACR) 11 | $E_rC_{50}/E_yC_{50}$ > 2020 | | | | |
| AF | | 100 | 10 | 100 | 10 | 10 | 10 | | | | |
| RAC (µg/L) | | 19.2 | 0.43 | 22.5 | 0.276 | 1.1 | > 202 | | | | |
| FOCUS Scenario | PEC $_{gl-max}$ (µg/L) | | | | | | | | | | |
| Step 3 | | | | | | | | | | | |
| D3/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Pond | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R1/Pond | 0.001 | <0.001 | 0.002 | <0.001 | 0.004 | 0.001 | <0.001 | | | | |
| R1/Stream | 0.002 | <0.001 | 0.005 | <0.001 | 0.007 | 0.002 | <0.001 | | | | |
| R3/Stream | 0.005 | <0.001 | 0.012 | <0.001 | 0.018 | 0.005 | <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 9.5-126: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for NOA 409480 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in chicory (chicory; modelling use Sugar beets II, BBCH 13 – 49, early -- 0.2 kg a.s./ha)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 1920** | **NOEC (parent) 4.3** | **$EC_{50}$ 2250** | **NOEC (parent) 2.76** | **NOEC (ACR) 11** | **$E_rC_{50}/E_yC_{50}$ > 2020** | | | | |
| **AF** | | **100** | **10** | **100** | **10** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **19.2** | **0.43** | **22.5** | **0.276** | **1.1** | **> 202** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D3/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Pond | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R1/Pond | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R1/Stream | 0.006 | <0.001 | 0.014 | <0.001 | 0.022 | 0.005 | <0.001 | | | | |
| R3/Stream | 0.007 | <0.001 | 0.016 | <0.001 | 0.025 | 0.006 | <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 9.5-127: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for NOA 409480 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in chicory (chicory; modelling use Sugar beets II, BBCH 13 - 49, late -- 0.2 kg a.s./ha )**

| **Group** | | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 1920** | **NOEC (parent) 4.3** | **$EC_{50}$ 2250** | **NOEC (parent) 2.76** | **NOEC (ACR) 11** | **$E_rC_{50}/E_yC_{50}$ > 2020** | | | | |
| **AF** | | **100** | **10** | **100** | **10** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **19.2** | **0.43** | **22.5** | **0.276** | **1.1** | **> 202** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D3/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Pond | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R1/Pond | 0.001 | <0.001 | 0.002 | <0.001 | 0.004 | 0.001 | <0.001 | | | | |
| R1/Stream | 0.003 | <0.001 | 0.007 | <0.001 | 0.011 | 0.003 | <0.001 | | | | |
| R3/Stream | 0.005 | <0.001 | 0.012 | <0.001 | 0.018 | 0.005 | <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 9.5-128: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for NOA 409480 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in flower bulbs (flower bulbs; modelling use VegBulb I -- VegBulb I (early) -- 0.2 kg a.s./ha)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 1920** | **NOEC (parent) 4.3** | **$EC_{50}$ 2250** | **NOEC (parent) 2.76** | **NOEC (ACR) 11** | **$E_rC_{50}/E_yC_{50}$ > 2020** | | | | |
| **AF** | | **100** | **10** | **100** | **10** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **19.2** | **0.43** | **22.5** | **0.276** | **1.1** | **> 202** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D3/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Pond | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D6/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D6/Ditch 2nd | 0.001 | <0.001 | 0.002 | <0.001 | 0.004 | 0.001 | <0.001 | | | | |
| R1/Pond | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R1/Stream | 0.006 | <0.001 | 0.014 | <0.001 | 0.022 | 0.005 | <0.001 | | | | |
| R2/Stream | 0.002 | <0.001 | 0.005 | <0.001 | 0.007 | 0.002 | <0.001 | | | | |
| R3/Stream | 0.006 | <0.001 | 0.014 | <0.001 | 0.022 | 0.005 | <0.001 | | | | |
| R4/Stream | 0.010 | 0.001 | 0.023 | <0.001 | 0.036 | 0.009 | <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 9.5-129: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for NOA 409480 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in flower bulbs (flower bulbs; modelling use VegBulb I -- VegBulb I (middle) -- 0.2 kg a.s./ha)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 1920** | **NOEC (parent) 4.3** | **$EC_{50}$ 2250** | **NOEC (parent) 2.76** | **NOEC (ACR) 11** | **$E_rC_{50}/E_yC_{50}$ > 2020** | | | | |
| **AF** | | **100** | **10** | **100** | **10** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **19.2** | **0.43** | **22.5** | **0.276** | **1.1** | **> 202** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D3/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Pond | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D6/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D6/Ditch 2nd | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R1/Pond | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R1/Stream | 0.004 | <0.001 | 0.009 | <0.001 | 0.014 | 0.004 | <0.001 | | | | |
| R2/Stream | 0.001 | <0.001 | 0.002 | <0.001 | 0.004 | 0.001 | <0.001 | | | | |
| R3/Stream | 0.005 | <0.001 | 0.012 | <0.001 | 0.018 | 0.005 | <0.001 | | | | |
| R4/Stream | 0.001 | <0.001 | 0.002 | <0.001 | 0.004 | 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 9.5-130: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for NOA 409480 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in flower bulbs (flower bulbs; modelling use VegBulb I -- VegBulb I (late) -- 0.2 kg a.s./ha)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 1920** | **NOEC (parent) 4.3** | **$EC_{50}$ 2250** | **NOEC (parent) 2.76** | **NOEC (ACR) 11** | **$E_rC_{50}$/$E_yC_{50}$ > 2020** | | | | |
| **AF** | | **100** | **10** | **100** | **10** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **19.2** | **0.43** | **22.5** | **0.276** | **1.1** | **> 202** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D3/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Pond | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D6/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D6/Ditch 2nd | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R1/Pond | 0.001 | <0.001 | 0.002 | <0.001 | 0.004 | 0.001 | <0.001 | | | | |
| R1/Stream | 0.003 | <0.001 | 0.007 | <0.001 | 0.011 | 0.003 | <0.001 | | | | |
| R2/Stream | 0.001 | <0.001 | 0.002 | <0.001 | 0.004 | 0.001 | <0.001 | | | | |
| R3/Stream | 0.005 | <0.001 | 0.012 | <0.001 | 0.018 | 0.005 | <0.001 | | | | |
| R4/Stream | 0.010 | 0.001 | 0.023 | <0.001 | 0.036 | 0.009 | <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 9.5-131: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for NOA 409480 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in flower bulbs (flower bulbs; modelling use VegBulb II -- VegBulb II (early) -- 5×0.075 kg a.s./ha, 7d int.)**

| Group | | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Inverteb. prolonged | Algae | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Test species | | *Oncorhynchus mykiss* | *Oncorhynchus mykiss* | *Daphnia magna* | *Daphnia magna* | *Daphnia magna* | *Pseudokirchneriella subcapitata* | | | | |
| Endpoint<br>(µg/L) | | $LC_{50}$<br>1920 | NOEC (parent)<br>4.3 | $EC_{50}$<br>2250 | NOEC (parent)<br>2.76 | NOEC (ACR)<br>11 | $E_rC_{50}/E_yC_{50}$<br>> 2020 | | | | |
| AF | | 100 | 10 | 100 | 10 | 10 | 10 | | | | |
| RAC (µg/L) | | 19.2 | 0.43 | 22.5 | 0.276 | 1.1 | > 202 | | | | |
| FOCUS Scenario | PEC $_{gl-max}$ (µg/L) | | | | | | | | | | |
| Step 3 | | | | | | | | | | | |
| D3/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Pond | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D6/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D6/Ditch 2nd | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R1/Pond | 0.001 | <0.001 | 0.002 | <0.001 | 0.004 | 0.001 | <0.001 | | | | |
| R1/Stream | 0.008 | <0.001 | 0.019 | <0.001 | 0.029 | 0.007 | <0.001 | | | | |
| R2/Stream | 0.003 | <0.001 | 0.007 | <0.001 | 0.011 | 0.003 | <0.001 | | | | |
| R3/Stream | 0.009 | <0.001 | 0.021 | <0.001 | 0.033 | 0.008 | <0.001 | | | | |
| R4/Stream | 0.016 | 0.001 | 0.037 | 0.001 | 0.058 | 0.015 | <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 9.5-132: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for NOA 409480 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in flower bulbs (flower bulbs; modelling use VegBulb II -- VegBulb II (late) -- 5×0.075 kg a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint**<br><br>**(µg/L)** | | **$LC_{50}$**<br><br>**1920** | **NOEC (parent)**<br><br>**4.3** | **$EC_{50}$**<br><br>**2250** | **NOEC (parent)**<br><br>**2.76** | **NOEC (ACR)**<br><br>**11** | **$E_rC_{50}$/$E_yC_{50}$**<br><br>**> 2020** | | | | |
| **AF** | | **100** | **10** | **100** | **10** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **19.2** | **0.43** | **22.5** | **0.276** | **1.1** | **> 202** | | | | |
| **FOCUS Scenario** | **PEC $_{gl\text{-}max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D3/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Pond | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D6/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D6/Ditch 2nd | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R1/Pond | 0.002 | <0.001 | 0.005 | <0.001 | 0.007 | 0.002 | <0.001 | | | | |
| R1/Stream | 0.005 | <0.001 | 0.012 | <0.001 | 0.018 | 0.005 | <0.001 | | | | |
| R2/Stream | 0.003 | <0.001 | 0.007 | <0.001 | 0.011 | 0.003 | <0.001 | | | | |
| R3/Stream | 0.009 | <0.001 | 0.021 | <0.001 | 0.033 | 0.008 | <0.001 | | | | |
| R4/Stream | 0.016 | 0.001 | 0.037 | 0.001 | 0.058 | 0.015 | <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 9.5-133: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for NOA 409480 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in chokeberry, elderberry and tree nursery (chokeberry, elderberry, tree nursery; modelling use Pome and stone fruit 2x200 g/ha -- BBCH 12-91, early -- 2×0.2 kg a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 1920** | **NOEC (parent) 4.3** | **$EC_{50}$ 2250** | **NOEC (parent) 2.76** | **NOEC (ACR) 11** | **$E_rC_{50}/E_yC_{50}$ > 2020** | | | | |
| **AF** | | **100** | **10** | **100** | **10** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **19.2** | **0.43** | **22.5** | **0.276** | **1.1** | **> 202** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D3/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Pond | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D5/Pond | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D5/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R1/Pond | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R1/Stream | 0.007 | <0.001 | 0.016 | <0.001 | 0.025 | 0.006 | <0.001 | | | | |
| R2/Stream | 0.003 | <0.001 | 0.007 | <0.001 | 0.011 | 0.003 | <0.001 | | | | |
| R3/Stream | 0.006 | <0.001 | 0.014 | <0.001 | 0.022 | 0.005 | <0.001 | | | | |
| R4/Stream | 0.016 | 0.001 | 0.037 | 0.001 | 0.058 | 0.015 | <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 9.5-134: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for NOA 409480 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in chokeberry, elderberry and tree nursery (chokeberry, elderberry, tree nursery; modelling use Pome and stone fruit 2x200 g/ha -- BBCH 12-91, late -- 2×0.2 kg a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint**<br><br>**(µg/L)** | | **$LC_{50}$**<br><br>**1920** | **NOEC (parent)**<br><br>**4.3** | **$EC_{50}$**<br><br>**2250** | **NOEC (parent)**<br><br>**2.76** | **NOEC (ACR)**<br><br>**11** | **$E_rC_{50}$/$E_yC_{50}$**<br><br>**> 2020** | | | | |
| **AF** | | **100** | **10** | **100** | **10** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **19.2** | **0.43** | **22.5** | **0.276** | **1.1** | **> 202** | | | | |
| **FOCUS Scenario** | **$PEC_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D3/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Pond | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D5/Pond | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D5/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R1/Pond | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R1/Stream | 0.005 | <0.001 | 0.012 | <0.001 | 0.018 | 0.005 | <0.001 | | | | |
| R2/Stream | 0.002 | <0.001 | 0.005 | <0.001 | 0.007 | 0.002 | <0.001 | | | | |
| R3/Stream | 0.010 | 0.001 | 0.023 | <0.001 | 0.036 | 0.009 | <0.001 | | | | |
| R4/Stream | 0.015 | 0.001 | 0.035 | 0.001 | 0.054 | 0.014 | <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 9.5-135: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for NOA 409480 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in lettuce, rocket (lettuce, rocket; modelling use Vegetable leafy 2x200 g/ha -- BBCH 12-49, early -- 2×0.2 kg a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 1920** | **NOEC (parent) 4.3** | **$EC_{50}$ 2250** | **NOEC (parent) 2.76** | **NOEC (ACR) 11** | **$E_rC_{50}/E_yC_{50}$ > 2020** | | | | |
| **AF** | | **100** | **10** | **100** | **10** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **19.2** | **0.43** | **22.5** | **0.276** | **1.1** | **> 202** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D3/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D3/Ditch 2nd | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Pond | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D6/Ditch | 0.002 | <0.001 | 0.005 | <0.001 | 0.007 | 0.002 | <0.001 | | | | |
| R1/Pond | 0.002 | <0.001 | 0.005 | <0.001 | 0.007 | 0.002 | <0.001 | | | | |
| R1/Pond 2nd | 0.003 | <0.001 | 0.007 | <0.001 | 0.011 | 0.003 | <0.001 | | | | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| R1/Stream | 0.012 | 0.001 | 0.028 | 0.001 | 0.043 | 0.011 | <0.001 | | | | |
| R1/Stream 2nd | 0.008 | <0.001 | 0.019 | <0.001 | 0.029 | 0.007 | <0.001 | | | | |
| R2/Stream | 0.002 | <0.001 | 0.005 | <0.001 | 0.007 | 0.002 | <0.001 | | | | |
| R2/Stream 2nd | 0.001 | <0.001 | 0.002 | <0.001 | 0.004 | 0.001 | <0.001 | | | | |
| R3/Stream | 0.012 | 0.001 | 0.028 | 0.001 | 0.043 | 0.011 | <0.001 | | | | |
| R3/Stream 2nd | 0.009 | <0.001 | 0.021 | <0.001 | 0.033 | 0.008 | <0.001 | | | | |
| R4/Stream | 0.018 | 0.001 | 0.042 | 0.001 | 0.065 | 0.016 | <0.001 | | | | |
| R4/Stream 2nd | 0.018 | 0.001 | 0.042 | 0.001 | 0.065 | 0.016 | <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 9.5-136: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for NOA 409480 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in lettuce, rocket (lettuce, rocket; modelling use Vegetable leafy 2x200 g/ha -- BBCH 12-49, late -- 2×0.2 kg a.s./ha, 7d int.)**

| Group | | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Inverteb. prolonged | Algae | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Test species | | *Oncorhynchus mykiss* | *Oncorhynchus mykiss* | *Daphnia magna* | *Daphnia magna* | *Daphnia magna* | *Pseudokirchneriella subcapitata* | | | | |
| Endpoint (µg/L) | | $LC_{50}$ 1920 | NOEC (parent) 4.3 | $EC_{50}$ 2250 | NOEC (parent) 2.76 | NOEC (ACR) 11 | $E_rC_{50}/E_yC_{50}$ > 2020 | | | | |
| AF | | 100 | 10 | 100 | 10 | 10 | 10 | | | | |
| RAC (µg/L) | | 19.2 | 0.43 | 22.5 | 0.276 | 1.1 | > 202 | | | | |
| FOCUS Scenario | PEC $_{gl\text{-}max}$ (µg/L) | | | | | | | | | | |
| Step 3 | | | | | | | | | | | |
| D3/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D3/Ditch 2nd | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Pond | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| D6/Ditch | 0.005 | <0.001 | 0.012 | <0.001 | 0.018 | 0.005 | <0.001 | | | | |
| R1/Pond | 0.003 | <0.001 | 0.007 | <0.001 | 0.011 | 0.003 | <0.001 | | | | |
| R1/Pond 2nd | 0.004 | <0.001 | 0.009 | <0.001 | 0.014 | 0.004 | <0.001 | | | | |
| R1/Stream | 0.009 | <0.001 | 0.021 | <0.001 | 0.033 | 0.008 | <0.001 | | | | |
| R1/Stream | 0.008 | <0.001 | 0.019 | <0.001 | 0.029 | 0.007 | <0.001 | | | | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 2nd | | | | | | | | | | | |
| R2/Stream | 0.002 | <0.001 | 0.005 | <0.001 | 0.007 | 0.002 | <0.001 | | | | |
| R2/Stream 2nd | 0.003 | <0.001 | 0.007 | <0.001 | 0.011 | 0.003 | <0.001 | | | | |
| R3/Stream | 0.007 | <0.001 | 0.016 | <0.001 | 0.025 | 0.006 | <0.001 | | | | |
| R3/Stream 2nd | 0.007 | <0.001 | 0.016 | <0.001 | 0.025 | 0.006 | <0.001 | | | | |
| R4/Stream | 0.018 | 0.001 | 0.042 | 0.001 | 0.065 | 0.016 | <0.001 | | | | |
| R4/Stream 2nd | 0.016 | 0.001 | 0.037 | 0.001 | 0.058 | 0.015 | <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 9.5-137: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for NOA 409480 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in tobacco (tobacco; modelling use Tobacco -- BBCH 11 - 39 -- 0.2 kg a.s./ha)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 1920** | **NOEC (parent) 4.3** | **$EC_{50}$ 2250** | **NOEC (parent) 2.76** | **NOEC (ACR) 11** | **$E_rC_{50}$/$E_yC_{50}$ > 2020** | | | | |
| **AF** | | **100** | **10** | **100** | **10** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **19.2** | **0.43** | **22.5** | **0.276** | **1.1** | **> 202** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| R3/Stream | 0.005 | <0.001 | 0.012 | <0.001 | 0.018 | 0.005 | <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 9.5-138: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for NOA 409480 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in hops (hops; modelling use Hops -- BBCH 37 - 79, early -- 2×0.15 kg a.s./ha, 14d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 1920** | **NOEC (parent) 4.3** | **$EC_{50}$ 2250** | **NOEC (parent) 2.76** | **NOEC (ACR) 11** | **$E_rC_{50}/E_yC_{50}$ > 2020** | | | | |
| **AF** | | **100** | **10** | **100** | **10** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **19.2** | **0.43** | **22.5** | **0.276** | **1.1** | **> 202** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| R1/Pond | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R1/Stream | 0.004 | <0.001 | 0.009 | <0.001 | 0.014 | 0.004 | <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 9.5-139: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for NOA 409480 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in hops (hops; modelling use Hops -- BBCH 37 - 79, late -- 2×0.15 kg a.s./ha, 14d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 1920** | **NOEC (parent) 4.3** | **$EC_{50}$ 2250** | **NOEC (parent) 2.76** | **NOEC (ACR) 11** | **$E_rC_{50}/E_yC_{50}$ > 2020** | | | | |
| **AF** | | **100** | **10** | **100** | **10** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **19.2** | **0.43** | **22.5** | **0.276** | **1.1** | **> 202** | | | | |
| **FOCUS Scenario** | **PEC $_{gl\text{-}max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| R1/Pond | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R1/Stream | 0.002 | <0.001 | 0.005 | <0.001 | 0.007 | 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

**Table 9.5-140: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for NOA 409480 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in berries (berries; modelling use Vines II -- early, BBCH 15 -- 2×0.2 kg a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 1920** | **NOEC (parent) 4.3** | **$EC_{50}$ 2250** | **NOEC (parent) 2.76** | **NOEC (ACR) 11** | **$E_rC_{50}/E_yC_{50}$ > 2020** | | | | |
| **AF** | | **100** | **10** | **100** | **10** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **19.2** | **0.43** | **22.5** | **0.276** | **1.1** | **> 202** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D6/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R1/Pond | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R1/Stream | 0.008 | <0.001 | 0.019 | <0.001 | 0.029 | 0.007 | <0.001 | | | | |
| R2/Stream | 0.003 | <0.001 | 0.007 | <0.001 | 0.011 | 0.003 | <0.001 | | | | |
| R3/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R4/Stream | 0.019 | 0.001 | 0.044 | 0.001 | 0.069 | 0.017 | <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 9.5-141: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for NOA 409480 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in berries (berries; modelling use Vines II -- middle, BBCH 65 -- 2×0.2 kg a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 1920** | **NOEC (parent) 4.3** | **$EC_{50}$ 2250** | **NOEC (parent) 2.76** | **NOEC (ACR) 11** | **$E_rC_{50}/E_yC_{50}$ > 2020** | | | | |
| **AF** | | **100** | **10** | **100** | **10** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **19.2** | **0.43** | **22.5** | **0.276** | **1.1** | **> 202** | | | | |
| **FOCUS Scenario** | **PEC $_{gl\text{-}max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D6/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R1/Pond | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R1/Stream | 0.005 | <0.001 | 0.012 | <0.001 | 0.018 | 0.005 | <0.001 | | | | |
| R2/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R3/Stream | 0.005 | <0.001 | 0.012 | <0.001 | 0.018 | 0.005 | <0.001 | | | | |
| R4/Stream | 0.010 | 0.001 | 0.023 | <0.001 | 0.036 | 0.009 | <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 9.5-142: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for NOA 409480 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in berries (berries; modelling use Vines II -- late, BBCH 89 -- 2×0.2 kg a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 1920** | **NOEC (parent) 4.3** | **$EC_{50}$ 2250** | **NOEC (parent) 2.76** | **NOEC (ACR) 11** | **$E_rC_{50}/E_yC_{50}$ > 2020** | | | | |
| **AF** | | **100** | **10** | **100** | **10** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **19.2** | **0.43** | **22.5** | **0.276** | **1.1** | **> 202** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D6/Ditch | 0.002 | <0.001 | 0.005 | <0.001 | 0.007 | 0.002 | <0.001 | | | | |
| R1/Pond | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R1/Stream | 0.005 | <0.001 | 0.012 | <0.001 | 0.018 | 0.005 | <0.001 | | | | |
| R2/Stream | 0.002 | <0.001 | 0.005 | <0.001 | 0.007 | 0.002 | <0.001 | | | | |
| R3/Stream | 0.005 | <0.001 | 0.012 | <0.001 | 0.018 | 0.005 | <0.001 | | | | |
| R4/Stream | 0.011 | 0.001 | 0.026 | <0.001 | 0.040 | 0.010 | <0.001 | | | | |

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

**Table 9.5-143: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for NOA 409480 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in grapes (grapes; modelling use vines VI -- early, BBCH 15 -- 2×0.05 kg a.s./ha, 14d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 1920** | **NOEC (parent) 4.3** | **$EC_{50}$ 2250** | **NOEC (parent) 2.76** | **NOEC (ACR) 11** | **$E_rC_{50}/E_yC_{50}$ > 2020** | | | | |
| **AF** | | **100** | **10** | **100** | **10** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **19.2** | **0.43** | **22.5** | **0.276** | **1.1** | **> 202** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D6/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R1/Pond | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R1/Stream | 0.002 | <0.001 | 0.005 | <0.001 | 0.007 | 0.002 | <0.001 | | | | |
| R2/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R3/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R4/Stream | 0.004 | <0.001 | 0.009 | <0.001 | 0.014 | 0.004 | <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 9.5-144: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for NOA 409480 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in grapes (grapes; modelling use vines VI -- middle, BBCH 65 -- 2×0.05 kg a.s./ha, 14d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 1920** | **NOEC (parent) 4.3** | **$EC_{50}$ 2250** | **NOEC (parent) 2.76** | **NOEC (ACR) 11** | **$E_rC_{50}/E_yC_{50}$ > 2020** | | | | |
| **AF** | | **100** | **10** | **100** | **10** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **19.2** | **0.43** | **22.5** | **0.276** | **1.1** | **> 202** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D6/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R1/Pond | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R1/Stream | 0.001 | <0.001 | 0.002 | <0.001 | 0.004 | 0.001 | <0.001 | | | | |
| R2/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R3/Stream | 0.001 | <0.001 | 0.002 | <0.001 | 0.004 | 0.001 | <0.001 | | | | |
| R4/Stream | 0.001 | <0.001 | 0.002 | <0.001 | 0.004 | 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 9.5-145: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for NOA 409480 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in grapes (grapes; modelling use vines VI -- late, BBCH 85 -- 2×0.05 kg a.s./ha, 14d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 1920** | **NOEC (parent) 4.3** | **$EC_{50}$ 2250** | **NOEC (parent) 2.76** | **NOEC (ACR) 11** | **$E_rC_{50}$/$E_yC_{50}$ > 2020** | | | | |
| **AF** | | **100** | **10** | **100** | **10** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **19.2** | **0.43** | **22.5** | **0.276** | **1.1** | **> 202** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D6/Ditch | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R1/Pond | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R1/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R2/Stream | <0.001 | <<0.001 | <0.002 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | | |
| R3/Stream | 0.001 | <0.001 | 0.002 | <0.001 | 0.004 | 0.001 | <0.001 | | | | |
| R4/Stream | 0.002 | <0.001 | 0.005 | <0.001 | 0.007 | 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

### 9.5.2.17 Metabolite CGA 357276

**Table 9.5-146: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357276 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in asparagus, garden cress, flower tubers and ornamentals (asparagus, garden cress, flower tubers, ornamentals; modelling use field beans I -- field beans (early) -- 0.2 kg a.s./ha)**

| Group | | Fish acute | Fish prolonged | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Test species | | *Oncorhynchus mykiss* | *Oncorhynchus mykiss* | *Fish prolonged* | *Daphnia magna* | *Daphnia magna* | *Pseudokirchneriella subcapitata* | | | | |
| Endpoint<br>(µg/L) | | $LC_{50}$<br>983 | NOEC (parent)<br>4.3 | NOEC (ACR)<br>9.83 | $EC_{50}$<br>514 | NOEC<br>2.59 | $E_rC_{50}/E_yC_{50}$<br>> 5880 | | | | |
| AF | | 100 | 10 | 10 | 100 | 10 | 10 | | | | |
| RAC (µg/L) | | 9.83 | 0.43 | 0.983 | 5.14 | 0.259 | > 588 | | | | |
| FOCUS Scenario | PEC $_{gl-max}$ (µg/L) | | | | | | | | | | |
| Step 3 | | | | | | | | | | | |
| D2/Ditch | 0.002 | <0.001 | 0.005 | 0.002 | <0.001 | 0.008 | <0.001 | | | | |
| D2/Stream | 0.002 | <0.001 | 0.005 | 0.002 | <0.001 | 0.008 | <0.001 | | | | |
| D3/Ditch | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| D4/Pond | 0.004 | <0.001 | 0.009 | 0.004 | 0.001 | 0.015 | <0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| D6/Ditch | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| D6/Ditch 2nd | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| R1/Pond | 0.004 | <0.001 | 0.009 | 0.004 | 0.001 | 0.015 | <0.001 | | | | |
| R1/Stream | 0.003 | <0.001 | 0.007 | 0.003 | 0.001 | 0.012 | <0.001 | | | | |
| R2/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| R3/Stream | 0.003 | <0.001 | 0.007 | 0.003 | 0.001 | 0.012 | <0.001 | | | | |
| R4/Stream | 0.005 | 0.001 | 0.012 | 0.005 | 0.001 | 0.019 | <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 9.5-147: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357276 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in asparagus, garden cress, flower tubers and ornamentals (asparagus, garden cress, flower tubers, ornamentals; modelling use field beans I -- field beans (late) -- 0.2 kg a.s./ha)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | |
| **Endpoint**<br><br>**(µg/L)** | | **$LC_{50}$**<br><br>**983** | **NOEC (parent)**<br><br>**4.3** | **NOEC (ACR)**<br><br>**9.83** | **$EC_{50}$**<br><br>**514** | **NOEC**<br><br>**2.59** | **NOEC (ACR)**<br><br>**10.28** | **$E_rC_{50}$/$E_yC_{50}$**<br><br>**> 5880** | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | **10** | | | |
| **RAC (µg/L)** | | **9.83** | **0.43** | **0.983** | **5.14** | **0.259** | **1.028** | **> 588** | | | |
| **FOCUS Scenario** | **PEC $_{gl\text{-}max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D2/Ditch | 0.038 | 0.004 | 0.088 | 0.039 | 0.007 | 0.147 | 0.037 | <0.001 | | | |
| D2/Stream | 0.032 | 0.003 | 0.074 | 0.033 | 0.006 | 0.124 | 0.031 | <0.001 | | | |
| D3/Ditch | 0.002 | <0.001 | 0.005 | 0.002 | <0.001 | 0.008 | 0.002 | <0.001 | | | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| D4/Pond | 0.004 | <0.001 | 0.009 | 0.004 | 0.001 | 0.015 | 0.004 | <0.001 | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | |
| D6/Ditch | 0.015 | 0.002 | 0.035 | 0.015 | 0.003 | 0.058 | 0.015 | <0.001 | | | |
| D6/Ditch 2nd | 0.003 | <0.001 | 0.007 | 0.003 | 0.001 | 0.012 | 0.003 | <0.001 | | | |
| R1/Pond | 0.004 | <0.001 | 0.009 | 0.004 | 0.001 | 0.015 | 0.004 | <0.001 | | | |
| R1/Stream | 0.002 | <0.001 | 0.005 | 0.002 | <0.001 | 0.008 | 0.002 | <0.001 | | | |
| R2/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | |
| R3/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | |
| R4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <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 9.5-148: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357276 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in beans and nurseries (beans and nurseries; modelling use field beans II -- field beans II, BBCH 19 -- 2×0.2 kg a.s./ha, 14d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | |
| **Endpoint** <br><br> **(µg/L)** | | **$LC_{50}$** <br><br> **983** | **NOEC (parent)** <br> **4.3** | **NOEC (ACR)** <br><br> **9.83** | **$EC_{50}$** <br><br> **514** | **NOEC** <br><br> **2.59** | **NOEC (ACR)** <br><br> **10.28** | **$E_rC_{50}/E_yC_{50}$** <br><br> **> 5880** | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | **10** | | | |
| **RAC (µg/L)** | | **9.83** | **0.43** | **0.983** | **5.14** | **0.259** | **1.028** | **> 588** | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D2/Ditch | 0.002 | <0.001 | 0.005 | 0.002 | <0.001 | 0.008 | 0.002 | <0.001 | | | |
| D2/Stream | 0.002 | <0.001 | 0.005 | 0.002 | <0.001 | 0.008 | 0.002 | <0.001 | | | |
| D3/Ditch | 0.001 | <0.001 | 0.002 | 0.001 | <0.001 | 0.004 | 0.001 | <0.001 | | | |
| D4/Pond | 0.008 | 0.001 | 0.019 | 0.008 | 0.002 | 0.031 | 0.008 | <0.001 | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | |
| D6/Ditch | 0.008 | 0.001 | 0.019 | 0.008 | 0.002 | 0.031 | 0.008 | <0.001 | | | |
| D6/Ditch 2nd | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | |
| R1/Pond | 0.008 | 0.001 | 0.019 | 0.008 | 0.002 | 0.031 | 0.008 | <0.001 | | | |
| R1/Stream | 0.005 | 0.001 | 0.012 | 0.005 | 0.001 | 0.019 | 0.005 | <0.001 | | | |
| R2/Stream | 0.001 | <0.001 | 0.002 | 0.001 | <0.001 | 0.004 | 0.001 | <0.001 | | | |
| R3/Stream | 0.004 | <0.001 | 0.009 | 0.004 | 0.001 | 0.015 | 0.004 | <0.001 | | | |
| R4/Stream | 0.008 | 0.001 | 0.019 | 0.008 | 0.002 | 0.031 | 0.008 | <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 9.5-149: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357276 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in beans and nurseries (beans and nurseries; modelling use field beans II -- field beans II, BBCH 89 -- 2×0.2 kg a.s./ha, 14d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 983** | **NOEC (parent) 4.3** | **NOEC (ACR) 9.83** | **$EC_{50}$ 514** | **NOEC 2.59** | **NOEC (ACR) 10.28** | **$E_rC_{50}/E_yC_{50}$ > 5880** | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | **10** | | | |
| **RAC (µg/L)** | | **9.83** | **0.43** | **0.983** | **5.14** | **0.259** | **1.028** | **> 588** | | | |
| **FOCUS Scenario** | **PEC $_{gl\text{-}max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D2/Ditch | 0.067 | 0.007 | 0.156 | 0.068 | 0.013 | 0.259 | 0.065 | <0.001 | | | |
| D2/Stream | 0.038 | 0.004 | 0.088 | 0.039 | 0.007 | 0.147 | 0.037 | <0.001 | | | |
| D3/Ditch | 0.002 | <0.001 | 0.005 | 0.002 | <0.001 | 0.008 | 0.002 | <0.001 | | | |
| D4/Pond | 0.008 | 0.001 | 0.019 | 0.008 | 0.002 | 0.031 | 0.008 | <0.001 | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | |
| D6/Ditch | 0.011 | 0.001 | 0.026 | 0.011 | 0.002 | 0.042 | 0.011 | <0.001 | | | |
| D6/Ditch 2nd | 0.003 | <0.001 | 0.007 | 0.003 | 0.001 | 0.012 | 0.003 | <0.001 | | | |
| R1/Pond | 0.008 | 0.001 | 0.019 | 0.008 | 0.002 | 0.031 | 0.008 | <0.001 | | | |
| R1/Stream | 0.003 | <0.001 | 0.007 | 0.003 | 0.001 | 0.012 | 0.003 | <0.001 | | | |
| R2/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | |
| R3/Stream | 0.002 | <0.001 | 0.005 | 0.002 | <0.001 | 0.008 | 0.002 | <0.001 | | | |
| R4/Stream | 0.005 | 0.001 | 0.012 | 0.005 | 0.001 | 0.019 | 0.005 | <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 9.5-150: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357276 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in asparagus (asparagus; modelling use field beans III -- field beans III, BBCH 23 -- 2×0.2 kg a.s./ha, 10d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 983** | **NOEC (parent) 4.3** | **NOEC (ACR) 9.83** | **$EC_{50}$ 514** | **NOEC 2.59** | **NOEC (ACR) 10.28** | **$E_rC_{50}$/$E_yC_{50}$ > 5880** | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | **10** | | | |
| **RAC (µg/L)** | | **9.83** | **0.43** | **0.983** | **5.14** | **0.259** | **1.028** | **> 588** | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D2/Ditch | 0.015 | 0.002 | 0.035 | 0.015 | 0.003 | 0.058 | 0.015 | <0.001 | | | |
| D2/Stream | 0.005 | 0.001 | 0.012 | 0.005 | 0.001 | 0.019 | 0.005 | <0.001 | | | |
| D3/Ditch | 0.002 | <0.001 | 0.005 | 0.002 | <0.001 | 0.008 | 0.002 | <0.001 | | | |
| D4/Pond | 0.008 | 0.001 | 0.019 | 0.008 | 0.002 | 0.031 | 0.008 | <0.001 | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | |
| D6/Ditch | 0.005 | 0.001 | 0.012 | 0.005 | 0.001 | 0.019 | 0.005 | <0.001 | | | |
| D6/Ditch 2nd | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | |
| R1/Pond | 0.008 | 0.001 | 0.019 | 0.008 | 0.002 | 0.031 | 0.008 | <0.001 | | | |
| R1/Stream | 0.005 | 0.001 | 0.012 | 0.005 | 0.001 | 0.019 | 0.005 | <0.001 | | | |
| R2/Stream | 0.001 | <0.001 | 0.002 | 0.001 | <0.001 | 0.004 | 0.001 | <0.001 | | | |
| R3/Stream | 0.005 | 0.001 | 0.012 | 0.005 | 0.001 | 0.019 | 0.005 | <0.001 | | | |
| R4/Stream | 0.008 | 0.001 | 0.019 | 0.008 | 0.002 | 0.031 | 0.008 | <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 9.5-151: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357276 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in asparagus (asparagus; modelling use field beans III -- field beans III, BBCH 95 -- 2×0.2 kg a.s./ha, 10d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | |
| **Endpoint**<br>**(µg/L)** | | **$LC_{50}$**<br>**983** | **NOEC (parent)**<br>**4.3** | **NOEC (ACR)**<br>**9.83** | **$EC_{50}$**<br>**514** | **NOEC**<br>**2.59** | **NOEC (ACR)**<br>**10.28** | **$E_rC_{50}/E_yC_{50}$**<br>**> 5880** | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | **10** | | | |
| **RAC (µg/L)** | | **9.83** | **0.43** | **0.983** | **5.14** | **0.259** | **1.028** | **> 588** | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D2/Ditch | 0.062 | 0.006 | 0.144 | 0.063 | 0.012 | 0.239 | 0.060 | <0.001 | | | |
| D2/Stream | 0.051 | 0.005 | 0.119 | 0.052 | 0.010 | 0.197 | 0.050 | <0.001 | | | |
| D3/Ditch | 0.002 | <0.001 | 0.005 | 0.002 | <0.001 | 0.008 | 0.002 | <0.001 | | | |
| D4/Pond | 0.007 | 0.001 | 0.016 | 0.007 | 0.001 | 0.027 | 0.007 | <0.001 | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | |
| D6/Ditch | 0.022 | 0.002 | 0.051 | 0.022 | 0.004 | 0.085 | 0.021 | <0.001 | | | |
| D6/Ditch 2nd | 0.007 | 0.001 | 0.016 | 0.007 | 0.001 | 0.027 | 0.007 | <0.001 | | | |
| R1/Pond | 0.007 | 0.001 | 0.016 | 0.007 | 0.001 | 0.027 | 0.007 | <0.001 | | | |
| R1/Stream | 0.004 | <0.001 | 0.009 | 0.004 | 0.001 | 0.015 | 0.004 | <0.001 | | | |
| R2/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | |
| R3/Stream | 0.002 | <0.001 | 0.005 | 0.002 | <0.001 | 0.008 | 0.002 | <0.001 | | | |
| R4/Stream | 0.004 | <0.001 | 0.009 | 0.004 | 0.001 | 0.015 | 0.004 | <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 9.5-152: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357276 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in baby leaf crops, beans, garden cress and strawberries (baby leaf crops, beans, garden cress, strawberries; modelling use field beans IV -- field beans IV, BBCH 40 -- 2×0.2 kg a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Inverteb. prolonged** | **Algae** | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 983** | **NOEC (parent) 4.3** | **NOEC (ACR) 9.83** | **$EC_{50}$ 514** | **NOEC 2.59** | **NOEC (ACR) 10.28** | **$E_rC_{50}/E_yC_{50}$ > 5880** | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | **10** | | | |
| **RAC (µg/L)** | | **9.83** | **0.43** | **0.983** | **5.14** | **0.259** | **1.028** | **> 588** | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D2/Ditch | 0.029 | 0.003 | 0.067 | 0.030 | 0.006 | 0.112 | 0.028 | <0.001 | | | |
| D2/Stream | 0.006 | 0.001 | 0.014 | 0.006 | 0.001 | 0.023 | 0.006 | <0.001 | | | |
| D3/Ditch | 0.002 | <0.001 | 0.005 | 0.002 | <0.001 | 0.008 | 0.002 | <0.001 | | | |
| D4/Pond | 0.008 | 0.001 | 0.019 | 0.008 | 0.002 | 0.031 | 0.008 | <0.001 | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | |
| D6/Ditch | 0.005 | 0.001 | 0.012 | 0.005 | 0.001 | 0.019 | 0.005 | <0.001 | | | |
| D6/Ditch 2nd | 0.001 | <0.001 | 0.002 | 0.001 | <0.001 | 0.004 | 0.001 | <0.001 | | | |
| R1/Pond | 0.009 | 0.001 | 0.021 | 0.009 | 0.002 | 0.035 | 0.009 | <0.001 | | | |
| R1/Stream | 0.005 | 0.001 | 0.012 | 0.005 | 0.001 | 0.019 | 0.005 | <0.001 | | | |
| R2/Stream | 0.001 | <0.001 | 0.002 | 0.001 | <0.001 | 0.004 | 0.001 | <0.001 | | | |
| R3/Stream | 0.004 | <0.001 | 0.009 | 0.004 | 0.001 | 0.015 | 0.004 | <0.001 | | | |
| R4/Stream | 0.009 | 0.001 | 0.021 | 0.009 | 0.002 | 0.035 | 0.009 | <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 9.5-153: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357276 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in baby leaf crops, beans, garden cress and strawberries (baby leaf crops, beans, garden cress, strawberries; modelling use field beans IV -- field beans IV, BBCH 89 -- 2×0.2 kg a.s./ha, 7d int.)**

| Group | | Fish acute | Fish prolonged | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Inverteb. prolonged | Algae | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Test species | | *Oncorhynchus mykiss* | *Oncorhynchus mykiss* | *Fish prolonged* | *Daphnia magna* | *Daphnia magna* | *Daphnia magna* | *Pseudokirchneriella subcapitata* | | | |
| Endpoint (µg/L) | | $LC_{50}$ 983 | NOEC (parent) 4.3 | NOEC (ACR) 9.83 | $EC_{50}$ 514 | NOEC 2.59 | NOEC (ACR) 10.28 | $E_rC_{50}/E_yC_{50}$ > 5880 | | | |
| AF | | 100 | 10 | 10 | 100 | 10 | 10 | 10 | | | |
| RAC (µg/L) | | 9.83 | 0.43 | 0.983 | 5.14 | 0.259 | 1.028 | > 588 | | | |
| FOCUS Scenario | PEC $_{gl-max}$ (µg/L) | | | | | | | | | | |
| Step 3 | | | | | | | | | | | |
| D2/Ditch | 0.082 | 0.008 | 0.191 | 0.083 | 0.016 | 0.317 | 0.080 | <0.001 | | | |
| D2/Stream | 0.045 | 0.005 | 0.105 | 0.046 | 0.009 | 0.174 | 0.044 | <0.001 | | | |
| D3/Ditch | 0.002 | <0.001 | 0.005 | 0.002 | <0.001 | 0.008 | 0.002 | <0.001 | | | |
| D4/Pond | 0.008 | 0.001 | 0.019 | 0.008 | 0.002 | 0.031 | 0.008 | <0.001 | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | |
| D6/Ditch | 0.005 | 0.001 | 0.012 | 0.005 | 0.001 | 0.019 | 0.005 | <0.001 | | | |
| D6/Ditch 2nd | 0.002 | <0.001 | 0.005 | 0.002 | <0.001 | 0.008 | 0.002 | <0.001 | | | |
| R1/Pond | 0.008 | 0.001 | 0.019 | 0.008 | 0.002 | 0.031 | 0.008 | <0.001 | | | |
| R1/Stream | 0.003 | <0.001 | 0.007 | 0.003 | 0.001 | 0.012 | 0.003 | <0.001 | | | |
| R2/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <0.001 | <<0.001 | | | |
| R3/Stream | 0.004 | <0.001 | 0.009 | 0.004 | 0.001 | 0.015 | 0.004 | <0.001 | | | |
| R4/Stream | 0.009 | 0.001 | 0.021 | 0.009 | 0.002 | 0.035 | 0.009 | <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 9.5-154: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357276 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in golf courses (golf courses; modelling use Golf courses -- Grass (Mar) -- 2×0.125 kg a.s./ha, 14d int.)**

| Group | | Fish acute | Fish prolonged | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Test species | | *Oncorhynchus mykiss* | *Oncorhynchus mykiss* | *Fish prolonged* | *Daphnia magna* | *Daphnia magna* | *Pseudokirchneriella subcapitata* | | | | |
| Endpoint (µg/L) | | $LC_{50}$ 983 | NOEC (parent) 4.3 | NOEC (ACR) 9.83 | $EC_{50}$ 514 | NOEC 2.59 | $E_rC_{50}/E_yC_{50}$ > 5880 | | | | |
| AF | | 100 | 10 | 10 | 100 | 10 | 10 | | | | |
| RAC (µg/L) | | 9.83 | 0.43 | 0.983 | 5.14 | 0.259 | > 588 | | | | |
| FOCUS Scenario | PEC $_{gl\text{-}max}$ (µg/L) | | | | | | | | | | |
| Step 3 | | | | | | | | | | | |
| D1/Ditch | 0.003 | <0.001 | 0.007 | 0.003 | 0.001 | 0.012 | <0.001 | | | | |
| D1/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| D2/Ditch | 0.020 | 0.002 | 0.047 | 0.020 | 0.004 | 0.077 | <0.001 | | | | |
| D2/Stream | 0.013 | 0.001 | 0.030 | 0.013 | 0.003 | 0.050 | <0.001 | | | | |
| D3/Ditch | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| D4/Pond | 0.004 | <0.001 | 0.009 | 0.004 | 0.001 | 0.015 | <0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| D5/Pond | 0.005 | 0.001 | 0.012 | 0.005 | 0.001 | 0.019 | <0.001 | | | | |
| D5/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| R2/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| R3/Stream | 0.002 | <0.001 | 0.005 | 0.002 | <0.001 | 0.008 | <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 9.5-155: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357276 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in golf courses (golf courses; modelling use Golf courses -- Grass (Jun) -- 2×0.125 kg a.s./ha, 14d int.)**

| Group | | Fish acute | Fish prolonged | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Test species | | *Oncorhynchus mykiss* | *Oncorhynchus mykiss* | *Fish prolonged* | *Daphnia magna* | *Daphnia magna* | *Pseudokirchneriella subcapitata* | | | | |
| Endpoint (µg/L) | | $LC_{50}$ 983 | NOEC (parent) 4.3 | NOEC (ACR) 9.83 | $EC_{50}$ 514 | NOEC 2.59 | $E_rC_{50}/E_yC_{50}$ > 5880 | | | | |
| AF | | 100 | 10 | 10 | 100 | 10 | 10 | | | | |
| RAC (µg/L) | | 9.83 | 0.43 | 0.983 | 5.14 | 0.259 | > 588 | | | | |
| FOCUS Scenario | PEC $_{gl-max}$ (µg/L) | | | | | | | | | | |
| Step 3 | | | | | | | | | | | |
| D1/Ditch | 0.104 | 0.011 | 0.242 | 0.106 | 0.020 | 0.402 | <0.001 | | | | |
| D1/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| D2/Ditch | 0.129 | 0.013 | 0.300 | 0.131 | 0.025 | 0.498 | <0.001 | | | | |
| D2/Stream | 0.092 | 0.009 | 0.214 | 0.094 | 0.018 | 0.355 | <0.001 | | | | |
| D3/Ditch | 0.003 | <0.001 | 0.007 | 0.003 | 0.001 | 0.012 | <0.001 | | | | |
| D4/Pond | 0.005 | 0.001 | 0.012 | 0.005 | 0.001 | 0.019 | <0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| D5/Pond | 0.006 | 0.001 | 0.014 | 0.006 | 0.001 | 0.023 | <0.001 | | | | |
| D5/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| R2/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| R3/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<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 9.5-156: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357276 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in golf courses (golf courses; modelling use Golf courses -- Grass (Sep) -- 2×0.125 kg a.s./ha, 14d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 983** | **NOEC (parent) 4.3** | **NOEC (ACR) 9.83** | **$EC_{50}$ 514** | **NOEC 2.59** | **$E_rC_{50}/E_yC_{50}$ > 5880** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9.83** | **0.43** | **0.983** | **5.14** | **0.259** | **> 588** | | | | |
| **FOCUS Scenario** | **PEC $_{gl\text{-}max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D1/Ditch | 0.085 | 0.009 | 0.198 | 0.086 | 0.017 | 0.328 | <0.001 | | | | |
| D1/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| D2/Ditch | 0.085 | 0.009 | 0.198 | 0.086 | 0.017 | 0.328 | <0.001 | | | | |
| D2/Stream | 0.053 | 0.005 | 0.123 | 0.054 | 0.010 | 0.205 | <0.001 | | | | |
| D3/Ditch | 0.001 | <0.001 | 0.002 | 0.001 | <0.001 | 0.004 | <0.001 | | | | |
| D4/Pond | 0.004 | <0.001 | 0.009 | 0.004 | 0.001 | 0.015 | <0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| D5/Pond | 0.005 | 0.001 | 0.012 | 0.005 | 0.001 | 0.019 | <0.001 | | | | |
| D5/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| R2/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| R3/Stream | 0.003 | <0.001 | 0.007 | 0.003 | 0.001 | 0.012 | <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 9.5-157: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357276 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in golf courses (golf courses; modelling use Golf courses -- Grass (Dec) -- 2×0.125 kg a.s./ha, 14d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 983** | **NOEC (parent) 4.3** | **NOEC (ACR) 9.83** | **$EC_{50}$ 514** | **NOEC 2.59** | **$E_rC_{50}/E_yC_{50}$ > 5880** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9.83** | **0.43** | **0.983** | **5.14** | **0.259** | **> 588** | | | | |
| **FOCUS Scenario** | **PEC $_{gl\text{-}max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D1/Ditch | 0.008 | 0.001 | 0.019 | 0.008 | 0.002 | 0.031 | <0.001 | | | | |
| D1/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| D2/Ditch | 0.015 | 0.002 | 0.035 | 0.015 | 0.003 | 0.058 | <0.001 | | | | |
| D2/Stream | 0.003 | <0.001 | 0.007 | 0.003 | 0.001 | 0.012 | <0.001 | | | | |
| D3/Ditch | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| D4/Pond | 0.003 | <0.001 | 0.007 | 0.003 | 0.001 | 0.012 | <0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| D5/Pond | 0.003 | <0.001 | 0.007 | 0.003 | 0.001 | 0.012 | <0.001 | | | | |
| D5/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| R2/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| R3/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<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 9.5-158: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357276 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in peas (peas; modelling use Legumes, BBCH 59 - 89 -- 2×0.2 kg a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 983** | **NOEC (parent) 4.3** | **NOEC (ACR) 9.83** | **$EC_{50}$ 514** | **NOEC 2.59** | **$E_rC_{50}/E_yC_{50}$ > 5880** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9.83** | **0.43** | **0.983** | **5.14** | **0.259** | **> 588** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D3/Ditch | 0.001 | <0.001 | 0.002 | 0.001 | <0.001 | 0.004 | <0.001 | | | | |
| D4/Pond | 0.007 | 0.001 | 0.016 | 0.007 | 0.001 | 0.027 | <0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| D5/Pond | 0.010 | 0.001 | 0.023 | 0.010 | 0.002 | 0.039 | <0.001 | | | | |
| D5/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| D6/Ditch | 0.001 | <0.001 | 0.002 | 0.001 | <0.001 | 0.004 | <0.001 | | | | |
| R1/Pond | 0.009 | 0.001 | 0.021 | 0.009 | 0.002 | 0.035 | <0.001 | | | | |
| R1/Stream | 0.005 | 0.001 | 0.012 | 0.005 | 0.001 | 0.019 | <0.001 | | | | |
| R2/Stream | 0.001 | <0.001 | 0.002 | 0.001 | <0.001 | 0.004 | <0.001 | | | | |
| R3/Stream | 0.002 | <0.001 | 0.005 | 0.002 | <0.001 | 0.008 | <0.001 | | | | |
| R4/Stream | 0.007 | 0.001 | 0.016 | 0.007 | 0.001 | 0.027 | <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 9.5-159: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357276 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in peas (peas; modelling use Legumes, BBCH 59 - 79 -- 2×0.2 kg a.s./ha, 14d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint** (µg/L) | | **$LC_{50}$** 983 | **NOEC (parent)** 4.3 | **NOEC (ACR)** 9.83 | **$EC_{50}$** 514 | **NOEC** 2.59 | **$E_rC_{50}/E_yC_{50}$** > 5880 | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9.83** | **0.43** | **0.983** | **5.14** | **0.259** | **> 588** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D3/Ditch | 0.001 | <0.001 | 0.002 | 0.001 | <0.001 | 0.004 | <0.001 | | | | |
| D4/Pond | 0.007 | 0.001 | 0.016 | 0.007 | 0.001 | 0.027 | <0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| D5/Pond | 0.010 | 0.001 | 0.023 | 0.010 | 0.002 | 0.039 | <0.001 | | | | |
| D5/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| D6/Ditch | 0.001 | <0.001 | 0.002 | 0.001 | <0.001 | 0.004 | <0.001 | | | | |
| R1/Pond | 0.009 | 0.001 | 0.021 | 0.009 | 0.002 | 0.035 | <0.001 | | | | |
| R1/Stream | 0.005 | 0.001 | 0.012 | 0.005 | 0.001 | 0.019 | <0.001 | | | | |
| R2/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| R3/Stream | 0.002 | <0.001 | 0.005 | 0.002 | <0.001 | 0.008 | <0.001 | | | | |
| R4/Stream | 0.007 | 0.001 | 0.016 | 0.007 | 0.001 | 0.027 | <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 9.5-160: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357276 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in celeriac (celeriac; modelling use Sugar beets, BBCH 40 - 49 (June - November) -- 2×0.125 kg a.s./ha, 14d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 983** | **NOEC (parent) 4.3** | **NOEC (ACR) 9.83** | **$EC_{50}$ 514** | **NOEC 2.59** | **$E_rC_{50}/E_yC_{50}$ > 5880** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9.83** | **0.43** | **0.983** | **5.14** | **0.259** | **> 588** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D3/Ditch | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| D4/Pond | 0.004 | <0.001 | 0.009 | 0.004 | 0.001 | 0.015 | <0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| R1/Pond | 0.005 | 0.001 | 0.012 | 0.005 | 0.001 | 0.019 | <0.001 | | | | |
| R1/Stream | 0.001 | <0.001 | 0.002 | 0.001 | <0.001 | 0.004 | <0.001 | | | | |
| R3/Stream | 0.002 | <0.001 | 0.005 | 0.002 | <0.001 | 0.008 | <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 9.5-161: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357276 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in chicory (chicory; modelling use Sugar beets, BBCH 13 - 49, early --0.2 kg a.s./ha)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint** (µg/L) | | **$LC_{50}$** 983 | **NOEC (parent)** 4.3 | **NOEC (ACR)** 9.83 | **$EC_{50}$** 514 | **NOEC** 2.59 | **$E_rC_{50}/E_yC_{50}$** > 5880 | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9.83** | **0.43** | **0.983** | **5.14** | **0.259** | **> 588** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D3/Ditch | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| D4/Pond | 0.004 | <0.001 | 0.009 | 0.004 | 0.001 | 0.015 | <0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| R1/Pond | 0.004 | <0.001 | 0.009 | 0.004 | 0.001 | 0.015 | <0.001 | | | | |
| R1/Stream | 0.003 | <0.001 | 0.007 | 0.003 | 0.001 | 0.012 | <0.001 | | | | |
| R3/Stream | 0.003 | <0.001 | 0.007 | 0.003 | 0.001 | 0.012 | <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 9.5-162: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357276 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in chicory (chicory; modelling use Sugar beets, BBCH 13 - 49, late -- 0.2 kg a.s./ha)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint** (µg/L) | | **$LC_{50}$** 983 | **NOEC (parent)** 4.3 | **NOEC (ACR)** 9.83 | **$EC_{50}$** 514 | **NOEC** 2.59 | **$E_rC_{50}/E_yC_{50}$** > 5880 | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9.83** | **0.43** | **0.983** | **5.14** | **0.259** | **> 588** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D3/Ditch | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| D4/Pond | 0.003 | <0.001 | 0.007 | 0.003 | 0.001 | 0.012 | <0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| R1/Pond | 0.004 | <0.001 | 0.009 | 0.004 | 0.001 | 0.015 | <0.001 | | | | |
| R1/Stream | 0.001 | <0.001 | 0.002 | 0.001 | <0.001 | 0.004 | <0.001 | | | | |
| R3/Stream | 0.002 | <0.001 | 0.005 | 0.002 | <0.001 | 0.008 | <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 9.5-163: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357276 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in flower bulbs (flower bulbs; modelling use VegBulb I -- VegBulb I (early) -- 0.2 kg a.s./ha)**

| Group | | Fish acute | Fish prolonged | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Test species | | *Oncorhynchus mykiss* | *Oncorhynchus mykiss* | *Fish prolonged* | *Daphnia magna* | *Daphnia magna* | *Pseudokirchneriella subcapitata* | | | | |
| Endpoint<br>(µg/L) | | $LC_{50}$<br>983 | NOEC (parent)<br>4.3 | NOEC (ACR)<br>9.83 | $EC_{50}$<br>514 | NOEC<br>2.59 | $E_rC_{50}/E_yC_{50}$<br>> 5880 | | | | |
| AF | | 100 | 10 | 10 | 100 | 10 | 10 | | | | |
| RAC (µg/L) | | 9.83 | 0.43 | 0.983 | 5.14 | 0.259 | > 588 | | | | |
| FOCUS Scenario | PEC $_{gl-max}$ (µg/L) | | | | | | | | | | |
| Step 3 | | | | | | | | | | | |
| D3/Ditch | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| D4/Pond | 0.004 | <0.001 | 0.009 | 0.004 | 0.001 | 0.015 | <0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| D6/Ditch | 0.007 | 0.001 | 0.016 | 0.007 | 0.001 | 0.027 | <0.001 | | | | |
| D6/Ditch 2nd | 0.010 | 0.001 | 0.023 | 0.010 | 0.002 | 0.039 | <0.001 | | | | |
| R1/Pond | 0.004 | <0.001 | 0.009 | 0.004 | 0.001 | 0.015 | <0.001 | | | | |
| R1/Stream | 0.003 | <0.001 | 0.007 | 0.003 | 0.001 | 0.012 | <0.001 | | | | |
| R2/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| R3/Stream | 0.003 | <0.001 | 0.007 | 0.003 | 0.001 | 0.012 | <0.001 | | | | |
| R4/Stream | 0.005 | 0.001 | 0.012 | 0.005 | 0.001 | 0.019 | <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 9.5-164: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357276 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in flower bulbs (flower bulbs; modelling use VegBulb I -- VegBulb I (middle) -- 0.2 kg a.s./ha)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint** <br><br> **(µg/L)** | | **$LC_{50}$** <br><br> **983** | **NOEC (parent)** <br> **4.3** | **NOEC (ACR)** <br> **9.83** | **$EC_{50}$** <br><br> **514** | **NOEC** <br><br> **2.59** | **$E_rC_{50}/E_yC_{50}$** <br><br> **> 5880** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9.83** | **0.43** | **0.983** | **5.14** | **0.259** | **> 588** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D3/Ditch | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| D4/Pond | 0.004 | <0.001 | 0.009 | 0.004 | 0.001 | 0.015 | <0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| D6/Ditch | 0.029 | 0.003 | 0.067 | 0.030 | 0.006 | 0.112 | <0.001 | | | | |
| D6/Ditch 2nd | 0.003 | <0.001 | 0.007 | 0.003 | 0.001 | 0.012 | <0.001 | | | | |
| R1/Pond | 0.005 | 0.001 | 0.012 | 0.005 | 0.001 | 0.019 | <0.001 | | | | |
| R1/Stream | 0.002 | <0.001 | 0.005 | 0.002 | <0.001 | 0.008 | <0.001 | | | | |
| R2/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| R3/Stream | 0.002 | <0.001 | 0.005 | 0.002 | <0.001 | 0.008 | <0.001 | | | | |
| R4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<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 9.5-165: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357276 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in flower bulbs (flower bulbs; modelling use VegBulb I -- VegBulb I (late) -- 0.2 kg a.s./ha)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 983** | **NOEC (parent) 4.3** | **NOEC (ACR) 9.83** | **$EC_{50}$ 514** | **NOEC 2.59** | **$E_rC_{50}$/$E_yC_{50}$ > 5880** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9.83** | **0.43** | **0.983** | **5.14** | **0.259** | **> 588** | | | | |
| **FOCUS Scenario** | **PEC $_{gl\text{-}max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D3/Ditch | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| D4/Pond | 0.004 | <0.001 | 0.009 | 0.004 | 0.001 | 0.015 | <0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| D6/Ditch | 0.029 | 0.003 | 0.067 | 0.030 | 0.006 | 0.112 | <0.001 | | | | |
| D6/Ditch 2nd | 0.003 | <0.001 | 0.007 | 0.003 | 0.001 | 0.012 | <0.001 | | | | |
| R1/Pond | 0.004 | <0.001 | 0.009 | 0.004 | 0.001 | 0.015 | <0.001 | | | | |
| R1/Stream | 0.001 | <0.001 | 0.002 | 0.001 | <0.001 | 0.004 | <0.001 | | | | |
| R2/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| R3/Stream | 0.002 | <0.001 | 0.005 | 0.002 | <0.001 | 0.008 | <0.001 | | | | |
| R4/Stream | 0.005 | 0.001 | 0.012 | 0.005 | 0.001 | 0.019 | <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 9.5-166: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357276 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in flower bulbs (flower bulbs; modelling use VegBulb II -- VegBulb II (early) -- 5×0.075 kg a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint** <br> **(µg/L)** | | **$LC_{50}$** <br> **983** | **NOEC (parent)** <br> **4.3** | **NOEC (ACR)** <br> **9.83** | **$EC_{50}$** <br> **514** | **NOEC** <br> **2.59** | **$E_rC_{50}$/$E_yC_{50}$** <br> **> 5880** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9.83** | **0.43** | **0.983** | **5.14** | **0.259** | **> 588** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D3/Ditch | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| D4/Pond | 0.005 | 0.001 | 0.012 | 0.005 | 0.001 | 0.019 | <0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| D6/Ditch | 0.021 | 0.002 | 0.049 | 0.021 | 0.004 | 0.081 | <0.001 | | | | |
| D6/Ditch 2nd | 0.004 | <0.001 | 0.009 | 0.004 | 0.001 | 0.015 | <0.001 | | | | |
| R1/Pond | 0.006 | 0.001 | 0.014 | 0.006 | 0.001 | 0.023 | <0.001 | | | | |
| R1/Stream | 0.004 | <0.001 | 0.009 | 0.004 | 0.001 | 0.015 | <0.001 | | | | |
| R2/Stream | 0.001 | <0.001 | 0.002 | 0.001 | <0.001 | 0.004 | <0.001 | | | | |
| R3/Stream | 0.004 | <0.001 | 0.009 | 0.004 | 0.001 | 0.015 | <0.001 | | | | |
| R4/Stream | 0.008 | 0.001 | 0.019 | 0.008 | 0.002 | 0.031 | <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 9.5-167: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357276 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in flower bulbs (flower bulbs; modelling use VegBulb II -- VegBulb II (late) -- 5×0.075 kg a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 983** | **NOEC (parent) 4.3** | **NOEC (ACR) 9.83** | **$EC_{50}$ 514** | **NOEC 2.59** | **$E_rC_{50}$/$E_yC_{50}$ > 5880** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9.83** | **0.43** | **0.983** | **5.14** | **0.259** | **> 588** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D3/Ditch | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| D4/Pond | 0.005 | 0.001 | 0.012 | 0.005 | 0.001 | 0.019 | <0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| D6/Ditch | 0.027 | 0.003 | 0.063 | 0.027 | 0.005 | 0.104 | <0.001 | | | | |
| D6/Ditch 2nd | 0.002 | <0.001 | 0.005 | 0.002 | <0.001 | 0.008 | <0.001 | | | | |
| R1/Pond | 0.005 | 0.001 | 0.012 | 0.005 | 0.001 | 0.019 | <0.001 | | | | |
| R1/Stream | 0.003 | <0.001 | 0.007 | 0.003 | 0.001 | 0.012 | <0.001 | | | | |
| R2/Stream | 0.001 | <0.001 | 0.002 | 0.001 | <0.001 | 0.004 | <0.001 | | | | |
| R3/Stream | 0.004 | <0.001 | 0.009 | 0.004 | 0.001 | 0.015 | <0.001 | | | | |
| R4/Stream | 0.008 | 0.001 | 0.019 | 0.008 | 0.002 | 0.031 | <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 9.5-168: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357276 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in chokeberry, elderberry and tree nursery (chokeberry, elderberry, tree nursery; modelling use Pome and stone fruit 2x200 g/ha -- BBCH 12-91, early -- 2×0.2 kg a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 983** | **NOEC (parent) 4.3** | **NOEC (ACR) 9.83** | **$EC_{50}$ 514** | **NOEC 2.59** | **$E_rC_{50}/E_yC_{50}$ > 5880** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9.83** | **0.43** | **0.983** | **5.14** | **0.259** | **> 588** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D3/Ditch | 0.023 | 0.002 | 0.053 | 0.023 | 0.004 | 0.089 | <0.001 | | | | |
| D4/Pond | 0.237 | 0.024 | 0.551 | 0.241 | 0.046 | 0.915 | <0.001 | | | | |
| D4/Stream | 0.004 | <0.001 | 0.009 | 0.004 | 0.001 | 0.015 | <0.001 | | | | |
| D5/Pond | 0.251 | 0.026 | 0.584 | 0.255 | 0.049 | 0.969 | <0.001 | | | | |
| D5/Stream | 0.006 | 0.001 | 0.014 | 0.006 | 0.001 | 0.023 | <0.001 | | | | |
| R1/Pond | 0.189 | 0.019 | 0.440 | 0.192 | 0.037 | 0.730 | <0.001 | | | | |
| R1/Stream | 0.004 | <0.001 | 0.009 | 0.004 | 0.001 | 0.015 | <0.001 | | | | |
| R2/Stream | 0.002 | <0.001 | 0.005 | 0.002 | <0.001 | 0.008 | <0.001 | | | | |
| R3/Stream | 0.009 | 0.001 | 0.021 | 0.009 | 0.002 | 0.035 | <0.001 | | | | |
| R4/Stream | 0.008 | 0.001 | 0.019 | 0.008 | 0.002 | 0.031 | <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 9.5-169:** **Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357276 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in chokeberry, elderberry and tree nursery (chokeberry, elderberry, tree nursery; modelling use Pome and stone fruit 2x200 g/ha -- BBCH 12-91, late -- 2×0.2 kg a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 983** | **NOEC (parent) 4.3** | **NOEC (ACR) 9.83** | **$EC_{50}$ 514** | **NOEC 2.59** | **$E_rC_{50}/E_yC_{50}$ > 5880** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9.83** | **0.43** | **0.983** | **5.14** | **0.259** | **> 588** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D3/Ditch | 0.017 | 0.002 | 0.040 | 0.017 | 0.003 | 0.066 | <0.001 | | | | |
| D4/Pond | 0.044 | 0.004 | 0.102 | 0.045 | 0.009 | 0.170 | <0.001 | | | | |
| D4/Stream | 0.002 | <0.001 | 0.005 | 0.002 | <0.001 | 0.008 | <0.001 | | | | |
| D5/Pond | 0.077 | 0.008 | 0.179 | 0.078 | 0.015 | 0.297 | <0.001 | | | | |
| D5/Stream | 0.003 | <0.001 | 0.007 | 0.003 | 0.001 | 0.012 | <0.001 | | | | |
| R1/Pond | 0.046 | 0.005 | 0.107 | 0.047 | 0.009 | 0.178 | <0.001 | | | | |
| R1/Stream | 0.003 | <0.001 | 0.007 | 0.003 | 0.001 | 0.012 | <0.001 | | | | |
| R2/Stream | 0.001 | <0.001 | 0.002 | 0.001 | <0.001 | 0.004 | <0.001 | | | | |
| R3/Stream | 0.005 | 0.001 | 0.012 | 0.005 | 0.001 | 0.019 | <0.001 | | | | |
| R4/Stream | 0.007 | 0.001 | 0.016 | 0.007 | 0.001 | 0.027 | <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 9.5-170: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357276 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in lettuce, rocket (lettuce, rocket; modelling use Vegetable leafy 2x200 g/ha -- BBCH 12-49, early -- 2×0.2 kg a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint** (µg/L) | | **$LC_{50}$** 983 | **NOEC (parent)** 4.3 | **NOEC (ACR)** 9.83 | **$EC_{50}$** 514 | **NOEC** 2.59 | **$E_rC_{50}/E_yC_{50}$** > 5880 | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9.83** | **0.43** | **0.983** | **5.14** | **0.259** | **> 588** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D3/Ditch | 0.001 | <0.001 | 0.002 | 0.001 | <0.001 | 0.004 | <0.001 | | | | |
| D3/Ditch 2nd | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| D4/Pond | 0.007 | 0.001 | 0.016 | 0.007 | 0.001 | 0.027 | <0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| D6/Ditch | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| R1/Pond | 0.008 | 0.001 | 0.019 | 0.008 | 0.002 | 0.031 | <0.001 | | | | |
| R1/Pond 2nd | 0.007 | 0.001 | 0.016 | 0.007 | 0.001 | 0.027 | <0.001 | | | | |
| R1/Stream | 0.006 | 0.001 | 0.014 | 0.006 | 0.001 | 0.023 | <0.001 | | | | |
| R1/Stream 2nd | 0.004 | <0.001 | 0.009 | 0.004 | 0.001 | 0.015 | <0.001 | | | | |
| R2/Stream | 0.001 | <0.001 | 0.002 | 0.001 | <0.001 | 0.004 | <0.001 | | | | |
| R2/Stream 2nd | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| R3/Stream | 0.005 | 0.001 | 0.012 | 0.005 | 0.001 | 0.019 | <0.001 | | | | |
| R3/Stream 2nd | 0.004 | <0.001 | 0.009 | 0.004 | 0.001 | 0.015 | <0.001 | | | | |
| R4/Stream | 0.008 | 0.001 | 0.019 | 0.008 | 0.002 | 0.031 | <0.001 | | | | |
| R4/Stream 2nd | 0.009 | 0.001 | 0.021 | 0.009 | 0.002 | 0.035 | <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 9.5-171: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357276 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in lettuce, rocket (lettuce, rocket; modelling use Vegetable leafy 2x200 g/ha -- BBCH 12-49, late -- 2×0.2 kg a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 983** | **NOEC (parent) 4.3** | **NOEC (ACR) 9.83** | **$EC_{50}$ 514** | **NOEC 2.59** | **$E_rC_{50}$/$E_yC_{50}$ > 5880** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9.83** | **0.43** | **0.983** | **5.14** | **0.259** | **> 588** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D3/Ditch | 0.001 | <0.001 | 0.002 | 0.001 | <0.001 | 0.004 | <0.001 | | | | |
| D3/Ditch 2nd | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| D4/Pond | 0.007 | 0.001 | 0.016 | 0.007 | 0.001 | 0.027 | <0.001 | | | | |
| D4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| D6/Ditch | 0.001 | <0.001 | 0.002 | 0.001 | <0.001 | 0.004 | <0.001 | | | | |
| R1/Pond | 0.009 | 0.001 | 0.021 | 0.009 | 0.002 | 0.035 | <0.001 | | | | |
| R1/Pond 2nd | 0.007 | 0.001 | 0.016 | 0.007 | 0.001 | 0.027 | <0.001 | | | | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| R1/Stream | 0.005 | 0.001 | 0.012 | 0.005 | 0.001 | 0.019 | <0.001 | | | | |
| R1/Stream 2nd | 0.004 | <0.001 | 0.009 | 0.004 | 0.001 | 0.015 | <0.001 | | | | |
| R2/Stream | 0.001 | <0.001 | 0.002 | 0.001 | <0.001 | 0.004 | <0.001 | | | | |
| R2/Stream 2nd | 0.001 | <0.001 | 0.002 | 0.001 | <0.001 | 0.004 | <0.001 | | | | |
| R3/Stream | 0.004 | <0.001 | 0.009 | 0.004 | 0.001 | 0.015 | <0.001 | | | | |
| R3/Stream 2nd | 0.003 | <0.001 | 0.007 | 0.003 | 0.001 | 0.012 | <0.001 | | | | |
| R4/Stream | 0.008 | 0.001 | 0.019 | 0.008 | 0.002 | 0.031 | <0.001 | | | | |
| R4/Stream 2nd | 0.008 | 0.001 | 0.019 | 0.008 | 0.002 | 0.031 | <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 9.5-172: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357276 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in tobacco (tobacco; modelling use Tobacco -- BBCH 11 - 39 -- 0.2 kg a.s./ha)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint**<br><br>**(µg/L)** | | **$LC_{50}$**<br><br>**983** | **NOEC (parent)**<br><br>**4.3** | **NOEC (ACR)**<br><br>**9.83** | **$EC_{50}$**<br><br>**514** | **NOEC**<br><br>**2.59** | **$E_rC_{50}/E_yC_{50}$**<br><br>**> 5880** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9.83** | **0.43** | **0.983** | **5.14** | **0.259** | **> 588** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| R3/Stream | 0.002 | <0.001 | 0.005 | 0.002 | <0.001 | 0.008 | <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 9.5-173: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357276 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in hops (hops; modelling use Hops -- BBCH 37 - 79, early -- 2×0.15 kg a.s./ha, 14d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 983** | **NOEC (parent) 4.3** | **NOEC (ACR) 9.83** | **$EC_{50}$ 514** | **NOEC 2.59** | **$E_rC_{50}/E_yC_{50}$ > 5880** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9.83** | **0.43** | **0.983** | **5.14** | **0.259** | **> 588** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| R1/Pond | 0.063 | 0.006 | 0.147 | 0.064 | 0.012 | 0.243 | <0.001 | | | | |
| R1/Stream | 0.002 | <0.001 | 0.005 | 0.002 | <0.001 | 0.008 | <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 9.5-174: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357276 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in hops (hops; modelling use Hops -- BBCH 37 - 79, late -- 2×0.15 kg a.s./ha, 14d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint**<br><br>**(µg/L)** | | **$LC_{50}$**<br><br>**983** | **NOEC (parent)**<br><br>**4.3** | **NOEC (ACR)**<br><br>**9.83** | **$EC_{50}$**<br><br>**514** | **NOEC**<br><br>**2.59** | **$E_rC_{50}/E_yC_{50}$**<br><br>**> 5880** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9.83** | **0.43** | **0.983** | **5.14** | **0.259** | **> 588** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| R1/Pond | 0.060 | 0.006 | 0.140 | 0.061 | 0.012 | 0.232 | <0.001 | | | | |
| R1/Stream | 0.002 | <0.001 | 0.005 | 0.002 | <0.001 | 0.008 | <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 9.5-175: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357276 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in berries (berries; modelling use Vines II -- early, BBCH 15 -- 2×0.2 kg a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint** (µg/L) | | **$LC_{50}$** 983 | **NOEC (parent)** 4.3 | **NOEC (ACR)** 9.83 | **$EC_{50}$** 514 | **NOEC** 2.59 | **$E_rC_{50}/E_yC_{50}$** > 5880 | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9.83** | **0.43** | **0.983** | **5.14** | **0.259** | **> 588** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D6/Ditch | 0.007 | 0.001 | 0.016 | 0.007 | 0.001 | 0.027 | <0.001 | | | | |
| R1/Pond | 0.022 | 0.002 | 0.051 | 0.022 | 0.004 | 0.085 | <0.001 | | | | |
| R1/Stream | 0.004 | <0.001 | 0.009 | 0.004 | 0.001 | 0.015 | <0.001 | | | | |
| R2/Stream | 0.001 | <0.001 | 0.002 | 0.001 | <0.001 | 0.004 | <0.001 | | | | |
| R3/Stream | 0.002 | <0.001 | 0.005 | 0.002 | <0.001 | 0.008 | <0.001 | | | | |
| R4/Stream | 0.009 | 0.001 | 0.021 | 0.009 | 0.002 | 0.035 | <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 9.5-176: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357276 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in berries (berries; modelling use Vines II -- middle, BBCH 65 -- 2×0.2 kg a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint** (µg/L) | | **$LC_{50}$** 983 | **NOEC (parent)** 4.3 | **NOEC (ACR)** 9.83 | **$EC_{50}$** 514 | **NOEC** 2.59 | **$E_rC_{50}/E_yC_{50}$** > 5880 | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9.83** | **0.43** | **0.983** | **5.14** | **0.259** | **> 588** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D6/Ditch | 0.115 | 0.012 | 0.267 | 0.117 | 0.022 | 0.444 | <0.001 | | | | |
| R1/Pond | 0.023 | 0.002 | 0.053 | 0.023 | 0.004 | 0.089 | <0.001 | | | | |
| R1/Stream | 0.003 | <0.001 | 0.007 | 0.003 | 0.001 | 0.012 | <0.001 | | | | |
| R2/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| R3/Stream | 0.003 | <0.001 | 0.007 | 0.003 | 0.001 | 0.012 | <0.001 | | | | |
| R4/Stream | 0.005 | 0.001 | 0.012 | 0.005 | 0.001 | 0.019 | <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 9.5-177: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357276 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in berries (berries; modelling use Vines II -- late, BBCH 89 -- 2×0.2 kg a.s./ha, 7d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint**<br>**(µg/L)** | | **$LC_{50}$**<br>**983** | **NOEC (parent)**<br>**4.3** | **NOEC (ACR)**<br>**9.83** | **$EC_{50}$**<br>**514** | **NOEC**<br>**2.59** | **$E_rC_{50}/E_yC_{50}$**<br>**> 5880** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9.83** | **0.43** | **0.983** | **5.14** | **0.259** | **> 588** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D6/Ditch | 0.121 | 0.012 | 0.281 | 0.123 | 0.024 | 0.467 | <0.001 | | | | |
| R1/Pond | 0.017 | 0.002 | 0.040 | 0.017 | 0.003 | 0.066 | <0.001 | | | | |
| R1/Stream | 0.002 | <0.001 | 0.005 | 0.002 | <0.001 | 0.008 | <0.001 | | | | |
| R2/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| R3/Stream | 0.003 | <0.001 | 0.007 | 0.003 | 0.001 | 0.012 | <0.001 | | | | |
| R4/Stream | 0.005 | 0.001 | 0.012 | 0.005 | 0.001 | 0.019 | <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 9.5-178: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357276 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in grapes (grapes; modelling use vines VI -- early, BBCH 15 -- 2×0.05 kg a.s./ha, 14d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint**<br>**(µg/L)** | | **$LC_{50}$**<br>**983** | **NOEC (parent)**<br>**4.3** | **NOEC (ACR)**<br>**9.83** | **$EC_{50}$**<br>**514** | **NOEC**<br>**2.59** | **$E_rC_{50}/E_yC_{50}$**<br>**> 5880** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9.83** | **0.43** | **0.983** | **5.14** | **0.259** | **> 588** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D6/Ditch | 0.002 | <0.001 | 0.005 | 0.002 | <0.001 | 0.008 | <0.001 | | | | |
| R1/Pond | 0.005 | 0.001 | 0.012 | 0.005 | 0.001 | 0.019 | <0.001 | | | | |
| R1/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| R2/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| R3/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| R4/Stream | 0.002 | <0.001 | 0.005 | 0.002 | <0.001 | 0.008 | <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 9.5-179: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357276 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in grapes (grapes; modelling use vines VI -- middle, BBCH 65 -- 2×0.05 kg a.s./ha, 14d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint (µg/L)** | | **$LC_{50}$ 983** | **NOEC (parent) 4.3** | **NOEC (ACR) 9.83** | **$EC_{50}$ 514** | **NOEC 2.59** | **$E_rC_{50}/E_yC_{50}$ > 5880** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9.83** | **0.43** | **0.983** | **5.14** | **0.259** | **> 588** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D6/Ditch | 0.025 | 0.003 | 0.058 | 0.025 | 0.005 | 0.097 | <0.001 | | | | |
| R1/Pond | 0.005 | 0.001 | 0.012 | 0.005 | 0.001 | 0.019 | <0.001 | | | | |
| R1/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| R2/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| R3/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| R4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<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 9.5-180: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for CGA 357276 for each organism group based on FOCUS Steps 3 calculations for the use of FLU+TFS SC 500 in grapes (grapes; modelling use vines VI -- late, BBCH 85 -- 2×0.05 kg a.s./ha, 14d int.)**

| **Group** | | **Fish acute** | **Fish prolonged** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Fish prolonged*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | | | | |
| **Endpoint**<br><br>**(µg/L)** | | **$LC_{50}$**<br><br>**983** | **NOEC (parent)**<br><br>**4.3** | **NOEC (ACR)**<br><br>**9.83** | **$EC_{50}$**<br><br>**514** | **NOEC**<br><br>**2.59** | **$E_rC_{50}/E_yC_{50}$**<br><br>**> 5880** | | | | |
| **AF** | | **100** | **10** | **10** | **100** | **10** | **10** | | | | |
| **RAC (µg/L)** | | **9.83** | **0.43** | **0.983** | **5.14** | **0.259** | **> 588** | | | | |
| **FOCUS Scenario** | **PEC $_{gl-max}$ (µg/L)** | | | | | | | | | | |
| **Step 3** | | | | | | | | | | | |
| D6/Ditch | 0.031 | 0.003 | 0.072 | 0.032 | 0.006 | 0.120 | <0.001 | | | | |
| R1/Pond | 0.004 | <0.001 | 0.009 | 0.004 | 0.001 | 0.015 | <0.001 | | | | |
| R1/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| R2/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| R3/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<0.001 | | | | |
| R4/Stream | <0.001 | <<0.001 | <0.002 | <0.001 | <<0.001 | <0.004 | <<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

**Risk assessment for FLU+TFS SC 500**

Here the uses in chokeberry, elderberry and tree nursery (2 × 0.8 L prod./ha, use group V) with Rautmann drift values for fruit crops (early), the use in lettuce (2 × 0.8 L prod./ha, use group AI) and flower bulbs (5 × 0.3 L prod./ha, use group W) with drift values for field crops, the use in berries (2 × 0.8 L prod./ha, use group AN) with drift values for vine and the use in hops (2 × 0.6 L prod./ha, use group AL) are addressed in the risk assessment covering all uses in elderberries in use group AH, all other uses in field crops in use groups X to AG and AI to AK and all other uses in berries and vine with the surrogate crop vine (use groups AM to AR).

**Table 9.5-181: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for FLU + TFS SC 500 for each organism group based on drift only calculations for the use in chokeberry, elderberry and tree nursery (2 × 0.8 L prod./ha, use group V, Rautmann drift value for fruit crops, early)**

| **Group** | | **Fish acute** | **Inverteb. acute** | **Algae** |
|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** |
| **Endpoint (µg/L)** | | $LC_{50}$ 88.4 | $EC_{50}$ 51 | $E_rC_{50}$ 419 |
| **AF** | | 100 | 100 | 10 |
| **RAC (µg/L)** | | 0.884 | 0.510 | 41.9 |
| **Entry via spray drift** | **$PEC_{sw\ gl\text{-}max}$ (µg/L)** | | | |
| **3 m buffer** | | | | |
| 0% DRN | 159.852 | **180.828** | **313.435** | **3.815** |
| 50% DRN | 79.926 | **90.414** | **156.718** | **1.908** |
| 75% DRN | 39.963 | **45.207** | **78.359** | 0.954 |
| 90% DRN | 15.985 | **18.083** | **31.343** | 0.382 |
| **5 m buffer** | | | | |
| 0% DRN | 105.629 | **119.490** | **207.116** | **2.521** |
| 50% DRN | 52.814 | **59.744** | **103.557** | **1.260** |
| 75% DRN | 26.407 | **29.872** | **51.778** | 0.630 |
| 90% DRN | 10.563 | **11.949** | **20.712** | 0.252 |
| **10 m buffer** | | | | |
| 0% DRN | 60.171 | **68.067** | **117.982** | **1.436** |
| 50% DRN | 30.086 | **34.034** | **58.992** | 0.718 |
| 75% DRN | 15.043 | **17.017** | **29.496** | 0.359 |
| 90% DRN | 6.017 | **6.807** | **11.798** | 0.144 |
| **15 m buffer** | | | | |
| 0% DRN | 35.126 | **39.735** | **68.875** | 0.838 |
| 50% DRN | 17.563 | **19.868** | **34.437** | 0.419 |
| 75% DRN | 8.782 | **9.934** | **17.220** | 0.210 |
| 90% DRN | 3.513 | **3.974** | **6.888** | 0.084 |

| Group | | Fish acute | Inverteb. acute | Algae |
|---|---|---|---|---|
| **20 m buffer** | | | | |
| 0% DRN | 16.217 | **18.345** | **31.798** | 0.387 |
| 50% DRN | 8.108 | **9.172** | **15.898** | 0.194 |
| 75% DRN | 4.054 | **4.586** | **7.949** | 0.097 |
| 90% DRN | 1.622 | **1.835** | **3.180** | 0.039 |
| **30 m buffer** | | | | |
| 0% DRN | 5.447 | **6.162** | **10.680** | 0.130 |
| 50% DRN | 2.724 | **3.081** | **5.341** | 0.065 |
| 75% DRN | 1.362 | **1.541** | **2.671** | 0.033 |
| 90% DRN | 0.545 | 0.617 | **1.069** | 0.013 |
| **50 m buffer** | | | | |
| 0% DRN | 1.377 | **1.558** | **2.700** | 0.033 |
| 50% DRN | 0.689 | 0.779 | **1.351** | 0.016 |
| 75% DRN | 0.344 | 0.389 | 0.675 | 0.008 |
| 90% DRN | 0.138 | 0.156 | 0.271 | 0.003 |
| **75 m buffer** | | | | |
| 0% DRN | 0.438 | 0.495 | 0.859 | 0.010 |
| 50% DRN | 0.219 | 0.248 | 0.429 | 0.005 |
| 75% DRN | 0.11 | 0.124 | 0.216 | 0.003 |
| 90% DRN | 0.044 | 0.050 | 0.086 | 0.001 |

DRN = Drift reducing nozzles

**Table 9.5-182: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for FLU + TFS SC 500 for each organism group based on drift only calculations for the use in lettuce (2 × 0.8 L prod./ha, use group AI, Rautmann drift value for field crops)**

| **Group** | | **Fish acute** | **Inverteb. acute** | **Algae** |
|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** |
| **Endpoint (µg/L)** | | $LC_{50}$ 88.4 | $EC_{50}$ 51 | $E_rC_{50}$ 419 |
| **AF** | | 100 | 100 | 10 |
| **RAC (µg/L)** | | 0.884 | 0.510 | 41.9 |
| **Entry via spray drift** | **$PEC_{sw\ gl\text{-}max}$ (µg/L)** | | | |
| **1 m buffer** | | | | |
| 0% DRN | 14.902 | **16.857** | **29.220** | **0.356** |
| 50% DRN | 7.451 | **8.429** | **14.610** | 0.178 |
| 75% DRN | 3.725 | **4.214** | **7.304** | 0.089 |
| 90% DRN | 1.49 | **1.686** | **2.922** | 0.036 |
| **5 m buffer** | | | | |

| Group | | Fish acute | Inverteb. acute | Algae |
|---|---|---|---|---|
| 0% DRN | 2.943 | **3.329** | **5.771** | 0.070 |
| 50% DRN | 1.471 | **1.664** | **2.884** | 0.035 |
| 75% DRN | 0.736 | 0.833 | **1.443** | 0.018 |
| 90% DRN | 0.294 | 0.333 | 0.576 | 0.007 |
| **10 m buffer** | | | | |
| 0% DRN | 1.503 | **1.700** | **2.947** | 0.036 |
| 50% DRN | 0.751 | 0.850 | **1.473** | 0.018 |
| 75% DRN | 0.376 | 0.425 | 0.737 | 0.009 |
| 90% DRN | 0.15 | 0.170 | 0.294 | 0.004 |
| **15 m buffer** | | | | |
| 0% DRN | 1.002 | **1.133** | **1.965** | 0.024 |
| 50% DRN | 0.501 | 0.567 | 0.982 | 0.012 |
| 75% DRN | 0.25 | 0.283 | 0.490 | 0.006 |
| 90% DRN | 0.1 | 0.113 | 0.196 | 0.002 |
| **20 m buffer** | | | | |
| 0% DRN | 0.751 | 0.850 | **1.473** | 0.018 |
| 50% DRN | 0.376 | 0.425 | 0.737 | 0.009 |
| 75% DRN | 0.188 | 0.213 | 0.369 | 0.004 |
| 90% DRN | 0.075 | 0.085 | 0.147 | 0.002 |
| **30 m buffer** | | | | |
| 0% DRN | 0.501 | 0.567 | 0.982 | 0.012 |
| 50% DRN | 0.25 | 0.283 | 0.490 | 0.006 |
| 75% DRN | 0.125 | 0.141 | 0.245 | 0.003 |
| 90% DRN | 0.05 | 0.057 | 0.098 | 0.001 |

DRN = Drift reducing nozzles

**Table 9.5-183: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for FLU + TFS SC 500 for each organism group based on drift only calculations for the use in flower bulbs (5 × 0.3 L prod./ha, use group W, Rautmann drift value for field crops)**

| **Group** | | **Fish acute** | **Inverteb. acute** | **Algae** |
|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** |
| **Endpoint (µg/L)** | | $LC_{50}$ 88.4 | $EC_{50}$ 51 | $E_rC_{50}$ 419 |
| **AF** | | 100 | 100 | 10 |
| **RAC (µg/L)** | | 0.884 | 0.510 | 41.9 |
| **Entry via spray drift** | **$PEC_{sw\ gl\text{-}max}$ (µg/L)** | | | |
| **1 m buffer** | | | | |
| 0% DRN | 10.273 | **11.621** | **20.143** | 0.245 |

| Group | | Fish acute | Inverteb. acute | Algae |
|---|---|---|---|---|
| 50% DRN | 5.136 | **5.810** | **10.071** | 0.123 |
| 75% DRN | 2.568 | **2.905** | **5.035** | 0.061 |
| 90% DRN | 1.027 | **1.162** | **2.014** | 0.025 |
| **5 m buffer** | | | | |
| 0% DRN | 2.113 | **2.390** | **4.143** | 0.050 |
| 50% DRN | 1.057 | **1.196** | **2.073** | 0.025 |
| 75% DRN | 0.528 | 0.597 | **1.035** | 0.013 |
| 90% DRN | 0.211 | 0.239 | 0.414 | 0.005 |
| **10 m buffer** | | | | |
| 0% DRN | 1.057 | **1.196** | **2.073** | 0.025 |
| 50% DRN | 0.528 | 0.597 | **1.035** | 0.013 |
| 75% DRN | 0.264 | 0.299 | 0.518 | 0.006 |
| 90% DRN | 0.106 | 0.120 | 0.208 | 0.003 |
| **15 m buffer** | | | | |
| 0% DRN | 0.704 | 0.796 | **1.380** | 0.017 |
| 50% DRN | 0.352 | 0.398 | 0.690 | 0.008 |
| 75% DRN | 0.176 | 0.199 | 0.345 | 0.004 |
| 90% DRN | 0.07 | 0.079 | 0.137 | 0.002 |
| **20 m buffer** | | | | |
| 0% DRN | 0.528 | 0.597 | **1.035** | 0.013 |
| 50% DRN | 0.264 | 0.299 | 0.518 | 0.006 |
| 75% DRN | 0.132 | 0.149 | 0.259 | 0.003 |
| 90% DRN | 0.053 | 0.060 | 0.104 | 0.001 |
| **30 m buffer** | | | | |
| 0% DRN | 0.352 | 0.398 | 0.690 | 0.008 |
| 50% DRN | 0.176 | 0.199 | 0.345 | 0.004 |
| 75% DRN | 0.088 | 0.100 | 0.173 | 0.002 |
| 90% DRN | 0.035 | 0.040 | 0.069 | 0.001 |

DRN = Drift reducing nozzles

**Table 9.5-184: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for FLU + TFS SC 500 for each organism group based on drift only calculations for the use in berries (2 × 0.8 L prod./ha, use group AN, Rautmann drift value for vine)**

| **Group** | | **Fish acute** | **Inverteb. acute** | **Algae** |
|---|---|---|---|---|
| **Test species** | | *Oncorhynchus mykiss* | *Daphnia magna* | *Pseudokirchneriella subcapitata* |
| **Endpoint (µg/L)** | | $LC_{50}$ 88.4 | $EC_{50}$ 51 | $E_rC_{50}$ 419 |
| **AF** | | 100 | 100 | 10 |
| **RAC (µg/L)** | | 0.884 | 0.510 | 41.9 |
| **Entry via spray drift** | **$PEC_{sw\ gl\text{-}max}$ (µg/L)** | | | |
| **3 m buffer** | | | | |
| 0% DRN | 45.269 | **51.209** | **88.763** | **1.080** |
| 50% DRN | 22.635 | **25.605** | **44.382** | 0.540 |
| 75% DRN | 11.317 | **12.802** | **22.190** | 0.270 |
| 90% DRN | 4.527 | **5.121** | **8.876** | 0.108 |
| **5 m buffer** | | | | |
| 0% DRN | 20.161 | **22.807** | **39.531** | 0.481 |
| 50% DRN | 10.081 | **11.404** | **19.767** | 0.241 |
| 75% DRN | 5.04 | **5.701** | **9.882** | 0.120 |
| 90% DRN | 2.016 | **2.281** | **3.953** | 0.048 |
| **10 m buffer** | | | | |
| 0% DRN | 6.7 | **7.579** | **13.137** | 0.160 |
| 50% DRN | 3.35 | **3.790** | **6.569** | 0.080 |
| 75% DRN | 1.675 | **1.895** | **3.284** | 0.040 |
| 90% DRN | 0.67 | 0.758 | **1.314** | 0.016 |
| **15 m buffer** | | | | |
| 0% DRN | 3.506 | **3.966** | **6.875** | 0.084 |
| 50% DRN | 1.753 | **1.983** | **3.437** | 0.042 |
| 75% DRN | 0.877 | 0.992 | **1.720** | 0.021 |
| 90% DRN | 0.351 | 0.397 | 0.688 | 0.008 |
| **20 m buffer** | | | | |
| 0% DRN | 2.254 | **2.550** | **4.420** | 0.054 |
| 50% DRN | 1.127 | **1.275** | **2.210** | 0.027 |
| 75% DRN | 0.564 | 0.638 | **1.106** | 0.013 |
| 90% DRN | 0.225 | 0.255 | 0.441 | 0.005 |
| **30 m buffer** | | | | |
| 0% DRN | 1.19 | **1.346** | **2.333** | 0.028 |
| 50% DRN | 0.595 | 0.673 | **1.167** | 0.014 |
| 75% DRN | 0.297 | 0.336 | 0.582 | 0.007 |

| Group | | Fish acute | Inverteb. acute | Algae |
|---|---|---|---|---|
| 90% DRN | 0.119 | 0.135 | 0.233 | 0.003 |
| **50 m buffer** | | | | |
| 0% DRN | 0.501 | 0.567 | 0.982 | 0.012 |
| 50% DRN | 0.25 | 0.283 | 0.490 | 0.006 |
| 75% DRN | 0.125 | 0.141 | 0.245 | 0.003 |
| 90% DRN | 0.05 | 0.057 | 0.098 | 0.001 |

DRN = Drift reducing nozzles

**Table 9.5-185: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for FLU + TFS SC 500 for each organism group based on drift only calculations for the use in hops (2 × 0.6 L prod./ha, use group AL, Rautmann drift value for hops)**

| **Group** | | **Fish acute** | **Inverteb. acute** | **Algae** |
|---|---|---|---|---|
| **Test species** | | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** |
| **Endpoint (µg/L)** | | $LC_{50}$<br>88.4 | $EC_{50}$<br>51 | $E_rC_{50}$<br>419 |
| **AF** | | 100 | 100 | 10 |
| **RAC (µg/L)** | | 0.884 | 0.510 | 41.9 |
| **Entry via spray drift** | **$PEC_{sw\ gl\text{-}max}$ (µg/L)** | | | |
| **3 m buffer** | | | | |
| 0% DRN | 83.26 | **94.186** | **163.255** | **1.987** |
| 50% DRN | 41.63 | **47.093** | **81.627** | 0.994 |
| 75% DRN | 20.815 | **23.546** | **40.814** | 0.497 |
| 90% DRN | 8.326 | **9.419** | **16.325** | 0.199 |
| **5 m buffer** | | | | |
| 0% DRN | 45.082 | **50.998** | **88.396** | **1.076** |
| 50% DRN | 22.541 | **25.499** | **44.198** | 0.538 |
| 75% DRN | 11.27 | **12.749** | **22.098** | 0.269 |
| 90% DRN | 4.508 | **5.100** | **8.839** | 0.108 |
| **10 m buffer** | | | | |
| 0% DRN | 19.629 | **22.205** | **38.488** | 0.468 |
| 50% DRN | 9.815 | **11.103** | **19.245** | 0.234 |
| 75% DRN | 4.907 | **5.551** | **9.622** | 0.117 |
| 90% DRN | 1.963 | **2.221** | **3.849** | 0.047 |
| **15 m buffer** | | | | |
| 0% DRN | 12.069 | **13.653** | **23.665** | 0.288 |
| 50% DRN | 6.034 | **6.826** | **11.831** | 0.144 |
| 75% DRN | 3.017 | **3.413** | **5.916** | 0.072 |
| 90% DRN | 1.207 | **1.365** | **2.367** | 0.029 |

| Group | | Fish acute | Inverteb. acute | Algae |
|---|---|---|---|---|
| **20 m buffer** | | | | |
| 0% DRN | 5.682 | **6.428** | **11.141** | 0.136 |
| 50% DRN | 2.841 | **3.214** | **5.571** | 0.068 |
| 75% DRN | 1.421 | **1.607** | **2.786** | 0.034 |
| 90% DRN | 0.568 | 0.643 | **1.114** | 0.014 |
| **30 m buffer** | | | | |
| 0% DRN | 1.784 | **2.018** | **3.498** | 0.043 |
| 50% DRN | 0.892 | **1.009** | **1.749** | 0.021 |
| 75% DRN | 0.446 | 0.505 | 0.875 | 0.011 |
| 90% DRN | 0.178 | 0.201 | 0.349 | 0.004 |
| **50 m buffer** | | | | |
| 0% DRN | 0.423 | 0.479 | 0.829 | 0.010 |
| 50% DRN | 0.211 | 0.239 | 0.414 | 0.005 |
| 75% DRN | 0.106 | 0.120 | 0.208 | 0.003 |
| 90% DRN | 0.042 | 0.048 | 0.082 | 0.001 |

DRN = Drift reducing nozzles

The conclusions of this risk assessment cannot be refined with higher tier endpoints. The approach does not cover all exposure routes and the agreed assumptions of the standard FOCUS drift scenarios. Exposure via runoff or drainage is not applicable for a product assessment. After application of the product the actives will separate in the soil in time and space due to their intrinsic properties. The assumptions for FOCUS drift exposure take into account the dimension of the water body, which leads to a spatially variable drift exposure. This is not reflected in a simple product drift assessment.

Moreover, it has been shown that the toxicity of both active substances is additive (see section below). In addition, a big data set of acute studies in fish and aquatic invertebrates in different species is available for Trifloxystrobin providing a better basis for the risk assessment than product studies in standard species. Consequently, the risk assessment based on active substances separately, in conjunction with the combined toxicity risk assessment are considered more appropriate to draw conclusions on risk mitigation measures relevant for the product FLU+TFS SC 500.

**Assessment of combined toxicity**

~~As required by the Central Zone when a product contains more than one active substance, an additional assessment on combined toxicity risk has to be presented~~

~~As stated in the AGD (part 10.3.7), "if the toxicity of the mixture is largely explained by the toxicity of a single a.s., a sufficient protection level might be achieved by simply basing the RA on the toxicity data for that single driver".~~

~~A substance is considered as a toxicity driver when it represents ≥ 90% of the sum of the toxicity units (TU).~~

~~The TU for each active substance and each organism groups are presented in the table below. The calculations were performed with a theoretical amount of 21.4% of fluopyram and trifloxystrobin in the mixture.~~

~~**Table 9.5-186: Calculation of toxicity units (TU) for trifloxystrobin and fluopyram per organism group**~~

| ~~**Substance**~~ | | ~~**Organism group**~~ | | | | | |
|---|---|---|---|---|---|---|---|
| | | ~~**Fish acute**~~ | ~~***Daphnia* acute**~~ | ~~**Algae**~~ | ~~**Fish prolonged**~~ | ~~***Daphnia* prolonged**~~ | ~~***Chironomus riparis***~~ |
| ~~Fluopyram~~ | ~~Endpoint (mg/L)~~ | ~~> 0.980~~ | ~~17.0~~ | ~~> 1.13~~ | ~~0.135~~ | ~~1.25~~ | ~~1.39~~ |
| ~~Trifloxystrobin~~ | ~~Endpoint (mg/L)~~ | ~~0.015~~ | ~~0.016~~ | ~~0.0174~~ | ~~0.0043~~ | ~~0.00276~~ | ~~0.14~~ |
| ~~Fluopyram~~ | ~~%TU*~~ | ~~2%~~ | ~~0%~~ | ~~2%~~ | ~~3%~~ | ~~0%~~ | ~~9%~~ |
| ~~Trifloxystrobin~~ | ~~%TU*~~ | ~~98%~~ | ~~100%~~ | ~~98%~~ | ~~97%~~ | ~~100%~~ | ~~91%~~ |

~~* Based on a theoretical amount of 21.4% of fluopyram and trifloxystrobin in the mixture~~

According to the AGD, it can be stated that a sufficient level of protection is achieved when basing the risk assessment of the formulation FLU+TFS SC 500 on trifloxystrobin. Therefore, the overall conclusions of trifloxystrobin risk assessment cover the combined toxicity assessment.

**zRMS comment:**

We agree that the conclusion of trifloxystrobin risk assessment cover the combined toxicity assessment.

## 9.5.3 Overall conclusions

For all intended uses the trigger value of 1 is not met for all tested species when the risk assessment with the active substance trifloxystrobin is considered. Therefore, a FOCUS Step 4 risk assessment was needed considering mitigation measures which are summarized in the table below.
In the combined toxicity assessment, it is shown that the toxicity of the product is clearly driven by trifloxystrobin. Thus, the aquatic risk assessment for the product is acceptable when mitigation measures are used that derived from the risk assessment for trifloxystrobin.

**Table 9.5-187: Overview of mitigation measures based on the risk assessment for trifloxystrobin per use group and crop**

| **Use group** | **Crops** | **Critical use ID** | **Modelling use** | **Mitigation options for worst case scenarios** |
|---|---|---|---|---|
| X | Asparagus, garden cress, flower tubers, ornamentals, Paeony, Sea lavender<br>(1 × 0.8 L prod./ha<br>BBCH 11-95) | 4, 62, 123, 172, 174, 215 | Field beans I (early/late) | 10 m drift buffer <u>or</u> 75% drift reduction <u>or</u> 5 m drift buffer with 50% drift reduction<br>(D2 ditch/stream, D3 ditch, D4 stream, D6 ditch, R1 stream, R2 stream, R3 stream, R4 stream) |
| Y | Beans, nurseries<br>(2 × 0.8 L prod./ha,<br>14 d interval<br>BBCH 19-89) | 19, 169 | Field beans II (early/late) | 10 m drift buffer <u>or</u> 75% drift reduction <u>or</u> 5 m drift buffer with 50% drift reduction<br>(D2 ditch/stream, D3 ditch, D4 stream, D6 ditch, R1 stream, R2 stream, R3 stream)<br>10 m VFS buffer (R4 stream) |
| Z | Asparagus<br>(2 × 0.8 L prod./ha,<br>10 d interval<br>BBCH 23-95) | 1 | Field beans III (early/late) | 10 m drift buffer <u>or</u> 75% drift reduction <u>or</u> 5 m drift buffer with 50% drift reduction<br>(D2 ditch/stream, D3 ditch, D4 stream, D6 ditch, R1 stream, R2 stream, R3 stream, R4 stream) |
| AA | Baby leaf crops, beans, garden cress, strawberries<br>(2 × 0.8 L prod./ha,<br>7 d interval<br>BBCH 40-89) | 5, 7, 60, 239 | Field beans IV (early/late) | 10 m drift buffer <u>or</u> 75% drift reduction <u>or</u> 5 m drift buffer with 50% drift reduction<br>(D2 ditch/stream, D3 ditch, D4 stream, D6 ditch, R1 stream, R2 stream, R3 stream)<br>10 m VFS buffer (R4 stream) |
| AB | Golf courses<br>(2 × 0.5 L prod./ha,<br>14 d interval<br>BBCH 29-33) | 124 | Grass (March, Jun, Sep, Dec) | 10 m drift buffer <u>or</u> 75% drift reduction <u>or</u> 5 m drift buffer with 50% drift reduction<br>(D2 stream) |
| AC | Peas<br>(2 × 0.8 L prod./ha,<br>7 d interval<br>BBCH 59-89) | 183 | Legumes I | 10 m drift buffer <u>or</u> 75% drift reduction <u>or</u> 5 m drift buffer with 50% drift reduction<br>(D3 ditch, D4 stream, D5 stream, D6 ditch, R1 stream, R2 stream, R3 stream, R4 stream) |
| AD | Peas<br>(2 × 0.8 L prod./ha,<br>14 d interval<br>BBCH 59-79) | 178 | Legumes II | 10 m drift buffer <u>or</u> 75% drift reduction <u>or</u> 5 m drift buffer with 50% drift reduction<br>(D3 ditch, D4 stream, D5 stream, D6 ditch, R1 stream, R2 stream, R3 stream, R4 stream) |
| AE | Celeriac<br>(2 × 0.5 L prod./ha,<br>14 d interval<br>BBCH 40-49) | 47 | Sugar beets I (June – November) | 5 m drift buffer <u>or</u> 75% drift reduction<br>(D3 ditch, R3 stream) |
| AF | Chicory<br>(1 × 0.8 L prod./ha<br>BBCH 13-49) | 49 | Sugar beets II (early, late) | 10 m drift buffer <u>or</u> 75% drift reduction <u>or</u> 5 m drift buffer with 50% drift reduction<br>(D3 ditch, D4 stream, R1 stream, R3 stream) |

| Use group | Crops | Critical use ID | Modelling use | Mitigation options for worst case scenarios |
|---|---|---|---|---|
| AG | Flower bulbs<br>(1 × 0.8 L prod./ha<br>BBCH 12-91) | 121 | VegBulb I (early, middle, late) | 10 m drift buffer <u>or</u> 90% drift reduction <u>or</u> 5 m drift buffer with 50% drift reduction (D3 ditch, D4 stream, R1 stream, R2 stream, R3 stream)<br>10 m VFS buffer (R4 stream) |
| W | Flower bulbs<br>(5 × 0.3 L prod./ha,<br>7 d interval<br>BBCH 12-91) | 120 | VegBulb II (early, late) | 5 m drift buffer <u>or</u> 50% drift reduction<br>(D3 ditch, D4 stream, D6 ditch, R1 stream, R2 stream, R3 stream, R4 stream) |
| V | Chokeberry, elderberry *, tree nursery<br>(2 × 0.8 L prod./ha,<br>7 d interval<br>BBCH 12-91) | 52, 109 *, 242 | Pome and stone fruit (early, late) | 50 m drift buffer <u>or</u> 30 m drift buffer with 75% drift reduction <u>or</u> 20 m drift buffer with 90% drift reduction (D3 ditch, D4 stream, D5 stream, R1 stream, R2 stream, R3 stream, R4 stream) |
| AH | Elderberry *<br>(2 × 0.6 L prod./ha,<br>14 d interval<br>BBCH 15-91) | 110 * | Pome and stone fruit (early, late) | 50 m drift buffer <u>or</u> 30 m drift buffer with 75% drift reduction <u>or</u> 20 m drift buffer with 90% drift reduction (D5 stream, R2 stream, R3 stream) |
| AI | Lamb's lettuce, lettuce, rocket salad<br>(2 × 0.8 L prod./ha,<br>7 d interval<br>BBCH 12-49) | 142, 158, 205 | Vegetable leafy (early/late) | 10 m drift buffer <u>or</u> 90% drift reduction <u>or</u> 5 m drift buffer with 50% drift reduction (D3 ditch, D4 stream, R1 stream, R2 stream, R3 stream)<br>10 m VFS buffer (R4 stream) |
| AJ | Endive, Lamb's lettuce, lettuce, radicchio, rocket salad<br>(1 × 0.8 L prod./ha<br>BBCH 12-49) | 113, 143, 151, 189, 206 | Vegetables leafy (early/late) | 10 m drift buffer <u>or</u> 90% drift reduction <u>or</u> 5 m drift buffer with 50% drift reduction (D3 ditch, D4 stream, R1 stream, R2 stream, R3 stream)<br>10 m VFS buffer (R4 stream) |
| AK | Tobacco<br>(1 × 0.8 L prod./ha<br>BBCH 11-39) | 241 | Tobacco | 10 m drift buffer <u>or</u> 75% drift reduction <u>or</u> 5 m drift buffer with 50% drift reduction<br>(R3 stream) |
| AL | Hops<br>(2 × 0.6 L prod./ha,<br>14 d interval<br>BBCH 37-79) | 141 | Hops (early, late) | 30 m drift buffer <u>or</u> 20 m drift buffer with 75% drift reduction <u>or</u> 10 m drift buffer with 90% drift reduction<br>(R1 stream) |
| AM | Blackberry, blueberry, cranberry, currant, gooseberry, raspberry (berries)<br>(2 × 0.6 L prod./ha,<br>7 d interval<br>BBCH 15-89) | 24, 35, 53, 79, 128, 194 | Vines I (early, middle, late) | 20 m drift buffer <u>or</u> 10 m drift buffer with 75% drift reduction <u>or</u> 5 m drift buffer with 90% drift reduction (D6 ditch) |
| AN | Blackberry, blueberry, cranberry, currant, dewberry, gooseberry, | 21, 32, 59, 63, 103, 125, 166, 191, 213, 109 * | Vines II (early, middle, late) | 30 m drift buffer <u>or</u> 20 m drift buffer with 50% drift reduction <u>or</u> 10 m drift buffer with 75% drift |

| **Use group** | **Crops** | **Critical use ID** | **Modelling use** | **Mitigation options for worst case scenarios** |
|---|---|---|---|---|
| | mulberry, raspberry, rosehip, elderberry * (berries)<br>(2 × 0.8 L prod./ha,<br>7 d interval<br>BBCH 15-89) | | | reduction or 5 m drift buffer with 90% drift reduction (D6 ditch, R2 stream, R3 stream) |
| AO | Blueberry, cranberry, currant, gooseberry, mulberry, rosehip, elderberry * (berries)<br>(2 × 0.6 L prod./ha,<br>14 d interval<br>BBCH 15-89) | 44, 58, 75, 136, 168, 212, 110 * | Vines III (early, middle, late) | 20 m drift buffer or 90% drift reduction or 10 m drift buffer with 75% drift reduction (D6 ditch, R2 stream, R3 stream) |
| AP | Blackberry, blueberry, currant, gooseberry, raspberry (berries)<br>(2 × 0.8 L prod./ha,<br>14 d interval<br>BBCH 15-89) | 29, 40, 71, 133, 199 | Vines IV (early, middle, late) | 30 m drift buffer or 20 m drift buffer with 50% drift reduction or 10 m drift buffer with 75% drift reduction or 5 m drift buffer with 90% drift reduction (R2 stream, R3 stream) |
| AQ | Blackberry, dewberry, raspberry (berries)<br>(2 × 0.6 L prod./ha,<br>21 d interval<br>BBCH 40-69) | 30, 106, 203 | Vines V (late) | 20 m drift buffer or 90% drift reduction or 10 m drift buffer with 75% drift reduction (D6 ditch, R2 stream, R3 stream) |
| AR | Grapes<br>(2 × 0.2 L prod./ha,<br>14 d interval<br>BBCH 15-85) | 140 | Vines VI (early/middle/late) | 10 m drift buffer or 75% drift reduction (R2 stream, R3 stream) |

* Please note: The surrogate crop for modelling for elderberries differs in some member states. In Austria, elderberries belong to orchards whereas in all other member states elderberries are covered by vines. Thus, elderberries are listed in this table with the surrogate crop orchards as well as vines. Thus, the mitigation measures for the use of the product in elderberries vary in different member states.

**Table 9.5-188: Overview of mitigation measures based on the risk assessment for the product per use group and crop**

| Use group | Crop | Rautmann drift value | Mitigation options |
|---|---|---|---|
| V | Chokeberry, elderberry and tree nursery (2 × 0.8 L prod./ha) | Fruit crops (early) | 75 m drift buffer or 50 m drift buffer with 75% drift reduction |
| AI | Lettuce (2 × 0.8 L prod./ha) | Field crops | 30 m drift buffer or 5 m drift buffer with 90% drift reduction or 10 m drift buffer with 75% drift reduction or 15 m drift buffer with 50% drift reduction |
| W | Flower bulbs (5 × 0.3 L prod./ha) | Field crops | 30 m drift buffer or 5 m drift buffer with 90% drift reduction or 10 m drift buffer with 75% drift reduction or 15 m drift buffer with 50% drift reduction |
| AN | Berries (2 × 0.8 L prod./ha) | Vine | 50 m drift buffer or 15 m drift buffer with 90% drift reduction or 30 m drift buffer with 75% drift reduction |
| AL | Hops (2 × 0.6 L prod./ha) | Hops | 50 m drift buffer or 30 m drift buffer with 75% drift reduction |

**zRMS comment:**

We agree with the risk assessment provided by the applicant for the active substance TFS and product Luna Sensation.
The PEC/RAC ratio for the most sensitive organism is below 1 when the risk mitigation measures are applied to surface water bodies ( please see in the Tables above).
The final risk mitigation measures should be decided at MSs level.

## 9.6 Effects on bees (KCP 10.3.1)

### 9.6.1 Toxicity data

Studies on the toxicity to bees have been carried out with trifloxystrobin. Full details of these studies are provided in the respective EU RAR and related documents as well as in Appendix 2 of this document when new studies are submitted.

Effects on bees of FLU+TFS SC 500 were not evaluated as part of the EU assessment of any of the active substances. New data submitted with this application in the core dossier are listed in Appendix 1 and summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process. Where the selection of studies and endpoints for the risk assessment deviates from the results of the EU review process, justifications are provided below.

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

| Species | Substance | Exposure System | Results | Reference |
|---|---|---|---|---|
| *Apis mellifera* | Trifloxystrobin | Acute oral, 48 h | $LD_{50}$ > 110 µg a.s./bee | KCA 8.3.1.1.1/04<br>KCA 8.3.1.1.1/01<br>RAR & EFSA [a] |
| *Apis mellifera* | Trifloxystrobin | Acute oral, 48 h | **$LD_{50}$ > 200 µg a.s./bee** | |
| *Apis mellifera* | Trifloxystrobin | Acute contact, 48 h | $LD_{50}$ > 100 µg a.s./bee | |
| *Apis mellifera* | Trifloxystrobin | Acute contact, 48 h | **$LD_{50}$ > 200 µg a.s./bee** | |
| *Apis mellifera* | Trifloxystrobin WG 50 | Chronic, 10 d | $LDD_{50}$ > 4.9 µg a.s./bee/day | |
| *Apis mellifera* | Trifloxystrobin | Chronic larvae, 22 d | NOEC = 79 mg a.s./kg food<br>NOED = 12.5 µg a.s./larva | Kleebaum, 2018<br>M-648913-01-1<br>See justification Appendix 2 |
| **Higher tier studies (tunnel studies, field studies)** | | | | |
| In a in a semi-field brood study, Trifloxystrobin WG 50 W applied at 200 g a.s./ha to full-flowering Phacelia tanacetifolia in presence of honeybees did not cause significant effects on mortality, flight intensity, behaviour, colony strength and brood development. | | | | RAR & EFSA [a] |

[a] Refer to Appendix 1 – List of data submitted or referred to and relied on, but already evaluated at EU peer review

**Table 9.6-2: Endpoints and effect values relevant for the risk assessment for bees**

| Species | Substance | Exposure System | Results | Reference |
|---|---|---|---|---|
| *Apis mellifera* | FLU + TFS SC 500 | Acute oral, 48 h | $LD_{50}$ > 208.8 µg prod./bee | Appendix 2<br>Schmitzer, 2007<br>M-288193-01-1 |
| *Apis mellifera* | FLU + TFS SC 500 | Acute contact, 48 h | $LD_{50}$ > 200 µg prod./bee | Appendix 2<br>Schmitzer, 2007<br>M-288193-01-1 |

### 9.6.1.1 Justification for new endpoints

In order to complete the data set and the knowledge on effects on developmental stages of honeybees, a chronic larva study with the active substance trifloxystrobin was conducted in the laboratory. Moreover, two studies assessing the acute contact and oral toxicity of trifloxystrobin to bumblebees (*Bombus terrestris*) were conducted. The studies are summarized in Appendix 2.

## 9.6.2 Risk assessment

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

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use in leafy vegetables (use group A) covers the risk for bees from all other intended uses (see 9.1.2).

<u>Fluopyram</u>

For the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009, the following guidance is given in the Document SANCO/2010/13170 for products containing two or more active substances:

- "when the 1st substance is renewed- there is no need to evaluate data related to the 2nd substance"
- "once the 2nd substance is renewed- there is no need to evaluate data related to the 1st substance because this has already been performed in the frame of the re-authorisation of the PPP following the renewal of the 1st active substance"
- "Where necessary a combitox assessment should be performed."

Therefore, a single risk assessment for Fluopyram is not performed as this would be out of scope of SANCO/2010/13170.

### 9.6.2.1 Hazard quotients for bees

**Table 9.6-3: First-tier assessment of the risk for bees due to the use of FLU+TFS SC 500 in leafy vegetables (use group A)**

| | | | |
|---|---|---|---|
| **Intended use** | Leafy vegetables, 2 × 0.8 L/ha | | |
| **Active substance** | Trifloxystrobin | | |
| **Application rate (g/ha)** | 2 × 200 | | |
| **Test design** | **$LD_{50}$ (lab.) (µg/bee)** | **Single application rate (g/ha)** | **$Q_{HO}$, $Q_{HC}$ criterion: $Q_H \leq 50$** |
| Oral toxicity | >200 | 200 | <1 |
| Contact toxicity | >200 | | <1 |
| **Product** | FLU+TFS SC 500 | | |
| **Application rate (g/ha)** | 2 × 939.2 | | |
| **Test design** | **$LD_{50}$ (lab.) (µg/bee)** | **Single application rate (g/ha)** | **$Q_{HO}$, $Q_{HC}$ criterion: $Q_H \leq 50$** |
| Oral toxicity | >208.8 | 939.2 | <4.5 |
| Contact toxicity | >200 | | <4.7 |

QHO, QHC: Hazard quotients for oral and contact exposure. QH values shown in bold breach the relevant trigger.
Product density = 1.174 kg/L.

**zRMS comments:**

The $Q_{HO}$ and $Q_{HC}$ values for both active substaces and the formulation Luna Sensation SC 500 are all below the trigger of 50 indicating as acceptable acute risk to adult bees based on the maximum intended use of product.
No chronic adult or larval study with the formulation was provided, despite being required under (EU) No. 284/2013 points 10.3.1.2 and 10.3.1.3. Whilst this is noted as a data gap, this is not a barrier to authorization and is noted for procedural correctness in the context of the applicable regulation and data requirements.

**Toxicology summary and further considerations regarding the risk to bees**

The active substance trifloxystrobin is of low toxicity to bees. The technical material exhibits an acute $LD_{50}$ value for adult bees in excess of 200 µg a.s./bee following oral and contact routes of administration. The formulated product FLU+TFS SC 500 is of low toxicity with acute oral and contact $LD_{50}$ values for adult bees in excess of 200 µg product/bee. HQ values based on the use in leafy vegetables (use group A) covering all use groups with identical or lower single application rates for both the active substance and the formulated product are considerably lower than the levels regarded to indicate a risk to bees. Consequently, based on the available acute data there is no evidence to suggest that FLU+TFS SC 500 is of greater toxicity than the active substance alone.

Furthermore, the chronic effects of trifloxystrobin to adult honey bees were determined in a 10-day chronic feeding test in the laboratory. Adult honey bees were exposed to a 50 % w/v aqueous sucrose application solution containing a nominal concentration of 120 mg a.s./kg feeding solution of the test item Trifloxystrobin WG50 (limit test) by continuous and ad libitum feeding. Mortality, sub-lethal effects and behavioural observations were assessed daily throughout the 10-day exposure period. Furthermore, the daily food uptake of test item was measured. The NOEC was determined to be 120 mg a.s./kg feeding solution. After 10 days of continuous exposure, by considering the actual food consumption of the honey bees, the accumulated nominal intakes of the test item at the treatment level of 120 mg a.s./kg feeding solution was 49.44 µg a.s./bee and the corresponding mean average daily dose was 4.9 µg a.s./bee/day. The results of the study indicate that there are no delayed or cumulative toxicity effects when exposure takes place chronically compared with acute testing, i.e. daily dosing with 4.9 µg a.s./bee/day of tri-floxystrobin over 10 days (total dose = 49.44 µg a.s./bee) did not give higher mortality than a single acute oral exposure at 200 µg a.s./bee.

In order to investigate whether trifloxystrobin would pose a risk to immature honey bee life stages and their development, a feeding test on honey bee larvae under laboratory conditions was conducted. The active substance trifloxystrobin was mixed into larval diets at concentrations of 317, 158, 79, 40 and 20 mg a.s./kg larval diet, together with a parallel running untreated control and a toxic reference item known to cause effects. The volume of the diet fed was increased over the four feeding events to account for higher demands at increasing age of the organisms. The actual cumulative dose levels of the test item over the entire feeding period amounted to 50, 25, 12.5, 6.3 and 3.1 µg a.s. per larva, respectively. In this test, larval and pupal mortality as well as emergence success after 22 days were assessed. Based on adult emergence on day 22, the NOEC was determined to be 79 mg a.s./kg diet and the NOED was determined to be 12.5 µg a.s/larva indicating that trifloxystrobin does not pose a risk to honey bee development under these laboratory severe exposure conditions.

Overall, the results obtained from comprehensive laboratory testing indicate that trifloxystrobin is of low acute and chronic toxicity to honey bees.

The low risk of trifloxystrobin to adult bees, immature life stages and bee colonies was further confirmed by a semi-field study assessing the potential effects of Trifloxystrobin WG 50 after application at 200 g a.s./ha onto the bee-attractive surrogate crop *Phacelia tanacetifolia* during full-flowering. Overall, exposure to trifloxystrobin at 200 g a.s./ha did not cause significant effects on mortality, flight intensity, behaviour, colony strength and brood development. For AIR the RMS which evaluated the study concluded that trifloxystrobin had no apparent detrimental effects on bee brood, survival/development at the rate of 200 g a.s./ha.

Additional studies addressing the chronic toxicity of FLU+TFS SC 500 to adult honey bees and immature life stages and acute oral and contact toxicity to bumblebees have been conducted in the laboratory. However, the study reports were not completed in time for this submission and will be made available upon finalization.

Furthermore, a comprehensive data package on the acute and chronic effects of fluopyram on adult honey bees and immature life stages and acute toxicity on adult bumblebees was generated in laboratory and under semi-field conditions (tunnel studies). Overall, the data indicate that fluopyram is of low risk to honey bees. The data are not yet renewed on EU-level and were not included in this submission in line with the guidance provided in the document SANCO/2010/13170 for the non-renewed mixing partner. However, the data can be made available upon request.

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

Considering the outcome of the Tier 1 risk assessment, the conduct of higher tier studies assessing the effects of FLU+TFS SC 500 at the maximum intended application rate is not required.

Having said this, a study assessing the effects of FLU+TFS SC 500 on honey bee colonies after two applications at 560 ml product/ha (corresponding to nominally 140 g a.s. fluopyram/ha + 140 g a.s. trifloxystrobin/ha), once before (BBCH 59 – 61) and during flowering (BBCH 64 -65) onto the bee-attractive crop *Phacelia tanacetifolia* under semi-field conditions (tunnels) was conducted and provides further information on the chronic effects of the product to adult honey bee and immature life stages under forced realistic exposure conditions. Overall, no adverse effects on honey bee mortality, behaviour, brood development and colony strength were observed and thus indicates that a low risk to honey bees is posed by FLU+TFS SC 500 also when the compound is applied during the flowering period of a bee-attractive crop. The study can be made available upon request.

**zRMS comments:**

zRMS considers that the risk posed by a formulation containing more than one active substance cannot be addressed with data on active substances alone.
The study assessing the effects of FLU+TFS SC 500 on honey bee colonies after two applications at 560 ml product/ha (corresponding to nominally 140 g a.s. fluopyram/ha + 140 g a.s. trifloxystrobin/ha), once before (BBCH 59 – 61) and during flowering (BBCH 64 -65) onto the bee-attractive crop *Phacelia tanacetifolia* under semi-field conditions (tunnels) was not conducted to this dossier for Luna Sensatio SC 500.
According to the new requirements of Reg. No. 284/2013, data on chronic effects on adult bees and on development of bees for the formulation should have been submitted.

### 9.6.3 Effects on bumble bees

Two studies assessing the acute contact and oral toxicity of trifloxystrobin to the non-*Apis* bee *Bombus terrestris* were conducted which have not been evaluated as part of the active substance renewal process and are submitted as additional information. Based on the obtained endpoints from acute contact and oral toxicity it can be concluded that there is no sensitivity difference between honey bees and bumblebees. The available new data on bumble bees is presented below and summarized under A 2.3.1.

**Table 9.6-4: Endpoints and effect values relevant for the risk assessment for bumble bees**

| Species | Substance | Exposure System | Results | Reference |
|---|---|---|---|---|
| *Bombus terrestris L.* | Trifloxystrobin | Acute contact, 48 h | $LD_{50}$ > 100 µg a.s./bumble bee | M-480774-01-1<br>A. Kling, 2014<br>Appendix 2 |
| *Bombus terrestris L.* | Trifloxystrobin | Acute oral, 48 h | $LD_{50}$ > 115.9 µg a.s./bumble bee | M-557014-01-1<br>V. Tänzler, 2016 |

| Species | Substance | Exposure System | Results | Reference |
|---|---|---|---|---|
| | | | | Appendix 2 |

### 9.6.4 Effects on solitary bees

Not required.

### 9.6.5 Overall conclusions

A safe use to bees can be demonstrated based on the low toxicity of trifloxystrobin and the product FLU+TFS SC 500, the outcome of the tier 1 risk assessment (HQ calculation) and the additional information provided on chronic toxicity to adult honey bees and immature life stages obtained from laboratory and semi-field testing with trifloxystrobin, fluopyram and FLU+TFS SC 500.

## 9.7 Effects on arthropods other than bees (KCP 10.3.2)

### 9.7.1 Toxicity data

Studies on the toxicity to non-target arthropods have been carried out with all active substances and relevant metabolites. Full details of these studies are provided in the respective EU DAR and RAR and related documents as well as in Appendix 2 of this document when new studies are submitted.

Effects on non-target arthropods of FLU + TFS SC 500 were not evaluated as part of the EU assessment of any of the active substances. New data submitted with this application in the core dossier 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 non-target arthropods**

| Species | Substance | Exposure System | Results | Reference |
|---|---|---|---|---|
| *Aphidius rhopalosiphi* (adults) | FLU + TFS SC 500 | Laboratory test glass plates (2D) | $LR_{50}$ > 3200 mL/ha<br>$ER_{50}$ > 3200 mL/ha | Appendix 2<br>Röhlig, 2007<br>M-283599-01-1 |
| *Typhlodromus pyri* (protonymphs) | FLU + TFS SC 500 | Laboratory test glass plates (2D) | $LR_{50}$ > 3200 mL/ha<br>$ER_{50}$ > 3200 mL/ha | Appendix 2<br>Röhlig, 2007<br>M-283552-01-1 |
| *Chrysoperla carnea* (larvae) | FLU + TFS SC 500 | Extended lab. test bean leaves (2D) | LR50 > 2340 mL/ha<br>No effect on reproduction | Appendix 2<br>Röhlig, 2014<br>M-482453-01-1 |
| *Orius laevigatus* (nymphs) | FLU + TFS SC 500 | Extended lab. test grape-vine leaves (2D) | $LR_{50}$ = 139 mL/ha<br>$ER_{50}$ > 100 mL/ha | Appendix 2<br>Barth, 2007 |

| Species | Substance | Exposure System | Results | Reference |
|---|---|---|---|---|
| | | | | M-297476-01-1 |
| *Orius laevigatus* (nymphs) | FLU + TFS SC 500 | Aged-residue test grape vine plants (3D) | 2 × 0.8 L/ha (7 d interval):<br><br>Corr. mortality:<br>96.1% at 0 DA(L)T<br>88.7% at 7 DA(L)T<br>51.9% at 14 DA(L)T<br>7.0% at 21 DA(L)T<br>7.3% at 28 DA(L)T<br><br>Effect on fecundity* :<br>2.9% at 21 DA(L)T<br>-5.6% at 28 DA(L)T<br><br>Effects on fertility *:<br>-1.8% at 21 DA(L)T<br>-2.1% at 28 DA(L)T | Appendix 2<br>Barth, 2008<br>M-297471-01-1 |

* Due to high mortality at 0, 7 and 14 DA(L)T effects on fecundity and fertility were not assessed.

**zRMS comment:**

The studies for formulation were evalued in previously registration of the product Luna Sensation SC 500. No new studies are conducted.

### 9.7.1.1 Justification for new endpoints

Studies with the formulation FLU + TFS SC 500 were performed and are submitted with this application. For the risk assessment the endpoints from these studies were used (see Table 9.7-1), since the endpoints listed in the List of Endpoints of the single active substances do not consider this formulation.

## 9.7.2 Risk assessment

The evaluation of the risk for non-target arthropods was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002), and in consideration of the recommendations of the guidance document ESCORT 2.

### 9.7.2.1 Risk assessment for in-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group A also covers the risk for non-target arthropods from all other intended uses in groups B to O, Q and R due to identical or lower application rates and number of applications (see 9.1.2).

**Table 9.7-2: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of FLU+TFS SC 500 in leafy vegetables (use group A)**

| | |
|---|---|
| **Intended use** | Leafy vegetables, 2 × 0.8 L prod./ha covering groups: B to O, Q and R |

| | | | |
|---|---|---|---|
| **Active substance/product** | FLU+TFS SC 500 | | |
| **Application rate** | 2 × 0.8 L prod./ha | | |
| **MAF** | 1.7 | | |
| **Test species Tier 1** | **$LR_{50}$ (lab.) (mL/ha)** | **$PER_{in-field}$ (mL/ha)** | **$HQ_{in-field}$ criterion: HQ ≤ 2** |
| *Typhlodromus pyri* | >3200 | 1360 | <0.4 |
| *Aphidius rhopalosiphi* | >3200 | | <0.4 |
| **Test species Higher-tier** | **Rate with ≤ 50% effect* (mL/ha)** | **$PER_{in-field}$ (mL/ha)** | **$PER_{in-field}$ below rate with ≤ 50 % effect?** |
| *Chrysoperla carnea* | >2340 | 1360 | yes |
| *Orius laevigatus* | 139 | 1360 | **no** |
| **Test species Higher-tier** | **Rate with ≤ 50% effect (mL/ha) at xxx DALT** | **$PER_{in-field}$ (mL/ha)** | **$PER_{in-field}$ below rate with ≤ 50 % effect?** |
| *Orius laevigatus* | 2 x 800, 7 d interval, at 21 DALT | 2 x 800, 7 d interval | 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 $LR_{50}$ or $ER_{50}$ from a relevant extended laboratory test is available, it is considered in place of the rate with ≤ 50 % effect.

**Table 9.7-3: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of FLU+TFS SC 500 in flower bulbs (use group P)**

| | | | |
|---|---|---|---|
| **Intended use** | Flower bulbs, 5 × 0.3 L prod./ha | | |
| **Active substance/product** | FLU+TFS SC 500 | | |
| **Application rate** | 5 × 0.3 L prod./ha | | |
| **MAF** | 3.0 | | |
| **Test species Tier 1** | **$LR_{50}$ (lab.) (mL/ha)** | **$PER_{in-field}$ (mL/ha)** | **$HQ_{in-field}$ criterion: HQ ≤ 2** |
| *Typhlodromus pyri* | >3200 | 900 | <0.3 |
| *Aphidius rhopalosiphi* | >3200 | | <0.3 |
| **Test species Higher-tier** | **Rate with ≤ 50% effect* (mL/ha)** | **$PER_{in-field}$ (mL/ha)** | **$PER_{in-field}$ below rate with ≤ 50 % effect?** |
| *Chrysoperla carnea* | >2340 | 900 | yes |
| *Orius laevigatus* | 139 | 900 | **no** |
| **Test species Higher-tier** | **Rate with ≤ 50% effect (mL/ha) at xxx DALT** | **$PER_{in-field}$ (mL/ha)** | **$PER_{in-field}$ below rate with ≤ 50 % effect?** |
| *Orius laevigatus* | 2 x 800, 7 d interval, at 21 DALT | 5 x 300, 7 d interval | 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 $LR_{50}$ or $ER_{50}$ from a relevant extended laboratory test is available, it is considered in place of the rate with ≤ 50 % effect.

The extended laboratory test with the most sensitive species *Orius laevigatus* resulted in a rate with effects ≤ 50% of 139 mL/ha. This rate is below the highest $PER_{in-field}$ in field crops and flower bulbs covering all use groups. Therefore, an aged residue study with this species was conducted with 2 x 0.8 L product/ha with an application interval of 7 days. No adverse effects on *Orius laevigatus* were observed 21 d after last treatment. As this application rate is identical to the highest application rate considered in this risk assessment (use group A), the in-field risk to non-target arthropods is considered to be acceptable. The application rate in flower bulbs (use group P) is 5 x 0.3 L product/ha. If it is considered that the product would be applied as a single application of 1.5 L product/ha this rate is lower than the cumulative application rate of 1.6 L product/ha applied in the aged residue study. Therefore, the use of the product in flower bulbs is also considered to be safe as a recolonization of the field crops is possible 21 days after the last treatment.

**zRMS comment:**

The risk in-field for NTA is considered as acceptable. The $HQ_{in\text{-}field}$ values for standard two species Typhlodromus pyri and and Aphidius rhopalosiphi are below HQ trigger value of 2 indicating an acceptable use of the product.
The PERin-field field corrected value was below rate with ≤ 50 % effect for the Chrysoperla carnea s (based on extended labolatory styudy) and for Orius levigatus species ( age residue study).

### 9.7.2.2 Risk assessment for off-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group A also covers the risk for non-target arthropods from all other intended uses in groups B, C, F, G, J, K, L, O and Q, use group D covers use group E and I, use group M covers use group N (see 9.1.2).

**Table 9.7-4: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of FLU+TFS SC 500 in leafy vegetables (use group A)**

| | |
|---|---|
| **Intended use** | Leafy vegetables, 2 × 0.8 L prod./ha |
| **Active substance/product** | FLU+TFS SC 500 |
| **Application rate** | 2 × 0.8 L prod./ha |
| **MAF** | 1.7 |
| **VDF** | 10 (2D) / 1 (3D) |

| **Test species Tier 1** | **$LR_{50}$ (lab.) (mL/ha)** | **Drift rate (%)** | **$PER_{off\text{-}field}$ (mL/ha)** | **CF** | **$HQ_{off\text{-}field}$ criterion: HQ ≤ 2** |
|---|---|---|---|---|---|
| *Typhlodromus pyri* | >3200 | 2.38 | 16.18 | 5 | <0.1 |
| *Aphidius rhopalosiphi* | >3200 | | | | <0.1 |
| **Test species Higher-tier** | **Rate with ≤ 50% effect* (mL/ha)** | **Drift rate (%)** | **$PER_{off\text{-}field}$ (mL/ha)** | **CF** | **corr. $PER_{off\text{-}field}$ with ≤ 50 % effect?** |
| *Chrysoperla carnea* | >2340 | 2.38 | 16.18 | 5 | yes |
| *Orius laevigatus* | 139 | 2.38 | 16.18 | 5 | yes |

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 $LR_{50}$ or $ER_{50}$ from a relevant extended laboratory test is available, it is considered in place of the rate with ≤ 50 % effect.

**Table 9.7-5: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of FLU+TFS SC 500 in berries (use group D)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Berries, 2 × 0.8 L prod./ha | | | | |
| **Active substance/product** | FLU+TFS SC 500 | | | | |
| **Application rate** | 2 × 0.8 L prod./ha | | | | |
| **MAF** | 1.7 | | | | |
| **VDF** | 10 (2D) / 1 (3D) | | | | |
| **Test species Tier 1** | **$LR_{50}$ (lab.) (mL/ha)** | **Drift rate (%)** | **$PER_{off-field}$ (mL/ha)** | **CF** | **$HQ_{off-field}$ criterion: HQ ≤ 2** |
| *Typhlodromus pyri* | >3200 | 7.23 | 49.16 | 5 | <0.1 |
| *Aphidius rhopalosiphi* | >3200 | | | | <0.1 |
| **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?** |
| *Chrysoperla carnea* | >2340 | 7.23 | 49.16 | 5 | yes |
| *Orius laevigatus* | 139 | 7.23 | 49.16 | 5 | yes |

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 $LR_{50}$ or $ER_{50}$ from a relevant extended laboratory test is available, it is considered in place of the rate with ≤ 50 % effect.

**Table 9.7-6: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of FLU+TFS SC 500 in grapes (use group H)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Grapes, 2 × 0.2 L prod./ha | | | | |
| **Active substance/product** | FLU+TFS SC 500 | | | | |
| **Application rate** | 2 × 0.2 L prod./ha | | | | |
| **MAF** | 1.7 | | | | |
| **VDF** | 10 (2D) / 1 (3D) | | | | |
| **Test species Tier 1** | **$LR_{50}$ (lab.) (mL/ha)** | **Drift rate (%)** | **$PER_{off-field}$ (mL/ha)** | **CF** | **$HQ_{off-field}$ criterion: HQ ≤ 2** |
| *Typhlodromus pyri* | >3200 | 7.23 | 12.29 | 5 | <0.1 |
| *Aphidius rhopalosiphi* | >3200 | | | | <0.1 |
| **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?** |
| *Chrysoperla carnea* | >2340 | 7.23 | 12.29 | 5 | yes |
| *Orius laevigatus* | 139 | 7.23 | 12.29 | 5 | yes |

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 $LR_{50}$ or $ER_{50}$ from a relevant extended laboratory test is available, it is considered in place of the rate with ≤ 50 % effect.

**Table 9.7-7: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of FLU+TFS SC 500 in elderberry and mulberry (use group M)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Elderberry, mulberry, 2 × 0.8 L prod./ha | | | | |
| **Active substance/product** | FLU+TFS SC 500 | | | | |
| **Application rate** | 2 × 0.8 L prod./ha | | | | |
| **MAF** | 1.7 | | | | |
| **VDF** | 10 (2D) / 1 (3D) | | | | |
| **Test species Tier 1** | **$LR_{50}$ (lab.) (mL/ha)** | **Drift rate (%)** | **$PER_{off-field}$ (mL/ha)** | **CF** | **$HQ_{off-field}$ criterion: HQ ≤ 2** |
| *Typhlodromus pyri* | >3200 | 25.53 | 173.6 | 5 | <0.1 |
| *Aphidius rhopalosiphi* | >3200 | | | | <0.1 |
| **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?** |
| *Chrysoperla carnea* | >2340 | 25.53 | 173.6 | 5 | yes |
| *Orius laevigatus* | 139 | 25.53 | 173.6 | 5 | **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 $LR_{50}$ or $ER_{50}$ from a relevant extended laboratory test is available, it is considered in place of the rate with ≤ 50 % effect.

**Table 9.7-8: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of FLU+TFS SC 500 in flower bulbs (use group P)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Flower bulbs, 5 × 0.3 L prod./ha | | | | |
| **Active substance/product** | FLU+TFS SC 500 | | | | |
| **Application rate** | 5 × 0.3 L prod./ha | | | | |
| **MAF** | 3.0 | | | | |
| **VDF** | 10 (2D) / 1 (3D) | | | | |
| **Test species Tier 1** | **$LR_{50}$ (lab.) (mL/ha)** | **Drift rate (%)** | **$PER_{off-field}$ (mL/ha)** | **CF** | **$HQ_{off-field}$ criterion: HQ ≤ 2** |
| *Typhlodromus pyri* | >3200 | 1.75 | 7.88 | 5 | <0.1 |
| *Aphidius rhopalosiphi* | >3200 | | | | <0.1 |
| **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?** |
| *Chrysoperla carnea* | >2340 | 1.75 | 7.88 | 5 | yes |
| *Orius laevigatus* | 139 | 1.75 | 7.88 | 5 | yes |

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 $LR_{50}$ or $ER_{50}$ from a relevant extended laboratory test is available, it is considered in place of the rate with ≤ 50 % effect.

**Table 9.7-9: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of FLU+TFS SC 500 in hops (use group R)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Hops, 2 × 0.6 L prod./ha | | | | |
| **Active substance/product** | FLU+TFS SC 500 | | | | |
| **Application rate** | 2 × 0.6 L prod./ha | | | | |
| **MAF** | 1.7 | | | | |
| **VDF** | 10 (2D) / 1 (3D) | | | | |
| **Test species Tier 1** | **$LR_{50}$ (lab.) (mL/ha)** | **Drift rate (%)** | **$PER_{off-field}$ (mL/ha)** | **CF** | **$HQ_{off-field}$ criterion: HQ ≤ 2** |
| *Typhlodromus pyri* | >3200 | 17.73 | 90.42 | 5 | <0.1 |
| *Aphidius rhopalosiphi* | >3200 | | | | <0.1 |
| **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?** |
| *Chrysoperla carnea* | >2340 | 17.73 | 90.42 | 5 | yes |
| *Orius laevigatus* | 139 | 17.73 | 90.42 | 5 | yes |

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 $LR_{50}$ or $ER_{50}$ from a relevant extended laboratory test is available, it is considered in place of the rate with ≤ 50 % effect.

The risk for all uses of the product is considered to be safe without risk mitigation measures except for the use in elderberries and mulberries (use group M) (based on drift values for fruit crops (early)). As the risk assessment for this use was done as risk envelope covering 2 applications with 0.6 L product/ha in elderberry and mulberry (use group N), a risk assessment for this use is presented in the following table.

**Table 9.7-10: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of FLU+TFS SC 500 in elderberry and mulberry (use group N)**

| | | | | | |
|---|---|---|---|---|---|
| **Intended use** | Elderberry, mulberry, 2 × 0.6 L prod./ha | | | | |
| **Active substance/product** | FLU+TFS SC 500 | | | | |
| **Application rate** | 2 × 0.6 L prod./ha | | | | |
| **MAF** | 1.7 | | | | |
| **VDF** | 10 (2D) / 1 (3D) | | | | |
| **Test species Tier 1** | **$LR_{50}$ (lab.) (mL/ha)** | **Drift rate (%)** | **$PER_{off-field}$ (mL/ha)** | **CF** | **$HQ_{off-field}$ criterion: HQ ≤ 2** |
| *Typhlodromus pyri* | >3200 | 25.53 | 130.2 | 5 | <0.1 |
| *Aphidius rhopalosiphi* | >3200 | | | | <0.1 |
| **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?** |
| *Chrysoperla carnea* | >2340 | 25.53 | 130.2 | 5 | yes |
| *Orius laevigatus* | 139 | 25.53 | 130.2 | 5 | yes |

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 $LR_{50}$ or $ER_{50}$ from a relevant extended laboratory test is available, it is considered in place of the rate with ≤ 50 % effect.

The use of 2 x 0.6 L product/ha in elderberry and mulberry (use group N) is safe without using any mitigation measures. A risk assessment considering drift reduction is only needed for use group M.

**zRMS comments:**

The risk for all uses of the product is considered to be safe without risk mitigation measures **except** for the use in elderberries and mulberries (use group M) (based on drift values for fruit crops (early)). As the risk assessment for this use was done as risk envelope covering 2 applications with 0.6 L product/ha in elderberry and mulberry (use group N), a risk assessment for this use was considered in further calculations.

### 9.7.2.3 Additional higher-tier risk assessment

For the most sensitive species *O. laevigatus* a $LR_{50}$ value of 139 mL product/ha has been determined, therefore initial effects on *O. laevigatus* or other NTA species in the in-field area with a similar sensitivity cannot be excluded. In case of initial effects, the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002) requires that the potential for recovery within one year has to be demonstrated for the most sensitive species. To address the potential for recovery an aged residue study has been conducted with *O. laevigatus* with the formulation FLU+TFS SC 500. FLU+TFS SC 500 was applied with 2 applications of 0.8 L product/ha and an interval of 7 days covering the worst case GAP of this product. The study resulted in effects < 50% on mortality and reduction of reproduction in the bioassays that were started on day 21 after the last application. Therefore, no unacceptable adverse effects on non-target arthropods are to be expected in the in-field area from the application of FLU+TFS SC 500 according to the intended use pattern.

### 9.7.2.4 Risk mitigation measures

In order to reduce the off-field exposure for the use of the product in elderberry and mulberry (use group M), 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 9.7-11: Risk assessment of the off-field risk for non-target arthropods due to the use of FLU+TFS SC 500 in elderberry and mulberry (use group M) considering drift reduction**

| | | | | | | |
|---|---|---|---|---|---|---|
| **Intended use** | Elderberry, mulberry, 2 × 0.8 L prod./ha | | | | | |
| **Active substance/product** | FLU+TFS SC 500 | | | | | |
| **Application rate** | 2 × 0.8 L prod./ha | | | | | |
| **MAF** | 1.7 | | | | | |
| **VDF** | 10 (2D) / 1 (3D) | | | | | |
| **Test species Higher-tier** | **Rate with ≤ 50% effect* (mL/ha)** | **No-spray buffer zone** | **Drift rate (%)** | **$PER_{off-field}$ (mL/ha)** | **CF** | **corr. $PER_{off-field}$ with ≤ 50 % effect?** |
| *Orius laevigatus* | 139 | 5 m | 16.87 | 114.72 | 5 | yes |

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.

A no-spray buffer zone of 5 m is needed for the use of FLU + TFS SC 500 in elderberry and mulberry (2 x 0.8 L product/ha, use group M).

**zRMS comment:**

In order to reduce the off-field exposure for the use of the product Luna Sensation in elderberry and mulberry (use group M), a non-spray buffer zone of 5 m should be applied to non-crop land.

### 9.7.3 Overall conclusions

The risk assessment based on extended laboratory data indicate acceptable in- and off-field risk for *Typhlodromus pyri*, *Aphidius rhopalosiphi* and *Chrysoperla carnea* and acceptable off-field risk for *Orius laevigatus* for all use groups except for use group M (2 × 0.8 L prod./ha in elderberry and mulberry). For the in-field risk for *Orius laevigatus*, a refined risk assessment based on an aged residue study was conducted and showed that a recovery is possible within 21 days after the last application for all use groups.
For the use in elderberry and mulberry (use group M), a 5 m no-spray buffer zone is needed for a safe use of the product.

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

### 9.8.1 Toxicity data

Studies on the toxicity to earthworms and other non-target soil organisms (meso- and macrofauna) have been carried out with trifloxystrobin and its relevant metabolites. Full details of these studies are provided in the respective EU RAR and related documents as well as in Appendix 2 of this document when new studies are submitted.

Effects on earthworms and other non-target soil organisms (meso- and macrofauna) of FLU + TFS SC 500 were not evaluated as part of the EU assessment of any of the active substances. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

**Table 9.8-1: Trifloxystrobin - 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 |
|---|---|---|---|---|
| *Eisenia fetida* | Trifloxystrobin | Mixed into substrate 56 d, chronic, 5% peat | NOEC = 3.5 mg a.s./kg d.w.soil* | KCA 8.4.1/03<br>RAR & EFSA, 2017 [a] |
| *Eisenia fetida* | CGA 357261 | Mixed into substrate chronic, 5% peat | NOEC = 50 mg metabolite/kg d.w.soil* | KCA 8.4.1/04<br>RAR & EFSA, 2017 [a] |
| *Eisenia fetida* | CGA 321113 | Mixed into substrate 56 d, chronic, 10% peat | NOEC = 50 mg metabolite/kg d.w.soil* | KCA 8.4.1/05<br>RAR & EFSA, 2017 [a] |
| *Eisenia fetida* | CGA 373466 | Mixed into substrate 56 d, chronic, 5% peat | NOEC = 100 mg metabolite/kg d.w.soil | KCA 8.4.1/06<br>RAR & EFSA, 2017 [a] |
| *Eisenia fetida* | CGA 381318 | Mixed into substrate 56 d, chronic, 10% peat | NOEC = 100 mg metabolite/kg d.w.soil | KCA 8.4.1/07<br>RAR & EFSA, 2017 [a] |
| *Eisenia fetida* | NOA 413161 | Mixed into substrate 56 d, chronic, 5% peat | NOEC = 100 mg metabolite/kg d.w.soil | KCA 8.4.1/08<br>RAR & EFSA, 2017 [a] |
| *Eisenia fetida* | NOA 413163 | Mixed into substrate 56 d, chronic, 10% peat | NOEC = 100 mg metabolite/kg d.w.soil | KCA 8.4.1/09<br>RAR & EFSA, 2017 [a] |
| *Eisenia fetida* | CGA 357276 | Mixed into substrate 56 d, chronic, 5% peat | NOEC = 25 mg metabolite/kg d.w.soil*<br>$EC_{10}$ = 58.9 mg metabolite/kg d.w.soil<br>$EC_{20}$ > 90 mg metabolite/kg d.w.soil | KCA 8.4.1/10<br>& M-584331-01-1<br>RAR & EFSA, 2017 [a] |
| *Eisenia fetida* | NOA 409480 | Mixed into substrate 56 d, chronic, 5% peat | NOEC = 50 mg metabolite/kg d.w.soil* | KCA 8.4.1/11<br>RAR & EFSA, 2017 [a] |
| *Folsomia candida* | Flint preparation | Mixed into substrate 28 d, chronic, 5% peat | NOEC = 249 mg a.s./kg d.w.soil* | KCA 8.4.2.1/03<br>RAR & EFSA, 2017 [a] |
| *Folsomia candida* | CGA 357261 | Mixed into substrate 28 d, chronic, 5% peat | NOEC = 50 mg metabolite/kg d.w.soil* | KCA 8.4.2.1/04<br>RAR & EFSA, 2017 [a] |
| *Folsomia candida* | CGA 321113 | Mixed into substrate 28 d, chronic, 10% peat | NOEC = 50 mg metabolite/kg d.w.soil*<br>$EC_{10}$ = 207 mg metabolite/kg d.w.soil<br>$EC_{20}$ = 382 mg metabolite/kg d.w.soil | KCA 8.4.2.1/01<br>& M-584315-01-1<br>RAR & EFSA, 2017 [a] |
| *Folsomia candida* | CGA 373466 | Mixed into substrate 28 d, chronic, 5% peat | NOEC = 100 mg metabolite/kg d.w.soil | KCA 8.4.2.1/05<br>RAR & EFSA, 2017 [a] |
| *Folsomia* | NOA 413161 | Mixed into substrate | NOEC = 10 mg metabolite/kg d.w.soil | KCA 8.4.2.1/02 |

| Species | Substance | Exposure System | Results | Reference |
|---|---|---|---|---|
| *candida* | | 28 d, chronic, 10% peat | | RAR & EFSA, 2017 [a] |
| *Folsomia candida* | NOA 413163 | Mixed into substrate 28 d, chronic, 5% peat | NOEC = 100 mg metabolite/kg d.w.soil | KCA 8.4.2.1/06 RAR & EFSA, 2017 [a] |
| *Folsomia candida* | CGA 357276 | Mixed into substrate 28 d, chronic, 5% peat | NOEC = 50 mg metabolite/kg d.w.soil* | KCA 8.4.2.1/08 RAR & EFSA, 2017 [a] |
| *Hypoaspis aculeifer* | Flint preparation | Mixed into substrate 14 d, chronic, 5% peat | NOEC = 249 mg a.s./kg d.w.soil* | KCA 8.4.2.1/07 RAR & EFSA, 2017 [a] |
| *Hypoaspis aculeifer* | CGA 357261 | Mixed into substrate 14 d, chronic, 5% peat | NOEC = 50 mg metabolite/kg d.w.soil* | KCA 8.4.2.1/12 RAR & EFSA, 2017 [a] |
| *Hypoaspis aculeifer* | CGA 321113 | Mixed into substrate 14 d, chronic, 5% peat | NOEC = 50 mg metabolite/kg d.w.soil* | KCA 8.4.2.1/11 RAR & EFSA, 2017 [a] |
| *Hypoaspis aculeifer* | CGA 373466 | Mixed into substrate 14 d, chronic, 5% peat | NOEC = 100 mg metabolite/kg d.w.soil | KCA 8.4.2.1/09 RAR & EFSA, 2017 [a] |
| *Hypoaspis aculeifer* | NOA 413161 | Mixed into substrate 14 d, chronic, 5% peat | NOEC = 100 mg metabolite/kg d.w.soil | KCA 8.4.2.1/13 RAR & EFSA, 2017 [a] |
| *Hypoaspis aculeifer* | CGA 357276 | Mixed into substrate 14 d, chronic, 5% peat | NOEC = 50 mg metabolite/kg d.w.soil* | KCA 8.4.2.1/10 RAR & EFSA, 2017 [a] |
| *Eisenia fetida* | FLU + TFS SC 500 | Overspray 56 d, chronic, 5% peat | NOEC = 23.3 mg prod./kg dws<br>$NOEC_{corr}$ = 11.65 mg prod./kg dws* | Appendix 2 Leicher, 2007 M-283637-01-1 |
| *Hypoaspis aculeifer* | FLU + TFS SC 500 | Mixed into substrate 14 d, chronic 5% peat content | NOEC = 316 mg prod./kg dws<br>$NOEC_{corr}$ = 158 mg prod./kg dws* | Appendix 2 Larnaudie Lopez, 2016 M-548820-01-1 |
| *Folsomia candida* | FLU + TFS SC 500 | Mixed into substrate 28 d, chronic 5% peat content | NOEC = 562 mg prod./kg dws<br>$NOEC_{corr}$ = 281 mg prod./kg dws* | Appendix 2 Friedrich, 2017 M-576685-01-1 |
| **Field studies** | | | | |
| No data | | | | |

[a] Refer to Appendix 1 – List of data submitted or referred to and relied on, but already evaluated at EU peer review
* Corrected by factor of 2 due to lipophilic substance (log $P_{OW}$ > 2)

**zRMS comment:**

The studies for formulation were evaluated in previously  in Registration of the product Luna Sensation SC 500. These studies were considered as acceptable.

**Table 9.8-2: 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 |
|---|---|---|---|---|
| *Eisenia fetida* | Fluopyram | Mixed into substrate<br>14 d, acute<br>5% peat | $LC_{50}$ > 1000 mg a.s./kg dw | EFSA Journal 2013;11(4):3052 |
| *Eisenia fetida* | Fluopyram SC 500 | Mixed into substrate<br>8 weeks, chronic<br>5% peat | NOEC = 27.31 mg prod./kg dw<br>NOEC = 11.42 mg a.s./kg dw | EFSA Journal 2013;11(4):3052 |
| | | | $NOEC_{corr}$ = 5.71 mg a.s./ kg dw * | See justification |
| *Folsomia candida* | Fluopyram SC 500 | Mixed into substrate<br>28 d, chronic<br>5% peat | NOEC = 250 mg prod./kg dw<br>NOEC = 103.8 mg a.s./kg dw | EFSA Journal 2013;11(4):3052 |
| | | | $NOEC_{corr}$ = 51.9 mg a.s./kg dw * | See justification |
| *Hypoaspis aculeifer* | Fluopyram SC 500 | Mixed into substrate<br>14 d, chronic<br>5% peat | NOEC = 1000 mg prod./kg dw<br>NOEC = 415 mg a.s./kg dw | EFSA Journal 2013;11(4):3052 |
| | | | $NOEC_{corr}$ = 207.5 mg a.s./kg dw * | See justification |
| **Field studies** | | | | |
| - | | | | |
| **Litter bag test** - EFSA Journal 2013;11(4):3052 | | | | |
| Field soil litter degradation | Fluopyram SC 500, 2 spray application with incorporation First one with 1535 g product/ha (= 642 g a.s./ha) into the upper 10 cm soil layer to achieve plateau concentration of 428 µg a.s./kg dw; Second spray application 13 days later with 717 g product/ha (= 300 g a.s./ha) | 183 days | % field soil litter degradation:<br>76% degradation in control after 133 days [b)] (trigger is 60%)<br>wheat straw degradation in treated plots (rel. to control):<br>after 30 days: 114.4% (n.s.)<br>after 92 days: 106.0% (n.s.)<br>after 173 days: 101.0% (n.s.)<br>NOEC ≥ 0.514 mg a.s./kg dw | EFSA Journal 2013;11(4):3052 |

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

The studies for fluopyram are not considered ny zRMS-PL in the current evaluation in the context of art 43 of the assessment for a.s.-TFS

### 9.8.1.1 Justification for new endpoints

No deviation from the EU agreed endpoints.

**Fluopyram:**

| Species | Substance | Exposure System | Justification* |
|---|---|---|---|
| *Eisenia fetida* | Fluopyram SC 500 | Overspray<br>56 d, chronic<br>5% peat content | The study endpoint, i.e. the NOEC = 11.42 mg a.s./kg dw was corrected to 5.71 mg a.s./kg dw by dividing the endpoint by a factor of 2 to account for the log $P_{ow}$ for fluopyram which is > 2. |

| Species | Substance | Exposure System | Justification* |
|---|---|---|---|
| *Folsomia candida* | Fluopyram SC 500 | Mixed into substrate<br>28 d, chronic<br>5% peat content | The study endpoint, i.e. the NOEC = 103.8 mg a.s./kg dw was corrected to 51.9 mg a.s./kg dw by dividing the endpoint by a factor of 2 to account for the log $P_{ow}$ for fluopyram which is > 2. |
| *Hypoaspis aculeifer* | Fluopyram SC 500 | Mixed into substrate<br>14 d, chronic<br>5% peat | The study endpoint, i.e. the NOEC = 415 mg a.s./kg dw was corrected to 207.5 mg a.s./kg dw by dividing the endpoint by a factor of 2 to account for the log $P_{ow}$ for fluopyram which is > 2. |

*The studies for fluopyram are not considered by zRMS-PL in the current evaluation in the context of art 43 of the assessment for a.s.-TFS.

## 9.8.2 Risk assessment

The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna) was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

<u>Fluopyram</u>
For the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009, the following guidance is given in the Document SANCO/2010/13170 for products containing two or more active substances:

- “when the 1st substance is renewed- there is no need to evaluate data related to the 2nd substance”
- “once the 2nd substance is renewed- there is no need to evaluate data related to the 1st substance because this has already been performed in the frame of the re-authorisation of the PPP following the renewal of the 1st active substance”
- “Where necessary a combitox assessment should be performed.”

Therefore, a single risk assessment for Flupyram is not performed as this would be out of scope of SANCO/2010/13170.

### 9.8.2.1 First-tier risk assessment

The relevant $PEC_{soil}$ for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2. According to the assessment of environmental-fate data, multi-annual accumulation in soil does not need to be considered for trifloxystrobin and the most metabolites but is considered for CGA 321113, NOA 413161 and CGA 373466.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use in lettuce and rocket salad (use group S) also covers the risk for earthworms and other non-target soil organisms (meso- and macrofauna) from all other intended uses (see 9.1.2) for trifloxystrobin and its metabolites CGA 357261, CGA 381318 and NOA 409480. For metabolite CGA 321113, the use in elderberries (use group T) covers the risk for earthworms and other non-target soil organisms (meso- and macrofauna) from all other intended uses (see 9.1.2) whereas the use in flower bulbs (use group U) resulted in the highest PECsoil values for CGA 373466, NOA 413161, NOA 413163 and CGA 357276 and the product.

**Table 9.8-3: First-tier assessment of the chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of FLU + TFS SC 500 in lettuce and rocket salad (use group S) (worst case for trifloxystrobin and its metabolites CGA 357261, CGA 381318 and NOA 409480), elderberries (use group T) (worst case for CGA 321113) and flower bulbs (use group U) (worst case for CGA 373466, NOA 413161, NOA 413163 and CGA 357276 and the product)**

| **Intended use** | Lettuce, rocket salad (2 × 0.8 L prod./ha, 7 d interval, 2 × 25% crop interception)<br>Elderberry (2 × 0.8 L prod./ha, 7 d interval, 2 × 60% crop interception)<br>Flower bulbs (5 × 0.3 L prod./ha, 7 d interval, 5 × 10% crop interception) | | |
|---|---|---|---|
| **Acute effects on earthworms (*Eisenia fetida*)** | | | |
| Not required according to Regulation (EC) 1107/2009. | | | |
| **Chronic effects on earthworms** | | | |
| **Product/active substance** | **NOEC # (mg/kg dw)** | **$PEC_{soil}$ * (mg/kg dw)** | **$TER_{lt}$ (criterion TER ≥ 5)** |
| FLU + TFS SC 500 | 11.65 [1] | 2.113 [2] | 5.51 |
| Trifloxystrobin | 3.5 | 0.297 | 11.8 |
| CGA 357261 | 50 | 0.038 | 1316 |
| CGA 321113 | 50 | 0.699 | 71.5 |
| CGA 373466 | 100 | 0.163 | 613 |
| CGA 381318 | 100 | 0.022 | 4545 |
| NOA 413161 | 100 | 0.070 | 1429 |
| NOA 413163 | 100 | 0.025 | 4000 |
| CGA 357276 | 25 | 0.018 | 1389 |
| NOA 409480 | 50 | 0.028 | 1786 |
| **Chronic effects on other soil macro- and mesofauna** | | | |
| **Product/active substance** | **NOEC # (mg/kg dw)** | **$PEC_{soil}$ * (mg/kg dw)** | **$TER_{lt}$ (criterion TER ≥ 5)** |
| *Hypoaspis aculeifer* | | | |
| FLU + TFS SC 500 | 158 [1] | 2.113 [2] | 74.8 |
| Trifloxystrobin | 249 | 0.297 | 838 |
| CGA 357261 | 50 | 0.038 | 1316 |
| CGA 321113 | 50 | 0.699 | 71.5 |
| CGA 373466 | 100 | 0.163 | 613 |
| NOA 413161 | 100 | 0.070 | 1429 |
| CGA 357276 | 50 | 0.018 | 2778 |
| *Folsomia candida* | | | |
| FLU + TFS SC 500 | 281 [1] | 2.113 [2] | 133 |
| Trifloxystrobin | 249 | 0.297 | 838 |
| CGA 357261 | 50 | 0.038 | 1316 |
| CGA 321113 | 50 | 0.699 | 71.5 |
| CGA 373466 | 100 | 0.163 | 613 |

| | | | |
|---|---|---|---|
| NOA 413161 | 10 | 0.070 | 143 |
| NOA 413163 | 100 | 0.025 | 4000 |
| CGA 357276 | 50 | 0.018 | 2778 |

[#] Endpoints expressed as mg a.s./kg dw for the parent and as mg p.m./kg dw for the metabolites
* $PEC_{accumulation}$= $PEC_{act}$ + $PEC_{soil\ plateau}$ expressed as mg a.s./kg dw for the parent and as mg p.m./kg dw for the metabolites
[1] Endpoint expressed in mg prod./kg dw
[2] $PEC_{soil}$ expressed in mg prod./kg dw, calculated regarding worst case assumption with 5 x 10% interception

**zRMS comments:**

We agree with the risk assessment for earthworm and other soil macroorganism form exposure of a.s.-TFS and its metabolites and for the product Luna Sensation SC 500. The $TER_{LT}$ values for these organism were above trigger of 5, indicating an acceptable risk for these group of organism.

#### 9.8.2.2 Higher-tier risk assessment

Not relevant.

### 9.8.3 Overall conclusions

The risk assessment demonstrates that the use of FLU + TFS SC 500 on the intended crops is unlikely to result in an unacceptable risk to earthworm and other soil macro- and mesofauna.

## 9.9 Effects on soil microbial activity (KCP 10.5)

### 9.9.1 Toxicity data

Studies on effects on soil microorganisms have been carried out with trifloxystrobin and its relevant metabolites. Full details of these studies are provided in the respective EU RAR and related documents as well as in Appendix 2 of this document when new studies are submitted.

Effects on soil microorganisms of FLU + TFS SC 500 were not evaluated as part of the EU assessment of any of the active substances. New data submitted with this application in the core dossier are listed in Appendix 1 and summarised in Appendix 2.

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

**Table 9.9-1: Trifloxystrobin - Endpoints and effect values relevant for the risk assessment for soil microorganisms**

| Endpoint | Substance | Exposure System | Results | Reference |
|---|---|---|---|---|
| N-mineralisation | Trifloxystrobin | 28 d | < 25% effect at day 28 at 13.33 mg a.s./kg d.w.soil | KCA 8.5/01<br>RAR & EFSA, 2017 [a] |
| N-mineralisation | CGA 357276 | N/A | < 25% effect at 1.33 mg metabolite/kg d.w.soil* | |

| Endpoint | Substance | Exposure System | Results | Reference |
|---|---|---|---|---|
| N-mineralisation | NOA 413163 | N/A | < 25% effect at 1.33 mg metabolite/kg d.w.soil* | |
| N-mineralisation | NOA 409480 | N/A | < 25% effect at 1.33 mg metabolite/kg d.w.soil* | |
| N-mineralisation | CGA 381318 | N/A | < 25% effect at 1.33 mg metabolite/kg d.w.soil* | |
| N-mineralisation | CGA 357261 | 42 d | < 25% effect at day 42 at 3.35 mg metab./kg d.w.soil | KCA 8.5/15<br>RAR & EFSA, 2017 [a] |
| N-mineralisation | CGA 321113 | 28 d | < 25% effect at day 28 at 3.26 mg metab./kg d.w. soil | KCA 8.5/16<br>RAR & EFSA, 2017 [a] |
| N-mineralisation | CGA 373466 | 28 d | < 25% effect at day 28 at 3.47 mg metab./kg d.w. soil | KCA 8.5/02<br>RAR & EFSA, 2017 [a] |
| N-mineralisation | NOA 413161 | 28 d | < 25% effect at day 28 at 3.41 mg metab./kg d.w. soil | KCA 8.5/08-11, 13, 14<br>RAR & EFSA, 2017 [a] |
| N-mineralisation | FLU + TFS SC 500 | 56 d, loamy sand | < 25% effect at day 56 at 10.67 µL product/kg dw<br>(8 L product/ha) | Appendix 2<br>Leicher, 2007<br>M-295282-01-1 |

[a] Refer to Appendix 1 – List of data submitted or referred to and relied on, but already evaluated at EU peer review
* No experimental data therefore assumed to be ten times more toxic than active substance

**Table 9.9-2: Fluopyram* - Endpoints and effect values relevant for the risk assessment for soil microorganisms**

| Endpoint | Substance | Exposure System | Results | Reference |
|---|---|---|---|---|
| N-mineralisation | Fluopyram | 28 d, aerobic silty sand | < 25% effect at day 28 at 3.33 mg a.s./kg dw (2.5 kg a.s./ha) | EFSA Journal 2013;11(4):3052 |
| C-mineralisation | Fluopyram | 28 d, aerobic silty sand | < 25% effect at 2.5 kg a.s./ha (3.33 mg a.s./kg dw) | EFSA Journal 2013;11(4):3052 |

*The studies  for flupyram are not considered by zRMS-PL in the current evaluation in the context of art 43 of the assessmeny for a.s.-TFS

**Table 9.9-3: Endpoints and effect values relevant for the risk assessment for soil microorganisms - FLU + TFS SC 500**

| Endpoint | Substance | Exposure System | Results | Reference |
|---|---|---|---|---|
| N-mineralisation | FLU + TFS SC 500 | 56 d,<br>loamy sand | < 25% effect at day 28 at 10.67 µL product/kg dw<br>(8 L product/ha) | Appendix 2<br>Leicher, 2007<br>M-295282-01-1 |

**zRMS comment:**

The studies for formulation were in previously  registration of the product  Luna Sensation SC 500 were evaluated by zRMS-PL. These studies  were considered as acceptable.

### 9.9.1.1 Justification for new endpoints

No deviation from the EU agreed endpoints.

### 9.9.2 Risk assessment

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

Flupyram
For the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009, the following guidance is given in the Document SANCO/2010/13170 for products containing two or more active substances:

- "when the 1st substance is renewed- there is no need to evaluate data related to the 2nd substance"
- "once the 2nd substance is renewed- there is no need to evaluate data related to the 1st substance because this has already been performed in the frame of the re-authorisation of the PPP following the renewal of the 1st active substance"
- "Where necessary a combitox assessment should be performed."

Therefore, a single risk assessment for Flupyram is not performed as this would be out of scope of SANCO/2010/13170.

Trifloxystrobin
The relevant $PEC_{soil}$ for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2 and were already used in the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) (see 9.8).

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use in lettuce and rocket salad (use group S) also covers the risk for earthworms and other non-target soil organisms (meso- and macrofauna) from all other intended uses (see 9.1.2) for trifloxystrobin and its metabolites CGA 357261, CGA 381318 and NOA 409480. For metabolite CGA 321113, the use in elderberries (use group T) covers the risk for earthworms and other non-target soil organisms (meso- and macrofauna) from all other intended uses (see 9.1.2) whereas the use in flower bulbs (use group U) resulted in the highest PECsoil values for CGA 373466, NOA 413161, NOA 413163 and CGA 357276 and the product.

**Table 9.9-4: Assessment of the risk for effects on soil micro-organisms due to the use of FLU + TFS SC 500 in lettuce and rocket salad (use group S) (worst case for trifloxystrobin and its metabolites CGA 357261, CGA 381318 and NOA 409480), elderberries (use group T) (worst case for CGA 321113) and flower bulbs (use group U) (worst case for CGA 373466, NOA 413161, NOA 413163 and CGA 357276)**

| **Intended use** | Lettuce, rocket salad (2 × 200 g a.s./ha, 7 d interval, 2 × 25% crop interception)<br>Elderberry (2 × 0.8 L prod./ha, 7 d interval, 2 × 60% crop interception)<br>Flower bulbs (5 × 0.3 L prod./ha, 7 d interval, 5 × 10% crop interception) | | |
|---|---|---|---|
| **N-mineralisation** | | | |
| **Product/active substance** | **Max. conc. with effects ≤ 25 % # (mg/kg dw)** | **$PEC_{soil}$ * (mg/kg dw)** | **Risk acceptable?** |
| FLU + TFS SC 500 | 12.53 (at 56 d) [1] | 2.113 [2] | yes |
| Trifloxystrobin | 13.33 (at 28 d) | 0.297 | yes |
| CGA 357276 | 1.33 [3] | 0.018 | yes |
| NOA 413163 | 1.33 [3] | 0.025 | yes |
| NOA 409480 | 1.33 [3] | 0.028 | yes |
| CGA 381318 | 1.33 [3] | 0.022 | yes |
| CGA 357261 | 3.35 (at 42 d) | 0.038 | yes |
| CGA 321113 | 3.26 (at 28 d) | 0.699 | yes |
| CGA 373466 | 3.47 (at 28 d) | 0.163 | yes |
| NOA 413161 | 3.41 (at 28 d) | 0.070 | yes |
| **C-mineralisation** | | | |
| Not required according to Regulation (EU) 1107/2009. | | | |

# Endpoints expressed as mg a.s./kg dw for the parent and as mg p.m./kg dw for the metabolites
* $PEC_{accumulation}$= $PEC_{act}$ + $PEC_{soil\ plateau}$ expressed as mg a.s./kg dw for the parent and as mg p.m./kg dw for the metabolites
[1] Endpoint expressed in mg prod./kg dw was recalculated: 10.67 µL product/kg dw x density of 1.174 mg/µL
[2] $PEC_{soil}$ expressed in mg prod./kg dw, calculated regarding worst case assumption with 5 x 10% interception
[3] No experimental data therefore assumed to be ten times more toxic than active substance

**zRMS comment:**

We agree with the risk assessment for the active substance .

## 9.9.3 Overall conclusions

The risk assessment demonstrates that the use of FLU + TFS SC 500 on the intended crops is unlikely to result in an unacceptable risk to the soil microbial activity.

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

### 9.10.1 Toxicity data

Studies on the toxicity to non-target terrestrial plants have been carried out with trifloxystrobin and relevant metabolites. Full details of these studies are provided in the respective EU RAR and related documents as well as in Appendix 2 of this document when new studies are submitted.

Effects on non-target terrestrial plants of FLU + TFS SC 500 were not evaluated as part of the EU assessment of any of the active substances. New data submitted with this application in the core dossier are listed in Appendix 1 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. For seedling emergence, a limit test at a rate of 0.75 L prod./ha and a limit test at a rate of 1.0 L prod./ha are available, each including ten plant species.

For vegetative vigour, the following studies are available: a limit test at a rate of 0.75 L prod./ha with ten species, a limit test involving two applications of the rate 0.8 L prod./ha with ten species, a dose-response study on three species with a highest test rate of 2.0 L prod./ha and finally a limit test with seven species at a rate of 1.0 L prod./ha.
In none of the studies listed above adverse effects > 50% were observed in any species tested. The only exception is buckwheat in the most recent vegetative vigour limit test (M-681185-01-1, 2020) at 1.0 L prod./ha. For this species a dry weight reduction of 52% was measured. A follow-up dose-response study will be conducted but will not be available in time for this submission. However, the results can be provided upon request after study finalization. Consequently, for the time being the relevant $ER_{50}$ for the risk assessment of buckwheat is set as > 0.8 L prod./ha.
For all other species the $ER_{50}$ is greater than the highest rate tested, respectively.

**Table 9.10-1: Endpoints and effect values relevant for the risk assessment for non-target terrestrial plants**

| Species | Substance | Exposure System | Results | Reference |
|---|---|---|---|---|
| *Zea mays* [1] m<br>*Avena sativa* [1] m<br>*Allium cepa* [1] m<br>*Cucumis sativus* [1] d<br>*Brassica napus* [1] d<br>*Glycine max* [1] d<br>*Beta vulgaris* [1] d<br>*Helianthus annuus* [1] d<br>*Lycopersicon esculentum* [1] d<br>*Fagopyrum esculentum* [1] d | FLU + TFS SC 500 | 21 d<br>Vegetative vigour<br>Tier 1 | [1] $ER_{50}$ > 0.75 L prod./ha | Appendix 2<br>Gosch & Nguyen, 2007<br>M-289527-01-1 |
| *Zea mays* [1] m<br>*Avena sativa* [1] m<br>*Lolium perenne* [1] m<br>*Cucumis sativus* [1] d<br>*Brassica napus* [1] d<br>*Glycine max* [1] d<br>*Beta vulgaris* [1] d<br>*Helianthus annuus* [1] d<br>*Lycopersicon esculentum* [1] d<br>*Fagopyrum esculentum* [1] d | FLU + TFS SC 500 | 21 d<br>Vegetative vigour<br>Tier 1 | [1] $ER_{50}$ > 2 x 0.8 L prod./ha | Appendix 2<br>Koehler, 2013<br>M-464310-01-1 |
| *Zea mays* [1] m<br>*Lolium perenne* [1] m<br>*Avena sativa* [1] m<br>*Allium cepa* [1] m<br>*Brassica napus* [1] d<br>*Glycine max* [1] d<br>*Fagopyrum esculentum* [2] d | FLU + TFS SC 500 | 21 d<br>Vegetative vigour<br>Tier 1 | [1] $ER_{50}$ > 1.0 L prod./ha<br>[2] $ER_{50}$ < 1.0 L prod./ha (52% reduction of sdw) | Appendix 2<br>Ripperger, 2020*<br>M-681185-01-1 |

| **Species** | **Substance** | **Exposure System** | **Results** | **Reference** |
|---|---|---|---|---|
| *Beta vulgaris* [1] d<br>*Cucumis sativus* [1] d<br>*Solanum lycopersicum* [1] d | FLU + TFS SC 500 | 21 d<br>Vegetative vigour<br>Tier 2 | [1] $ER_{50}$ > 2.0 L prod./ha | Appendix 2<br>Nöding, 2018*<br>M-612774-01-1 |
| *Zea mays* [1] m<br>*Avena sativa* [1] m<br>*Lolium perenne* [1] m<br>*Cucumis sativus* [1] d<br>*Brassica napus* [1] d<br>*Glycine max* [1] d<br>*Beta vulgaris* [1] d<br>*Helianthus annuus* [1] d<br>*Lycopersicon esculentum*[1] d<br>Fagopyrum esculentum [1] d | FLU + TFS SC 500 | 14 d<br>Seedling emergence<br>Tier 1 | [1] $ER_{50}$ > 0.75 L prod./ha | Appendix 2<br>Gosch & Nguyen, 2007<br>M-289525-01-1 |
| *Beta vulgaris* [1] d<br>*Brassica napus* [1] d<br>*Cucumis sativus* [1] d<br>*Fagopyrum esculentum* [1] d<br>*Glycine max* [1] d<br>*Helianthus annuus* [1] d<br>*Allium cepa* [1] d<br>*Avena sativa* [1] d<br>*Lolium perenne* [1] d<br>*Zea mays* [1] m | FLU + TFS SC 500 | 21 d<br>Seedling emergence<br>Tier 1 | [1] $ER_{50}$ > 1.0 L prod./ha | Appendix 2<br>Ripperger, 2020*<br>M-681165-01-1 |

m: monocotyledonous; d: dicotyledonous
*The new studies for Lena Sensation

**zRMS comment:**

The studies for formulation were evaluated in previously registration of the product Luna Sensation SC 500. In addition, applicant provided further studies for Luna Sensation. All studies were considered as acceptable.

#### 9.10.1.1 Justification for new endpoints

Studies with the formulation FLU + TFS SC 500 were performed and are submitted with this application. For the risk assessment the endpoints from these studies were used, since the endpoints listed in the List of Endpoints of the single active substance do not consider this formulation.

### 9.10.2 Risk assessment

#### 9.10.2.1 Tier-1 risk assessment (based screening data)

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 (see 9.1.2). As it is demonstrated by the available set of studies that the single application rate of 0.8 L prod./ha does not result in effects ≥ 50 %, according to the “Guidance Document on Terrestrial Ecotoxicology” (SANCO/10329/2002 rev. 2 final, 2002), no risk for non-target terrestrial plants is expected. Thus, no further risk assessment is required and the need for risk mitigation measures is excluded.

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 arthropods from all other intended uses in groups B, C, F, G, J, K, L, O and Q, use group D covers use group E and I, use group M covers use group N (see 9.1.2).

**zRMS comments:**

**Deterministic risk assessment**

According to the Terrestrial Guidance Document[3], the risk to non-target terrestrial plants is assessed by comparing the exposure in field margins caused by drift with the lowest $ER_{50}$ obtained from the non-target plant studies. The MAF value of 1 according Sanco GD, 2002 and an assessment factor of 5 was used. $ER_{50}$ for the risk assessment was set 0.8 L prod./ha.

**Deterministic risk assessment based on $ER_{50}$ of 0.8 L product/ha.**

| **Distance from the field edge [m]** | **Drift with conventional spraying equipment [%]** | **PER obtained with conventional spraying equipment [L/ha]** | **TERs** |
|---|---|---|---|
| | | | **conv.** |
| **Application rate 0.8 L product/ha: vegetables and field crops (leafy vegtablesrooting vegetables, tab-occo, pulses, low berries with downward spray, flower bulbs, ornamentals<50 cm )** | | | |
| 1 | 2.77 | 0.0222 | > 36.0 |
| Application rate 0.8 L product/ha: vegetables and field crops (leafy vegtablesrooting vegetables, tabocco, pulses, low berries with downward spray, flower bulbs, ornamentals>50 cm ) | | | |
| 3 | 8.02 | 0.0802 | 13.33 |
| **Aplication rate 0.8 L/ha: Blackberry, chokeberry (red), currant (black, red, white), dewberry, gooseberry, raspberry, nurseries, rosehip, grapevine** | | | |
| 1 | 8.02 | 0.064 | >12.5 |
| **Application rate 0.8 L product/ha: Elderberry, mulberry** | | | |
| 3 | 29.20 | 0.233 ( early application) | **3.43** |
| 5 | 19.89 | 0.159 | 5.03 |
| 1 m + 50% drift reduction nozzels | - | 0.08 | 10 |
| 3 | 15.73 | 0.125 ( late application) | 6.4 |

According to the results of the deterministic approach, the trigger of 5 is met at:
- 1 m distance for vegatables and field crops and 3 m distance for aplication rate 0.8 L/ha for Blackberry, chokeberry (red), currant (black, red, white), dewberry, gooseberry, raspberry, nurseries, rosehip, grapevine with conventional spraying equipment.

In case of application for elderberry, mulberry the trigger of 5 is met at:
- 5 m buffer zone or 1 m buffer zone +50% drift reduction nozzels to non – crop area

[3] Anonymous (2002b), Guidance Document on Terrestrial Ecotoxicology under Council Directive 91/414/EEC, SANCO/10329/2002, 17 October 2002

**The final risk mitigation measures should be considered at MSs level.**

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

Not relevant.

### 9.10.2.3 Higher-tier risk assessment

Not relevant.

### 9.10.2.4 Risk mitigation measures

No risk mitigation needed.

### 9.10.3 Overall conclusions

From the information presented above it is concluded that the use of the product will not produce unacceptable effects on terrestrial non-target plants growing near treated fields and that no mitigation measures are necessary for the intended use rate.

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

No further information is available or considered to be necessary.

## 9.12 Monitoring data (KCP 10.8)

No further information is available or considered to be necessary.

## 9.13 Classification and Labelling

**Classification in accordance with Regulation (EC) N° 1272/2008 on classification, labelling and packaging of substances and mixtures, as amended**

| | |
|---|---|
| Hazard class(es), categories: | Acute aquatic toxicity: category 1<br>Chronic aquatic toxicity: category 1 |

| | |
|---|---|
| Hazard pictograms: |  GHS09 |
| Signal word: | Warning |
| Hazard statement(s): | H400 Very toxic to aquatic life<br>H410 Very toxic to aquatic life with long lasting effects |
| Precautionary statement(s): | P501 Dispose of contents/container in accordance with local regulation. |
| Additional labelling phrases: | [EUH401] To avoid risks to man and the environment, comply with the instructions for use. |

# Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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

**List of data submitted by the applicant and relied on**

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Owner |
|---|---|---|---|---|---|
| KCP 10.1.1 / 01<br>... also filed:<br>KCP 10.1.2 / 01<br>KCP 10.2 / 01 | xxx. | 2017 | Technical stand-alone combined toxicity assessment for the Central zone<br>Report No.: M-571377-02-1<br>xxx<br>GLP/GEP: n.a.<br>unpublished | No | Bayer |
| KCP 10.1.1.2 / 01 | xxx. | 2014 | Dissipation of triadimenol and fluopyram on barley seeds in Germany<br>Report No.: M-499850-01-1<br>xxx<br>GLP/GEP: Yes<br>unpublished | Yes | Bayer |
| KCP 10.1.1.2 / 02 | Rossbach, A. | 2017 | 1st revised final report amendment - Dissipation of triadimenol, prothioconazole and fluopyram on wheat seeds and seedlings in Germany<br>Report No.: B13017-1, Edition Number: M-486407-03-1<br>tier3 solutions GmbH, Leverkusen, Germany<br>**... amended: 2017-05-24**<br>GLP/GEP: Yes<br>unpublished | No | Bayer |

| **Data point** | **Author(s)** | **Year** | **Title**<br>**Company Report No.**<br>**Source (where different from company)**<br>**GLP or GEP status**<br>**Published or not** | **Vertebrate study Y/N** | **Owner** |
|---|---|---|---|---|---|
| KCP 10.1.1.2 / 03 | xxx | 2013 | Residue decline of fluopyram on arthropods after spray application in vines in Germany<br>Report No.: M-453376-01-1<br>xxx<br>GLP/GEP: Yes<br>unpublished | Yes | Bayer |
| KCP 10.1.1.2 / 04 | Kley, C.;<br>Zerbe, P. | 2016 | Kinetic evaluation of fluopyram residues in foliage dwellers and flying insects in vines - Fluopyram (AE C656948)<br>Report No.: EnSa-15-0934, Edition Number: M-544286-01-1<br>Bayer CropScience AG, Environmental Science, Monheim, Germany<br>GLP/GEP: No<br>unpublished | No | Bayer |
| KCP 10.1.1.2 / 05 | Rossbach, A.;<br>Lelle, M. | 2015 | Residue decline of fluopyram and prothioconazole on arthropods after spray application on oilseed rape fields in Western Germany<br>Report No.: P13067, Edition Number: M-544190-01-1<br>tier3 solutions GmbH, Leverkusen, Germany<br>GLP/GEP: Yes<br>unpublished | No | Bayer |
| KCP 10.1.1.2 / 06 | Kley, C.;<br>Ellerich, C. | 2016 | Kinetic evaluation of fluopyram residues in foliage dwellers and flying insects in oilseed rape<br>Report No.: EnSa-16-0035, Edition Number: M-545077-01-1<br>Bayer CropScience AG, Monheim, Germany<br>GLP/GEP: No<br>unpublished | No | Bayer |
| KCP 10.1.1.2 / 07 | Rossbach, A. | 2018 | Residue decline of fluopyram and tebuconazole on arthropods after spray applications in pome fruit orchards in Germany<br>Report No.: EBGM0105, Edition Number: M-644049-01-1<br>tier3 solutions GmbH, Leverkusen, Germany<br>GLP/GEP: Yes<br>unpublished | No | Bayer |

| Data point | Author(s) | Year | **Title**<br>**Company Report No.**<br>**Source (where different from company)**<br>**GLP or GEP status**<br>**Published or not** | Vertebrate study Y/N | Owner |
|---|---|---|---|---|---|
| KCP 10.1.1.2 / 08 | Kley, C.; Ellerich, C. | 2018 | Fluopyram (FLU) - Kinetic evaluation of green plant residues in cereals<br>Report No.: EnSa-17-0484, Edition Number: M-617837-01-1<br>Bayer AG, Crop Science Division, Monheim, Germany<br>GLP/GEP: No<br>unpublished | No | Bayer |
| KCP 10.1.1.2 / 09 | xxx | 2007 | Bird species in lettuce fields in Brittany (northern France): field data for the determination of focal species<br>Report No.: RA05-225/3, Edition Number: M-291775-01-1<br>xxx<br>GLP/GEP: No<br>unpublished | Yes | Syngenta |
| KCP 10.1.1.2 / 10 | xxx | 2007 | Letter of access for generic behavioural ecology data - Study report Syngenta limited document N/1087 - Grouping: Vegetables, post emergence (foliar stages)<br>Report No.: M-347167-01-1<br>xxx<br>GLP/GEP: n.a.<br>unpublished | Yes | Bayer |
| KCP 10.1.1.2 / 11 | xxx | 2016 | Bird species in leafy vegetables in central Europe - Field data for the determination of focal species<br>Report No.: 281, Edition Number: M-572583-01-1<br>xxx<br>GLP/GEP: Yes<br>unpublished | Yes | Bayer |
| KCP 10.1.1.2 / 12 | xxx | 2019 | GLP compliant field study to record PT values of linnet and serin for leafy vegetable in Central Europe (Germany)<br>Report No.: R1740067, Edition Number: M-655399-01-1<br>xxx<br>GLP/GEP: Yes<br>unpublished | Yes | Bayer |

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Owner |
|---|---|---|---|---|---|
| KCP 10.1.1.2 / 13 | xxx | 2013 | Focal species of birds in european crops for higher tier pesticide risk assessment<br>xxx<br>Volume: 9999<br>Pages: 1-13<br>Year: 2013<br>Report No.: M-497434-02-1<br>GLP/GEP: n.a.<br>published | Yes | published |
| KCP 10.1.1.2 / 14 | xx | 2008 | Generic monitoring of birds in vegetable fields in Great Britain<br>Report No.: R07-034, Edition Number: M-302416-01-1<br>xxx<br>GLP/GEP: Yes<br>unpublished | Yes | Syngenta |
| KCP 10.1.1.2 / 15 | xxx | 2008 | Letter of Access for generic behavioural ecology data: Study report Syngenta Limited document NA_10088; Grouping: vegetables, post emergence (foliar stages): Generic monitoring of birds in vegetable fields in Great Britain<br>Report No.: M-311248-01-1<br>xxx<br>GLP/GEP: n.a.<br>unpublished | Yes | Bayer |
| KCP 10.1.1.2 / 16 | Hahne, J.; Schabacker, J.; Foudoulakis, M.; Ludwigs, J. D.; Murfitt, R.; Ristau, K. | 2019 | New proposed Residues on Fruits (RUD's) for frugivore scenarios in EFSA bird and mammal risk assessment<br>Journal: Poster<br>Pages: 1<br>Year: 2019<br>Report No.: M-665829-01-1<br>GLP/GEP: n.a.<br>published | No | published |

| Data point | Author(s) | Year | **Title**<br>**Company Report No.**<br>**Source (where different from company)**<br>**GLP or GEP status**<br>**Published or not** | Vertebrate study Y/N | Owner |
|---|---|---|---|---|---|
| KCP 10.1.1.2 / 17<br>... also filed:<br>KCP 10.1.2.2 / 03 | Reinken, G.; Alt, F. | 2015 | Kinetic evaluation of trifloxystrobin residues in lettuce to derive a foliar DT50<br>Report No.: EnSa-15-0361, Edition Number: M-519770-01-1<br>Bayer CropScience AG, Monheim, Germany<br>GLP/GEP: No<br>unpublished | No | Bayer |
| KCP 10.1.1.2 / 18 | xxx | 2006 | Feeding ecology of the relevant insectivorous bird species in strawberry fields in Germany<br>Report No.: RC06-054, Edition Number: M-342897-01-1<br>xxx<br>GLP/GEP: Yes<br>unpublished | Yes | Irvita Plant Protection |
| KCP 10.1.1.2 / 19 | xxx | 2009 | Letter of access for generic behavioural ecology data - Study report R-20183 - Grouping: strawberry (foliar stages) - Author, year: Moosmayer P, 2006<br>Report No.: M-347237-01-1<br>xxx<br>GLP/GEP: n.a.<br>unpublished | Yes | Bayer |
| KCP 10.1.1.2 / 20 | xxx | 2010 | Consolidation of bird and mammal PT data for use in risk assessment<br>Report No.: M-429545-01-1<br>xxx<br>GLP/GEP: n.a.<br>unpublished | Yes | Bayer |
| KCP 10.1.2 / 01<br>... also filed:<br>KCP 10.1.1 / 01<br>KCP 10.2 / 01 | xxx | 2017 | Technical stand-alone combined toxicity assessment for the Central zone<br>Report No.: M-571377-02-1<br>xxx<br>GLP/GEP: n.a.<br>unpublished | No | Bayer |

| Data point | Author(s) | Year | **Title**<br>**Company Report No.**<br>**Source (where different from company)**<br>**GLP or GEP status**<br>**Published or not** | Vertebrate study Y/N | Owner |
|---|---|---|---|---|---|
| KCP 10.1.2.2 / 01 | Reinken, G.; Alt, F. | 2015 | Kinetic evaluation of trifloxystrobin residues in cereals to derive a foliar DT50<br>Report No.: EnSa-15-0374, Edition Number: M-520275-01-1<br>Bayer CropScience AG, Monheim, Germany<br>GLP/GEP: No<br>unpublished | No | Bayer |
| KCP 10.1.2.2 / 02 | Reinken, G.; Kallweit, W. | 2019 | Trifloxystrobin (TFS) - Kinetic evaluation of residue dissipation after application on wheat<br>Report No.: EnSa-19-0088, Edition Number: M-659518-01-1<br>Bayer AG, Crop Science Division, Monheim, Germany<br>GLP/GEP: No<br>unpublished | No | Bayer |
| KCP 10.1.2.2 / 03<br>... also filed:<br>KCP 10.1.1.2 / 17 | Reinken, G.; Alt, F. | 2015 | Kinetic evaluation of trifloxystrobin residues in lettuce to derive a foliar DT50<br>Report No.: EnSa-15-0361, Edition Number: M-519770-01-1<br>Bayer CropScience AG, Monheim, Germany<br>GLP/GEP: No<br>unpublished | No | Bayer |
| KCP 10.1.2.2 / 04 | xxx | 2013 | Voles in fields with leafy vegetables<br>Report No.: BAR/FS065, Edition Number: M-449690-01-1<br>xxx<br>GLP/GEP: Yes<br>unpublished | Yes | Bayer |
| KCP 10.1.2.2 / 05 | xxx | 2016 | GLP-compliant field study to assess the presence and abundance of common voles in strawberry fields in central Europe<br>Report No.: R1540015, Edition Number: M-570937-01-1<br>xxx<br>GLP/GEP: Yes<br>unpublished | Yes | Bayer |

| **Data point** | **Author(s)** | **Year** | **Title**<br>**Company Report No.**<br>**Source (where different from company)**<br>**GLP or GEP status**<br>**Published or not** | **Vertebrate study Y/N** | **Owner** |
|---|---|---|---|---|---|
| KCP 10.1.2.2 / 06 | xxx | 2010 | Nutritional ecology of Microtus arvalis (Pallas, 1779) in sown wild flower fields and quasi-natural habitats<br>xxx<br>Volume: 117<br>Issue: 4<br>Pages: 811-828<br>Year: 2010<br>Report No.: M-440511-01-1<br>GLP/GEP: n.a.<br>published | Yes | published |
| KCP 10.1.2.2 / 07 | xxx | 1999 | Nahrungspraeferenzen der Feldmaus Microtus arvalis in der Agrarlandschaft unter Beruecksichtigung der Pflanzeninhaltsstoffe<br>xxx<br>Volume: 64<br>Pages: 154;168<br>Year: 1999<br>Report No.: C040328, Edition Number: M-228713-01-1<br>GLP/GEP: n.a.<br>published | Yes | published |
| KCP 10.1.2.2 / 08 | xxx | 1990 | Nutritional ecology of Microtus arvalis (Pallas, 1779) on permanent grassland<br>Journal: Zeitschrift fuer Saeugetierkunde<br>Volume: 55<br>Pages: 106-114<br>Year: 1990<br>Report No.: C044034, Edition Number: M-228620-01-2<br>GLP/GEP: n.a.<br>published | Yes | published |

| Data point | Author(s) | Year | **Title**<br>**Company Report No.**<br>**Source (where different from company)**<br>**GLP or GEP status**<br>**Published or not** | Vertebrate study Y/N | Owner |
|---|---|---|---|---|---|
| KCP 10.1.2.2 / 09 | xxx. | 2010 | Wild mammals on golf courses<br>Report No.: BAR/FS 053, Edition Number: M-362381-01-1<br>xxx<br>GLP/GEP: Yes<br>unpublished | Yes | Bayer |
| KCP 10.2 / 01<br>... also filed:<br>KCP 10.1.1 / 01<br>KCP 10.1.2 / 01 | xxx | 2017 | Technical stand-alone combined toxicity assessment for the Central zone<br>Report No.: M-571377-02-1<br>xxx<br>GLP/GEP: n.a.<br>unpublished | No | Bayer |
| KCP 10.2.1 / 01 | xxx. | 2018 | CGA 357276 and NOA 409480 - Estimation of acute toxicity to fish<br>Report No.: EnSa-18-0483, Edition Number: M-627447-01-1<br>xxx<br>GLP/GEP: No<br>unpublished | Yes | Bayer |
| KCP 10.2.1 / 02 | xxx | 2007 | Acute toxicity of fluopyram & trifloxystrobin SC 500 (250+250) G to fish (Oncorhynchus mykiss) under static conditions<br>Report No.: EBGMP030, Edition Number: M-294350-01-1<br>xxx<br>GLP/GEP: Yes<br>unpublished | Yes | Bayer |
| KCP 10.2.1 / 03<br>... also filed:<br>KCP 5.1.2.6 / 01 | xxx | 2018 | Fluopyram + trifloxystrobin SC 500 (250 + 250 g/L) - Acute toxicity to rainbow trout (Oncorhynchus mykiss) in a 96-hour semi-static test<br>Report No.: 134621230, Edition Number: M-636236-01-1<br>xxx<br>GLP/GEP: Yes<br>unpublished | Yes | Bayer |

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Owner |
|---|---|---|---|---|---|
| KCP 10.2.1 / 04 | Bruns, E. | 2007 | Acute toxicity of AE C656948 + trifloxystrobin SC 250 + 250 G to the waterflea Daphnia magna in a static laboratory test system<br>Report No.: EBGMP031, Edition Number: M-292365-01-1<br>Bayer CropScience AG, Monheim, Germany<br>GLP/GEP: Yes<br>unpublished | No | Bayer |
| KCP 10.2.1 / 05<br>... also filed:<br>KCP 5.1.2.6 / 02 | Börschig, C.;<br>Kobel, A. | 2018 | Fluopyram + trifloxystrobin SC 500 (250 + 250 g/L): Acute toxicity to Daphnia magna in a semi-static 48-hour immobilisation test<br>Report No.: 134621220, Edition Number: M-636231-01-1<br>IBACON GmbH, Rossdorf, Germany<br>GLP/GEP: Yes<br>unpublished | No | Bayer |
| KCP 10.2.1 / 06 | Dorgerloh, M. | 2007 | Pseudokirchneriella subcapitata growth inhibition test with fluopyram & trifloxystrobin SC 500 (250 + 250)G<br>Report No.: EBGMP032, Edition Number: M-292579-01-1<br>Bayer CropScience AG, Monheim, Germany<br>GLP/GEP: Yes<br>unpublished | No | Bayer |
| KCP 10.2.1 / 07<br>... also filed:<br>KCP 5.1.2.6 / 04 | Kuhl, K. | 2018 | Pseudokirchneriella subcapitata growth inhibition test with fluopyram + trifloxystrobin SC 500 G - Final report<br>Report No.: EBGM0016, Edition Number: M-615579-01-1<br>Bayer AG, Crop Science Division, Monheim, Germany<br>GLP/GEP: Yes<br>unpublished | No | Bayer |

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Owner |
|---|---|---|---|---|---|
| KCP 10.2.1 / 08<br>... also filed:<br>KCP 5.1.2.6 / 05 | Börschig, C.;<br>Kobel, A. | 2018 | Fluopyram + trifloxystrobin SC 500 (250 + 250 g/L): Toxicity to Pseudokirchneriella subcapitata in an algal growth inhibition test<br>Report No.: 134621210, Edition Number: M-636234-01-1<br>IBACON GmbH, Rossdorf, Germany<br>GLP/GEP: Yes<br>unpublished | No | Bayer |
| KCP 10.2.3 / 01 | Sinclair, C. J. | 2009 | Predicting the environmental fate and ecotoxicological and toxicological effects of pesticide transformation products<br>Publisher: unknown<br>Journal: unknown<br>Year: 2009<br>Report No.: M-551653-01-1<br>GLP/GEP: n.a.<br>published | No | published |
| KCP 10.2.3 / 02 | xxx | 2018 | CGA 357261 (BCS-AR14200) - Estimation of bioconcentration factors<br>Report No.: EnSa-18-0320, Edition Number: M-626557-01-1<br>xxx<br>GLP/GEP: No<br>unpublished | Yes | Bayer |
| KCP 10.2.3 / 03 | xxx | 2018 | CGA 357262 (BCS-BJ39463) - Estimation of bioconcentration factors<br>Report No.: EnSa-18-0321, Edition Number: M-626560-01-1<br>xxx<br>GLP/GEP: No<br>unpublished | Yes | Bayer |
| KCP 10.2.3 / 04 | xxx | 2018 | NOA 409480 (BCS-CR74871) - Estimation of bioconcentration factors<br>Report No.: EnSa-18-0322, Edition Number: M-626562-01-1<br>xxx<br>unpublished | Yes | Bayer |

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Owner |
|---|---|---|---|---|---|
| KCP 10.2.3 / 05 | xxx | 2018 | CGA 357276 ( BCS-AB39835) - Estimation of bioconcentration factors<br>Report No.: EnSa-18-0323, Edition Number: M-626564-01-1<br>xxx<br>GLP/GEP: No<br>unpublished | Yes | Bayer |
| KCP 10.2.3 / 06 | Ahlers, J.; Riedhammer, C.; Vogliano, M.; Ebert, R.; Kuehne, R.; Schueuermann, G. | 2006 | Acute to chronic ratios in aquatic toxicity - Variation across trophic levels and relationship with chemical structure<br>Journal: Environmental Toxicology and Chemistry<br>Year: 2006<br>Report No.: M-634467-01-1<br>GLP/GEP: No<br>published | No | published |
| KCP 10.2.3 / 07 | Kienzler, A.; Halder, M.; Worth, A. | 2016 | Waiving chronic fish tests: possible use of acute-to-chronic relationships and interspecies correlations<br>Publisher: Taylor & Francis<br>Journal: Toxicological and Environmental Chemistry<br>Volume: 99<br>Issue: 7-8<br>Pages: 1129-1151<br>Year: 2017<br>Report No.: M-632126-01-1<br>GLP/GEP: n.a.<br>published | No | published |
| KCP 10.2.3 / 08 | May, M.; Drost, W.; Germer, S.; Juffernholz, T.; Hahn, S. | 2016 | Evaluation of acute-to-chronic ratios of fish and Daphnia to predict acceptable no-effect levels<br>Journal: Environmental Sciences Europe<br>Year: 2016<br>Report No.: M-634484-01-1<br>GLP/GEP: No<br>published | No | published |

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Owner |
|---|---|---|---|---|---|
| KCP 10.3.1.1 / 01 | Schmitzer, S. | 2007 | Effects of AE C656948+trifloxystrobin SC 250+250 g/L (acute contact and oral) on honey bees (Apis mellifera L.) in the laboratory<br>Report No.: 34491035, Edition Number: M-288193-01-1<br>IBACON GmbH, Rossdorf, Germany<br>GLP/GEP: Yes<br>unpublished | No | Bayer |
| KCP 10.3.1.1 / 02 | Taenzler, V. | 2016 | Trifloxystrobin tech.: Effects (acute oral) on bumble bees (Bombus terrestris L.) in the laboratory<br>Report No.: 99931105, Edition Number: M-557014-01-1<br>IBACON GmbH, Rossdorf, Germany<br>GLP/GEP: Yes<br>unpublished | No | Bayer |
| KCP 10.3.1.1 / 03 | Kling, A. | 2014 | Trifloxystrobin (tech.): Acute contact toxicity to the bumble bee, Bombus terrestris L. under laboratory conditions<br>Report No.: S13-01491, Edition Number: M-480774-01-1<br>Eurofins Agroscience Services GmbH, Niefern-Oeschelbronn, Germany<br>GLP/GEP: Yes<br>unpublished | No | Bayer |
| KCP 10.3.1.3 / 01<br>... also filed:<br>KCP 5.1.2.6 / 27 | Kleebaum, K. | 2019 | Trifloxystrobin tech. - Repeated exposure to honey bee (Apis mellifera) larvae under laboratory conditions (in vitro)<br>Report No.: 18 48 BLC 0044, Edition Number: M-648913-01-1<br>BioChem agrar GmbH, Gerichshain, Germany<br>GLP/GEP: Yes<br>unpublished | No | Bayer |
| KCP 10.3.2.1 / 01 | Roehlig, U. | 2007 | Dose-response toxicity (LR50) of AE C656948 & trifloxystrobin SC 250 + 250 g/L to the parasitic wasp Aphidius rhopalosiphi (Destefani-Perez) under laboratory conditions<br>Report No.: 06 10 48 189, Edition Number: M-283599-01-1<br>BioChem agrar GmbH, Gerichshain, Germany<br>GLP/GEP: Yes<br>unpublished | No | Bayer |

| **Data point** | **Author(s)** | **Year** | **Title**<br>**Company Report No.**<br>**Source (where different from company)**<br>**GLP or GEP status**<br>**Published or not** | **Vertebrate study Y/N** | **Owner** |
|---|---|---|---|---|---|
| KCP 10.3.2.1 / 02 | Roehlig, U. | 2007 | Dose-response toxicity (LR50) of AE C656948 & trifloxystrobin SC 250 + 250 g/L to the predatory mite Typhlodromus pyri (Scheuten) under laboratory conditions<br>Report No.: 06 10 48 190, Edition Number: M-283552-01-1<br>BioChem agrar GmbH, Gerichshain, Germany<br>GLP/GEP: Yes<br>unpublished | No | Bayer |
| KCP 10.3.2.2 / 01 | Roehlig, U. | 2014 | Effects of fluopyram + trifloxystrobin SC 500 (250+250 g/L) on the green lacewing Chrysoperla carnea (STEPH.) under extended laboratory conditions<br>Report No.: 14 10 48 022 A, Edition Number: M-482453-01-1<br>BioChem agrar GmbH, Gerichshain, Germany<br>GLP/GEP: Yes<br>unpublished | No | Bayer |
| KCP 10.3.2.2 / 02 | Barth, M. | 2007 | Dose-response toxicity of AE C656948 & Trifloxystrobin SC 250 + 250 to the predatory bug Orius laevigatus (FIEBER) (Heteroptera: Anthocoridae) under extended laboratory conditions<br>Report No.: 07 10 48 049 A, Edition Number: M-297476-01-1<br>BioChem agrar GmbH, Gerichshain, Germany<br>GLP/GEP: Yes<br>unpublished | No | Bayer |
| KCP 10.3.2.2 / 03 | Barth, M. | 2008 | Toxicity of AE C656948 & Trifloxystrobin SC 250 + 250 to the predatory bug Orius laevigatus (FIEBER) (Heteroptera: Anthocoridae) under extended laboratory conditions using semi-field-aged residues on grape-vine<br>Report No.: 07 10 48 005 A, Edition Number: M-297471-01-1<br>BioChem agrar GmbH, Gerichshain, Germany<br>GLP/GEP: Yes<br>unpublished | No | Bayer |

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Owner |
|---|---|---|---|---|---|
| KCP 10.4.1.1 / 01 | Leicher, T. | 2007 | AE C656948 & trifloxystrobin SC 250 & 250 G: effects on survival, growth and reproduction on the earthworm Eisenia fetida tested in artificial soil with 5 percent peat<br>Report No.: LRT-RG-R-28/06, Edition Number: M-283637-01-1<br>Bayer CropScience AG, Monheim, Germany<br>GLP/GEP: Yes<br>unpublished | No | Bayer |
| KCP 10.4.2 / 01 | Larnaudie Lopez, M. I. | 2016 | Fluopyram + trifloxystrobin SC 500 (250+250) G: Influence on mortality and reproduction of the soil mite species Hypoaspis aculeifer tested in artificial soil<br>Report No.: E 428 4844-4, Edition Number: M-548820-01-1<br>Bayer CropScience AG, Monheim, Germany<br>GLP/GEP: Yes<br>unpublished | No | Bayer |
| KCP 10.4.2 / 02 | Friedrich, S. | 2017 | Fluopyram + trifloxystrobin SC 500 (250+250) G: Effects on mortality and reproduction of the collembolan species Folsomia candida tested in artificial soil<br>Report No.: 16 10 48 273 S, Edition Number: M-576685-01-1<br>BioChem agrar GmbH, Gerichshain, Germany<br>GLP/GEP: Yes<br>unpublished | No | Bayer |
| KCP 10.5 / 01 | Leicher, T. | 2007 | Fluopyram + trifloxystrobin SC 500 (250+250) G: Determination of effects on nitrogen transformation in soil<br>Report No.: LRT-N-91/07, Edition Number: M-295282-01-1<br>Bayer CropScience AG, Monheim, Germany<br>GLP/GEP: Yes<br>unpublished | No | Bayer |

| Data point | Author(s) | Year | **Title**<br>**Company Report No.**<br>**Source (where different from company)**<br>**GLP or GEP status**<br>**Published or not** | Vertebrate study Y/N | Owner |
|---|---|---|---|---|---|
| KCP 10.6.2 / 01 | Gosch, H.; Nguyen, D. H. | 2007 | Non-target terrestrial plants: an evaluation of the effects of AE C656948 + Trifloxystrobin SC 250 + 250 g/L in the vegetative vigour test (Tier 1)<br>Report No.: VV07/03, Edition Number: M-289527-01-1<br>Bayer CropScience AG, Frankfurt am Main, Germany<br>GLP/GEP: No<br>unpublished | No | Bayer |
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**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.

**Fluopyram**

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| | xxx | 2005 | Generic field monitoring of birds in potato cultivation in northern Germany<br>Bayer; Report No.: WFC/FS 019; Edition Number: M-090336-02-1; Date: 2004-09-29 **... amended: 2005-01-04;** GLP/GEP: Yes, unpublished | Yes | Bayer |
| | xxx | 2008 | Acute toxicity of AE C656948 (tech.) to fish (Oncorhynchus mykiss) under static conditions<br>Bayer; Report No.: EBGMP017; Edition Number: M-277770-02-1; Date: 2006-09-18 **... amended: 2008-02-01;** GLP/GEP: Yes, unpublished | Yes | Bayer |
| | xxx | 2008 | Acute toxicity of AE C656948 (tech.) to fish (Lepomis macrochirus) under static conditions<br>Bayer; Report No.: EBGMP052; Edition Number: M-278441-02-1; Date: 2006-10-09 **... amended: 2008-02-01;** GLP/GEP: Yes, unpublished | Yes | Bayer |
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| | Stuke, S.; Teubner, L. | 2013 | Modification M001 of the residue analytical method 01313 for the determination of trifloxystrobin (CGA279202) and its metabolites/isomers CGA357261, CGA357262, CGA331409, CGA321113, and CGA373466 in plant sample material at an LOQ of 0.01 mg/kg by HPLC-MS/MS<br>Bayer; Report No.: 01313/M001; Edition Number: M-448498-01-1; Date: 2013-03-04; GLP/GEP: Yes, unpublished | No | Bayer |

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| KCA 8.1.1.1 /01 | xxx | 1995 | CGA 279202 - Acute oral toxicity (LD50) to the bobwhite quail<br>xxx,<br>Report No.: CBG 703/942994,<br>Edition Number: M-032008-01-1<br>EPA MRID No.: 44496606<br>Date: 1995-03-06<br>GLP/GEP: yes, unpublished | Y | Bayer |
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| KCA 8.2.1 /02 | xxx | 1997 | Acute toxicity test of CGA 279202 WG 50 (A-9360 B) to rainbow trout (Oncorhynchus mykiss) in the dynamic system<br>xxx<br>Report No.: 963623,<br>Edition Number: M-030572-01-1<br>Date: 1997-02-05<br>GLP/GEP: yes, unpublished | Y | Bayer |
| KCA 8.2.1 /03 | xxx | 1997 | Acute toxicity of CGA 279202 to bluegill (Lepomis macrochirus) under flow-through conditions<br>xxx,<br>Report No.: 963541, | Y | Bayer |

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| KCA 8.2.1 /13 | xxx | 1997 | Acute toxicity of CGA 357261 (metabolite of CGA 279202) to rainbow trout (Oncorhynchus mykiss) in a 96 hour semi-static test<br>xxx,<br>Report No.: 649304,<br>Edition Number: M-032074-01-1<br>Date: 1997-07-01<br>GLP/GEP: yes, unpublished | Y | Bayer |
| KCA 8.2.1 /14 | xxx | 1996 | Acute toxicity of CGA 321113 (metabolite of CGA 279202) to rainbow trout (Oncorhynchus mykiss) in the flow-through system<br>xxx<br>Report No.: 953568,<br>Edition Number: M-032076-01-1<br>EPA MRID No.: 44527502<br>Date: 1996-02-09<br>GLP/GEP: yes, unpublished | Y | Bayer |
| KCA 8.2.1 /15 | xxx | 1997 | Acute toxicity of CGA 373466 (metabolite of CGA 279202) to rainbow trout (Oncorhynchus mykiss) in a 96 hour static test<br>xxx,<br>Report No.: 649361,<br>Edition Number: M-032078-01-1<br>Date: 1997-06-09<br>GLP/GEP: yes, unpublished | Y | Bayer |

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Owner |
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| KCA 8.2.1 /16 | xxx | 1997 | Acute toxicity of CGA 107170 (metabolite of CGA 279202) to rainbow trout (Oncorhynchus mykiss) in a 96 hour semi-static test<br>xxx,<br>Report No.: 649247,<br>Edition Number: M-032079-01-1<br>Date: 1997-06-02<br>GLP/GEP: yes, unpublished | Y | Bayer |
| KCA 8.2.1 /17 | xxx | 1998 | Acute toxicity of NOA 413161 (metabolite of CGA 279202) for rainbow trout<br>xxx<br>Report No.: G 528 04,<br>Edition Number: M-033964-01-1<br>Date: 1998-10-29<br>GLP/GEP: yes, unpublished | Y | Bayer |
| KCA 8.2.1 /21 | xxx | 1997 | Acute toxicity test of CGA 279202 EC 125 (A-9604 A) to rainbow trout (Oncorhynchus mykiss) in the flow-through system<br>xxx,<br>Report No.: 963512,<br>Edition Number: M-052374-01-1<br>Date: 1997-04-10<br>GLP/GEP: yes, unpublished | Y | Bayer |
| KCA 8.2.1 /22 | xxx | 2012 | Acute toxicity of BCSBJ39463 (tech) to fish (Oncorhynchus mykiss) under static conditions (limit test)<br>xxx,<br>Report No.: EBTFL017,<br>Edition Number: M-430569-01-1<br>Date: 2012-05-02<br>GLP/GEP: yes, unpublished | Y | Bayer |
| KCA 8.2.2 /01 | xxx | 1999 | Prolonged toxicity test of CGA321113 (Metabolite of CGA279202) to rainbow trout (Oncorhynchus mykiss) under flow-through conditions<br>xxx<br>Report No.: 983887,<br>Edition Number: M-070819-01-1<br>Date: 1999-08-02<br>GLP/GEP: yes, unpublished | Y | Bayer |

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Owner |
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| KCA 8.2.2.3 /01 | xxx | 1997 | [Phenyl(A)-U-14C]-CGA-279202 - Flow-through bioconcentration and metabolism study with bluegill sunfish (Lepomis macrochirus)<br>xxx,<br>Report No.: 96-8-6608,<br>Edition Number: M-032004-01-1<br>EPA MRID No.: 44496813<br>Date: 1997-09-29<br>GLP/GEP: yes, unpublished | Y | Bayer |
| KCA 8.2.4 /01 | Boeri, R. L.;<br>Magazu, J. P.;<br>Ward, T. J. | 1996 | Acute flow-through mollusc shell deposition test with CGA 279202<br>Wilbury Laboratories, Inc., Marblehead, MA, USA<br>Bayer CropScience,<br>Report No.: 674-CG,<br>Edition Number: M-032088-01-1<br>EPA MRID No.: 44496613<br>Date: 1996-12-20<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.2.4 /02 | Rufli, H. | 2000 | Acute toxicity test of CGA 279202 tech. to three invertebrate species Daphnia pulex Leydig, Thamnocephalus platyurus, and Brachionus calyciflorus in a static laboratory test under realistic environmental conditions<br>Novartis Crop Protection AG, Basel, Switzerland<br>Bayer CropScience,<br>Report No.: 993537,<br>Edition Number: M-052570-01-1<br>Date: 2000-01-11<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.2.4 /03 | Rufli, H. | 1999 | Acute toxicity test of CGA 279202 tech. to five invertebrate species from a natural pond assemblage in a static laboratory test under realistic environmental conditions<br>Novartis Crop Protection AG, Basel, Switzerland | N | Bayer |

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| KCA 8.2.4 /04 | Ward, T. J.;<br>Magazu, J. P.;<br>Boeri, R. L. | 1998 | Acute toxicity of CGA 279202 to the crayfish, Procambarus acutus acutus<br>Wilbury Laboratories, Inc., Marblehead, MA, USA<br>Bayer CropScience,<br>Report No.: 335-98,<br>Edition Number: M-052687-01-1<br>Date: 1998-06-17<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.2.4 /05 | Rufli, H. | 2000 | Acute toxicity of CGA 279202 tech. to the invertebrate species Gammarus sp. in a static laboratory test under realistic environmental conditions<br>Novartis Crop Protection AG, Basel, Switzerland<br>Bayer CropScience,<br>Report No.: 993545,<br>Edition Number: M-052583-01-1<br>Date: 2000-01-12<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.2.4 /06 | Chim, L. | 1999 | A-9626 B: 96-hour toxicity study to a marine shrimp Penaeus vannamei under static conditions<br>IFREMER, Centre Óceanogique du Pacifique, Thaiti, Franc. Polynesia<br>Bayer CropScience,<br>Report No.: 993500,<br>Edition Number: M-048951-01-1<br>Date: 1999-12-22<br>GLP/GEP: yes, unpublished | N | Bayer |

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| KCA 8.2.4.1 /01 | Boeri, R. L.; Magazu, J. P.; Ward, T. J. | 1997 | Acute toxicity of CGA 279202 to the daphnid, Daphnia magna<br>Wilbury Laboratories, Inc., Marblehead, MA, USA<br>Bayer CropScience,<br>Report No.: 1116-CG,<br>Edition Number: M-032084-01-1<br>EPA MRID No.: 44496611<br>Date: 1997-03-27<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.2.4.1 /02 | Neumann, C. | 1997 | Acute toxicity of CGA 279202 to the cladoceran Daphnia magna Straus under flow-through conditions<br>Novartis Crop Protection AG, Basel, Switzerland<br>Bayer CropScience,<br>Report No.: 963542,<br>Edition Number: M-032085-01-1<br>Date: 1997-09-22<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.2.4.1 /03 | Grade, R. | 1999 | Acute toxicity of CGA 279202 tech. to the cladoceran Daphnia magna Straus in the static system<br>Novartis Crop Protection AG, Basel, Switzerland<br>Bayer CropScience,<br>Report No.: 993543,<br>Edition Number: M-051128-01-1<br>Date: 1999-12-16<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.2.4.1 /04 | Memmert, U. | 1997 | Acute toxicity of CGA 357261 (metabolite of CGA 279202) to Daphnia magna in a 48 hour immobilization test<br>RCC Ltd., Itingen, Switzerland<br>Bayer CropScience,<br>Report No.: 649293,<br>Edition Number: M-032090-01-1<br>Date: 1997-06-23 | N | Bayer |

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| KCA 8.2.4.1 /05 | Neumann, C. | 1996 | Acute toxicity of CGA 321113 (metabolite of CGA 279202) to the cladoceran Daphnia magna Straus under static conditions<br>Novartis Crop Protection AG, Basel, Switzerland<br>Bayer CropScience,<br>Report No.: 953569,<br>Edition Number: M-032091-01-1<br>EPA MRID No.: 44527503<br>Date: 1996-05-14<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.2.4.1 /06 | Memmert, U. | 1997 | Acute toxicity of CGA 373466 (metabolite of CGA 279202) to Daphnia magna in a 48 hour immobilization test<br>RCC Ltd., Itingen, Switzerland<br>Bayer CropScience,<br>Report No.: 649350,<br>Edition Number: M-032092-01-1<br>Date: 1997-06-06<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.2.4.1 /07 | Memmert, U. | 1997 | Acute toxicity of CGA 107170 (metabolite of CGA 279202) to Daphnia magna in a 48 hour immobilization test<br>RCC Ltd., Itingen, Switzerland<br>Bayer CropScience,<br>Report No.: 649236,<br>Edition Number: M-032096-01-1<br>Date: 1997-05-27<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.2.4.1 /08 | Maetzler, P. | 1998 | Acute toxicity of NOA 413161 (metabolite of CGA 279202) to Daphnia magna<br>Novartis Crop Protection AG, Basel, Switzerland<br>Bayer CropScience,<br>Report No.: G 528 14,<br>Edition Number: M-033972-01-1<br>Date: 1998-10-28<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.2.4.1 /09 | Maetzler, P. | 1998 | Acute toxicity of NOA 413163 (metabolite of CGA 279202) to Daphnia magna<br>Novartis Crop Protection AG, Basel, Switzerland | N | Bayer |

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| KCA 8.2.4.1 /10 | Knauer, K. | 2000 | Acute toxicity of leachate from lysimeter (No. 5 and 6, Project 97GN01) treated with CGA 279202 to the cladoceran Daphnia magna Strauss in a static system<br>Novartis Crop Protection AG, Basel, Switzerland<br>Bayer CropScience,<br>Report No.: 993531,<br>Edition Number: M-051135-02-1<br>Date: 2000-01-25<br>GLP/GEP: no, unpublished | N | Bayer |
| KCA 8.2.4.1 /11 | Dorgerloh, M. | 2002 | Acute toxicity of CGA 279202-CGA 321113 (tech.) to water fleas (Daphnia magna)<br>Bayer AG, Leverkusen, Germany<br>Bayer CropScience,<br>Report No.: DOM 22061,<br>Edition Number: M-070759-01-1<br>Date: 2002-11-12<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.2.4.1 /12 | Dorgerloh, M. | 2002 | Acute toxicity of CGA 279202-NOA 414412 (tech.) to water fleas (Daphnia magna)<br>Bayer AG, Leverkusen, Germany<br>Bayer CropScience,<br>Report No.: DOM 22062,<br>Edition Number: M-070743-01-1<br>Date: 2002-11-12<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.2.4.1 /13 | Neumann, C. | 1997 | Acute toxicity of CGA 279202 WG 50 (A-9360 B) to the cladoceran Daphnia magna Straus under static conditions<br>Novartis Crop Protection AG, Basel, Switzerland<br>Bayer CropScience,<br>Report No.: 963624,<br>Edition Number: M-051484-01-1<br>Date: 1997-09-15<br>GLP/GEP: yes, unpublished | N | Bayer |

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| KCA 8.2.4.1 /15 | Rufli, H. | 1999 | Acute toxicity test of CGA 279202 50 WG (A-9360 B) to the cladoceran Daphnia magna Straus in a semi-static laboratory test under realistic conditions<br>Novartis Crop Protection AG, Basel, Switzerland<br>Bayer CropScience,<br>Report No.: 983865,<br>Edition Number: M-048117-01-1<br>Date: 1999-04-08<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.2.4.1 /16 | Riebschlaeger, T. | 2012 | Acute toxicity of BCS-BJ39463 (tech.) to the waterflea Daphnia magna in a static laboratory test system<br>Bayer CropScience,<br>Report No.: EBTFL019,<br>Edition Number: M-431690-01-1<br>Date: 2012-05-11<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.2.4.1 /17 | Riebschlaeger, T. | 2012 | Acute toxicity of BCS-AB39835 (tech.) to the waterflea Daphnia magna in a static laboratory test system<br>Bayer CropScience,<br>Report No.: EBTFX195,<br>Edition Number: M-433856-01-1<br>Date: 2012-06-15<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.2.4.1 /18 | Riebschlaeger, T. | 2012 | Acute toxicity of BCS-CR74871 (tech.) to the waterflea Daphnia magna in a static laboratory test system<br>Bayer CropScience,<br>Report No.: EBTFX201,<br>Edition Number: M-432300-01-1<br>Date: 2012-06-04<br>GLP/GEP: yes, unpublished | N | Bayer |

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| KCA 8.2.4.1 /20 | Morrison, S. A.;<br>Mcmurry, S. T.;<br>Smith, L. M.;<br>Belden, J. B. | 2013 | Acute toxicity of pyraclostrobin and trifloxystrobin to Hyalella azteca<br>Publisher:SETAC,<br>Journal:Environmental Toxicology and Chemistry,<br>Volume:32,<br>Issue:7,<br>Pages:1516-1525,<br>Year:2013,<br>Report No.: M-462365-01-1,<br>Edition Number: M-462365-01-1<br>Date: 2013-04-02<br>GLP/GEP: no, published | N | Bayer |
| KCA 8.2.4.1 /21<br>KCA 8.2.6.1 /15 | Ochoa-Acuna, H.; Bialkowski, W.; Yale, G.; Hahn, L. | 2009 | Toxicity of soybean rust fungicides to freshwater algae and Daphnia magna<br>Publisher:Springer Science+Business Media,<br>Journal:Ecotoxicology,<br>Volume:18,<br>Issue:4,<br>Pages:440-446,<br>Year:2009,<br>Report No.: M-459634-01-1,<br>Edition Number: M-459634-01-1<br>Date: 2009-01-12<br>GLP/GEP: no, published | N | Bayer |
| KCA 8.2.5.1 /01 | Boeri, R. L.;<br>Magazu, J. P.;<br>Ward, T. J. | 1996 | Chronic toxicity of CGA 279202 to the daphnid, Daphnia magna<br>Wilbury Laboratories, Inc., Marblehead, MA, USA<br>Bayer CropScience,<br>Report No.: 1117-CG,<br>Edition Number: M-032097-01-1<br>EPA MRID No.: 44496615 | N | Bayer |

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| KCA 8.2.5.3 /01<br>KCA 8.2.5.4 /01 | Grade, R. | 1998 | Toxicity test of CGA 279202 tech. on sediment-dwelling Chironomus riparius (syn. Chironomus thummi) under static conditions<br>Novartis Crop Protection AG, Basel, Switzerland<br>Bayer CropScience,<br>Report No.: 983812,<br>Edition Number: M-033988-01-1<br>Date: 1998-12-11<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.2.5.3 /02<br>KCA 8.2.5.4 /02 | Grade, R. | 1998 | Toxicity test of CGA 321113 (metabolite of CGA 279202) on sediment-dwelling Chironomus riparius (syn. Chironomus thummi) under static conditions<br>Novartis Crop Protection AG, Basel, Switzerland<br>Bayer CropScience,<br>Report No.: 983811,<br>Edition Number: M-033991-01-1<br>Date: 1998-12-14<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.2.6.1 /01 | Grade, R. | 1995 | Growth inhibition test of CGA 279202 tech. to green algae (Scenedesmus subspicatus) in a static system<br>Ciba-Geigy Limited, Basel, Switzerland<br>Bayer CropScience,<br>Report No.: 943533,<br>Edition Number: M-032098-01-1<br>Date: 1995-06-30<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.2.6.1 /04 | Grade, R. | 1996 | Growth inhibition test of CGA 321113 (metabolite of CGA 279202) to green algae (Selenastrum capricornutum) in a static system<br>Novartis Crop Protection AG, Basel, Switzerland<br>Bayer CropScience,<br>Report No.: 953570,<br>Edition Number: M-032651-01-1<br>EPA MRID No.: 44527504<br>Date: 1996-02-01<br>GLP/GEP: yes, unpublished | N | Bayer |

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| KCA 8.2.6.1 /08 | Maetzler, P. | 1998 | Toxicity of NOA 413163 (metabolite of CGA 279202) to green algae (growth inhibition test)<br>Novartis Crop Protection AG, Basel, Switzerland<br>Bayer CropScience,<br>Report No.: G 529 17,<br>Edition Number: M-033983-01-1<br>Date: 1998-10-28<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.2.6.1 /11 | Bruns, E. | 2012 | Pseudokirchneriella subcapitata growth inhibition test with BCS - BJ39463 limit test<br>Bayer CropScience,<br>Report No.: EBTFL018,<br>Edition Number: M-429959-01-1<br>Date: 2012-04-30<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.2.6.1 /12 | Bruns, E. | 2012 | Pseudokirchneriella subcapitata growth inhibition test with BCS-AB39835<br>Bayer CropScience,<br>Report No.: EBTFX196,<br>Edition Number: M-434282-01-1<br>Date: 2012-06-19<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.2.6.1 /13 | Hoffmann, K. | 2013 | Pseudokirchneriella subcapitata - Growth inhibition test with BCS-CR74871<br>Bayer CropScience,<br>Report No.: EBTFL032,<br>Edition Number: M-467271-01-1<br>Date: 2013-10-10<br>GLP/GEP: yes, unpublished | N | Bayer |
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| KCA 8.2.8 /18 | Junges, C. M.;<br>Peltzer, P. M.;<br>Lajmanovich, R. C.; Attademo, A. M.; Cabagna Zenklusen, M. C.; Basso, A. | 2012 | Toxicity of the fungicide trifloxystrobin on tadpoles and its effect on fish-tadpole interaction<br>Publisher:Elsevier Ltd.,<br>Journal:Chemosphere,<br>Volume:87,<br>Issue:11,<br>Pages:1348-1354,<br>Year:2012,<br>Report No.: M-459339-01-1,<br>Edition Number: M-459339-01-1<br>Date: 2012-05-03<br>GLP/GEP: no, published | N | Bayer |

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| KCA 8.3.1.1.1 /02<br>KCA 8.3.1.1.2 /02 | Schmitzer, S. | 1996 | Laboratory testing for toxicity (acute contact and oral LD50) of CGA 279202 125 EC (A-9604 A) to honey bees (Apis mellifera l.) (Hymenoptera, Apidae)<br>IBACON GmbH, Rossdorf, Germany<br>Bayer CropScience,<br>Report No.: 1550036,<br>Edition Number: M-052630-01-1<br>Date: 1996-10-10<br>GLP/GEP: yes, unpublished | N | Bayer |
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| KCA 8.3.2 /23 | Candolfi, M. P. | 1997 | CGA 279202 EC 125 (A-9604 A): Laboratory toxicity test with the rove beetle, Aleochara bilineata Gyllenhal (Coleoptera: Staphylinidae)<br>Springborn Laboratories AG, Horn, Switzerland<br>Bayer CropScience,<br>Report No.: 97-178-1008,<br>Edition Number: M-050424-01-1<br>Date: 1997-02-28<br>GLP/GEP: yes, unpublished | N | Bayer |
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| KCA 8.3.2.2 /04 | Reber, B. | 1997 | Acute toxicity of CGA 279202 EC 125 (A-9604 A) to the predaceous mite Typhlodromus pyri Scheuten<br>Novartis Crop Protection AG, Basle, Switzerland<br>Bayer CropScience,<br>Report No.: 972001,<br>Edition Number: M-052259-01-1<br>Date: 1997-10-09<br>GLP/GEP: yes, unpublished | N | Bayer |
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| Data point | Author(s) | Year | **Title**<br>**Company Report No.**<br>**Source (where different from company)**<br>**GLP or GEP status**<br>**Published or not** | Vertebrate study Y/N | Owner |
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| | | | Report No.: KRA-RG-R-111/11,<br>Edition Number: M-428262-02-1<br>Date: 2012-03-28<br>**...Amended: 2012-11-09**<br>GLP/GEP: yes, unpublished | | |
| KCA 8.4.1 /05 | Kratz, M. A. | 2013 | Trifloxystrobin-CGA 321113 (BCS-AL58660): Effects on survival, growth and reproduction of the earthworm Eisenia fetida tested in artificial soil<br>Bayer CropScience,<br>Report No.: kra/Rg-R-149/13,<br>Edition Number: M-464328-01-1<br>Date: 2013-09-03<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.4.1 /06 | Leicher, T. | 2011 | Trifloxystrobin - CGA373466: Effects on survival, growth and reproduction on the earthworm Eisenia fetida tested in artificial soil with 5% peat - LIMIT - Test<br>Bayer CropScience,<br>Report No.: LRT-RG-R-114/11,<br>Edition Number: M-414741-01-1<br>Date: 2011-09-28<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.4.1 /07 | Kratz; M. A. | 2013 | Trifloxystrobin-CGA 381318 (BCS-CU98569): Effects on survival, growth and reproduction of the earthworm Eisenia fetida tested in artificial soil<br>Bayer CropScience,<br>Report No.: kra/Rg-R-150/13,<br>Edition Number: M-466037-02-1<br>Date: 2013-09-20<br>**...Amended: 2013-11-15**<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.4.1 /08 | Leicher, T. | 2011 | Trifloxystrobin - NOA 413161: Effects on survival, growth and reproduction on the earthworm Eisenia fetida tested in artificial soil with 5% peat - limit test<br>Bayer CropScience,<br>Report No.: LRT-RG-R-116/11,<br>Edition Number: M-416856-01-1<br>Date: 2011-11-07<br>GLP/GEP: yes, unpublished | N | Bayer |

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Owner |
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| KCA 8.4.1 /09 | Moser, T.;<br>Scheffczyk, A. | 2012 | Trifloxystrobin-NOA413163 (BCS-AL58659): Reproduction toxicity to the earthworm Eisenia fetida in an artificial soil test<br>ECT Oekotoxikologie GmbH, Floersheim, Germany<br>Bayer CropScience,<br>Report No.: 12P35RR,<br>Edition Number: M-445494-01-1<br>Date: 2012-12-05<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.4.1 /10 | Kratz, M. A. | 2012 | Trifloxystrobin-CGA357276 (BCS-AB39835): Effects on survival, growth and reproduction on the earthworm Eisenia fetida tested in artificial soil<br>Bayer CropScience,<br>Report No.: KRA-RG-R-115/12,<br>Edition Number: M-437130-01-1<br>Date: 2012-08-22<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.4.1 /11 | Kratz, M. A. | 2012 | Trifloxystrobin-NOA409480 (BCS-CR74871): Effects on survival, growth and reproduction on the earthworm Eisenia fetida tested in artificial soil<br>Bayer CropScience,<br>Report No.: KRA-RG-R-106/11,<br>Edition Number: M-424075-01-1<br>Date: 2012-01-27<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.4.1 | xxx | 2017a | Statistical re-evaluation of the Eisenia fetida reproduction study with trifloxystrobin - CGA 357276 (Kratz, 2012; M-437130-01-1) using the probit analysis.<br>xxx<br>Report No.: M-584331-01-1<br>GLP : No | Y | Bayer |
| KCA 8.4.2.1 /01 | Moser, T.;<br>Scheffczyk, A. | 2002 | Acute and reproduction toxicity of CGA 279202 - CGA 321113 to the collembolan species Folsomia candida<br>ECT Oekotoxikologie GmbH, Floersheim, Germany<br>Bayer CropScience,<br>Report No.: P25CR,<br>Edition Number: M-030523-01-1<br>Date: 2002-01-10<br>GLP/GEP: yes, unpublished | N | Bayer |

| Data point | Author(s) | Year | **Title**<br>**Company Report No.**<br>**Source (where different from company)**<br>**GLP or GEP status**<br>**Published or not** | Vertebrate study Y/N | Owner |
|---|---|---|---|---|---|
| KCA 8.4.2.1 /02 | Moser, T.;<br>Scheffczyk, A. | 2002 | Acute and reproduction toxicity of CGA 279202 - NOA 413161 to the collembolan species Folsomia candida<br>ECT Oekotoxikologie GmbH, Floersheim, Germany<br>Bayer CropScience,<br>Report No.: P26CR,<br>Edition Number: M-090863-02-1<br>Date: 2002-01-10<br>**...Amended: 2002-01-17**<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.4.2.1 /03 | Frommholz, U. | 2011 | Trifloxystrobin WG 50 W: Influence on the reproduction of the collembolan species Folsomia candida tested in artificial soil<br>Bayer CropScience,<br>Report No.: FRM-COLL-121/11,<br>Edition Number: M-415346-01-1<br>Date: 2011-10-07<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.4.2.1 /04 | Frommholz, U. | 2012 | Trifloxystrobin-CGA 357261 (BCS-AR14200): Influence on the reproduction of the collembolan species Folsomia candida tested in artificial soil<br>Bayer CropScience,<br>Report No.: FRM-COLL-150/12,<br>Edition Number: M-443697-01-1<br>Date: 2012-12-18<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.4.2.1 /05 | Frommholz, U. | 2012 | Trifloxystrobin-CGA 373466 (BCA-AL58690):: Influence on the reproduction of the collembolan species Folsomia candida tested in artificial soil<br>Bayer CropScience,<br>Report No.: FRM-COLL-146/12,<br>Edition Number: M-440109-01-1<br>Date: 2012-08-27<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.4.2.1 /06 | Moser, T.;<br>Scheffczyk, A. | 2013 | Trifloxystrobin-NOA413163 (BCS-AL58659): Acute and reproduction toxicity to the collembolan species Folsomia candida in artificial soil<br>ECT Oekotoxikologie GmbH, Floersheim, Germany<br>Bayer CropScience,<br>Report No.: 12P49CR, | N | Bayer |

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study<br>Y/N | Owner |
|---|---|---|---|---|---|
| | | | Edition Number: M-444419-01-1<br>Date: 2013-01-09<br>GLP/GEP: yes, unpublished | | |
| KCA 8.4.2.1 /07 | Kratz, M. A. | 2012 | Trifloxystrobin WG 50 W: Influence on mortality and reproduction on the soil mite species Hypoaspis aculeifer tested in artificial soil<br>Bayer CropScience,<br>Report No.: KRA-HR-76/12,<br>Edition Number: M-443226-01-1<br>Date: 2012-12-07<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.4.2.1 /08 | Frommholz, U. | 2012 | Trifloxystrobin-CGA 357276 (BCS-AB39835): Influence on the reproduction of the collembolan species Folsomia candida tested in artificial soil<br>Bayer CropScience,<br>Report No.: FRM-Coll-145/12,<br>Edition Number: M-441251-01-1<br>Date: 2012-11-12<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.4.2.1 /09 | Kratz, M.A. | 2012 | Trifloxystrobin-CGA 373466 (BCS-AL58690): Influence on mortality and reproduction on the soil mite species Hypoaspis aculeifer tested in artificial soil<br>Bayer CropScience,<br>Report No.: KRA-HR-73/12,<br>Edition Number: M-440955-01-1<br>Date: 2012-10-31<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.4.2.1 /10 | Kratz, M. A. | 2012 | Trifloxystrobin-CGA 357276 (BCS-AB39835): Influence on mortality and reproduction on the soil mite species Hypoaspis aculeifer tested in artificial soil<br>Bayer CropScience,<br>Report No.: KRA-HR-74/12,<br>Edition Number: M-440367-01-1<br>Date: 2012-10-22<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.4.2.1 /11 | Kratz, M. A. | 2012 | Trifloxystrobin-CGA 321113 (BCS-AL58660): Influence on mortality and reproduction on the soil mite species Hypoaspis aculeifer tested in artificial soil | N | Bayer |

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Owner |
|---|---|---|---|---|---|
| | | | Bayer CropScience,<br>Report No.: KRA-HR-75/12,<br>Edition Number: M-443145-01-1<br>Date: 2012-12-05<br>GLP/GEP: yes, unpublished | | |
| KCA 8.4.2.1 /12 | Kratz, M. A. | 2012 | Trifloxystrobin-CGA 357261 (BCS-AR14200): Influence on mortality and reproduction on the soil mite species Hypoaspis aculeifer tested in artificial soil<br>Bayer CropScience,<br>Report No.: KRA-HR-80/12,<br>Edition Number: M-443311-01-1<br>Date: 2012-12-10<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.4.2.1 /13 | Kratz, M. A. | 2013 | Trifloxystrobin-NOA 413161 (BCS-AL58658): Influence on mortality and reproduction of the soil mite species Hypoaspis aculeifer tested in artificial soil<br>Bayer CropScience,<br>Report No.: kra-HR-91/13,<br>Edition Number: M-455220-01-1<br>Date: 2013-05-31<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.4.2.1 | xxx | 2017b | Statistical re-evaluation of the Folsomia candida reproduction study with CGA 321113 (Moser & Scheffczyk, 2002; M-030523-01-1) using the probit analysis<br>xxx<br>Report No.: M-584315-01-1<br>GLP : No | Y | Bayer |
| KCA 8.5 /01<br>KCA 8.7 /04 | Grade, R. | 1998 | The effect of CGA 279202 tech. on soil respiration and nitrification<br>Novartis Crop Protection AG, Basel, Switzerland<br>Bayer CropScience,<br>Report No.: 973591,<br>Edition Number: M-034686-01-1<br>Date: 1998-01-15<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.5 /02 | Anderson, J. P. E. | 2002 | Influence of the metabolite trifloxystrobin (CGA 279202)-CGA 373466 on the microbial mineralization of nitrogen in soils | N | Bayer |

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Owner |
|---|---|---|---|---|---|
| | | | Bayer AG, Leverkusen, Germany<br>Bayer CropScience,<br>Report No.: AJO/230902,<br>Edition Number: M-070537-01-1<br>Date: 2002-07-05<br>GLP/GEP: yes, unpublished | | |
| KCA 8.5 /03<br>KCA 8.7 /05 | Anderson, J. P. E. | 2001 | Influence of trifloxystrobin - CGA 321113 on growth of pure cultures of a soil fungus Mucor circinelloides (order Zygomycetes) on nutrient medium<br>Bayer AG, Leverkusen, Germany<br>Bayer CropScience,<br>Report No.: AJO/221901,<br>Edition Number: M-057437-01-1<br>Date: 2001-07-04<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.5 /04<br>KCA 8.7 /06 | Anderson, J. P. E. | 2001 | Influence of trifloxystrobin - CGA 321113 on growth of pure cultures of a soil fungus, Penicillium janthinellum (order Ascomycetes) on nutrient medium<br>Bayer AG, Leverkusen, Germany<br>Bayer CropScience,<br>Report No.: AJO/222001,<br>Edition Number: M-057439-01-1<br>Date: 2001-07-04<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.5 /05<br>KCA 8.7 /07 | Anderson, J. P. E. | 2001 | Influence of trifloxystrobin - CGA 321113 on growth of pure cultures of a soil fungus Cladorrhinum foecundissimum (order Deuteromycetes) on nutrient medium<br>Bayer AG, Leverkusen, Germany<br>Bayer CropScience,<br>Report No.: AJO/222101,<br>Edition Number: M-057448-01-1<br>Date: 2001-07-04<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.5 /06<br>KCA 8.7 /08 | Anderson, J. P. E. | 2001 | Influence of trifloxystrobin - CGA 321113 on growth of pure cultures of a soil fungus Suillus granulatus (order Basidiomycetes) on nutrient medium<br>Bayer AG, Leverkusen, Germany<br>Bayer CropScience, | N | Bayer |

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study<br>Y/N | Owner |
|---|---|---|---|---|---|
| | | | Report No.: AJO/222201,<br>Edition Number: M-057454-01-1<br>Date: 2001-07-04<br>GLP/GEP: yes, unpublished | | |
| KCA 8.5 /07<br>KCA 8.7 /09 | Anderson, J. P. E. | 2001 | Influence of trifloxystrobin - CGA 321113 on growth of pure cultures of a soil fungus, Phytophthora nicotianae (order Oomycetes) on nutrient medium<br>Bayer AG, Leverkusen, Germany<br>Bayer CropScience,<br>Report No.: AJO/222301,<br>Edition Number: M-057444-01-1<br>Date: 2001-07-04<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.5 /08<br>KCA 8.7 /10 | Anderson, J. P. E. | 2001 | Influence of trifloxystrobin-NOA 413161 on growth of pure cultures of a soil fungus, Mucor circinelloides (Order Zygomycetes), on nutrient medium<br>Bayer AG, Leverkusen, Germany<br>Bayer CropScience,<br>Report No.: AJO/222401,<br>Edition Number: M-068199-01-1<br>Date: 2001-08-15<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.5 /09<br>KCA 8.7 /11 | Anderson, J. P. E. | 2001 | Influence of trifloxystrobin-NOA 413161 on growth of pure cultures of a soil fungus, Cladorrhinum foecundissimum (order Deuteromycetes), on nutrient medium<br>Bayer AG, Leverkusen, Germany<br>Bayer CropScience,<br>Report No.: AJO/222601,<br>Edition Number: M-068211-01-1<br>Date: 2001-08-15<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.5 /10<br>KCA 8.7 /12 | Anderson, J. P. E. | 2001 | Influence of trifloxystrobin-NOA 413161 on growth of pure cultures of a soil fungus, Suillus granulatus (order Basidiomycetes), on nutrient medium<br>Bayer AG, Leverkusen, Germany<br>Bayer CropScience,<br>Report No.: AJO/222701,<br>Edition Number: M-068231-01-1 | N | Bayer |

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Owner |
|---|---|---|---|---|---|
| | | | Date: 2001-08-15<br>GLP/GEP: yes, unpublished | | |
| KCA 8.5 /11<br>KCA 8.7 /13 | Anderson, J. P. E. | 2001 | Influence of trifloxystrobin-NOA 413161 on growth of pure cultures of a soil fungus, Phytophthora nicotianae (order Oomycetes), on nutrient medium<br>Bayer AG, Leverkusen, Germany<br>Bayer CropScience,<br>Report No.: AJO/222801,<br>Edition Number: M-068223-01-1<br>Date: 2001-08-15<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.5 /12 | Anderson, J. P. E. | 2002 | Influence of the metabolite trifloxystrobin (CGA 279202)-CGA 373466 on glucose stimulated respiration in soils<br>Bayer AG, Leverkusen, Germany<br>Bayer CropScience,<br>Report No.: AJO/230802,<br>Edition Number: M-072462-01-1<br>Date: 2002-07-16<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.5 /13 | Anderson, J. P. E. | 2002 | Influence of the metabolite trifloxystrobin (CGA 279202)-NOA 413161 on the microbial mineralization of nitrogen in soils<br>Bayer AG, Leverkusen, Germany<br>Bayer CropScience,<br>Report No.: AJO/231102,<br>Edition Number: M-071668-01-1<br>Date: 2002-07-15<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.5 /14 | Anderson, J. P. E. | 2002 | Influence of the metabolite trifloxystrobin (CGA 279202)-NOA 413161 on glucose stimulated respiration in soils<br>Bayer AG, Leverkusen, Germany<br>Report No.: AJO/231002,<br>Edition Number: M-072472-01-1<br>Date: 2002-07-18<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.5 /15 | Schulz, L. | 2013 | Trifloxystrobin-CGA 357261- (BCS-AR14200): Effects on the activity of soil microflora (nitrogen transformation test) | N | Bayer |

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study<br>Y/N | Owner |
|---|---|---|---|---|---|
| | | | BioChem Agrar GmbH, Gerichshain, Germany<br>Bayer CropScience,<br>Report No.: 13 10 48 093 N,<br>Edition Number: M-464875-01-1<br>Date: 2013-09-11<br>GLP/GEP: yes, unpublished | | |
| KCA 8.5 /16 | Schulz, L. | 2013 | Trifloxystrobin-CGA 321113 (BCS-AL58660): Effects on the activity of soil microflora (nitrogen transformation test)<br>BioChem Agrar GmbH, Gerichshain, Germany<br>Bayer CropScience,<br>Report No.: 13 10 48 092 N,<br>Edition Number: M-464870-01-1<br>Date: 2013-08-12<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.6 /01<br>KCA 3.5 /02<br>KCA 8.6.2 /06 | Gsell, B. | 1998 | Crop tolerance of CGA 279202 formulated as EC 125 (A-9604 A) and WG 50 (A-9360 B) on field crops<br>Novartis Crop Protection Muenchwilen AG, Muenchwilen, Switzerland<br>Bayer CropScience,<br>Report No.: 98001,<br>Edition Number: M-047698-01-1<br>Date: 1998-01-08<br>GLP/GEP: no, unpublished | N | Bayer |
| KCA 8.6.2 /01 | Waelder, L. | 2000 | Herbicide profiling test to evaluate the phytotoxicity of CGA 279202 125EC (A-9604 A) to terrestrial non-target higher plants<br>Novartis Crop Protection AG, Stein, Switzerland<br>Bayer CropScience,<br>Report No.: 25,<br>Edition Number: M-048974-01-1<br>Date: 2000-02-28<br>GLP/GEP: no, unpublished | N | Bayer |
| KCA 8.6.2 /02 | Schwab, D. | 1997 | Evaluating the effects of CGA-279202 on the emergence and vegetative vigor of non-target terrestrial plants<br>ABC Laboratories, Inc., Columbia, MO, USA<br>Bayer CropScience,<br>Report No.: 43964,<br>Edition Number: M-034000-01-1 | N | Bayer |

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|---|---|---|---|---|---|
| | | | EPA MRID No.: 44496723<br>Date: 1997-10-21<br>GLP/GEP: yes, unpublished | | |
| KCA 8.6.2 /03 | Spatz, B. | 2001 | Effects of CGA 279202-CGA 321113 on terrestrial (non-target) plants: Seedling emergence and seedling growth test<br>IBACON GmbH, Rossdorf, Germany<br>Bayer CropScience,<br>Report No.: 11111086,<br>Edition Number: M-084157-02-1<br>Date: 2001-11-09<br>**...Amended: 2001-12-13**<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.6.2 /04 | Friedrich, S. | 2002 | CGA 279202-NOA 413161: Vegetative vigour test on terrestrial non-target plants of 6 families (2 monocotyledoneae, 4 dicotyledoneae)<br>BioChem agrar GmbH, Gerichshain, Germany<br>Bayer CropScience,<br>Report No.: 02 10 48 005,<br>Edition Number: M-067518-01-1<br>Date: 2002-06-06<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.6.2 /05<br>KCA 3.5 /03 | Nienstedt, K. M. | 2002 | CGA 279202-NOA 413161: Seedling emergence test with Avena sativa (oat), Allium cepa (common onion), Brassica napus (oilseed rape), Glycine max (soybean), Lactuca sativa (lettuce), and Beta vulgaris (sugar beet)<br>Spingborn Lab. AG, Horn, Switzerland<br>Bayer CropScience,<br>Report No.: 1022.022.600,<br>Edition Number: M-033895-01-1<br>Date: 2002-01-28<br>GLP/GEP: yes, unpublished | N | Bayer |
| KCA 8.6.2 /07 | Spatz, B.;<br>Moll, M. | 2002 | CGA279202-CGA321113: Effects on terrestrial (non-target) plants - vegetative vigour test<br>IBACON GmbH, Rossdorf, Germany<br>Bayer CropScience,<br>Report No.: 11112087,<br>Edition Number: M-070976-01-1<br>Date: 2002-07-10 | N | Bayer |

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study<br>Y/N | Owner |
|---|---|---|---|---|---|
| | | | GLP/GEP: yes, unpublished | | |
| KCA 8.7 /01<br>KCA 5.2.1 /01 | xxx | 1994 | Acute oral toxicity study of CGA-279202 technical in rats<br>xxx<br>xxx,<br>Report No.: HWI 40702444,<br>Edition Number: M-039034-01-1<br>EPA MRID No.: 44496622<br>Date: 1994-10-05<br>GLP/GEP: yes, unpublished | Y | Bayer |
| KCA 8.7 /02<br>KCA 5.3.2 /01 | xxx | 1995 | CGA 279202 tech. - 3-month oral toxicity study in rats (administration in food)<br>xxx,<br>Report No.: 933164,<br>Edition Number: M-040135-01-1<br>EPA MRID No.: 44496701<br>Date: 1995-01-19<br>GLP/GEP: yes, unpublished | Y | Bayer |
| KCA 8.7 /03<br>KCA 5.6.1 /01 | xxx | 1997 | CGA 279202 Technical - Rat dietary two-generation reproduction study<br>xxx,<br>Report No.: 943045,<br>Edition Number: M-039264-02-1<br>Date: 1997-10-20<br>**...Amended: 2001-01-29**<br>GLP/GEP: yes, unpublished | Y | Bayer |

The following tables are to be completed by MS

**List of data submitted by the applicant and not relied on**

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

**List of data relied on not submitted by the applicant but necessary for evaluation**

| **Data point** | **Author(s)** | **Year** | **Title**<br>**Company Report No.**<br>**Source (where different from company)**<br>**GLP or GEP status**<br>**Published or not** | **Vertebrate study**<br>**Y/N** | **Owner** |
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# 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: | Comment on study; acceptable or not; deficiencies, corrections, according to recent guidelines or not, used in evaluation or only as additional information |

| | |
|---|---|
| Reference: | **KCP 10.1.1/01** |
| Title: | Technical stand-alone combined toxicity assessment for the Central zone |
| Report: | xxx |
| Authority registration No: | |
| Guideline(s): | none |
| Deviations: | -- |
| GLP/GEP: | not applicable |
| Acceptability: | |
| Duplication<br>(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

**zRMS comments:**

The studies for non-renewed a.s.-Fluoropyram were not evaluated in the current dossier in the context of art.43 for risk assessment for TFS.

| | |
|---|---|
| Reference: | **KCP 10.1.1.2/01** |
| Title: | Dissipation of triadimenol and fluopyram on barley seeds in Germany |
| Report: | xxx |
| | |
| Guideline(s): | No official test guideline available at present type of study. The study was conducted under consideration of the EFSA Guidance Document on Risk Assessment for Birds & Mammals (EFSA 2009). |
| Deviations: | not specified |
| GLP/GEP: | yes |
| | |
| Duplication (if vertebrate study): | No |

**Objective:**

The purpose of the study was to quantify the amount of triadimenol and fluopyram residues after seed treatment with Baytan Trio (Fluopyram + Fluoxastrobin + Triadimenol FS 180) on spring barley under field conditions.

**Materials and methods:**

Study sites: The study was conducted from 24 April 2012 to 05 June 2012 on plain field stripes at 3 different locations distributed over Germany. An area of approximately 50-60 $m^2$ of fallow land was demarcated per study site.
Test item and application: Fluopyram + Fluoxastrobin + Triadimenol FS 180 was applied with nominal 200 mL product/100 kg seeds on spring barley.
Sampling: Treated seeds scattered on the soil surface were collected on DAT +1, +2, +3, + 5, +7, +10, +14, +21 and +28. On the day of sowing (DAT 0), seed samples were taken directly from the package.
Residue analysis: All samples were analysed for their content of fluopyram via HPLC-MS/MS. Residues are reported in terms of mg active substance/kg, LOQ value 0.01 mg/kg.
Calculations: The residue decline ($DT_{50}$) on barley seeds was determined with KinGUI 2.1 (assuming SFO kinetics).

**Results and discussions:**

| **Compound** | **SFO simulation** | **$DT_{50}$ (days) in seeds ($chi^2$-error (%))** | | |
|---|---|---|---|---|
| | | **West** | **South** | **East** |
| Fluopyram | Per location | n.d. | 1.66 (13.87) | 3.99 (18.36) |

n.d.: not determined due to heavy rainfall

**Conclusion:**

$DT_{50}$ values of 1.66 days (South Germany) and 3.99 days (East Germany) were measured in spring barley seeds.

| | |
|---|---|
| The study previously evaluated.Reference: | **KCP 10.1.1.2/02** |
| Title: | 1st revised final report amendment - Dissipation of triadimenol, prothioconazole and fluopyram on wheat seeds and seedlings in Germany |
| Report: | Rossbach, A.; 2017; B13017-1; M-486407-03-1 |
| | |
| Guideline(s): | For the present study type no official test guideline is available. The study was conducted under consideration of the recommendations in the current guidance document on risk assessment for birds & mammals (EFSA 2009) |
| Deviations: | none |
| GLP/GEP: | yes |
| | |
| Duplication (if vertebrate study): | |

**Objective:**

The purpose of the study was to quantify residue amounts after seed treatment with Baytan 3 (Fluopyram + Prothioconazole + Triadimenol FS 217.5) on spring wheat under field conditions.

**Materials and methods:**

Study sites: The study was conducted from 17 April 2013 to 05 June 2013 on plain field stripes (headland) at four different locations distributed over Germany. An area of approximately 150 $m^2$ of fallow land was demarcated per study site. Three plots, serving as replicates, were installed at each location.
Test item and application: Fluopyram + Prothioconazole + Triadimenol FS 217.5 (Baytan 3) was applied with nominal 200 mL product/100 kg seeds on spring wheat.
Sampling: Treated seeds scattered on the soil surface were collected on DAT +1, +2, +3, + 5, +7, +10, +15, +21 and +28. On the day of sowing (DAT 0), seed samples were taken directly from the package.
Residue analysis: All samples were analysed for their content of fluopyram via HPLC-MS/MS. Residues are reported in terms of mg active substance/kg, LOQ value 0.01 mg/kg.
Calculations: The residue decline ($DT_{50}$) on wheat seeds was determined with KinGUI 2.1 (assuming SFO kinetics).

**Results and discussions:**

| **Compound** | **SFO simulation** | **$DT_{50}$ (days) in seeds ($chi^2$-error (%))** | | | |
|---|---|---|---|---|---|
| | | **West** | **South** | **North** | **East** |
| Fluopyram | Per location | 5.78 (18.9) | 12.2 (2.2) | n.d. | 4.60 (8.5) |

n.d.: not determined due to heavy rainfall

**Conclusion:**

$DT_{50}$ values of 5.78 days (West Germany), 12.2 days (South Germany) and 4.60 days (East Germany) were measured in spring wheat seeds.

| | |
|---|---|
| Reference: | **KCP 10.1.1.2/03** |
| Title: | Residue decline of fluopyram on arthropods after spray application in vines in Germany |
| Report: | xxx |
| | |
| Guideline(s): | Regulation (EC) No 1107/2009, EFSA Guidance Document on Risk Assessment for Birds and Mammals (2009)<br>US EPA OCSPP Guideline No. 850.SUPP |
| Deviations: | not specified |
| GLP/GEP: | yes |
| | |
| Duplication (if vertebrate study): | No |

**Objective:**

The purpose of the study was to determine the residue decline of fluopyram in foliage dwelling and flying arthropods following application with the formulated product fluopyram SC 500 (containing 500 g a.s./L) at the application rate of 1 × 0.5 L product/ha in vineyards in Germany following the recommendations of the Guidance Document on Risk Assessment for Birds & Mammals on request form EFSA. EFSA Journal 2009; 7 (12):1438.

**Materials and methods:**

**Study site:** The study was conducted in vineyards in the vicinity of Neustadt an der Weinstrasse. Three vineyards were selected and in each vineyard on a plot with a size > 1 ha was established.

**Test item and application:** The tested item was fluopyram, a fungicide. Fluopyram was applied as SC 500 formulation on each plot at a nominal application rate 0.5 L product/ha, corresponding to 250 g a.s./ha with a spray volume of 400 L/ha according to Good Laboratory Practice and Good Agricultural Practice. The actual application rate was 0.49 – 0.51 L product/ha.

**Arthropod sampling:** Foliage dwelling arthropods were collected by inventory spraying and flying insects were collected with Malaise traps In order to collect foliage dwelling arthropods from the canopy of grapevines, whole plants within the vineyard were sprayed with a “knock down” insecticide (Aquapy®) at approximately 25 mL product in 1 L water with a motor driven knapsack sprayer from Stihl (SR 430) (non-GLP application). Malaise traps consisted of large, tent-like structures. Insects which flew into the tent wall were funnelled into a collecting vessel attached to the highest point. One trap per plot was placed between the rows. The trap was installed during the day and emptied after approximately 24 hours. Targeted biomass per sample was approximately 1 g. Sampling period was 21 days after the application. After identification and quantification of the main taxonomic groups, the samples were stored deep frozen until residue analysis.

**Residue analysis:** All samples were analysed for their content of fluopyram residues via HPLC-MS/MS. Residues are reported in terms of mg a.s./kg fresh weight. The Limit of quantification (LOQ) value was 0.01 mg/kg.

**Calculations and statistics:** The residue decline (DT50) of fluopyram in leaf dwelling arthropods and flying insects was determined to assess the time course of potential exposure of arthropods and in consequence of insectivorous birds. It was assumed that the residue decline followed a first-order kinetic.

**Results and discussions:**

The geometric mean $DT_{50}$ of fluopyram on foliage-dwelling arthropods was 2.83 days. The geometric mean $DT_{50}$ for fluopyram on flying insects was 2.50 days

**DT50 of fluopyram on foliage-dwelling arthropods in vines**

| SFO kinetics | $DT_{50}$ fluopyram [days] | | |
|---|---|---|---|
| | Plot 1 | Plot 2 | Plot 3 |
| Per replicate[A] | 2.43 (DAT 0) | 5.63 (DAT +1) | 1.66 (DAT +3) |
| Geomean (n=3) | 2.83 | | |

A: simulation performed starting with maximum value

**DT50 of fluopyram on flying arthropods in vines**

| SFO kinetics | $DT_{50}$ fluopyram [days] | | |
|---|---|---|---|
| | Plot 1 | Plot 2 | Plot 3 |
| Per replicate[A] | 5.55 (DAT 2) [B] | 1.27 (DAT 1) | 2.23 (DAT +2) |
| Geomean (n=3) | 2.50 | | |

A: simulation performed starting with maximum value
B: Simulation conducted excluding value on DAT +21

**Conclusion:**

The study provides realistic field data on the time course of residue decline of fluopyram in foliage-dwelling arthropods and flying insects. These data provide a reliable basis for use in higher tier risk assessments of insectivorous birds.

| | |
|---|---|
| Comments of zRMS: | Comment on study; acceptable or not; deficiencies, corrections, according to recent guidelines or not, used in evaluation or only as additional information |

| | |
|---|---|
| Reference: | **KCP 10.1.1.2/04** |
| Title: | Kinetic evaluation of fluopyram residues in foliage dwellers and flying insects in vines - Fluopyram (AE C656948) |
| Report: | Kley, C.; Zerbe, P.; 2016; EnSa-15-0934; M-544286-01-1 |
| | |
| Guideline(s): | not applicable |
| Deviations: | not applicable |
| GLP/GEP: | no |
| | |
| Duplication (if vertebrate study): | |

The purpose of this evaluation was the determination of the dissipation kinetics of residues of fluopyram on foliage-dwelling and flying arthropods after different periods of aging under field conditions in German vineyards. The residue results for foliage dwellers and flying insects treated with fluopyram were originally reported by Peters and Rossbach (2013). The model fit as well as the statistical evaluation of the results were carried out with the in-house developed software KinGUI, version 2.1. The selection of the most appropriate kinetic model was based on a detailed statistical analysis including visual assessment, $\chi 2$ statistics, randomness of residuals and t-test significance following the FOCUS guidance (2006, 2014). Finally, the most appropriate models and parameters for further use in ecotoxicological risk assessments for each trial are summarised in the following table (details can be found in the full report).

**Appropriate dissipation parameters of fluopyram in foliage-dwelling arthropods and flying insects, best approach for ecotoxicological purpose**

| | **Kinetic model**<br>SFO<br>FOMC<br>DFOP<br>HS | DT50<br>**DT50**<br>**DT50 fast**<br>DT50 fast | **DT90**<br>**DT50 slow**<br>DT50 slow | α / β<br>g<br>tb, in d | DT50 recalc. = DT90 / 3.32 | Residue at end < 10% |
|---|---|---|---|---|---|---|
| | | [d] | [d] | | [d] | |
| | | | **Foliage dwelling-arthropods** | | | |
| Plot 1 | DFOP | **1.107** | **17.38** | **0.75204** | 6.86 | No |
| Plot 2 | SFO | **5.567** | | | 5.567 | Yes |
| Plot 3 | FOMC | **1.402** | **7.86** | **1.7542 / 2.894** | 2.37 | Yes |
| | | | **Flying insects** | | | |
| Plot 1 | SFO | **5.551** | | | 5.551 | No |
| Plot 2 | FOMC | **1.018** | **7.849** | **1.1557 / 1.2393** | 2.36 | Yes |
| Plot 3 | SFO | **2.543** | | | 2.543 | Yes |

| Comments of zRMS: | Comment on study; acceptable or not; deficiencies, corrections, according to recent guidelines or not, used in evaluation or only as additional information |
|---|---|

| | |
|---|---|
| Reference: | **KCP 10.1.1.2/05** |
| Title: | Residue decline of fluopyram and prothioconazole on arthropods after spray application on oilseed rape fields in Western Germany |
| Report: | Rossbach, A.; Lelle, M.; 2015; P13067; M-544190-01-1 |
| | |
| Guideline(s): | Regulation (EC) No 1107/2009,<br>EFSA Guidance Document on Risk Assessment for Birds and Mammals (2009) |
| Deviations: | Yes, but acceptable (see Appendix 38) |
| GLP/GEP: | yes |
| | |
| Duplication (if vertebrate study): | |

**Objective:**

The purpose of the study was to determine the residue decline of fluopyram, prothioconazole and the metabolite JAU 6476-desthio in foliage dwelling and flying arthropods after application with the formulated product Propulse® (SE formulation containing 125 g fluopyram + 125 g prothioconazole per L) at the application rate of 1 x 1.0 L product/ha on oilseed rape fields in Western Germany following the recommendations of the Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA. EFSA Journal 2009; 7(12):1438.

This summary is limited to the results obtained with the analysis for fluopyram (according to the use of the study in the evaluation conducted here)

**Materials and methods:**

Study site: The study was conducted on winter oil seed rape fields in the vicinity of Zuelpich-

Nemmenich, North Rhine-Westphalia in Germany. Three oilseed rape fields were selected and in each field one replicate with a size of approximately 1 ha was established.

Test item and application: The test item Propulse® was applied on each replicate at a nominal application rate of 1.0 L product per ha, corresponding to 125 g fluopyram and 125 g prothioconazole per ha with a spray volume of 400 L/ha according to Good Laboratory Practice and Good Agricultural Practice. (The actual application rate ranged between 0.92 – 1.08 L product per ha).

Arthropod sampling: Foliage dwelling arthropods were collected by inventory spraying and flying insects were collected with Malaise traps. In order to collect foliage dwelling arthropods from plants, whole plants within the sample area were sprayed with a 'knock down' insecticide (AquaPy®) at approx. 30 mL product in 1 L water with a motor driven knapsack sprayer (NON-GLP application). Flying insects were collected with Malaise traps, a large, tent-like structure. Insects which flew into the tent wall were funneled into a collecting vessel attached to the highest point. Two traps per replicate were placed between the oil seed rape plants. The traps were installed during the day and emptied after approximately 24 h. Targeted biomass per sample was ≥ 1.5 g for both inventory spray and Malaise trap catches. Sampling period was 10 days after the application. After identification and quantification of the main taxonomic groups, the samples were stored deep frozen until residue analysis.

Residue analysis: All samples were analysed for their content of fluopyram, prothioconazole and JAU 6476-desthio via HPLC-MS/MS. Residues are reported in terms of mg active substance/kg fresh weight (mg a.s./kg fw). The Limit of quantification (LOQ) value was 0.01 mg/kg. Calculations and statistics: The $DT_{50}$ was determined to assess the time course of potential exposure of arthropods and in consequence of insectivorous birds and mammals. It was assumed that the residue decline followed a first-order kinetic.

**Results and discussions:**

**Residues of fluopyram in foliage dwelling and flying insects**

LOD = Limit of detection, 0.005 mg/kg f.w.; LOQ = Limit of Quantification, 0.010 mg/kg f.w.;

| DAT | Residues of fluopyram [mg a.s./kg f.w.] | | | | | |
|---|---|---|---|---|---|---|
| | Foliage-dwelling arthropods | | | | | Flying insects |
| | Replicate 1 | Replicate 2 | Replicate 3 | Mean | SD | Replicate 1-3 |
| -1 | < LOD | < LOD | < LOD | - | - | 0.03 * |
| 0 | 45.40 | 29.19 | 14.81 | 29.80 | 15.30 | - ** |
| +1 | 15.11 | 4.67 | 3.37 | 7.72 | 6.44 | 0.91 |
| +2 | 6.72 | 3.11 | 4.02 | 4.62 | 1.88 | 0..57 |
| +3 | 3.26 | 2.62 | 3.02 | 2.97 | 0.32 | 0.29 |
| +4 | 1.70 | 4.15 | - | 2.92 | 1.74 | 0.46 |
| +5 | 1.57 | 2.70 | 1.08 | 1.78 | 0.83 | 0.14 |
| +7 | 0.82 | 1.40 | 0.83 | 1.02 | 0.33 | 0.26 |
| +10 | 1.44 | 1.15 | 0.29 | 0.96 | 0.60 | 0.07 |

* Contamination of pre-application sample probably due to insects flying in from nearby fields treated with fluopyram-containing products; ** no sampling; SD: standard deviation

The originally reported geometric mean $DT_{50}$ of fluopyram on foliage-dwelling arthropods was 0.62 days (including DAT 0), and 2.4 days when starting with the residues on DAT +1. The originally reported $DT_{50}$ for fluopyram on flying insects was 2.1 day.

**$DT_{50}$ of compounds on foliage-dwelling arthropods in oilseed rape fields**

| Compound | SFO simulation | $DT_{50}$ [days] on foliage-dwellers | | |
|---|---|---|---|---|
| | | Replicate 1 | Replicate 2 | Replicate 3 |
| Fluopyram | per replicate | 0.68 | 0.44 | 0.79 |
| | geomean (n=3) | 0.62* | | |

* $DT_{50}$ fitting for fluopyram (when starting on DAT +1), resulted in DT50 values of 0.94, 4.98 and 2.96 days, with a geomean $DT_{50}$ of 2.4 days.

**$DT_{50}$ of compounds on flying insects in oilseed rape fields**

| Compound | $DT_{50}$ [days] on flying insects |
|---|---|
| Fluopyram | 2.1 |

**Conclusion:**

The study provides realistic field data on the time course of residue decline of fluopyram in foliage-dwelling arthropods and flying insects. These data provide a reliable basis for use in higher tier risk assessments of insectivorous birds.

| Comments of zRMS: | Comment on study; acceptable or not; deficiencies, corrections, according to recent guidelines or not, used in evaluation or only as additional information |
|---|---|

| | |
|---|---|
| Reference: | **KCP 10.1.1.2/06** |
| Title: | Kinetic evaluation of fluopyram residues in foliage dwellers and flying insects in oilseed rape |
| Report: | Kley, C.; Ellerich, C.; 2016; EnSa-16-0035; M-545077-01-1 |
| | |
| Guideline(s): | none |
| Deviations: | none |
| GLP/GEP: | no |
| | |
| Duplication (if vertebrate study): | |

The purpose of this evaluation was the determination of the dissipation kinetics of residues of fluopyram on foliage dwelling and flying arthropods after different periods of aging under field conditions in German oilseed rape fields.
The residue results for foliage dwellers and flying insects treated with fluopyram were originally reported by Rossbach and Lelle (2015).
The model fit as well as the statistical evaluation of the results were carried out with the in-house developed software KinGUI, version 2.1. The selection of the most appropriate kinetic model was based on a detailed statistical analysis including visual assessment, $\chi 2$ statistics, randomness of residuals, and t-test significance following the FOCUS guidance (2006, 2014).
Finally, the most appropriate models and parameters for further use in ecotoxicological risk assessments for each trial are summarised in the following table.

**Appropriate dissipation parameters of fluopyram in foliage dwelling arthropods and flying insects, in oilseed rape, best approach for ecotoxicological purpose**

| | Kinetic model:<br>SFO<br>FOMC<br>DFOP<br>HS | **DT50**<br>DT50<br>DT50 fast<br>**DT50 fast** | <br>DT90<br>DT50 slow<br>**DT50 slow** | <br>α / β<br>g<br>**tb, in d** | DT50 recalc.<br>= DT90 /3.32 |
|---|---|---|---|---|---|
| | | [d] | [d] | | [d] |
| **Foliage dwelling arthropods** | | | | | |
| Plot 1 | SFO | **0.685** | | | 0.685 |
| Plot 2 | HS | **0.378** | **5.876** | **1.0966** | 1.078 |
| Plot 3 | HS | **0.488** | **2.954** | **0.8957** | 1.594 |
| **Flying insects** | | | | | |
| Plot 1-3 | SFO | **2.13** | | | 2.13 |

| | |
|---|---|
| Comments of zRMS: | Comment on study; acceptable or not; deficiencies, corrections, according to recent guidelines or not, used in evaluation or only as additional information |

| | |
|---|---|
| Reference: | **KCP 10.1.1.2/07** |
| Title: | Residue decline of fluopyram and tebuconazole on arthropods after spray applications in pome fruit orchards in Germany |
| Report: | Rossbach, A.; 2018; EBGM0105; M-644049-01-1 |
| | |
| Guideline(s): | No official test guideline available for this type of study.<br>The study was conducted under consideration of the EFSA Guidance Document on Risk Assessment for Birds & Mammals (EFSA 2009).<br>Regulation (EC) No 1107/2009,<br>Directive 2003-01 (Canada/PMRA)<br>US EPA OCSPP Not Applicable |
| Deviations: | None |
| GLP/GEP: | yes |
| | |
| Duplication (if vertebrate study): | |

**Objective:**

The purpose of the study was to determine the residue decline of fluopyram and tebuconazole following two applications (application interval: minimum 7 days) of the formulated product LUNA® Experience (SC formulation, containing 200 g/L fluopyram and 200 g/L tebuconazole) at a rate of nominal 0.25 L product/ha/m crown height in pome fruit orchards in Germany, following the recommendations of the guidance document on risk assessment for birds & mammals on request from EFSA. EFSA Journal 2009; 7(12):1438.

**Materials and methods:**

Study site: The study was conducted in the vicinity of Leichlingen, Northrhine-Westphalia in western Germany. Three pome fruit orchards with sizes of 1.57, 1.76 and 0.78 ha were selected.
Test item and application: The test item Luna® Experience was applied in each orchard at a nominal application rate of 0.25 L product/ha/m crown height, corresponding to nominal 50 g fluopyram and 50 g tebuconazole per ha and m crown height with a spray volume of 500 L tap water according to Good Laboratory Practice and Good Agricultural Practice. Two applications with an interval of 7 days in two

orchards and 14 days in the third orchard were conducted. With the actual canopy height of 2.21 m, 2.36 m and 2.31 m for Replicate 1, 2 and 3 respectively, the nominal application rate was 110.5, 118 and 115.5 g a.s./ha.

Arthropod sampling: Ground dwelling arthropods were collected with pitfall traps, foliage dwelling arthropods by inventory spraying and flying insects with Malaise traps. Pitfall traps were placed within the apple rows, in the middle of two trees in an adequate, evenly distributed set-up. For inventory spraying, whole trees within the sample area were sprayed with a 'knock down' insecticide (Aquapy®) at approx. 20 mL product in 1 L water with a motor driven knapsack sprayer (non-GLP application). Two Malaise traps per orchard were placed between the tree rows. Targeted biomass per sample was ≥ 1.5 g for all sampling methods.
Sampling period was until 21 days after the second application (with exception of Inventory spray, replicate 3, last sampling shifted to 22 days). After identification and quantification of the main taxonomic groups, the samples were stored deep frozen until residue analysis.

Residue analysis: All samples were analysed for their content of fluopyram and tebuconazole via HPLC-MS/MS. Residues are reported in terms of mg active substance/kg fresh weight (mg a.s./kg fw). The Limit of quantification (LOQ) value was 0.01 mg/kg.

**Results and discussions:**

**Measured concentrations, RUDs and 21 d TWAs (moving time window)**

| **Fluopyram concentrations in foliage dwellers [mg/kg f.w.]** | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **measured concentrations (for 110.5, 118 and 115.5 g a.s./ha)** | | | | **RUD (re-calculated for 1 kg a.s./ha)** | | | |
| **DAFT/*DALT*** | **Replicate 1** | **Replicate 2** | **Replicate 3** | **mean** | **Replicate 1** | **Replicate 2** | **Replicate 3** | **mean** |
| -1* | < 0.01 | 0.17 | 0.055 | - | - | - | - | - |
| 0 | 1.27 | 1.58 | 4.79 | 2.55 | 11.49 | 13.39 | 41.47 | 22.12 |
| 1 | 1.76 | 1.94 | 1.85 | 1.85 | 15.93 | 16.44 | 16.02 | 16.13 |
| 2 | 2.02 | 2.19 | 1.64 | 1.95 | 18.28 | 18.56 | 14.20 | 17.01 |
| 4 | 1.16 | 1.15 | 0.58 | 0.96 | 10.50 | 9.75 | 5.02 | 8.42 |
| 6 | 1.38 | 0.88 | 0.91 | 1.06 | 12.49 | 7.46 | 7.88 | 9.28 |
| 14 | - | - | 0.13 | 0.13 | - | - | 1.13 | 1.13 |
| *0* | 3.05 | 9.40 | 3.18 | 5.21 | 27.60 | 79.66 | 27.53 | 44.93 |
| *1* | 2.84 | 2.64 | 1.61 | 2.36 | 25.70 | 22.37 | 13.94 | 20.67 |
| *3* | 2.09 | 2.65 | 1.17 | 1.97 | 18.91 | 22.46 | 10.13 | 17.17 |
| *5* | 0.76 | 2.64 | 0.96 | 1.45 | 6.88 | 22.37 | 8.31 | 12.52 |
| *7* | 0.94 | 0.80 | 0.81 | 0.85 | 8.51 | 6.78 | 7.01 | 7.43 |
| *10* | 0.84 | 0.35 | 0.30 | 0.50 | 7.60 | 2.97 | 2.60 | 4.39 |
| *14* | 0.41 | 0.21 | 0.29 | 0.30 | 3.71 | 1.78 | 2.51 | 2.67 |
| *17* | 0.29 | 0.32 | 0.28 | 0.30 | 2.62 | 2.71 | 2.42 | 2.59 |
| *21* | 0.23 | 0.12 | 0.077*** | 0.15 | 2.08 | 1.02 | 0.67 | 1.26 |
| $TWA_{21d}$ max** | 1.35 | 1.73 | 1.15 | 1.43 | 12.2 | 14.7 | 9.95 | 12.3 |

| **Fluopyram concentrations on ground dwellers [mg/kg f.w.]** | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **measured concentrations (for 110.5, 118 and 115.5 g a.s./ha)** | | | | **RUD (re-calculated for 1 kg a.s./ha)** | | | |
| **DAFT/DALT** | **Replicate 1** | **Replicate 2** | **Replicate 3** | **mean** | **Replicate 1** | **Replicate 2** | **Replicate 3** | **mean** |
| -1* | < 0.01 | < 0.01 | < 0.01 | - | - | - | - | - |
| 1 | 0.033 | 0.049 | 0.15 | 0.077 | 0.30 | 0.42 | 1.30 | 0.67 |
| 2 | 0.096 | 0.035 | 0.10 | 0.077 | 0.87 | 0.30 | 0.87 | 0.68 |
| 4 | 0.075 | 0.035 | 0.056 | 0.055 | 0.68 | 0.30 | 0.48 | 0.49 |
| 6 | 0.025 | 0.041 | 0.11 | 0.059 | 0.23 | 0.35 | 0.95 | 0.51 |
| 14 | - | - | 0.010 | 0.010 | - | - | 0.087 | 0.09 |
| *1* | 0.15 | 0.14 | 0.10 | 0.13 | 1.36 | 1.19 | 0.87 | 1.14 |
| *3* | 0.062 | 0.10 | 0.078 | 0.080 | 0.56 | 0.85 | 0.68 | 0.69 |
| *5* | 0.16 | 0.36 | 0.043 | 0.19 | 1.45 | 3.05 | 0.37 | 1.62 |
| *7* | 0.038 | 0.99 | 0.065 | 0.36 | 0.34 | 8.39 | 0.56 | 3.10 |
| *10* | 0.097 | 0.018 | 0.021 | 0.045 | 0.88 | 0.15 | 0.18 | 0.40 |
| *14* | 0.31 | 0.61 | 0.092 | 0.34 | 2.81 | 5.17 | 0.80 | 2.92 |
| *17* | 0.16 | 0.079 | 0.017 | 0.085 | 1.45 | 0.67 | 0.15 | 0.75 |
| *21* | 0.13 | 0.020 | 0.036 | 0.062 | 1.18 | 0.17 | 0.31 | 0.55 |
| $TWA_{21d}$ max** | 0.14 | 0.29 | 0.071 | 0.16 | 1.31 | 2.48 | 0.62 | 1.47 |

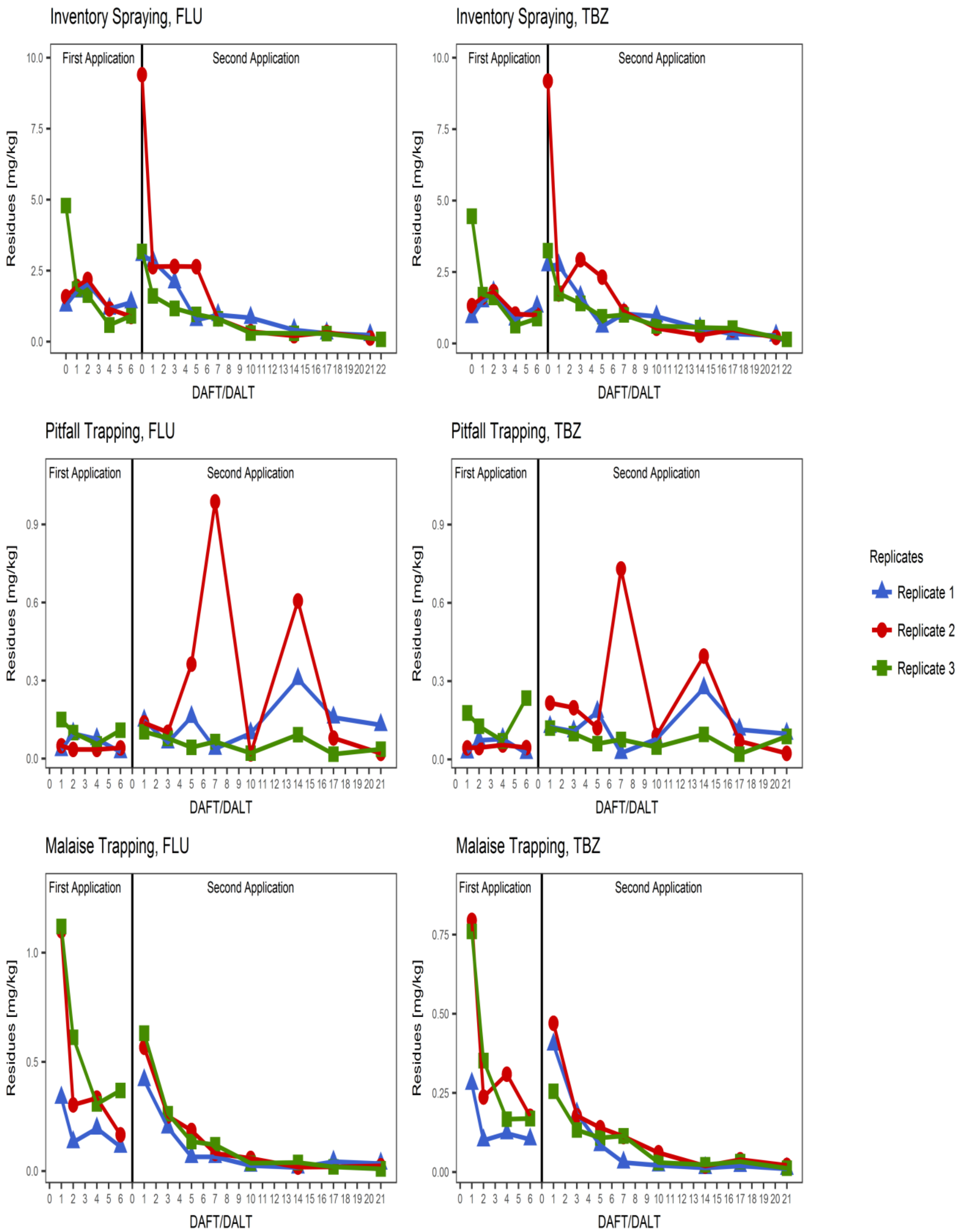
| **Fluopyram concentrations in arthropods in Malaise traps [mg/kg f.w.]** | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **measured concentrations (for 110.5, 118 and 115.5 g a.s./ha)** | | | | **RUD (re-calculated for 1 kg a.s./ha)** | | | |
| **DAFT/DALT** | **Replicate 1** | **Replicate 2** | **Replicate 3** | **mean** | **Replicate 1** | **Replicate 2** | **Replicate 3** | **mean** |
| -1* | < 0.01 | 0.013 | 0.052 | - | - | - | - | - |
| 1 | 0.34 | 1.1 | 1.12 | 0.85 | 3.08 | 9.32 | 9.70 | 7.37 |
| 2 | 0.13 | 0.3 | 0.61 | 0.35 | 1.18 | 2.54 | 5.28 | 3.00 |
| 4 | 0.20 | 0.33 | 0.31 | 0.28 | 1.81 | 2.80 | 2.68 | 2.43 |
| 6 | 0.11 | 0.17 | 0.37 | 0.22 | 1.00 | 1.44 | 3.20 | 1.88 |
| 14 | - | - | 0.017 | 0.017 | - | - | 0.15 | 0.15 |
| *1* | 0.42 | 0.57 | 0.63 | 0.54 | 3.80 | 4.83 | 5.45 | 4.70 |
| *3* | 0.20 | 0.25 | 0.26 | 0.24 | 1.81 | 2.12 | 2.25 | 2.06 |
| *5* | 0.065 | 0.19 | 0.13 | 0.13 | 0.59 | 1.61 | 1.13 | 1.11 |
| *7* | 0.065 | 0.081 | 0.12 | 0.089 | 0.59 | 0.69 | 1.04 | 0.77 |
| *10* | 0.025 | 0.058 | 0.036 | 0.040 | 0.23 | 0.49 | 0.31 | 0.34 |
| *14* | 0.016 | 0.018 | 0.039 | 0.024 | 0.14 | 0.15 | 0.34 | 0.21 |
| *17* | 0.043 | 0.019 | 0.019 | 0.027 | 0.39 | 0.16 | 0.16 | 0.24 |
| *21* | 0.034 | 0.024 | 0.01 | 0.023 | 0.31 | 0.20 | 0.09 | 0.20 |
| $TWA_{21d}$ max** | 0.12 | 0.22 | 0.26 | 0.20 | 1.10 | 1.88 | 2.27 | 1.75 |

DAFT=Day after first treatment, DALT=Day after last treatment, RUD=residue per unit dose, TWA=time weighted average calculated with interpolated data on DAFTs/DALTs without residue data
* before 1st application
** maximum TWA calculated for 21 days (TWA0(1)-21d) with a moving time window (without DAFT -1)
*** DALT 22 values shifted to DALT 21 for calculations
Values < 0.01 were set to 0.01 for calculations

DAFT 14 on replicate 3 was not considered for TWA calculations

**Residue decline of fluopyram and tebuconazole**

FLU = fluopyram (left column), TBZ = tebuconazole (right column); DAFT = Day After First application, DALT = Day After Last application (DAFT +14 on Replicate 3 is not depicted in the graphs)



**Dissipation parameter of fluopyram on arthropods in pome fruit orchards**

| **Fluopyram** | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Replicate** | **Kinetic model** | **$DT_{50}$ (days)** | **$DT_{90}$ (days)** | **$chi^2$ error** | **visual fit** | **α (FOMC)** | **β (FOMC)** | **t-test of k (SFO)** |
| **Foliage dwellers** | | | | | | | | |
| 1 | SFO | 4.1 | 13.7 | 15.45 | + | - | - | <0.001 |
| 2 | FOMC | 2.7 | 9.0 | 25.63 | o | 0.6052 | 0.2056 | - |
| 3 | FOMC | 5.3 | 17.8 | 13.37 | + | 0.7650 | 0.922 | - |
| **Malaise traps** | | | | | | | | |
| 1 | FOMC | 2.4 | 8.1 | 15.30 | + | 1.9251 | 3.5175 | - |
| 2 | SFO | 2.2 | 7.4 | 12.98 | + | - | - | <0.001 |
| 3 | SFO | 1.9 | 6.2 | 14.05 | + | - | - | <0.001 |
| **Ground dwellers** | | | | | | | | |
| Residue data were not suitable for $DT_{50}$ evaluation | | | | | | | | |

SFO=single first order
FOMC= first order multi-compartment (Gustafson and Holden); DT50 = DT90/3.32
k = rate constant
α, β = constant parameters for FOMC
SFO fit preferred where feasible
+: good fit
o: acceptable fit (small systematic deviation or large random scatter)

It should be noted that the constant parameters α and β for FOMC allow a more precise residue decline calculation than the back-calculation with FOMC-DT50 = DT90/3.32 mentioned in the EFSA GD for Birds and Mammals (2009).

**Arthropod composition**

In terms of biomass, groups of foliage dwellers were Saltatoria (25.8 %), Coleoptera (15.8 %), Heteroptera (11.6 %), Dermaptera (11.4 %) and Opiliones (11.3 %). Dominant ground dwelling arthropods were Coleoptera (78.4 %). In Malaise traps, mainly Dipteran flies (74.2 %) and Hymenopteran species (17.9 %) were found.

**Weather conditions**

Total rainfall during the sampling phase (01 Jun 2017 – 27 Jul 2017) was 181 mm (41.2 mm in June and 139.8 mm in July) with the highest precipitation towards the end after the sampling phase of the first two replicates (102.6 mm). The mean air temperature ranged between minimum 7.8°C and 18.2°C and maximum 16.1°C and 33.6°C (mean 14°C and 24°C).

**Conclusion:**

The study provides field realistic residue data for fluopyram in pome fruit orchards following 2 applications with 110.5, 118 and 115.5 g a.s./ha.
Fluopyram concentrations fluctuated due to interaction of different influencing factors like sample compositions over time, food web interactions and in addition mobility of the arthropod communities.
Mean 21 day time weighted average values (TWA 21d) with a moving time window and expressed as RUD (normalized for 1 kg/ha of active substance, for two applications with a 7 day interval) were 12.3 for foliage dwellers, 1.47 for ground dwellers and 1.75 mg a.s./kg for arthropods caught in Malaise traps for fluopyram.
SFO and FOMC DT50 values were calculated for residue data on foliage dwellers and arthropods caught in Malaise traps. An acceptable fit for the use of $DT_{50}$ values in risk assessments was determined by visual comparison of both kinetic models.
The FOMC $DT_{50}$s were back-calculated with $DT_{90}$/3.32 and represent a conservative approach for the

residue decline. A more precise representation of the residue decline curve is obtained when the kinetic parameters α and β are employed in a suitable calculation program. However, this was not done within the scope of this report.

Taking into account the complexity of the interactions studied, the fit of most of decline curves was considered visually acceptable. However, for ground dwellers peak concentrations at later time points did not allow kinetic evaluations.

$DT_{50}$s with acceptable fits for fluopyram ranged from 2.7 to 5.3 days for foliage dwellers and 1.8 to 2.7 days in Malaise traps.

| | |
|---|---|
| Comments of zRMS: | Comment on study; acceptable or not; deficiencies, corrections, according to recent guidelines or not, used in evaluation or only as additional information |

| | |
|---|---|
| Reference: | **KCP 10.1.1.2/08** |
| Title: | Fluopyram (FLU) - Kinetic evaluation of green plant residues in cereals |
| Report: | Kley, C.; Ellerich, C.; 2018; EnSa-17-0484; M-617837-01-1 |
| | |
| Guideline(s): | none |
| Deviations: | none |
| GLP/GEP: | no |
| | |
| Duplication (if vertebrate study): | |

Fluopyram has been analysed in several crop residue decline studies in the field, based on total residues, not only washable residues. Trials carried out on green material of cereals, spring barley and wheat, have been selected here (Glaubitz and Szeley, 2013, Glaubitz and Hennes 2016 a, b).
A spray application has been carried out in all trials. It took place in spring and early summer, March - June. Average temperatures ranged between 6.3 and 18.7°C.
The BBCH growth stages at application have been mainly 29 to 30, in a single case already starting from 24.

A kinetic modelling analysis of crop residue data of fluopyram was conducted using the software tool KinGUI 2.1, implementing the IRLS error model (Iteratively reweighted least square). The identification of the appropriate kinetic model, SFO, FOMC, DFOP or HS, is based primarily upon the recommendations given by FOCUS kinetics (FOCUS, 2006, 2014a), i.e. detailed statistical analysis including visual assessment, $\chi^2$ statistic, significance t-test and correlation analysis.

The kinetic evaluation can be appropriate for 2 different purposes:
1. In an ecotoxicological context, plant foliage residue trials are used to describe the dissipation or decline behaviour of fluopyram in potential food for birds and mammals. Dissipation curves can be used to estimate the exposure of herbivorous birds or mammals, mainly by calculating the area under the dissipation curve.
To allow for calculation of time weighted averaged residues or area under the curve, after single or multiple applications, it is most appropriate to use a full kinetic parameter set of SFO or biphasic models.

2. In general in a modelling context, for certain predictive leaching, soil or surface water models, a foliar half-life of a fluopyram on plant surfaces is needed which is valid in combination with a wash-off process. Such DT50 values can be estimated conservatively based on total residues, not only washable residues. There, the total green plant above soil surface should be analysed for its residues. However, the total residues in the plant should not be influenced or washed off by rain or irrigation during the evaluated period. Otherwise the decline might be caused by wash-off and not only by foliar dissipation.

Based on this, evaluations of foliar half-lives of fluopyram for total trial periods (Table 1), as well as evaluations without a potential precipitation impact have been carried out (Table 2). Resulting DT50 values and appropriate fitted dissipation curves are given in the following.

**Table 1: Dissipation parameters of fluopyram in green material of cereals, all residue data, for ecotoxicological purpose**

| | Kine-tic model | DT50 recalc | DT90 trigger | visual fit (link) | $\chi^2$ error | k1 (DFOP, HS) / α (FOMC) | k2 (SFO/ DFOP, HS) / β (FOMC) | $g_{fast}$ (DFOP) / $t_b$ (HS) | DT50 1 fast | DT50 2 slow |
|---|---|---|---|---|---|---|---|---|---|---|
| | | (d) | (d) | | (%) | (1/d / -) | (1/d / d) | (- / d) | (d) | (d) |
| **13-2950-01 Burscheid, DE** | SFO | **1.95** | 6.47 | + | 10.0 | | 0.3557 | | | |
| **13-2950-02 Langförden, DE** | HS | 2.03 | 6.74 | + | 1.9 | 1.5450 | 0.1332 | **0.995** | **0.45** | **5.20** |
| **13-2950-03 Saint-Amand, BE** | HS | 1.20 | 3.99 | + | 2.8 | 1.6415 | 0.2310 | **0.979** | **0.42** | **3.00** |
| **13-2950-04 Middenmeer, NL** | SFO | **1.25** | 4.14 | o | 23.0 | | 0.5566 | | | |
| **15-2952-01 Wieringerwerf, NL** | SFO | **3.37** | 11.2 | + | 8.6 | | 0.2060 | | | |
| **15-2952-02 Vieille Maison, BE** | SFO | **7.59** | 25.2 | o | 12.8 | | 0.0913 | | | |
| **15-2952-03 Andria, IT** | SFO | **2.86** | 9.51 | + | 12.1 | | 0.2422 | | | |
| **15-2952-04 Brenes, ES** | SFO | **4.19** | 13.9 | o | 11.3 | | 0.1655 | | | |
| **15-2953-01 Chambourg sur Indre, FR** | HS | **1.05** | 3.48 | + | **2.8** | **1.0098** | **0.2810** | **1.818** | **0.69** | **2.47** |
| **15-2953-02 Great Chishill, UK** | SFO | **4.23** | **14.1** | o | **18.1** | | **0.1637** | | | |
| **15-2953-03 C. da Reitana, IT** | SFO | **4.64** | **15.4** | o | **12.7** | | **0.1495** | | | |
| **Geomean M** | | **2.60** | | | | | | | | |

visual fit + good, o acceptable, - not acceptable
DT50 recalc = DT90 trigger / 3.32 (FOMC, DFOP, HS), for SFO no recalculation needed
DT90 trigger time for first 90 % of residues to dissipate
DT50 1 fast = ln(2)/k1
DT50 2 slow = ln(2)/k2 (DFOP, HS)
M DT50 recalc used for geomean

**Table 2: Dissipation parameters of fluopyram in green material of cereals, without precipitation impact, for ecotoxicological purpose and modelling purpose**

| | Kinetic model | DT50 recalc | DT90 trigger | visual fit (link) | $\chi^2$ error | k1 (DFOP, HS) / α (FOMC) | k2 (SFO/ DFOP, HS) / β (FOMC) | g fast (DFOP) / $t_b$ (HS) | DT50 1 fast | DT50 2 slow |
|---|---|---|---|---|---|---|---|---|---|---|
| | | (d) | (d) | | (%) | (1/d / -) | (1/d / d) | (- / d) | (d) | (d) |
| **13-2950-01 Burscheid, DE** | SFO | **2.28** | 7.57 | + | 10.1 | | 0.3044 | | | |
| **13-2950-02 Langförden, DE** | SFO | **5.20** | 17.3 | + | 3.2 | | 0.1332 | | | |
| **13-2950-03 Saint-Amand, BE** | SFO | **3.00** | 9.97 | + | 5.6 | | 0.2310 | | | |
| **13-2950-04 Middenmeer, NL** | SFO | **2.69** | 8.93 | +o | 8.8 | | 0.2580 | | | |
| **15-2952-01 Wieringerwerf, NL** | SFO | **3.44** | 11.4 | o+ | 8.1 | | 0.2016 | | | |
| **15-2952-02 Vieille Maison, BE** | SFO | **7.59** | 25.2 | o | 12.8 | | 0.0913 | | | |
| **15-2952-03 Andria, IT** | SFO | **3.47** | 11.52 | + | 7.1 | | 0.1998 | | | |
| **15-2952-04 Brenes, ES** | SFO | **4.52** | 15.0 | o | 9.7 | | 0.1534 | | | |
| **15-2953-01 Chambourg sur Indre, FR** | SFO | **2.47** | 8.20 | + | 9.3 | | 0.2810 | | | |
| **15-2953-02 Great Chishill, UK** | SFO | **9.12** | 30.3 | o | 9.6 | | 0.0760 | | | |
| **15-2953-03 C. da Reitana, IT** | SFO | **4.64** | 15.4 | o | 12.7 | | 0.1495 | | | |
| **Geomean [M]** | | **3.99** | | | | | | | | |

visual fit + good, o acceptable, - not acceptable
DT50 recalc = DT90 trigger / 3.32 (FOMC, DFOP, HS), for SFO no recalculation needed
DT90 trigger time for first 90 % of residues to dissipate
DT50 1 fast = ln(2)/k1
DT50 2 slow = ln(2)/k2 (DFOP, HS)
[M] DT50 recalc used for geomean

**Figure 2:** **Dissipation of fluopyram in cereals in Burscheid, 13-2950-01, all residue data (in mg/kg)**

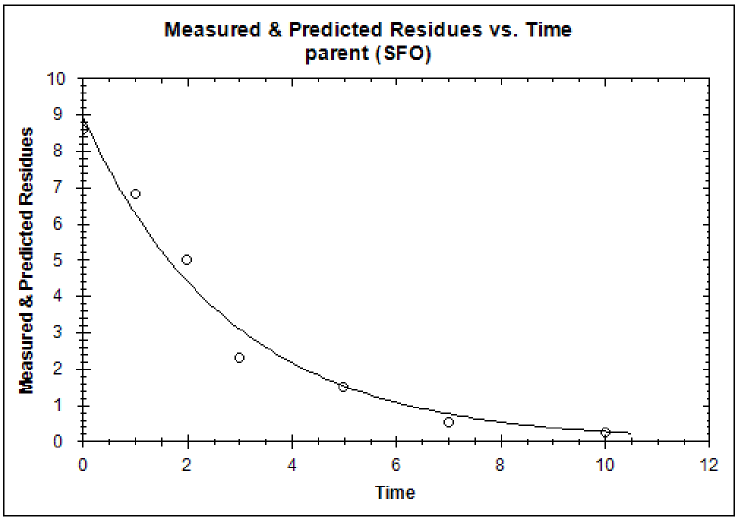



**Figure 3:** **Dissipation of fluopyram in cereals in Burscheid, 13-2950-01, without precipitation impact (in mg/kg)**

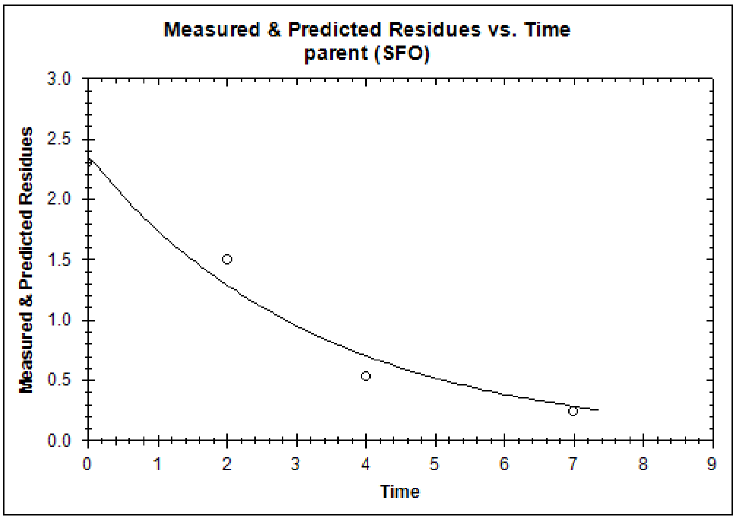


**Figure 4:** **Dissipation of fluopyram in cereals in Langförden, 13-2950-02, all residue data (in mg/kg)**

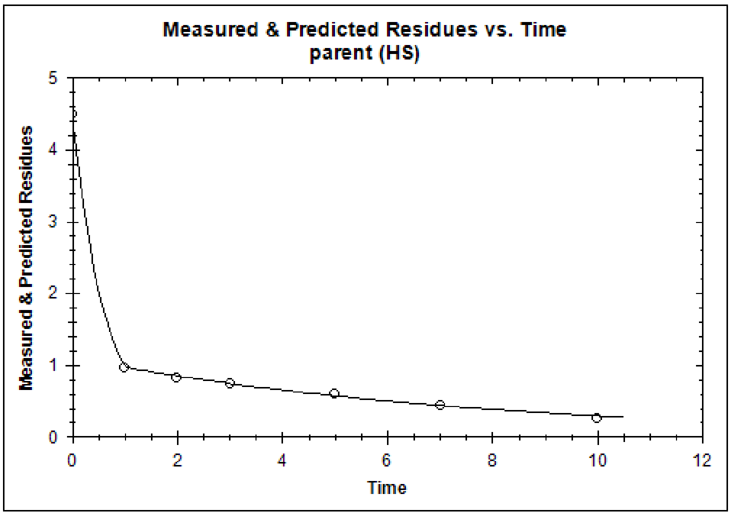



**Figure 5:** **Dissipation of fluopyram in cereals in Langförden, 13-2950-02, without precipitation impact (in mg/kg)**

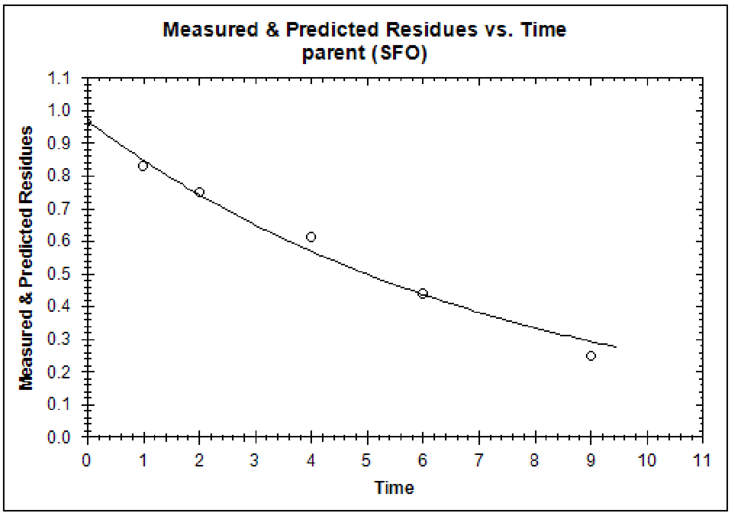



**Figure 6:** **Dissipation of fluopyram in cereals in Saint-Amand, 13-2950-03, all residue data (in mg/kg)**

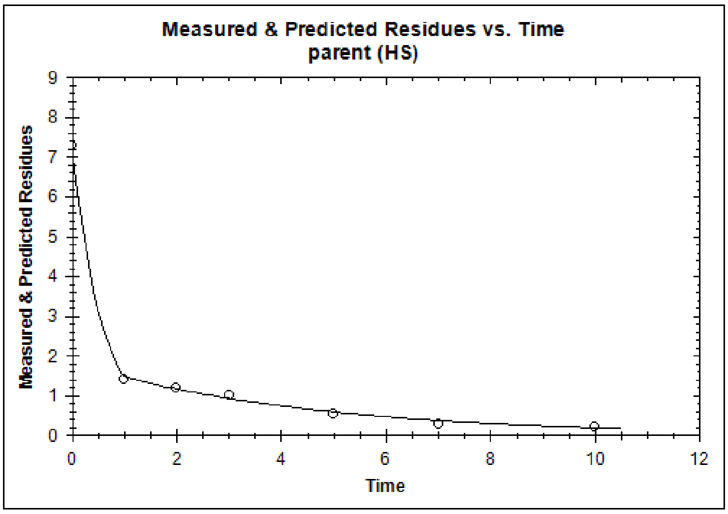


**Figure 7: Dissipation of fluopyram in cereals in Saint-Amand, 13-2950-03, without precipitation impact (in mg/kg)**

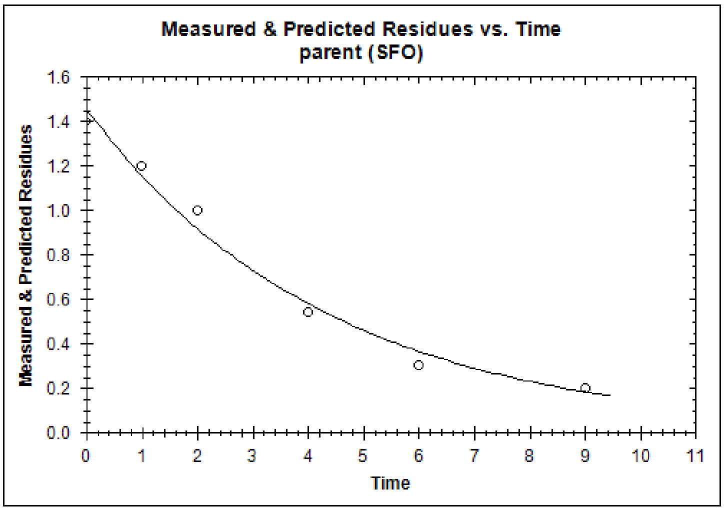



**Figure 8: Dissipation of fluopyram in cereals in Middenmeer, 13-2950-04, all residue data (in mg/kg)**

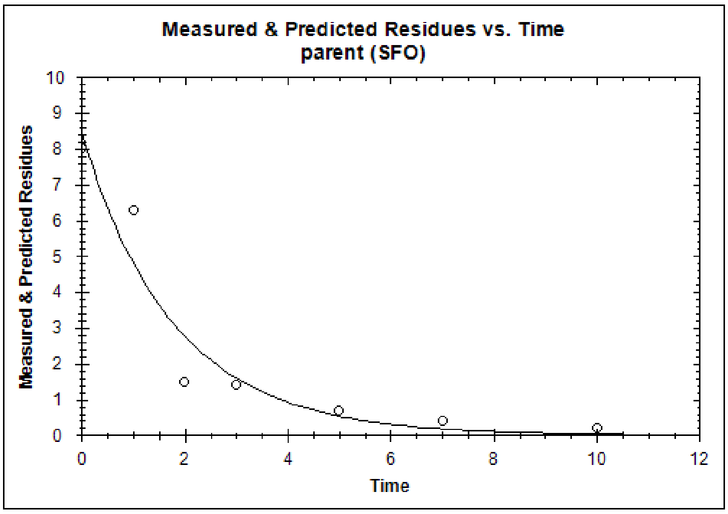


**Figure 9:** **Dissipation of fluopyram in cereals in Middenmeer, 13-2950-04, without precipitation impact (in mg/kg)**

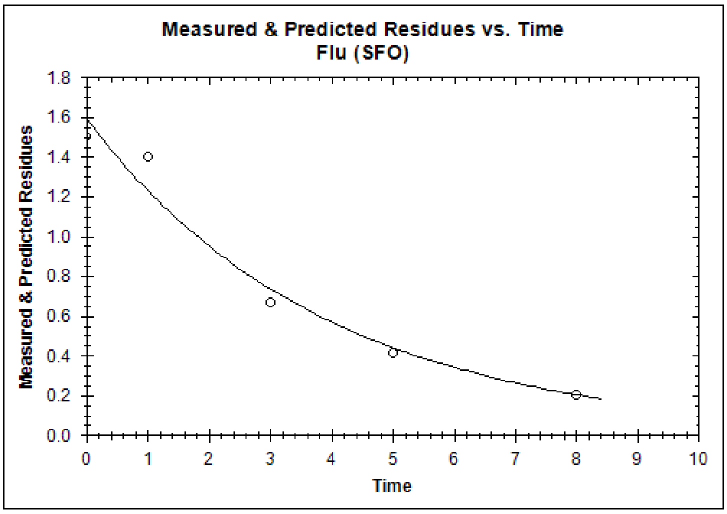



**Figure 10:** **Dissipation of fluopyram in cereals in Wieringerwerf, 15-2952-01, all residue data (in mg/kg)**

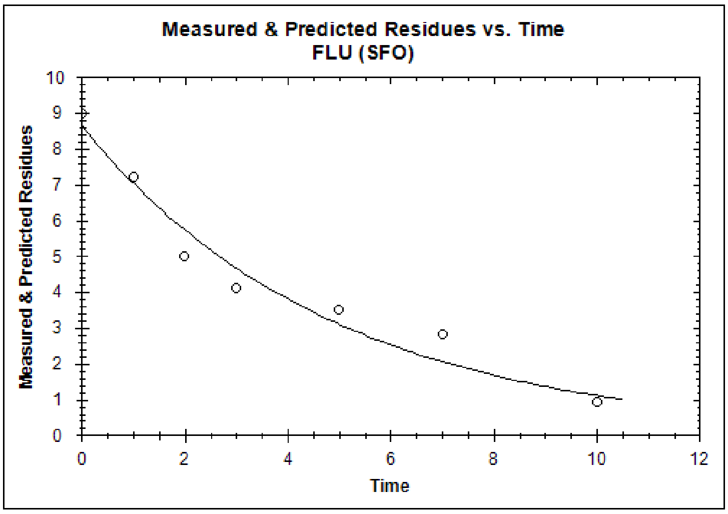



**Figure 11:** **Dissipation of fluopyram in cereals in Wieringerwerf, 15-2952-01, without precipitation impact (in mg/kg)**

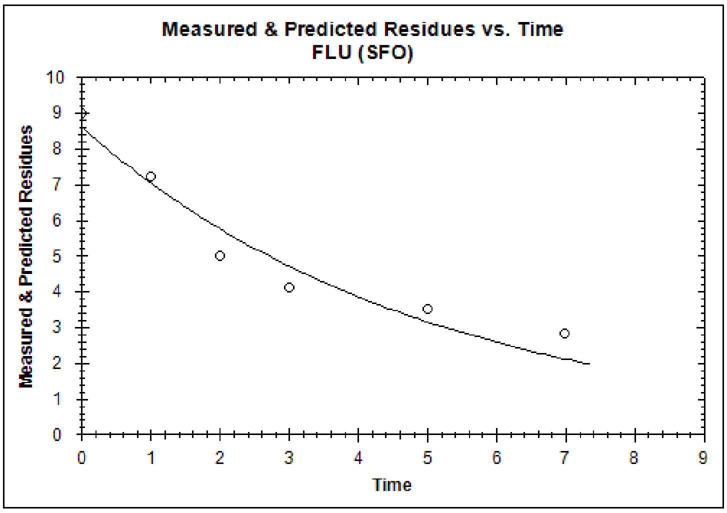


**Figure 12: Dissipation of fluopyram in cereals in Vielle Maison, 15-2952-02, all residue data, without precipitation impact (in mg/kg)**

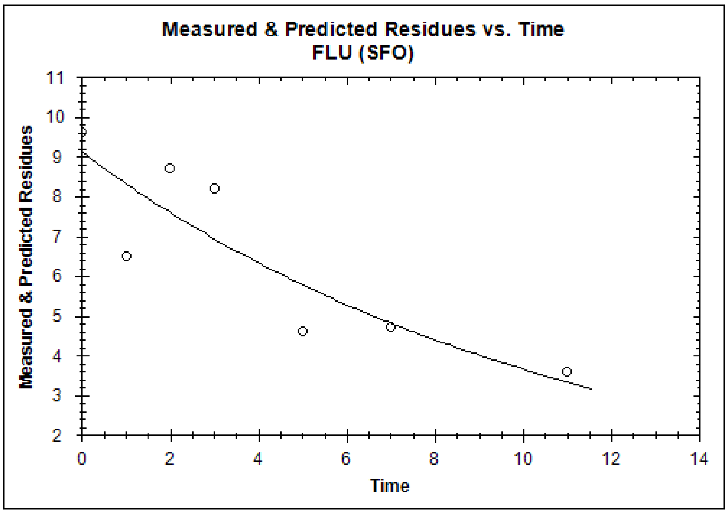



**Figure 13: Dissipation of fluopyram in cereals in Andria, 15-2952-03, all residue data (in mg/kg)**

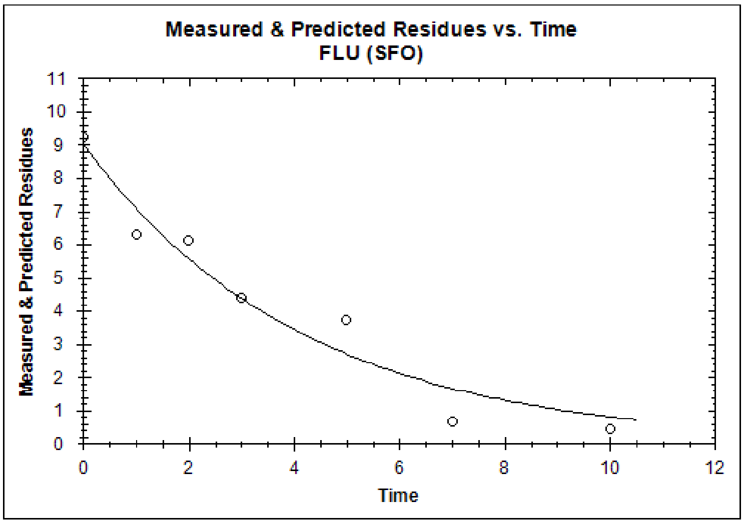


**Figure 14: Dissipation of fluopyram in cereals in Andria, 15-2952-03, without precipitation impact (in mg/kg)**

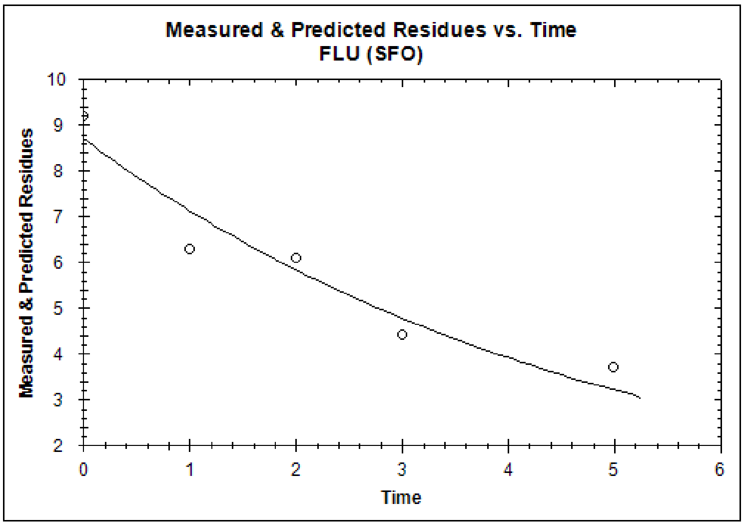



**Figure 15: Dissipation of fluopyram in cereals in Brenes, 15-2952-04, all residue data (in mg/kg)**

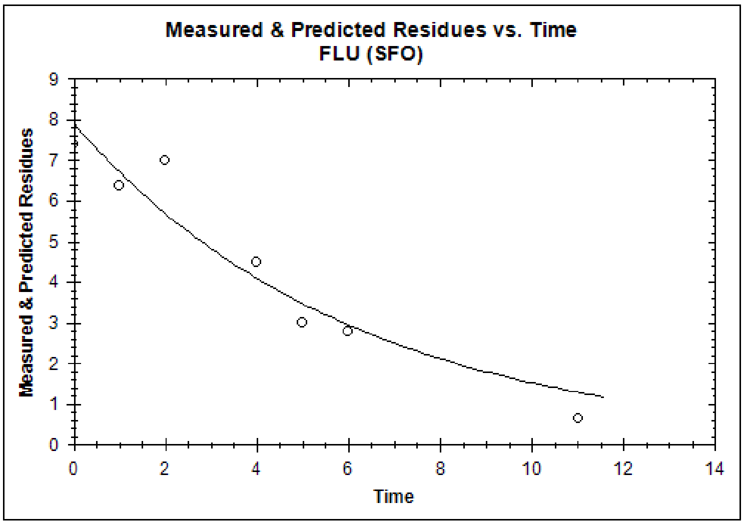



**Figure 16: Dissipation of fluopyram in cereals in Brenes, 15-2952-04, without precipitation impact (in mg/kg)**

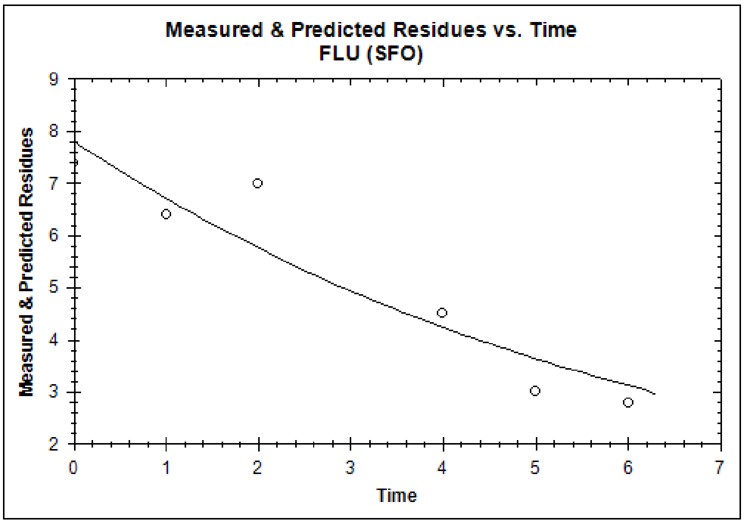


**Figure 17: Dissipation of fluopyram in cereals in Chambourg sur Indre, 15-2953-01, all residue data (in mg/kg)**

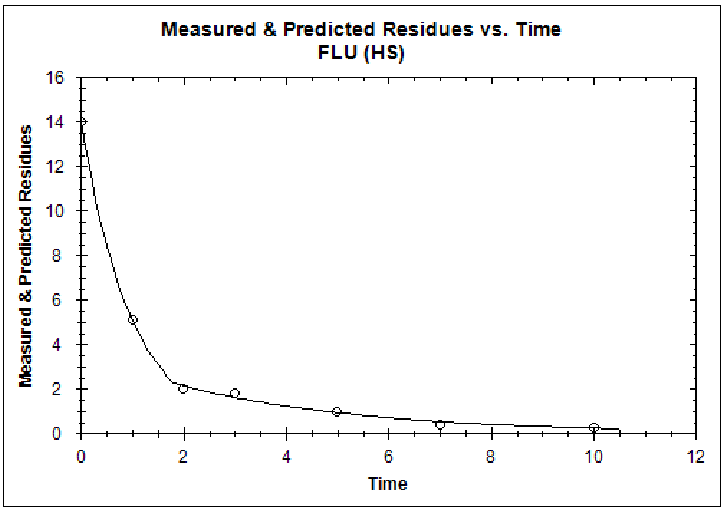



**Figure 18: Dissipation of fluopyram in cereals in Chambourg sur Indre, 15-2953-01, without precipitation impact (in mg/kg)**

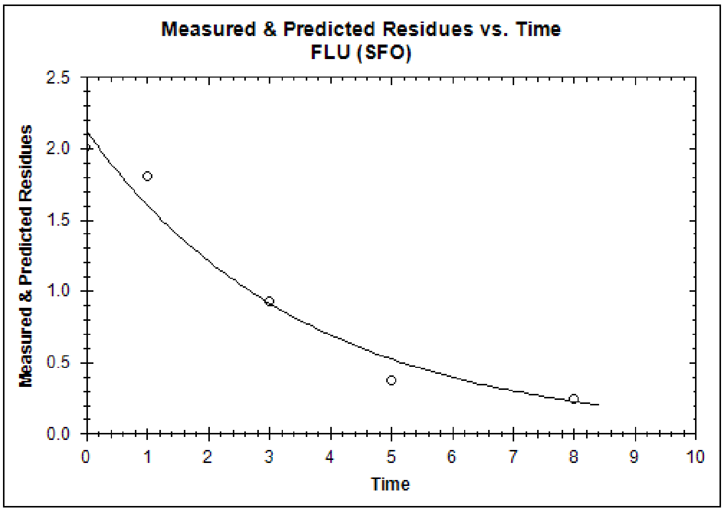


**Figure 19: Dissipation of fluopyram in cereals in Great Chishill, 15-2953-02, all residue data (in mg/kg)**

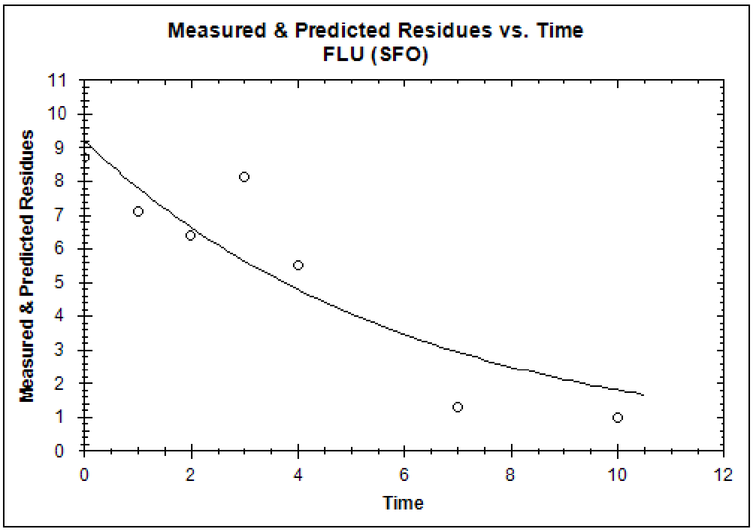



**Figure 20: Dissipation of fluopyram in cereals in Great Chishill, 15-2953-02, without precipitation impact (in mg/kg)**

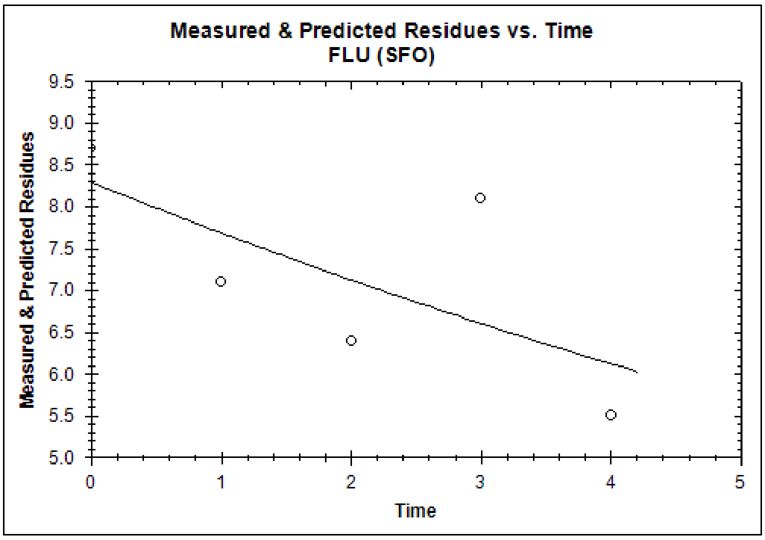
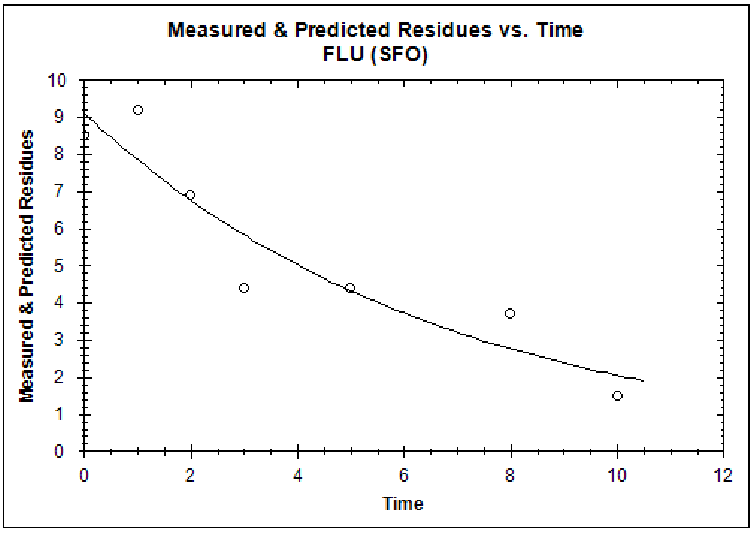



**Figure 21: Dissipation of fluopyram in cereals in C. da Reitana, 15-2953-03, all residue data, without precipitation impact (in mg/kg)**



| Comments of zRMS: | Comment on study; acceptable or not; deficiencies, corrections, according to recent guidelines or not, used in evaluation or only as additional information |
|---|---|

| | |
|---|---|
| Reference: | **KCP 10.1.1.2/09** |
| Title: | Bird species in lettuce fields in Brittany (northern France): field data for the determination of focal species |
| Report: | xxx |
| | |
| Guideline(s): | Bibby et al. 1992. Bird census techniques. Academic Press, London |
| Deviations: | none |
| GLP/GEP: | no |
| | |
| Duplication (if vertebrate study): | No |

| | |
|---|---|
| Reference: | **KCP 10.1.1.2/10** |
| Title: | Letter of access for generic behavioural ecology data - Study report Syngenta limited document N/1087 - Grouping: Vegetables, post emergence (foliar stages) |
| Report: | xxx |
| | |
| Guideline(s): | -- |
| Deviations: | -- |
| GLP/GEP: | not applicable |
| | |
| Duplication (if vertebrate study): | No |

**Objectives:**

The objectives of this generic study were to determine the qualitative and quantitative composition of the bird community employing the parameters, frequency of occurrence ($FO_{field}$ and $FO_{survey}$) and dominance as overall or lettuce growth stage specific descriptors, respectively. Another objective was to then allocate the selected species to defined foraging guilds, diet guilds and size classes.

**Materials and methods:**

Study area: Brittany region of northern France served as study area, encompassing 20 lettuce fields (average transect length 304 ± 31 m; range 131 – 610 m; median 264 m) selected to represent average lettuce crops, field size and the structure of the landscape.

Method and parameters: In order to cover different lettuce growth stages, three line transect surveys were conducted in 2006 for each field in May (Leaf development; survey 1) and June (Early development of harvestable vegetative plant parts; survey 2/Late development of harvestable vegetative plant parts; survey 3). All field surveys were conducted under comparable weather conditions. A line transect survey consisted of an ‘in-crop transect band’ (a 100 m wide recording band of 50 m to either side of the observer moving along a longitudinal in-crop field transect). For the assessment of the bird community, frequency of occurrence ($FO_{field}$ and $FO_{survey}$), and dominance were determined.

Data recording and analysis: Data were analysed using standard spreadsheet applications. The ranking of species within the list of focal species candidates was carried out in decreasing order of importance, i.e. $FO_{field}$ > $FO_{survey}$ > dominance. This list of candidates of focal species was then used to allocate the respective species to defined foraging guilds, diet guilds and size classes.

**Results and discussions:**

A total of 164 individual bird contacts, comprising 19 different species, was recorded throughout all surveys within the 'in-crop transect bands'. The following nine species listed in the table below were recorded with a frequency of occurrence ($FO_{field}$) exceeding 20% and were thus determined as the main candidates for focal bird species. The findings were supported by $FO_{survey}$ and dominance data (see table below).

| **Species** | **$FO_{field}$ n = 20 [%]** | **$FO_{survey}$ n = 60 [%]** | **Dominance n = 20 [%]** |
|---|---|---|---|
| Skylark (*Alauda arvensis*) | 30.0 | 20.0 | 11.6 |
| Carrion crow (*Corvus corone*) | 30.0 | 11.7 | 22.0 |
| Magpie (*Pica pica*) | 30.0 | 10.0 | 4.3 |
| Yellow wagtail (*Motacilla flava*) | 25.0 | 15.0 | 10.4 |
| Wood pigeon (*Columba palumbus*) | 25.0 | 10.0 | 16.5 |
| White wagtail (*Motacilla alba*) | 25.0 | 10.0 | 4.9 |
| Barn swallow (*Hirundo rustica*) | 20.0 | 10.0 | 5.5 |
| Yellowhammer (*Emberiza citrinella*) | 20.0 | 6.7 | 3.0 |
| Blackbird (*Turdus merula*) | 20.0 | 6.7 | 3.0 |

When analysing bird frequencies at the three different lettuce stages the focal species determined showed some variation with regard to their occurrence over time. The skylark, carrion crow and magpie showed moderate FO throughout the season with a peak during the second survey period (20.0 – 25.0%, each), whereas the yellow wagtail displayed a peak during the second and third survey period (20.0%, respectively). All the other species showed low FO values throughout the season with a peak during the second (white wagtail) or third survey period (wood pigeon, barn swallow, blackbird and yellowhammer). The recorded candidates of focal bird species were assigned to the following guilds in accordance with the SANCO guidance document (ranked by their respective frequency of occurrence and dominance):

| | |
|---|---|
| Small insectivore | yellow wagtail > white wagtail (both ground) > barn swallow (aerial) |
| Small omnivore | skylark > yellowhammer (both ground) |
| Medium herbivore | wood pigeon (ground) |
| Medium omnivore | carrion crow (ground) > magpie > blackbird (both ground/ foliage) |

**Conclusion:**

The skylark was the most characteristic and stable element of the bird community in lettuce fields in Brittany region of northern France across all lettuce growth stages. Other species, showing peak FO values ≥ 20% for individual lettuce growth stages, were the carrion crow and magpie (for survey 2) and yellow wagtail (for survey 2 and 3). All the species listed in the table above can be considered as potential candidates for focal bird species in a refined risk assessment for plant protection products in lettuces in

France.

| Comments of zRMS: | Comment on study; acceptable or not; deficiencies, corrections, according to recent guidelines or not, used in evaluation or only as additional information |
|---|---|

| | |
|---|---|
| Reference: | **KCP 10.1.1.2/11** |
| Title: | Bird species in leafy vegetables in central Europe - Field data for the determination of focal species |
| Report: | xxx |
| | |
| Guideline(s): | Regulation (EC) 1107/2009; Guidance of EFSA: Risk Assessment for Birds and Mammals (2009) |
| Deviations: | none |
| GLP/GEP: | yes |
| | |
| Duplication (if vertebrate study): | No |

**Objective:**

To identify a range of candidate focal species in cabbage fields (representative for leafy vegetables as EFSA crop group) in Bavaria, Germany, during different crop growth stages[4] (BBCH 11 − 15, BBCH 19 and BBCH 41 − 43) for use in risk assessment.

**Materials and methods:**

In order to provide an overview of bird communities present in cabbage fields during different crop growth stages, three line transect surveys were conducted in each of the 21 study fields (white and red cabbage fields), the first survey in May 2016, the second survey in June 2016 and the third survey in July 2016. A transect was defined for each study field (range 131 – 608 m) as a 50 m band centred along the axis. This transect (termed the 'in-crop transect band') was surveyed by an observer walking along the centre line of the study field. All birds present within individual in-crop transect bands were recorded. Frequencies of occurrence ($FO_{field}$ and $FO_{survey}$) and dominance were determined for each species and used to describe both overall and seasonal variation within the resident bird community. Additionally, abundance values were calculated for each species.
In order to gain information on the bird community of the surroundings of the cabbage fields, point counts were established in the vicinity of each of the 21 study fields.

Study sites
A total of 21 study fields (white and red cabbage fields) were selected to represent typical conditions for the cultivation of cabbage fields in Bavaria. This study site is considered to be representative for Central Europe.

Data recording and analysis
All data were collated and analysed using standard spreadsheet applications. Individual species were ranked by considering the number of study fields in which the species was present ($FO_{field}$), its frequency of occurrence during the three surveys in all observed study fields ($FO_{survey}$), dominance and abundance. A list of observed species was then compiled and ranked according to $FO_{field}$. Those species with $FO_{field}$ values of 20.0% and higher were deemed focal species candidates and assigned to their preferred feeding

strata and diet guilds. According to the filtering process described by Dietzen et al. (2014) focal bird species were identified for each diet guild.

**Results and discussions:**

Transect counts - Focal species candidates during the study as a whole
A total of 232 individual bird contacts comprising 20 species were recorded during the transect counts. From these data, $FO_{field}$ values ≥ 20.0% were calculated for three species which were subsequently deemed candidates for focal bird species for the observed cabbage fields. Each of the three candidate focal species was assigned to one of the following guilds in accordance with the EU guidance document on Risk Assessment for Birds and Mammals (EFSA, 2009):

**Candidate focal bird species of cabbage fields in Germany**

| **Bird species** | **$FO_{field}$[a)] [%]** | **$FO_{survey}$[b)] [%]** | **Dominance[c)] [%]** | **Body weight[d)] [g]** | **Stratum use[e)]** | **Diet guild[e)]** |
|---|---|---|---|---|---|---|
| Skylark (*Alauda arvensis*) | 66.7 | 49.2 | 27.5 | 37.2 | ground | omnivorous |
| White wagtail (*Motacilla alba*) | 61.9 | 27.0 | 10.0 | 21.0 | ground | insectivorous |
| Yellow wagtail (*Motacilla flava*) | 57.1 | 31.7 | 14.9 | 17.6 | ground | insectivorous |

[a] Based on 21 cabbage fields monitored during the survey;
[b] Based on 63 surveys;
[c] Based on the number of individuals of one species in relation to the total number of individuals of all species;
[d] Body weight [g] according to Dunning (2008);
[e] According to Perrins (1998)

For each diet guild one focal bird species was identified using the filtering process according to Dietzen et al. 2014. Feeding strata are given in brackets:

**Identified focal bird species for cabbage fields in Germany as determined according to Dietzen et al. (2014)**

| Diet guild | Selected focal bird species |
|---|---|
| **Omnivorous** | skylark (ground) |
| **Insectivorous** | yellow wagtail (ground) |
| **Granivorous** | none identified |
| **Herbivorous** | none identified |

The skylark was identified as focal species for the guild of omnivorous birds, the yellow wagtail as focal species for the guild of insectivorous birds. No focal bird species candidate could be identified for the guild of herbivorous or granivorous birds (maximum $FO_{field}$ = 9.5% for granivorous birds e.g. linnets, serins and goldfinches, maximum $FO_{field}$ = 14.3% for herbivorous birds e.g. the wood pigeon).

Transect counts - Focal species candidates during individual survey periods
Comparison of the frequency of occurrence (FO) values recorded for the candidate focal bird species at the study site in Bavaria (Germany) revealed a slight pattern of variation over the three survey periods (see tables below). Bird species exceeding FO values of 20.0% during individual survey periods are summarised in the tables below.

**Candidate focal bird species of cabbage fields in Germany observed during the first survey**

| **Observation period [DD Month YYYY]** | 17 May 2016 – 20 May 2016 | | | | |
|---|---|---|---|---|---|
| **BBCH growth stage**[5] | 11 – 15 | | | | |
| **Number of surveys** | 21 | | | | |
| **Bird species** | **FO**[6] **[%]** | **Dominance [%]** | **Body weight [%]** | **Stratum use** | **Diet guild** |
| Skylark (Alauda arvensis) | 57.1 | 40.3 | 37.2 | ground | omnivorous |
| White wagtail (Motacilla alba) | 28.6 | 12.9 | 21.0 | ground | insectivorous |
| Yellow wagtail (Motacilla flava) | 23.8 | 9.7 | 17.6 | ground | insectivorous |

**Candidate focal bird species of cabbage fields in Germany observed during the second survey**

| **Observation period [DD Month YYYY]** | 28 June 2016 – 29 June 2016 | | | | |
|---|---|---|---|---|---|
| **BBCH growth stage**[5] | 19 | | | | |
| **Number of surveys** | 21 | | | | |
| **Bird species** | **FO [%]** | **Dominance [%]** | **Body weight [%]** | **Stratum use** | **Diet guild** |
| Skylark (Alauda arvensis) | 57.1 | 37.8 | 37.2 | ground | omnivorous |
| Yellow wagtail (Motacilla flava) | 47.6 | 18.9 | 17.6 | ground | insectivorous |

**Candidate focal bird species of cabbage fields in Germany observed during the third survey**

| **Observation period [DD Month YYYY]** | 19 July 2016 – 22 July 2016 |
|---|---|

| **BBCH growth stage**[7] | 41 – 43 | | | | |
|---|---|---|---|---|---|
| **Number of surveys** | 21 | | | | |
| **Bird species** | **FO [%]** | **Dominance [%]** | **Body weight [%]** | **Stratum use** | **Diet guild** |
| Skylark (Alauda arvensis) | 33.3 | 21.9 | 37.2 | ground | omnivorous |
| White wagtail (Motacilla alba) | 33.3 | 14.6 | 21.0 | ground | insectivorous |
| Yellow wagtail (Motacilla flava) | 23.8 | 20.8 | 17.6 | ground | insectivorous |

An overview of the diet guilds and identified focal bird species for each survey according to Dietzen et al. 2014 is summarized below. Feeding strata are given in brackets:

**Identified focal bird species for cabbage fields in Germany during individual survey periods as determined according to Dietzen et al. (2014)**

| **Diet guild** | **Candidate focal bird species during** | | |
|---|---|---|---|
| | **First survey** | **Second survey** | **Third survey** |
| **Omnivorous** | skylark (ground) | skylark (ground) | skylark (ground) |
| **Insectivorous** | yellow wagtail (ground) | yellow wagtail (ground) | yellow wagtail (ground) |
| **Granivorous** | none identified | none identified | none identified |
| **Herbivorous** | none identified | none identified | none identified |

Point counts – Bird community in the vicinity of the study fields

A total of 541 individual bird contacts comprising 42 species were recorded during the point counts. A total of 19 bird species including representatives of all diet guilds (omnivores, insectivores, granivores and herbivores) were recorded exceeding FO values of 20.0%.

Contrary to the low frequency of occurrence in the cabbage fields, occurrence in the surroundings was high for the wood pigeon (FO = 57.1%), goldfinch (FO = 33.3%) and linnet (FO = 23.8%). Obviously, the cabbage fields were of low attractivity for these species.

**Conclusion:**

Overall, the skylark, the white wagtail and the yellow wagtail were the focal species candidates and thus the most characteristic and stable elements of the bird community in cabbage fields in Germany during all three survey periods.

Cabbage fields in Germany were consistently found to contain the skylark as identified focal species for the guild of omnivore birds and the yellow wagtail for the guild of insectivore birds over a period of three surveys in May, June and July 2016.

Granivore and herbivore species were not detected as focal species candidates in cabbage fields in Germany although several species (goldfinch, linnet and wood pigeon) have been detected with FO values ≥ 20.0% in the surrounding of the cabbage fields during the point counts.

During individual survey periods, the skylark, the yellow wagtail and the white wagtail reached the threshold value of 20.0. The skylark and the yellow wagtail were found to have moderate to high FO values across all three surveys (23.8% – 57.1%). The white wagtail displayed moderate to high FO values during the first and the third survey (28.6% and 33.3%). [8]

**Conclusions on focal bird species for cabbage fields in Germany as determined according to Dietzen et al. (2014)**

| **Diet guild** | **Selected focal bird species over a period of three surveys** |
|---|---|
| **Omnivorous** | skylark (ground) |
| **Insectivorous** | yellow wagtail (ground) |
| **Granivorous** | none identified |
| **Herbivorous** | none identified |

| | |
|---|---|
| Comments of zRMS: | The study is considered acceptable.<br><br>The study was conducted in leafy vegetable fields in a leafy vegetable-growing region in Southern Germany. The study areas were located between Reisbach and Eichendorf and near Wallersdorf (district Dingolfing- Landau) in Lower Bavaria. Based on the outcome for granivorous bird species, leafy vegetable fields with a BBCH growth stage ≥ 40 onwards were selected for **linnet and serin trapping and radio-tracking**.<br><br>**Results:**<br><br>Linnet<br><br>Taking all 20 radio-tracking sessions together, the mean PT of linnets (all potential consumers) in leafy vegetable fields was about 9% (**90th percentile 20.4%).**<br>Serin<br><br>Taking all 20 radio-tracking sessions together, the mean PT of serins (all potential consumers) in leafy vegetable fields was about 4% (**90th percentile 9.8%).**<br><br>The study was not used in the risk assessment. |

| | |
|---|---|
| Reference: | **KCP 10.1.1.2/12** |
| Title: | GLP compliant field study to record PT values of linnet and serin for leafy vegetable in Central Europe (Germany) |
| Report: | xxx; 2019; R1740067; M-655399-01-1 |
| Authority registration No: | |
| Guideline(s): | Guidance of EFSA: Risk Assessment for Birds and Mammals (2009) |
| Deviations: | None |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication (if vertebrate study): | No |

**Objective:**

This study was conducted to to determine PT values of linnets (*Linaria cannabina*) and serins (*Serinus serinus*) in leafy vegetable fields in the Central zone, although the focal species studies had already shown that the attractivity of such fields to granivorous birds is very low (FO < 20%). Twenty full day radio-tracking sessions of 19 individuals of each species were performed. This resulted in reliable and appropriate data for wildlife risk assessments and showed that linnets and serins spend on average about 9% and 4%, respectively, of their potential foraging time in leafy vegetable fields.

**Materials and methods:**

Study area:
The study was conducted in leafy vegetable fields in a leafy vegetable-growing region in Southern Germany. The study areas were located between Reisbach and Eichendorf and near Wallersdorf (district Dingolfing- Landau) in Lower Bavaria. Based on the outcome of the RIFCON GmbH GLP Study No. 281 for granivorous bird species, leafy vegetable fields with a BBCH growth stage ≥ 40 onwards were selected for linnet and serin trapping and radio-tracking. The final extent of the study area is defined by the home ranges of the tracked individuals. The different habitat types within the linnets' and serins' home ranges were mapped within three days after each radiotracking session.

Weed seed and seed-bearing weed plant counts
Weed seed and seed-bearing weed plant counts were conducted once in 63 randomly chosen leafy vegetable fields in the study area. Along a transect line across each leafy vegetable field, four 1 m x 1 m frames were placed. In each frame, the number of seeds of weed plants (= non-crop plants) according to three categories (small: < 0.3 cm, medium: 0.3 – 0.6 cm and large: > 0.6 cm) were counted. Small seeds (< 0.3 cm) are favoured by both species, large seeds (> 0.6 cm) are rather unpopular and/or too large for the small bills, while medium-sized seeds are eaten more by linnets than by serins. Additionally, the number of seed bearing weed plants (nonflowering, flowering and seed bearing) was counted and, if possible, the plant species or family were determined. Also, the percentage of ground cover by weed plants was estimated.

Bird trapping and radio-tracking:
Birds were trapped with mist nets in or right next to leafy vegetable fields determining all tracked birds as potential consumers due to the trapping location. For all captured linnets and serins sex and age was determined, according to the literature (e.g. Svensson 1992, Svensson et al. 1999). All individuals were marked with an aluminum ring on one tarsus and tagged with radio transmitters. The transmitters were attached on the back of the birds using the 'Rappole-Harness' method (Rappole & Tipton 1991).
Radio-tracking sessions lasted for the entire activity period of the respective individual from dawn until dusk. During each session the bird was tracked continuously, i.e. it was constantly followed by car or afoot. Every change in behaviour and/or location and the time of this change was recorded.
Unidirectional Yagi-antennas were used to determine the location and behavior of the tagged birds. Each location of the bird was recorded as coordinates of a map-grid-system. When possible the observer watched the tagged bird to describe the behaviour as accurately as possible and to verify its location.
In addition to the radio-tracking sessions, single telemetry checks (i.e. telemetry checks of a few minutes to determine the location of the bird) were performed for every tagged individual at least once at the beginning and the end of the Field Phase to obtain information on the whereabouts of the tagged birds and the tag's proper functioning. Birds trapped at the end of the Field Phase were only checked once.

Data analysis:
The data was analysed to determine the PT of linnets and serins in leafy vegetable fields and the sizes of their daily home ranges. The PT value was calculated as the time spent potentially foraging in leafy vegetable fields (including unknown habitats for a worst-case calculation) related to the overall time spent potentially foraging over the course of the entire tracking session in all habitats. The home range sizes were estimated by plotting a Minimum Convex Polygon around the outermost locations (fixed as midpoint of 'map grids') that were recorded for a bird during one tracking session. All birds were trapped and tagged on or close to leafy vegetable fields and are thus considered and evaluated as "potential consumers". Those birds, which were recorded at least once as present on a leafy vegetable field (by trapping, by single telemetry fixes, or during continuous radio-tracking) were defined and evaluated as "confirmed consumers".

**Results and discussions:**

Weed seed and seed-bearing weed plant counts
In 63 leafy vegetable fields weed seed and seed-bearing weed plant counts were performed. This included

broccoli, cauliflower, broccoli/cauliflower mix, red cabbage, white cabbage, Chinese cabbage, lettuce, and parsley fields. Overall, very small numbers of weed seeds (on average 4.23 small seeds, 2.48 medium size seeds and 0.02 large seeds per m2) were recorded. Weed counts resulted in on average 7.18 non-flowering plants, 0.52 flowering plants and 0.09 seed-bearing plants per m2. The mean coverage of weed plants was 4 %.

<u>Trapping and radio-tracking</u>
The radio-tracking sessions took place from 21 July 2018 to 26 August 2018. For both species, 19 individuals each were radio-tracked. One individual each was radio-tracked twice to obtain 20 radio-tracking sessions in total.

<u>Linnet</u>
Taking all 20 radio-tracking sessions together, the mean PT of linnets (all potential consumers) in leafy vegetable fields was about 9% (90th percentile 20.4%). The PT ranged from 0.0% to 26.7%. The sizes of the home ranges varied from 2.5 ha to 927.0 ha with an average of 353.3 ha ± 60.9 ha (SEM).

**Overview of the 20 individual PTs of linnets given for potential and confirmed consumers**
Given are ring number, trapping location, number of single telemetry fixes within leafy vegetables (LV) and the PT for LV for potential and confirmed consumers. Entries in bold mark events (i.e. trapping, single telemetry or telemetry for PT) with confirmed LV usage.

| Ring No. | Trapping location | Single telemetry fixes within LV | PT LV [%] Potential consumers | PT LV [%] Confirmed consumers |
|---|---|---|---|---|
| B4X7652 | trapped 40 m outside LV | 0 | 0.00 | - |
| B4X7653 | trapped 40 m outside LV | **1** | 0.00 | 0.00 |
| B4X7654 | trapped 40 m outside LV | 0 | **6.97** | **6.97** |
| B4X7655 | trapped in LV field margin | **1** | 0.00 | 0.00 |
| B4X7662 | **trapped on LV field** | 0 | **10.57** | **10.57** |
| B4X7665 | **trapped on LV field** | 0 | 0.00 | 0.00 |
| B4X7676 | **trapped on LV field** | 0 | **26.73** | **26.73** |
| B4X7677 | **trapped on LV field** | 0 | **14.13** | **14.13** |
| B4X7678 | **trapped on LV field** | 0 | **8.40** | **8.40** |
| B4X7679 | **trapped on LV field** | 0 | **5.58** | **5.58** |
| B4X7680 | **trapped on LV field** | 0 | **23.58** | **23.58** |
| B4X7686 | **trapped on LV field** | 0 | 0.00 | 0.00 |
| B4X7712 | **trapped on LV field** | 0 | **14.54** | **14.54** |
| B4X7713 | **trapped on LV field** | 0 | **8.66** | **8.66** |
| B4X7714 | **trapped on LV field** | 0 | **1.36** | **1.36** |
| B4X7715 | **trapped on LV field** | 0 | **11.08** | **11.08** |
| B4X7716 | **trapped on LV field** | 0 | **20.00** | **20.00** |
| B4X7716* | **trapped on LV field** | 0 | **16.11** | **16.11** |
| B4X7719 | **trapped on LV field** | **5** | **10.42** | **10.42** |
| B4X7720 | **trapped on LV field** | 0 | 0.00 | 0.00 |
| | | **mean:** | **8.91** | **9.37** |
| | | **90th percentile:** | **20.36** | **20.72** |

<u>Serin</u>
Taking all 20 radio-tracking sessions together, the mean PT of serins (all potential consumers) in leafy vegetable fields was about 4% (90th percentile 9.8%). The PT ranged from 0.0% to 21.1%. The sizes of the home ranges varied from 11.5 ha to 891.8 ha with an average of 143.7 ha ± 44.5 ha (SEM).

**Overview of the 20 individual PTs of serins given for potential and confirmed consumers**
Given are ring number, trapping location, number of single telemetry fixes within leafy vegetables (LV) and the PT for LV for potential and confirmed consumers. Entries in bold mark events (i.e. trapping, single telemetry or telemetry for PT) with confirmed LV usage. Note that the serins with the ring numbers B4X7661, B4X7684 and B4X7685 were confirmed consumers due to trapping location or single telemetry, but during telemetry for PT were only potentially foraging in non-leafy-vegetable and unknown habitats. For worst case calculations, the latter was set to leafy vegetable (as for all other individuals with unknown habitat).

| Ring No. | Trapping location | Single telemetry fixes within LV | PT LV [%] potential consumers | PT LV [%] confirmed consumers |
|---|---|---|---|---|
| B4X7657 | trapped 50 m outside LV | 0 | **2.97** | **2.97** |
| B4X7658 | trapped 50 m outside LV | 0 | 0.00 | - |
| B4X7659 | trapped 50 m outside LV | 0 | **4.90** | **4.90** |
| B4X7660 | trapped 50 m outside LV | 0 | **9.64** | **9.64** |
| B4X7661 | trapped 50 m outside LV | **1** | 2.23 | 2.23 |
| B4X7663 | **trapped on LV field** | **1** | **2.68** | **2.68** |
| B4X7666 | **trapped on LV field** | 0 | **3.31** | **3.31** |
| B4X7669 | trapped in LV field margin | 0 | **4.34** | **4.34** |
| B4X7670 | trapped in LV field margin | 0 | 0.00 | - |
| B4X7671 | trapped in LV field margin | 0 | **21.08** | **21.08** |
| B4X7674 | trapped in LV field margin | 0 | 0.00 | - |
| B4X7675 | trapped in LV field margin | 0 | **9.14** | **9.14** |
| B4X7681 | **trapped on LV field** | 0 | 0.00 | 0.00 |
| B4X7682 | **trapped on LV field** | 0 | 0.00 | 0.00 |
| B4X7684 | **trapped on LV field** | 0 | 1.95 | 1.95 |
| B4X7685 | **trapped on LV field** | 0 | 0.94 | 0.94 |
| B4X7704 | trapped 40 m outside LV | **1** | **3.10** | **3.10** |
| B4X7711 | **trapped on LV field** | 0 | **10.79** | **10.79** |
| B4X7711* | **trapped on LV field** | 0 | **5.09** | **5.09** |
| B4X7717 | **trapped on LV field** | 0 | 0.00 | 0.00 |
| | | **mean:** | **4.11** | **4.83** |
| | | **90th percentile:** | **9.76** | **10.10** |

**Conclusion:**

This study provides reliable and appropriate data for wildlife risk assessments and showed that linnets and serins spend on average about 9% and 4%, respectively, of their potential foraging time in leafy vegetable fields. All tracking sessions pooled (N = 20/ species) represent a robust empirical data set for the use in long-term wildlife risk assessments for linnet and serin populations in leafy vegetable growing areas in Central Europe.

| | |
|---|---|
| Reference: | **KCP 10.1.1.2/13** |
| Title: | Focal species of birds in european crops for higher tier pesticide risk assessment |
| Report: | xxx |
| | |
| Guideline(s): | not applicable |
| Deviations: | not applicable |
| GLP/GEP: | not applicable |
| | |
| Duplication (if vertebrate study): | No |

Public literature

| | |
|---|---|
| Reference: | **KCP 10.1.1.2/14** |
| Title: | Generic monitoring of birds in vegetable fields in Great Britain |
| Report: | xxx |
| | |
| Guideline(s): | not applicable; the test was especially designed for the purpose of this study |
| Deviations: | none |
| GLP/GEP: | yes |
| | |
| Duplication (if vertebrate study): | No |

| | |
|---|---|
| Reference: | **KCP 10.1.1.2/15** |
| Title: | Letter of Access for generic behavioural ecology data: Study report Syngenta Limited document NA_10088; Grouping: vegetables, post emergence (foliar stages): Generic monitoring of birds in vegetable fields in Great Britain |
| Report: | xxx |
| | |
| Guideline(s): | -- |
| Deviations: | -- |
| GLP/GEP: | not applicable |
| | |
| Duplication (if vertebrate study): | No |

**Objective:**

The aim of this generic study was to obtain estimates of diet and the proportions of diet taken from vegetable fields by three focal bird species, woodpigeon (*Columba palumbus*), skylark (*Alauda arvensis*) and yellow wagtail (*Motacilla [flava] flavissima*).

Objectives:

- to determine the proportion of diet obtained in vegetable fields (PT estimate) by radio tracking individual birds based on the assumption that the time a bird spends ‘active’ or, more specifically, foraging in a habitat, is a reliable measure of the proportion of food obtained in this defined area
- to determine the proportion of different food types in the diet (PD estimates) of skylarks (*Alauda arvensis*) and yellow wagtails (*Motacilla [flava] flavissima*) by analysing faecal contents and to

obtain a list of food items found in the faeces of woodpigeon (*Columba palumbus*).

Study area:
The study was conducted in the fenlands of Cambridgeshire and Norfolk near the town of Littleport, Cambridgeshire, England, a typical area of vegetable cultivation in Europe.

**Materials and methods:**

The study was carried out during spring and summer 2007. A total of 26 woodpigeons, 24 skylarks and 24 yellow wagtails were trapped with mist nets, whoosh nets, spring and perch traps in or in close vicinity of vegetable fields. These birds were marked with a metal and colour ring in order to enable recognition of individuals during subsequent visual contacts and fitted with a radio tag. For trapping location, special emphasis was given to vegetable crops as follows: onion/leek, carrot, lettuce/Chinese cabbage and celery. Additionally radish and red beet were regarded as vegetables for the purpose of this study. Twenty-one individuals of each species were successfully tracked. The birds were tracked continuously over one whole daily activity period (from dawn till dusk), keeping the bird under continuous visual observation. Three individuals of woodpigeons, one skylark and one yellow wagtail were tracked for two daily activity periods. For analysis the respective sessions were pooled. The proportion of time foraging in vegetable fields (compared with the total potential foraging time) was estimated with the help of data obtained by radio tracking and visual observation. These values were regarded as equivalent to the proportion of diet obtained from the treated area (PT). To estimate the proportion of different food types in the diet (PD), faeces were sampled and analysed. Correction factors derived from the literature were applied to estimate the number of items actually ingested by the birds from the number of arthropods and seeds recognised in the faeces samples. Estimations of the prey length provided information on food size selection of the birds. Literature-derived weight-length regressions of invertebrates and seeds were used to calculate the proportion of dry weight of each food type in the diet actually ingested by the birds. Since no correction factors are currently available for the typical diet of woodpigeons, a list of identified food items found in the faeces samples of woodpigeons is provided in the tables below.

**Results and discussions:**

PT values
Results are presented in the table below. The combination of radio tracking with visual observations and the trapping scheme as presented here, allowed an accurate and representative assessment of potential foraging times in given home ranges in order to calculate reliable PT values. All birds were closely associated with vegetable fields and had the opportunity to use these fields as foraging habitat. The results can be considered a worst case in terms of potential exposure. PT data were analysed using four different approaches as defined below. The first three approaches sum the time spent 'potentially foraging' in all vegetable crops, so represent a worst-case assumption that all vegetables are treated simultaneously with the same pesticide. The final approach (single crop) considers the highest (worst-case) PT value for any single vegetable crop in each tracking session, and hence is relevant for situations where different vegetable crops are not treated simultaneously with the same pesticide.

All birds"-approach
All tracking sessions were considered to determine PT estimate. This approach gives an indication of the risk to the wider farmland population that was in the vicinity of vegetable fields but did not necessarily happen to visit any vegetable fields during the tracking session.

“Home range”-approach

For each tracking session the home range used by the bird was determined. Within the “home range”-approach, sessions were considered in calculation of PT if vegetables were part of the home range, irrespective of whether these fields were used by the birds or not i.e. sessions with PT = 0 were included provided that a vegetable field was available within the home range of the tracked individual during the tracking session. This approach considers risk for the local population that is closely associated with vegetables i.e. with vegetables in home range.

“Consumer”-approach

PT is estimated from only those individuals shown by radio tracking to have used vegetable fields as a foraging habitat, i.e. PT > 0. The consumer approach has been proposed elsewhere for use when considering birds trapped in the general agricultural landscape. If the home range is established through radio tracking, as in this study, then any bird where vegetables appear in the home range can justifiably be included in the PT sample. Exclusion of a bird because it did not visit the crop in question during a single days tracking, ignores the fact that some birds may choose to avoid the crop, and so may represent a significant bias in the estimation of PT.

“Home range - single crop” -approach

In this approach, the highest PT value was taken for any one vegetable crop for each tracking session where vegetables were present in the home range, rather than summing the time spent in all vegetable crops. This assumes that different vegetable crops are not treated simultaneously with the same pesticide and hence PT should be expressed for a worst-case, single vegetable rather than across all vegetable crops.

Diet (PD) value (skylark and yellow wagtail)

Results are presented in the table below. Categories have been grouped to allow estimation of exposure to pesticide residues (RUD’s). To do this an attempt has been made to group food items into relevant categories of foraging strata and size.

**Overview of PT in vegetable crops**

| **PT in vegetable fields (all vegetables combined)** | | | | | |
|---|---|---|---|---|---|
| **Species** | **Percentiles** | **PT approach** | | | |
| | | **"All birds"[1)]** | **„Home range"[2)]** | **„Consumer"[3)]** | **„Single crop"[4)]** |
| Woodpigeon (based on 21 individuals/24 tracking session) | 50%tile | 0.00 | 0.00 | 0.18 | 0.00 |
| | 90%tile | 0.27 | 0.28 | 0.33 | 0.27 |
| | Mean | 0.09 | 0.09 | 0.20 | 0.09 |
| Skylark (based on 21 individuals/22 tracking sessions) | 50%tile | 0.03 | 0.39 | 0.84 | 0.39 |
| | 90%tile | 0.96 | 0.96 | 0.97 | 0.85 |
| | Mean | 0.35 | 0.41 | 0.67 | 0.38 |
| Yellow wagtail (based on 21 individuals/22 tracking sessions) | 50%tile | 0.38 | 0.40 | 0.42 | 0.32 |
| | 90%tile | 0.85 | 0.86 | 0.87 | 0.55 |
| | Mean | 0.39 | 0.41 | 0.43 | 0.32 |

1) All sessions were included in this approach.
2) Sessions with vegetables as part of the home range, irrespective of whether these fields were used by the birds or not.
3) PT was estimated including only those individuals, shown by radio tracking to have used vegetable fields as a foraging habitat, i.e. PT > 0.
4) Highest PT for any single vegetable crop for "home range" birds.

**Table: Proportion of time skylarks spent 'potentially foraging' in different habitats during 21 tracking sessions according to the "consumer" approach. A figure for the respective habitat is given only if PT > 0.**

| | PT [%] | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | vegetable | | | | | | | Other crops | | | |
| session no. | onion | leek | carrot | lettuce | celery | red beet | radish | potato | cereal | drilled field | Other (non-crop habitats) |
| 3 | | | | | | | | | | | 100.0 |
| 4/6 | | | | | | | | | | 1.3 | 98.7 |
| 11 | | | | 33.8 | | | | | | | 66.2 |
| 12 | | | | | | | | | | | 100.0 |
| 13 | 5.1 | | | 47.7 | | | | | | | 47.2 |
| 14 | 61.4 | | | 34.5 | | | | | | | 4.1 |
| 17 | | | | | | | | | | | 100.0 |
| 23 | | | 84.6 | | | | | | | | 15.4 |
| 26 | 83.0 | | | | | 13.7 | | | | | 3.3 |
| 28 | | | | 3.2 | | | | | | | 96.8 |
| 31 | | | | | | | | | | | 100.0 |
| 32 | | | | | | | | | | | 100.0 |
| 33 | | | | | | | | | | | 100.0 |
| 39 | | | | | 43.9 | | | | | | 56.1 |
| 47 | | | 84.3 | | | | | | | | 15.7 |
| 48 | | | 85.5 | | | | | | | | 14.5 |
| 49 | | | 100.0 | | | | | | | | 0.0 |
| 52 | | | | | 57.9 | | | | | | 42.1 |
| 56 | | | | | | | | | | | 100.0 |
| 58 | | | | | | | | | | | 100.0 |
| 68 | | | | | | | | | | | 100.0 |
| n | 3 | 0 | 4 | 4 | 2 | 1 | 0 | 0 | 0 | 1 | 21 |
| 50%tile | 61.4 | | 85.1 | 34.1 | 50.9 | 13.7 | | | | 1.3 | 96.8 |
| 90%tile | 78.7 | | 95.7 | 43.7 | 56.5 | 13.7 | | | | 1.3 | 100.0 |
| mean | 49.9 | | 88.6 | 29.8 | 50.9 | 13.7 | | | | 1.3 | 64.8 |
| SD | 40.2 | | 7.6 | 18.8 | 9.9 | | | | | | 40.8 |

**Table:** **Proportion of time woodpigeons spent 'potentially foraging' in different habitats during 21 tracking sessions**
**A figure for the respective habitat is given only if PT > 0.**

| session no. | PT [%] | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | vegetables | | | | | | | Other crops | | | | | | | |
| | onion | leek | carrot | lettuce | celery | red beet | radish | non-vegetable 1) | sugar beet | potato | cereal | bean | drilled field | other (non-crop habitats) | Unknown (but not vegetable)2) |
| 1 | | | | | | | | | | | 3.3 | | | 96.3 | 0.4 |
| 2 | | | | | | | | | | | | | | 98.3 | 1.7 |
| 5 | | | | | | | | | | | | | | 100.0 | |
| 7 | | | | | | | | | | | 10.8 | | | 89.2 | |
| 8 | 1.8 | | | | | | | | | | | | | 98.2 | |
| 9 | | | | | | | | | | | 1.9 | | | 98.1 | |
| 10/20 | 1.2 | | 0.3 | 10.4 | | | | | | | 0.5 | | | 87.6 | |
| 18 | | | | | | | | | | 5.5 | | | | 94.5 | |
| 19/25 | | | | 12.2 | | | | | | | | | | 80.5 | 7.3 |
| 22 | | | | 4.7 | | | | | | | | | | 95.3 | |
| 24 | | | | 27.2 | | | | | | | | | | 72.8 | |
| 34 | | | | 49.2 | | | | | | | | | | 50.8 | |
| 35 | | 15.4 | | 2.6 | | | | | | | | | | 82.0 | |
| 36 | | | | | | | | | | | | | | 100.0 | |
| 37/41 | | | | 28.2 | 0.9 | | | | 0.2 | 0.2 | | | | 70.5 | |
| 38 | | | | | | | | | 3.1 | | | | | 93.4 | 3.5 |
| 55 | | | | | | | | | | 0.6 | | | | 99.4 | |
| 63 | | | | | | | | | | | 14.5 | | | 85.5 | |
| 65 | 12.6 | | | 12.4 | | | | | | | | | | 75.0 | |
| 66 | | | | | | | | | | | 1.6 | | | 98.4 | |
| 67 | | | | | | | | | | | 0.8 | | | 99.2 | |
| n | 3 | 1 | 1 | 8 | 1 | 0 | 0 | 0 | 2 | 3 | 7 | 0 | 0 | 21 | 4 |
| 50%tile | 1.8 | 15.4 | 0.3 | 12.3 | 0.9 | | | | 1.7 | 0.6 | 1.9 | | | 94.5 | 2.6 |
| 90%tile | 10.5 | 15.4 | 0.3 | 34.5 | 0.9 | | | | 2.9 | 4.5 | 12.3 | | | 99.4 | 6.2 |
| mean | 5.2 | 15.4 | 0.3 | 18.4 | 0.9 | | | | 1.7 | 2.1 | 4.8 | | | 88.8 | 3.2 |
| SD | 6.4 | | | 15.6 | | | | | 2.1 | 3.0 | 5.5 | | | 12.9 | 3.0 |

1) In some cases the actual crop was not specified. However, in all these cases in can be excluded that it concerns a vegetable.
2) If the position of the bird could not be assigned definitely, then this category was applied. However, in all these cases it could be excluded that the birds was located in a vegetable field.

**Table: Proportion of time yellow wagtails spent 'potentially foraging' in different habitats during 21 tracking sessions according to the "consumer" approach
A figure for the respective habitat is given only if PT > 0.**

| session no. | PT [%] | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | vegetable | | | | | | | Other crops | | | | | | |
| | onion | leek | carrot | lettuce | celery | red beet | radish | sugar beet | potato | cereal | bean | drilled field | Other (non-crop habitats) | Unknown (but not vegetable)[1] |
| 15 | | | | 1.7 | | | | | | 67.9 | | | 28.9 | 1.5 |
| 16 | | | | | | | | | | | | | 98.7 | 1.3 |
| 21 | 7.7 | | 48.2 | | | | | | | 27.0 | | | 17.2 | |
| 27 | 1.3 | | | 25.6 | | | | | 1.3 | | | | 71.8 | |
| 28 | | | | 7.7 | | | | | | 0.3 | | | 92.0 | |
| 29 | | | | 51.9 | | | | | | 0.3 | | | 47.8 | |
| 30 | | | | 12.8 | 0.4 | | 3.8 | 5.9 | 2.9 | | | | 74.2 | |
| 40 | | | | 17.3 | 0.1 | | | | 12.8 | 0.9 | | | 68.9 | |
| 42 | | | 8.7 | | | 83.1 | | | | 1.7 | | | 6.5 | |
| 43 | | | 79.5 | | | 15.1 | | | | | | | 5.3 | |
| 44 | | | | | | | | | 80.6 | | | | 19.4 | |
| 45 | | | | | 0.2 | | | | 68.8 | | | | 30.9 | |
| 46 | 45.6 | | 11.2 | | | 23.8 | | | | | | | 19.4 | |
| 50 | 3.4 | | | 9.6 | | | | | 79.7 | | | | 7.3 | |
| 51 | 3.5 | | | 39.0 | 2.8 | | | | 14.9 | | | | 39.8 | |
| 53 | | | | | 43.3 | | | | | 0.7 | | | 56.0 | |
| 54 | | | | 2.5 | 39.3 | | | | | 0.8 | | | 57.4 | |
| 59/62 | | 17.2 | | 14.0 | 6.8 | | | | 32.1 | | | | 29.9 | |
| 60 | | | | 33.8 | 51.3 | | | | 2.4 | | | | 12.4 | |
| 61 | | 14.7 | | 18.3 | 2.1 | | | | 25.9 | | | | 39.1 | |
| 64 | | | | 46.0 | 31.7 | | | | | | | | 22.3 | |
| n | 5 | 2 | 4 | 13 | 10 | 3 | 1 | 1 | 10 | 8 | 0 | 0 | 21 | 2 |
| 50%tile | 3.5 | 15.9 | 29.7 | 17.3 | 4.8 | 23.8 | 3.8 | 5.9 | 20.4 | 0.8 | | | 30.9 | 1.4 |
| 90%tile | 30.5 | 16.9 | 70.1 | 44.6 | 44.1 | 71.3 | 3.8 | 5.9 | 79.8 | 39.2 | | | 74.2 | 1.5 |
| mean | 12.3 | 15.9 | 36.9 | 21.6 | 17.8 | 40.7 | 3.8 | 5.9 | 32.1 | 12.4 | | | 40.2 | 1.4 |
| SD | 18.8 | 1.7 | 33.7 | 16.4 | 20.9 | 37.0 | | | 32.2 | 24.2 | | | 28.2 | 0.1 |

[1] If it the position of the bird could not be assigned definitely this category was applied. However, in all these cases it could be excluded that the birds was located in a vegetable field.

**Overview of PD in vegetable crops**

**Proportion of different food types in the diet (PD) (skylark and yellow wagtail)**
= invertebrate and plant items actually eaten by individuals foraging in and around vegetable fields [proportions of dry weight] or in the faeces (woodpigeon)

| Food type | | Habitat * | Skylark | Yellow wagtail | Woodpigeon |
|---|---|---|---|---|---|
| | | | **Deduced from 18 faeces samples** | **Deduced from 18 faeces samples** | **In 14 faeces samples** |
| Invertebrate matter | Arachnida | G, F | 0.048 | 0.039 | 0.0004 |
| | Diplopoda | G | 0.058 | - | 0.012 |
| | Coleoptera | G | 0.231 | 0.021 | 0.0014 |
| | Coleoptera larvae | G | - | 0.006 | - |
| | Heteroptera | G, F | 0.068 | 0.156 | - |
| | Homoptera | F | 0.014 | 0.067 | - |
| | Diptera | F (A) | 0.092 | 0.254 | - |
| | Hymenoptera | G, F (A) | 0.009 | 0.007 | 0.0007 |
| | Hymenoptera larvae | F | - | 0.003 | - |
| | Lepidoptera | F (A) | - | 0.006 | - |
| | Lepidoptera larvae | F | 0.025 | 0.027 | - |
| | Odonata | F (A) | - | 0.386 | - |
| | Dermaptera | F | 0.001 | - | - |
| | Other Insecta | G, F (A) | - | 0.01 | - |
| | Gastropoda | G | 0.019 | - | - |
| | Oligochaeta | G | 0.050 | - | 0.229 |
| | *TOTAL* | | *0.615* | *0.998* | *0.244* |
| Plant matter (seeds / leaves) | Caryophyllaceae | | 0.053 | | 0.044 / 0.171 |
| | Fabaceae | | | | 0.004 |
| | Poaceae | | 0.184 / 0.024 | 0.002 | 0.178 / 0.053 |
| | Polygonaceae | | 0.028 | - | - |
| | Ranunculaceae | | 0.004 | - | - |
| | Utricaceae | | 0.003 | - | - |
| | Asteraceae | | - | - | - / 0.002 |
| | Plantaginaceae | | - | - | - / 0.0004 |
| | Dicotyledonae | | 0.002 / 0.087 | - | 0.140 / 0.053 |
| | *TOTAL* | | *0.274 / 0.111* | *0.002* | *0.366 / 0.280* |
| Other plant | Bark | | - | - | 0.021 |
| Invertebrate habitat type | Foliage (Air) | | 0.174 (0.088) | 0.866 (0.653) | - |
| | Ground | | 0.230 | 0.017 | 0.242 |
| | Foliage, Ground | | 0.211 | 0.115 | 0.002 |

* G=ground, F=foliage, (A)=Air (foliage dwellers including insects with potential high flight activity),

**Conclusion:**

Overall this study provides reliable refined parameters of PT and PD for use in higher tier risk assessments for birds foraging in vegetable fields.

| Comments of zRMS: | The additional information wich was not used in the risk assessment. |
|---|---|

| Reference: | **KCP 10.1.1.2/16** |
|---|---|
| Title: | New proposed Residues on Fruits (RUD's) for frugivore scenarios in EFSA bird and mammal risk assessment |
| Report: | Hahne, J.; Schabacker, J.; Foudoulakis, M.; Ludwigs, J. D.; Murfitt, R.; Ristau, K.; 2019; M-665829-01-1 |
| Authority registration No: | |
| Guideline(s): | -- |
| Deviations: | -- |
| GLP/GEP: | not applicable |
| Acceptability: | |
| Duplication (if vertebrate study): | |

**Introduction**

The Guidance Document on Risk Assessment for Birds and Mammals (EFSA 2009) provides default 'Residue per unit dose' or RUD values for food items to be used in wildlife risk assessments. Most of these RUD values are based on large numbers of registration relevant residue studies conducted by industry members and provided to EFSA. However, RUD values for fruits were taken from Baril et al. (2005) and comprise only relatively few trials of unclear relevance for European regulatory purpose.

Therefore, field study data of fruit residue levels from applications of pesticides in different crops from five companies (ADAMA, BASF, Bayer, Corteva, FMC, Syngenta), all conducted during the last 20 years, were evaluated.

This comprehensive data set provides a solid basis for reviewing the registration relevant RUD values for fruits as diet items in wildlife risk assessments as given in the current EFSA (2009) Guidance Document.

**Material and methods**

From a large data set of residue field trials which were conducted in different climate zones throughout Europe, studies were selected based upon the following criteria:

- Studies providing residue values at appropriate fruit ripening stages on the day of application and shortly thereafter
- GLP-studies evaluated at EU member state level
- For 'grapes' and 'large fruits from orchards' trials with only 1 application were considered due to large dataset (N ≥ 100)
- For 'other berries', 'gourds', 'small fruits from orchards' and 'strawberries', studies with 1 to 4 application were used.

Analysis of data extrapolation

- Calculation of RUDs selecting the highest value after the last application (irrespective of the sampling time), including multiple applications
- Fruit groups showing different residue loads related to the same application rate (due to e.g. fruit type, texture of peel, leaf cover, climatic zones) were checked

**Results and Recommendations**

| Food item | Proposed RUD values for frugivore scenarios | | | Current default RUD values of EFSA (2009) GD | | |
|---|---|---|---|---|---|---|
| | Mean ± s.d. [mg/kg] | 90th percentile [mg/kg] | Number of trials | Mean ± s.d. [mg/kg] | 90th percentile [mg/kg] | N |
| Grapes | 1.6 ± 1.2 | 3.3 | 100 | 8.3 ± 7.2* | 16.7* | 9* |
| Berries[1] | 5.0 ± 3.6 | 9.2 | 180 | | | |
| Large fruits from orchards[2] | 0.9 ± 0.6 | 1.5 | 126 | 19.5 ± 16.8 | 41.1 | 33 |
| Gourds[3] | 0.7 ± 0.6 | 1.3 | 267 | 34.3 ± 54.7 | 61.5 | 19 |
| Small fruits from orchards[4] | 2.6 ± 1.4 | 4.3 | 126 | 3.3 ± 2.6 | 6.5 | 33 |
| Strawberries | 1.3 ± 1.4 | 2.3 | 143 | *Not given, substituted by values of berries* | | |

1. currants, raspberries and gooseberries; 2. apple, peach, pear, lemon, mandarin and orange; 3. pumpkins, cucumbers, squash and melons; 4. apricot, cherry, plum; * Grapes and berries taken together in the current GD

- The database for **'grapes'**, is the most homogeneous in terms of fruit type, development stage (all within BBCH 79 - 95) and number of applications (one).

• The database for 'grapes', is the most homogeneous in terms of fruit type, development stage (all within BBCH 79 - 95) and number of applications (one).
There is no significant difference between the data from Southern and Central Europe. Therefore it is proposed to derive one RUD for risk assessments.
• In the category 'large fruits from orchards', different fruits have been combined (apple, peach, pear, lemon, mandarin, orange (BBCH 75-88) as in EFSA (2009)). There are no differences between the different fruits or between Southern and Central Europe. One RUD for frugivorous scenarios seems appropriate.
• In the category 'gourds', pumpkins, cucumbers, squash and melons have been combined as in EFSA (2009). Here no difference in RUD values between round and elongated fruits was found, and the number of applications had no significant effect on the residue level measured. Comparing the results of the geographical sub-sets resulted in small but statistically significant differences in residue data from Central (0.5 mg/kg) and Southern Europe (0.7 mg/kg) (Mann-Whitney U Test P = <0.05). However, in order to define a single conservative value the mean and 90th percentile of the Southern data is proposed

as a new default RUD value.
• No difference was found between different berries (currants, raspberries, gooseberries). The number of applications and the geographical location had no
significant influence on the residue level. The RUD values of pooled data showed the highest level and largest standard deviation (though less than the
current value in EFSA (2009). Therefore, also here a new default RUD value is proposed.
• In the category of 'small fruits from orchards', different fruits have been combined (apricot, cherry, plum as per EFSA 2009). Residues of one or two
application studies do not differ as well as the location of the study showed no influence. Plums exhibited significantly lower residues (0.6 mg/kg) than
cherries and apricot (2.6 mg/kg). Therefore it may seem justified to give a separate value for plums. However, a single default value is proposed that covers
all small fruits for the lower Tier assessments.
• A separate RUD for strawberries is proposed here as a separate Tier 1 scenario for wildlife risk assessment. There were no significant differences in RUDs
following one or multiple applications or between Southern and Central Europe. So a single RUD value is given for this category.

**Regulatory Conclusion:**
The objective of this project was to investigate and derive robust residue levels in fruits determined under field conditions in different climatic zones in Europe
and in the course of a fruiting season. Based on a large and reliable dataset of £100 residue trials per 'fruit group' from studies evaluated and considered
valid at EU level significantly lower RUD's compared to the default RUD's (EFSA 2009) were found. These new RUD values are proposed as more relevant
and robust values than current defaults for use in bird and mammal risk assessments.

REFERENCES:

EFSA (2009) Guidance of EFSA - Risk assessment for birds and mammals on request of EFSA. EFSA Journal 7: 1438
Baril A., Whiteside M. and C. Boutin. 2005. Analysis of a database of pesticide residues on plants for wildlife risk assessment. Environmental Toxicology and Chemistry, Vol. 24. No. 2, pp. 360-371.
M-665829-

| | |
|---|---|
| Reference: | **KCP 10.1.1.2/17** |
| Title: | Kinetic evaluation of trifloxystrobin residues in lettuce to derive a foliar DT50 |
| Report: | Reinken, G.; Alt, F.; 2015; EnSa-15-0361; M-519770-01-1 |
| | |
| Guideline(s): | not applicable |
| Deviations: | not applicable |
| GLP/GEP: | no |
| | |
| Duplication (if vertebrate study): | |

This report provides a kinetic evaluation of residue data of trifloxystrobin in lettuce plant, as available from regulatory plant residue decline studies at European field conditions. Detailed results and model outputs are available in the report.
In Table 1 the single first-order (SFO) half-lives of trifloxystrobin derived in this evaluation are summarised.

**Table 1: Summary of foliar $DT_{50}$ values for trifloxystrobin after application on lettuce**

| **Trial code** | **Trial description** | **Crop** | **$DT_{50}$ [days]** |
|---|---|---|---|
| L01 | R 2002 0083/8 Spain | Lettuce | 3.83 |
| L02 | R 2002 0192/3 Italy | Lettuce | 4.49 |
| L03 | R 2002 0193/1 France | Lettuce | 2.12 |
| L04 | R 2002 0195/8 Portugal | Lettuce | 2.84 |
| L05 | 2043/00 Switzerland | Lettuce | 1.90 |

| | | | |
|---|---|---|---|
| L06 | R 2002 0084/6 Netherlands | Lettuce | 5.11 |
| L07 | R 2002 0196/6 Germany | Lettuce | 3.23 |
| L08 | R 2002 0197/4 UK | Lettuce | 3.98 |
| L09 | R 2002 0198/2 Netherlands | Lettuce | 4.06 |
| | | Minimum | 1.90 |
| | | Maximum | 5.11 |
| | | Geomean (N=9) | 3.35 |
| | | Median (N=9) | 3.83 |

The geomean $DT_{50}$ of 3.35 days is used in the refined risk assessment.

| | |
|---|---|
| Reference: | **KCP 10.1.1.2/18** |
| Title: | Feeding ecology of the relevant insectivorous bird species in strawberry fields in Germany |
| Report: | xxx |
| Authority registration No: | |
| Guideline(s): | not applicable; the test was especially designed for the purpose of this study |
| Deviations: | none |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication (if vertebrate study): | No |

| | |
|---|---|
| Reference: | **KCP 10.1.1.2/19** |
| Title: | Letter of access for generic behavioural ecology data - Study report R-20183 - Grouping: strawberry (foliar stages) - Author, year: Moosmayer P, 2006 |
| Report: | xxx |
| Authority registration No: | |
| Guideline(s): | -- |
| Deviations: | -- |
| GLP/GEP: | not applicable |
| Acceptability: | |
| Duplication (if vertebrate study): | No |

**Aim:**
The aim of this generic study was to obtain refined dietary estimates for two focal bird species (yellow wagtail and skylark) in strawberry fields that can be used as revised input data for the recalculation of toxicity-to-exposure ratios (TER) based on the risk of exposure due to foraging preferences.

**Objective:**

• to determine the proportion of diet obtained in strawberry fields (PT estimate) by radio tracking individual birds (including visual observations) based on the assumption that the time a bird spends 'active' or, more specifically, foraging in a habitat, is a reliable measure of the proportion of food obtained in this defined area
• to determine the proportion of different food types in the diet (PD estimates) by analysing faeces and/or stomach contents

Study area:

The study was conducted in two strawberry growing regions in Germany. One was located in North-Rhine Westphalia and one in Baden-Wurttemberg. The total study area was 512 ha including 66 strawberry fields with a total area of 148 ha. The chosen areas reflect typical strawberry field distribution patterns for Germany.

**Materials and methods:**

Thirteen yellow wagtails and 14 skylarks which were previously trapped and tagged were subsequently radio tracked. This radio tracking study was carried out during spring/early summer 2006 (tracking period 30th April to 13th of June 2006). The individual birds were continuously radio-tracked and simultaneously visually observed (combined radio tracking) for two non-consecutive whole daylight periods (exceptions were 3 skylarks and 3 yellow wagtails that were only tracked once).
From the radio tracking data and visual contact, the proportion of time foraging in strawberry fields (compared with the total potential foraging time) was estimated. These values were used for deriving the proportion of diet obtained from the treated area (PT). For the estimation of the proportion of different food types in the diet (PD), faeces (yellow wagtail), and faeces and stomach contents (skylark) were sampled and analysed. In order to calculate the proportion of dry weight, correction factors derived from the literature were applied to the number of arthropods and seeds recognised within the food samples. Estimations of the prey length provided insight into the food size selection of the birds. Length-weight regressions of invertebrates and seeds identified via the literature were used to calculate the proportion of dry weight of each food type in the diet actually ingested by the birds.

**Results and discussions:**

<u>PT values</u>
The combination of radio-tracking with visual appraisal and the trapping scheme as presented here, provided for an accurate and representative assessment of potential foraging times in given home ranges and consequently the calculation of reliable PT-values.
All birds were closely associated with strawberry fields and had the opportunity to use these fields as a foraging habitat. Therefore the results can be considered a worst case in terms of potential dietary exposure.
Based on the study results, the mean PT-value derived for skylarks living within or in close vicinity to strawberry fields in spring/summer was 0.73 (90th percentile = 0.99). The mean PT-value for yellow wagtails living within or in close vicinity to strawberry fields in spring/summer was 0.54 (90th percentile = 0.94). On average, skylarks spent about three quarters of their potentially foraging time within strawberry fields, whereas yellow wagtails spent around half of their potentially foraging time there. It is important to emphasize that these values represent the total potentially foraging time in strawberry fields. These values include times when birds may not actually be foraging but information is not available to exclude this possibility. Therefore, the calculated PT-values for both species can be regarded as a conservative assumption.

<u>PD values</u>
Invertebrates represented a higher proportion of the diet ingested by skylarks than plant seeds. With respect to single food items overall cereal seeds made up for 33% (PD = 0.33) of the dry weight proportion ingested and therefore represent the most important single food item in the diet of skylarks. Within the invertebrate taxa consumed, when considering dry weight insect adults (22.3% of total dry weight) were the most important.
Arthropods contribute the entire diet for yellow wagtails. Within the invertebrate taxa consumed, when considering dry weight, insect adults (72.8% of total dry weigh) were the most important.

**Conclusion:**

Overall this study provides reliable refined parameters (PT, PD) for use in higher tier risk assessment for birds foraging in strawberry fields.

**Table:** Overview of the PT and PD determined

| | **Proportion of diet obtained in strawberry fields determined by combined radio tracking (PT)** | |
|---|---|---|
| 'potential foraging' time in strawberry fields as a proportion of the total 'potential foraging' time equals the proportion of diet obtained | **skylark** based on 25 tracking sessions of 14 individuals | **yellow wagtail** based on 23 tracking sessions of 13 individuals |
| **50%tile** | 0.86 | 0.58 |
| **90%tile** | 0.99 | 0.94 |
| **mean** | 0.73 ± 0.33 | 0.54 ± 0.34 |

| | **Proportion of different food types in the diet (PD)** | | |
|---|---|---|---|
| invertebrate and plant items actually eaten by individuals foraging in and around strawberry fields [proportions of dry weight] | Food type | **skylark** based on 13 faeces and 5 flushing samples | **yellow wagtail** based on 25 faeces samples |
| **Invertebrate matter** | Insecta* (adult) | 0.223 | 0.728 |
| | Insecta* (larvae) | 0.155 | 0.139 |
| | Araneida | 0.041 | 0.117 |
| | Opiliones | - | 0.001 |
| | Isopoda | 0.007 | - |
| | Myriapoda | - | 0.018 |
| | Diplopoda | 0.013 | - |
| | Stylommatophora | 0.005 | - |
| | Lumbricidae | 0.123 | - |
| | *TOTAL* | *0.567* | *1* |
| **Plant matter** | Poaceae seeds (cereal) | 0.325 | - |
| | Poaceae seeds | 0.096 | - |
| | Euphorbiaceae seeds | 0.004 | - |
| | Small seeds (n.s.)[+] | 0.003 | - |
| | Brassica seeds | 0.002 | - |
| | Chenopodiaceae seeds | 0.001 | - |
| | Lamiaceae seeds | < 0.001 | - |
| | Ranunculaceae seeds | < 0.001 | - |
| | *TOTAL* | *0.433* | - |

| | **Proportion of different item length in the diet (PD)** | | |
|---|---|---|---|
| Length of food items actually eaten by individuals foraging in and around strawberry fields [proportions of dry weight] | **Size class [mm]** | **skylark °** based on 13 faeces and 5 flushing samples | **yellow wagtail** based on 25 faeces samples |
| **Length of food item** | **≤ 5** | 0.143 | 0.178 |
| | **> 5 – 10** | 0.508 | 0.434 |
| | **> 10 – 15** | 0.076 | 0.116 |
| | **> 15 – 20** | 0.151 | 0.272 |
| | **> 20** | 0.123 | - |

* Summarised values for all insect taxa / + n.s.: not specified / °Considering the total part of the skylark diet made up of arthropods, in terms of dry weight 19.73 % were below or equal to 5 mm and 80.27% were greater than 5 mm.

| | |
|---|---|
| Comments of zRMS: | **Comment on study; acceptable or not; deficiencies, corrections, according to recent guidelines or not, used in evaluation or only as additional information** |

| | |
|---|---|
| Reference: | **KCP 10.1.1.2/20** |
| Title: | Consolidation of bird and mammal PT data for use in risk assessment |
| Report: | xxx |
| Authority registration No: | |
| Guideline(s): | not applicable |
| Deviations: | not applicable |
| GLP/GEP: | not applicable |
| Acceptability: | |
| Duplication (if vertebrate study): | No |

**Public literature**

## A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

| | |
|---|---|
| Comments of zRMS: | Accepted. |

| | |
|---|---|
| Reference: | **KCP 10.1.2/01** |
| Title: | Technical stand-alone combined toxicity assessment for the Central zone |
| Report: | xxx |
| Authority registration No: | |
| Guideline(s): | none |
| Deviations: | -- |
| GLP/GEP: | not applicable |
| Acceptability: | |
| 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

| | |
|---|---|
| Comments of zRMS: | **The study by Reinken & Alt 2015 M-520275-01-1 was previously evaluated in the Registration Report for Luna Sensation by zRMS-NL, July 2018. The evaluation of this study is copied by zRMS PL from this report and presented below:**<br><br>**Methods:**<br>Study performed in accordance with relevant guidelines (OECD 307, FOCUS Kinetics, EFSA guidance, EFSA Guidance Document |

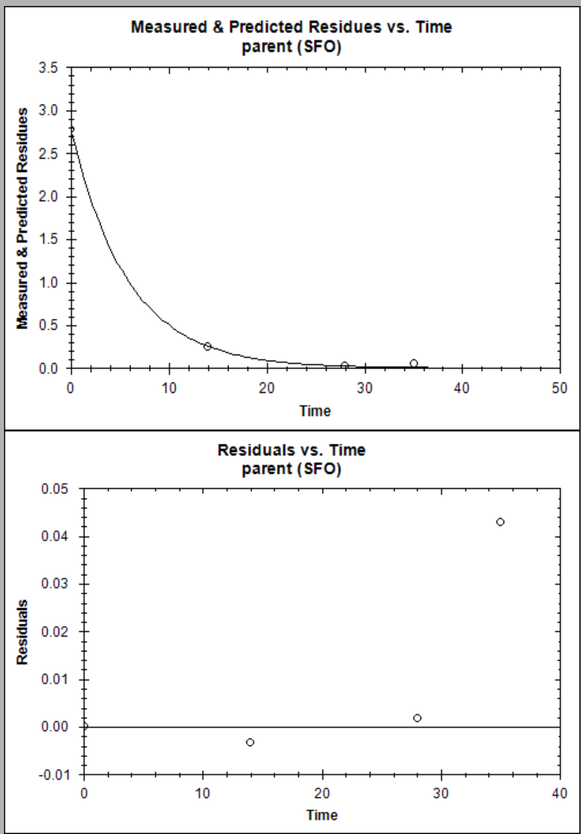
on Risk Assessment for Birds & Mammals (EFSA 2009)).

Study quality:
Three out of five datasets showed a low number of datapoints (3). This low number of datapoints introduces additional uncertainty into the results. Nevertheless, the statistical test and distribution of the residues is acceptable. Therefore, all trials were included.

Results:
Below, the fits as presented by the applicant in the report are shown. For each trial, it is marked whether the fit is considered acceptable or re-analysis by the evaluator is needed.

Trial C01:

Fits:



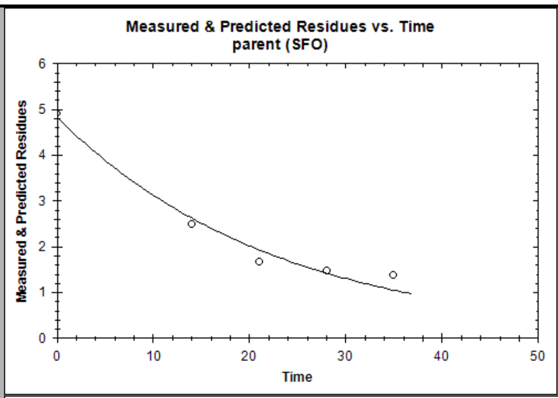

Statistics:
Chi^2: 2.274
Prob > t : 0.00123

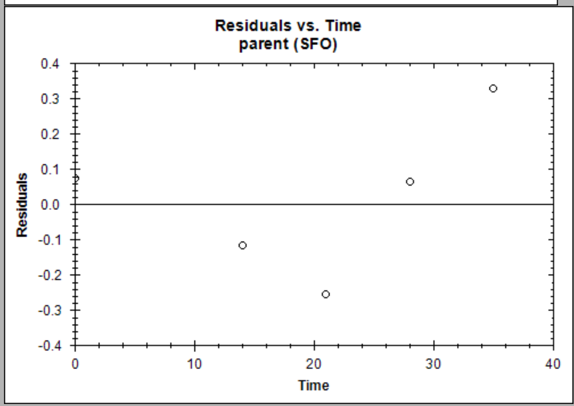
Discussion:
Visual fit is acceptable, slight deviation of last data point from average, but very low compared to total residue. Statistics are very good.

Acceptability: acceptable

Trial C02:

Fits:

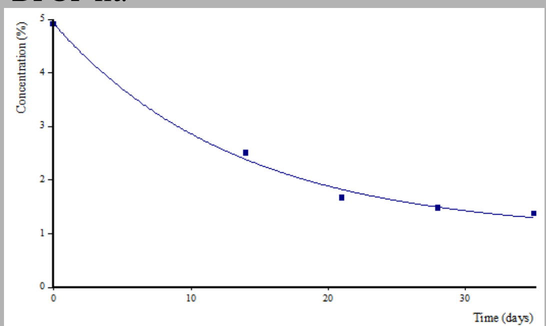


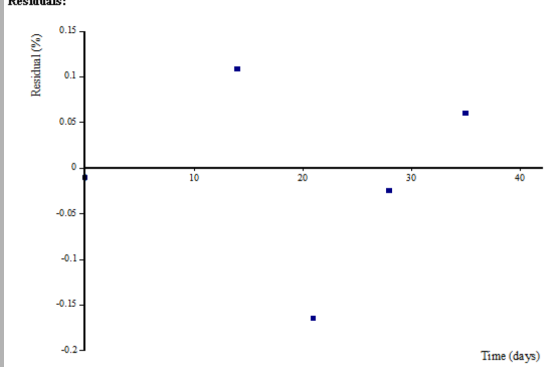

Statistics:
Chi^2: 6.638
Prob > t : 0.000856

Discussion SFO:
Visual fit and distribution of residues show biphasic degradation pattern. Although statistics are good, biphasic fits are presented by evaluator.

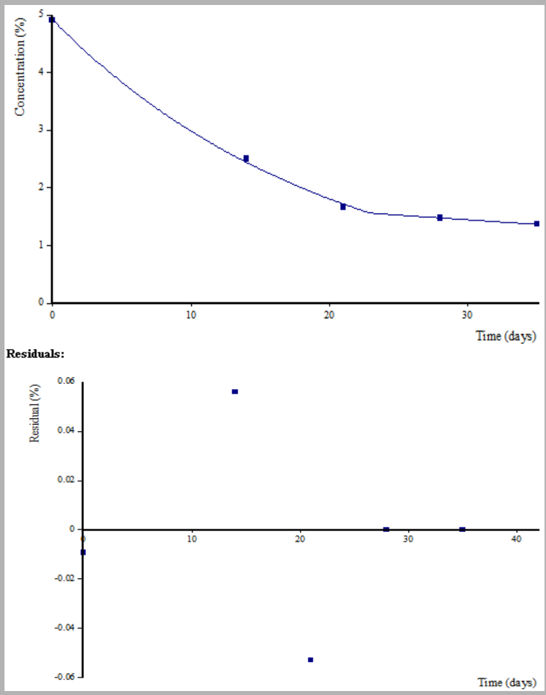
DFOP fit:




Residuals:



HS fit:

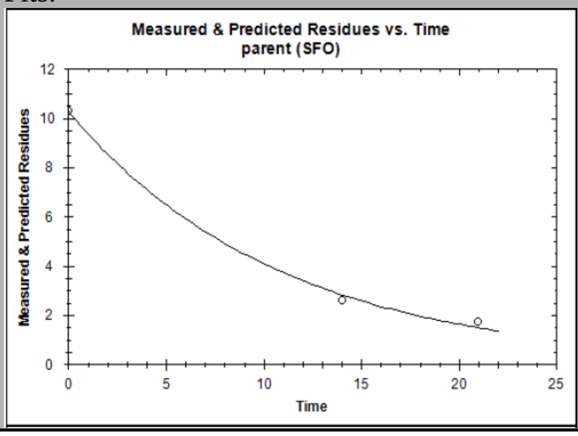


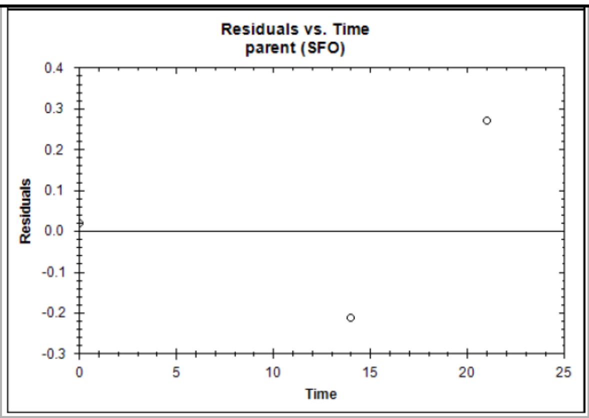

Discussion biphasic fits:
According to Fig 7-2 of FOCUS degradation kinetics HS and DFOP kinetic models could be applied as more than 10% of the initial residue concentration is present at the end of the trial. DFOP kinetics gives an improvement of the $Chi^2$, visual fit and distribution of the residues compared to SFO. The lowest $Chi^2$ and best visual fit and distribution of the residues was found for HS kinetics. However, because the Confidence interval of the $k_1$ and $k_2$ contain 0 for both fits, these fits cannot be accepted. Therefore, the SFO fit is proposed for modelling.

Acceptability: Although a biphasic degradation pattern appears more suitable for this trial, the statistical parameters and visual fits for SFO are considered to be sufficient. SFO fit is acceptable.

Trial C03:

Fits:





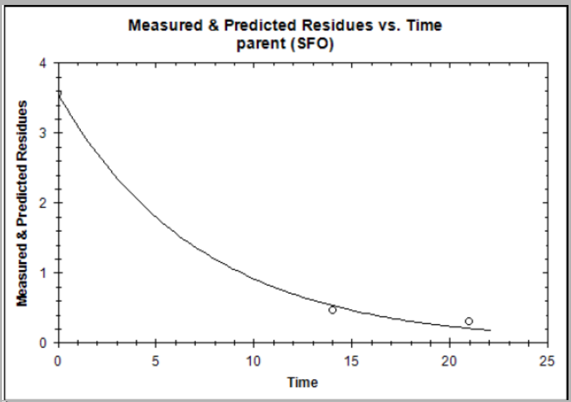

Statistics:
Chi^2: 3.602
Prob > t : 0.0247

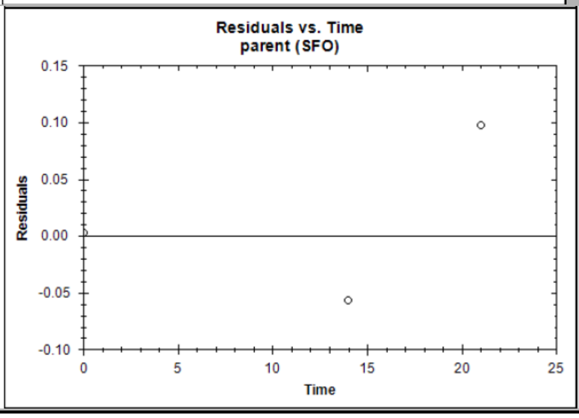
Discussion:
Low number of datapoints (3). Although the visual fit is acceptable and statistical parameters are acceptable (Prob >t < 5%), based on this data it cannot be excluded that the residue follows a biphasic decline pattern. Because the reported residues at days 14 and 21 are still ~ 20% of the initial concentration, it cannot be excluded that significant residues remains on the plant. Therefore, no acceptable fit is derived.

Acceptability:
no acceptable fit is derived.

Trial C04:

Fits:



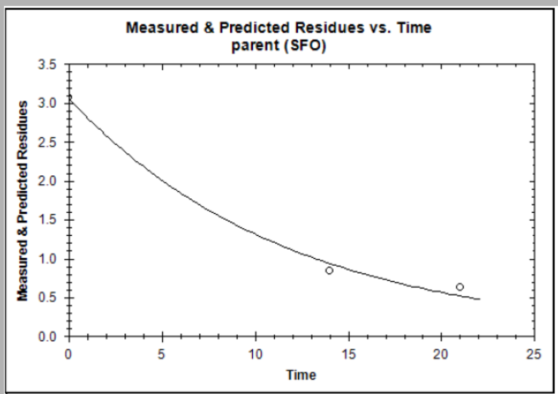
Statistics:
Chi^2: 3.983
Prob > t : 0.0312

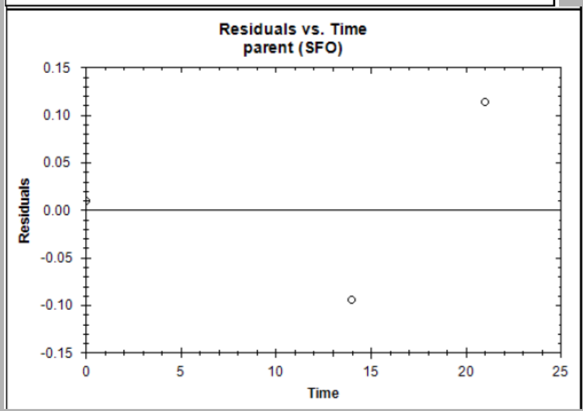
Discussion:
Low number of datapoints (3). Although the visual fit is acceptable and statistical parameters are acceptable (Prob >t < 5%), based on this data it cannot be excluded that the residue follows a biphasic decline pattern. However, the reported residues at day 21 are > 10% of the initial concentration. Therefore, the SFO fit is accepted.

Acceptability: SFO fit is acceptable

Trial C05:

Fits:




Statistics:
Chi^2: 4.993
Prob > t : 0.0345

Discussion:
Low number of datapoints (3). Although the visual fit is acceptable and statistical parameters are acceptable (Prob >t < 5%), based on this data it cannot be excluded that the residue follows a biphasic decline pattern. Because the reported residues at days 14 and 21 are still ~ 25% of the initial concentration, it cannot be excluded that significant residues remains on the plant. Therefore, no acceptable fit is derived.

Acceptability: SFO fit is acceptable

Summary of results:

The evaluator agrees with the conclusions of the applicant. Therefore, the final acceptable endpoints are taken from the study report and presented below:

| Trial code | Trial description | Crop | Number of data points | DT50 [days] | ε [%] |
|---|---|---|---|---|---|
| C01 | 2013/96 Switzer-land | Wheat | 4 | 4.05 | 2.3 |
| C02 | FR0196 UK | Winter Wheat | 5 | 15.80 | 6.6 |
| C03 | FR0796 Denmark | Winter Barley | 3 | not accep-table | |
| C04 | FR1096 Denmark | Winter Wheat | 3 | 5.08 | 4.0 |
| C05 | FR1196 Denmark | Winter Wheat | 3 | not accep-table | |
| Minimum | | | | 4.05 | |
| Maximum | | | | 15.80 | |
| Geomean (N=3) | | | | 6.88 | |
| Median (N=3) | | | | 8.31 | |

These data points may be combined with other data in order to show significant difference from the default value of 10 days. However, for the case these are not available, the data are compared by the evaluator to the default value of 10 days, using the EFSA DegT50 endpoint selector with a significance level of 5%, nor on a less strict significance level of 10% (see Appendix 1).
Based on this comparison it is concluded that the DT50 of trifloxystrobin on wheat does not significantly differ from the default value of 10 days. This fact, in combination with the uncertainty due to the low number of data points in three trials and the uncertainty in the SFO fit for trial C02 lead to the conclusion that no proposed DT50 can be recommended by the evaluator that deviates from the default value of 10 days.

Conclusion:

The trials are acceptable and the evaluator agrees with the proposed fits with a maximum, minimum and geomean DT50 of 15.8 days, 4.08 days and 7.25 days, respectively. However, there is some uncertainty in the SFO fit chosen for trial CO2. In addition, uncertainty is caused by a low number of data points (3) in trails C03, C04 and C05.
The proposed geomean DT50 value does not significantly deviate from the default value of 10 days.
Therefore, it is recommended not to change the default DT50 of 10 days based on this study.

**Agreed endpoint:**

**Endpoints from studies not recommended by zRMS-NL and was not used in the risk assessment by zRMS –PL.**

| | |
|---|---|
| Report: | KIIIA 10.3.2/01 Reinken, G., Alt, F.; 2015 |
| Title: | Kinetic evaluation of Trifloxystrobin residues in lettuce to derive a foliar DT50 |
| BCS Edition no. (report) | M-519770-01-1 (EnSa-15-0361) |
| Guidelines: | - |
| GLP/GEP | No |

This report provides a kinetic evaluation of residue data of trifloxystrobin in lettuce plant, as available from regulatory plant residue decline studies at European field conditions. Detailed results and model outputs are available in the report.
In Table 10.3.2- 1 the single first-order (SFO) half-lives of trifloxystrobin derived in this evaluation are summarised.

Table 10.3.2- 1: Summary of foliar $DT_{50}$ values for trifloxystrobin after application on lettuce

| Trial code | Trial description | Crop | DT50 [days] |
|---|---|---|---|
| L01 | R 2002 0083/8 Spain | Lettuce | 3.83 |
| L02 | R 2002 0192/3 Italy | Lettuce | 4.49 |
| L03 | R 2002 0193/1 France | Lettuce | 2.12 |
| L04 | R 2002 0195/8 Portugal | Lettuce | 2.84 |
| L05 | 2043/00 Switzerland | Lettuce | 1.90 |
| L06 | R 2002 0084/6 Netherlands | Lettuce | 5.11 |
| L07 | R 2002 0196/6 Germany | Lettuce | 3.23 |
| L08 | R 2002 0197/4 UK | Lettuce | 3.98 |
| L09 | R 2002 0198/2 Netherlands | Lettuce | 4.06 |
| | | Minimum | 1.90 |
| | | Maximum | 5.11 |
| | | Geomean (N=9) | 3.35 |
| | | Median (N=9) | 3.83 |

The geomean $DT_{50}$ of 3.35 days is used in the refined risk assessment.

**ZRMS comment:**

**NL comments from previously evaluated report for Luna Sensation 2018**
This report provides a kinetic evaluation of residue data of trifloxystrobin in lettuce plant, as available from the following plant residue decline studies at European field conditions

- Kissling, M. (2000): Residue study with CGA 279202 in or on cos lettuce in Switzerland. Novartis Crop Protection AG, Basel, Switzerland. Report Date: September 07, 2000., Study Report Number: 2043/00.
- Nuesslein, F. (2003a): Determination of residues of trifloxystrobin and CGA 321113 in/on lettuce following spray application of Flint 50 WG in the field in Spain, Italy, Southern France and Portugal. Bayer CropScience AG, Monheim, Germany. Report Date: April 28, 2003. Study Report Number: RA-2039/02.
- Nuesslein, F. (2003b): Determination of residues of trifloxystrobin and CGA 321113 in/on lettuce following spray application of Flint 50 WG in the Field in the Netherlands, Germany and Great Britain. Bayer CropScience AG, Monheim, Germany. Report Date: February 25, 2003. Study Report Number: RA-2040/02.

Detailed summaries of studies Kissling, M.,2000) and Nuesslein, F. (2003b) are available in Section 4: Metabolism and Residues (KIIIA 8.3.3/01 and KIIIA 8.3.3/02). Futhermore, these studies have been previously evaluated for setting/modification of MRLs for trifloxystrobin (Evaluation report trifloxistrobin-NL, rev3, prepared by EMS the

Netherlands, EFSA Scientific Report (2009) 273, 1-27). From a residues perspective the studies are acceptable.

The residue values for all acceptable studied residue trials are summarised in the table below.

| Study, Trial No., Trial SubID, GLP, Year | Portion analysed | DALT (days) | Trifloxystrobin (mg/kg) |
|---|---|---|---|
| L05<br>2043/00<br>SWZ-2043-00<br>GLP: yes<br>2000 | head | 0<br>3<br>7<br>14<br>14 | 6.7<br>2.3<br>0.43<br>0.02<br>0.03 |
| L06<br>RA-2040/02<br>R 2002 0084/6<br>0084-02<br>GLP: yes<br>2002 | head | 0<br>3<br>7<br>14 | 3.9<br>3.3<br>1.3<br>0.48 |
| L07<br>RA-2040/02<br>R 2002 0196/6<br>0196-02<br>GLP: yes<br>2002 | head | 0<br>3<br>7<br>14 | 3.6<br>2.1<br>0.61<br>0.23 |
| L08<br>RA-2040/02<br>R 2002 0197/4<br>0197-02<br>GLP: yes<br>2002 | head | 0<br>7<br>14 | 3.5<br>1.1<br>0.20 |
| L09<br>RA-2040/02<br>R 2002 0198/2<br>0198-02<br>GLP: yes<br>2002 | head | 0<br>7<br>14 | 4.4<br>1.2<br>0.61 |

| | |
|---|---|
| Report: | RA-2039/02 |
| Title: | Determination of Residues of Trifloxystrobin and CGA 321113 in/on Lettuce Following Spray Application of Flint 50 WG in the Field in Spain, Italy, Southern France and Portugal. |
| Guidelines: | Council Directive 91/414/EEC of July 15, 1991, Annex II, part A, point 6 and Annex III, part A, point 8 (Residues in or on Treated Products, Food and Feed) |
| GLP: | Yes |
| Acceptable: | Yes |

Four supervised field trials in Spain, Italy, Southern France, and Portugal were performed and the residues of trifloxystrobin in/on lettuce heads harvested after three spray applications (0.25 kg as/ha, 7 day intervals) with Flint 50 WG were evaluated. For residue analysis, lettuce heads were sampled from treated and untreated plots directly before the last application and on day 0, 3, 7, and 14 after the last application in two trials (R 2002 0083/8, Spain; R 2002 0192/3, Italy). In two other trials, samples were taken on day 0, 7, and 14 after the last application (R 2002 0193/1, France; R 2002 0195/8, Portugal). Samples were stored and analysed within the demonstrated storage stability period.

Residues of trifloxystrobin and metabolite CGA 321113 were determined according to method 00742. The LOQ in lettuce was 0.02 mg/kg for trifloxystrobin and CGA 321113 each. Procedural recoveries were within the 70-110 % range with RSD values <20%. No residues of trifloxystrobin or metabolite CGA 321113 were measured in the control samples. The analytical method is considered acceptable.

Residue levels of trifloxystrobin and metabolite CGA 321113 of the treated samples are presented in the table below. A reduction of trifloxystrobin and CGA 321113 was observed with prolonged PHIs.

| Trial No., country | Portion analysed | DALA1 | Residues [mg/kg] | |
|---|---|---|---|---|
| | | | Trifloxystrobin | CGA 321113 |
| R 2002 0083/8, Spain,L01 | Head | 0*<br>0<br>3<br>7<br>14 | 1.3<br>4.7<br>2.6<br>1.3<br>0.55 | 0.12<br>0.18<br>0.10<br>0.10<br>0.04 |
| R 2002 0192/3, Italy, L02 | Head | 0*<br>0<br>3<br>7<br>14 | 0.49<br>2.7<br>1.6<br>0.97<br>0.24 | 0.02<br>0.03<br>0.03<br><0.02<br><0.02 |
| R 2002 0193/1, Southern France, L03 | Head | 0<br>7<br>14 | 5.7<br>0.57<br>0.09 | 0.07<br>0.07<br><0.02 |
| R 2002 0195/8, Portugal, L04 | Head | 0<br>7<br>14 | 6.6<br>1.2<br>0.21 | 0.04<br>0.03<br><0.02 |

1 DALA: days after last application.
* Before the last treatment.

The study shows that the geometric mean DT50 for the dissipation of trifloxystrobin from lettuce plants in South, Central and West Europe is 3,34 days and is significantly different from the default value of 10 days. There is no reason to differentiate the DT50 between regions.

**Conclusion:**

**For the risk assessment $DT_{50}$=3.35 d was used for dicot plants in the ferined risk assessment**

| | |
|---|---|
| Reference: | **KCP 10.1.2.2/01** |
| Title: | Kinetic evaluation of trifloxystrobin residues in cereals to derive a foliar DT50 |
| Report: | Reinken, G.; Alt, F.; 2015; EnSa-15-0374; M-520275-01-1 |
| Authority registration No: | |
| Guideline(s): | not applicable |
| Deviations: | not applicable |
| GLP/GEP: | no |
| Acceptability: | |
| Duplication (if vertebrate study): | |

This report provides a kinetic evaluation of residue data of trifloxystrobin in cereals, as available from regulatory plant residue decline studies at European field conditions. Detailed results and model outputs are available in the report.
In the next table, the single first-order (SFO) half-lives of trifloxystrobin derived in this evaluation are summarised.

**Summary of foliar $DT_{50}$ values for trifloxystrobin after application on cereals**

| **Trial code** | **Trial description** | **Crop** | **$DT_{50}$ (days)** |
|---|---|---|---|
| C01 | 2013/96 Switzerland | Wheat | 4.05 |
| C02 | FR0196 UK | Winter Wheat | 15.80 |
| C03 | FR0796 Denmark | Winter Wheat | 7.51 |
| C04 | FR1096 Denmark | Winter Barley | 5.08 |
| C05 | FR1196 Denmark | Winter Wheat | 8.18 |
| | | Minimum | 4.05 |
| | | Maximum | 15.80 |
| | | Geomean (n=5) | 7.25 |
| | | Median (n=5) | 7.51 |

**Table 9.13-1: Evaluation of $DT_{50}$ for trifloxystrobin for monocot leaves**

| Trial code | Kinetic parameters | | | | | Ref. |
|---|---|---|---|---|---|---|
| | **Model** | **SFO: $DT_{50}$ (d) FOMC: alpha (-) DFOP: $DT_{50,fast}$ (d) HS: $DT_{50,fast}$ (d)** | **SFO: - FOMC: beta (-) DFOP: $DT_{50,slow}$ (d) HS: $DT_{50,slow}$ (d)** | **SFO: - FOMC: - DFOP: g (-) HS: $t_b$ (d)** | **$DT_{50,recalc}$ (d) [a)]** | |
| 2013/96 Switzerland | SFO | 4.05 | - | - | 4.05 | Appendix 2 Reinken & Alt 2015 M-520275-01-1 |
| FR0106 United Kingdom | SFO | 15.8 | - | - | 15.8 | |
| FR0796 Denmark | SFO | 7.51 | - | - | 7.51 | |
| FR1096 Denmark | SFO | 5.08 | - | - | 5.08 | |
| FR1196 Denmark | SFO | 8.18 | - | - | 8.18 | |
| 15-2953-01 France N | SFO | 2.22 | - | - | 2.22 | Appendix 2 Reinken & Kallweit 2019 M-659518-01-1 |
| 15-2953-02 UK | SFO | 5.36 | - | - | 5.36 | |
| 16-2951-01 France N | DFOP | 0.264 | 8.76 | 0.45829 | 6.42 [a)] | |
| 16-2951-02 Germany | SFO | 4.46 | - | - | 4.46 | |
| 16-2951-03 Belgium | SFO | 2.97 | - | - | 2.97 | |
| 16-2951-04 Germany | SFO | 4.93 | - | - | 4.93 | |
| 17-2950-01 Germany | SFO | 1.31 | - | - | 1.31 | |
| 17-2950-02 France N | FOMC | 1.16 | 0.3664 | - | 0.69 [a)] | |
| 17-2950-03 Netherlands | SFO | 1.97 | - | - | 1.97 | |
| 17-2950-04 Belgium | SFO | 1.04 | - | - | 1.04 | |
| **Geometric mean (n=15)** | | | | | **3.56** | |

[a)] $DT_{50,recalc} = DT_{90,trigger}$ / 3.32 (FOMC, DFOP); for SFO no recalculation needed

Using the moving time window, the refined $MAF_m$ and TWA factor for different application scenarios are presented in the following table.

**zRMS comment:**

The geomean $DT_{50}$ of 3.56 d for monocot plants value presented in the Table 9.3-57 above was not considered at the risk assessment by zRMS-PL.
The reason for this that it based on two studies which are considered as an unacceptable.

**zRMS comments:**

The Applicant submitted four new studies examining the decline of the residues of trifloxystrobin on crops cereals and another study report, in which the results obtained for that compound were subjected to the kinetic analysis aimed on the determination of $DT_{50}$ and $DT_{90}$ values characterising the dissipation of trifloxystrobin from crop plants (cereals).
The residue trials were presented in four study reports:
Study No. 15-2953 by [Glaubitz and Hennes; 2016];
Study No. 16-2955 by [Glaubitz and Hennes; 2017];
Study No. 16-2951 by [Schulte; 2017]; and
Study No. 17-2950 by [Van Berkum; 2018]

However, the summaries of this studies are not included in dRR Section Ecotoxicology and in dRR Section Residues.

The careful analysis of the study report showed the following issues that may be considered problems, deficiencies or deviations from the reference Guidelines:

- In all four studies were used four different formulations, containing more than one active substance: fluopyram and trifloxystobin in study No. 15-2953, prothioconazole and trifloxystrobin in studies No. 16-2951 and No. 16-2955, and phothioconazole, spiroxamine and trifloxystrobin in study 17-2950;
- The target application rates of trifloxystrobin were different in all four studies: 200 g/ha in study No. 15-2953, 150 g/ha in study No. 16-2955, 150 g/ha in study No. 162951 and 120 g/ha in study No. 17-2950;
- In none of the study reports was provided the information on the verification of the application rate of trifloxystrobin – the measured field application rate;
- It was noticed that the samples were stored deep-frozen for more than 200 days before the analysis of the content of trifloxystrobin: between 355 and 393 days in case of study No. 15-2953, between 329 and 395 days in case of study No. 16-2955, between 445 and 534 days in case of the study No. 16-2951, and between 238 and 322 days in case of the study No. 17-2950;
- The acknowledged, evaluated and validate analytical methods were used in all four studies, however, while in studies No. 15-2953, 16-2955 and 17-2950 was used the method 01313/M001, developed specifically for trifloxystrobin and its degradation products, in study No. 16-2951 was used the method 01013, developed for prothioconazole;

All that taken into account zRMS is of the opinion that the studies may be considered as reliable studies when:

- the information on the true application rates is provided alongside that on the intended application rates;
- the information on the storage stability of the residues of trifloxystrobin in the plant material stored deep-frozen for a long time is provided (preferably in form of the relevant study reports);
- the reasons for changing of the analytical method in the study No. 16-2951 are provided with the evaluation of the possible influence of that change on the reliability of the results obtained for trifloxystrobin.

Additionally zRMS is of the opinion that the relevance of the four above studies for the present evaluation should be discussed, with special emphasis on the differences in used formulations and different, lower than proposed in the GAP for this evaluation, application rates – the Applicant is kindly asked for providing such rationale, subsequently evaluated at peer-review.

In case of the kinetic analysis presented separately in the study report No. EnSa-19-008 by [Reinken and Kallweit; 2019] zRMS stated that:

1) the kinetic analysis was performed correctly from the methodological point of view and the data sets were assigned correctly and processed in line with recommendations of the FOCUS Work Group on the Degradation Kinetics;
2) the thorough examination of the provided kinetic fits showed that as acceptable can be considered the following fits:

- SFO fit for the trial 15-2953-01, France;
- SFO fit for the trial 15-2953-02, UK
- SFO fit for the trial 15-2953-03, Italy;
- SFO fit for the trial 16-2955-01 France;
- SFO fit for the trial 16-2955-02, Spain;
- SFO fit for the trial 16-2955-03, Greece;
- SFO fit for the trial 16-2951-02, Germany;

- SFO fit for the trial 16-2951-03, Belgium;
- SFO fit for the trial 16-2951-04, Germany;
- SFO fit for the trial 172950-01, Germany (with zRMS's recommendation to check whether improvement of the fitting results may be obtained with any of the available bi-phasic fits);
- SFO fit 17-2950-03, Netherlands for the whole data set;
- SFO fit 17-2950-04, Belgium for the whole data set (with zRMS's recommendation to check whether improvement of the fitting results may be obtained with any of the available bi-phasic fits);
- In case of the trial 16-2951-01, France, zRMS agrees with the Applicant's statement that bi-phasic models provide better fits, but disagrees that DFOP is appropriate, due to the fact that it does not return fully reliable kinetic parameters; therefore HS fit, also provided by the Applicant, should be used here, being visually and statistically better then DFOP and providing fully reliable set of kinetic parameters;
- In case of the trial 15-2953-04, Greece the conclusion drawn by the Applicant is correct and fully supported by the results of the fitting

3) zRMS noticed that in case of several trials, namely 16-2955-01 Italy, 16-2951-01 France, 17-2950-02 North France, 17-2950-03 03 the Netherlands and 17-2950-04 Belgium, some data points were discarded from the data set as a refinement in the kinetic analysis; that was done without explanation why those points were removed from the repeated kinetic analysis and Applicant is kindly requested to provide such justifications;
4) zRMS cannot agree with Applicant's proposal to adjust the DAT 0 point to the first remaining point when the real DAT 0 point, in case of trials: 16-2951-01 France, 17-2950-03 the Netherlands, because that would influence (shorten) the rate constant and the resulting kinetic endpoints – $DT_{50}$ and $DT_{90}$, same applies to the similar approach used in case of the trial 17-2950-02 North France for the time points DAT0 – DAT2;
5) Not acceptable are the following fits:

- FOMC fit for the trial 17-2950-02 North France because one of the kinetic parameters - β, lacks reliability (its CI contains zero); at the same time zRMS would recommend to the Applicant to check two other bi-phasic modes, before it is stated that for this trial no reliable kinetic fit could be found;
- SFO kinetic fit for the trial 17-2950-04 Belgium with the modified data set (with data points DAT 3, DAT 5, DAT 7 and DAT 11 excluded) – the modified data base contains only three points rendering the fit highly uncertain (and hence of limited reliability)

The kinetic analysis amended in line with the above recommendations may be considered acceptable provided that the source studies are found acceptable and reliable as regulatory studies (at present they are conditionally acceptable).
Also taken into consideration should be the relevance of the trials performed in Southern Europe (Spain, Greece and possibly Italy) for the present assessment.

**Applicant's comment during Commenting period:**

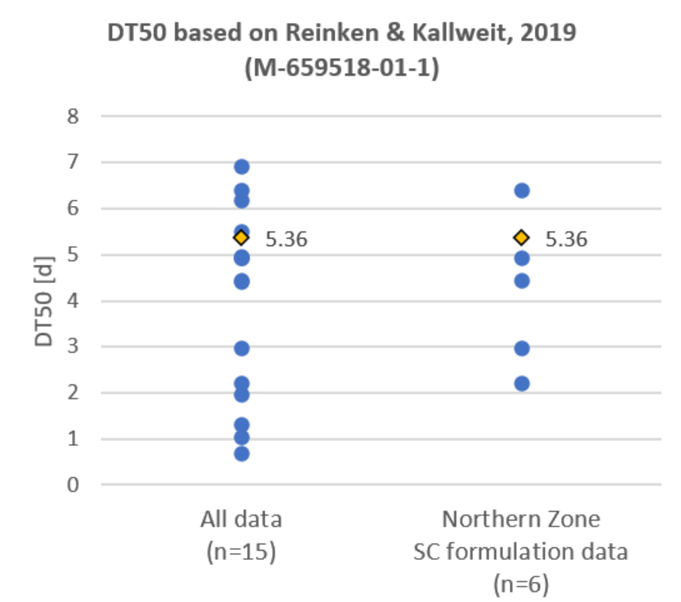
zRMS does not agree with the refined twa and MAF for trifloxystrobin based on a DT50=3.56 for monocots derived from Reinken & Alt (2015; M-520275-01-1) and Reinken & Kallweit (2019; M-659518-01-1) as these studies are considered unacceptable by the zRMS.
The specified issues that are considered problems, deficiencies or deviations by the zRMS are addressed in the following:

1. "In all four studies were used four different formulations, containing more than one active substance."

For this issue, the applicant provides below an overview of all measured DT50 values from Reinken & Kallweit 2019 (M-659518-01-1) including data from the Southern residue zone as well as data from the EC formulation (PTZ+SPX+TFS EC 280) in comparison to data only from the Northern residue zone and SC formulations (PTZ+TFS SC 325 and FLU+TFS SC 500). The comparison shows that DT50 values of the investigated SC formulations tend to show lower variability than the complete data set including also the Southern residue zone data and the EC formulation data.

SC formulation data show that a DT50 value of 5.36 d would represent a conservative approach as on the one hand it represents the second highest DT50 value of all Northern residue zone data. On the other hand, it is the highest measured DT50 value of the formulation under assessment, FLU+TFS SC 500. Further, it is higher than 10 out of 14 of all investigated DT50 values. Though, three out of the remaining 4 values represent Southern Zone data points.

Based on this evaluation, the applicant proposes to use a trifloxystrobin DT50 of 5.36 d for the higher tier refinement for monocots for all relevant vole scenarios leading to the exemplary calculated TER values presented in the table below.

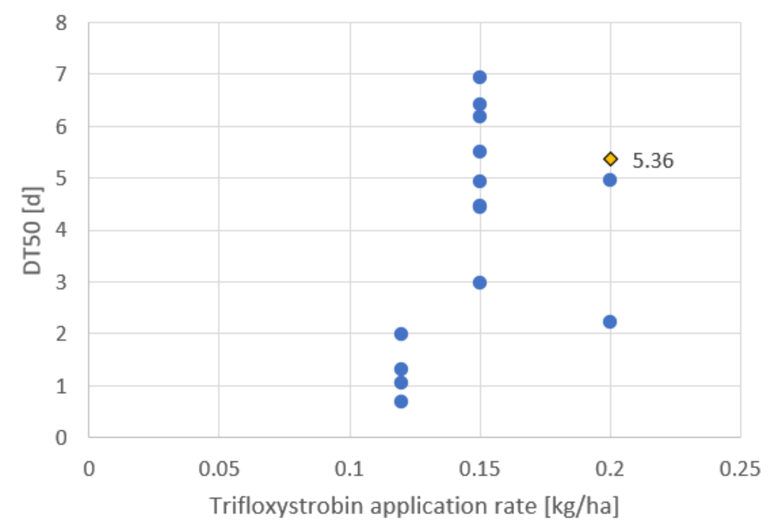



| Group | $TER_{mix}$ according to zRMS | $TER_{mix}$ with a DT50=5.36 d |
|---|---|---|
| A | 1.50 | 1.6 |
| D | BBCH 20-39, 7d: 2.94<br>BBCH 40, 7d: **4.78** | BBCH >10, 7d: 2.65<br>BBCH 20-39, 7d: 3.18<br>BBCH >40, 7d: **5.20**<br><br>BBCH >10, 14d: 2.9<br>BBCH 20-39, 14d: 3.5 |
| F | 3.70 | BBCH >40, 7d: 3.98<br>BBCH >40, 14d: 4.39 |
| I | BBCH 40-49: 1.42<br>BBCH >50: **4.76** | BBCH 40-49, 7d: 1.59<br>BBCH >50, 7d: **5.3**<br><br>BBCH 40-49, 7d 0.150 kg/h: 2.12<br>BBCH 40-49, 14d, 0.150 kg/ha: 2.34 |
| J | BBCH 40-49: 2.94<br>BBCH >50: 8.47 | BBCH 40-49: 3.05 |
| K | BBCH 10-29: 2.32<br>BBCH >30: 5.10 | BBCH <30: 3.05 |
| M | BBCH >10:1.81<br>BBCH >20:2.5<br>BBCH >40: **4.78** | BBCH 10-19, 7d: 1.99<br>BBCH 20-40, 7d: 2.65<br>BBCH >40, 7d: **5.3** |
| N | BBCH >10: 2.70<br>BBCH >20: 3.57<br>BBCH >40: **7.14** | BBCH 10-19, 7d: 2.92<br><br>BBCH 20-40, 7d: 3.9 |

| | | |
|---|---|---|
| O | 4.35 | BBCH >40: **5.08** |
| P | 5x: 4.34<br>2x: **6.25** | BBCH >40, 7d: 4.46 |

2. "The target application rates of trifloxystrobin were different in all four studies"

The applicant provides below a graph representing all DT50 data from Reinken & Kallweit 2019 (M-659518-01-1) versus the target trifloxystrobin application rates. There is no apparent correlation between the DT50 and the application rate ($R^2$ = 0.19). Therefore, the applicant considers that there is no influence of the application rate on the DT50 and thus, the different applications rates do not seem to be an issue.




3. "In none of the study reports was provided the information on the verification of the application rate of trifloxystrobin – the measured field application rate"

All studies included in Reinken & Kallweit 2019 (M-659518-01-1) provide information that the measured application rates were within + 5% of the planned rates (s. Glaubitz and Hennes, 2016: M-566828-01-1, Glaubitz and Hennes, 2017: M-595043-01-1, Schulte, 2017: M-609766-01-1, Schulte, 2017: M-609766-01-1). Therefore, it is assumed that the differences between the planned and the actual application rates do not have a significant effect on the DT50 values.

If the ZRMS would like to have a deeper look to our new of DT50 from Reinken Reinken & Kallweit evaluation we can offer to provide on request the following supportive study summary:
Study No. 15-2953 by [Glaubitz and Hennes; 2016];
Study No. 16-2955 by [Glaubitz and Hennes; 2017];
Study No. 16-2951 by [Schulte; 2017]; and
Study No. 17-2950 by [Van Berkum; 2018]

4. "It was noticed that the samples were stored deep-frozen for more than 200 days before the analysis of the content of trifloxystrobin"

The freezer stability of trifloxystrobin in plant commodities (bean dry seed, corn green material, rye gain, rape seed and orange fruit) was examined by Schulte & Diehl (2013; M-468560-04-1, submitted with this commenting table) for about 730 days. In this study, it is described that trifloxystrobin is stable over a deep-freezer storage period of about 24 months.Therefore, it can be considered that the storage of samples for more than 200 days does not affect the determined residues significantly.

5. "The acknowledged, evaluated and validate analytical methods were used in all four studies, however, while in studies No. 15-2953, 16-2955 and 17-2950 was used the method 01313/M001, developed

specifically for trifloxystrobin and its degradation products, in study No. 16-2951 was used the method 01013, developed for prothioconazole "

The target residue definition in study 16-2951 (method 01013) essentially differs from the other studies (method 01313/M001). Since in study 16-2951, only the parent molecules, i.e. trifloxystrobin and prothioconazole, were analyzed, both actives could be analyzed using the same analyte group. In the other studies, next to the parent molecules, also several isomers were analyzed. Due to this reason, method 01013 could not be used in these studies and method 01313/M001 had to be applied. However, this difference does not have an effect on the validity, quality or reliability of the residue analysis.

Overall, a DT50 of 5.36 d would represent a conservative approach to refine the assessed scenarios as this value considers the correct formulation type with an application rate of 0.200 kg/ha and Northern residue zone data.

6. Kinetic analysis

In the following, the zRMS comments regarding the kinetic analysis of report No. EnSa-19-0088 by Reinken and Kallweit, 2019 are discussed:

Acceptable fits with recommendations from zRMS:

- *SFO fit for the trial 172950-01, Germany (with zRMS's recommendation to check whether improvement of the fitting results may be obtained with any of the available bi-phasic fits)*
- *SFO fit 17-2950-04, Belgium for the whole data set (with zRMS's recommendation to check whether improvement of the fitting results may be obtained with any of the available bi-phasic fits)*

The presented SFO fits are from the applicants´ point of view all acceptable based on the presented statistical evaluation. Additional kinetic evaluations would be needed to in order to check in detail if a bi-phasic model may provide a more suitable fit. The parameter uncertainty would need to be carefully considered as bi-phasic model may provide a visually better fit but with increased uncertainty.

- *In case of the trial 16-2951-01, France, zRMS agrees with the Applicant's statement that bi-phasic models provide better fits, but disagrees that DFOP is appropriate, due to the fact that it does not return fully reliable kinetic parameters; therefore HS fit, also provided by the Applicant, should be used here, being visually and statistically better then DFOP and providing fully reliable set of kinetic parameters*

HS may be selected instead of DFOP (only minor difference in the statistical and visual evaluation).

- *zRMS noticed that in case of several trials, namely 16-2955-01 Italy, 16-2951-01 France, 17-2950-02 North France, 17-2950-03 03 the Netherlands and 17-2950-04 Belgium, some data points were discarded from the data set as a refinement in the kinetic analysis; that was done without explanation why those points were removed from the repeated kinetic analysis and Applicant is kindly requested to provide such justifications*

Additional fits were conducted for some trials excluding data points when the initial fits clearly showed a potential influence by rainfall events, e.g. a sudden drop in residue concentrations. The applicants´ proposal would be to exclude the effect of heavy rainfall events for the derivation of a residue decline DT50. This should be a conservative approach. The report includes always both fits (all data, reduced data).

- *zRMS cannot agree with Applicant's proposal to adjust the DAT 0 point to the first remaining point when the real DAT 0 point, in case of trials: 16-2951-01 France, 17-2950-03 the Netherlands, because that would influence (shorten) the rate constant and the resulting kinetic endpoints – DT50 and DT90, same applies to the similar approach used in case of the trial 17-2950-02 North France for the time points DAT0 – DAT2*

DAT 0 residues were never adjusted but for some fits excluded as alternative refinement fit. But it should be noted that the time scale of these fits was adjusted in such a way that the first considered residue day represents always day zero for the fit.

The following fits were not accepted:

- *FOMC fit for the trial 17-2950-02 North France because one of the kinetic parameters - β, lacks* *reliability (its CI contains zero); at the same time zRMS would recommend to the Applicant to check two other bi-phasic modes, before it is stated that for this trial no reliable kinetic fit could be found*

Agreed, the kinetic parameters beta of the FOMC lacks some reliability. Could be checked against additional bi-phasic fits.

- *SFO kinetic fit for the trial 17-2950-04 Belgium with the modified data set (with data points DAT 3, DAT 5, DAT 7 and DAT 11 excluded) – the modified data base contains only three points rendering the fit highly uncertain (and hence of limited reliability)*

Agreed, the fit with reduced data (excluding DAT 3, DAT 5, DAT 7 and DAT 11) may be not considered as it is based on 3 data points only. The statistical evaluation of the fit itself is looking OK

**zRMS comment:**

No further action taken. The studies summary which was used to refine $DT_{50}$ for monocot should be provided in updated RR, B9 and also the in dRR, B6 to evaluate the analytical methods used.

At this stage of the assessment the defult value od $DT_{50}$ TFS for monoct plants are 10 days.

| Reference: | **KCP 10.1.2.2/02** |
|---|---|
| Title: | Trifloxystrobin (TFS) - Kinetic evaluation of residue dissipation after application on wheat |
| Report: | Reinken, G.; Kallweit, W.; 2019; EnSa-19-0088; M-659518-01-1 |
| Authority registration No: | |
| Guideline(s): | none |
| Deviations: | none |
| GLP/GEP: | no |
| Acceptability: | |
| Duplication (if vertebrate study): | |

This statement provides kinetic evaluation of the residues of trifloxystrobin in the green material of wheat that may represent food items for leaf-eating herbivorous birds or mammals. Detailed model outputs are shown in the Appendix of the report.

The model fits as well as the statistical evaluation of the results were carried out with the in-house developed software KinGUI, version 2.1.

The results of the fitting procedure for all residue trials with residues of trifloxystrobin and the selection of the best fit models are summarised in Table 2 for evaluation including total residues and in Table 3 for evaluation where a potential precipitation impact has been excluded.

**Table 2: Final dissipation parameters of trifloxystrobin in wheat (total residues)**

| **Trial code** | **Kinetic parameters** | | | | |
|---|---|---|---|---|---|
| | **Model** | **SFO: $DT_{50}$ (d)**<br>**FOMC: alpha (-)**<br>**DFOP: $DT_{50,fast}$ (d)**<br>**HS: $DT_{50,fast}$ (d)** | **SFO: -**<br>**FOMC: beta (-)**<br>**DFOP: $DT_{50,slow}$ (d)**<br>**HS: $DT_{50,slow'}$(d)** | **SFO: -**<br>**FOMC: -**<br>**DFOP: g (-)**<br>**HS: $t_b$ (d)** | **$DT_{50,recalc}$ (d) a)** |
| 15-2953-01, France | SFO | 2.22 | - | - | 2.22 |
| 15-2953-02, United Kingdom | SFO | 5.36 | - | - | 5.36 |
| 15-2953-03, Italy | SFO | 4.96 | - | - | 4.96 |
| 15-2953-04, Greece a) | SFO | n.r. | - | - | n.r. |
| 16-2955-01, France | SFO | 6.93 | - | - | 6.93 |
| 16-2955-02, Spain | SFO | 5.50 | - | - | 5.50 |
| 16-2955-03, Italy | SFO | 6.18 | - | - | 6.18 |

| | | | | | |
|---|---|---|---|---|---|
| 16-2955-04, Greece | SFO | 4.42 | - | - | 4.42 |
| 16-2951-01, France | DFOP | 0.264 | 8.76 | 0.45829 | 6.42 |
| 16-2951-02, Germany | SFO | 4.46 | - | - | 4.46 |
| 16-2951-03, Belgium | SFO | 2.97 | - | - | 2.97 |
| 16-2951-04, Germany | SFO | 4.93 | - | - | 4.93 |
| 17-2950-01, Germany | SFO | 1.31 | - | - | 1.31 |
| 17-2950-02, Northern France | FOMC | 1.16 | 0.3664 | - | 0.6928 |
| 17-2950-03, Netherlands | SFO | 1.97 | - | - | 1.97 |
| 17-2950-04, Belgium | SFO | 1.04 | - | - | 1.04 |
| **Geometric mean (n=15)** | | | | | **3.25** |

[a)] $DT_{50,recalc} = DT_{90,trigger} / 3.32$ (FOMC, DFOP, HS); for SFO no recalculation needed

The results of the fitting procedure for all residue trials with residues of trifloxystrobin without a potential precipitation impact and the selection of the best fit models are summarised in Table 3.

**Table 3: Final dissipation parameters of trifloxystrobin in wheat (without precipitation impact)**

| **Trial code** | **Kinetic parameters** | | | |
|---|---|---|---|---|
| | **Model** | **SFO: $DT_{50}$ (d)**<br>**FOMC: alpha (-)**<br>**DFOP: $DT_{50,fast}$ (d)**<br>**HS: $DT_{50,fast}$ (d)** | **SFO: -**<br>**FOMC: beta (-)**<br>**DFOP: $DT_{50,slow}$ (d)**<br>**HS: $DT_{50,slow}$'(d)** | **SFO: -**<br>**FOMC: -**<br>**DFOP: g (-)**<br>**HS: $t_b$ (d)** |
| 15-2953-01, France | SFO | 2.22 | - | - |
| 15-2953-02, United Kingdom | SFO | 5.36 | - | - |
| 15-2953-03, Italy | SFO | 4.96 | - | - |
| 15-2953-04, Greece[a)] | SFO | n.r. | - | - |
| 16-2955-01, France | SFO | 6.93 | - | - |
| 16-2955-02, Spain | SFO | 5.50 | - | - |
| 16-2955-03, Italy | SFO | 9.44 | - | - |
| 16-2955-04, Greece | SFO | 4.42 | - | - |
| 16-2951-01, France | SFO | 8.09 | - | - |
| 16-2951-02, Germany | SFO | 4.46 | - | - |
| 16-2951-03, Belgium | SFO | 2.97 | - | - |
| 16-2951-04, Germany | SFO | 4.93 | - | - |
| 17-2950-01, Germany | SFO | 1.31 | - | - |
| 17-2950-02, Northern France | SFO | 3.61 | - | - |
| 17-2950-03, Netherlands | SFO | 2.80 | - | - |
| 17-2950-04, Belgium | SFO | 1.20 | - | - |
| **Geometric mean (n=15)** | | **3.92** | | |

[a)] Samples probably mixed up in the field (Glaubitz and Hennes 2016), therefore not evaluable

| | |
|---|---|
| Comments of zRMS: | The study previously evaluated in the Registration Report for Luna Sensation, July 2018 by zRMS-NL.<br>**Agreed endpoint:**<br><br>$DT_{50}$=3.35 d in lettuce is considered accepteable by zRMS- NL and zRMS-PL |

| | |
|---|---|
| Reference: | **KCP 10.1.2.2/03** |
| Title: | Kinetic evaluation of trifloxystrobin residues in lettuce to derive a foliar DT50 |
| Report: | Reinken, G.; Alt, F.; 2015; EnSa-15-0361; M-519770-01-1 |
| Authority registration No: | |
| Guideline(s): | not applicable |
| Deviations: | not applicable |
| GLP/GEP: | no |
| Acceptability: | |
| Duplication (if vertebrate study): | |

This report provides a kinetic evaluation of residue data of trifloxystrobin in lettuce plant, as available from regulatory plant residue decline studies at European field conditions. Detailed results and model outputs are available in the report.
In Table 1 the single first-order (SFO) half-lives of trifloxystrobin derived in this evaluation are summarised.

**Table 1: Summary of foliar $DT_{50}$ values for trifloxystrobin after application on lettuce**

| Trial code | Trial description | Crop | $DT_{50}$ [days] |
|---|---|---|---|
| L01 | R 2002 0083/8 Spain | Lettuce | 3.83 |
| L02 | R 2002 0192/3 Italy | Lettuce | 4.49 |
| L03 | R 2002 0193/1 France | Lettuce | 2.12 |
| L04 | R 2002 0195/8 Portugal | Lettuce | 2.84 |
| L05 | 2043/00 Switzerland | Lettuce | 1.90 |
| L06 | R 2002 0084/6 Netherlands | Lettuce | 5.11 |
| L07 | R 2002 0196/6 Germany | Lettuce | 3.23 |
| L08 | R 2002 0197/4 UK | Lettuce | 3.98 |
| L09 | R 2002 0198/2 Netherlands | Lettuce | 4.06 |
| | | Minimum | 1.90 |
| | | Maximum | 5.11 |
| | | Geomean (N=9) | 3.35 |
| | | Median (N=9) | 3.83 |

The geomean $DT_{50}$ of 3.35 days is used in the refined risk assessment.

| | |
|---|---|
| Comments of zRMS: | The study previously evaluated for the product Luna Sensation, july 2018 by zRMS.<br>**The evaluation provided by zRMS-NL is copied and presented below:**<br><br>„This study was submitted to and evaluated by zRMS (NL) for a previous national authorization of Luna Privilege (13832 N).<br>Certain cabbage fields used one common control surrounding. This is acceptable in case this common surrounding is within close proximity of all of the cabbage fields concerned. This was the case for Gäuboden 6/7/8 and Rhineland 8/9 control surrounding. Rhineland 1/5 control surrounding however was located close to Rhineland cabbage plot 1, but not close to Rhineland cabbage plot 5 (2 fields in between Rhineland 1/5 surrounding and Rhineland cabbage plot 5). Dithmarschen 1/2/3 control surrounding was located close to Dithmarschen cabbage plot 2, but not to Dithmarschen cabbage plot 1 and 3 (1-2 fields in between Dithmarschen 1/2/3 control surrounding and Dithmarschen cabbage plot 2 and 3). Filder 1/2/3 control surrounding was located close to Filder cabbage plot 1 and 2, but not to |

| | |
|---|---|
| | Filder cabbage plot 3 (4 fields in between Filder 1/2/3 surrounding and Filder cabbage plot 3). Several sources on the internet state home ranges of the common vole of 30 up to 1500 m2. Considering this small home range (far less than 1 ha), control surroundings should be located in close proximity to the cabbage fields. As a consequence, no adequate control surroundings were included for the following cabbage fields: Rhineland plot 5; Dithmarschen plot 1 and 3; Filder plot 3. This is taken into consideration in the analysis below.<br>In Rhineland and Dithmarschen the occurrence of voles in cabbage fields was studied at cabbage growth stage 41-45 (one exception: Rhineland plot 1, BBCH 49), hence for these regions no measurements of vole density are available at growth stages higher than 45. In Gäuboden, Filder and Heilbronn, the occurrence of voles in cabbage fields was studied at cabbage growth stage 45-48, hence for these regions no measurements of vole density are available at growth stages below 45. This raises the question whether the relatively low occurrence of voles at growth stage less than 45 is a site specific instead of a growth stage specific finding. The analysis below considers the findings per region.<br>Growth stage less than 45, Rhineland and Dithmarschen<br>In Dithmarschen only plot 2 had an adequate control surrounding (see above). The results for plot 1 and 3 (very low vole occurrence: 0 and 1.3 vole captures / 100 trap nights) are therefore not reliable since it cannot be ruled out that there were no or only very few voles in the surroundings of cabbage plot 1 and 3. In cabbage plot 2 (BBCH 43), no voles were captured, whereas in the control surrounding 19.4 voles per 100 trap nights were captured. This is a clear difference, but obtained from one plot only.<br>In Rhineland, cabbage plot 6 had no adequate control surrounding (see above), and is not further considered. In the remaining 5 cabbage plots (4 plots BBCH 41-43, one plot BBCH 49), no voles were captured, but it should be taken into consideration that in 2 out of 4 control surroundings also no voles were captured (with 15 and 155 vole captures / 100 trap nights in the remaining two control surroundings).<br>Growth stage 45 and higher, Gäuboden, Filder and Heilbronn<br>In plot 1 of Gäuboden, more voles were found in the surrounding than in the cabbage field, in plot 4 the number of voles in-field and off-field were the same, and in plot 6, 7 and 8, no voles were found in the surrounding control, whilst in the cabbage fields no voles (plot 6) or few voles were found (plot 7 and 8, 1.3 and 6.3 captures / 100 trap nights). Thus, the trappings at Gäuboden (5 cabbage plots) do not provide an unequivocal picture.<br>In two of three plots at Heilbronn, more voles were found in the surrounding than in the cabbage field, but in one plot more voles were found in-field than off-field. Thus, the trappings at Heilbronn (3 cabbage plots) do not provide an unequivocal picture.<br>In Filder, cabbage plot 3 had no adequate control surrounding (see above), and is not further considered. In the remaining two plots at Filder, more voles were found in the surrounding than in the cabbage field.<br>The results from 5 plots at BBCH 41-43 in Dithmarschen and Rhineland suggest that voles are not or only very rarely trapped in cabbage fields at growth stage 41-43, but in 2 out of 5 control surroundings also no voles were trapped. Hence there is reliable data from 3 plots only at BBCH 41-43. When considering cabbage fields at growth stage 45-48 in Gäuboden, Filder and Heilbronn, the general picture is that far more voles are found within the cabbage fields in Gäuboden, Filder and Heilbronn than in cabbage fields in Dithmarschen and Rhineland at BBCH 41-43, but this is likely to be, at least in part, related to the vole calamity that occurred that year. Concerning the preference of voles for cabbage fields at BBCH 45-48, the results for Gäuboden and Heilbronn do not provide an unequivocal picture, whereas at Filder (2 plots) more voles were found in the |

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| | surrounding than in the cabbage field. Considering further that not at every location all growth stages of cabbage under consideration (41-49) were studied, but that there was a correlation between growth stage and location (BBCH <45 at Rhineland and Dithmarschen; BBCH >45 in the remaining locations suffering from a vole calamity), it is not considered to be justified to plot all the data in one graph in the way it was done in Figure 1. The results of Figure 1 suggest a relationship between cabbage growth stage and vole occurrence, which however might actually be the result of a relationship between location and vole occurrence.<br>Conclusion<br>The study is not suitable to establish a robust relationship between growth stage of cabbage in the range 41-49 and vole occurrence since not at every location all growth stages of cabbage under consideration (BBCH 41-49) were studied, but there was a correlation between growth stage and location (BBCH <45 at Rhineland and Dithmarschen; BBCH >45 in the remaining locations).<br>Results from three plots at BBCH 41-43 indicate that the common vole prefers the surroundings (15-155 captures/100 trapnights) to cabbage fields (0 captures/100 trapnights).<br>Results for preference of voles for cabbage fields at BBCH 45-48 are equivocal: although on 4 plots the common vole prefers the surroundings, on 5 plots this was not the case.<br>**The vole cannot be eliminated as a focal species in-field. The results of the field study may be considered in a weight-of-evidence analysis (qualitatively), but will not be used in the quantitative risk assessment''** |

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| Reference: | **KCP 10.1.2.2/04** |
| Title: | Voles in fields with leafy vegetables |
| Report: | xxx |
| Authority registration No: | |
| Guideline(s): | Commission Directive 96/46EC of 16 July 1996 amending Council Directive 91/414EEC Concerning the Placing of Plant Protection Compounds on the Market |
| Deviations: | not specified |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication (if vertebrate study): | No |

**Objective:**

According to the EFSA GD on risk assessment for birds and wild mammals, exposure of small herbivorous mammals on fields cropped with leafy vegetables should be considered from growth stage BBCH 40 upwards.
This field study was conducted in order to generate information on the occurrence of Common voles (*Microtus arvalis*) on arable fields cropped with leafy vegetables (lettuce, cabbages) which could be used in more realistic, refined risk assessments.

**Materials and methods:**

The study site selection for the main study was based on the results of pre-trappings (non-GLP) conducted during spring at 9 candidate sites in Germany and one site in the Netherlands. This pre-trapping was conducted in suitable vole prime habitats in the vicinity of vegetable fields, in order to ensure the presence of a source population with the potential for colonisation of the vegetable fields. Only sites where Common voles were identified during spring were selected for the main study.

Based on the results of this pre-trapping, the main study was conducted in 5 different regions of Germany: Gäuboden (Lower Bavaria): 5 sites; Rhineland (North Rhine-Westphalia): 6 sites; Filder (Württemberg): 3 sites; Heilbronner Becken (Württemberg) 3 sites and Dithmarschen (Schleswig-Holstein): 3 sites.
During the main study trapping was conducted during summer, at a time when the vole population development in the source habitats could have induced colonisation of adjacent secondary habitats like the vegetable fields.
In the second year of the study, additional surveys where conducted in late spring in order to complement the information also for vegetable fields in earlier development stages.

Altogether 20 fields with different types of leafy vegetables and different growth stages (BBCH-scale) were studied.

As a standard, 40 Ugglan life traps were placed inside each field. In order to confirm the presence of voles in the landscape, and to estimate their density in potential source habitats, traps were also placed outside the fields in optimal vole habitats in the surrounding up to 500 m distance (“control” traps).

It was originally intended to complement each study field (40 traps) with one “control” with 20 traps each. However, in some areas one set of control traps was able to cover more than one plot. The number of control traps was enlarged for Dithmarschen (32 traps to cover all three sites with one control); for Filder only 14 traps were available as a common control for all plots. In the Heilbronn area some traps were destroyed during the 2nd trapping. This was considered when calculating the trapping rate.

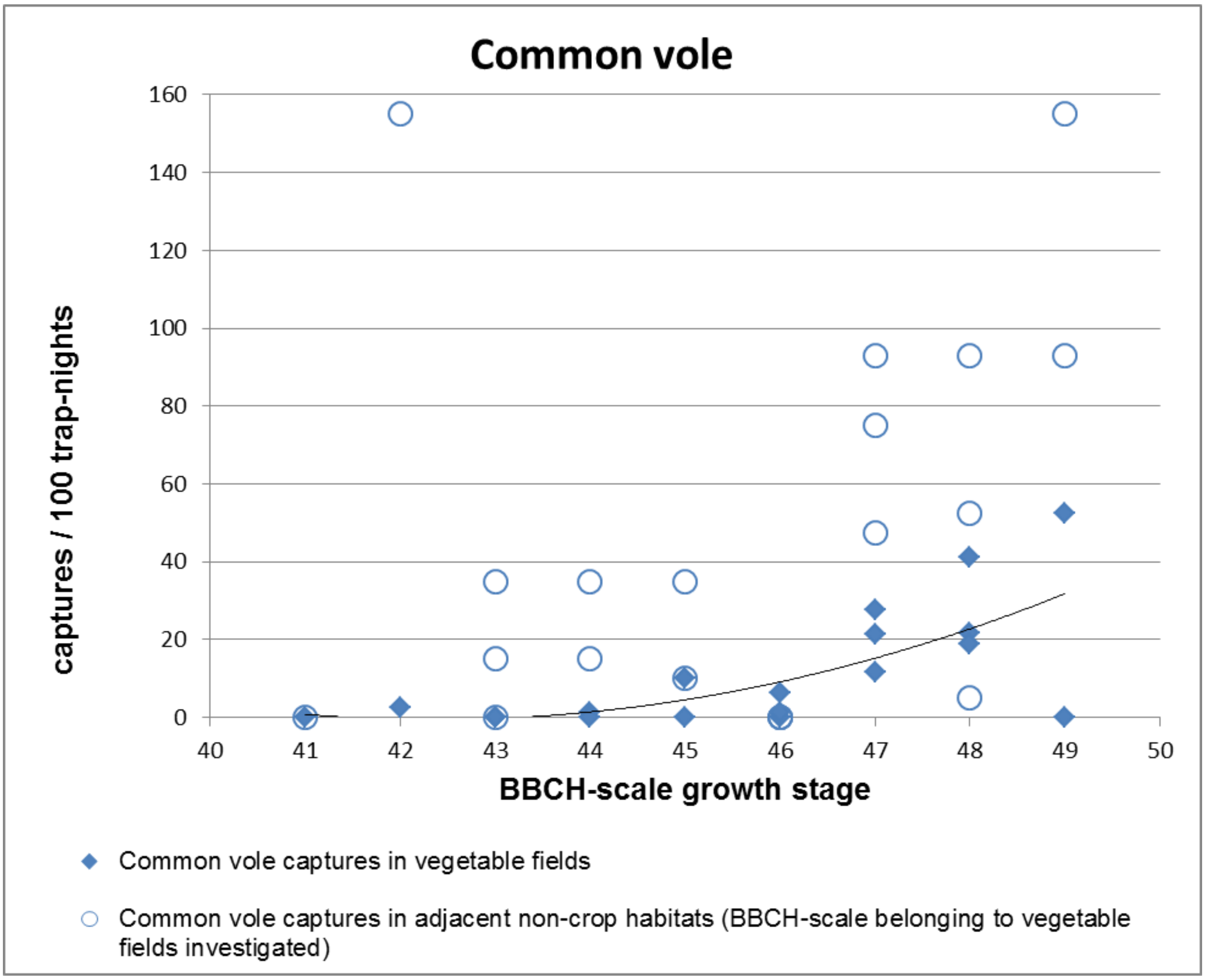
The trapping was carried out on each field or control for two consecutive nights. Species, sex, weight and reproductive state of voles captured were recorded. The traps were equipped with oat flakes as bait.

Dates
Experimental Starting Date: 2011-07-26
Experimental Completion Date: 2012-06-04

**Results and discussions:**

In total, 348 Common voles (*Microtus arvalis*) trappings were recorded over 2045 trap nights. Overall the trapping success in the fields was 10.6 voles/100 trap nights compared to 36.8 voles/100 trap nights in the surroundings (“controls”).
Additional to Common voles, other species were trapped on the fields (mainly Wood mice *Apodemus sylvaticus*) or the surroundings (mainly bank voles *Myodes glareolus*). Other species trapped included Yellow-necked mice (*Apodemus flavicollis*) and Field vole (Microtus agrestis).
Typically, voles were trapped early and more frequently in the surroundings than in the field. However, at later stages or in regions with a vole calamity, voles were also observed within the vegetable fields. Plotting the vole in-field abundance against the BBCH stage of the vegetable field suggests that colonisation is typically not observed before BBCH 45, and secondary to population development in the off-field habitat.

**Figure 22** **Common voles in fields with leafy vegetables**




**Conclusion:**

This finding supports the thesis that vegetable fields are no primary habitat for voles. The grassy surroundings serve as base habitat from which vole may migrate to the fields, if the population density increases.

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| Comments of zRMS: | The study is considered as acceptable.<br>The occurrence of voles was low inside the strawberry fields compared to off-crop habitats during all sessions in particular at early plant development stages i.e. BBCH 16-19 and 55-73. The trapping efficiency was more than 100 times lower at BBCH 16- 19 in in-crop areas compared to off-crop grass habitats. During later crop growth stages the number of captured voles also increased inside the strawberry fields; however it remained lower compared to off-crop grass habitats.<br>**The study can be used in the weight evidence approach by MSs.** |

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| Reference: | **KCP 10.1.2.2/05** |
| Title: | GLP-compliant field study to assess the presence and abundance of common voles in strawberry fields in central Europe |
| Report: | xxx; 2016; R1540015; M-570937-01-1 |
| Authority registration No: | |
| Guideline(s): | none |
| Deviations: | none |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication<br>(if vertebrate study): | No |

### Objective

According to the Regulation (EC) 1107/2009 the possible adverse effects of crop protection products on wild vertebrates have to be assessed. Effects are depending on the inherent toxicity of those products and their exposure to wild vertebrates as well as on the biology of those species. The present study aims at investigating the presence and abundance of common voles (*Microtus arvalis*) in strawberry fields and their adjacent off-crop habitats as well as the abundance of weeds in strawberry fields.

### Materials and methods:

The study was conducted on 15 strawberry fields in different areas of the federal state of Rhineland-Palatinate, Germany. Five study fields were located near Landau, six study fields near Eisenberg (Pfalz) and four study fields near Frankenthal. All selected study fields were directly adjacent to off-crop habitat which was suitable for common voles.
A pre-trapping (non-GLP) was conducted and at least one common vole was captured in every adjacent off-crop habitat. Therefore, all selected study fields had common voles present in directly adjacent off-crop habitats, which had potential access to the adjacent strawberry fields.

<u>Trapping</u>
A live trapping regime was carried out in order to assess the presence and abundance of common voles in strawberry fields and in adjacent off-crop habitats.
Three trapping sessions were conducted at eleven study fields (near Landau and Eisenberg): prior to flowering (BBCH 16 – 19), prior to ripening (BBCH 55 – 71) and during the second harvest (BBCH 85 – 91). Because four study fields were covered with plastic, they were already flowering early in season, hence only two trapping sessions were conducted at these study fields: once before ripening (BBCH 73) and once during the second harvest (BBCH 89). Data from these four study fields are included in the trapping sessions of the remaining study fields according to their BBCH developmental stage (i.e. trapping session 2 and 3).

The Field Phase of this study was conducted between April and June 2015.

Ugglan multiple-capture traps were used to live-trap small mammals. A total of 60 traps were set up on each study field (10 or 20 traps off-crop and 40 or 50 traps in-crop). Live trapping of small mammals was carried out following a 'Capture-Mark-Recapture' (CMR) design. This involved individual marking of captured common voles with a Passive Integrated Transponder (PIT). Individual animals can be recognized after trapping them again using this method and therefore a precise assessment of the abundance of common voles can be made.

The following parameters were recorded for each captured animal: species, sex, body weight and reproductive status.

Data analyses include the following parameters:

<u>Abundance measurements:</u>
1. Number of captures (in-crop and off-crop)
2. Number of individuals (in-crop and off-crop)
3. Frequency of occurrence (in-crop and off-crop)
4. Trapping efficiency (captures/100 trap nights)

**Results**

Only the trapping efficiency was corrected for the different trapping efforts made in off-crop and in-crop habitats. During the first trapping session 31.2 animals were captured in 100 trap nights off-crop and 0.20 animals were captured in 100 trap nights in in-crop habitats. The trapping efficiency for off-crop habitats was also higher compared to in-crop habitats in trapping session 2 (off-crop: 15.22 captures/100 trap nights; in-crop: 1.19 captures/100 trap nights) as well as in trapping session 3 (off-crop: 5.43 captures/100 trap nights; in-crop: 1.87 captures/100 trap nights). In trapping session 1, 106 captures of common voles (71 individuals) were done in 90.9% (10 out of 11) of the off-crop habitats compared to 2 captures (2 individuals) in 18.1% (2 out of 11) of the in-crop habitats. The number of individuals and the frequency of occurrence decreased afterwards (70 captures (47 individuals), $FO_{off\text{-}crop}$ = 80.00% in trapping session 2 and 25 captures (23 individuals), $FO_{off\text{-}crop}$ = 53.33% in trapping 3) but increased in-crop (16 captures (12 individuals), $FO_{in\text{-}crop}$ = 33.33% in trapping session 2, and 25 captures (20 individuals, $FO_{in\text{-}crop}$ = 40.00%), $FO_{in\text{-}crop}$ = 40.0% in trapping session 3). However, the number of common voles trapped in off-crop habitats was higher in almost every trapping session compared to in-crop habitats (Table S 1).
The mean number as well as the range of counted weeds per square meter inside the strawberry fields only varied slightly between trapping sessions (Table S 2). A relationship of food availability and the number of common voles trapped inside the strawberry is unlikely.

**Table S 1: Summary of small mammal trapping results**

| | Trapping session | | | | | |
|---|---|---|---|---|---|---|
| | 1 (BBCH 16 – 19) | | 2 (BBCH 55 – 73) | | 3 (BBCH 85 – 91) | |
| | in-crop | off-crop | in-crop | off-crop | in-crop | off-crop |
| **Captures** | 2 | 106 | 16 | 70 | 25 | 25 |
| **Individuals** | 2 | 71 | 12 | 47 | 20 | 23 |
| **FO [%]** | 18.18 | 90.91 | 33.33 | 80.00 | 40.00 | 53.33 |
| **Trapping efficiency [captures/100 trap nights]** | 0.20 | 31.18 | 1.19 | 15.22 | 1.87 | 5.43 |

**Table S 2: Summary of weed counts results**

| | **1st Trapping (BBCH 16 – 19)** | **2nd Trapping (BBCH 55 – 73)** | **3rd Trapping (BBCH 85 – 91)** |
|---|---|---|---|
| **Number of weeds/m$^2$ (mean)** | 12.98 | 14.00 | 11.76 |
| **Number of weeds/m$^2$ (min-max)** | 0.40 - 42.80 | 0.40 - 64.40 | 2.40 - 28.00 |

## Conclusion

The occurrence of voles was low inside the strawberry fields compared to off-crop habitats during all sessions in particular at early plant development stages i.e. BBCH 16-19 and 55-73. The trapping efficiency was more than 100 times lower at BBCH 16- 19 in in-crop areas compared to off-crop grass habitats. During later crop growth stages the number of captured voles also increased inside the strawberry fields; however it remained lower compared to off-crop grass habitats.

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| Comments of zRMS: | The study evaluated by zRMS-NL in the previous Registration for Luna Sensation 500 SC, July 2018.<br>zRMS-NL concluded that based on the avalible information from this study and study by Rinke 1990; Percentage of volume versus number of species: Availability and intake of grasses and forbs in microtus arvalis. *Folia zoological* 40(2) 143-151, that the diet for voles can be set at 50/50 monocots/dicots in agricultural fields (like leafy vegetable crop fields) for the chronic risk assessment. |

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|---|---|
| Reference: | **KCP 10.1.2.2/06** |
| Title: | Nutritional ecology of Microtus arvalis (Pallas, 1779) in sown wild flower fields and quasi-natural habitats |
| Report: | xxx.; 2010; M-440511-01-1 |
| Authority registration No: | |
| Guideline(s): | not applicable |
| Deviations: | not applicable |
| GLP/GEP: | not applicable |
| Acceptability: | |
| Duplication (if vertebrate study): | No |

Summary:
Recently, sown wild flowerfields (SWFF) were established as ecological compensation areas to en - hance and preserve animal and plant biodiversity. Besides their positive effects, SWFF can also shelter potential pest species, like *Microtus arvalis*, which stay preferentially in those fields. To analyse the nutritional ecology of *M. arvalis* in SWFF and in quasi-natural habitats, 100 voles were trapped in each habitat type near Bern, from October 2006 to July 2007. Stomach content and faecal pellets were examined microscopically. Ingested plant fragments were identified using reference slides. The ingested quantity of each plant was assessed according to the covered surface on a microscopic slide. Rank preference indices of Johnson were calculated by comparing food-composition with food-offer in the vegetation. The food spectrum was rather wide, including numerous grasses and herbs. Monocots constituted the main part in both habitats, although they were not as frequent in SWFF as dicots. Neither for monocots nor for dicots a clear preference was found. SWFF seem not to be the main reason for the frequent occurrence of *M. arvalis* in these areas. Further studies are needed to determine why common voles are attracted by the naturally growing grasses.

INTRODUCTION

The intensification of agriculture has increased mainly in the second half of the 20th century. The impact of fertilizers and pesticides has considerably reduced the number and diversity of plant and animal species. As a consequence, natural and quasinatural habitats for animals and plants were lost.
A change was initiated in the last decades through the reorientation of the agricultural policy, with ecological compensations areas (ECA) and with new goals related to structural improvements of the landscape. The focus is directed on the diversity of species, valuable habitats and attractive cultural landscapes. Therefore ECAs, such as extensively used meadows, sown wild flower areas (SWFF), hedges or fallow land, were established and associated with direct payments to the farmers. These areas should preserve and enhance biodiversity in agro-ecosystem
SWFF are part of these ECAs, which have been progressively introduced into the agricultural landscape during the last two decades (Nentwig, 2000). These habitats are sown with a seed mixture of about 30 native annual weeds and perennial ruderals. Since 1993 farmers receive subsidy from the Swiss government to maintain at least 7% of their farmland as ECAs. The farmers are not allowed to use chemical plant pro - tection agents and fertilizers.
ECAs increase the diversity of flowers (Heitzmann & Nentwig, 1993) and the number of small mammals (Baumann, 1996) and birds (Lille 1996). Frank & Nentwig (1995) showed positive effects of SWFF on arthropod density. SWFF can also shelter animals, including small mammals, considered as pest species because these fields are left uncultivated for longer periods and therefore can serve as refuges for them. The common vole, *Microtus arvalis*, is such a potential agricultural pest species due to its high reproductive rate and its exclusive herbivorous nutrition. Population densities of more than 3000 individuals per hectare were reported (Truszkowski, 1982). Due to its high adaptability, the common vole has to be considered as a hemerophil animal, i.e. an animal taking advantage of the anthropogenic changes in the environment and following therefore humans into the cultural landscape (Leicht, 1979). SWFF, which are a part of the cultural landscape, offer high floral diversity and biomass (Heitzmann & Nentwig, 1993). Briner *et al*. (2005) showed that they are an appropriate habitat for the common vole.
Admittedly, the intensive agriculture and the loss of perennial grassland have decreased the density of the common vole as well. But the implementation of ECAs led to a new concern of farmers about the immigration of voles from SWFF into cropland. Furthermore, voles of the genus *Microtus* constitute the main part of the kestrel's and long-eared owl's diet (Aschwanden *et al*., 2005) and common buzzards, foxes, stoats or weasels feed on voles as well (Niethammer & Krapp, 1982).
The nutritional ecology of *M. arvalis* in quasi-natural habitats has been investigated by Yu *et al*. (1980), Leutert (1983) and Rinke (1987, 1990, 1991). The study of Yu *et al*. (1980) done in France cannot be compared directly with the present one. Rinke (1990) worked in Germany. For Leutert (1983), the main focus was not food ecology but the effects of common vole on plant composition in meadows. Except for the work of Balmelli *et al*. (1999), in which choice-trials were conducted, no studies about food ecology of *M. arvalis* in SWFF are available.
The aim of the present study was to analyse the nutritional ecology of *M. arvalis* in SWFF compared to quasi-natural habitats. The main questions were: what kind of plant species are ingested in SWFF and in quasi-natural habitats, respectively. Furthermore, to what extent does the food intake differ in SWFF from that in quasinatural habitats, particularly since in SWFF a large number of additional plants is available, which voles could possibly use as food resources? Does *M. arvalis* prefer sown wild flowers or does it feed on grasses and other forbs naturally growing in SWFF, but which are not contained in the seed mixture? If the typical plants of SWFF were eaten more often and in larger quantities, these plants could be a possible reason for the preferential occupation of SWFF. Conversely, if only few fragments of sown wild flowers can be detected in the diet, the reason for the high density of *M. arvalis*

in such fields must be another one.

MATERIAL AND METHODS

DIET ANALYSIS IN GENERAL

Several methods exist to investigate the nutritional ecology of a given organism.
A first approach is the direct observation of an organism in the field.
Analysis of the stomach content has the advantage that the plant fragments are mostly well preserved, but the animals need to be killed (Batzli & Pitelka, 1983). Stomach analysis was favoured in the present study, because food items in the stomach are not exposed to gastric secretions as long as faecal samples and are therefore easier to identify.
A source of error in faecal and stomach analyses lies in the fact that not every plant fragment can be identified (Hansson, 1970). Only the epidermis has distinctive features and is therefore identifiable. The other ingested plant structures, like vascular bundles, roots, seeds, can hardly be assigned to a precise plant species. It is assumed that the ratio of unidentified food particles to identified epidermis material remains constant. Another potential source of error for both methods is the observer's bias. Even with an excellent reference collection, it is impossible to classify an ingested plant, if the relevant identification characteristic features are not observable under the microscope (Westoby *et al*., 1976).

VEGETATION SURVEY

Three SWFF (Grauholz [GH, 46°59'38" N, 7°29'03" E, 606 m], Niederwangen [NW, 46°55'41 N, 7°21'10" E, 655 m], Uettligen [UE, 46°58'37" N, 7°22'42" E, 576 m]) and three quasi-natural habitats (Riedbach [RB, 46°56'24" N, 7°19'31" E, 565 m], Hinterkappelen [HK, 46°58'19" N, 7°22'35" E, 566 m], Moosseedorf [MD, 47°00'43" N, 7°28'34", 545 m]) were chosen as study areas. In each site, the vegetation was mapped and recorded in mid October and March and at the beginning of June on five subplots of one m2 and along the trapping line, because common voles generally graze on their paths (Stein 1958). Only vegetation structures below 80 cm were considered. All plant species were identified (Eggenberg & Möhl, 2007, Eggenschwiler & Jacot, 2001, Lauber & Wagner, 2001) and the cover index ranged from 1 to 5, according to Braun-Blanquet (1964) (1 = cover 1-5%, 2 = 5-25%, 3 = 25-50%, 4 = 50-75%, 5 = 75-100%). The results of the five subplots were averaged to get the total cover for each plant species within one plot and are expressed in percent, representing the availability of the plants for an animal.

TRAPPING

A total of 200 *M. arvalis* were captured in Longworth live traps from October 2006 to July 2007 in the six plots. Hundred voles were trapped in the three SWFF and in the three quasi-natural habitats, respectively. First of all, the habitats were scanned for signs of vole presence. Then the traps were placed in the middle of the habitat with a buffer zone of at least 10 m in sown wild flower fields on each end and 2 m in the quasi-natural habitats according to the size of the fields. The traps were placed in one line at a distance of 1-2 m between them, depending on the frequency of activity signs of *M. arvalis*, i.e. holes, food remains, feeding places, droppings or pathways. The nest box of the traps was filled with dry hay for bedding; cheese, pieces of apple and
nutRitional ecology of *microtus arvalis* 813
hamster food served as bait. Normally 32 traps per habitat were used. They remained open at night to enhance the trapping success. Nineteen animals, or 9.5%, died in the traps, but it was still possible to analyse the stomach contents or the droppings. The traps were checked once a day, but twice when the weather was hot or very cold. All animals caught were killed using carbon dioxide and put in a plastic bag with a label.

Some faecal pellets found in the traps were also collected to get enough material in case the stomach was empty (Putman, 1984). In the laboratory the voles and pellets were deep frozen for better conservation.

LABORATORY ANALYSIS

In the laboratory the voles were measured, weighed, sexed, their reproduction status and the estimated age according to body-weight (adult, sub-adult or juvenile) were recorded. Furthermore, the animals were dissected, the amount of stomach content was estimated, and five groups were defined: 1 = almost empty, 2 = 25%, 3 = 50%, 4 = 75% and 5 = 100%. The next step was to check if the stomach contained roottissue, which as such is easy to recognize, but in our case, identification at the specieslevel was not possible. Therefore, only an estimation of the quantity was made. After chemical treatment (see below), root-tissue was removed. If the amount of food items in the stomach was low or the stomachs were almost empty, the collected pellets were used instead (14 cases in all).

PREPARATION OF THE EPIDERMIS

A micro-histological approach based on the technique developed by Zettel (1974) was used to assess the dietary composition of the voles. This method assumes that fragments of epidermis and cuticula of plants ingested by animals remain intact as they pass through the digestive system and can be identified in the dung or in the stomach (Stewart, 1966). The time intervals of the chemical treatment were shortened and the whole method was adapted to delicate grasses and forbs.

In order to identify the ingested plant species, epidermis fragments were pre - pared from the stomach content or faeces. For each trapped vole, one to four slides were prepared, depending on the amount of stomach content or pellets. A total of about 650 microscopic slides were made.

First of all, the stomach content/faecal pellets were softened with distilled water in a glass tube to be able to tease apart the fragments with tweezers. After removing the water, ca. 3 ml of 10% caustic potash solution (KOH) was mixed with the disintegrated droppings and heated in boiling water for about 5-7 minutes. Distilled water was then added to clean the samples. After removing the water, ca. 3 ml of a 1:1 mixture of 10% nitric acid (HNO3) and 10% chromate acid (H3CrO3) was added. To bleach the epidermis, the glass tube was put into boiling water for ca. 20 seconds until the solution became brownish and bubbles appeared on the epidermis. Thereafter, the acid was immediately removed and distilled water added for cleaning. Parts of the mesophyll were loosened from the epidermis by strong pipetting. Then the plant fragments were allowed to settle for at least five minutes. The water was removed again and 3 ml of an alcoholic solution of Sudan III (96%), a lipophilic dye used for dyeing the cuticle was added. The colouration lasted at least one hour. Finally, the solution was washed with distilled water. The epidermis and the mesophyll were separated through sedimen -

814 M. lüthi *et al*.

tation. The epidermis-fragments were transferred with a pipette onto a microscopic slide (24 x 60 mm) and then embedded in glycerol gelatine, which was heated. A cover slip (24 x 32 mm) was placed on the slide and sealed with wax to get permanent preparations.

Reference slides from the available plant species in the study sites were made using the same procedure as described above. The time intervals had to be adjusted for the different types of epidermis. At the end of the "acid-treatment" the delicate epidermis was pulled off. Even better preparations were obtained from faecal pellets of test voles fed in the laboratory with known plant species. The droppings were collected after 24 hours and prepared as described above.

SLIDE ANALYSIS

The microscopic slides were analysed under the microscope at 100x and 400x magnifications. The fragments were identified at the species or plant group level based on the shape and distribution of epidermal cells, the trichomes, the stomata with their guard and subsidiary cells and the structure of the epidermal cells. The lipophilic

colouring of the fragments with Sudan III (Zettel, 1974) was helpful as well.
Information on these species-specific traits was obtained from a reference collection of epidermis cells of the plants growing in the study sites made at the beginning of the study and some photographs (Rinke, 1987; Zettel, 1974). All identifiable fragments of one plant species were counted by screening the whole slide at low magnification (100x). Since epidermal fragments vary in size, the different sizes of the fragments were taken into account. If there were too many fragments on the slide, so that counting each of them was impossible, the relative abundance on the slide was estimated. From the number of fragment units it was possible to estimate the relative abundance of each plant species in the stomach or in the faeces with an accuracy of 5%.

STATISTICAL ANALYSIS

Non-parametric Mann-Whitney-U-test was used to analyse all the differences between the consumed amount of monocots and dicots within the SWFF and the quasinatural habitats, respectively. The same test was used to compare the differences of the consumed amount of monocots between the two habitat types. The numbers compared were the percentages for each vole.

To examine if a preference for a given plant species exists, the rank preference index of Johnson (1980) was calculated. The usage of a food resource (quantity of that food resource eaten by an animal) and its availability (presence and accessibility to an animal) were ranked. Then the difference in these two rankings was used as a measure of relative preference.

Johnson (1980) pointed out that the result of this method will be a ranking of relative preferences and that conclusions on absolute preferences should be avoided. As for both usage and availability *ranks* are employed, usage and availability need not be estimated exactly. The sampling procedures (cover estimation) used in this study to determine availability values for the various plants cannot faithfully reflect the true availabilities for the animal and so indications accurate to 1 percent were not possible or reasonable. The same applies to the calculation of the quantity of food items (usage), therefore steps of 5% were used. The rank preference index gives less subjective

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results, in the sense that they are less affected by erroneous decisions or observations made by the investigator. It is for these reasons that Manly's alpha (Manly *et al*., 1972), another measure of preference, very sensitive to data fluctuations or outliers, was not applied. To calculate the rank preference index (RPI), the following procedure was carried out for each animal (Krebs, 1999):

The rank of usage (r) of the food resource from *1* (most used) to *m* (least used; *m* is also the number of food types) was determined.

The rank of availability of *m* food types in the environment for each species was calculated. To simplify matters it was assumed that these availability ranks were perceived as being the same for all individuals, i.e. each vole was able to reach and eat every plant growing on the site.

The rank difference between usage and availability for each species was calculated.

The rank differences across all individuals were averaged (Tbar). The calculated Tbar-values were ranked to give an overall relative preference for all food types.

Note that the calculation of the rank preference index based on frequency of occurrence is problematic, because the Tbar-values (difference between the rank of usage/frequency and the rank of availability, measure of preference) cannot be averaged across individuals since the frequency of occurrence of a plant in the sampled stomachs will only result in one value (see material and methods). Therefore, the RPI according to frequency of occurrence must be calculated without averaging the differences.

For a difference between two ranks (Tbar) to be significant, it must exceed in absolute value W.S, where W is obtained from tables or in our case by the program PREFER provided by Johnson (1980). S stands for the standard error of the difference between two Tbar-values. To determine W one has to select a value for K, the Type I

to Type II error-seriousness-ratio. In the present study K=100 was used, which can be regarded as the analogue of the usual Type I significance level of p=0.05 (Johnson, 1980).
Plants connected by a same line (see Tab. 4-9) are not significantly different with regard to preference by the voles; absence of a line means that the food items differ significantly ($p \leq 0.05$). There are no lines in the RPI of frequency of occur rence because the significance of a difference cannot be computed without the standard error of the difference between two means.
Preference will be detected when the usage of a plant is higher than its availability (this is more likely when a plant is relatively rare). If the usage of a plant is less than its availability, no clear preference will appear. Hence, even if the common vole consumes large quantities of a frequent plant A (while usage is *lower* than availability), no preference will be detected. But if it consumes small quantities of a rare plant B (while usage being *higher* than availability), a preference will be detected for plant B although the amount ingested of plant A is much higher than that of plant B.

**RESULTS**

VEGETATION COVER IN SWFF
A total of 51 different plant species was recorded in the three sown wild flower fields: 42 dicots and 9 monocots. The most abundant species over all sites were *Achillea millefolium*, *Leucanthemum vulgare* and *Trifolium pratense*, all dicots (Tab. 1).
In Grauholz 31 plant species were identified. *A. millefolium* was the most abundant species (25%), followed by *L. vulgare* (24%) and the monocot *Poa pratensis* (12%) (Tab. 1).
In Niederwangen 25 species were identified. *T. pratense* was the most abundant species (32.5%), followed by *L. vulgare* (20%) and *Poa annua/trivialis* (18%) (both species occurred but were not distinguishable at the microscopic level, so were treated as one species) (Tab. 1).
In Uettligen 23 species were identified. *A. millefolium* was the most abundant species (20%), followed by *P. annua/trivialis* (18%) and *Origanum vulgare* (18%) (Tab.1).
VEGETATION COVER IN qUASI-NATURAL HABITATS
A total of 33 different plant species was recorded in the quasi-natural habitats: 23 dicots and 10 monocots. The most abundant species over all sites were three monocots, *Bromus erectus, Agropyron repens* and *Arrhenatherum elatius* (Tab. 1).
In Riedbach 22 species were identified. *B. erectus* was the most abundant species (52%), followed by *A. elatius* (20%) and the dicot *Galium mollugo* (14%) (Tab. 1).
In Hinterkappelen 16 species were identified. *A. repens* was the most abundant species (52%), followed by *A. elatius* (15%) and *P. annua/trivialis* (15%) (Tab. 1).
In Moosseedorf 22 species were identified. *B. erectus* was the most abundant species (32%), followed by *Deschampsia caespitosa* (30%) and *G. mollugo* (15%) (Tab.1).
qUALITATIVE AND qUANTITATIVE ANALYSIS OF DETECTED PLANTS
An ingested plant is assessed here in a qualitative and in a quantitative way. qualitative means in how many stomachs a given plant species was found (indicated in %). quantitative means the amount of a plant found in a single stomach (% of the total stomach content). In general, an animal does not feed equally on plants. Usually the plant species occur in different quantities and different frequencies in the stomachs.
*Qualitative and quantitative analysis in SWFF*
All in all, the epidermis of 22 different plant species were identified in the stomachs/faeces of voles trapped in sown wild flower fields (14 dicots or 32.6% of the recorded dicots; 8 monocots or 88.9% of the recorded monocots) (Tab. 2). Normally,

each vole ingested several plant species, ranging from 1 to 6, with a mode at 3 species. No animal parts were found except one flea, probably ingested during grooming activities.

In Grauholz (34 voles examined) 10 different species were detected (Tab. 2).

TAB. 1: Plant species and corresponding cover for SWFF (Sown Wild Flower Fields) and quasi-natural habitats. Species found in stomachs or faeces of voles are in bold face. GH: Grauholz; NW: Niederwangen; UE: Uettligen; RB: Riedbach; HK: Hinterkappelen; MD: Moosseedorf

| Order | Family | SWFF | GH % | NW % | UE % | quasi-natural habitats | RB % | HK % | MD % |
|---|---|---|---|---|---|---|---|---|---|
| **Dicots** | Apiaceae | ***Daucus carota*** | | **5** | | ***Daucus carota*** | 5 | 0.5 | |
| | | *Pastinaca sativa* | | 2 | | | | | |
| | Asteraceae | ***Achillea millefolium*** | 25 | 2 | **20** | ***Achillea millefolium*** | **0.5** | 4 | 0.5 |
| | | ***Anthemis tinctoria*** | 0.5 | **0.1** | 4 | *Erigeron annuus* | 0.5 | | |
| | | *Centaurea cyanus* | 5 | | | *Leontodon autumnalis* | 0.5 | | 0.1 |
| | | ***Centaurea jacea*** | **3** | | **15** | *Solidago canadensis* | 0.5 | | 0.5 |
| | | *Cichorium intybus* | | 2 | | ***Tanacetum vulgare*** | | 5 | |
| | | *Cirsium arvense* | 0.1 | 0.1 | | | | | |
| | | *Cirsium vulgare* | | | 0.5 | | | | |
| | | *Erigeron annuus* | | | 3 | | | | |
| | | *Hieracium caespitosum* | | 0.1 | | | | | |
| | | ***Leucanthemum vulgare*** | **24** | 20 | 3 | | | | |
| | | ***Tanacetum vulgare*** | 12 | | 2 | | | | |
| | | *Taraxacum officinale* | 0.5 | | | | | | |
| | Boraginaceae | *Echium vulgare* | | | 0.5 | | | | |
| | | *Myosotis arvensis* | 2 | | | | | | |
| | Brassicaceae | *Cardamine pratensis* | 0.5 | 2 | | *Cardamine pratensis* | 0.5 | | |
| | Caryophyllaceae | *Agrostemma githago* | | 0.5 | | ***Silene vulgaris*** | **0.5** | | 0.5 |
| | | *Silene alba* | 0.5 | 0.5 | | | | | |
| | | *Stellaria media* | | 0.1 | | | | | |
| | Dipsacaceae | *Dipsacus fullonum* | 2 | | 5 | ***Knautia arvensis*** | **0.5** | | |
| | Fabaceae | ***Medicago sativa*** | 12 | **15** | | ***Medicago lupulina*** | **0.5** | | |
| | | *Onobrychis viciifolia* | 0.5 | | | ***Vicia cracca*** | **4** | | 5 |
| | | ***Trifolium pratense*** | | 32.5 | **16** | | | | |
| | | ***Trifolium repens*** | **0.5** | | | | | | |
| | Geraniaceae | ***Geranium dissectum*** | 0.5 | 2 | | ***Geranium pyrenaicum*** | **0.5** | | 0.5 |
| | Hypericaceae | *Hypericum perforatum* | 12 | | 0.5 | *Hypericum perforatum* | | 0.5 | |
| | Lamiaceae | *Lamium purpureum* | 0.5 | 0.1 | | *Lamium purpureum* | 0.5 | 0.5 | 0.5 |
| | | *Origanum vulgare* | 3 | | 18 | *Origanum vulgare* | | 5 | 0.5 |
| | | *Thymus pulegioides* | 0.5 | | | *Salvia pratensis* | 0.5 | | 0.5 |
| | | | | | | *Thymus pulegioides* | 0.5 | | 4 |
| | Malvaceae | *Malva moschata* | 0.5 | | | *Malva moschata* | | | 0.5 |
| | Onagraceae | *Epilobium angustifolium* | 0.5 | | 0.5 | | | | |
| | Papaveraceae | *Papaver rhoeas* | | 0.5 | | *Papaver rhoeas* | | | 0.5 |
| | Plantaginaceae | ***Plantago lanceolata*** | **0.5** | **3** | | *Plantago lanceolata* | | 1 | |
| | | ***Plantago major*** | | **3** | | | | | |
| | Ranunculaceae | | | | | *Ranunculus acer* | | 4 | |
| | Rosaceae | *Fragaria vesca* | | | 4 | *Fragaria vesca* | 0.5 | | 0.5 |
| | Rubiaceae | *Galium aparine* | | | 4 | ***Galium mollugo*** | **14** | 5 | **15** |
| | | ***Galium mollugo*** | | | **3** | | | | |
| | Scrophulariaceae | *Verbascum densiflorum* | 0.5 | 3 | | | | | |
| | | *Verbascum thapsiforme* | 0.5 | | 0.5 | | | | |
| | Urticaceae | *Urtica dioica* | 0.5 | | | | | | |
| | Veronicaceae | ***Veronica persica*** | **0.5** | | | | | | |
| **Monocots** | Poaceae | ***Agropyron repens*** | | **4** | **3** | ***Agropyron repens*** | | 52 | |
| | | ***Alopecurus geniculatus*** | **0.5** | | | ***Alopecurus geniculatus*** | **3** | | **3** |
| | | ***Arrhenatherum elatius*** | **0.5** | 5 | **3** | ***Anthoxanthum odoratum*** | **3** | 4 | 0.5 |
| | | ***Dactylis glomerata*** | | | **4** | ***Arrhenatherum elatius*** | **20** | **15** | 5 |
| | | ***Holcus lanatus*** | | **0.1** | | ***Bromus erectus*** | 52 | | 32 |
| | | ***Lolium perenne*** | | 5 | 0.5 | ***Dactylis glomerata*** | **4** | **0.5** | 6 |
| | | *Phleum pratense* | | | 0.5 | *Deschampsia caespitosa* | | 0.5 | 30 |
| | | ***Poa annua/trivialis*** | 5 | **18** | **18** | ***Holcus lanatus*** | **0.5** | 2 | 4 |
| | | ***Poa pratensis*** | 12 | | | ***Poa annua/trivialis*** | | **15** | 5 |
| | | | | | | ***Poa pratensis*** | | 5 | |

TAB. 2: Ingested plant species from SWFF, listed alphabetically; comparison of vegetation cover in the field, average quantity (% of the total stomach content) and frequency of occurrence (% of the total number of stomachs). The values of the three highest ranking plant species of each site are in bold italics. Number of examined voles is 99. Abbreviations as in Table 1.

| Plant species | Cover (%) | | | Quantity ingested (%) | | | | Frequency (%) | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | GH | NW | UE | GH | NW | UE | aver. | GH | NW | UE | average |
| **Dicots** | | | | | | | | | | | |
| *Achillea millefolium* | 25.0 | 2.0 | 20.0 | ***9.0*** | 1.1 | 1.5 | **3.87** | ***42.4*** | 10.0 | 20.0 | **24.13** |
| *Anthemis tinctoria* | 0.5 | 0.1 | 4.0 | - | 0.1 | - | **0.03** | - | 2.5 | - | **0.83** |
| *Centaurea jacea* | 3.0 | - | 15.0 | 1.8 | - | 2.8 | **1.53** | 9.1 | - | 15.0 | **8.03** |
| *Cichorium intybus* | - | 2.0 | - | - | 1.5 | - | **0.50** | - | 10.0 | - | **3.33** |
| *Daucus carota* | - | 5.0 | - | - | 4.0 | - | **1.33** | - | 25.0 | - | **8.33** |
| *Galium verum* | - | | 3.0 | - | - | 1.8 | **0.60** | - | - | 10.0 | **3.33** |
| *Geranium dissectum* | 0.5 | 2.0 | - | - | 0.1 | - | **0.03** | - | 2.5 | - | **0.83** |
| *Leucanthemum vulgare* | 24.0 | 20.0 | 3.0 | 0.5 | - | - | **0.16** | 6.1 | - | - | **2.03** |
| *Medicago sativa* | 12.0 | 15.0 | - | - | 1.0 | - | **0.33** | - | 7.5 | - | **2.50** |
| *Plantago sp.* | 0.5 | 3.0 | - | 3.9 | ***12.5*** | - | **5.47** | 21.2 | ***37.5*** | | **19.57** |
| *Tanacetum vulgare* | 12.0 | - | 2.0 | - | - | 0.8 | **0.27** | - | - | 15.0 | **5.00** |
| *Trifolium pratense* | 0.5 | 32.5 | 16.0 | - | ***12.9*** | 2.5 | **5.13** | - | ***37.5*** | 15.0 | **17.50** |
| *Trifolium repens* | 0.5 | - | 16.0 | 0.9 | - | - | **0.30** | 6.1 | - | - | **2.02** |
| *Veronica persica* | 0.5 | - | - | 0.2 | - | - | **0.07** | 3.1 | - | - | **1.03** |
| **Monocots** | | | | | | | | | | | |
| *Agropyron repens* | - | 4.0 | 3.0 | - | 9.6 | ***27.2*** | **12.27** | - | ***50.0*** | ***65.0*** | **38.33** |
| *Alopecurus geniculatus* | 0.5 | - | - | 0.9 | - | - | **0.30** | 6.1 | - | - | **2.03** |
| *Arrhenatherum elatius* | 0.5 | 5.0 | 3.0 | 2.7 | 5.3 | ***8.7*** | **5.57** | 12.1 | 27.5 | ***30.0*** | **23.20** |
| *Dactylis glomerata* | - | - | 4.0 | - | - | 0.4 | **0.13** | - | - | 5.0 | **1.67** |
| *Holcus lanatus* | | 0.1 | - | - | 0.5 | - | **0.17** | - | 2.5 | - | **0.83** |
| *Lolium perenne* | - | 5.0 | 0.5 | - | 0.5 | - | **0.17** | - | 5.0 | - | **1.67** |
| *Poa annua/trivialis* | 5.0 | 18.0 | 18.0 | ***15.6*** | ***20.6*** | ***17.0*** | 17.73 | ***63.6*** | ***65.0*** | ***45.0*** | 57.87 |
| *Poa pratensis* | 12.0 | - | - | ***23.9*** | - | - | 7.97 | ***78.8*** | - | - | 26.27 |
| **Seeds** | | | | 14.8 | 16.5 | 27.0 | **19.43** | 76.0 | 83.0 | 90.0 | **83.00** |

16.3%) and more often (frequency of occurrence of 78.8% vs 42.4%). Seeds were found at an average quantity of 14.8% and a frequency of occurrence of 76.0%. The remaining 25.8% stomach content were roots and unidentified material.

*Poa pratensis* was the main food plant (average quantity of 23.9% and frequency of 78.8% for all sampled stomachs). *Poa annua/trivialis* represented 15.6% of the diet and occurred in 63.6% of all stomachs. An important food plant was also *Achillea millefolium* (9% of the diet and in 42.4% of all sampled stomachs).

In Niederwangen (42 voles examined) 13 plant species were found in the stomachs (Tab. 2). Monocots were ingested in larger quantities than dicots (average quantity of 36.5% vs 33.2%) and more often (frequency of occurrence of 65.0% vs 37.5%). Seeds were found at an average quantity of 16.5% and with a frequency of 83.0%. The remaining 13.8% of stomach content were roots and unidentified material.

*Poa annua/trivialis* was the main food plant (average quantity of 20.6%) and reached the highest frequency of occurrence (65.0%). *Trifolium pratense* was ingested at an average quantity of 12.9% and reached a frequency of 37.5%. The average quantity of *Agropyron repens* in the diet was 9.6%. It appeared with a frequency of 50.0% in all sampled stomachs.

In Uettligen (23 voles examined) 9 different plant species were found in the diet (Tab. 2). The average quantity of consumed monocots was 53.3% and their frequency of occurrence 65.0% of the sampled stomachs. The average quantity of consumed dicots was 9.4% only. Dicots were found in 20.0% of the sampled stomachs and seeds at an average quantity of 27.0% and with a frequency of 90.0%. The remaining 10.3% of stomach content were roots and unidentified material.

*Agropyron repens* was an important food plant as well (average quantity of 27.2% and found in 65.0% of all sampled stomachs). *Poa annua/trivialis* was consumed at an average quantity of 17.0% and a frequency of occurrence of 45.0% and *Arrhenatherum elatius* amounted to an average quantity of 8.7% with a frequency of occurrence of 30.0% of all sampled stomachs.

*Differences between monocots and dicots*

For this comparison, we took into account the percentages (0 – 100%) of occurrences of each plant species ingested, separately for each site. The values of all three sites were then combined. The total number of observations is greater than the number of captured voles, as several species of plants can be found in a given vole. A Mann-Whitney-U-test showed a significant difference in favour of monocots ($p < 0.0001$, $n_{monocots}=380$, $n_{dicots}=562$).

*Qualitative and quantitative analysis in quasi-natural habitats*

Overall, the epidermis of 18 different plant species were identified in the stomachs / faeces of voles trapped in quasi-natural habitats (9 dicots, 37.5%% of the growing dicots; 9 monocots, 90% of the growing monocots) (Tab. 3). Each vole ingested several plant species, ranging from 1 to 5, with a mode at 3. No animal parts were found.

In Riedbach (53 voles examined) 14 different species were found. Monocots were ingested in larger quantities than dicots (65.0% vs 17.1%) and a frequency of occurrence of 88.7% vs 32.1%. Seeds amounted to 6.6%, with a frequency of 14.0%. The remaining 11.3% of stomach content were roots and unidentified material.

*Arrhenatherum elatius* was the most important food plant. The stomachs contained 25.9% of this monocot, while 88.7% of all stomachs had fragments of this grass species. The average quantity of *Bromus erectus* was 37.1% and was found in 83.0% of all sampled stomachs. *Galium mollugo* amounted to 7.0%, with a frequency of 26.4%.

In Hinterkappelen (30 voles examined) 8 species were found. Monocots were ingested in larger quantities than dicots (81.9% vs 6.2%) and found in 100% vs 40.7% of the sampled stomachs. Seeds amounted to 8.4%, with a frequency of 67.0%. The remaining 3.5% of stomach content were roots and unidentified material.

The average quantity of *Arrhenatherum elatius* was 54.5% and the grass appeared in 100% of all examined stomachs. *Agropyron repens* reached 10.4% and a frequency of 59.3%, whereas *Poa pratensis* amounted to 6.9%, with a frequency of 48.1%.

In Moosseedorf (15 voles examined) the diet comprised only 5 species. Monocots were ingested in larger quantities than dicots (66.0% vs 9.6%) and appeared in 63.6% vs 36.4% of the stomachs. In this site, the only dicot found in the stomach

TAB. 3: Ingested plant species from quasi-natural habitats, listed alphabetically; comparison of vegetation cover in the field, average quantity (% of the total stomach content) and frequency of occurrence (% of the total number of stomachs). The values of the three highest ranking plant species of each site are in bold italics. Number of examined voles is 99. Abbreviations as in Table 1.

| | Cover (%) | | | Quantity ingested (%) | | | | Frequency (%) | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Plant species | RB | HK | MD | RB | HK | MD | aver. | RB | HK | MD | aver. |
| **Dicots** | | | | | | | | | | | |
| *Achillea millefolium* | 0.5 | 4.0 | 0.5 | 1.3 | - | - | **0.43** | 7.6 | - | - | **2.53** |
| *Daucus carota* | 4.0 | 0.5 | - | 1.2 | - | - | **0.40** | 11.3 | - | - | **3.77** |
| *Galium mollugo* | 14.0 | 3.0 | 15.0 | ***7.0*** | 6.0 | ***9.6*** | **7.53** | 26.4 | 40.7 | ***36.4*** | **34.50** |
| *Geranium pyrenaicum* | 0.5 | - | 0.5 | 0.2 | - | - | **0.07** | 1.9 | - | - | **0.63** |
| *Knautia arvensis* | 0.5 | - | - | 0.2 | - | - | **0.07** | 1.9 | - | - | **0.63** |
| *Medicago lupulina* | 0.5 | - | - | 0.2 | - | - | **0.07** | 1.9 | - | - | **0.63** |
| *Silene vulgaris* | 0.5 | - | 0.5 | 1.0 | - | - | **0.33** | 1.9 | - | - | **0.63** |
| *Tanacetum vulgare* | 0.5 | 2.0 | - | - | 0.2 | - | **0.07** | - | 3.7 | - | **1.23** |
| *Vicia cracca* | 4.0 | - | - | 6.0 | - | - | **2.00** | ***32.1*** | - | - | **10.70** |
| **Monocots** | | | | | | | | | | | |
| *Agropyron repens* | - | 52.0 | - | - | ***10.4*** | - | **3.46** | - | ***59.3*** | - | **19.77** |
| *Alopecurus pratense* | 3.0 | - | 3.0 | 0.3 | - | 6.4 | **2.23** | 1.9 | - | 18.2 | **6.70** |
| *Anthoxantum odoratum* | 3.0 | 3.0 | 0.5 | 0.04 | - | - | **0.01** | 1.9 | - | - | **0.63** |
| *Arrhenatherum elatius* | 20.0 | 15.0 | 5.0 | ***25.9*** | ***54.5*** | ***27.7*** | **36.03** | ***88.7*** | ***100.0*** | ***63.6*** | **84.10** |
| *Bromus erectus* | 52.0 | - | 32.0 | ***37.1*** | - | ***22.3*** | **19.80** | ***83.0*** | - | ***63.6*** | **48.89** |
| *Dactylis glomerata* | 4.0 | 0.5 | - | 1.2 | 1.3 | - | **0.83** | 13.2 | 11.1 | - | **8.10** |
| *Holcus lanatus* | 0.5 | 2.0 | 3.0 | 0.5 | 1.0 | - | **0.50** | 5.7 | 11.1 | - | **5.60** |
| *Poa annua/trivialis* | - | 15 | 4.0 | - | ***7.8*** | ***9.6*** | **5.80** | - | 29.6 | 18.2 | **15.93** |
| *Poa pratensis* | - | 5.0 | - | - | 6.9 | - | **2.30** | - | ***48.1*** | - | **16.03** |
| **Seeds** | | | | 6.6 | 8.4 | 17.0 | **10.67** | 14.0 | 67.0 | 100.0 | **60.33** |

was *Galium mollugo*. Seeds represented 17%, with a frequency of 100%. The remaining 7.4% of stomach content were roots and unidentified material.

*Arrhenatherum elatius* appeared at an average quantity of 27.7% and at a frequency of 63.6% of all sampled stomachs. *Bromus erectus* amounted to 22.3% and appeared in 63.6% of all sampled stomachs. The corresponding values for *G. mollugo* are 9.6% and 36.4%, and for *Poa annua/trivialis* 9.6% and 18.2%.

*Differences between monocots and dicots*

Using the same calculations as above, the Mann-Whitney-U-test showed a significant difference ($p < 0.0001$, $n_{monocots}$=489, $n_{dicots}$=496) between monocots and dicots, again in favour of monocots.

COMPARISON BETWEEN HABITATS BASED ON MONOCOTS, SEEDS AND ROOTS INGESTED

We took into account the percentages (0 - 100%) of occurrences of each monocot species ingested, separately for each site. The values of all three sites from SWFF, respectively quasi-natural habitat, were then combined. Again the total number of observations is greater than the number of captured voles, for the reasons mentioned above. A Mann-Whitney-U-test showed no significant difference ($p = 0.270$, $n_{swff}$ = 380, $n_{quasi}$ = 496) between the habitats.

The quantity of seeds ingested showed a significant difference (Mann-Whitney-U-test, $p < 0.001$, $n_{swff} = 99$, $n_{quasi} = 98$, zero-percentage-values were included), whereby seeds were ingested in larger quantities in the SWFF than in the quasi-natural habitats.

There was more root-tissue in the stomachs of voles from SWFF than from quasi-natural habitats, but the difference was not significant (Mann-Whitney-U-test, $p = 0.214$ $n_{swff} = 99$, $n_{quasi} = 98$, zero-percentage-values were included).

### Food Preference in SWFF

In each site (Tab. 4-6), the null hypothesis "all components are equally preferred" was always rejected, i.e. preferences for different plants exist. However, no clear preference pattern was found. Although *Poa annua/trivialis* was the most ingested species (Tab. 2), *M. arvalis* had no clear preference for that plant. *Agropyron repens* was the second most ingested species, which was highly preferred in Uettligen, but only selected at an average level in Niederwangen. Overall, neither the monocots nor the dicots were primarily selected, although the amount of ingested monocots was higher than the dicots. The preferences for quantity and for frequency of occurrence showed a similar pattern, since both factors were positively correlated.

### Food preferences in quasi-natural habitats

As shown in Tab. 7-9 there is a preference for some plants, although no clear preference pattern appears. *Arrhenatherum elatius* was the most ingested species, but *M. arvalis* had no clear preference for it. Also *Bromus erectus*, the second most ingested plant species, was not clearly preferred. In Hinterkappelen, *Galium mollugo* was highly preferred, whereas in Riedbach it was the least preferred food item. Again, the preference for quantity and for frequency of occurrence showed a similar pattern, due to their positive correlation.

## DISCUSSION

### Diet composition

The diet of *M. arvalis* in SWFF and in quasi-natural habitats included various dicots and almost every monocot growing locally. Other studies showed as well that the common vole has a species-rich food spectrum. With one exception, we did no find animal components in its diet contrary to Holisova (1975) who noted that they ingested considerable amounts of animal fragments.

Although more plant species were growing in SWFF than in quasi-natural habitats, the common vole did not consume higher amounts, or more often, the additional sown wild flowers. On the contrary, the present study shows that the vole fed most often on grasses even in the SWFF where grasses were less abundant than sown wild flowers. It seems that the additional sown wild flowers are not attractive to the common vole as food plants. Briner *et al*. (2005) mention that the abundance of food resources in SWFF is a key factor that accounts for the small home range sizes in these habitats, suggesting that the distribution of food is the major factor influencing the spacing system of voles and hence its higher density in SWFF. This seems to be

TAB. 4: Rank preference index according to Johnson for quantity and frequency of occurrence in the field Grauholz. All plants were not equally preferred: $F (9, 25) = 227.9$, $p<0.001$, $W=1.85$ Plants connected by a same line are not significantly different in preference by the voles; no line means that the food items differ significantly ($p \leq 0.05$). There are no lines in the frequency of occurrence because the significance of a difference cannot be computed without the standard error of the difference between two means.

| Rank | Quantity | Tbar | Rank | Frequency of occurrence |
|---|---|---|---|---|
| 1 | *Plantago lanceolata* | -2.411 | 1 | *Plantago lanceolata* |
| 2 | *Arrhenatherum elatius* | -1.779 | 2 | *Arrhenatherum elatius* |
| 3 | *Alopecurus pratensis* | -1.500 | 3 | *Poa pratensis* |
| 4 | *Trifolium pratense* | -1.485 | 4 | *Poa trivialis* |
| 5 | *Veronica persica* | -1.368 | 5 | *Alopecurus pratensis* |
| 6 | *Poa trivialis* | -0.559 | 6 | *Trifolium pratensis* |
| 7 | *Poa pratensis* | -0.324 | 7 | *Veronica persica* |
| 8 | *Centaurea jacea* | 1.309 | 8 | *Centaurea jacea* |
| 9 | *Achillea millefolium* | 3.559 | 9 | *Achillea millefolium* |
| 10 | *Leucanthemum vulgare* | 4.559 | 10 | *Leucanthemum vulgare* |

TAB. 5: Rank preference index according to Johnson for quantity and frequency of occurrence in the field Niederwangen. All plants were not equally preferred: $F (12, 30) = 183.47$, $p<0.001$, $W=1.82$

| Rank | Quantity | Tbar | Rank | Frequency of occurrence |
|---|---|---|---|---|
| 1 | *Holcus lanatus* | -4.238 | 1 | *Agropyron repens* |
| 2 | *Anthemis tinctoria* | -4.200 | 2 | *Plantago sp.* |
| 3 | *Cichorium intybus* | -2.163 | 3 | *Achillea millefolium* |
| 4 | *Achillea millefolium* | -2.100 | 4 | *Cichorium intybus* |
| 5 | *Plantago sp.* | -2.063 | 5 | *Poa trivialis* |
| 6 | *Agropyron repens* | -1.813 | 6 | *Arrhenatherum elatius* |
| 7 | *Geranium pyrenaicum* | -1.688 | 7 | *Anthemis tinctoria* |
| 8 | *Arrhenatherum elatius* | 1.750 | 8 | *Holcus lanatus* |
| 9 | *Poa trivialis* | 1.925 | 9 | *Daucus carota* |
| 10 | *Daucus carota* | 1.938 | 10 | *Geranium pyrenaicum* |
| 11 | *Lolium perenne* | 2.988 | 11 | *Trifolium pratense* |
| 12 | *Trifolium pratense* | 4.713 | 12 | *Lolium perenne* |
| 13 | *Medicago sativa* | 4.950 | 13 | *Medicago sativa* |

TAB. 6: Rank preference index according to Johnson for quantity and frequency of occurrence in the field Uettligen. All plants were not equally preferred: $F (8, 15) = 42.51$, $p<0.001$, $W=1.90$

| Rank | Quantity | Tbar | Rank | Frequency of occurrence |
|---|---|---|---|---|
| 1 | *Agropyron repens* | -3.225 | 1 | *Agropyron repens* |
| 2 | *Galium mollugo* | -2.650 | 2 | *Arrhenatherum elatius* |
| 3 | *Tanacetum vulgare* | -1.900 | 3 | *Tanacetum vulgare* |
| 4 | *Arrhenatherum elatius* | -1.575 | 4 | *Poa trivialis* |
| 5 | *Centaurea jacea* | 0.650 | 5 | *Gallium mollugo* |
| 6 | *Trifolium pratense* | 1.750 | 6 | *Centaurea jacea* |
| 7 | *Dactylis glomerata* | 1.900 | 7 | *Achillea millefolium* |
| 8 | *Poa trivialis* | 2.150 | 8 | *Trifolium pratense* |
| 9 | *Achillea millefolium* | 2.900 | 9 | *Dactylis glomerata* |

TAB. 7: Rank preference index according to Johnson for quantity and frequency of occurrence in the field Riedbach. All plants were not equally preferred: $F(13, 40) = 146.95$, $p<0.001$, $W=1.79$

| Rank | Quantity | Tbar | Rank | Frequency of occurrence |
|---|---|---|---|---|
| 1 | *Vicia cracca* | -4.566 | 1 | *Holcus lanatus* |
| 2 | *Achillea millefolium* | -3.066 | 2 | *Vicia cracca* |
| 3 | *Holcus lanatus* | -2.755 | 3 | *Alopecurus pratensis* |
| 4 | *Silene vulgaris* | -2.707 | 4 | *Arrhenatherum elatius* |
| 5 | *Medicago lupulina* | -2.698 | 5 | *Achillea millefolium* |
| 6 | *Knautia arvensis* | -2.689 | 6 | *Dactylis glomerata* |
| 7 | *Arrhenatherum elatius* | 0.622 | 7 | *Geranium pyrenaicum* |
| 8 | *Authoxanthum odoratum* | 1.141 | 8 | *Bromus erectus* |
| 9 | *Alopecurus pratensis* | 1.292 | 9 | *Galium mollugo* |
| 10 | *Bromus erectus* | 1.575 | 10 | *Daucus carota* |
| 11 | *Dactylis glomerata* | 3.047 | 11 | *Knautia arvensis* |
| 12 | *Daucus carota* | 3.141 | 12 | *Medicago lupulina* |
| 13 | *Geranium pyrenaicum* | 3.594 | 13 | *Authoxanthum odoratum* |
| 14 | *Galium mollugo* | 4.066 | 14 | *Silene vulgaris* |

TAB. 8: Rank preference index according to Johnson for quantity and frequency of occurrence in the field Hinterkappelen. All plants were not equally preferred: $F(7, 23) = 95.57$, $p<0.001$, $W=1.89$

| Rank | Quantity | Tbar | Rank | Frequency of occurrence |
|---|---|---|---|---|
| 1 | *Dactylis glomerata* | -2.315 | 1 | *Galium mollugo* |
| 2 | *Holcus lanatus* | -1.333 | 2 | *Arrhenatherum elatius* |
| 3 | *Galium mollugo* | -1.278 | 3 | *Dactylis glomerata* |
| 4 | *Arrhenatherum elatius* | -1.259 | 4 | *Poa pratensis* |
| 5 | *Poaa pratensis* | -0.278 | 5 | *Holcus lanatus* |
| 6 | *Tanacetum vulgare* | 1.407 | 6 | *Agropyron repens* |
| 7 | *Poa trivialis* | 2.259 | 7 | *Poa trivialis* |
| 8 | *Agropyron repens* | 2.786 | 8 | *Tanacetum vulgare* |

TAB. 9: Rank preference index according to Johnson for quantity and frequency of occurrence in the field Moosseedorf. All plants were not equally preferred: $F(4, 11) = 34.90$, $p< 0.001$, $W=2.21$

| Rank | Quantity | Tbar | Rank | Frequency of occurrence |
|---|---|---|---|---|
| 1 | *Alopecurus pratensis* | -1.773 | 1 | *Galium mollugo* |
| 2 | *Arrhenatherum elatius* | -0.727 | 2 | *Bromus erectus* |
| 3 | *Poa trivialis* | -0.500 | 3 | *Poa trivialis* |
| 4 | *Galium mollugo* | 1.227 | 4 | *Alopecurus pratensis* |
| 5 | *Bromus erectus* | 1.772 | 5 | *Arrhenatherum elatius* |

verified in our study plots, as plants growing there naturally, mainly grasses, are a major food supply, while flowers are not. It is possible that the root- and seed-supply in SWFF is another key factor, which attracts the voles, as seeds were significantly more often ingested in SWFF than in quasi-natural habitats. The same applies to roots. More root-tissue was found in the stomachs of voles from SWFF than from quasi-natural habitats, although the difference was non significant. Roots were only consumed in small amounts. This could be related to the unusually mild winter of 2006/07 with temperatures in February 3 to 4 degrees above average. It is possible that the proportion of roots would have been higher during a harsh winter, i.e. when annual plants are less abundant.

It is important to note that a lot of plants recorded by Balmelli *et al*. (1999) and Baumann (1996) showed feeding signs on roots and seeds and not on leaves. With the method used in our study it was not possible to identify roots and seeds at the species level and only the epidermis from green plant parts was considered. Therefore, these studies are not directly comparable with each other, as they are based on different approaches. Nonetheless, it can be assumed that the food-spectrum of *M. arvalis* is even broader than the present work suggests. This assumption agrees with data from other authors, which show longer lists of ingested species (Rinke, 1990; Truszkowski 1982).

Food preference

No clear food preference pattern was found. Although monocots were the most frequently ingested plants and the amount consumed was high, they were not always the most preferred, when comparing usage to availability. In contrast, dicots were eaten in significant lower proportions than monocots, but nevertheless, they were preferred in some cases. Many studies have shown that voles do select certain plant species (Balmelli *et al*., 1999; Leutert, 1983; Rinke, 1990; Yu *et al*., 1980). These studies and the present work show that the food intake of *M. arvalis* depends only to some extent on the availability of the food-components, at least in habitats with a broad spectrum of food-supply.

Our results do not always agree with the observations of other authors. Yu *et al*. (1980) found that *Taraxacum officinale* was the most important food plant in the studied population, followed by *Medicago lupulina*, *Anthoxanthum odoratum* and *Bromus erectus*. In our case, *T. officinale* occurred only in one site, and at small density. Further important food resources in the study of Yu *et al*. (1980) were *Arrhenatherum elatius*, *Holcus lanatus*, *Trifolium repens*, *Lolium perenne* and *Phleum pratense*, which corresponds largely to our results. Rinke (1990) observed that *Poa pratensis*, *Poa trivialis* and *A. elatius* were ingested frequently and in large quantities, a fact consistent with our data. In agreement with Rinke (1989), *Leucanthemum vulgare*, *Achillea millefolium* and *Centaurea jacea* (frequent plants in our study plots) were rarely detected in the voles' stomachs/faeces and only in small quantities.

Balmelli *et al*. (1999) studied food preferences in laboratory feeding tests and analysed the plant nutritional components (nitrogen, sugar, starch and phenolics) as well as energy and water content. They found clear preferences, but were unable to find any relationship between preference and nutritional parameters. Preferences are probably influenced by a complex of different factors. Apart from the nutrient content and chemical substances, physical properties such as leaf thickness, hardness of leaves, trichomes or water content can play a role as well.

Rank preference index

The calculated rank preference index suggests that there is a preference of *M. arvalis* for sown wild flowers in some sites. A significant preference will only be detected when the usage of a plant is higher than its availability. *Bromus erectus* in Riedbach grew in large quantities and was ingested frequently and in relatively high amounts, as well. As the usage was lower than the availability, no significant preference for this plant was observed. On the contrary, a plant like *Tanacetum vulgare*, growing in small quantities, resulted in a high preference because its usage was higher than availability.

| | |
|---|---|
| Comments of zRMS: | The article is written by Deutch and was not validated by zRMS.<br>. |

| | |
|---|---|
| Reference: | **KCP 10.1.2.2/07** |
| Title: | Nahrungspraeferenzen der Feldmaus Microtus arvalis in der Agrarlandschaft unter Beruecksichtigung der Pflanzeninhaltsstoffe |
| Report: | xxx 1999; C040328; M-228713-01-1 |
| Authority registration No: | |
| Guideline(s): | -- |
| Deviations: | -- |
| GLP/GEP: | not applicable |
| Acceptability: | |
| Duplication<br>(if vertebrate study): | No |

Public literature

| Comments of zRMS: | The article is considered as additional information. |
|---|---|

| | |
|---|---|
| Reference: | **KCP 10.1.2.2/08** |
| Title: | Nutritional ecology of Microtus arvalis (Pallas, 1779) on permanent grassland |
| Report: | Xxx 1990; C044034; M-228620-01-2 |
| Authority registration No: | |
| Guideline(s): | -- |
| Deviations: | -- |
| GLP/GEP: | not applicable |
| Acceptability: | |
| Duplication (if vertebrate study): | No |

**Abstract**
Nutrition ecology ofMicrotus arvalis (Pallas, 1779) on permanent meadow
I. General food preferences
Investigated were the food preferences of a population of the common European vole Micdrotus arvalis (Rodentia, Microtidae) inhabiting permanent meadow. The stomach contents of 363 individuals (186 $$,177 *<$<$)* caught in 1984-7 with baited snap traps were microscopically analyzed. Plant species were determined using a new reference catalogue of photomicrographs taken from the epidermal structures of the 48 plant species of the volus' territory.
Species composition of the diet of the voles was not correlated to species composition of the vegetation, i.e. voles fed selectively on various plant species. The results indicate that the 48 available species may be divided into four categories, according to their importance as diet components:
1. Major food species (taken very frequently and at high volume percentage): 8 species,
2. Minor food species (taken frequently, but only with low to medium volume percentage): 12 species,
3. Casual diet (taken rarely and with low volume percentage): 20 further species, and
4. Species totally avoided: SSpeices.
Taraxacum officinale and Trifolium pratense were by far the most important food species concerning the frequency of occurrence as well as the volume percentage.

Intraduction:
In central Europe, the common vole *Microtus arvalis* (Pallas 1779) lives mainly on cultivated land and by eating field crops can therefore become an agricultural pest, especially if population densities are high. The impact of the vole's feeding habits on crops has therefore been the subject of several previous studies (Babinska-Werka 1979; Holisova 1975; Kokes 1976; Ryszkowski et al. 1973; Tertil 1977; Truszkowski 1982).
In single crop fields such as cereal, turnips or lucerne the available choice of plants to be consumed is obviously very limited. By contrast, *Microtus arvalis* populations living on

permanent grassland have a wide selection of plant species as potential food sources. This

variety raises the question whether the relative proportions of individual plant species in the vole's diet match the species composition of the vegetation or whether *Microtus arvalis* is selective in its grazing activities. Yu et al. (1980) observed in a French population that the percentage of a particular plant species in the diet of the common vole did not correlate with its prevalence in the plant biomass, and the results of a study conducted in Switzerland by Leutert (1983) point in the same direction.
There are as yet no quantitative data from German-speaking regions to indicate which plants are highly attractive to vole populations on permanent grassland, despite their relative scarcity in the available vegetation, and which plants might be eaten rarely or even avoided completely, even though they may be more abundant. The purpose of this study was to describe quantitative relationships between the species composition of the available vegetation and the diet composition *of Microtus arvalis.*

## Materials and methods

The study area comprised five permanent grassland areas of about 0.5 hectares each in the Pohlheim-Holzheim district in the north Wetterau region of Hesse.
In the period from October 1984 to May 1987 a total of 363 individuals (186 $? and 177 *<$$* of all ages post weaning) of the European common vole *Microtus arvalis* (Rodentia, Microtidae) were captured with snap traps, using mainly raisins as bait. The carcasses were stored at -20°C until needed for analysis.
After thawing the stomach was removed and the contents examined under the microscope. The plant fragments found were differentiated by species using a reference catalogue of over 600 photomicrographs taken previously of the epidermal structures of all above-ground parts of 48 plant species which had been identified in the study area. In addition to the species differentiation the proportion of each plant species by volume in the total stomach contents was estimated based on the space covered on the slide.
The measure of the availability of a plant species is its percentage of the ground cover vegetation as a whole. This value was determined from five photomicrographs taken in May and August respectively.
In order to determine and compare the feeding preference of *Microtus arvalis* for different plant species a score is needed which takes into account the abundance of each species in the vegetation. The preference index which meets this condition and which we adopted in our study was that suggested by Reichman (1975) and Burton and Black (1978): the quotient of isolation frequency or volume percentage in the stomach contents on the one hand and the percentage in the ground cover vegetation on the other hand. Preference indices greater than 1.00 indicate preference and scores below 1.00, refusal (Reichman 1975).

Results:

**Table 1: Proportion of different plant species in the floor cover vegetation of the study area, isolation frequency in the analysed stomachs and preference index by frequency, proportion of the total food volume of all studied animals and preference index by volume**

| Species | Proportion of ground cover vegetation (%) | Isolation frequency (%) | Preference index by frequency | Proportion of total food volume (%) | Preference index by volume |
|---|---|---|---|---|---|
| Arrhenatherum elatius | 13,50 | 32,51 | 2,41 | 5,15 | 0,38 |
| Alopecurus pratensis | 12,97 | 24,52 | 1,89 | 4,75 | 0,37 |
| Dactylis glomerata | 11,41 | 4,68 | 0,41 | 0,44 | 0,04 |
| Trisetum flavescens | 7,24 | 15,43 | 2,13 | 2,25 | 0,31 |
| Poa pratensis | 6,68 | 41,32 | 6,19 | 5,91 | 0,88 |
| Holcus lanatus | 5,07 | 5,51 | 1,09 | 1,31 | 0,26 |
| Lolium perenne | 3,09 | 26,72 | 8,65 | 3,35 | 1,08 |
| Achillea millefolium | 3,01 | 14,33 | 4,76 | 3,27 | 1,09 |
| Galium mollugo | 2,53 | 6,61 | 2,61 | 1,31 | 0,52 |
| Bromus mollis | 2,12 | 18,46 | 8,71 | 1,92 | 0,91 |
| Poa trivialis | 2,06 | 33,06 | 16,05 | 4,90 | 2,38 |
| Ranunculus acris | 2,00 | 1,38 | 0,69 | 0,07 | 0,04 |
| Anthirscus sylvestris | 1,89 | 15,15 | 8,02 | 3,22 | 1,70 |
| Geranium pratense | 1,89 | 1,10 | 0,58 | 0,41 | 0,22 |
| Festuca pratensis | 1,81 | 0,28 | 0,15 | 0,01 | 0,01 |
| Heracleum sphondylium | 1,59 | 5,79 | 3,64 | 1,39 | 0,87 |
| Vicia sepium | 1,48 | 8,82 | 5,96 | 2,86 | 1,93 |
| Cerastium holosteoides | 1,39 | 4,13 | 2,97 | 0,46 | 0,33 |
| Trifolium pratense | 1,36 | 8,82 | 6,49 | 2,03 | 1,49 |
| Phleum pratense | 1,25 | 10,19 | 8,15 | 1,42 | 1,14 |
| Plantago lanceolata | 1,17 | 5,79 | 4,95 | 0,96 | 0,82 |
| Bellis perennis | 1,03 | - | - | - | - |
| Anthoxanthum odoratum | 0,97 | 4,96 | 5,11 | 0,23 | 0,24 |
| Lotus corniculatus | 0,86 | 0,28 | 0,33 | 0,01 | 0,01 |
| Poa annua | 0,83 | 23,42 | 28,22 | 4,60 | 5,54 |
| Taraxacum officinale | 0,83 | 47,93 | 57,75 | 23,95 | 28,86 |
| Glechoma hederacea | 0,78 | - | - | - | - |
| Leucanthemum ircutianum | 0,75 | 2,75 | 3,67 | 0,14 | 0,19 |

| | | | | | |
|---|---|---|---|---|---|
| Lolium multiflorum | 0,75 | 3,03 | 4,04 | 0,23 | |
| Trifolium repens | 0,67 | 39,39 | 58,79 | 18,60 | 2 |
| Ajuga reptans | 0,67 | 0,83 | 1,24 | 0,01 | |
| Centaurea jacea | 0,64 | 2,75 | 4,30 | 0,42 | |
| Cirsium arvense | 0,53 | - | - | - | |
| Vicia angustifolia | 0,50 | 3,03 | 6,06 | 0,74 | |
| Veronica arvensis | 0,50 | 6,89 | 13,78 | 1,83 | |
| Daucus carota | 0,50 | - | - | - | |
| Ranunculus repens | 0,47 | 1,10 | 2,34 | 0,26 | |
| Plantago media | 0,45 | 0,28 | 0,62 | 0,03 | |
| Campanula rotundifolia | 0,42 | 0,55 | 1,31 | 0,01 | |
| Rumex obtusifolius | 0,31 | 1,10 | 3,55 | 0,51 | |
| Medicago varia | 0,31 | 0,55 | 1,77 | 0,12 | |
| Myosotis arvensis | 0,31 | 0,28 | 0,90 | 0,01 | |
| Crepis biennis | 0,31 | - | - | - | |
| Lamium album | 0,28 | 0,28 | 1,00 | 0,01 | |
| Trifolium dubium | 0,28 | - | - | - | |
| Rumex crispus | 0,19 | 4,41 | 23,21 | 0,77 | |
| Cynosurus cristatus | 0,19 | - | - | - | |
| Urtica dioica | 0,17 | - | - | - | |

1. Species with very high preference (PI ≥ 10):
   *Trifolium repens, Taraxacum officinale, Poa annua, Rumex crispus, Poa trivialis, Veronica arvensis* (6 species which together account for 5.08 % of the plant cover).
2. Species with high preference (10 > PI ≥ 5):
   *Bromus mollis, Lolium perenne, Phleum pratense, Anthriscus sylvestris, Trifolium pratense, Poa pratensis, Vicia angustifolia, Vicia sepium, Anthoxanthum odoratum* (9 species, together accounting for 19.34 %).
3. Species with moderate preference (5 > PI ≥ 2):
   *Plantago lanceolata, Achillea millefolium, Centaurea jacea, Lolium multiflorum, Leucanthemum ircutianum, Heracleum sphondylium, Rumex obtusifolius, Cerastium holosteoides, Galium mollugo, Arrhenatherum elatius, Ranunculus repens, Trisetum flavescens* (12 species, together 33.35 %).
4. Species with low preference (2 > PI ≥ 1):
   *Alopecurus pratensis, Medicago varia, Campanula rotundifolia, Ajuga reptans, Holcus lanatus, Lamium album* (6 species, together 19.72 %).
5. Species with negative preference (1 > PI > 0):
   *Myosotis arvensis, Ranunculus acris, Plantago media, Geranium pratense, Dactylis glomerata, Lotus corniculatus, Festuca pratensis* (7 species, together 18.73 %).

*Lamium album, Myosotis arvensis, Campanula rotundifolia, Lotus corniculatus, Festuca pratensis* (26 species, together 78.25 %).

6. Species avoided completely (PI = 0):
   *Urtica dioica, Cynosurus cristatus, Trifolium dubium, Crepis biennis, Daucus carota, Cirsium arvense, Glechoma bederacea, Bellis perennis* (8 species, together 3.79 %).

In total, 15 species, together accounting for about one quarter of the vegetation in the study area, are strongly or very strongly favoured. A further 15 species, which together make up just over one-fifth of the plant cover, are rejected or avoided completely.

**Volume percentage of food plants**

The procedure described in the previous chapter for assessing the importance of different plant species as a food source for *Microtus arvalis* carries the risk that the importance of species consumed frequently, but always in small quantities, is consistently overestimated. In this chapter we therefore propose to investigate whether different results are obtained if the calculation is based not on the frequency with which a plant species is eaten but on its share of the fill volume of each stomach.

This is done in the last two columns of Table 1. Column 5 shows the percentage share of each plant species in the total contents of all stomachs while column 6 gives the preference index by volume, i.e. the quotient of the values from columns 5 and 2.

It can be seen that the preference for certain species becomes even more marked if volume is adopted as the assessment criterion. The 15 Gramineae species, which together account for almost 70 % of the biomass of the plant cover, make up barely 37 % of the diet volume, whereas the 33 Dicotyledone species account for only about 30 % of the biomass but represent over 60 % of the ingested food volume. The most striking finding was that two species which together represent only 1.5 % of the vegetation, namely *Taraxacum officinale* and *Trifolium repens*, constitute well over 40 % of the total diet volume.

A breakdown into categories by preference indices produces the following picture:

1. Species with extremely high preference (PI ≥ 10):
   *Taraxacum officinale, Trifolium repens* (2 species which together account for 1.5 % of the vegetation).
2. Species with high preference (10 > PI ≥ 5):
   *Poa annua* (1 species, 0.86 %).
3. Species with moderate preference (5 > PI ≥ 2):
   *Rumex crispus, Veronica arvensis, Poa trivialis* (3 species, together 2.75 %).
4. Species with low preference (2 > PI ≥ 1):
   *Vicia sepium, Anthriscus sylvestris, Rumex obtusifolius, Trifolium pratense, Vicia angustifolia, Phleum pratense, Achillea millefolium, Lolium perenne* (8 species, together 12.89 %).
5. Species with negative preference (1 > PI > 0):
   *Bromus mollis, Poa pratense, Heracleum sphondylium, Plantago lanceolata, Centaurea jacea, Ranunculus repens, Galium mollugo, Arrhenatherum elatius, Alopecurus pratensis, Cerastium holosteoides, Trisetum flavescens, Lolium multiflorum, Medicago varia, Holcus lanatus, Anthoxanthum odoratum, Geranium pratense, Leucanthemum ircutianum, Plantago media, Dactylis glomerata, Ranunculus acris, Ajuga reptans,*

*Lamium album, Myosotis arvensis, Campanula rotundifolia, Lotus corniculatus, Festuca pratensis* (26 species, together 78.25 %).

6. Species avoided completely (PI = 0):
*Urtica dioica, Cynosurus cristatus, Trifolium dubium, Crepis biennis, Daucus carota, Cirsium arvense, Glechoma bederacea, Bellis perennis* (8 species, together 3.79 %).

The 14 species of the first four categories, whose proportion in the diet is higher than their abundance in the vegetation, together make up only 18 % of the plant cover. The remaining 34 species account for over 80 % of the floor cover but are consistently consumed in amounts less than their percentage of the biomass.

It is interesting to note that the two sequences based on preference indices show few marked differences between assessment by isolation frequency and by volume. In this respect the two procedures can be considered equivalent. On the other hand, comparing the results of the two scoring systems also illustrates that the establishment of a ranking order alone gives a distorted picture of the importance of individual species in the diet of *Microtus arvalis*. By analysing volume percentages we can see that the common vole feeds mainly on just a few core plant species whereas the bulk of the available species are either secondary components of the diet or are eaten rarely and on a casual basis.

**Composition of the dietary spectrum of *Microtus arvalis* on permanent grassland**

From the results presented so far it is concluded that an assessment of the importance of different plant species as components in the diet of *Microtus arvalis* must be based both on the consumption frequency and the ingested volume.

Taking this consideration and the results of the two previous chapters into account, the 40 plant species isolated in the analysed stomachs can be ranked with regard to their importance as components in the dietary spectrum of *Microtus arvalis* as shown below:

1. Core components of the diet:
1.1 Species eaten very frequently and at very high volume percentage: *Taraxacum officinale, Trifolium repens.*
1.2 Species eaten very frequently and at high volume percentage: *Arrhenatherum elatius, Poa pratensis.*
1.3 Species eaten very frequently but at low volume percentage: *Alopecurus pratensis. Lolium perenne, Poa trivialis, Poa annua.*
2. Secondary components of the diet:
2.1 Species eaten frequently but at moderate volume percentage: *Trisetum flavescens, Achillea millefolium, Anthriscus sylvestris.*
2.2 Species eaten frequently but at low volume percentage or less frequently but at higher volume percentage: *Bromus mollis, Phleum pratense, Vicia sepium, Trifolium pratense.*
2.3 Species eaten less frequently and at low volume percentage: *Holeus lanatus, Galium mollugo, Heracleum sphondylium, Plantago lanceolata, Veronica arvensis.*
3. Casual diet (species eaten rarely and at low to very low volume percentage): *Dactylis glomerata, Ranunculus acris, R. repens, Geranium pratense, Festuca pratensis, Cerastium holosteoides, Anthoxanthum odoratum, Lotus corniculatus, Leucanthemum ircutianum, Lolium multiflorum, Ajuga reptans, Centaurea jacea, Vicia angustifolia,*

*Plantago media, Campanula rotundifolia, Rumex crispus, R. obtusifolius, Medicago varia, Myosotis arvensis, Lamium album.*

In total, eight of the utilised species are core components of the diet, twelve are secondary components while the remaining 20 species are eaten rarely.

**Discussion**

Since the groundbreaking work by Summerhayes (1941) numerous investigators have contributed to our knowledge of the nutritional ecology of *Microtus* species. Nevertheless, the picture is still incomplete and fragmented. This is due partly to the species diversity of this genus - in central and eastern Europe studies have focused mainly on *M. arvalis*, in Scandinavia and the UK on *M. agrestis* and in North America on *M. pennsylvanicus* - and in part to differences in the choice of methodology (analysis of stomach contents or faeces vs. choice feeding trials), but also the fact that food preferences can only be expressed within the limitations of the available resources. Food resources vary not only from habitat to habitat but also from population to population, which makes comparing the results of different studies immensely difficult.

What is certain and has also been demonstrated in the present study is that the food choices of *Microtus arvalis*, at least in meadow habitats where there is a varied selection, are determined only partially by the availability of the different dietary components and are primarily influenced by marked preferences (Yu et al., 1980; Leutert 1983). Holisova (1975) on the other hand observed no demonstrable preferences in suboptimal biotopes close to water courses.

Where preferences for various plant species have been recorded, some are in agreement with our results while others show discrepancies. For the population studied by Yu et al. (1980) *Taraxacum officinale* was the core food plant, as in our study, but it was followed by *Festuca ovina, Medicago lupulina, Cynosurus cristatus, Anthoxanthum odoratum* and *Bromus erectus;* the five last-named genera (in some cases with different species) played only a minor role in the dietary spectrum of the population studied here. Other important food resources were *Arrhenatherum elatius, Holcus lanatus, Trifolium repens* (although only 9$^{th}$ in the ranking order), *Lolium perenne* and *Phleum pratense*, which is largely in agreement with our findings, as is the low utilisation rate of *Daucus carota* (Yu et al., 1980). But contrary to the preferences observed in our study, *Trifolium pratense, Poa annua, Poa pratensis, Achillea millefolium* and *Plantago lanceolata* were consumed only in small amounts (Yu et al., 1980).

Leutert (1983), who studied the impact of vole populations on the species composition of different meadow biotopes, found that the proportions of *Dactylis glomerata, Festuca pratensis, Myosotis arvensis, Glechoma bederacea, Poa pratensis* and *Achillea millefolium* increased after colonisation of an area by voles while cover rates of *Arrhenatherum elatius* and especially of *Taraxacum officinale* decreased and the prevalence of *Trisetum flavescens, Plantago lanceolata* and *Plantago media* in the vegetation remained roughly unchanged. As an increase in the cover rate is synonymous with refusal of the food resource by the voles and a decline with heavy utilisation, all the plant species named above, with the exception of *Poa pratensis* and *Achillea millefolium,* fitted the preference pattern.

Food preferences were also observed in several other *Microtus* species, for example by Bangs (1984), Belanger and Bergeron (1987), Lindroth and Batzli (1984a), Thompson (1965) and Zimmerman (1965) in *M. pennsylvanicus*, by Batzli and Jung (1980) in *M. oeconomus*, by Gill (1977) and by Batzli and Pitelka (1970; 1971) in *M. californicus*, by Ferns (1976) in *M. agrestis* and by Fleharty and Olson ((1969), Cole and Batzli (1979) and by Zimmerman (1965) in *M. ochrogaster*.

Different results were reported by Bergeron and Juillet (1979) in *M. pennsylvanicus*, Godfrey (1953) in *M. agrestis* - although the latter only studied the proportion of different grasses - and Spencer (1984) in *M. longicaudus* from a mountainous biotope.

Little is known so far about the causes of the preferences described, but some research has been done to address this question.

Partridge (1981), who studied the effect of experimentally induced food habits in four small mammalian species including *M. agrestis*, found a persistent preference for the food that was supplied as the sole diet early in life, even after the animals were given access to a more varied selection. The author's explanation for this phenomenon is the enhanced efficiency of the digestive tract for processing familiar foods.

Stenseth et al. (1977) developed a mathematical model to test the hypothesis that the food selection of herbivorous microtine rodents is ruled by the endeavour to optimise the relationship between energy lost through searching for food and energy gained through consuming food. This model was compatible with their observations regarding the food habits of *M. agrestis*.

More recently several authors have looked for a causal relationship between preference for or strict refusal of certain plants and their species-specific components (Lindroth and Batzli 1984b; Jean and Bergeron 1986; Belanger and Bergeron 1987; Bergeron et al. 1987). Some studies focus on the pathogenic or repellent effect of secondary components, others on the relationship between nutrient content and attractiveness.

As none of these studies were conducted in *Microtus arvalis* it is impossible to say at this time whether any of these factors - and if so which one - determines the food selection habits of the common vole.

| | |
|---|---|
| Comments of zRMS: | Additional information.<br>The golf courses are not included in the GAP. |

| | |
|---|---|
| Reference: | **KCP 10.1.2.2/09** |
| Title: | Wild mammals on golf courses |
| Report: | xxx |
| Authority registration No: | |
| Guideline(s): | The test was specifically designed for this study |
| Deviations: | none |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication<br>(if vertebrate study): | No |

**Materials and methods:**

The study was performed on two typical golf courses in North Rhine-Westphalia, Germany which were selected for sake of contrasting exposure situations with regard to landscape, height, slope and style.
One golf course (‘Velderhof’) is located northwest from the city of Cologne in the lowlands of the river Rhine; the other one ‘Georgshausen’ is located east northeast from Cologne in a low mountain range.
In a first step the occurrence of wild mammals in the most natural habitats on golf courses - hard roughs and surroundings - was evaluated with life trapping. These structures of golf courses are the most similar to natural habitats of wild mammals among the various sub-areas and thus most suited to support small mammal populations.
The second step was to check to what extent these wild mammals will use the less natural, more intensively managed sub-areas like greens or tees.
On both golf courses, 60 Ugglan life traps were installed in 4 transects and equipped with a bait oat flakes. The traps remained open for 5 to 6 days, so that mice could get used to them. After that period the traps were equipped with fresh bait, activated in the evening and controlled the morning after. The number of small mammals and the species were recorded. This procedure was repeated the next evening and morning, so that the total number of trap nights amounted to 240.
As in Georgshausen (“Forest golf course”) the majority of mice were species of the woodlands (bank voles) which do not enter open areas without any shelter, no further activities were performed on this site.
On the “Parkland golf course” (Velderhof) also grassland species (voles) were caught. Therefore and to check if wood mice enter greens and tees additionally 8 observation sessions with a thermal heat camera were performed at night (duration 2 hours each) at this site, scanning tees and greens and at one session also fairway and rough. The aim was to check if there were small mammal feeding activities on these most managed open grass areas.

**Results and discussions:**

Although both sites differ in regard of region and landscape structure, the relative sizes of different grass type are similar.
The trapping result was as follows:

| **Species** | **Georgshausen** | | **Velderhof** | |
|---|---|---|---|---|
| | **Mice trapped** | **Per 100 trap nights** | **Mice trapped** | **Per 100 trap nights** |
| Bank vole (*C. glareolus*) | 28 | 23.3 | 13 | 10.8 |
| Common vole (*M. arvalis*) | - | - | 12 | 10.0 |
| Yellow-necked mouse (*A. flavicollis*) | 1 | 0.8 | 2 | 1.6 |
| Wood mouse (*A. sylvaticus*) | 6 | 5.5 | 2 | 1.6 |
| Shrew (*Sorex* spec.) | 3 | 2.5 | 2 | 1.6 |

Overall, on both golf courses the overall trapping success was high: In Georgshausen 31.7 mammals were trapped per 100 trap nights, in Velderhof 25.8 mammals. But 70% of all mammals in Georgshausen and 52% in Velderhof were bank voles (*Clethrionomys glareolus*) caught close to hedges or forest. In Velderhof also common voles (*Microtus arvalis*) were caught (10.0 catches /100 trap nights; 38.7% dominance), but all in medium-high grass very close to a hedge.
Wood mice (*Apodemus sylvaticus*) - well known to enter open land without shelter – were more frequently caught in Georgshausen (6.6. mice/100 trap nights; 20% of all catches), while they were rare in Velderhof (1.6 mice/100 trap nights or 6.5% of all catches).
Insectivorous shrews (*Sorex spec*.) were caught in low numbers (3 and 2, corresponding to 2.5 and 1.6 per 100 trap nights).

<u>Mammal observation:</u>
Only three small mammal activities were detected: One small mammal was seen next to a hedge (the species could not be identified), one wood mouse and one vole were seen running across the green. Feeding activity of small mammals on green and tees were never observed.
On tees, greens and fairways no holes could be detected.
In addition four rabbits were seen over a 20 minute period on a green, but they were not feeding.

**Conclusion:**

Golf courses sustain different species of small mammals. Bank voles as well as common voles were abundantly caught in trap lines close to hedges or forests of the rough where the grass height provides good shelter combined with a growth density of swords easily to cross for small animals. On golf greens, tees and fairways no voles could be detected with thermal heat cameras except one vole and one wood mouse crossing quickly a green. No mouse holes and no surface runways could be detected on greens, tees or fairways.
Small mammals are not species of concern on golf course areas without any shelter as greens, tees and fairways.

## A 2.1.3 KCP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)

## A 2.2 KCP 10.2 Effects on aquatic organisms

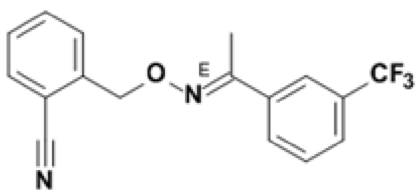
## A 2.2.1 KCP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes

### A 2.2.1.1 Fish

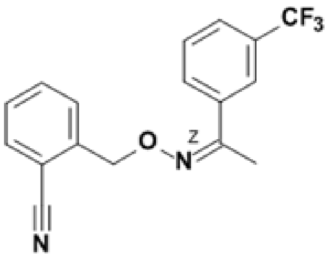
| | |
|---|---|
| Comments of zRMS: | The reliability of the study was not fully assessed since not used to finalise the risk assessment in this specific case.<br>According to the risk assessment scheme for metabolites in EFSAs aquatic GD, it is acceptable in this case to assume that the acute toxicity of the metabolites to fish is equal to the toxicity of the a.s. |

| | |
|---|---|
| Reference: | **KCP 10.2.1/01** |
| Title: | CGA 357276 and NOA 409480 - Estimation of acute toxicity to fish |
| Report: | xxx |
| Authority registration No: | |
| Guideline(s): | not applicable |
| Deviations: | none |
| GLP/GEP: | no |
| Acceptability: | |
| Duplication (if vertebrate study): | No |

The acute toxicity to fish of compounds CGA 357276 and NOA 409480 was estimated using the EPI Suite module ECOSAR v1.11 and the OECD QSAR Toolbox v4.1. Within ECOSAR a classification into chemical classes according to their (eco)toxicological properties is combined with a linear regression for each class based on the octanol-water partition coefficient (log Kow). The QSAR Toolbox estimate was produced by the automated workflow feature, which gathers experimental data from curated databases, selects similar compounds according to several profilers and performs a trend analysis based on the calculated log Kow value. The estimates of the two different methods are in very good agreement with each other for both substances, which supports their reliability. The validity according to the OECD principles was checked for both methods and the models were deemed applicable for the query compounds. Other models were considered, but were not adequate for the intended use in risk assessments.

| **Compound** | **Results** |
|---|---|
| CGA 357276; BCS-AB39835<br> | **ECOSAR v1.11, $LC_{50}$ (fish, 96h):**<br>$LC_{50}$ from most toxic class: 0.983 mg/L<br>Within Applicability Domain?<br>Yes – the parameters molecular weight, log Kow and calculated $LC_{50}$ are within the ranges determined by the training set molecules and within the limitations described in the manual. |

| | |
|---|---|
| SMILES code:<br>C\C(=N/OCc1ccccc1C#N)\c2cccc(c2)C(F)(F)F<br>log Kow: 4.7 (Bogdoll and Peschke 2012, M-428439-01-1) | **OECD QSAR Toolbox v4.1 automated workflow, Fish, $LC_{50}$($EC_{50}$) at 96h for *Pimephales promelas* (mortality):**<br>$LC_{50}$ (fish, 96h): 1.92 mg/L<br>Within Applicability Domain?<br>Yes – the target chemical is within the descriptor (Kow) and response ($LC_{50}$) range. It is also within the subcategories defined by the profilers. |

| **Compound** | **Results** |
|---|---|
| NOA 409480; BCS-CR74871<br><br>SMILES code:<br>C\C(=N\OCc1ccccc1C#N)\c2cccc(c2)C(F)(F)F<br>log Kow: 4.2 (Bogdoll and Peschke 2012, M-427343-01-1) | **ECOSAR v1.11, $LC_{50}$ (fish, 96h):**<br>$LC_{50}$ from most toxic class: 2.192 mg/L<br>Within Applicability Domain?<br>Yes – the parameters molecular weight, log Kow and calculated $LC_{50}$ are within the ranges determined by the training set molecules and within the limitations described in the manual.<br><br>**OECD QSAR Toolbox v4.1 automated workflow, Fish, $LC_{50}$($EC_{50}$) at 96h for *Pimephales promelas* (mortality):**<br>$LC_{50}$ (fish, 96h): 1.92 mg/L<br>Within Applicability Domain?<br>Yes – the target chemical is within the descriptor (Kow) and response ($LC_{50}$) range. It is also within the subcategories defined by the profilers. |

Additionally, a trend analysis for a set of benzonitrile compounds was carried out. With a predicted $LC_{50}$ of 4.42 mg/L for both substances, it showed that the benzonitrile group does not increase the fish toxicity.

**Conclusion:**

The worst case prediction is selected for each substance: the $LC_{50}$ for fish is 0.983 mg/L and 1.92 mg/L for CGA 357276 and NOA 409480, respectively.

| | |
|---|---|
| Comments of zRMS: | The study is not valid according to previously assessment for Luna Sensation , Registrattion report, Luna Sensation, 2018, zRMS-NL.<br><br>This study was submitted to and evaluated by zRMS (NL) for a previous national authorization of Luna Sensation (14437 N) and re-evaluated by NL for registration of Luna Sensation in 2018.<br>The test conditions met all validity criteria. Based on nominal concentrations, the 96 h - LC50 was calculated by probit analysis to be 0.091 mg/L test item (C.I.95%: not determined due to mathematical reasons). The NOEC (highest concentration without sub-lethal effects) is considered to be 0.0625 mg test item/L.<br>The minimum concentration causing 100% mortality is 0.125 mg test item / L. The maximum concentration which did not cause any mortality (no-observed-lethal-effect<br>However, the content of the active substance fluopyram in exposure solutions was measured for verification of the exposed test item concentrations but not also the content of the other active substance trifloxystrobin. Therefore, as fluopyram does |

| | |
|---|---|
| | not degrade faster than trifloxystrobin and the toxicity for fish is higher for trifloxystrobin compared to fluopyram (see LoEPs above), the test is considered unacceptable and cannot be used for the risk assessment.<br>**The study is considered not acceptable by the zRMS, as the content of trifloxystrobin should have been measured.** |

| | |
|---|---|
| Reference: | **KCP 10.2.1/02** |
| Title: | Acute toxicity of fluopyram & trifloxystrobin SC 500 (250+250) G to fish (Oncorhynchus mykiss) under static conditions |
| Report: | xxx; 2007; EBGMP030; M-294350-01-1 |
| Authority registration No: | |
| Guideline(s): | EPA-FIFRA § 72-1/SEP-EPA-540/9-85-006 (1982/1985)<br>OPPTS 850.1075 (Public Draft, 1996)<br>Directive 92/69/EEC, C.1 (1992)<br>OECD No. 203 (rev.1992); Equivalent to US EPA OPPTS Guideline No. 850.1075 SUPP |
| Deviations: | none |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication (if vertebrate study): | No |

**Materials and methods:**

A. Materials

| | |
|---|---|
| 1. Test material: | AE C656948 + Trifloxystrobin SC 250 + 250 G |
| Material number: | 06033007 |
| Batch ID: | 2007-000441 |
| Visual appearance: | white fluid |
| Physical density: | 1.174 g/mL |
| Active substance 1: | AE C656948, fluopyram |
| Active ingredient 2: | CGA 279202, trifloxystrobin |
| Nominal content of active substance: | fluopyram: 250 g/L<br>trifloxystrobin: 250 g/L) |
| Analyzed content of active substance: | fluopyram: 21.4% (251.5 g/L)<br>trifloxystrobin: 21.6% (253.5 g/L) |
| Expiration date: | 2008-02-21 |
| 2. Test organism | |
| Species | Rainbow trout (Oncorhynchus mykiss), |
| mean body length (mean ± S.D.) | 5.5 ± 06 cm |
| mean body weight (mean ± S.D.) | 1.6 ± 0.6 g |
| Age | Juvenile |
| Source | Lot F 10 / 07 A was obtained from Fischzucht Trostadt, 98646 Trostadt, Germany on July, 20, 2007 |
| Acclimation period | All test fish were held in culture tanks under a 16/8 hour light/dark photoperiod and observed for at least 14 days prior to testing. Less than 5 % mortality was noted during the acclimatization period and 48 hours prior to the test initiation<br>They were fed daily (commercial trout food) except for the last 48 hours prior to testing. No prophylactic and therapeutic treatments of fish from this lot before and during testing was carried out |
| Total number of fish in the definitive test | 60 |

| 3. Environmental conditions | |
|---|---|
| Water | Test water was reconstituted water prepared by adding salt stock solutions to demineralized water (conductivity <0.2 µS/cm).<br>Ionic concentrations and hardness (40-60 mg $CaCO_3$/L) |
| Temperature | 10 to 14°C with a max. deviation of ± 1°C in any given 24h range |
| Photoperiod | 16 hours light / 8 hours dark |

B. Study design and methods

| 1. In life dates | 2007-09-13 to 2007-09-21 |
|---|---|
| 2. Experimental conditions: | |
| Test duration | 96 hours |
| Test system | Static (no renewal) |
| Test vessel material | All glass |
| Test vessel size | 32 × 36 × 38 cm (l × d ×h), total volume 44 L |
| Test medium volume | 40 L |
| Test vessel loading | The biomass loading was 0.40 g fish/L test medium. |
| Number of test levels | 1 water control,<br>5 treatment concentrations |
| Number of replicates | One replicate of 10 fish per test level |
| Solvent carrier | None |
| Solvent load | - |
| The test was performed under a static regime. All solutions were prepared by weighing in an adequate amount of the test item into a glass with test water by mixing and transferring the needed amounts of the solutions into the vessels. Fish were randomly distributed to each test chamber until ten fish were distributed to each test chamber (total number of 60 fish). Fish were not fed during the test.<br>Test solutions were not aerated. | |

| 3. Observations |
|---|
| Endpoints and water quality<br>The primary endpoint for acute toxicity was mortality. Sublethal and behavioral effects were also assessed during the course of the study.<br>During the test, fish were examined after approximately 4, 24, 48, 72 and 96 hours for survival and sublethal behavioral effects by visual observations.<br>Dissolved oxygen, water temperature and pH values were determined daily in each aquarium. Water temperature in the control aquarium was additionally measured and recorded hourly with a data logger.<br>Test water was reconstituted water prepared by adding salt stock solutions to demineralized water (conductivity <0.2 µS/cm).<br>Ionic concentrations and hardness (40-60 mg $CaCO_3$/L) measurements were made in the test water.<br>Statistical method<br>Whenever possible, the $LC_{50}$ values and the 95%-confidence intervals were calculated every 24-hour using a computer program, which estimated the $LC_{50}$ using one of three statistical techniques: moving average, logit analysis or probit analysis. The appropriate method was determined according to the data characteristics.<br>All values calculated with Microsoft® Excel were shown as rounded values.<br><br>Analytical verification<br>Analytical determinations (in water via HPLC-MS/MS, of the active substance fluopyram were made in the test medium at the beginning (Day 0), on Day 2 and at test termination (Day 4). |

**Results and discussions:**

A. Findings

Water chemistry and concentrations

| | |
|---|---|
| Temperature range | 11.7.0 to 12.2 °C |
| Dissolved oxygen range | 88 to 100% of oxygen saturation |
| pH range | 6.8 to 7.2 |
| Precipitates during exposure | No |

Mean measured values over the entire test period of 96 hours ranged between 96 % and 108 % of nominal values of fluopyram

B. Observations

The test conditions met all validity criteria, given by the mentioned guidelines (≤ 5% mortality within the 48-hour settling-in period; ≤ 10% mortality in the control; dissolved oxygen saturation ≥ 60% throughout the test; pH variation ≤ 1.0 units).

In the controls no mortalities or sub-lethal finding were observed.
Various behavioral observations were made at test concentrations concentration ≥ 0,125 mg/L. The lowest concentration causing 100% mortality was 0.125 mg product/L. The highest concentration which did not result in any mortality within the exposure period (NOLEC) was 0.0625 mg product/L. The no-observed-effect-concentration (NOEC) was 0.0625 mg product/L.

**Cumulative mortality and behavioral observations:**

| Nominal conc. product mg/L | 4 h | | 24 h | | 48 h | | 72 h | | 96 h | |
|---|---|---|---|---|---|---|---|---|---|---|
| | No | Symptoms | No | Symptoms | No | Symptoms | No | Symptoms | No | Symptoms |
| Control | 10 | N | 10 | N | 10 | N | 10 | N | 10 | N |
| 0.0313 | 10 | N | 10 | N | 10 | N | 10 | N | 10 | N |
| 0.0625 | 10 | N | 10 | N | 10 | N | 10 | N | 10 | N |
| 0.125 | 3 | N | 0 | N | | | | | | |
| | 5 | BO, SR, AT, AP | 2 | HF, SR, TS, AT | | | | | | |
| | 2 | AP, AT | 4 | BO, SR, AT, KR, HF | | | | | | |
| | 0 | TF | 4 | TF | 10 | TF | - | - | - | - |
| 0.250 | 0 | N | | | | | | | | |
| | 7 | BO, SR, AT, AP | | | | | | | | |
| | 3 | TF | 10 | TF | - | - | - | - | - | - |
| 0.500 | 10 | TF | 10 | TF | - | - | - | - | - | - |

| | |
|---|---|
| AP: | were inactive or displayed abnormally low activity |
| AT: | showed labored respiration |
| BO: | remained for unusually long periods on the bottom of the aquarium |
| DF: | turned dark in coloration |
| HF: | showed weaker coloration |
| N: | did not show any abnormal signs |
| SR: | laid on their sides or backs |
| TF: | were dead |
| TS: | showed loss of equilibrium with lateral deviation from their normal orientation |

- = no observations, all fish dead

**Conclusion:**

The test conditions met all validity criteria, given by the mentioned guidelines.
Based on nominal concentrations, the 96 h - $LC_{50}$ was calculated by probit analysis to be 0.091 mg product/L (C.I.95%: not determined due to mathematical reasons). The NOEC (highest concentration without sub-lethal effects) is considered to be 0.0625 mg product/L.
The minimum concentration causing 100% mortality is 0.125 mg product/L.
The maximum concentration which did not cause any mortality (no-observed-lethal-effect concentration = NOLEC) after 96h is 0.0625 mg product/L.

| | |
|---|---|
| Comments of zRMS: | The new study for formulation was provided. The study is considered as acceptable.<br>All validity criteria were met.<br><br>**Agreed endpoints:** |

| **Endpoints (mortality)** | **mg test item/L** |
|---|---|
| **96-hour $LC_{50}$ (95% C.I.)** | 0.0884<br>(0.0625 - 0.125) |
| **96-hour concentration with no mortality** | 0.0625 |
| **96-hour concentration with 100% mortality** | 0.125 |
| **96-hour NOEC** | 0.0625 |
| **96-hour LOEC** | 0.125 |

| | |
|---|---|
| Reference: | **KCP 10.2.1/03** |
| Title: | Fluopyram + trifloxystrobin SC 500 (250 + 250 g/L) - Acute toxicity to rainbow trout (Oncorhynchus mykiss) in a 96-hour semi-static test |
| Report: | xxx 2018; 134621230; M-636236-01-1 |
| Authority registration No: | |
| Guideline(s): | - Commission Regulation (EC) No 440/2008, Annex, Part C, C.1: "Acute Toxicity for Fish", Official Journal of the European Union, May 30, 2008<br>- EPA Guideline 712-C-16-007:OCSPP 850.1075, " Freshwater and Saltwater Fish Acute Toxicity Test" October 2016<br>- Japanese MAFF, Notification No. 12-Nousan-8147, JMAFF Test Guideline, 2-7-1-1, Fish acute toxicity studies, 2005<br>- OECD Guideline for Testing of Chemicals, Section 2, No. 203: "Daphnia sp., “Fish, Acute Toxicity Test" adopted July 17, 1992<br>- SANCO/3029/99 rev.4 11/07/00: Residues: Guidance for generating and reporting methods of Analysis in Support of preregistration 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: | |
| Duplication (if vertebrate study): | No |

## Materials and methods:

| | |
|---|---|
| Test material | Fluopyram + Trifloxystrobin SC 500 (250 + 250 g/L); lot no.: 2015- 009127-01; content of a.s: Fluopyram (AE C656948): 250 g/L (nominal), 248.7 g/L (analytical), Trifloxystrobin (CGA 279202): 250 g/L (nominal), 250.7 g/L (analytical) |
| Guideline(s) adaptation | none |
| Test species | Juvenile rainbow trout (*Oncorhynchus mykiss*)<br>Origin: Forellenzuchtbetrieb Störk, 88348 Bad Saulgau, Germany |
| Culturing conditions | All fish were obtained and held in the laboratory for at least 12 days before the start of the test. They were held in water of the quality to be used in the test for at least seven days immediately before testing.<br>Light: 16 hours photoperiod daily; Temperature: 13 - 17°C |

| | |
|---|---|
| | Oxygen concentration: at least 80% of the air saturation value<br>Feeding: three times per week or daily until 48 hours before the test. |
| Organism age/size at study initiation | Juveniles; mean body length: 4.68 cm ± 0.25 cm (Mean ± SD),<br>mean body wet weight: 1.11 g ± 0.18 g (Mean ±SD) |
| Biomass loading | 0.79 g fish/L test water |
| Test solutions | Test medium: Reconstituted water (ISO medium)<br>Nominal concentrations: 0.250, 0.125, 0.0625, 0.0313 and 0.0156 mg test item/L<br>All results based on nominal concentrations<br>Control: reconstituted water<br>Solvent control: no solvent used hence no solvent control necessary<br>No remarkable observations in the test solutions |
| Replication | No. of vessels per concentration (replicates): 1<br>No. of vessels per control (replicates): 1 |
| Organisms per replicate | No. of organisms per vessel: 10 |
| Exposure | Semi-static conditions<br>Total exposure duration: 96 h |
| Feeding during test | None |
| Test conditions | Temperature during test: 13.9 - 14.8°C<br>Photoperiod: 16 h light : 8 h dark; 30 min dawn/dusk period was provided<br>Light intensity: 560 to 680 lux<br>pH: 7.4 – 8.0<br>Water hardness: 2.5 mmol/L (= 250.0 mg/L) as $CaCO_3$ (nominal)<br>Conductivity: not determined<br>Dissolved oxygen: 93 to 101% of the air saturation value<br>Aeration: The test media were slightly aerated during the test. |
| Parameters Measured / Observations | The test fish were observed at test start and after approximately 2, 24, 48, 72 and 96 hours test duration for sublethal effects and mortality. Dead fish were removed at least once daily and discarded.<br>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. |
| Sampling for chemical analysis | One sample of the freshly prepared stock solution and duplicate samples from the freshly prepared test media of all test concentrations and the control were taken at the start of the test and each test medium renewal (day 1, 2, and 3). During the test period, samples were taken in duplicate out of all test media and the control at each test medium renewal (day 1, 2, and 3) and at the end of the test (96 hours) from the approximate centre of the aquaria. All samples were diluted by a factor of 2 with a diluent consisting of acetonitrile / water / formic acid 400/600/2 (v/v/v). The measurements were performed with LC-MS/ MS. |
| Data analysis | The $LC_{50}$ and the corresponding confidence intervals were estimated by Weibull analysis (after 24 h) and as the geometric mean of the highest concentration showing 0% mortality and the lowest concentration showing 100 % mortality for the observations at 48, 72 and 96 h according to the OECD 203. The corresponding confidence intervals at 48, 72 and 96 h were determined as the tested concentrations surrounding the calculated $LC_{50}$ values. The $LC_{50}$ for 2 h was not determinable. The NOEC, the LOEC, the $LC_0$ and the $LC_{100}$ were determined directly from the raw data. The software used to perform the statistical analysis was ToxRat Professional, Version 3.2.1. |

**Results and discussions:**

The study fulfilled all validity criteria of the current version of OECD 203 guideline.

| **Validity criteria of OECD guideline 203** | **Required** | **Obtained** |
|---|---|---|
| Control mortality | ≤ 10% | 0% |
| Dissolved oxygen concentration | ≥ 60% of air saturation | ≥ 93% of air saturation |

Analytical results:

**Trifloxystrobin**

| **Sample description Nominal (mg test item/L)** | **% of nominal [1]** | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **Day 0 – 0h** | **Day 1 – 24h** | **Day 1 – 0h** | **Day 2 – 24h** | **Day 2 – 0h** | **Day 3 – 24h** | **Day 3 – 0h** | **Day 4 – 24h** |
| Control | n.a. | n.a. | n.a. | n.a. | n.a. | n.a. | n.a. | n.a. |
| 0.0156 | 115.5 | 78.5 | 112 | 82 | 109 | 87 | 105.5 | 81 |
| 0.0313 | 102 | 79 | 103 | 77 | 103.5 | 84 | 105 | 79 |
| 0.0625 | 107.5 | 78 | 99.5 | 78 | 101 | 88 | 114.5 | 84.5 |
| 0.125 | 105 | 83.5 | 104.5 | 92.5 | - | - | - | - |
| 0.250 | 100 | 92.5 | - | - | - | - | - | - |

[1] mean value (n=2) measured samples per treatment group per sampling timepoint, not given in report; n.a.: not applicable; - = no measurement (after mortality reached 100%)

**Fluopyram**

| **Sample description Nominal (mg test item/L)** | **% of nominal [1]** | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **Day 0 – 0h** | **Day 1 – 24h** | **Day 1 – 0h** | **Day 2 – 24h** | **Day 2 – 0h** | **Day 3 – 24h** | **Day 3 – 0h** | **Day 4 – 24h** |
| Control | n.a. | n.a. | n.a. | n.a. | n.a. | n.a. | n.a. | n.a. |
| 0.0156 | 104.5 | 103.5 | 110 | 102 | 108 | 105 | 102.5 | 100 |
| 0.0313 | 106.5 | 104 | 104 | 99.5 | 106 | 107 | 103.5 | 97 |
| 0.0625 | 105.5 | 106 | 102 | 100.5 | 106.5 | 108 | 110 | 102.5 |
| 0.125 | 105.5 | 104 | 106 | 100.5 | - | - | - | - |
| 0.250 | 102.5 | 103 | - | - | - | - | - | - |

[1] mean value (n=2) measured samples per treatment group per sampling timepoint, not given in report; n.a.: not applicable; - = no measurement (after mortality reached 100%)

The analytical results proved a correct dosing at test start and constant exposure concentrations within the whole test duration. The accompanying chemical analysis resulted in test item concentrations within ± 20% of the nominal concentrations for both active ingredients. All reported results refer to nominal values as a correct dosing at test initiation was proven and as the toxicity has to be attributed to the test formulation as a whole.

Biological results:

Observations

In the control and at the concentrations up to 0.0625 mg test item/L, all fish survived until the end of the experiment and no signs of intoxication occurred. At the concentrations 0.125 and 0.250 mg test item/L, all fish were dead at the end of the test.

Sublethal effects such as convulsions, strongly extended gills, fish on the bottom of the aquarium, and fish tumbling when swimming, were observed at 4 and 24h at the 2 highest concentrations.

| **Nominal test concentrations (mg test item/L)** | **Mortality** | | | | | |
|---|---|---|---|---|---|---|
| | **0 h** | **2 h** | **24 h** | **48 h** | **72 h** | **96 h** |
| Control | 0 | 0 | 0 | 0 | 0 | 0 |
| 0.0156 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0.0313 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0.0625 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0.125 | 0 | 0 | 8 | 10 | 10 | 10 |
| 0.250 | 0 | 8 | 10 | 10 | 10 | 10 |
| $LC_{50}$ (mg test item/L) | n.d. | n.d. | 0.105 | 0.0884 | 0.0884 | 0.0884 |
| 95% CI. | n.d. | n.d. | 0.0891-0.125 | 0.0625-0.125 | 0.0625-0.125 | 0.0625-0.125 |

n.d.: not determined

**Conclusion:**

All validity criteria were met. The endpoints based on nominal concentrations are expressed as mg test item/L.

| **Endpoints (mortality)** | **mg test item/L** |
|---|---|
| **96-hour $LC_{50}$ (95% C.I.)** | 0.0884<br>(0.0625 - 0.125) |
| **96-hour concentration with no mortality** | 0.0625 |
| **96-hour concentration with 100% mortality** | 0.125 |
| **96-hour NOEC** | 0.0625 |
| **96-hour LOEC** | 0.125 |

## A 2.2.1.2 KCA 8.2.4.1 and KCA 8.2.4.2 and KCP 10.2.1 Aquatic invertebrates

| | |
|---|---|
| Comments of zRMS: | The study is considered valid. All validity criteria were met.<br>**Agreed endpoint:**<br>$EC_{50}$ > 1.2577 mg a.s./$L_{mm}$<br>**The study not used in the risk assesDaphniasment.** |

| | |
|---|---|
| Reference: | **KCA 8.2.4.2/01** |
| Title: | Trifloxystrobin - Acute toxicity test with Brachionus calyciflorus, basic test conditions following OECD TG 202 |
| Report: | Kosak, L.; Hennecke, S.; 2018; EBTF0035; M-637834-01-1 |
| Authority registration No: | |
| Guideline(s): | The basic test conditions were according to the OECD guideline 202 and EC method C.2 |
| Deviations: | None |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication (if vertebrate study): | |

## Material and methods:

| | |
|---|---|
| Test material | Trifloxystrobin<br>lot/batch: BCHR 1484-2<br>purity: 96.5% |
| Guideline(s) adaptation | none |
| Test species | *Brachionus calyciflorus*<br>Origin: MicroBio Tests Inc. Specimens |
| Culturing conditions | Similar environmental conditions as used in the test. The parental daphnids were cultured in M4 Medium |
| Organism age/size at study initiation | Neonates |
| Test solutions | Test medium: EPA Medium<br>Nominal concentrations: 128, 320, 800, 2000 and 5000 µg a.s./L<br>Geometric mean measured concentrations: 94.4, 117.6, 615.9, 1257.7 and 1097 µg a.s./L<br>Control: test medium<br>Solvent control: test medium with 100 µg DMF/L<br>The test solutions were clear and colorless and without any irregularities |
| Replication | No. of vessels per concentration (replicates): 6<br>No. of vessels per control (replicates): 6 |
| Organisms per replicate | No. of organisms per vessel: 5 |
| Exposure | Static conditions<br>Total exposure duration: 24 h |
| Feeding during test | None |
| Test conditions | Temperature during test: 23.2 – 25.1°C<br>Photoperiod: dark conditions<br>Light intensity: --<br>pH: 8.11 – 8.37<br>Water hardness: 273.0 mg/L as $CaCO_3$ (15.3 °dH)<br>Conductivity: not determined<br>Dissolved oxygen: 9.1 - 12.0 mg/L (99% of saturation)<br>Aeration: none |
| Parameters Measured / Observations | The numbers of immobile organisms were visually determined at test start and after 24 h. Immobility was determined according to the OECD guideline 202. Specimens which were not able to swim within 10 seconds after gentle agitation of the test vessel were considered to be immobilized. |

| | |
|---|---|
| | The total hardness of the dilution water was measured at test start.<br>The pH was measured in new and old medium at 0, 24 and 48 h of the test. |
| Sampling for chemical analysis | Samples of test item solutions were taken for quantification of the test item concentrations in the test solutions at test start and at the end of the test period (24 hours) from the pooled replicates of each test concentration and the controls. The measurements were performed with LCMS/ MS. |
| Data analysis | $EC_{10}$, $EC_{20}$, and $EC_{50}$ values were not determined as no immobility of the test animals occurred.<br>NOEC and LOEC values were determined by the Chi² 2x2 Table Test with Bonferroni Correction. All statistical calculations were performed using the computer programme ToxRat® |

**Results:**

| **Validity criteria of OECD guideline** | **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 | ≥ 8.1 mg/L |

Analytical results:

Effective concentrations ranged from 77.7 % to 86.0 % in the freshly prepared media and from 59.2 % to 73.1 % in the media after 24 hours of exposure.

| Date | Time | Measuring time | Test item concentration [mg/L] | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | 3.13 | 6.25 | 12.5 | 25 | 50 | 100 |
| 2017-07-18 | 0 h | 0 h | 2.552 | 5.014 | 9.715 | 20.061 | 39.990 | 81.035 |
| 2017-07-19 | 24 h | 24 h | 2.111 | 3.949 | 8.407 | 16.478 | 33.063 | 66.262 |
| | | 0 h | 2.688 | 5.326 | 10.514 | 21.490 | 42.508 | --- |
| 2017-07-20 | 48 h | 24 h | 2.289 | 4.288 | 8.768 | 14.801 | 35.154 | --- |

Geometric 24 h: 2.321, 4.450, 9.037, 18.181, 36.362, 73.277
Geometric 48 h: 2.399, 4.611, 9.315, 18.007, 37.492, 73.277

The applicability of an HPLC-UV/VIS method for the analysis of CGA 10710 in test water was tested. The data presented in part B5 demonstrate that the method allows the determination of CGA 10710 with satisfactory accuracy, precision and repeatability according to guideline SANCO/3029/99 and can therefore be regarded as fit for purpose.

Biological results:

Observations

No immobile daphnids were observed in the controls or at 24h in any test concentrations. Some daphnids were immobile at 48h, in concentrations higher or equal than 12.5 mg/L. No sublethal effects were observed in any group.

| **Nominal test concentrations (mg p.m./L)** | **% of immobilized daphnids** | |
|---|---|---|
| | **24 h** | **48 h** |
| Control | 0 | 0 |

| | | |
|---|---|---|
| 3.13 | 0 | 0 |
| 6.25 | 0 | 0 |
| 12.5 | 0 | 50 |
| 25 | 40 | 80 |
| 50 | 65 | 100 |
| 100 | 100 | 100 |

~~**Conclusion**~~

~~The endpoints are expressed in terms of geometric mean measured concentrations:~~

| | |
|---|---|
| ~~**$EC_{50}$ 48 hours (95% C.I.):**~~ | ~~**10.7 mg p.m./L (20.1 - 30.9 mg p.m./L)**~~ |
| ~~$EC_{50}$ 24 hours (95% C.I.):~~ | ~~24.8 mg p.m./L (8.8 – 13.1)~~ |

| | |
|---|---|
| Comments of zRMS: | The study is considered acceptable. All validity criteria were met.<br>**Agreed endpoints:**<br>24 h $EC_{50}$ = 0.03705 mg a.s./$L_{mm}$<br>The study is not considered in the risk assessment. |

| | |
|---|---|
| Reference: | **KCA 8.2.4.2/02** |
| Title: | Trifloxystrobin - Acute toxicity test with Thamnocephalus platyurus, basic test conditions following OECD TG 202 - Report - |
| Report: | Kosak, L.; Hennecke, S.; 2018; EBTF0036; M-638530-01-1 |
| Authority registration No: | |
| Guideline(s): | OECD guideline 202 and EC method C.2 |
| Deviations: | None |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication (if vertebrate study): | |

**Material and methods:**

| | |
|---|---|
| Test material | Trifloxystrobin<br>batch: AE C642802-01-19<br>specification: 102000007792-03<br>purity: 96.5% w/w |
| Guideline(s) adaptation | No guideline is available for acute tests with *Thamnocephalus sp.* so the OECD guideline 202 was used, in addition to the supplier's instructions regarding environmental conditions. Due to the short generation time of this species, the test duration is limited to 24 hours to exclude any reproduction. |
| Test species | *Thamnocephalus platyurus* (Crustacea, Branchiopoda)<br>Cysts were supplied by MicroBioTests Inc. |
| Culturing conditions | The cysts hatched over approx. 20-22 hours under continuous illumination at 25°C |
| Organism age/size at study | < 24 h old |

| | |
|---|---|
| initiation | |
| Test solutions | Test medium: EPA medium<br>Nominal concentrations: 4.3, 9.4, 20.7, 45.5, 100 µg a.s./L<br>Geometric mean measured concentrations: 3.4, 6.0, 15.6, 33.5, 73.9 µg a.s./L.<br>Controls: water control and solvent control (DMF at 100 µL/L)<br>Evidence of undissolved material: the test solutions were clear and colourless and without any irregularities |
| Replication | No. of vessels per concentration (replicates): 5<br>No. of vessels per control (replicates): 5<br>No. of vessels per solvent control (replicates): 5 |
| Organisms per replicate | No. of organisms per vessel: 6 |
| Exposure | Static<br>Total exposure duration: 24 h |
| Test Vessel Loading | 6 individuals in 3 mL of medium |
| Feeding during test | None |
| Test conditions | Temperature: 21.6-27.2°C. The variation in temperature of more than ±1°C during the test did not impair the mobility of the test animals, as in the controls no immobility occurred<br>Photoperiod: test in the dark<br>pH: 7.96 – 8.29<br>Dissolved oxygen: 9.3 – 12.3 mg/L |
| Parameters Measured / Observations | Oxygen concentration, pH value, and temperature of the test solutions were checked at test start, and end.<br>The numbers of immobile organisms were visually determined at test start and after 24 h. Specimens which were not able to swim within 15 seconds after gentle agitation of the test vessel were considered to be immobilized |
| Sampling for chemical analysis | Concentrations of trifloxystrobin in the water phase were quantified by chemical analysis using LC-MS/MS.<br>Samples of freshly prepared test media were taken from all five test solutions, the control and the solvent control at the beginning of the test prior to distribution to the test vessels and after 24 hours. Samples were taken directly from the pooled replicates of each test concentration and the controls. |
| Data analysis | ECx values together with 95% confidence intervals (where possible) were calculated by Probit-analysis assuming log-normal distribution of the values. NOEC and LOEC values were determined by the Step-down Cochran-Armitage Test. All statistical calculations were performed using the computer programme ToxRat®. Controls were pooled for the statistical analysis since there was no statistical difference between the water control and the solvent control. |

**Results:**

| **Validity criteria of OECD guideline 202** | **Required** | **Obtained** |
|---|---|---|
| % immobilisation in controls | ≤ 10% | 0% |
| Dissolved oxygen concentration at the end of the test in control and test vessels. | ≥ 3 mg/L | ≥ 9.3 mg/L |

Analytical results:

In water control and solvent control, trifloxystrobin concentrations were below the limit of quantification of 0.1 µg/L.

| Nominal Concentration (µg a.s./L) | 0 h measured concentrations (µg a.s./L) | 0 h % Nominal | 24 h measured concentrations (µg a.s./L) | 24 h % Nominal | Geometric mean measured concentrations (µg a.s./L) | % of nominal |
|---|---|---|---|---|---|---|
| 4.3 | 3.97 | 92.2 | 2.9 | 67.0 | 3.4 | 78.6 |
| 9.4 | 7.06 | 75.1 | 5.0 | 53.5 | 6.0 | 63.4 |
| 20.7 | 18.8 | 91.0 | 12.9 | 62.1 | 15.6 | 75.2 |
| 45.5 | 40.9 | 89.8 | 27.4 | 60.2 | 33.5 | 73.5 |
| 100 | 81.0 | 81.0 | 67.4 | 67.4 | 73.9 | 73.9 |

Biological results:

Observations

Neither significant signs of disease nor stress like discoloration or abnormal behavior were observed in any replicate up to nominal test concentration of 45.5 µg a.s./L. All surviving specimens gave the impression of healthy condition.

Immobility

| Geometric mean measured concentrations (µg a.s./L) | Total introduced | Immobile | % immobility at 24 h |
|---|---|---|---|
| Control | 30 | 0 | 0 |
| Solvent control | 30 | 0 | 0 |
| 3.4 | 30 | 0 | 0 |
| 6.0 | 30 | 0 | 0 |
| 15.6 | 30 | 0 | 0 |
| 33.5 | 30 | 7 | 23.3* |
| 73.9 | 30 | 30 | 100* |

*Statistically significant (alpha = 0.05) vs pooled controls according to Step-down Cochran-Armitage test

Conclusion

The endpoints based on geometric mean measured concentrations are:

| | |
|---|---|
| **$EC_{50}$ 24 hours (95% C.I.):** | **37.05 µg a.s. / L** (not determined due to mathematical reasons) |
| LOEC: lowest concentration with an effect on immobility | 33.5 µg a.s. / L |
| NOEC: highest concentration without effects on immobility | 15.6 µg a.s. / L |

| | |
|---|---|
| Comments of zRMS: | The study is considered acceptable. All validity criteria were met.<br>**Agreed endpoints:**<br>$EC_{50}$ = 0.00242 mg a.s./$L_{mm}$<br>NOEC < 1.1 µg a.s. / $L_{mm}$ |

| | |
|---|---|
| Reference: | **KCA 8.2.4.2/03** |
| Title: | Trifloxystrobin - Acute toxicity test with Daphnia longispina, basic test conditions following OECD TG 202 - Report - |
| Report: | Hommen, U.; Hennecke, S.; 2018; EBTF0038; M-638527-01-1 |
| Authority registration No: | |
| Guideline(s): | OECD guideline 202 and EC method C.2 |
| Deviations: | None |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication (if vertebrate study): | |

**Material and methods:**

| | |
|---|---|
| Test material | Trifloxystrobin<br>batch: AE C642802-01-19<br>specification: 102000007792-03<br>purity: 96.5% w/w |
| Guideline(s) adaptation | The preferred species in guideline OECD 202 is *Daphnia magna* but it is also applicable to other *Daphnia* sp. such as *D. longispina*. |
| Test species | *Daphnia longispina*<br>Origin of the test animals were uncontaminated outdoors mesocosms located at Schneebergweg 30, 52056 Aachen, Germany. |
| Culturing conditions | Adult Daphnia, at least 3 weeks old, were cultured in M4 medium. Daphnia were fed daily and transferred into fresh medium in regular intervals.<br>Newborn Daphnia were separated by sieving, the first generation was discarded. |
| Organism age/size at study initiation | Neonates < 24 h old |
| Test solutions | Test medium: Elendt M4<br>Nominal concentrations: 1.3, 3.2, 8.0, 20 and 50 µg a.s./L<br>Geometric mean measured concentrations: 1.1, 2.6, 6.1, 15.8, 37.1 µg a.s./L.<br>Controls: water control and solvent control (DMF at 100 µL/L)<br>Evidence of undissolved material: The test solutions were clear and colourless and without any irregularities |
| Replication | No. of vessels per concentration (replicates): 4<br>No. of vessels per control (replicates): 4<br>No. of vessels per solvent control (replicates): 4 |
| Organisms per replicate | No. of organisms per vessel: 5. |
| Exposure | Semi-static with daily renewal<br>Total exposure duration: 48 h |
| Test Vessel Loading | 5 daphnids in 21 mL of medium |

| | |
|---|---|
| Feeding during test | None |
| Test conditions | Temperature: 19.7 – 21.2°C. The variation in temperature of more than ±1°C during the test did not impair the mobility of the test animals, as in the controls no immobility occurred.<br>Photoperiod: test in the dark<br>pH: 7.78-7.96<br>Dissolved oxygen: 7.29 – 8.66 mg/L |
| Parameters Measured / Observations | Oxygen concentration, pH value, and temperature of the test solutions were checked at test<br>start, end and after each renewal of the test media.<br>The numbers of immobile daphnids were visually determined after 5 hours after test start, after 24 h, 29 h and after 48 h. 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 were still moving their antennae) and dead specimens were removed. |
| Sampling for chemical analysis | Concentrations of trifloxystrobin in the water phase were quantified by chemical analysis using LC-MS/MS.<br>Samples of freshly prepared test media were taken from all five test solutions, the control and the solvent control at the beginning of the test and after 24h at media renewal prior to distribution to the test vessels. Samples of aged test concentrations were taken after 24h at media renewal and at the end of the test (48 hours) directly from the pooled replicates of each test concentration and the controls |
| Data analysis | ECx values were calculated by Weibull analysis using ToxRat software<br>NOEC was determined by Step-down Cochran-Armitage test with trend analysis by contrasts using proportions.<br>Controls were pooled for the statistical analysis since there was no statistical difference between the water control and the solvent control. |

**Results:**

| **Validity criteria** | **Required** | **Obtained** |
|---|---|---|
| % immobilisation in controls | ≤ 10% | 0% |
| Dissolved oxygen concentration at the end of the test in control and test vessels. | ≥ 3 mg/L | ≥ 7.29 mg/L |

<u>Analytical results</u>:

In water control and solvent control, trifloxystrobin concentrations were below the limit of quantification of 0.1 µg/L.

| **Nominal Concentration (µg a.s./L)** | **0 h % Nominal** | **24 h - aged % Nominal** | **24 h - new % Nominal** | **48 h % Nominal** | **Geometric mean measured concentrations (µg a.s./L)** | **% of nominal** |
|---|---|---|---|---|---|---|
| 1.3 | 86.9 | 77.1 | 87.5 | 73.8 | 1.1 | 81.1 |
| 3.2 | 82.5 | 73.2 | 87.9 | 79.0 | 2.6 | 80.5 |
| 8.0 | 80.5 | 69.9 | 79.7 | 73.3 | 6.1 | 75.7 |
| 20 | 89.5 | 71.2 | 87.4 | 69.6 | 15.8 | 78.9 |
| 50 | 75.8 | 64.4 | 84.0 | Not analysed | 37.1 | 74.3 |

<u>Biological results</u>:

Observations

All surviving specimens up to the test concentration of 8.0 µg a.s./L showed neither significant signs of disease nor stress like discolouration or abnormal behavior.

Immobility

| **Geometric mean measured concentrations (µg a.s./L)** | **Total introduced** | **Immobile** | **% immobility at 48 h** |
|---|---|---|---|
| Control | 20 | 0 | 0 |
| Solvent control | 20 | 0 | 0 |
| 1.1 | 20 | 9 | 45* |
| 2.6 | 20 | 10 | 50* |
| 6.1 | 20 | 11 | 55* |
| 15.8 | 20 | 20 | 100* |
| 37.1 | 20 | 20 | 100* |

*Statistically significant (alpha = 0.05) vs pooled controls according to Step-down Cochran-Armitage test

<u>Conclusion</u>

The endpoints based on geometric mean measured concentrations are:

| | |
|---|---|
| **$EC_{50}$ 48 hours (95% C.I.):** | **2.423 µg a.s. / L**<br>(n.d. – 6.809) |
| LOEC:<br>lowest concentration with an effect on immobility | 1.1 µg a.s. / L |
| NOEC:<br>highest concentration without effects on immobility | < 1.1 µg a.s. / L |

n.d.: not determined due to mathematical reasons

| | |
|---|---|
| Comments of zRMS: | The study is considered acceptable. All validity criteria were met.<br>**Agreed endpoints:**<br>$EC_{50}$ = 0.0305 mg a.s./$L_{mm}$<br>NOEC = 0.014 mg a.s./$L_{mm}$ |

| | |
|---|---|
| Reference: | **KCA 8.2.4.2/04** |
| Title: | 1st report amendment - Trifloxystrobin - Acute toxicity test with Daphnia pulex, basic test conditions following OECD TG 202 |
| Report: | Kosak, L.; Hennecke, S.; 2019; EBTF0039; M-630875-02-1 |
| Authority registration No: | |
| Guideline(s): | OECD 202 (13 April 2004): Guideline for Testing of Chemicals - Daphnia sp., Acute Immobilisation Test |
| Deviations: | None |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication<br>(if vertebrate study): | |

**Material and methods:**

| | |
|---|---|
| Test material | Trifloxystrobin<br>batch: AE C642802-01-19<br>specification: 102000007792-03<br>purity: 96.5% w/w |
| Guideline(s) adaptation | The preferred species in guideline OECD 202 is *Daphnia magna* but it is also applicable to other *Daphnia* sp. such as *D. pulex*. |
| Test species | *Daphnia pulex*<br>Origin of the test animals were uncontaminated outdoors mesocosms located at Schneebergweg 30, 52056 Aachen, Germany. |
| Culturing conditions | Adult Daphnia, at least 3 weeks old, were cultured in M4 medium. Daphnia were fed daily and transferred into fresh medium in weekly intervals.<br>Newborn Daphnia were separated by sieving, the first generation was discarded. Individuals used in the test were transferred with a bore Pasteur pipette a few hours after sieving to ensure applying only healthy specimens. |
| Organism age/size at study initiation | Neonates < 24 h old |
| Test solutions | Test medium: Elendt M4<br>Nominal concentrations: 4.3, 9.4, 20.7, 45.5, 100 µg a.s./L<br>Geometric mean measured concentrations: 2.8, 6.1, 14.0, 30.5, 77.9 µg a.s./L.<br>Controls: water control and solvent control (DMF at 100 µL/L)<br>Evidence of undissolved material: not reported |
| Replication | No. of vessels per concentration (replicates): 4<br>No. of vessels per control (replicates): 4<br>No. of vessels per solvent control (replicates): 4 |
| Organisms per replicate | No. of organisms per vessel: 5. 4 individuals were introduced instead of 5 in one water control replicate |
| Exposure | Semi-static with daily renewal<br>Total exposure duration: 48 h |
| Test Vessel Loading | 5 daphnids in 21 mL of medium |
| Feeding during test | None |
| Test conditions | Temperature: 19.5 – 20.7°C<br>Photoperiod: test in the dark<br>pH: 7.77-8.00<br>Dissolved oxygen: 8.8 – 12.1 mg/L |
| Parameters Measured / Observations | Oxygen concentration, pH value, and temperature of the test solutions were checked at test<br>start, end and after each renewal of the test media.<br>The numbers of immobile daphnids were visually determined after 5 hours after test start, after 24 h, 29 h and after 48 h. 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 were still moving their antennae) and dead specimens were removed. |
| Sampling for chemical analysis | Concentrations of trifloxystrobin in the water phase were quantified by chemical analysis using LC-MS/MS.<br>Samples of freshly prepared test media were taken from all five test solutions, the control and the solvent control at the beginning of the test and after 24h at media renewal prior to distribution to the test vessels. Samples of aged test concentrations were taken after 24h at media renewal and at the end of the test (48 hours) directly from the pooled replicates of each test concentration and the controls |
| Data analysis | ECx values were calculated by Probit analysis using ToxRat software |

| | |
|---|---|
| | NOEC was determined by Step-down Cochran-Armitage test with trend analysis by contrasts using proportions.<br>Controls were pooled for the statistical analysis since there was no statistical difference between the water control and the solvent control. |

**Results:**

| Validity criteria | Required | Obtained |
|---|---|---|
| % immobilisation in controls | ≤ 10% | 0% |
| Dissolved oxygen concentration at the end of the test in control and test vessels. | ≥ 3 mg/L | ≥ 8.8 mg/L |

Analytical results:

In water control and solvent control, trifloxystrobin concentrations were below the limit of quantification of 0.1 µg/L.

| Nominal Concentration (µg a.s./L) | 0 h % Nominal | 24 h - aged % Nominal | 24 h - new % Nominal | 48 h % Nominal | Geometric mean measured concentrations (µg a.s./L) | % of nominal |
|---|---|---|---|---|---|---|
| 4.3 | 84.2 | 74.7 | 57.8 | 51.8 | 2.83 | 65.9 |
| 9.4 | 77.6 | 76.4 | 55.9 | 51.8 | 6.05 | 64.4 |
| 20.7 | 103.5 | 73.3 | 55.3 | 50.4 | 14.04 | 67.8 |
| 45.5 | 97.1 | 76.0 | 54.8 | 50.1 | 30.53 | 67.1 |
| 100 | 86.0 | 73.4 | 77.3 | 75.3 | 77.86 | 77.9 |

Biological results:

Observations

Neither significant signs of disease nor stress like discolouration or abnormal behaviour were observed in any replicate up to and including the highest test concentration of nominal 100 µg a.s./L. All surviving specimens, up to and including the highest concentration gave the impression of healthy condition.

Immobility

| Geometric mean measured concentrations (µg a.s./L) | Total introduced | Immobile | % immobility at 48 h |
|---|---|---|---|
| Control | 19 | 0 | 0 |
| Solvent control | 20 | 0 | 0 |
| 2.8 | 20 | 0 | 0 |
| 6.1 | 20 | 2 | 10 |
| 14.0 | 20 | 0 | 0 |
| 30.5 | 20 | 8 | 40* |
| 77.9 | 20 | 20 | 100* |

*Statistically significant (alpha = 0.05) vs pooled controls according to Step-down Cochran-Armitage test

Conclusion

The endpoints based on geometric mean measured concentrations are:

| | |
|---|---|
| **$EC_{50}$ 48 hours (95% C.I.):** | **30.5 µg a.s. / L**<br>(not determined due to mathematical reasons) |
| LOEC:<br>lowest concentration with an effect on immobility | 30.5 µg a.s. / L |
| NOEC:<br>highest concentration without effects on immobility | 14.0 µg a.s. / L |

| | |
|---|---|
| Comments of zRMS: | The study is considered valid. All validity criteria were met.<br>**Agreed endpoints:**<br>$EC_{50}$ = 0.0838 mg a.s./$L_{mm}$<br>NOEC = 0.0163 mg a.s./$L_{mm}$ |

| | |
|---|---|
| Reference: | **KCA 8.2.4.2/05** |
| Title: | Trifloxystrobin - Acute toxicity test with Chydorus spec., basic test conditions following OECD TG 202 - Report |
| Report: | Hommen, U.; Hennecke, S.; 2018; EBTF0040; M-638519-01-1 |
| Authority registration No: | |
| Guideline(s): | OECD guideline 202 and EC method C.2 |
| Deviations: | None |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication (if vertebrate study): | |

**Material and methods:**

| | |
|---|---|
| Test material | Trifloxystrobin<br>batch: AE C642802-01-19<br>specification: 102000007792-03<br>purity: 96.5% w/w |
| Guideline(s) adaptation | There are no guidelines for acute tests on *Chydorus* sp so the OECD guideline 202 was used. |
| Test species | *Chydorus sp.* (Crustacea, Branchiopoda)<br>Origin of the test animals were uncontaminated outdoors mesocosms located at Schneebergweg 30, 52056 Aachen, Germany. |
| Culturing conditions | The organisms were gradually transferred into M4 medium and cultured in the laboratory for 7 months. |
| Organism age/size at study initiation | Adults |
| Test solutions | Test medium: Elendt M4<br>Nominal concentrations: 8.5, 18.8, 41.3, 90.9 and 200 µg a.s./L<br>Geometric mean measured concentrations: 7.2, 16.3, 35.9, 79.5 and 167.9 µg a.s./L.<br>Controls: water control and solvent control (DMF at 100 µL/L)<br>Evidence of undissolved material: The test solutions were clear and colourless and without any irregularities |
| Replication | No. of vessels per concentration (replicates): 4 |

| | |
|---|---|
| | No. of vessels per control (replicates): 4<br>No. of vessels per solvent control (replicates): 4 |
| Organisms per replicate | No. of organisms per vessel: 5. |
| Exposure | Semi-static with daily renewal<br>Total exposure duration: 48 h |
| Test Vessel Loading | 5 specimens in 21 mL of medium |
| Feeding during test | None |
| Test conditions | Temperature: 19.7 – 20.5°C.<br>Photoperiod: test in the dark<br>pH: 7.78-7.98<br>Dissolved oxygen: 7.63 – 8.28 mg/L |
| Parameters Measured / Observations | Oxygen concentration, pH value, and temperature of the test solutions were checked at test<br>start, end and after each renewal of the test media.<br>The numbers of immobile *Chydorus* were determined with a stereomicroscope after 24 h and after 48 h. 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 were still moving their antennae) and dead specimens were removed. |
| Sampling for chemical analysis | Concentrations of trifloxystrobin in the water phase were quantified by chemical analysis using LC-MS/MS.<br>Samples of freshly prepared test media were taken from all five test solutions, the control and the solvent control at the beginning of the test and after 24h at media renewal prior to distribution to the test vessels. Samples of aged test concentrations were taken after 24h at media renewal and at the end of the test (48 hours) directly from the pooled replicates of each test concentration and the controls |
| Data analysis | ECx values were calculated by Probit analysis using ToxRat software<br>NOEC was determined by Step-down Cochran-Armitage test with trend analysis by contrasts using proportions.<br>Controls were pooled for the statistical analysis since there was no statistical difference between the water control and the solvent control. |

**Results:**

| **Validity criteria** | **Required** | **Obtained** |
|---|---|---|
| % immobilisation in controls | ≤ 10% | 0% |
| Dissolved oxygen concentration at the end of the test in control and test vessels. | ≥ 3 mg/L | ≥ 7.63 mg/L |

Analytical results:

In water control and solvent control, trifloxystrobin concentrations were below the limit of quantification of 0.1 µg/L.

| **Nominal Concentration (µg a.s./L)** | **0 h % Nominal** | **24 h - aged % Nominal** | **24 h - new % Nominal** | **48 h % Nominal** | **Geometric mean measured concentrations (µg a.s./L)** | **% of nominal** |
|---|---|---|---|---|---|---|
| 8.5 | 92.5 | 91.3 | 91.3 | 67.4 | 7.2 | 85.0 |
| 18.8 | 91.2 | 84.2 | 88.5 | 83.7 | 16.3 | 86.9 |
| 41.3 | 85.0 | 84.0 | 99.7 | 79.5 | 35.9 | 86.9 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 90.9 | 95.1 | 84.2 | 90.3 | 80.4 | 79.5 | 87.4 |
| 200 | 86.7 | 84.3 | 85.8 | 78.8 | 167.9 | 84.0 |

Biological results:

Observations

Neither significant signs of disease nor stress like discolouration or abnormal behavior were observed in any replicate up to and including the highest test concentration of nominal 200 µg a.s./L in the surviving test animals. Juvenile test animals, which were born during the test, could be differentiated by size and color from the adult test organisms. The number of juveniles was documented and not further evaluated.

Immobility

| **Geometric mean measured concentrations (µg a.s./L)** | **Total introduced** | **Immobile** | **% immobility at 48 h** |
|---|---|---|---|
| Control | 20 | 0 | 0 |
| Solvent control | 20 | 0 | 0 |
| 7.2 | 20 | 0 | 0 |
| 16.3 | 20 | 1 | 5 |
| 35.9 | 20 | 5 | 25* |
| 79.5 | 20 | 9 | 45* |
| 167.9 | 20 | 15 | 75* |

*Statistically significant (alpha = 0.05) vs pooled controls according to Step-down Cochran-Armitage test

Conclusion

The endpoints based on geometric mean measured concentrations are:

| **$EC_{50}$ 48 hours (95% C.I.):** | **83.8 µg a.s. / L** (60.9 – 127.7) |
|---|---|
| LOEC: lowest concentration with an effect on immobility | 35.9 µg a.s. / L |
| NOEC: highest concentration without effects on immobility | 16.3 µg a.s. / L |

| | |
|---|---|
| Comments of zRMS: | The study is considered valid. All validity criteria were met.<br>**Agreed endpoints:**<br>$EC_{50}$ = 0.0450 mg a.s./$L_{mm}$<br>NOEC = 0.0197 mg a.s./$L_{mm}$ |

| | |
|---|---|
| Reference: | **KCA 8.2.4.2/06** |
| Title: | Trifloxystrobin - Acute toxicity test with Cyclopoidae, basic test conditions following OECD TG 202 - Report - |
| Report: | Kosak, L.; Hennecke, S.; 2018; EBTF0041; M-638524-01-1 |
| Authority registration No: | |
| Guideline(s): | OECD guideline 202 and EC method C.2 |
| Deviations: | None |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication (if vertebrate study): | |

**Material and methods:**

| | |
|---|---|
| Test material | Trifloxystrobin<br>batch: AE C642802-01-19<br>specification: 102000007792-03<br>purity: 96.5% w/w |
| Guideline(s) adaptation | There are no guidelines for acute tests on *Cyclopidae* so the OECD guideline 202 was used. |
| Test species | *Cyclopidae.* (Crustacea, Copepoda)<br>Origin of the test animals were uncontaminated outdoors mesocosms located at Schneebergweg 30, 52056 Aachen, Germany. |
| Culturing conditions | The organisms were gradually transferred into M4 medium and cultured in the laboratory for 2 days |
| Organism age/size at study initiation | < 24 h old |
| Test solutions | Test medium: Elendt M4<br>Nominal concentrations: 3.8, 9.6, 24, 60 and 150 µg a.s./L<br>Geometric mean measured concentrations: 3.2, 8.6, 19.7, 47.0 and 114.7 µg a.s./L.<br>Controls: water control and solvent control (DMF at 100 µL/L)<br>Evidence of undissolved material: The test solutions were clear and colourless and without any irregularities |
| Replication | No. of vessels per concentration (replicates): 4<br>No. of vessels per control (replicates): 4<br>No. of vessels per solvent control (replicates): 4 |
| Organisms per replicate | No. of organisms per vessel: 5. |
| Exposure | Semi-static with daily renewal<br>Total exposure duration: 48 h |
| Test Vessel Loading | 5 specimens in 21 mL of medium |
| Feeding during test | None |
| Test conditions | Temperature: 19.7 – 20.6°C.<br>Photoperiod: test in the dark<br>pH: 7.87-7.98<br>Dissolved oxygen: 7.78 – 8.46 mg/L |
| Parameters Measured / Observations | Oxygen concentration, pH value, and temperature of the test solutions were checked at test<br>start, end and after each renewal of the test media.<br>The numbers of immobile *Cyclopidae* were determined visually 5 h after test start, |

| | |
|---|---|
| | after 24 h, 29 h and after 48 h. Specimens which were not able to swim within 15 seconds after gentle agitation of the test vessel were considered to be immobilized. |
| Sampling for chemical analysis | Concentrations of trifloxystrobin in the water phase were quantified by chemical analysis using LC-MS/MS.<br>Samples of freshly prepared test media were taken from all five test solutions, the control and the solvent control at the beginning of the test and after 24h at media renewal prior to distribution to the test vessels. Samples of aged test concentrations were taken after 24h at media renewal and at the end of the test (48 hours) directly from the pooled replicates of each test concentration and the controls |
| Data analysis | ECx values were calculated by Weibull analysis using ToxRat software<br>NOEC was determined by Step-down Cochran-Armitage test with trend analysis by contrasts using proportions.<br>Controls were pooled for the statistical analysis since there was no statistical difference between the water control and the solvent control. |

**Results:**

| Validity criteria | Required | Obtained |
|---|---|---|
| % immobilisation in controls | ≤ 10% | 10 % in water control and 5% in solvent control. Therefore 7.5% in the pooled controls used for statistical analysis |
| Dissolved oxygen concentration at the end of the test in control and test vessels. | ≥ 3 mg/L | ≥ 7.78 mg/L |

Analytical results:

In water control and solvent control, trifloxystrobin concentrations were below the limit of quantification of 0.1 µg/L.

| Nominal Concentration (µg a.s./L) | 0 h % Nominal | 24 h - aged % Nominal | 24 h - new % Nominal | 48 h % Nominal | Geometric mean measured concentrations (µg a.s./L) | % of nominal |
|---|---|---|---|---|---|---|
| 3.8 | 90.4 | 80.7 | 86.6 | 79.1 | 3.2 | 84.1 |
| 9.6 | 94.4 | 82.1 | 98.0 | 85.0 | 8.6 | 89.6 |
| 24.0 | 90.7 | 80.4 | 82.2 | 76.4 | 19.7 | 82.2 |
| 60.0 | 78.4 | 73.8 | 86.5 | 75.3 | 47.0 | 78.4 |
| 150 | 77.0 | 71.5 | 84.0 | 73.9 | 114.7 | 76.5 |

Biological results:

Observations

Neither significant signs of disease nor stress like discolouration or abnormal behaviour were observed in any replicate up to nominal 60 µg a.s./L. All surviving specimens, gave the impression of healthy condition.

Immobility

| Geometric mean measured concentrations (µg a.s./L) | Total introduced | Immobile | % immobility at 48 h |
|---|---|---|---|
| Control | 20 | 2 | 10 |
| Solvent control | 19# | 1 | 5 |
| 3.2 | 20 | 0 | 0 |
| 8.6 | 20 | 2 | 10 |
| 19.7 | 20 | 1 | 5 |
| 47.0 | 20 | 10 | 50* |
| 114.7 | 20 | 20 | 100* |

*Statistically significant (alpha = 0.05) vs pooled controls according to Step-down Cochran-Armitage test

# One test animal was killed during handling and was therefore not considered in the evaluation

Conclusion

The endpoints based on geometric mean measured concentrations are:

| | |
|---|---|
| **$EC_{50}$ 48 hours (95% C.I.):** | **45.0 µg a.s. / L**<br>(34.4 – 57.1) |
| LOEC:<br>lowest concentration with an effect on immobility | 47.0 µg a.s. / L |
| NOEC:<br>highest concentration without effects on immobility | 19.7 µg a.s. / L |

| | |
|---|---|
| Comments of zRMS: | The study is considered valid. All validity criteria were met.<br>**Agreed endpoints:**<br>$EC_{50}$ = 0.01321 mg a.s./$L_{mm}$<br>NOEC < 7.1 µg a.s. / L |

| | |
|---|---|
| Reference: | **KCA 8.2.4.2/07** |
| Title: | Amendment no. 01: Trifloxystrobin - Acute toxicity test with Chaoborus crystallinus, basic test conditions following OECD TG 202 |
| Report: | Kosak, L.; Hennecke, S.; 2020; EBTF0042; M-637890-02-1 |
| Authority registration No: | |
| Guideline(s): | OECD guideline 202 and EC method C.2 |
| Deviations: | Not specified |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication<br>(if vertebrate study): | |

**Material and methods:**

| | |
|---|---|
| Test material | Trifloxystrobin<br>batch: AE C642802-01-19<br>specification: 102000007792-03<br>purity: 96.5% w/w |
| Guideline(s) adaptation | There are no guidelines for acute tests on *Chaoborus* so the OECD guideline 202 was used. |
| Test species | *Chaoborus crystallinus*<br>Origin of the test animals were uncontaminated outdoors mesocosms located at Schneebergweg 30, 52056 Aachen, Germany. |
| Culturing conditions | Specimens were transferred into the laboratory, transferred into M4 medium, were fed with daphnia and were cultured for three days. |
| Organism age/size at study initiation | Fourth larval stage |
| Test solutions | Test medium: Elendt M4<br>Nominal concentrations: 8.9, 20.5, 47.3, 108.7, 250 µg a.s./L<br>Geometric mean measured concentrations: 7.1, 16.9, 41.3, 93.9, 212.2 µg a.s./L.<br>Controls: water control (test medium only) and solvent control (DMF at 100 µL/L)<br>Evidence of undissolved material: The test solutions were clear and colourless and without any irregularities |
| Replication | No. of vessels per concentration (replicates): 20 |

| | |
|---|---|
| | No. of vessels per control (replicates): 20<br>No. of vessels per solvent control (replicates): 20 |
| Organisms per replicate | No. of organisms per vessel: 1 to avoid cannibalism. |
| Exposure | Semi-static with daily renewal<br>Total exposure duration: 48 h |
| Test Vessel Loading | 1 organism in 20 mL of medium |
| Feeding during test | None |
| Test conditions | Temperature: 19.7 – 20.5°C.<br>Photoperiod: test in the dark<br>pH: 7.72-7.97<br>Dissolved oxygen: 7.21 – 8.34 mg/L |
| Parameters Measured / Observations | Oxygen concentration, pH value, and temperature of the test solutions were checked at test start, end and after each renewal of the test media.<br>The numbers of immobile organisms were visually determined after 5 hours after test start, after 24 h, 29 h and after 48 h. Those larvae that were at the water surface and show no reaction after repeated gentle agitation with stainless steel tweezers, were considered dead. Larvae, only twitching after repeated stimulus were considered as immobile. For the statistical evaluation of larval immobilisation, all dead and immobile animals per treatment will be added up. |
| Sampling for chemical analysis | Concentrations of trifloxystrobin in the water phase were quantified by chemical analysis using LC-MS/MS.<br>Samples of freshly prepared test media were taken from all five test solutions, the control and the solvent control at the beginning of the test and after 24h at media renewal prior to distribution to the test vessels. Samples of aged test concentrations were taken after 24h at media renewal and at the end of the test (48 hours) directly from the pooled replicates of each test concentration and the controls |
| Data analysis | ECx values were calculated by probit analysis using ToxRat software<br>NOEC was determined by Step-down Cochran-Armitage test with trend analysis by contrasts using proportions.<br>Controls were pooled for the statistical analysis since there was no statistical difference between the water control and the solvent control. |

**Results:**

| **Validity criteria** | **Required** | **Obtained** |
|---|---|---|
| % immobilisation in controls | $\leq$ 10% | 5 and 10% |
| Dissolved oxygen concentration at the end of the test in control and test vessels. | $\geq$ 3 mg/L | $\geq$ 7.21 mg/L |

<u>Analytical results</u>:

In water control and solvent control, trifloxystrobin concentrations were below the limit of quantification of 0.1 µg/L.
Since the measured concentrations were not in a range between 80 and 120% of nominal, it was decided to perform the evaluation of the concentration-effect-relationships and the calculations of effect concentrations based on the geometric mean measured test concentrations.

| Nominal Concentration (µg a.s./L) | 0 h % Nominal | 24 h - aged % Nominal | 24 h - new % Nominal | 48 h % Nominal | Geometric mean measured concentrations (µg a.s./L) | % of nominal |
|---|---|---|---|---|---|---|
| 8.9 | 86.1 | 75.6 | 86.2 | 72.7 | 7.1 | 79.9 |
| 20.5 | 84.2 | 74.3 | 91.9 | 79.7 | 16.9 | 82.3 |
| 47.3 | 93.9 | 81.8 | 103.4 | 72.9 | 41.3 | 87.2 |
| 108.7 | 89.8 | 78.5 | 91.5 | - | 93.9 | 86.4 |
| 250 | 86.2 | 80.4 | 88.3 | - | 212.2 | 84.9 |

- no measurements, all animals were dead

Biological results:

Observations

All surviving specimens, up to mean measured 41.3 µg a.s./L, gave the impression of healthy condition. Neither significant signs of disease nor stress like discolouration or abnormal behavior were observed in the surviving specimens.

Immobility

| Geometric mean measured concentrations (µg a.s./L) | Total introduced | Immobile | % immobility at 48 h |
|---|---|---|---|
| Control | 20 | 1 | 5 |
| Solvent control | 20 | 2 | 10 |
| 7.1 | 20 | 7 | 35* |
| 16.9 | 20 | 9 | 45* |
| 41.3 | 20 | 18 | 90* |
| 93.9 | 20 | 20 | 100* |
| 212.2 | 20 | 20 | 100* |

*Statistically significant (alpha = 0.05) vs pooled controls according to Step-down Cochran-Armitage test

Conclusion

The endpoints based on geometric mean measured concentrations are:

| | |
|---|---|
| **$EC_{50}$ 48 hours (95% C.I.):** | **13.205 µg a.s. / L** (8.534 – 18.268) |
| LOEC: lowest concentration with an effect on immobility | 7.1 µg a.s. / L |
| NOEC: highest concentration without effects on immobility | < 7.1 µg a.s. / L |

| | |
|---|---|
| Comments of zRMS: | The study is considered valid. All validity criteria were met.<br>**Agreed endpoints:**<br>$EC_{50}$ = 0.184 mg a.s./$L_{mm}$<br>NOEC = 0.0144 mg a.s./$L_{mm}$ |

| | |
|---|---|
| Reference: | **KCA 8.2.4.2/08** |
| Title: | Trifloxystrobin - Acute toxicity test with Baetis rhodani, basic test conditions following OECD TG 202 |
| Report: | Kosak, L.; Hennecke, S.; 2018; EBTF0043; M-637847-01-1 |
| Authority registration No: | |
| Guideline(s): | OECD guideline 202 and EC method C.2 |
| Deviations: | None |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication (if vertebrate study): | |

**Material and methods:**

| | |
|---|---|
| Test material | Trifloxystrobin<br>batch: AE C642802-01-19<br>specification: 102000007792-03<br>purity: 96.5% w/w |
| Guideline(s) adaptation | There are no guidelines for acute tests on *Baetiss* so the OECD guideline 202 was used. |
| Test species | *Baetis rhodani*<br>Origin of the Baetis rhodani larvae is the Senserbach in Lemiers, which is the border between the Netherlands and Germany. |
| Acclimation | The *Baetis rhodani* larvae were taken from the stream Senserbach and transferred to M4-Medium with the same temperature as measured in their home waters (7 °C). Over a period of at least 45 hours the organisms were acclimated in M4-Medium to the pre-test conditions of 10 °C. Stones overgrown with periphyton from the same origin as the larvae were used as food source during the pre-treatment. |
| Organism age/size at study initiation | Larvae of unspecified age |
| Test solutions | Test medium: Elendt M4<br>Nominal concentrations: 17.1, 37.6, 82.6, 181.8, 400.0 µg a.s./L<br>Geometric mean measured concentrations: 14.4, 31.2, 73.5, 147.6, 325.6 µg a.s./L.<br>Controls: water control (test medium only) and solvent control (DMF at 100 µL/L)<br>Evidence of undissolved material: The test solutions were clear and colourless and without any irregularities |
| Replication | No. of vessels per concentration (replicates): 30<br>No. of vessels per control (replicates): 30<br>No. of vessels per solvent control (replicates): 30 |
| Organisms per replicate | No. of organisms per vessel: 1 to avoid cannibalism. |
| Exposure | Semi-static with daily renewal<br>Total exposure duration: 48 h |
| Test Vessel Loading | 1 organism in 20 mL of medium |
| Feeding | None |

| | |
|---|---|
| during test | |
| Test conditions | Temperature: 9.2 – 10.3°C.<br>Photoperiod: test in the dark<br>pH: 7.59-7.80<br>Dissolved oxygen: 8.7 – 13.8 mg/L |
| Parameters Measured / Observations | Oxygen concentration, pH value, and temperature of the test solutions were checked at test start, end and after each renewal of the test media.<br>The numbers of immobile organisms were visually determined after 5 hours after test start, after 24 h, 28 h and after 48 h. Additionally, moulting was recorded for replicates containing exuviae. Those animals that were not able to swim within 10 seconds after gentle agitation of the test vessel or an additional slight stimulation with the pipette were considered to be immobilized |
| Sampling for chemical analysis | Concentrations of trifloxystrobin in the water phase were quantified by chemical analysis using LC-MS/MS.<br>Samples of freshly prepared test media were taken from all five test solutions, the control and the solvent control at the beginning of the test and after 24h at media renewal prior to distribution to the test vessels. Samples of aged test concentrations were taken after 24h at media renewal and at the end of the test (48 hours) directly from the pooled replicates of each test concentration and the controls |
| Data analysis | ECx values were calculated by probit analysis using ToxRat software<br>NOEC was determined by Step-down Cochran-Armitage test with trend analysis by contrasts using proportions.<br>Controls were pooled for the statistical analysis since there was no statistical difference between the water control and the solvent control. |

**Results:**

| **Validity criteria** | **Required** | **Obtained** |
|---|---|---|
| % immobilisation in controls | $\leq$ 10% | 0 and 1.7% |
| Dissolved oxygen concentration at the end of the test in control and test vessels. | $\geq$ 3 mg/L | $\geq$ 8.7 mg/L |

<u>Analytical results</u>:

In water control and solvent control, trifloxystrobin concentrations were below the limit of quantification of 0.1 µg/L.
Since some measured concentrations were not in a range between 80 and 120% of nominal, it was decided to perform the evaluation of the concentration-effect-relationships and the calculations of effect concentrations based on the geometric mean measured test concentrations.

| **Nominal Concentration (µg a.s./L)** | **0 h % Nominal** | **24 h - aged % Nominal** | **24 h - new % Nominal** | **48 h % Nominal** | **Geometric mean measured concentrations (µg a.s./L)** | **% of nominal** |
|---|---|---|---|---|---|---|
| 17.1 | 86.0 | 85.3 | 84.7 | 81.8 | 14.4 | 84.5 |
| 37.6 | 85.0 | 81.3 | 84.4 | 81.3 | 31.2 | 83.0 |
| 82.6 | 97.3 | 79.5 | 99.2 | 81.8 | 73.5 | 89.0 |
| 181.8 | 80.8 | 74.8 | 90.5 | 79.5 | 147.6 | 81.2 |
| 400 | 85.1 | 77.8 | 85.3 | 77.7 | 325.6 | 81.4 |

Biological results:

Observations

Neither significant signs of disease nor stress like discoloration or abnormal behaviour were observed in any replicate up to and including the highest test concentration of nominal 400 µg/L. All survived specimens, up to and including the highest loading, gave the impression of healthy condition. Moulting of the test animals was observed after 4, 24, 28 and 48 hours in the controls and in the test concentrations of nominal 17.1, 37.6 and 82.6 µg/L.

Immobility

| **Geometric mean measured concentrations (µg a.s./L)** | **Total introduced** | **Immobile** | **% immobility at 48 h** |
|---|---|---|---|
| Control | 30 | 0 | 0 |
| Solvent control | 30 | 1 | 1.7 |
| 14.4 | 30 | 2 | 6.7 |
| 31.2 | 30 | 3 | 10.0* |
| 73.5 | 30 | 5 | 16.7* |
| 147.6 | 30 | 12 | 40.0* |
| 325.6 | 30 | 22 | 73.3* |

*Statistically significant (alpha = 0.05) vs pooled controls according to Step-down Cochran-Armitage test

Conclusion

The endpoints based on geometric mean measured concentrations are:

| **$EC_{50}$ 48 hours (95% C.I.):** | **184.0 µg a.s. / L** (131.4 – 300.4) |
|---|---|
| LOEC: lowest concentration with an effect on immobility | 31.2 µg a.s. / L |
| NOEC: highest concentration without effects on immobility | 14.4 µg a.s. / L |

| | |
|---|---|
| Comments of zRMS: | The study is considered as an acceptable. All validity criteria were met.<br>**Agreed endpoints:**<br>$EC_{50}$ = 0.1339 mg a.s./$L_{mm}$<br>NOEC= 0.0303 mg a.s./$L_{mm}$ |

| | |
|---|---|
| Reference: | **KCA 8.2.4.2/09** |
| Title: | Trifloxystrobin - Acute toxicity test with Gammarus sp., basic test conditions following OECD TG 202 - Report - |
| Report: | Kosak, L.; Hennecke, S.; 2018; EBTF0044; M-638529-01-1 |
| Authority registration No: | |
| Guideline(s): | the OECD guideline 202 and EC method C.2 |
| Deviations: | None |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication (if vertebrate study): | |

## Material and methods:

| | |
|---|---|
| Test material | Trifloxystrobin<br>batch: AE C642802-01-19<br>specification: 102000007792-03<br>purity: 96.5% w/w |
| Guideline(s) adaptation | There are no guidelines for acute tests on *Gammarus* so the OECD guideline 202 was used. |
| Test species | *Gammarus sp.*<br>Origin of the gammarids was Blades Biological Ltd. (Cowden, Edenbridge, Kent TN8 7DX, United Kingdom). |
| Acclimation | Individuals used in the test were acclimated for 2 days in M4 medium in the laboratory and fed with alder leaves. |
| Organism age/size at study initiation | Non reproducing stage |
| Test solutions | Test medium: Elendt M4<br>Nominal concentrations: 17.9, 41.1, 94.5, 217.4, 500 µg a.s./L<br>Geometric mean measured concentrations: 13.5, 30.3, 71.3, 163.7, 387.9 µg a.s./L.<br>Controls: water control (test medium only) and solvent control (DMF at 100 µL/L)<br>Evidence of undissolved material: The test solutions were clear and colourless and without any irregularities |
| Replication | No. of vessels per concentration (replicates): 20<br>No. of vessels per control (replicates): 20<br>No. of vessels per solvent control (replicates): 20 |
| Organisms per replicate | No. of organisms per vessel: 1 |
| Exposure | Semi-static with daily renewal<br>Total exposure duration: 48 h |
| Test Vessel Loading | 1 organism in 20 mL of medium |
| Feeding during test | None |
| Test conditions | Temperature: 15.2 – 16.5°C.<br>Photoperiod: test in the dark<br>pH: 7.51 – 7.98<br>Dissolved oxygen: 7.91 – 8.47 mg/L |
| Parameters Measured / Observations | Oxygen concentration, pH value, and temperature of the test solutions were checked at test start, end and after each renewal of the test media.<br>The numbers of immobile organisms were visually determined after 4 hours after test start, after 24 h, 28.5 h and after 48 h. Specimens which were not able to swim within |

| | |
|---|---|
| | 15 seconds after gentle agitation of the test vessel were considered to be immobilized. |
| Sampling for chemical analysis | Concentrations of trifloxystrobin in the water phase were quantified by chemical analysis using LC-MS/MS.<br>Samples of freshly prepared test media were taken from all five test solutions, the control and the solvent control at the beginning of the test and after 24h at media renewal prior to distribution to the test vessels. Samples of aged test concentrations were taken after 24h at media renewal and at the end of the test (48 hours) directly from the pooled replicates of each test concentration and the controls |
| Data analysis | ECx values were calculated by Weibull analysis using ToxRat software<br>NOEC was determined by Step-down Cochran-Armitage test with trend analysis by contrasts using proportions.<br>Controls were pooled for the statistical analysis since there was no statistical difference between the water control and the solvent control. |

**Results:**

| **Validity criteria** | **Required** | **Obtained** |
|---|---|---|
| % immobilisation in controls | ≤ 10% | 0 and 5% |
| Dissolved oxygen concentration at the end of the test in control and test vessels. | ≥ 3 mg/L | ≥ 7.91 mg/L |

Analytical results:

In water control and solvent control, trifloxystrobin concentrations were below the limit of quantification of 0.1 µg/L.
Since the measured concentrations were not in a range between 80 and 120% of nominal, it was decided to perform the evaluation of the concentration-effect-relationships and the calculations of effect concentrations based on the geometric mean measured test concentrations.

| **Nominal Concentration (µg a.s./L)** | **0 h % Nominal** | **24 h - aged % Nominal** | **24 h - new % Nominal** | **48 h % Nominal** | **Geometric mean measured concentrations (µg a.s./L)** | **% of nominal** |
|---|---|---|---|---|---|---|
| 17.9 | 84.8 | 67.2 | 89.2 | 63.8 | 13.5 | 75.5 |
| 41.1 | 85.0 | 62.4 | 85.7 | 65.3 | 30.3 | 73.8 |
| 94.5 | 81.5 | 62.4 | 97.9 | 65.2 | 71.3 | 75.4 |
| 217.4 | 86.2 | 66.0 | 87.8 | 64.4 | 163.7 | 75.3 |
| 500.0 | 83.1 | 65.9 | 92.6 | 71.5 | 387.9 | 77.6 |

Biological results:

Observations

Neither significant signs of disease nor stress like discolouration or abnormal behaviour were observed in any replicate up to and including nominal 217.4 µg a.s./L in the surviving test animals.

Immobility

| **Geometric mean measured concentrations (µg a.s./L)** | **Total introduced** | **Immobile** | **% immobility at 48 h** |
|---|---|---|---|
| Control | 20 | 0 | 0 |
| Solvent control | 20 | 1 | 5 |
| 13.5 | 20 | 0 | 0 |
| 30.3 | 20 | 1 | 5 |
| 71.3 | 20 | 3 | 15* |
| 163.7 | 20 | 13 | 65* |
| 387.9 | 20 | 20 | 100* |

*Statistically significant (alpha = 0.05) vs pooled controls according to Step-down Cochran-Armitage test

<u>Conclusion</u>

The endpoints based on geometric mean measured concentrations are:

| **$EC_{50}$ 48 hours (95% C.I.):** | **133.9 µg a.s. / L**<br>(104.2 – 170.3) |
|---|---|
| LOEC:<br>lowest concentration with an effect on immobility | 71.3 µg a.s. / L |
| NOEC:<br>highest concentration without effects on immobility | 30.3 µg a.s. / L |

| Comments of zRMS: | The study is considered as an acceptable. All validity criteria were met.<br>**Agreed endpoint:**<br>$EC_{50}$ >2.66 mg p.m./$L_{gm}$ |
|---|---|

| Reference: | **KCA 8.2.4.1/01** |
|---|---|
| Title: | Acute toxicity of CGA357261 (technical metabolite) to the waterflea Daphnia magna in a static renewal laboratory test system |
| Report: | Riebschläger, T.; 2018; EBTF0037; M-630021-01-1 |
| Authority registration No: | |
| Guideline(s): | OECD guideline 202,(2004); EC Council Regulation No 440/2008, Method C.2 (2008); U.S. EPA Pesticide Assessment Guidelines, Subdivision E, § 72-2 (1982); OCSPP Guideline 850.1010, public draft (2016), modified; JMAFF 12 Nousan No. 8147 (2000). |
| Deviations: | None |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication (if vertebrate study): | |

**Material and methods:**

| | |
|---|---|
| Test material | CGA 357261<br>lot/batch: AE 1393224-PU-01<br>specification: not specified<br>purity: 99.4% |
| Guideline(s) adaptation | none |
| Test species | *Daphnia magna* (Strauss)<br>Origin: Lab in-house culture |
| Culturing conditions | Similar environmental conditions as used in the test. The parental daphnids were cultured in Elendt M7 medium |
| Organism age/size at study initiation | Less than 24 h old. First instar neonates |
| Test solutions | Test medium: Elendt M7<br>Nominal concentrations: 0.593 – 0.889 – 1.34 – 2.00 – 3.00 mg pm/L<br>Geometric mean measured concentrations: 0.584 – 0.839 – 1.25 – 1.81 – 2.66 mg p.m./L<br>Controls: test medium<br>Solvent control: dimethylformamide 0.1 mL/L<br>Evidence of undissolved material: not observed, clear uncoloured medium |
| Replication | No. of vessels per concentration (replicates):6<br>No. of vessels per control (replicates): 6<br>No. of vessels per solvent control (replicates): 6 |
| Organisms per replicate | No. of organisms per vessel: 5 |
| Exposure | Semi-static conditions, renewal at 24h<br>Total exposure duration: 48 h |
| Feeding during test | None |
| Test conditions | Temperature: 21.4 – 21.8°C<br>Photoperiod: 16h light<br>Light intensity: max 1200 lux<br>pH: 7.8 – 8.0<br>Water hardness: 213.6 mg/L as $CaCO_3$<br>Conductivity: 594 µS/cm<br>Dissolved oxygen: minimum 9.2 mg/L |
| Parameters Measured / Observations | The mobility of the daphnids was determined by visual observation after 24 and 48 hours. |
| Sampling for chemical analysis | Duplicate samples from the freshly prepared test media of all test concentrations and control were taken at the start of the test and duplicate samples of the pooled media of each concentrations and control at the end of the test |
| Data analysis | Probit analysis with ToxRat software |

**Results:**

| **Validity criteria of OECD guideline** | **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 | ≥ 9.2 mg/L |

Analytical results:

The highest concentration is the solubility limit of the substance in the test conditions. Since some measured concentrations were out of the range 80-120% of nominal concentrations, the geometric mean measured concentrations were calculated.

| **Nominal concentrations** | **Measured concentrations** | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **Day 0** | | **Day 1** | | | | **Day 2** | | **geometric mean measured concentrations** |
| | **Fresh solution** | | **Aged solution** | | **Fresh solution** | | **Aged solution** | | |
| **mg p.m./L** | **mg p.m./L** | **% of nominal** | **mg p.m./L** | **% of nominal** | **mg p.m./L** | **% of nominal** | **mg p.m./L** | **% of nominal** | **mg p.m./L** |
| Control | < LOQ | - | < LOQ | - | < LOQ | - | < LOQ | - | - |
| Solvent control | < LOQ | - | < LOQ | - | < LOQ | - | < LOQ | - | - |
| 0.593 | 0.603 | 102 | 0.556 | 94 | 0.636 | 107 | 0.546 | 92 | 0.584 |
| 0.889 | 0.869 | 97 | 0.814 | 91 | 0.907 | 101 | 0.773 | 86 | 0.839 |
| 1.34 | 1.12 | 84 | 1.13 | 84 | 1.42 | 106 | 1.35 | 101 | 1.25 |
| 2.00 | 1.94 | 97 | 1.63 | 82 | 2.19 | 110 | 1.55 | 78 | 1.81 |
| 3.00 | 2.18 | 73 | 2.05 | 68 | 2.91 | 97 | 3.86 | 129 | 2.66 |

LOQ = 0.0156 µg/L

Concurrent validation:
For the determination of AE 1393224 the analytical method 01555 (Krebber R.;Leppelt L.; 2018; M-623236-01-1) was used and validated concurrently.

The linearity of MS detection was determined for AE 1393224 in the concentration range from 0.501 µg/L to 20.1 µg/L and was shown to be linear (y= 2.4543e+005 – 1193.5). The correlation coefficient was 0.9999 (1/x weighted). 5 concentrations were measured. If necessary, samples were diluted to achieve final concentrations falling within the calibrated range of detector response.

Because of the direct measurement of the samples recovery rates cannot be calculated. The evaluation of measurements based on HPLC-MS/MS for precision was done by comparison of the peak areas of the samples with the peak areas of the external standard solutions. For this purpose standard solutions of AE 1393224 in test water/acetonitrile (80/20, v/v) were used. The relative standard deviation of AE 1393224 peak areas and retention times are shown in the table below.

**Table 4.1.2- 2: Validation of Method 01555 for AE 1393224 by HPLC-MS/MS**

| AE 1393224 Standard concentration | | AE 1393224 | | | |
|---|---|---|---|---|---|
| | | Peak area | | Retention time | |
| [µg/L] | n | Mean value [area counts] | Rel. std. dev. [%] | Mean value [min]* | Rel. std. dev. [%] |
| 0.501 | 3 | 128691 | 8.6 | 3.16 | <0.1 |
| 0.501 | 4 | 116877 | 1.3 | 2.98 | 0.2 |
| 0.501 | 4 | 120522 | 0.9 | 2.99 | 0.2 |
| 0.501 | 6 | 117253 | 1.3 | 2.99 | 0.2 |
| 1.00 | 4 | 239664 | 1.5 | 3.16 | <0.1 |
| 1.00 | 4 | 235251 | 1.4 | 2.98 | <0.1 |
| 1.00 | 4 | 236794 | 0.8 | 2.98 | <0.1 |
| 1.00 | 6 | 226611 | 1.4 | 2.99 | 0.2 |
| 5.01 | 4 | 1198508 | 0.8 | 3.16 | <0.1 |
| 5.01 | 4 | 1161390 | 1.1 | 2.99 | 0.2 |
| 5.01 | 4 | 1199286 | 1.0 | 2.98 | 0.2 |
| 5.01 | 6 | 1120134 | 1.8 | 2.99 | 0.2 |
| 10.0 | 4 | 2427714 | 0.4 | 3.16 | <0.1 |
| 10.0 | 4 | 2368552 | 0.3 | 2.98 | 0.2 |
| 10.0 | 4 | 2426502 | 1.6 | 2.98 | <0.1 |
| 10.0 | 6 | 2309436 | 1.5 | 2.99 | 0.2 |
| 20.1 | 4 | 4986686 | 0.8 | 3.16 | <0.1 |
| 20.1 | 4 | 4811625 | 0.8 | 2.98 | <0.1 |
| 20.1 | 4 | 4973220 | 1.8 | 2.98 | <0.1 |
| 20.1 | 6 | 4542690 | 1.8 | 2.99 | 0.1 |

* : different retention times due to different oven temperatures

<u>Conclusion</u>

The applicability of the HPLC-MS/MS method 01555 for the analysis of AE 1393224 in water samples was tested. The data presented demonstrate that the method allows the determination of AE 1393224 with satisfactory accuracy, precision and repeatability according to guideline SANCO/3029/99. This method was used for analysis of AE 1393224 concentrations in specimens derived from an ecotoxicity study of Riebschläger, T.; 2018; M-630021-01-1.

<u>Biological results</u>:

Observations

No immobile daphnids were observed in the controls or at 24h in any test concentrations. Some daphnids were immobile at 48h, in concentrations 1.81 and 2.66 mg/L. No sublethal effects were observed in any group.

| **Geometric mean measured concentrations (mg p.m./L)** | **% of immobilized daphnids** | |
|---|---|---|
| | **24 h** | **48 h** |
| Control | 0 | 0 |
| Solvent control | 0 | 0 |
| 0.584 | 0 | 0 |
| 0.839 | 0 | 0 |
| 1.25 | 0 | 0 |
| 1.81 | 0 | 3.3 |
| 2.66 | 0 | 16.7 |

**Conclusion**

The endpoints based on geometric mean measured concentrations are:

| | |
|---|---|
| **$EC_{50}$ 48 hours (95% C.I.):** | **> 2.66 mg p.m./L (not applicable)** |
| $EC_{50}$ 24 hours (95% C.I.): | > 2.66 mg p.m./L (not applicable) |
| LOEC: lowest concentration with an effect | 1.81 mg p.m./L |
| NOEC: highest concentration without adverse effects | 1.25 mg p.m./L |

| | |
|---|---|
| Comments of zRMS: | The study is considered valid . All validity criteria were met.<br>**Agreed endpoint:**<br>$EC_{50}$ 48 hours (95% C.I.) = 10.7 mg p.m./L |

| | |
|---|---|
| Reference: | **KCA 8.2.4.1/02** |
| Title: | Daphnia sp., acute immobilisation test with trifloxystrobin - TFMAP |
| Report: | Neuhahn, A.; 2017; 2017/0043/03; M-602375-01-1 |
| Authority registration No: | |
| Guideline(s): | Council Regulation (EC) No 440/2008, Method C.2 ‘Acute toxicity for Daphnia’ (2008) which is equivalent to OECD Guideline for Testing of Chemicals No. 202 'Daphnia sp., Acute Immobilisation Test' (adopted April 13, 2004). |
| Deviations: | none |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication (if vertebrate study): | |

**Material and methods:**

| | |
|---|---|
| Test material | Trifloxystrobin-TFMAP (CGA 107170)<br>lot/batch: EK2T000179<br>specification: 102000022656<br>purity: 95.2% |
| Guideline(s) adaptation | none |
| Test species | *Daphnia magna* (Strauss) |

| | |
|---|---|
| | Origin: Strain of Bundesgesundheitsamt Berlin |
| Culturing conditions | Similar environmental conditions as used in the test. The parental daphnids were cultured in M4 Medium |
| Organism age/size at study initiation | Neonates |
| Test solutions | Test medium: M4 Medium<br>Nominal concentrations: 3.13, 6.25, 12.5, 25, 50 and 100 mg/L<br>Geometric mean measured concentrations after 24 h: 2.321, 4.450, 9.037, 18.181, 36.362, 73.277 mg/L<br>Geometric mean measured concentrations after 48 h: 2.399, 4.611, 9.315, 18.007, 37.492, 73.277 mg/L<br>Controls: test medium<br>Evidence of undissolved material: not observed |
| Replication | No. of vessels per concentration (replicates): 4<br>No. of vessels per control (replicates): 4 |
| Organisms per replicate | No. of organisms per vessel: 5 |
| Exposure | Semi-static conditions, renewal at 24h<br>Total exposure duration: 48 h |
| Feeding during test | None |
| Test conditions | Temperature of incubation unit: 20.2 – 20.7°C<br>Temperature in test medium: 20.0 – 20.5°C<br>Photoperiod: 16h light<br>Light intensity: not determined<br>pH: 7.8 – 8.0<br>Water hardness: 273.0 mg/L as $CaCO_3$ (15.3 °dH)<br>Conductivity: not determined<br>Dissolved oxygen: minimum 7.8 (99% of saturation) mg/L |
| Parameters Measured / Observations | Observations were made on the swimming ability and the immobilization rate after 24 and 48 hours of exposure.<br>The total hardness of the dilution water was measured at test start.<br>The pH was measured in new and old medium at 0, 24 and 48 h of the test. |
| Sampling for chemical analysis | Analysis of all test item concentrations in the freshly prepared media and in the media after 24 h of exposure according to the semi-static conditions |
| Data analysis | Probit analysis with ToxRatPro software Version 2.10 |

**Results:**

| **Validity criteria of OECD guideline** | **Required** | **Obtained** |
|---|---|---|
| Immobilisation in control | $\leq$ 10% | 0% |
| Signs of disease or stress or unusual behavior in control | $\leq$ 10% | 0% |
| Dissolved $O_2$ concentration in test media | $\geq$ 3 mg/L | $\geq$ 8.1 mg/L |

Analytical results:

Effective concentrations ranged from 77.7 % to 86.0 % in the freshly prepared media and from 59.2 % to 73.1 % in the media after 24 hours of exposure.

| Date | Time | Measuring time | Test item concentration [mg/L] | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | 3.13 | 6.25 | 12.5 | 25 | 50 | 100 |
| 2017-07-18 | 0 h | 0 h | 2.552 | 5.014 | 9.715 | 20.061 | 39.990 | 81.035 |
| 2017-07-19 | 24 h | 24 h | 2.111 | 3.949 | 8.407 | 16.478 | 33.063 | 66.262 |
| | | 0 h | 2.688 | 5.326 | 10.514 | 21.490 | 42.508 | --- |
| 2017-07-20 | 48 h | 24 h | 2.289 | 4.288 | 8.768 | 14.801 | 35.154 | --- |

Geometric 24 h: 2.321, 4.450, 9.037, 18.181, 36.362, 73.277
Geometric 48 h: 2.399, 4.611, 9.315, 18.007, 37.492, 73.277

The applicability of an HPLC-UV/VIS method for the analysis of CGA 10710 in test water was tested. The data presented in part B5 demonstrate that the method allows the determination of CGA 10710 with satisfactory accuracy, precision and repeatability according to guideline SANCO/3029/99 and can therefore be regarded as fit for purpose.

Biological results:

Observations

No immobile daphnids were observed in the controls or at 24h in any test concentrations. Some daphnids were immobile at 48h, in concentrations higher or equal than 12.5 mg/L. No sublethal effects were observed in any group.

| **Nominal test concentrations (mg p.m./L)** | **% of immobilized daphnids** | |
|---|---|---|
| | **24 h** | **48 h** |
| Control | 0 | 0 |
| 3.13 | 0 | 0 |
| 6.25 | 0 | 0 |
| 12.5 | 0 | 50 |
| 25 | 40 | 80 |
| 50 | 65 | 100 |
| 100 | 100 | 100 |

**Conclusion**

The endpoints are expressed in terms of geometric mean measured concentrations:

| | |
|---|---|
| **$EC_{50}$ 48 hours (95% C.I.):** | **10.7 mg p.m./L<br>(20.1 - 30.9 mg p.m./L)** |
| $EC_{50}$ 24 hours (95% C.I.): | 24.8 mg p.m./L<br>(8.8 - 13.1) |

| | |
|---|---|
| Comments of zRMS: | The study is not considered as acceptable by zRMS –NL for previous registration report for Luna Sensation, July 2018.<br>Based on nominal concentrations of AE C656948+Trifloxystrobin SC250+250 G, the $EC_{50}$ for immobilisation after 48 hours of static exposure was 86 µg form./l. (95 % confidence limits: 77 µg/l to 95 µg/l). After 24 hours of exposure only 46.7% immobilisation was observed at the highest test concentration of 160µg form./l. Therefore, appropriate calculation of an $EC_{50}$ for immobilisation was not applicable.<br>However, the content of the active substance AE C656948 in exposure solutions was measured for verification of the exposed test item concentrations but not also the content of the other active substance Trifloxystrobin. Therefore, as fluopyram does not degrade faster than trifloxystrobin and the toxicity for fish is higher for trifloxystrobin compared to fluopyram (see LoEPs above), the test is considered unacceptable and cannot be used for the risk assessment. |

| | |
|---|---|
| Reference: | **KCP 10.2.1/04** |
| Title: | Acute toxicity of AE C656948 + trifloxystrobin SC 250 + 250 G to the waterflea Daphnia magna in a static laboratory test system |
| Report: | Bruns, E.; 2007; EBGMP031; M-292365-01-1 |
| Authority registration No: | |
| Guideline(s): | OECD guideline 202,(2004); EEC Directive 92/69/EWG, part C.2 (1992); U.S. EPA Pesticide Assessment Guidelines, Subdivision E, § 72 2 (1982), OPPTS Guideline 850.1010 public draft 1996 (modified); JMAFF 12 Nousan No. 8147 (2000); Equivalent to US EPA OPPTS Guideline No. 850.1010 SUPP |
| Deviations: | not specified |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication (if vertebrate study): | |

**Materials and methods:**

A. Materials

| | |
|---|---|
| 1. Test material: | AE C656948 + Trifloxystrobin SC 250+250 G |
| Specification No. | 102000012886 |
| Batch ID: | 2007-000441 |
| Visual appearance: | white fluid |
| Physical density: | 1.174 g/mL |
| Active substance 1: | AE C656948, fluopyram |
| Active ingredient 2: | CGA 279202, trifloxystrobin |
| Nominal content of active substance: | fluopyram: 250 g/L<br>trifloxystrobin: 250 g/L) |
| Analyzed content of active substance: | fluopyram: 21.4% (251.5 g/L)<br>trifloxystrobin: 21.6% (253.5 g/L) |
| Expiration date: | 2008-02-21 |
| 2. Test organism | |
| Species | *Daphnia magna* |
| Age | Neonates < 24 hours old at initiation |
| Source | Bayer laboratory stock breeding |
| Acclimation period | Fed with Desmodesmus subspicatus three times per week. |
| Quality check of the breeding stock: | |

| | |
|---|---|
| Date | January 2007 |
| Test duration | 24 hours |
| Reference substance | $K_2Cr_2O_7$ |
| Test system | Static (no renewal) |
| Test treatment levels (nominal) | 0 (control), 0.56, 0.75, 1.00, 1.33 and 1.78 mg/L |
| Test result | 24 hour $EC_{50}$ = 1.04 mg/L |

B. Study design and methods

| | |
|---|---|
| 1. In life dates | 2007-04-02 to 2007-06-26 |
| 2. Experimental treatments | |
| Test duration | 48 hours |
| Test system | Static (no renewal) |
| Test vessel material | All glass – 100 mL beakers |
| Test medium volume | 50 mL |
| Number of test levels | 1 water control, 5 treatment concentration |
| Number of replicates | Six replicates of 5 daphnids per test level |
| Number of daphnids per test level | 30 |
| Solvent carrier | None |
| Solvent load | - |

The study covered five geometrically spaced nominal concentrations (10, 20, 40, 80 and 160 µg product/L = factor 2.0, supplemented by an untreated dilution water (blank) control. A non-GLP preliminary assay (rangefinder) was conducted in order to estimate the approximate toxicity level of the test item

Six vessels (replicates), each provided with five daphnids (= 10 mL test solution per daphnid), were utilized per treatment group and control (=30 animals per study group). The beakers were covered with transparent glass plates and placed in a climate controlled environment (isolated chamber) between 18 and 22°C (maximum allowed deviation ± 1 °C within 48 hours). They were illuminated by "cool white" fluorescent bulbs in a 16:8 hours light dark cycle, at a light intensity of max. 1200 lux.

The water fleas were not fed and the test solutions were not artificially aerated during exposure. Any surface in contact with the test solution was made of glass or other chemical inert material.

Readily prepared test solutions were distributed to the corresponding replicate vessels and five < 24 hours old first instar daphnids were introduced below the water surface of each test beaker. A computer generated random number sequence was used to assign the test animals impartially to the test beakers.

The test was started within 30 min. after the test solutions have been added and uniformly distributed to the test vessels.

For verification of the aspired exposure concentrations, content of the active substance AE C656948 was chosen to be analytically determined. The other active ingredient trifloxystrobin was not analyzed since they are present in the formulated product in a fixed ratio to the analyzed component.

For this purpose, duplicate samples containing 20 mL of the freshly prepared test media (without daphnids) were taken from bulk preparation for all test levels and the untreated control immediately after preparation and again from pooled replicates of the corresponding aged media at the end of the 48 hours exposure interval.

Daphnia magna were observed for immobilization and sublethal behavioral effects at 24 and 48 hours.

Test water was artificial water (M7 Elendt medium) of conductivity: 579 µS/cm, total hardness: 231 mg/L $CaCO_3$ and alkalinity 53 mg/L $CaCO_3$.

3. Observations

Endpoints and water quality

The parameters measured in this study were immobilization and sublethal behavioral effects by visual enumeration or observations after approx. 24 and 48 hours.

Interval of water quality measurements was at 0 hours and 48 hours The temperature was measured hourly.
Prior to test initiation, conductivity, total hardness and alkalinity of the dilution media (Elendt M7) were determined.
The dissolved oxygen and pH values were measured in the freshly prepared test solutions of each treatment level and control and repeatedly in the pooled replicates of the aged media at test termination.
Light intensity was measured at start of the study.
Temperature of the test media inside one vessel of the untreated control and of the highest test concentration were continuously recorded during exposure.
Statistical method
No statistical methods were necessary since no test concentration resulted in >50% of daphnids immobilized or experiencing sublethal effects.
For EC50 determination, a dose sigmoid response relationship curve had to be modeled by Probit Analysis after Finney, fitted by an iterative weighed linear regression according to the Maximum Likelihood principle which allows computation of EC50 and 95 percent confidence limits for immobility rates if possible. The described statistical procedures are carried out by using the ToxRat Professional© Software, V.2.09
Analytical verification
Analytical determinations of fluopyram were made by HPLC –MS/MS. The LOQ is 0.05 µg/L and the LOD 0.02 µg/L. The active substance concentrations were analyzed in the test medium at the beginning (Day 0) and at test termination (48h).

**Results and discussions:**

A. Findings

Water chemistry and concentrations

| | |
|---|---|
| Temperature range | 20.9 °C to 21.2 °C |
| Dissolved oxygen range | 8.3 to 8.8 mg $O_2$/L |
| pH range | 8.1 |

Analysed Concentrations of AE C656948 in Test Solutions

| Nominal Concentrations | | Analyzed Concentrations | | | |
|---|---|---|---|---|---|
| | | Freshly Prepared Solutions | | Aged Solutions after 48h. | |
| µg product/L | µg a.s./L[1)] | µg a.s./L | % of nominal | µg a.s./L | % of nominal |
| Control | | < 0.209 | --- | < 0.209 | --- |
| 10 | 2.14 | 2.051 | 96 | 2.151 | 100 |
| 20 | 4.28 | 4.224 | 99 | 4.276 | 100 |
| 40 | 8.56 | 8.611 | 101 | 8.383 | 98 |
| 80 | 17.1 | 17.07 | 100 | 17.84 | 104 |
| 160 | 34.2 | 33.82 | 99 | 34.84 | 102 |
| | | Mean: 99 % of nominal | | Mean: 101 % of nominal | |

[1)] = measured a.s. component : AE C 656948

The measured AE C656948 concentrations in the freshly prepared test solutions at test initiation ranged between 96% and 101% (mean: 99%) of the corresponding nominal concentrations.
The corresponding concentrations of the aged test solutions at the end of the 48 hours exposure period ranged between 98% and 104% (mean: 101%) of nominal.
No amounts of AE C656948 were detected in samples from untreated water control.
Given that the toxicity cannot be attributed to any one of the active substances alone but to the product as a whole, all results are based on nominal test concentrations of the product.

B. Observations

Toxicity to *Daphnia magna* (based on nominal concentrations):

| Nominal Test Concentrations (µg product/L) | Exposed Daphnids (=100%) | Immobilized Daphnids | | | |
|---|---|---|---|---|---|
| | | 24 h. | | 48 h. | |
| | | n | % | n | % |
| Control | 30 | 0 | 0 | 0 | 0 |
| 10 | 30 | 0 | 0 | 0 | 0 |
| 20 | 30 | 0 | 0 | 0 | 0 |
| 40 | 30 | 0 | 0 | 0 | 0 |
| 80 | 30 | 0 | 0 | 11 | 36.7 |
| 160 | 30 | 14 | 46.7 | 30 | 100 |

**Conclusion:**

Based on nominal concentrations of AE C656948 + Trifloxystrobin SC250 + 250 G, the $EC_{50}$ for immobilization after 48 hours of static exposure was 86 µg product/l. (95 % confidence limits: 77 µg/L to 95 µg/L). After 24 hours of exposure only 46.7% immobilization was observed at the highest test concentration of 160 µg product/L. Therefore, appropriate calculation of an $EC_{50}$ for immobilization was not applicable.

| | |
|---|---|
| Comments of zRMS: | The study is considered acceptable. All validity criteria were met.<br>**Agreed endpoints:**<br>48-h $EC_{50}$ (95% C.I.) =0.051 mg propduct/L (0.041 - 0.063)<br>48-h $EC_{20}$ (95% C.I)=0.031 mg product/L (0.024 - 0.041)<br>48-h $EC_{10}$ (95% C.I.)=0.024 mg product/L (0.018 - 0.033)<br>48-h NOEC=0.01 mg product/L<br>48-h LOEC=0.02 mg product/L |

| | |
|---|---|
| Reference: | **KCP 10.2.1/05** |
| Title: | Fluopyram + trifloxystrobin SC 500 (250 + 250 g/L): Acute toxicity to Daphnia magna in a semi-static 48-hour immobilisation test |
| Report: | Börschig, C.; Kobel, A.; 2018; 134621220; M-636231-01-1 |
| Authority registration No: | |
| Guideline(s): | - Commission Regulation (EC) No 440/2008, Annex, Part C, C.2: "Daphnia sp. Acute Immobilsisation Test", Official Journal of the European Union (EN), dated May 30, 2008<br>- EPA Guideline 712-C-16-013:OCSPP 850.1010, "Aquatic Invertebrate Acute Toxicity Test, Freshwater Daphnids" October 2016<br>- Japanese MAFF, Notification No. 12-Nousan-8147, JMAFF Test Guideline, 2-7-2-1, Daphnia acute immobilization studies, 2005<br>- OECD Guideline for Testing of Chemicals No. 202: "Daphnia sp., Acute Immobilisation Test" adopted Aprils 13, 2004<br>- SANCO/3029/99 rev.4 11/07/00: Residues: Guidance for generating and reporting methods of Analysis in Support of preregistration for Annex II (part A; Section 4) and Annex III (part A; Section 5) of directive 91/414 |
| Deviations: | None |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication (if vertebrate study): | |

**Materials and methods:**

| | |
|---|---|
| Test material | Fluopyram + Trifloxystrobin SC 500 (250 + 250 g/L); lot no.: 2015- 009127-01; content of a.s.: Fluopyram (AE C656948): 250 g/L (nominal), 248.7 g/L (analytical), Trifloxystrobin (CGA 279202): 250 g/L (nominal), 250.7 g/L (analytical), |
| Guideline(s) adaptation | none |
| Test species | *Daphnia magna*, clone 5<br>Origin: Ibacon laboratories in-house culture |
| Culturing conditions | The daphnids were bred in the laboratories of ibacon under similar temperature and light conditions as used in the test. The cultivation of the parental daphnids was performed in Elendt M4 medium. The test organisms were not first brood progeny. The daphnids in the stock culture were fed at least on all working days with green algae. |
| Organism age/size at study initiation | 1.5 to 18 hours old, females |
| Test solutions | Test units: 150mL glass beakers with lids<br>Test medium: Elendt M4 medium<br>Nominal concentrations: 0.16, 0.08, 0.04, 0.02 and 0.01 mg test item/L<br>All results based on nominal concentrations<br>Control: Elendt M4 medium<br>Solvent control: not required<br>There were no remarkable observations in the appearance of the test solutions |
| Replication | No. of vessels per concentration (replicates): 4<br>No. of vessels per control (replicates): 4 |
| Organisms per replicate | No. of organisms per vessel: 5 |
| Exposure | Semi-static conditions<br>Total exposure duration: 48 h |
| Feeding during test | None |
| Test conditions | Temperature during test: 20.4 to 21.0 °C<br>Photoperiod: 16 h light - 8 h dark<br>Light intensity: 780 to 840 lux<br>pH: 7.8 to 8.1<br>Water hardness: 2.5 mmol/L (= 250 mg/L) as $CaCO_3$ (nominal)<br>Conductivity: not determined<br>Dissolved oxygen: 8.7 to 9.2 mg/L respectively 99 to 104 % of air saturation<br>Aeration: none |
| Parameters Measured / Observations | The mobility of the daphnids was determined by visual observation after 24 and 48 hours. Those animals that are not able to swim within 15 seconds after gentle agitation of the test beaker were considered to be immobile (even if they could still move their antennae). The water temperature, pH-values and the dissolved oxygen concentrations were determined in all freshly prepared and aged test media of each treatment group. |
| Sampling for chemical analysis | Samples from the freshly prepared stock solution and from the freshly prepared test media of all test concentrations and the control were taken at the start of the test and at the test medium renewal on day 1. For the determination of the stability of the test item under the test conditions and of the maintenance of the test item concentrations during the test period, duplicate samples from the aged test media of all test concentrations and the control were collected after 24 hours of exposure and at the end of the test from a pooled sample of all beakers per treatment. All samples were diluted by a factor of 2with a diluent consisting of acetonitrile / water / formic acid 400/600/2 (v/v/v). Measurements were |

| | |
|---|---|
| | performed with LC-MS/ MS. |
| Data analysis | The 24-hour and 48-hour $EC_{50}$, $EC_{20}$ and $EC_{10}$ and the 95% confidence limits were calculated by probit analysis. The NOEC and LOEC after 24 and 48 hours were determined directly from the raw data. The software used to perform the statistical analysis was ToxRat Professional, Version 3.2.1. |

**Results and discussions:**

| **Validity criteria** | **Required according to OECD 202** | **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 | ≥ 8.7 mg |

Analytical results:

**Trifloxystrobin**

| **Sample description Nominal (mg test item/L)** | **% of nominal [1]** | | | |
|---|---|---|---|---|
| | **Day 0 – 0 h** | **Day 1 – 24 h** | **Day 1 – 0 h** | **Day 2 – 24 h** |
| Control | n.a. | n.a. | n.a. | n.a. |
| 0.01 | 96.5 | 83 | 86.5 | 81.5 |
| 0.02 | 92 | 79.5 | 84.5 | 78 |
| 0.04 | 97.5 | 90 | 87 | 80 |
| 0.08 | 96 | 87.5 | 87.5 | 79 |
| 0.16 | 97.5 | 85 | 91 | 80 |

[1] mean value of n=2 measured samples per treatment group per sampling timepoint, not given in report; n.a.: not applicable

**Fluopyram**

| **Sample description Nominal (mg test item/L)** | **% of nominal [1]** | | | |
|---|---|---|---|---|
| | **Day 0 – 0 h** | **Day 1 – 24 h** | **Day 1 – 0 h** | **Day 2 – 24 h** |
| Control | n.a. | n.a. | n.a. | n.a. |
| 0.01 | 103 | 96 | 95 | 94.5 |
| 0.02 | 102.5 | 95.5 | 97 | 92.5 |
| 0.04 | 102.5 | 101 | 101 | 99 |
| 0.08 | 104.5 | 101 | 99.5 | 96.5 |
| 0.16 | 102 | 103 | 98.5 | 97.5 |

[1] mean value of n=2 measured samples per treatment group per sampling timepoint, not given in report; n.a.: not applicable

The initial concentrations and the maintenance of the exposure concentrations during the test were verified in the analytical part. The analytical results proved a correct dosing at test start and constant exposure concentrations within the whole test duration. The accompanying chemical analysis resulted in test item concentrations within ± 20% of the nominal concentrations for both active ingredients. All reported results refer to nominal values as a correct dosing at test initiation was proven and as the toxicity has to be attributed to the test formulation as a whole.

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 0.01 mg test item/L. At the concentration of 0.02 mg test item/L one daphnid was immobile and 8 daphnids were immobile at the concentration of 0.04 mg test item/L. At the concentration of 0.08 mg test item/L 14 daphnids were immobile and at the highest test concentration 20 daphnids were immobile.

| **Nominal test concentrations (mg test item/L)** | **% of immobilized daphnids** | |
|---|---|---|
| | **24 h** | **48 h** |
| Control | 0 | 0 |
| 0.01 | 0 | 0 |
| 0.02 | 5 | 5 |
| 0.04 | 15 | 40 |
| 0.08 | 20 | 70 |
| 0.16 | 50 | 100 |
| $EC_{50}$ (mg test item/L)<br>95% C.I. (mg test item/L) | > 0.16<br>n.d. | 0.051<br>0.041-0.063 |
| NOEC (mg test item/L)<br>LOEC (mg test item/L) | 0.01<br>0.02 | 0.01<br>0.02 |

Values refer to nominal test concentrations
C.I.: Confidence Interval
n.d.: not determinable

**Conclusion:**

All validity criteria were met. The endpoints based on nominal concentrations are:

| **Parameter** | **Enpoints (mg test item/L)** |
|---|---|
| **48-hour $EC_{50}$** (95% C.I.) | 0.051<br>(0.041 - 0.063) |
| **48-hour $EC_{20}$** (95% C.I). | 0.031<br>(0.024 - 0.041) |
| **48-hour $EC_{10}$** (95% C.I.) | 0.024<br>(0.018 - 0.033) |
| **48-hour NOEC** | 0.01 |
| **48-hour LOEC** | 0.02 |

### A 2.2.1.3 Effects on aquatic algae

| | |
|---|---|
| Comments of zRMS: | The study is considered acceptable. All validity criteria were met.<br><br>**Agreed endpoints:**<br>72h $E_rC_{50}$ > 2.72 mg CGA 357261/L (geometric mean measured)<br>72h $E_bC_{50}$ > 2.72 mg CGA 357261/L (geometric mean measured)<br>72h $E_yC_{50}$ > 2.72 mg CGA 357261/L (geometric mean measured) |

| | |
|---|---|
| Reference: | **KCA 8.2.6.2/01** |
| Title: | Desmodesmus subspicatus growth inhibition test with AE1393224 (BCS-AR14200) |
| Report: | Kuhl, K.; 2018; EBTF0046; M-629680-01-1 |
| Authority registration No: | |
| Guideline(s): | OECD Guideline 201: “Freshwater Alga and Cyanobacteria, Growth Inhibition Test” (July 28, 2011), OCSPP Guideline 850.4500: “Algal Toxicity” (January 2012) |
| Deviations: | Yes (see report) |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication (if vertebrate study): | |

**Material and methods:**

| | |
|---|---|
| Test material | CGA 357261 (synonym AE 1393224)<br>Batch AE 1393224-PU-01<br>Specification: not reported<br>99.4 % w/w |
| Guideline(s) adaptation | OECD 201 recommends an initial cell number of 2 to 5 x $10^3$ cells/mL for *Desmodesmus subcapitatus*; whereas OCSPP 850.4500, requests not less than $10^4$ cells/mL. Since an initial cell number of 10,000 cells/mL result in an acceptable population density after 72 and 96 hours, it was decided to deviate from the OECD recommendation and adapt the initial cell number to the recommendation of OCSPP 850.4500. |
| Test species | Freshwater green algae *Desmodesmus subspicatus*<br>Strain SAG 86.81 ESP from the University of Gottingen (Germany) |
| Culturing conditions | The algae were cultured in the same medium and under similar conditions to those of the test.<br><br>400 µL of a 7-10 days old stock culture was transferred into a 300 mL cotton plugged Erlenmeyer flask containing about 100 mL of nutrient medium every 7-10 days. Stock cultures of algae were kept at 22 ± 2 °C with 24 hours light (4.50 – 7.00 klux). Culture vessels were placed on a shaker table at 100 rpm to prevent sedimentation of the cells. All operations were conducted under sterile conditions to handle an axenic (culture with one organism) algae culture. |
| Organism age/size at study initiation | The algal cells used for the test cultures were taken from a pre-culture which was initiated 3 days prior to the test under the same conditions as in the test. |

| | |
|---|---|
| Test solutions | Nominal concentrations: 0.188 - 0.375 - 0.750 - 1.50 - 3.00 mg p.m./L<br>Corresponding geometric mean measured concentrations at 72 h: 0.161 – 0.329 – 0.628 – 1.29 – 2.72 mg p.m./L<br>Corresponding geometric mean measured concentrations at 96 h: 0.156 – 0.319 – 0.609 – 1.25 – 2.62 mg p.m./L<br>Controls: water control<br>Solvent control: dimethylformamide (DMF) at 0.1 mL/L<br>Evidence of undissolved material: test medium was clear in all concentrations |
| Replication | No. of vessels per concentration (replicates): 4<br>No. of vessels per control (replicates): 4<br>No. of vessels per solvent control (replicates): 4 |
| Exposure | Static<br>Total exposure duration: 96 hours |
| Initial cells density | 1 x $10^4$ cells/mL in each replicate |
| Test conditions | Temperature: 23.9 - 24.4°C<br>Photoperiod: continuous light<br>Light intensity at surface of test vessels: 4730 - 4860 lux<br>pH of controls: 7.8 – 7.9<br>pH of test solutions: 7.8 – 8.0<br>Water hardness: not specified<br>Conductivity: not specified<br>Growth medium same as culture medium: Yes<br>Type of light: fluorescent lamps |
| Parameters Measured / Observations | Temperature was determined by a continuous measurement in one additional incubated glass vessel filled with the same amount of de-ionised water as in the test vessels.<br>The pH was measured at the start of the study and additionally after 72 and after 96 hours in all test levels and the control.<br>Cell numbers per volume were estimated photometrically after 24, 48, 72 and 96 hours of the exposure period.<br>Morphological examination of cells using a microscope were made after 0, 72 and 96 hours. |
| Sampling for chemical analysis | For the verification of the test item concentrations duplicate water samples of 10 mL (+ 2.25 mL acetonitrile) were taken from the bulk solution at test start and from the corresponding aged media (pooled replicates) after 72 and 96 hours of exposure from each test concentration and the control. |
| Data analysis | Using ToxRat software<br>$EC_x$ values were calculated using Probit method.<br>NOECs were determined by using Williams multiple sequential t-test procedure. |

**Results:**

| Validity criteria acc. to OECD TG 201 (adopted 2006) | Required | Obtained |
|---|---|---|
| 1) The biomass in the control cultures should have increased exponentially by a factor of at least 16 within the 72-hour test period. | 16 | 53.1 |
| 2) The mean coefficient of variation for section-by-section specific growth rates in the control cultures must not exceed 35%. | < 35% | 22.9 |
| 3) The coefficient of variation of average specific growth rates during the whole test period in replicate control cultures must not exceed 7%. | < 7% | 1.3 |

**Analytical results:**

Some recoveries were not within the range of 80 – 120% of nominal (see table below). Thus the biological results are based on geometric mean measured concentrations of CGA 357261 after either 72h or 96h.

| Nominal Concentration (mg p.m./L) | 0-hour % Nominal | 72-hour % Nominal | 96-hour % Nominal |
|---|---|---|---|
| control | <LOQ | <LOQ | <LOQ |
| Solvent control | <LOQ | <LOQ | <LOQ |
| 0.188 | 95 | 77 | 74 |
| 0.375 | 97 | 80 | 75 |
| 0.750 | 95 | 74 | 73 |
| 1.50 | 93 | 79 | 70 |
| 3.00 | 99 | 83 | 74 |

LOQ = Quantification limit (0.000626 mg p.m./L)

| Nominal Concentration (mg p.m./L) | Geometric mean measured concentrations (0-72h) (mg p.m./L) | Geometric mean measured concentrations (0-96h) (mg p.m./L) |
|---|---|---|
| 0.188 | 0.161 | 0.156 |
| 0.375 | 0.329 | 0.319 |
| 0.750 | 0.628 | 0.609 |
| 1.50 | 1.29 | 1.25 |
| 3.00 | 2.72 | 2.62 |

Concurrent validation:
For the determination of AE 1393224 the analytical method 01555 (Krebber R.;Leppelt L.; 2018; M-623236-01-1) was used and validated concurrently.

The linearity of MS detection was determined for AE 1393224 in the concentration range from 0.501 µg/L to 20.1 µg/L and was shown to be linear (y= 180731.2x + 11429.83). The correlation coefficient was 0.9990 (1/x weighted). 5 concentrations in duplicate were measured. If necessary, samples were diluted to achieve final concentrations falling within the calibrated range of detector response.

Because of the direct measurement of the samples recovery rates cannot be calculated. The evaluation of measurements based on HPLC-MS/MS for precision was done by comparison of the peak areas of the samples with the peak areas of the external standard solutions. For this purpose standard solutions of AE 1393224 in test water/acetonitrile (80/20, v/v) were used. The relative standard deviation of AE 1393224 peak areas and retention times are shown in the table below.

**Table 4.1.2- 2 Validation of Method 01555 for AE 1393224 by HPLC-MS/MS**

| AE 1393224 Standard concentration | | AE 1393224 | | | |
|---|---|---|---|---|---|
| | | Peak area | | Retention time | |
| [µg/L] | n | Mean value [area counts] | Rel. std. dev. [%] | Mean value [min]* | Rel. std. dev. [%] |
| 0.501 | 4 | 97064 | 5.2 | 2.89 | <0.1 |
| 1.00 | 4 | 192786 | 5.5 | 2.89 | <0.1 |
| 5.01 | 4 | 953269 | 3.7 | 2.89 | <0.1 |
| 10.0 | 4 | 1888726 | 2.3 | 2.89 | <0.1 |
| 20.1 | 4 | 3542056 | 1.6 | 2.89 | <0.1 |

* : different retention times due to different oven temperatures

Conclusion

The applicability of the HPLC-MS/MS method 01555 for the analysis of AE 1393224 in water samples was tested. The data presented demonstrate that the method allows the determination of AE 1393224 with satisfactory accuracy, precision and repeatability according to guideline SANCO/3029/99 with the minor exception of the precision data. Here only four instead of five determinations per fortification level were performed. However, this deviation can be regarded as acceptable due to the fact that three additional fortification levels were presented and that the overall relative standard deviation is with 5.5% far lower than the highest acceptable value of 20%. The method is suitable for the determination of AE 1393224 in test water and can be regarded as fit for purpose with regard to the study Kuhl, K.; 2018; M-629680-01-1.

Biological results:

No morphological change in algae was observed in the test concentrations. The test concentrations and controls showed clear test media.

Results at 72h

| **Nominal concentrations (mg p.m./L)** | **Geometric mean measured concentrations (mg p.m./L)** | **Cell number after 72 h (means)** | **(0-72h)-average specific growth rates [days$^{-1}$]** | **Inhibition of average specific growth rate (%) at 72 h** |
|---|---|---|---|---|
| Pooled control | -- | 518 000 | 1.315 | 0.0 |
| 0.188 | 0.161 | 506 000 | 1.308 | 0.5 |
| 0.375 | 0.329 | 468 000 | 1.281 | 2.6 |
| 0.750 | 0.628 | 510 000 | 1.310 | 0.4 |
| 1.50 | 1.29 | 445 000 | 1.264 | 3.9* |
| 3.00 | 2.72 | 339 000 | 1.174 | 10.8* |

* significantly ($\alpha$=0.05, one-sided smaller) reduced, based on Williams multiple sequential t-test procedure

Results at 96h

| **Nominal concentrations (mg p.m./L)** | **Geometric mean measured concentrations (mg p.m./L)** | **Cell number after 96 h (means)** | **(0-96h)-average specific growth rates [days$^{-1}$]** | **Inhibition of average specific growth rate (%) at 96 h** |
|---|---|---|---|---|
| Pooled control | -- | 1 160 000 | 1.188 | 0.0 |

| | | | | |
|---|---|---|---|---|
| 0.188 | 0.156 | 1 165 000 | 1.189 | -0.1 |
| 0.375 | 0.319 | 1 315 000 | 1.220 | -2.6 |
| 0.750 | 0.609 | 1 200 000 | 1.196 | -0.7 |
| 1.50 | 1.25 | 1 192 000 | 1.195 | -0.6 |
| 3.00 | 2.62 | 983 000 | 1.147 | 3.5* |

* significantly (α=0.05, one-sided smaller) reduced, based on Williams multiple sequential t-test procedure

Exponential growth in the control: yes

**Conclusion**

The study meets the validity criteria of both OECD and OCSPP guidelines. The endpoints based on geometric mean measured concentrations are:

| Results in mg p.m./L (95% CI) | Growth rate | Yield | Biomass (area under the curve) |
|---|---|---|---|
| 72 h | | | |
| $EC_{50}$ | > 2.72 (n.d.) | > 2.72 (n.d.) | > 2.72 (n.d.) |
| $EC_{20}$ | > 2.72 (n.d.) | 1.597 (1.231 – 1.915) | 1.531 (1.147 – 2.046) |
| $EC_{10}$ | > 2.72 (n.d.) | 0.938 (0.553 – 1.22) | 0.619 (0.324 – 0.872) |
| NOEC | 0.628 | 0.628 | 0.161 |
| 96 h | | | |
| $EC_{50}$ | > 2.62 (n.d.) | > 2.62 (n.d.) | > 2.62 (n.d.) |
| $EC_{20}$ | > 2.62 (n.d.) | > 2.62 (n.d.) | 2.270 (1.885 – 2.716) |
| $EC_{10}$ | > 2.62 (n.d.) | 2.024 (1.216 – 5.890) | 1.483 (0.893 – 1.808) |
| NOEC | 1.25 | 1.25 | 0.609 |

n.d.: not determined

| | |
|---|---|
| Comments of zRMS: | The study is considered acceptable. All validity criteria were met.<br><br>**Agreed endpoints:**<br>72h-$E_rC_{50}$ > 100 mg CGA 373466/L (nominal)<br>72h-$E_bC_{50}$ > 100 mg CGA 373466/L (nominal)<br>72h-$E_yC_{50}$ > 100 mg CGA 373466/L (nominal) |

| | |
|---|---|
| Reference: | **KCA 8.2.6.2/02** |
| Title: | Desmodesmus subspicatus growth inhibition test with AE 1344148 (BCS-AL58690) |
| Report: | Kuhl, K.; 2018; EBTF0047; M-628915-01-1 |
| Authority registration No: | |
| Guideline(s): | OECD Guideline 201: Freshwater Alga and Cyanobacteria, Growth Inhibition Test (July 28, 2011) , OCSPP Guideline 850.4500: Algal Toxicity (January 2012) |
| Deviations: | OECD 201 recommends an initial cell number of 2 to 5 x 103 cells/mL for Desmodesmus subcapitatus. OCSPP 850.4500 stated that no test should be started with less than 10,000 cells/mL. Since an initial cell number of 10,000 cells/mL result in an acceptable population density after 72 it was decided to deviate from the OECD recommendation and adapt the initial cell number to the recommendation of OCSPP 850.4500. Since all validity criteria were fulfilled, this deviation is not considered to impact the quality of the study. |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication<br>(if vertebrate study): | |

**Material and methods:**

| | |
|---|---|
| Test material | CGA 373466 (synonym AE 1344148)<br>Batch AE 1344148-PU-01<br>Specification: not reported<br>98.4 % w/w |
| Guideline(s) adaptation | OECD 201 recommends an initial cell number of 2 to 5 x $10^3$ cells/mL for *Desmodesmus subcapitatus*; whereas OCSPP 850.4500, requests not less than $10^4$ cells/mL. Since an initial cell number of 10,000 cells/mL result in an acceptable population density after 72 and 96 hours, it was decided to deviate from the OECD recommendation and adapt the initial cell number to the recommendation of OCSPP 850.4500. |
| Test species | Freshwater green algae *Desmodesmus subspicatus (Scenedesmus subspicatus)*<br>Strain SAG 86.81 ESP from the University of Gottingen (Germany) |
| Culturing conditions | The algae were cultured in the same medium and under similar conditions to those of the test.<br>400 µL of a 7-10 days old stock culture was transferred into a 300 mL cotton plugged Erlenmeyer flask containing about 100 mL of nutrient medium every 7-10 days. Stock cultures of algae were kept at 22 ± 2 °C with 24 hours light (4.50 – 7.00 klux). Culture vessels were placed on a shaker table at 100 rpm to prevent sedimentation of the cells. All operations were conducted under sterile conditions to handle an axenic (culture with one organism) algae culture. |
| Organism age/size at study initiation | The algal cells used for the test cultures were taken from a pre-culture which was initiated 96 hours prior to the test under the same conditions as in the test. |
| Test solutions | Nominal concentrations: 0.954-3.05-9.77-31.3-100 mg p.m./L<br>Controls: water control |

| | |
|---|---|
| | Evidence of undissolved material: test medium was clear in all concentrations |
| Replication | No. of vessels per concentration (replicates): 4<br>No. of vessels per control (replicates): 4 |
| Exposure | Static<br>Total exposure duration: 96 hours |
| Initial cells density | 1 x $10^4$ cells/mL in each replicate |
| Test conditions | Temperature: 22.6 – 23.0°C<br>Photoperiod: continuous light<br>Light intensity at surface of test vessels: 4610-4810 lux<br>pH of controls: 7.7-8.1<br>pH of test solutions: 7.5-8.2<br>Water hardness: not specified<br>Conductivity: not specified<br>Growth medium same as culture medium: Yes<br>Type of light: fluorescent lamps |
| Parameters Measured / Observations | Temperature was determined by a continuous measurement in one additional incubated glass vessel filled with the same amount of de-ionised water as in the test vessels.<br>The pH was measured at the start of the study and additionally after 72 and after 96 hours in all test levels and the control.<br>Cell numbers per volume were estimated photometrically after 24, 48, 72 and 96 hours of the exposure period.<br>Morphological examination of cells using a microscope were made after 0, 24, 48 72 and 96 hours. |
| Sampling for chemical analysis | For the verification of the test item concentrations duplicate water samples of 10 mL + 2.5 ml acetonitrile (ACN) were taken from the bulk solution at test start and from the corresponding aged media (pooled replicates) after 72 and 96 hours of exposure from each test concentration and the control. |
| Data analysis | Using ToxRat software<br>$EC_x$ values were calculated using Probit method.<br>NOECs were determined by using Williams multiple sequential t-test procedure. |

**Results:**

| Validity criteria acc. to OECD TG 201 (adopted 2006) | Required | Obtained |
|---|---|---|
| 1) The biomass in the control cultures should have increased exponentially by a factor of at least 16 within the 72-hour test period. | 16 | 19.1 |
| 2) The mean coefficient of variation for section-by-section specific growth rates in the control cultures must not exceed 35%. | < 35% | 31.7 |
| 3) The coefficient of variation of average specific growth rates during the whole test period in replicate control cultures must not exceed 7%. | < 7% | 2.2 |

**Analytical results:**

Recoveries were within the range of 80 – 120% of nominal (see table below). Thus the biological results are based on nominal concentrations of CGA 107170.

| Nominal Concentration (mg p.m./L) | 0-hour % Nominal | 72-hour % Nominal | 96-hour % Nominal |
|---|---|---|---|
| control | <LOQ | <LOQ | <LOQ |

| | | | |
|---|---|---|---|
| 0.954 | 112 | 113 | 114 |
| 3.05 | 113 | 113 | 110 |
| 9.77 | 109 | 110 | 111 |
| 31.3 | 108 | 109 | 108 |
| 100 | 107 | 110 | 109 |

LOQ = Quantification limit (0.000626 mg p.m./L)

Concurrent validation:
For the determination of AE 1344148 the analytical method 01555 (Krebber R.;Leppelt L.; 2018; M-623236-01-1) was used and validated concurrently.

The linearity of MS detection was determined for AE 1344148 in the concentration range from 0.501 µg/L to 20 µg/L and was shown to be linear (y= 31807.49x + 369.024). The correlation coefficient was 0.9999 (1/x weighted). 5 concentrations in duplicate were measured. If necessary, samples were diluted to achieve final concentrations falling within the calibrated range of detector response.

Because of the direct measurement of the samples recovery rates cannot be calculated. The evaluation of measurements based on HPLC-MS/MS for precision was done by comparison of the peak areas of the samples with the peak areas of the external standard solutions. For this purpose standard solutions of AE 1344148 in test water/acetonitrile (80/20, v/v) were used. The relative standard deviation of AE 1344148 peak areas and retention times are shown in the table below.

**Table 4.1.2- 2 Validation of Method 01555 for AE 1344148 by HPLC-MS/MS**

| AE 1344148 Standard concentration | | AE 1344148 | | | |
|---|---|---|---|---|---|
| | | Peak area | | Retention time | |
| [µg/L] | n | Mean value [area counts] | Rel. std. dev. [%] | Mean value [min]* | Rel. std. dev. [%] |
| 0.501 | 6 | 16152 | 1.7 | 2.79 | <0.1 |
| 1.00 | 4 | 32101 | 1.8 | 2.79 | <0.1 |
| 5.01 | 6 | 160374 | 0.6 | 2.79 | <0.1 |
| 10.0 | 6 | 322975 | 0.8 | 2.79 | <0.1 |
| 20.1 | 6 | 631531 | 1.2 | 2.79 | <0.1 |

* : different retention times due to different oven temperatures

Conclusion
The applicability of the HPLC-MS/MS method 01555 for the analysis of AE 1344148 in water samples was tested. The data presented demonstrate that the method allows the determination of AE 1344148 with satisfactory precision and repeatability according to guideline SANCO/3029/99. This method was used for analysis of AE 1344148 concentrations in specimens derived from an ecotoxicity study of Kuhl, K.; 2018; M-628915-01-1 can be regarded as fit for purpose.

Biological results:

No morphological change in algae was observed in the test concentrations. The test concentrations and control showed clear test media.

Results at 72h

| **Nominal concentrations** | **Cell number after 72 h (means)** | **(0-72h)-average specific growth** | **Inhibition of average specific growth rate (%)** |
|---|---|---|---|

| **(mg p.m./L)** | | **rates [days-1]** | **at 72 h** |
|---|---|---|---|
| control | 191000 | 0.983 | - |
| 0.954 | 201000 | 0.998 | -1.5 |
| 3.05 | 181000 | 0.964 | 1.9 |
| 9.77 | 170000 | 0.937 | 4.7 |
| 31.3 | 156000 | 0.915 | 6.9* |
| 100 | 129000 | 0.853 | 13.2* |

* significantly (α=0.05, one-sided smaller) reduced, based on Williams multiple sequential t-test procedure

Results at 96h

| **Nominal concentrations (mg p.m./L)** | **Cell number after 96 h (means)** | **(0-96h)-average specific growth rates [days-1]** | **Inhibition of average specific growth rate (%) at 96 h** |
|---|---|---|---|
| control | 632000 | 1.036 | - |
| 0.954 | 664000 | 1.048 | -1.2 |
| 3.05 | 599000 | 1.022 | 1.3 |
| 9.77 | 564000 | 1.003 | 3.1 |
| 31.3 | 473000 | 0.963 | 7.0* |
| 100 | 368000 | 0.901 | 13.0* |

* significantly (α=0.05, one-sided smaller) reduced, based on Williams multiple sequential t-test procedure

Exponential growth in the control: yes

**Conclusion**

The study meets the validity criteria of both OECD and OCSPP guidelines. The endpoints based on nominal measured concentrations are:

| Results in mg p.m./L (95% CI) | Growth rate | Yield | Biomass (area under the curve) |
|---|---|---|---|
| 72 h | | | |
| $EC_{50}$ | > 100 (n.d.) | > 100 (n.d.) | > 100 (n.d.) |
| $EC_{20}$ | > 100 (n.d.) | 23.9 (8.87-47.6) | 32.1 (12.7-95.2) |
| $EC_{10}$ | 51.6 (24.5-110) | 5.22 (0.44-12.4) | 3.99 (0.185-10.7) |
| NOEC | 9.77 | 9.77 | 3.05 |
| 96 h | | | |
| $EC_{50}$ | > 100 (n.d.) | > 100 (n.d.) | > 100 (n.d.) |
| $EC_{20}$ | > 100 (n.d.) | 18.0 (8.96-27.8) | 20.4 (9.61-33.8) |
| $EC_{10}$ | 57.8 (40.8-83.8) | 5.66 (1.53-10.8) | 5.17 (1.05-10.6) |
| NOEC | 9.77 | 9.77 | 9.77 |

n.d.: not determined

| | |
|---|---|
| Comments of zRMS: | The study is considered acceptable. All validty criteria were met.<br>**Agreed endpoints:**<br>72h-$E_rC_{50}$ = 13.9 mg CGA 107170/L (geometric mean measured)<br>72h-$E_yC_{50}$ = 11.2 mg CGA 107170/L (geometric mean measured)<br>72h-$E_bC_{50}$ = 10.9 mg CGA 107170/L (geometric mean measured) |

| | |
|---|---|
| Reference: | **KCA 8.2.6.2/03** |
| Title: | Amendment no. 1 to final report: Desmodesmus subspicatus growth inhibition test with AE 1344132 tech. (BCS-AB55122) |
| Report: | Kuhl, K.; 2018; E 201 05127 - 8; M-629159-02-1 |
| Authority registration No: | |
| Guideline(s): | OECD Guideline 201: Freshwater Alga and Cyanobacteria, Growth Inhibition Test (July 28, 2011) , OCSPP Guideline 850.4500: “Algal Toxicity” (January 2012) |
| Deviations: | According to OCSPP 850.4500 the measured test substance concentration at test initiation is considered appropriate to use for unstable test items. However, in this study the ECx calculations after 96 hours were performed using the mean measured values to follow the recommendations from OPPTS 850.1000. OECD 201 recommends an initial cell number of 2 to 5 x 103 cells/mL for Desmodesmus subcapitatus. OCSPP 850.4500 stated that no test should be started with less than 10,000 cells/mL. Since an initial cell number of 10,000 cells/mL result in an acceptable population density after 72 and 96 hours, it was decided to deviate from the OECD recommendation and adapt the initial cell number to the recommendation of OCSPP 850.4500. |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication<br>(if vertebrate study): | |

**Material and methods:**

| | |
|---|---|
| Test material | CGA 107170 (synonym AE 1344132)<br>Batch AE 1344132 00 1B98 0001<br>Specification: not reported<br>99.1 % w/w |
| Guideline(s) adaptation | OECD 201 recommends an initial cell number of 2 to 5 x $10^3$ cells/mL for *Desmodesmus subcapitatus*; whereas OCSPP 850.4500, requests not less than $10^4$ cells/mL. Since an initial cell number of 10,000 cells/mL result in an acceptable population density after 72 and 96 hours, it was decided to deviate from the OECD recommendation and adapt the initial cell number to the recommendation of OCSPP 850.4500. |
| Test species | Freshwater green algae *Desmodesmus subspicatus (Scenedesmus subspicatus)*<br>Strain SAG 86.81 ESP from the University of Gottingen (Germany) |
| Culturing conditions | The algae were cultured in the same medium and under similar conditions to those of the test.<br><br>400 µL of a 7-10 days old stock culture was transferred into a 300 mL cotton plugged Erlenmeyer flask containing about 100 mL of nutrient medium every 7-10 days. Stock cultures of algae were kept at 22 ± 2 °C with 24 hours light (4.50 – 7.00 klux). Culture vessels were placed on a shaker table at 100 rpm to prevent sedimentation of the cells. All operations were conducted under sterile conditions to handle an axenic (culture |

| | |
|---|---|
| | with one organism) algae culture. |
| Organism age/size at study initiation | The algal cells used for the test cultures were taken from a pre-culture which was initiated 96 hours prior to the test under the same conditions as in the test. |
| Test solutions | Nominal concentrations: 0.954 – 3.05 – 9.77 – 31.3 – 100 mg p.m./L<br>Corresponding geometric mean measured concentrations at 72 h: 0.833 – 2.52 – 7.50 – 26.5 – 87.2 mg p.m./L<br>Corresponding geometric mean measured concentrations at 96 h: 0.819 – 2.49 – 7.43 – 26.2 – 85.3 mg p.m./L<br>Controls: water control<br>Evidence of undissolved material: test medium was clear in all concentrations |
| Replication | No. of vessels per concentration (replicates): 4<br>No. of vessels per control (replicates): 4 |
| Exposure | Static<br>Total exposure duration: 96 hours |
| Initial cells density | 1 x $10^4$ cells/mL in each replicate |
| Test conditions | Temperature: 22.5 – 23.1°C<br>Photoperiod: continuous light<br>Light intensity at surface of test vessels: 4530 - 4920 lux<br>pH of controls: 7.5 – 7.9<br>pH of test solutions: 7.5 – 8.0<br>Water hardness: not specified<br>Conductivity: not specified<br>Growth medium same as culture medium: Yes<br>Type of light: fluorescent lamps |
| Parameters Measured / Observations | Temperature was determined by a continuous measurement in one additional incubated glass vessel filled with the same amount of de-ionised water as in the test vessels.<br>The pH was measured at the start of the study and additionally after 72 and after 96 hours in all test levels and the control.<br>Cell numbers per volume were estimated photometrically after 24, 48, 72 and 96 hours of the exposure period.<br>Morphological examination of cells using a microscope were made after 0, 24, 48 72 and 96 hours. |
| Sampling for chemical analysis | For the verification of the test item concentrations duplicate water samples of 5 mL (+ 1.25 mL acetonitrile + 1.8 µL formic acid to set the pH at 4-5) were taken from the bulk solution at test start and from the corresponding aged media (pooled replicates) after 24, 48, 72 and 96 hours of exposure from each test concentration and the control. |
| Data analysis | Using ToxRat software<br>$EC_x$ values were calculated using Weibull method.<br>NOECs were determined by using Step-down Jonckheere-Terpstra test procedure and Williams multiple sequential t-test procedure. |

**Results:**

| Validity criteria acc. to OECD TG 201 (adopted 2006) | Required | Obtained |
|---|---|---|
| 1) The biomass in the control cultures should have increased exponentially by a factor of at least 16 within the 72-hour test period. | 16 | 38.4 |
| 2) The mean coefficient of variation for section-by-section specific growth rates in the control cultures must not exceed 35%. | < 35% | 34.2 |
| 3) The coefficient of variation of average specific growth rates during the whole test period in replicate control cultures must not exceed 7%. | < 7% | 1.6 |

**Analytical results:**

Some recoveries were not within the range of 80 – 120% of nominal (see table below). Thus the biological results are based on geometric mean measured concentrations of CGA 107170 after either 72h or 96h.

| Nominal Concentration (mg p.m./L) | 0-hour % Nominal | 24-hour % Nominal | 48-hour % Nominal | 72-hour % Nominal | 96-hour % Nominal |
|---|---|---|---|---|---|
| control | <LOQ | <LOQ | <LOQ | <LOQ | <LOQ |
| 0.954 | 102 | 89 | 81 | 83 | 79 |
| 3.05 | 90 | 82 | 82 | 79 | 78 |
| 9.77 | 83 | 77 | 74 | 77 | 71 |
| 31.3 | 107 | 81 | 81 | 80 | 82 |
| 100 | 95 | 87 | 87 | 81 | 79 |

LOQ = Quantification limit (0.0626 mg p.m./L)

| Nominal Concentration (mg p.m./L) | Geometric mean measured concentrations (0-72h) (mg p.m./L) | Geometric mean measured concentrations (0-96h) (mg p.m./L) |
|---|---|---|
| 0.954 | 0.833 | 0.819 |
| 3.05 | 2.52 | 2.49 |
| 9.77 | 7.50 | 7.43 |
| 31.3 | 26.5 | 26.2 |
| 100 | 87.2 | 85.3 |

<u>Concurrent validation:</u>
For the determination of AE 1344132 the analytical method 01556 (Krebber R.;Leppelt L.; 2018; M-6233236-01-1) was used and validated concurrently.

The linearity of MS detection was determined for AE 1393224 in the concentration range from 0.0501 mg/L to 2.50 mg/L and was shown to be linear (y= 2295.01x + 18.6137). The correlation coefficient was 0.9980 (1/x weighted). 5 concentrations in triplicate were measured. If necessary, samples were diluted to achieve final concentrations falling within the calibrated range of detector response.

Because of the direct measurement of the samples recovery rates cannot be calculated. The evaluation of measurements based on HPLC-UV for precision was done by comparison of the peak areas of the samples with the peak areas of the external standard solutions. For this purpose standard solutions of AE 1344132 in test water/acetonitrile (80/20, v/v) were used. The relative standard deviation of AE 1344132 peak areas and retention times are shown in the table below.

**Table 4.1.2- 2 Validation of Method 01556 for AE 1344132 by HPLC-MS/MS**

| AE 1344132 Standard concentration | | AE 1344132 | | | |
|---|---|---|---|---|---|
| | | Peak area | | Retention time | |
| [mg/L] | n | Mean value [area counts] | Rel. std. dev. [%] | Mean value [min]* | Rel. std. dev. [%] |
| 0.0501 | 6 | 125 | 5.0 | 2.75 | 0.2 |
| 0.100 | 4 | 253 | 4.9 | 2.75 | 0.2 |
| 0.501 | 4 | 1248 | 3.7 | 2.75 | 0.2 |
| 1.00 | 6 | 2390 | 6.2 | 2.75 | 0.1 |
| 2.50 | 4 | 5570 | 3.7 | 2.75 | 0.2 |

* : different retention times due to different oven temperatures

Conclusion
The applicability of the HPLC-UV method 01556 for the analysis of AE 1344132 in water samples was tested. The data presented demonstrate that the method allows the determination of AE 1344132 with satisfactory precision and repeatability according to guideline SANCO/3029/99. This method was used for analysis of AE 1344132 concentrations in specimens derived from an ecotoxicity study of Kuhl, K.; 2018; M-629159-01-1.

Biological results:

No morphological change in algae was observed in the test concentrations. The test concentrations and control showed clear test media.

Results at 72h

| **Nominal concentrations (mg p.m./L)** | **Geometric mean measured concentrations (mg p.m./L)** | **Cell number after 72 h (means)** | **(0-72h)-average specific growth rates [days-1]** | **Inhibition of average specific growth rate (%) at 72 h** |
|---|---|---|---|---|
| control | control | 384000 | 1.216 | -- |
| 0.954 | 0.833 | 315000 | 1.149 | 5.5 |
| 3.05 | 2.52 | 361000 | 1.195 | 1.7 |
| 9.77 | 7.50 | 288000 | 1.120 | 7.9* |
| 31.3 | 26.5 | 7000 | -0.138 | 111* |
| 100 | 87.2 | 9000 | -0.054 | 104* |

* significantly (α=0.05, one-sided smaller) reduced, based on Step-down Jonckheere-Terpstra test procedure

Results at 96h

| **Nominal concentrations (mg p.m./L)** | **Geometric mean measured concentrations (mg p.m./L)** | **Cell number after 96 h (means)** | **(0-96h)-average specific growth rates [days-1]** | **Inhibition of average specific growth rate (%) at 96 h** |
|---|---|---|---|---|
| control | control | 1118700 | 1.194 | -- |
| 0.954 | 0.819 | 968000 | 1.143 | 4.3* |
| 3.05 | 2.49 | 1005000 | 1.152 | 3.5* |

| | | | | |
|---|---|---|---|---|
| 9.77 | 7.43 | 921000 | 1.131 | 5.3* |
| 31.3 | 26.2 | 14000 | 0.087 | 92.8 |
| 100 | 85.3 | 6000 | -0.142 | 112* |

* significantly (α=0.05, one-sided smaller) reduced, based on Williams multiple sequential t-test procedure

Exponential growth in the control: yes

**Conclusion**

The study meets the validity criteria of both OECD and OCSPP guidelines. The endpoints based on geometric mean measured concentrations are:

| Results in mg p.m./L (95% CI) | Growth rate | Yield | Biomass (area under the curve) |
|---|---|---|---|
| 72 h | | | |
| $EC_{50}$ | 13.9 (13.3-14.6) | 11.2 (10.4-12.2) | 10.9 (10.1-11.8) |
| $EC_{20}$ | 8.27 (7.75-8.77) | 6.22 (5.67-6.73) | 5.55(4.96-6.09) |
| $EC_{10}$ | 5.86 (5.39-6.31) | 4.22 (3.65-4.73) | 3.55 (3.02-4.05) |
| NOEC | 2.52 | < 0.833 | < 0.833 |
| 96 h | | | |
| $EC_{50}$ | 16.9 (14.8-18.6) | 11.4 (10.2-12.8) | 11.2 (10.3-12.2) |
| $EC_{20}$ | 11.6 (6.24-13.5) | 6.01 (5.08-6.85) | 5.91 (5.24-6.52) |
| $EC_{10}$ | 9.08 (6.73-11.01) | 3.94 (3.08-4.7) | 3.88 (3.25-4.45) |
| NOEC | < 0.819 | < 0.819 | < 0.819 |

| | |
|---|---|
| Comments of zRMS: | The study is considered acceptable. All validty criteria were met.<br>**Agreed endpoints:**<br>$E_rC_{50\ (72h)}$ = 29.0 mg p.m./$L_{mm}$<br>$NOE_rC_{(72h)}$ = 15.0 mg p.m./$L_{mm}$ |

| | |
|---|---|
| Reference: | **KCA 8.2.6.2/04** |
| Title: | Alga, groth inhibition test with trifloxystrobin-TFMAP |
| Report: | Spoo-Klöppel, M.; 2017; 2017/0043/04; M-602410-01-1 |
| Authority registration No: | |
| Guideline(s): | Commission Regulation (EC) No 761/2009 amending Regulation No 440/2008, Method C.3 ‘Freshwater Alga and Cyanobacteria, Growth inhibition test’ (2009) which is equivalent to OECD Guideline for Testing of Chemicals No. 201 (2006) |
| Deviations: | none |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication (if vertebrate study): | |

**Material and methods:**

| | |
|---|---|
| Test material | Trifloxystrobin -TFMAP (CGA 107170)<br>Batch EK2T000179 |

| | |
|---|---|
| | Specification: 102000022656<br>95.2 % w/w |
| Guideline(s) adaptation | none |
| Test species | Freshwater green algae *Desmodesmus subspicatus*<br>Strain SAG 86.81 SAG from the University of Göttingen (Germany) |
| Culturing conditions | The algal inocula for the test were taken from an exponentially growing pre culture and were mixed with the growth medium to make up to a final cell density of about 5000 cells per mL in the test medium (OECD medium) |
| Test solutions | Nominal concentrations: 6.3, 12.5, 25, 50 and 100 mg/L<br>Corresponding geometric mean measured concentrations at 72 h: 3.650, 7.339, 15.419, 29.710, 61.569 mg/L<br>Controls: water control<br>Evidence of undissolved material: undissolved particles of the test item were removed by filtration using a folded filter with a pore size of 7-12 µm |
| Replication | No. of vessels per concentration (replicates): 3<br>No. of vessels per control (replicates): 3 |
| Exposure | Static<br>Total exposure duration: 72 hours |
| Initial cells density | approx.. 5000 cells/mL in each replicate |
| Test conditions | Temperature: 21 – 24°C<br>Photoperiod: continuous light (spectral range 400 to 700 nm)<br>Light intensity: 4000 - 8000 lux<br>pH of controls: 7.9 – 9.2<br>pH of test solutions: 7.9 – 10.2<br>Water hardness: 1.3 °dH (22.5 mg/L $CaCO_3$)<br>Conductivity: not specified<br>Growth medium same as culture medium: No, the growth medium is from Bringmann1 Kuehn (1977), the test medium is OECD medium. Pre-culture was performed in the test medium<br>Type of light: not determined |
| Parameters Measured / Observations | Temperature was measured and recorded daily. The pH was measured at the beginning of the test and after 72 h of exposure. The light intensity was checked before the start of the test.<br>The cell densities were measured at 24 hour intervals. Inhibition of the algal population was measured as reduction in growth rate (index r), relative to control cultures grown under identical conditions. |
| Sampling for chemical analysis | The maintenance of the test item concentrations was proved by analytical measurements. In order to avoid an impairment of the test system, an additional replicate for each test item concentration was used for analysis at all measuring points (0, 24, 48 and 72 hours). |
| Data analysis | All calculations were carried out using ToxRat software<br>$EC_x$ values were calculated using probit analysis |

| | |
|---|---|
| | NOECs and LOECs were determined according to Welch-t test for inhomogeneous Variances with Bonferroni-Holm adjustment |

**Results:**

| Validity criteria acc. to OECD 201 (adopted 2006) | Required | Obtained |
|---|---|---|
| The biomass in the control cultures should have increased exponentially by a factor of at least 16 within the 72-hour test period. | 16 | 148 |
| The mean coefficient of variation for section-by-section specific growth rates in the control cultures must not exceed 35%. | < 35% | 20.9% |
| The coefficient of variation of average specific growth rates during the whole test period in replicate control cultures must not exceed 7%. | < 7% | 1.6 |

**Analytical results:**

The results are expressed in terms of geometric mean measured concentrations. Effective concentrations ranged from 80.9 % to 86.0 % of nominal values at 0 hours, from 66.1 % to 68.8 % of nominal values at 24 hours, from 52.0 % to 56.0 % of nominal values at 48 hours and from 38.9 % to 46.8 % of nominal values at 72 hours.

| Nominal Concentration (mg p.m./L) | 0-hour mg/L | 24-hour mg/L | 48-hour mg/L | 72-hour mg/L |
|---|---|---|---|---|
| control | --- | --- | --- | < 0.040 |
| 6.3 | 5.209 | 4.184 | 3.325 | 2.450 |
| 12.5 | 10.352 | 8.525 | 6.556 | 5.013 |
| 25 | 21.496 | 17.203 | 14.002 | 10.916 |
| 50 | 40.448 | 33.108 | 25.978 | 22.397 |
| 100 | 84.678 | 66.306 | 55.839 | 45.835 |
| 100 without algae | 85.794 | 66.102 | 53.527 | 46.754 |

Geometric mean [mg/L] : 3.650, 7.339, 15.419, 29.710, 61.569

The applicability of an HPLC-UV/VIS method for the analysis of CGA 10710 in test water was tested. The data presented in part B5 demonstrate that the method allows the determination of CGA 10710 with satisfactory accuracy, precision and repeatability according to guideline SANCO/3029/99. And can therefore be regarded as fit for purpose

<u>Biological results</u>:

Results at 72h

| **Nominal concentrations (mg p.m./L)** | **Geometric mean concentrations (mg p.m./L)** | **Cell number after 72 h (means)*** | **Inhibition of average specific growth rate (%) at 72 h** |
|---|---|---|---|
| control | control | 74.000 | -- |
| 6.3 | 3.650 | 93.333 | -4.7 |
| 12.5 | 7.339 | 86.667 | -3.2 |

| | | | |
|---|---|---|---|
| 25 | 15.419 | 74.333 | -0.1 |
| 50 | 29.710 | 4.000 | 58.8 |
| 100 | 61.569 | 1.333 | 81.5 |

* values of cell number were divided by a factor of 10000

Exponential growth in the control: yes

**Conclusion**

The study meets the validity criteria. The endpoints based on geometric mean measured concentrations are:

| | | |
|---|---|---|
| $E_rC_{50}$ (0-72 h) | 29 mg p.m./L | 95% C.I. 26 - 34 mg p.m./L |
| $E_rC_{10}$ (0-72 h) | 15 mg p.m./L | 95% C.I. 10 - 19 mg p.m./L |
| $NOE_rC$ | 15 mg p.m./L | |
| $LOE_rC$ | 30 mg p.m./L | |
| $E_yC_{50}$ (0-72 h) | 22 mg p.m./L | 95% C.I. 21 - 23 mg p.m./L |
| $E_yC_{10}$ (0-72 h) | 15 mg p.m./L | 95% C.I. 14 - 16 mg p.m./L |
| $NOE_yC$ | 15 mg p.m./L | |
| $LOE_yC$ | 30 mg p.m./L | |

| | |
|---|---|
| Comments of zRMS: | The study was not considered as acceptable in the previous Registration Report for Luna Sensattion, July 2018, zRMS-NL.<br>The (0 - 72h)-$E_rC_{50}$ for fluopyram & trifloxystrobin SC 500 (250 + 250) G is 0.292 mg formulation/L (95 % CI: 0.236 – 0.361 mg formulation/L) and the (0 - 72h)-$NOE_rC$ is < 0.0286 mg form./L.<br>However, the content of the active substance fluopyram in exposure solutions was measured for verification of the exposed test item concentrations but not also the content of the other active su.2.1bstance trifloxystrobin. . Therefore, as fluopyram does not degrade faster than trifloxystrobin and the toxicity for fish is higher for trifloxystrobin compared to fluopyram (see LoEPs above), the test is considered unacceptable and cannot be used for the risk assessment. |

| | |
|---|---|
| Reference: | **KCP 10.2.1/06** |
| Title: | Pseudokirchneriella subcapitata growth inhibition test with fluopyram & trifloxystrobin SC 500 (250 + 250)G |
| Report: | Dorgerloh, M.; 2007; EBGMP032; M-292579-01-1 |
| Authority registration No: | |
| Guideline(s): | OECD Guideline 201: Freshwater Alga and Cyanobacteria, Growth Inhibition Test (March 23, 2006); Equivalent to US EPA OPPTS Guideline No. 850.5400 SUPP |
| Deviations: | none |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication (if vertebrate study): | |

**Materials and methods:**

A. Materials

| | |
|---|---|
| 1. Test material: | AE C656948 + Trifloxystrobin SC 250+250 G |
| Specification No. | 102000012886 |
| Batch ID: | 2007-000441 |
| Visual appearance: | white fluid |
| Physical density: | 1.174 g/mL |
| Active substance 1: | AE C656948, fluopyram |
| Active ingredient 2: | CGA 279202, trifloxystrobin |
| Nominal content of active substance: | fluopyram: 250 g / L<br>trifloxystrobin: 250 g / L) |
| Analyzed content of active substance: | fluopyram: 21.4% (251.5 g / L)<br>trifloxystrobin: 21.6% (253.5 g / L) |
| Expiration date: | 2008-02-21 |
| 2. solvent carrier | No solvent |
| 3. Test organism | |
| Species | *Pseudokirchneriella subcapitata* formerly named *Selenastrum capricornutum*, strain SAG 61.81 |
| Age | In-house 4 day old batch culture in log phase growth |
| Source | Collection of Algal Cultures, Inst. for Plant Physiology, University of Göttingen, Nikolausberger Weg 18, 37077 Göttingen, Germany |
| Acclimation period | photoperiod during culture period: 16 hours light, temperature: 23 ± 2.0°C |
| Algal medium | Algae Media (Filter sterilized ,0.20 μm filter) |

B. Study design and methods

1. In life dates 2007-05-25 to 2007-06-20

2. Experimental treatments

The test vessels consisted of 300 mL sterile Erlenmeyer flasks, filled with 150 mL nutrient medium and an initial cell density of 1.0 x $10^4$ cells/mL (shaken cultures at 100 rpm on a rotating shaker table). Number of replicates: 3 per level (6 for the control), all held under test conditions at all levels including the control and exposed under static conditions for 72 hours. The test item was applied into the test medium on day 0.

The green algae *Pseudokirchneriella subcapitata* were exposed under static (shaken cultures) conditions for 72 hours. The definitive test concentrations were 0 (control), 0.0286, 0.0916, 0.293, 0.938, and 3.00 mg product/L (nominal). The toxicity values were calculated based on the nominal concentrations.

3. Observations

Endpoints and water quality

Each day, density was determined in the three test replicates at each test concentration using a microscope. Visual inspection on the cells was conducted daily via light microscope. Observation parameters were cell density, cumulative biomass and growth rate after 72-hours.

The water quality data were measured hourly (temperature) or at each observation time (pH).

Statistical method

ECx values (e.g. x = 50) and confidence intervals were calculated for the stated exposure period, using a commercial program (Statistical Software "ToxRat Professional", version 2.09,).

The LOEC determinations from the appropriate parameter (inhibition) were done, using the ANOVA procedure (p = 0.05, one sided) and properly selected multiple t-tests of a commercial program (Statistical Software "ToxRat Professional", version 2.09).

Analytical verification

Samples were analyzed (HPLC-UV) for the actual concentration of fluopyram present in the test medium at all treatment levels and the control on day 0 and day 3. At exposure termination, the contents of all replicate vessels were combined, and the pH was measured. The test solutions were then submitted for the day 3 analyses. The other active ingredient was not analyzed since it is present in the added formulation in a fixed ratio to the analyzed active ingredient.

**Results and discussions:**

A. Findings

Water chemistry and concentrations

| | |
|---|---|
| Temperature range | 21.1 to 22°C |
| Light intensity | 5620 to 7090 lux (mean 6230) |
| pH range | 7.8 to 9.1 |
| Nominal concentrations of fluopyram, day 0. (only fluopyram was analyzed) | Water control <0.5214; 6, 18.3, 59.3, 189 and 603 µg fluopyram/L |

Analytical Results on day 0 for fluopyram

| **Nominal Concentration in mg product/L (µg fluopyram/L)** | **Actual Concentration (µg fluopyram/L)** | | | |
|---|---|---|---|---|
| | **1. Determination** | **2. Determination** | **Average** | **%** |
| Control | < 0.5214 | < 0.5214 | < 0.5214 | -- |
| 0.0286 (6.12) | 5.97 | 6.03 | 6.00 | 98 |
| 0.0916 (19.6) | 18.9 | 17.7 | 18.3 | 93 |
| 0.293 (62.7) | 60.2 | 58.4 | 59.3 | 95 |
| 0.938 (201) | 191 | 187 | 189 | 94 |
| 3.00 (642) | 591 | 615 | 603 | 94 |
| | | | Mean | 94.8 |

The analytical findings of fluopyram in the treatment levels found on day 0 were 93 to 98% of nominal (average 94.8%). On day 3 analytical findings of 90 to 94% of nominal were found. Only in the lowest test concentration level 152% of nominal were found. This high analytical finding in the aged solution can be most likely explained by a handling error while taking samples, which did not influence the outcome of the study negatively. Given that the toxicity cannot be attributed to any one of the active substances alone but to the product as a whole, all results are based on nominal test concentrations of the product.

B. Observations

The static 72 hour algae growth inhibition test provided the following effects

| **Nominal Concentration [mg product/L]** | **Cell Number after 72 h (means) per mL*** | **(0-72h)-Average Specific Growth Rates [days$^{-1}$]** | **Inhibition of Average Specific Growth Rate [%]** | **Doubling Time of Algae Cells [days]** |
|---|---|---|---|---|
| control | 859 000 | 1.482 | -- | 0.468 |
| 0.0286 | 537 000 | 1.324 | 10.7 | 0.524 |
| 0.0916 | 240 000 | 1.059 | 28.5 | 0.655 |
| 0.293 | 107 000 | 0.782 | 47.2 | 0.886 |
| 0.938 | 30 000 | 0.363 | 75.5 | 1.91 |
| 3.00 | 17 000 | 0.167 | 88.7 | 4.15 |

* test initiation with 10,000 cells/mL

Test conditions met all validity criteria, given by the mentioned guideline. Biomass increased in the control by more than 16-fold within the evaluation period. The percent coefficient of variation of sectional growth rates from day 0-1, day 1-2, and day 2-3 in the control did not exceed 35%. The percent coefficient of variation of the average growth rate in each control replicate did not exceed 7%.

**Toxicity of AE C656948 + Trifloxystrobin SC 500 G to *Pseudokirchneriella subcapitata*:**

| | |
|---|---|
| Test item | AE C656948 + trifloxystrobin SC 500 G |
| Test object | *Pseudokirchneriella subcapitata* |
| Exposure | 72 h, static |
| 0-72 h $E_rC50$ growth rate | 0.292 mg product/L (95 % CI: 0.236 – 0.361 mg product/L) |
| Control Biomass Increase (minimum recommended multiplication factor is 16) (0-72 hour growth period) | A factor of approximately 23 (control) |
| Mean coefficient of variation for section-by-section specific growth rates (days 0-1, 1-2, 2-3) in the control (criterion is = 35%) (0-72 hour growth period) | 22.8% |
| Coefficient of variation for average specific growth rates during the 0 to 72 hour test period in replicate control cultures (criterion is = 7%) | 2.8% |

**Conclusion:**

The (0 - 72h)-$E_rC_{50}$ for Fluopyram + Trifloxystrobin SC 500 (250 + 250) G is 0.292 mg product/L (95% CI: 0.236 – 0.361 mg product/L) and the (0 - 72h)-$NOE_rC$ is < 0.0286 mg product/L.
The 72h-$E_bC_{50}$ for Fluopyram + Trifloxystrobin SC 500 (250 + 250) G is 0.050 mg product/L.

Comments of zRMS: The new study for formulation was submitted.

**Agreed endpoints:**

| **Endpoints (mg test item/L)** | **Growth rate** | **Yield** |
|---|---|---|
| **72-hour $EC_{50}$** (95% C.I.) | 4.252 (3.72 – 4.90) | 0.040 (0.038 – 0.041) |
| **72-hour $EC_{20}$** (95% C.I). | 0.048 (0.040 – 0.056) | 0.008 (0.007 – 0.008) |
| **72-hour $EC_{10}$** (95% C.I.) | 0.005 (0.003 – 0.006) | 0.003 (0.003 – 0.004) |
| **72-hour LOEC** | ≤ 0.00182 | ≤ 0.00182 |
| **72-hour NOEC** | < 0.00182 | < 0.00182 |
| **96-hour $EC_{50}$** (95% C.I.) | 1.99 (1.66 – 2.41) | 0.044 (0.043 – 0.045) |
| **96-hour LOEC** | ≤ 0.00182 | ≤ 0.00182 |
| **96-hour NOEC** | < 0.00182 | < 0.00182 |

**Final Conclusion after Commenting period:**

Since for trifloxystrobin the analytical measurements showed initial concentrations of 97 to 120% of nominal, but within the study duration the measured trifloxystrobin concentrations declined over the whole study with concentrations outside the 80%-120% of nominal AT ran the stats with the sum of the average concentration of the nominal concentration of the two active substances per duration (72h and 96h).

| | |
|---|---|
| | $E_rC_{50}$(72h) 1.838 (1.363-2.594) mg formulation/L<br>$E_rC_{50}$(72h) 0.674 (0.5-0.953) mg (sum average % active substaces/L |

| | |
|---|---|
| Reference: | **KCP 10.2.1/07** |
| Title: | Pseudokirchneriella subcapitata growth inhibition test with fluopyram + trifloxystrobin SC 500 G - Final report |
| Report: | Kuhl, K.; 2018; EBGM0016; M-615579-01-1 |
| Authority registration No: | |
| Guideline(s): | EU Directive 91/414/EEC<br>Regulation1107/2009 (Europe)<br>OECD Test Guideline 201<br>US EPA OCSPP 850.4500 |
| Deviations: | None |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication (if vertebrate study): | |

**Materials and methods:**

| | |
|---|---|
| Test material | Fluopyram + Trifloxystrobin SC 500 (250+250) G<br>Content a.s.: Fluopyram: 246.7 g/L (21.1% w/w)<br>Trifloxystrobin: 251.9 g/L (21.6% w/w)<br>Supplier batch ID : PAIS00524 |
| Guideline(s) adaptation | none |
| Test species | *Pseudokirchneriella subcapitata*, strain SAG 61.81<br>Origin: Collection of Algal Cultures, Inst. for Plant Physiology, University of Göttingen, Nikolausberger Weg 18, 37073 Göttingen, Germany |
| Culturing conditions | 400 µL of a 7-10 days old stock culture was transferred into a 300 mL cotton plugged Erlenmeyer flask containing about 100 mL of nutrient medium (Bringmann and Kühn, 1980) every 7-10 days. Stock cultures of algae were kept at 22 ± 2 °C with 24 hours light (4.50 – 7.00 klux). Test vessels were placed on a tablet rotating 100 rpm to prevent sedimentation of the cells. All operations were conducted under sterile conditions to handle an axenic algae culture. Pre-cultures were prepared from stock cultures 3 days before the start of the test using OECD medium. |
| Test solutions | Test units: 300 mL Erlenmeyer flasks sealed with cellulose plugs.<br>Test medium: OECD medium<br>Nominal concentrations: 0.00182, 0.00582, 0.0186, 0.0596, 0.191, 0.610, 1.95, 6.25 and 20.0 mg test item/L<br>Control: test medium<br>Solvent control: not required<br>The test solutions were clear and without any irregularities, except all replicates of treatment level 20.0 mg test item/L, which appeared turbid throughout the test. |
| Replication | No. of vessels per concentration (replicates): 4<br>No. of vessels per control (replicates): 4 |

| | |
|---|---|
| Initial cell density | 10000 cells/mL |
| Exposure | Static conditions<br>Total exposure duration: 72 hours with a prolongation to 96 hours in order to cover OCSPP guideline. |
| Test conditions | Temperature during test: 23.1 to 23.7°C,<br>Photoperiod: 24 hour light<br>Light intensity: 4.44 – 8.88 klux (± 15%)<br>pH: 8.1 – 9.9<br>Agitation: Test vessels were placed on rotating tablet at 100 rpm<br>Water hardness/Conductivity/Dissolved oxygen: not determined<br>Aeration: none |
| Parameters Measured / Observations | Morphological examination of cells using a microscope were made after 24, 48, 72 and 96 hours. Cell numbers per volume were estimated photometrically after 24, 48, 72 hours and 96 hours of the exposure period. Temperature was determined by a continuous measurement in one additional incubated glass vessel filled with the same amount of de-ionised water as in the test vessels. The pH was measured at the start of the study and additionally after 72 and after 96 hours in all test levels and the control. |
| Sampling for chemical analysis | For the verification of the test item concentrations water samples of 10 mL (+2.5 ml acetonitrile and pH 3 - 4 with formic acid, added for stabilisation) were taken from the bulk solution at test start and from the corresponding aged media (pooled replicates) after 72 and 96 hours of exposure from each test concentration and the control.<br>The measurements were performed with HPLC-MS/ MS. |
| Data analysis | $EC_x$ values and confidence intervals were calculated for the stated exposure period, using the commercial program ToxRat Professional. The NOEC/LOEC determinations were done, using the ANOVA procedure (p = 0.05, one sided) and properly selected multiple t-tests. All statistical evaluations were done using the commercial program ToxRat Professional. |

**Results and discussions:**

| **Validity criteria** | **Required according to OECD 201** | **Obtained** |
|---|---|---|
| Biomass in the control cultures should have increased exponentially by a factor of at least 16 within the 72 hour test period | ≥ 16 | 103.7 |
| Mean coefficient of variation for section-by-section specific growth rates (days 0-1, 1-2 and 2-3) in the control cultures should not exceed 35% | ≥ 35% | 31.6% |
| Coefficient of variation of average specific growth rates duringthe whole test period between the replicate control cultures should not exceed 7% | ≤ 7% | 0.3% |
| **Validity criteria** | **Required according to OCSPP 850.4500** | **Obtained** |
| The biomass in the control cultures should have increased exponentially by a factor of at least 100 within the 96-hour test period | ≥ 100 | 226.3 |
| The coefficient of variation for mean control yield at test termination should be ≤ 15 % | ≤ 15% | 1.9% |
| The coefficient of variation for average specific growth rates of controls at test termination should be ≤ 15 % | ≤ 15% | 0.3% |

Analytical results:

| **Sample description Nominal (mg test item/L)** | **Fluopyram (% of nominal concentration)** | | | **Trifloxystrobin (% of nominal concentration)** | | |
|---|---|---|---|---|---|---|
| | **0 h** | **72 h** | **96 h** | **0 h** | **72 h** | **96 h** |
| Control | -- | -- | -- | -- | -- | -- |
| 0.00182 | 108 | 101 | 109 | 116 | 122 | 45 |
| 0.00582 | 112 | 111 | 93 | 112 | 73 | 15 |
| 0.0186 | 112 | 97 | 112 | 109 | 62 | 37 |
| 0.0596 | 113 | 113 | 113 | 117 | 70 | 54 |
| 0.191 | 113 | 113 | 108 | 109 | 69 | 56 |
| 0.610 | 112 | 109 | 110 | 103 | 65 | 61 |
| 1.95 | 108 | 103 | 104 | 97 | 62 | 55 |
| 6.25 | 108 | 106 | 109 | 120 | 71 | 69 |
| 20.0 | 100 | 91 | 108 | 118 | 76 | 80 |

The analytical results showed a correct dosing at test start. Therefore, and since the toxicity has to be attributed to the tested formulation as a whole, all calculated results were related to the nominal concentration of the formulation.

Biological results:

Observations

No morphological change in algae was observed in any test concentration over the whole testing period. The test concentrations of 20.0 mg test item/L appeared turbid over the whole testing period. All other test concentrations and the control showed clear media.

| **Nominal test concentrations (mg test item/L)** | **mean growth rate (µ) [1/d] and % inhibition** | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **0 – 24 h** | | **0 – 48 h** | | **0 – 72 h** | | **0 – 96 h** | |
| | **µ** | **%** | **µ** | **%** | **µ** | **%** | **µ** | **%** |
| Control | 2.105 | 0.0 | 1.721 | 0.0 | 1.547 | 0.0 | 1.355 | 0.0 |
| 0.00182 | 2.084 | 1.0 | 1.697 | 1.4 | 1.527 | 1.3 [a] | 1.341 | 1.1[a] |
| 0.00582 | 2.051 | 2.5 | 1.672 | 2.8 [b] | 1.501 | 3.0 [a] | 1.337 | 1.4[a] |
| 0.0186 | 1.930 | 8.3 [a] | 1.595 | 7.3 [b] | 1.410 | 8.8 [a] | 1.267 | 6.6[a] |
| 0.0596 | 1.849 | 12.2 [a] | 1.389 | 19.3 [b] | 1.232 | 20.4 [a] | 1.135 | 16.3[a] |
| 0.191 | 1.691 | 19.7 [a] | 1.180 | 31.5 [b] | 1.012 | 34.6 [a] | 0.927 | 31.6[a] |
| 0.610 | 1.459 | 30.7 [a] | 0.931 | 45.9 [b] | 0.836 | 45.9 [a] | 0.737 | 45.6[a] |
| 1.95 | 1.479 | 29.7 [a] | 0.903 | 47.5 [b] | 0.722 | 53.3 [a] | 0.649 | 52.1[a] |
| 6.25 | 1.760 | 16.4 | 0.958 | 44.3 [b] | 0.731 | 52.7 [a] | 0.597 | 55.9[a] |
| 20.0 | 2.562 | 21.7 | 1.404 | 18.4 [b] | 0.818 | 47.1 [a] | 0.407 | 70.0[a] |

a significantly (α=0.05, one-sided smaller) reduced, based on multiple sequentially rejective Welsh-test after Bonferroni Holm.
b significantly (α=0.05, one-sided smaller) reduced, based on Williams multiple sequential t-test.

| **Nominal test concentrations (mg test item/L)** | **mean cell numbers [x $10^4$/mL]** | | | |
|---|---|---|---|---|
| | **0 – 24 h** | **0 – 48 h** | **0 – 72 h** | **0 – 96 h** |
| Control | 8.2 | 31.3 | 103.7 | 226.3 |
| 0.00182 | 8.0 | 29.8 | 97.6 | 213.6 |
| 0.00582 | 7.8 | 28.3 | 90.3 | 209.9 |
| 0.0186 | 6.9 | 24.3 | 68.9 | 158.7 |
| 0.0596 | 6.4 | 16.1 | 40.3 | 93.7 |
| 0.191 | 5.4 | 10.6 | 20.8 | 40.8 |
| 0.610 | 4.3 | 6.4 | 12.3 | 19.1 |
| 1.95 | 4.4 | 6.1 | 8.7 | 13.4 |
| 6.25 | 5.9 | 6.8 | 9.0 | 10.9 |
| 20.0 | 13.0 | 16.6 | 12.5 | 6.9 |

| **Nominal test concentrations (mg test item/L)** | **mean cell yield [x $10^4$/mL]** | | | |
|---|---|---|---|---|
| | **0 – 24 h** | **0 – 48 h** | **0 – 72 h** | **0 – 96 h** |
| Control | 7.2 | 30.3 | 102.7 | 225.3 |
| 0.00182 | 7.0 | 28.8 | 96.6 | 212.6 |
| 0.00582 | 6.8 | 27.3 | 89.3 | 208.9 |
| 0.0186 | 5.9 | 23.3 | 67.9 | 157.7 |
| 0.0596 | 5.4 | 15.1 | 39.3 | 92.7 |
| 0.191 | 4.4 | 9.6 | 19.8 | 39.8 |
| 0.610 | 3.3 | 5.4 | 11.3 | 18.1 |
| 1.95 | 3.4 | 5.1 | 7.7 | 12.4 |

| | | | | |
|---|---|---|---|---|
| 6.25 | 4.9 | 5.8 | 8.0 | 9.9 |
| 20.0 | 12.0 | 15.6 | 11.5 | 5.9 |

**Conclusion:**

All validity criteria according to OECD 201 (72 hours) and OCSPP 850.4500 (96 hours) were met. The endpoints based on nominal concentrations are expressed as mg test item/L.

| **Endpoints (mg test item/L)** | **Growth rate** | **Yield** |
|---|---|---|
| **72-hour $EC_{50}$** (95% C.I.) | 4.252 (3.72 – 4.90) | 0.040 (0.038 – 0.041) |
| **72-hour $EC_{20}$** (95% C.I). | 0.048 (0.040 – 0.056) | 0.008 (0.007 – 0.008) |
| **72-hour $EC_{10}$** (95% C.I.) | 0.005 (0.003 – 0.006) | 0.003 (0.003 – 0.004) |
| **72-hour LOEC** | ≤ 0.00182 | ≤ 0.00182 |
| **72-hour NOEC** | < 0.00182 | < 0.00182 |
| **96-hour $EC_{50}$** (95% C.I.) | 1.99 (1.66 – 2.41) | 0.044 (0.043 – 0.045) |
| **96-hour LOEC** | ≤ 0.00182 | ≤ 0.00182 |
| **96-hour NOEC** | < 0.00182 | < 0.00182 |

Comments of zRMS:

The study is considered as acceptable.

**Agreed endpoints:**

| **Parameter** | **Endpoints (mg test item/L)** | | |
|---|---|---|---|
| | **Growth rate** | **Yield** | **Biomass Integral** |
| **72-hour $EC_{50}$ (95% C.I.)** | 0.419 (0.405 – 0.433) | 0.0432 (0.0412 – 0.0453) | 0.0405 (0.0391 – 0.0420) |
| **72-hour $EC_{20}$ (95% C.I.)** | 0.0624 (0.0592 – 0.0657) | 0.0147 (0.0136 – 0.0159) | 0.0117 (0.0110 – 0.0124) |
| **72-hour $EC_{10}$ (95% C.I.)** | 0.0230 (0.0214 – 0.0248) | 0.0084 (0.0076 – 0.0093) | 0.0061 (0.0056 – 0.0066) |
| **72-hour NOEC** | 0.0089 | 0.0089 | < 0.0089 |
| **72-hour LOEC** | 0.0286 | 0.0286 | ≤ 0.0089 |
| **96-hour $EC_{50}$ (95% C.I.)** | 0.709 (0.686 – 0.734) | 0.0815 (0.0782 – 0.0849) | 0.0563 (0.0545 – 0.0583) |
| **96-hour $EC_{20}$ (95% C.I.)** | 0.128 (0.122 – 0.135) | 0.0320 (0.0300 – 0.0342) | 0.0188 (0.0178 - 0.0198) |
| **96-hour $EC_{10}$ (95% C.I.)** | 0.0525 (0.0488 – 0.0564) | 0.0197 (0.0181 – 0.0214) | 0.0106 (0.0099 – 0.0114) |
| **96-hour NOEC** | 0.0089 | 0.0089 | 0.0089 |
| **96-hour LOEC** | 0.0286 | 0.0286 | 0.0286 |

Final Conclusion after Commentong period:

AT performed a Probit analysis using the linear max. likelihood regression for ECx calculations, based on the nominal Formulation concentrations. Since for trifloxystrobin the analytical measurements showed initial concentrations of 97 to 120% of nominal, but within the study duration the measured trifloxystrobin concentrations declined over the whole study with concentrations outside the 80%-120% of nominal AT ran the stats with the sum of the average concentration of the nominal concentration of the two active substances per duration (72h and 96h).

$E_rC_{50}$(72h) 0.419 (0.375-0.470) mg formulation/L

$E_rC_{50}$(72h) 0.157 (0.141-0.176) mg (sum average % active substaces/L

| Reference: | **KCP 10.2.1/08** |
|---|---|
| Title: | Fluopyram + trifloxystrobin SC 500 (250 + 250 g/L): Toxicity to Pseudokirchneriella subcapitata in an algal growth inhibition test |
| Report: | Börschig, C.; Kobel, A.; 2018; 134621210; M-636234-01-1 |
| Authority registration No: | |
| Guideline(s): | -OECD Guidelines for the Testing of Chemicals, Section 2, No. 201: "Feshwater Alga and Cyanobacteria, Growth Inhibition Test", adopted March 23, 2006, corrected July 28, 2011<br>- Commission Regulation (EC) No 761/2009, Annex, Part C, C.3: "Feshwater Alga and Cyanobacteria, Growth Inhibition Test", Official Journal of the European Union (EN), dated August 24, 2009<br>- EPA Guideline 712-C-006: OCSPP 850.4500, "Algal Toxicity", January 2012<br>- Japanese MAFF, Gueidelines for preparation of Study Results, Algae growth Inhibition studies. Notification No. 12-Nousan-8147, JMAFF Test Guideline, 2-7-7, Algae growth Inhibition, 2005<br>- SANCO/3029/99 rev. 4 11/07/00: Residues: Guidance for generating and reporting methods of Analysis in Support of preregistation data requiremetns for Annex II (part A; Section 4) and Annex III (part A; Section 5) of directive 91/414 |
| Deviations: | None |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication (if vertebrate study): | |

**Materials and methods:**

| | |
|---|---|
| Test material | Fluopyram + Trifloxystrobin SC 500 (250 + 250 g/L); lot no.: 2015- 009127-01; content of a.s: Fluopyram (AE C656948): 250 g/L (nominal), 248.7 g/L (analytical), Trifloxystrobin (CGA 279202): 250 g/L (nominal), 250.7 g/L (analytical) |
| Guideline(s) adaptation | none |
| Test species | *Pseudokirchneriella subcapitata*, formerly known as *Selenastrum capricornutum*, and recently renamed as *Raphidocelis subcapitata*<br>Strain No. 61.81 SAG<br>Origin: Sammlung von Algenkulturen, Albrecht-von-Haller-Institut für Pflanzenwissenschaften, Universität Göttingen, Göttingen, Germany |
| Culturing conditions | The algae were cultivated under standardised conditions according to the test guidelines. |
| Test solutions | Test units: Erlenmeyer flasks of 200 mL volume with approximately 100 mL of test medium<br>Test medium: Reconstituted water (OECD medium)<br>Nominal concentrations: 3.00, 0.938, 0.293, 0.0916, 0.0286 and 0.0089 (spacing factor 3.2) mg test item/L<br>All results based on nominal concentrations<br>Control: reconstituted water<br>Solvent control: no solvent used hence no solvent control necessary<br>No remarkable observations in the test solutions. |
| Replication | No. of vessels per concentration (replicates): 4<br>No. of vessels per control (replicates): 6 |
| Organisms per | Initial cell density: 10000 cells/mL |

| | |
|---|---|
| replicate | |
| Exposure | Static conditions<br>Total exposure duration: 72 hours with a prolongation to 96 hours in order to cover OCSPP guideline. |
| Test conditions | Water temperature: 22.5 - 23.8°C<br>Photoperiod: Continuous illumination<br>Light intensity: 4550 to 5990 lux (mean: 5343 lux)<br>pH: 7.9 to 8.2 at test start, 8.1 to 9.7 at 72 hours and 7.9 to 10.0 at test end<br>Water hardness: 0.24 mmol/L (= 24.0 mg/L) as $CaCO_3$<br>Conductivity/Dissolved oxygen: not determined<br>Aeration: none |
| Parameters Measured / Observations | The cell density on each observation time was determined by spectrophotometric measurement. Therefore, defined volumes of the algal suspensions from all replicates and from the blanks were sampled after 24, 48, 72 and 96 hours of exposure, and were not replaced. |
| Sampling for chemical analysis | One sample from the freshly prepared stock solution was taken at test start. Duplicate samples from the freshly prepared test media (containing algae) of all test concentrations and from the control were taken at the start of the test. For the determination of the stability of the test item under the test conditions and of the maintenance of the test item concentrations during the test period, duplicate samples from the test media of all test concentrations and the control (containing algae) were taken after 24, 48 and 72 hours and at the end of the test (after the 96 hours test period) by pooling aliquots of the contents of the test beakers of each treatment. All samples were diluted by a factor of 2 with a diluent consisting of acetonitrile / water / formic acid 400/600/2 (v/v/v). The measurements were performed using liquid chromatography with MS/MS detection. |
| Data analysis | Based on the calculated cell densities, the 72 hours and 96 hours $E_rC_{50}$, $E_yC_{50}$ and the $E_bC_{50}$, the corresponding $EC_{20}$ and $EC_{10}$ values and where possible their 95%-confidence limits were calculated by Probit analysis. For the determination of the 72 and 96 hours LOEC and NOEC, the calculated growth rates and yields and biomass integral at each test concentration were tested for significant differences compared to the control values by Welch t-test after Bonferroni-Holm. The software used to perform the statistical analysis was ToxRat Professional, Version 3.2.1, ToxRat® Solutions GmbH. |

**Results and discussions:**

The study fulfilled all validity criteria of the current versions of OECD 201 and OCSPP 850.4500 guidelines.

| Validity criteria | Required according to OECD 201 | Obtained |
|---|---|---|
| The biomass in the control cultures should have increased exponentially by a factor of at least 16 within the 72-hour test period. | ≥ 16 | 183 |
| The mean coefficient of variation for section-by-section specific growth rates in the control cultures must not exceed 35%. | ≤ 35% | 22% |
| The coefficient of variation of average specific growth rates during the whole test period in replicate control cultures must not exceed 7%. | ≤ 7% | 1.6% |
| **Validity criteria** | **Required according** | **Obtained** |

| | **to OCSPP 850.4500** | |
|---|---|---|
| The biomass in the control cultures should have increased exponentially by a factor of at least 100 within the 96-hour test period | ≥ 100 | 335 |
| The coefficient of variation for mean control yield at test termination should be ≤ 15 % | ≤ 15% | 7.6% |
| The coefficient of variation for average specific growth rates of controls at test termination should be ≤ 15 % | ≤ 15% | 1.3% |

Analytical results:

**Trifloxystrobin**

| **Sample description Nominal (mg test item/L)** | **% of nominal [1]** | | | | |
|---|---|---|---|---|---|
| | **0 h** | **24 h** | **48 h** | **72 h** | **96 h** |
| Control | n.a. | n.a. | n.a. | n.a. | n.a. |
| 0.0089 | 111 | 91 | 74 | 27.5 | 2 |
| 0.0286 | 99 | 86.5 | 75.5 | 45.5 | 1 |
| 0.0916 | 97 | 87.5 | 76.5 | 65.5 | 34.5 |
| 0.293 | 96 | 89 | 77 | 68 | 62 |
| 0.938 | 93.5 | 82 | 75.5 | 66.5 | 65 |
| 3.00 | 90.5 | 83.5 | 79 | 70.5 | 69 |

[1] mean value of n=2 measured samples per treatment group per sampling timepoint, not given in report; n.a.: not applicable

**Fluopyram**

| **Sample description Nominal (mg test item/L)** | **% of nominal [1]** | | | | |
|---|---|---|---|---|---|
| | **0 h** | **24 h** | **48 h** | **72 h** | **96 h** |
| Control | n.a. | n.a. | n.a. | n.a. | n.a. |
| 0.0089 | 90.5 | 85 | 89.5 | 93.5 | 90 |
| 0.0286 | 90.5 | 87.5 | 90.5 | 90.5 | 88.5 |
| 0.0916 | 95.5 | 94 | 93.5 | 98.5 | 97.5 |
| 0.293 | 96 | 96.5 | 96.5 | 97.5 | 100 |
| 0.938 | 94.5 | 92.5 | 96 | 95.5 | 96 |
| 3.00 | 97 | 97.5 | 99 | 98 | 99.5 |

[1] mean value of n=2 measured samples per treatment group per sampling timepoint, not given in report; n.a.: not applicable

The analytical results proved a correct dosing at test start and constant exposure concentrations within the whole test duration. The accompanying chemical analysis resulted in test item concentrations within ± 20% of the nominal concentrations for fluopyram. For trifloxystrobin the accompanying chemical analysis revealed 98% of nominal at test start followed by a decrease of the trifloxystrobin concentrations over time. All reported results refer to nominal values as a correct dosing at test initiation was proven and as the toxicity has to be attributed to the test formulation as a whole.

Biological results:

**Mean Algal Cell Densities during the Test Period of 96 Hours**

| Nominal test concentrations (mg test item/L) | Mean density of algal cells (10000/mL) after | | | |
|---|---|---|---|---|
| | 24 h | 48 h | 72 h | 96 h |
| Control | 7.282 | 49.506 | 182.995 | 335.017 |
| 0.0089 | 6.428 | 37.233 | 170.804 | 340.179 |
| 0.0286 | 5.200 | 26.104 | 111.240 | 275.611 |
| 0.0916 | 4.025 | 13.646 | 52.628 | 155.291 |
| 0.293 | 3.491 | 6.005 | 14.388 | 39.822 |
| 0.938 | 3.117 | 3.791 | 6.406 | 12.244 |
| 3.00 | 2.957 | 3.182 | 3.368 | 4.798 |

At test start approx. 10000 algal cells/mL were incubated

**Mean Growth rate during the Test Period of 96 Hours**

| Nominal test concentrations (mg test item/L) | Mean growth rates µ (1/ day) after | | | |
|---|---|---|---|---|
| | 0 - 24 h | 0 - 48 h | 0 - 72 h | 0 - 96 h |
| Control | 1.981 | 1.950 | 1.735 | 1.435 |
| 0.0089 | 1.860 | 1.808 | 1.712 | 1.457 |
| 0.0286 | 1.648 | 1.630 | 1.570 | 1.405 |
| 0.0916 | 1.392 | 1.304 | 1.320 | 1.260 |
| 0.293 | 1.250 | 0.896 | 0.889 | 0.921 |
| 0.938 | 1.136 | 0.665 | 0.618 | 0.625 |
| 3.00 | 1.084 | 0.577 | 0.404 | 0.391 |

**Mean Yield during the Test Period of 96 Hours**

| Nominal test concentrations (mg test item/L) | Mean yield (10000 cells/mL) after | | | |
|---|---|---|---|---|
| | 24 h | 48 h | 72 h | 96 h |
| Control | 3.141 | 30.535 | 145.785 | 403.791 |
| 0.0089 | 2.714 | 23.544 | 126.562 | 381.054 |
| 0.0286 | 2.100 | 16.751 | 84.423 | 276.849 |
| 0.0916 | 1.513 | 9.348 | 41.485 | 144.445 |
| 0.293 | 1.246 | 4.994 | 14.190 | 40.295 |
| 0.938 | 0.794 | 2.983 | 7.082 | 15.407 |
| 3.00 | 1.432 | 3.956 | 6.231 | 9.314 |

**Conclusion:**

All validity criteria according to OECD 201 and OCSPP 850.4500 were met. The endpoints are based on nominal concentrations.

| **Parameter** | **Endpoints (mg test item/L)** | | |
|---|---|---|---|
| | **Growth rate** | **Yield** | **Biomass Integral** |
| **72-hour $EC_{50}$ (95% C.I.)** | 0.419 (0.405 – 0.433) | 0.0432 (0.0412 – 0.0453) | 0.0405 (0.0391 – 0.0420) |
| **72-hour $EC_{20}$ (95% C.I.)** | 0.0624 (0.0592 – 0.0657) | 0.0147 (0.0136 – 0.0159) | 0.0117 (0.0110 – 0.0124) |
| **72-hour $EC_{10}$ (95% C.I.)** | 0.0230 (0.0214 – 0.0248) | 0.0084 (0.0076 – 0.0093) | 0.0061 (0.0056 – 0.0066) |
| **72-hour NOEC** | 0.0089 | 0.0089 | < 0.0089 |
| **72-hour LOEC** | 0.0286 | 0.0286 | ≤ 0.0089 |
| **96-hour $EC_{50}$ (95% C.I.)** | 0.709 (0.686 – 0.734) | 0.0815 (0.0782 – 0.0849) | 0.0563 (0.0545 – 0.0583) |
| **96-hour $EC_{20}$ (95% C.I.)** | 0.128 (0.122 – 0.135) | 0.0320 (0.0300 – 0.0342) | 0.0188 (0.0178 - 0.0198) |
| **96-hour $EC_{10}$ (95% C.I.)** | 0.0525 (0.0488 – 0.0564) | 0.0197 (0.0181 – 0.0214) | 0.0106 (0.0099 – 0.0114) |
| **96-hour NOEC** | 0.0089 | 0.0089 | 0.0089 |
| **96-hour LOEC** | 0.0286 | 0.0286 | 0.0286 |

## 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: | The study is considered acceptable. All validity criteria were met.<br><br>**Agreed endpoint:**<br>NOEC = 9.92 mg p.m./$L_{nom}$ |

| | |
|---|---|
| Reference: | **KCA 8.2.5.2/01** |
| Title: | Metabolite of trifloxystrobin: BCS-AL58660: Influence to Daphnia magna in a semi-static reproduction test - 1st final report amendment |
| Report: | Börschig, C.; Emnet, P.; 2019; 140421221; M-670324-02-1 |
| Authority registration No: | |
| Guideline(s): | Commission Regulation (EC) No 440/2008, Annex, Part C, C.20.: "Daphnia magna Reproduction Test", Official Journal of the European Union (EN), dated May 30, 2008<br>EPA Guideline 712-C-16-005: OCSPP 850.1300, "Daphnid Chronic Toxicity Test", October 2016<br>EPA Guideline 712-C-16-014: OCSPP 850.1000, "Background and Special Considerations-Tests with Aquatic and Sediment-Dwelling Fauna and Aquatic Microcosms", October 2016<br>OECD Guideline for Testing of Chemicals, No. 211: "Daphnia magna Reproduction Test", adopted October 02, 2012<br>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: | |
| Duplication (if vertebrate study): | |

## Material and methods

| | |
|---|---|
| Test material | Name of substance BCS-AL58660, synonym: CGA 321113<br>lot/batch: BCOO6132-5-4<br>purity:99.2% |
| Guideline(s) adaptation | none |
| Test species | Waterflea: *Daphnia magna*<br>Clone 5 |
| Culturing conditions | The Daphnia were bred in the laboratory under similar temperature and light conditions as in the test. The cultivation of the parental Daphnia was performed in Elendt M4 medium. The test organisms were not first brood progeny. The Daphnia in the stock culture were fed at least all working days with green algae (*Desmodesmus subspicatus*). |
| Acclimation | Not necessary |
| Organism age/size at study initiation | 0.75 to 20.5 hours old at test start |
| Test solutions | Test medium: Elendt M4<br>Nominal concentrations: 0.254-0.635-1.59-3.97-9.92 mg pm/L<br>Controls: test medium<br>Evidence of undissolved material: no precipitation was observed in the test media |
| Replication | No. of vessels per concentration (replicates): 10<br>No. of vessels per control (replicates): 10 |
| Organisms per replicate | No. of organisms per vessel: 1 |
| Exposure | Test type: semi-static, 3 renewals per week<br>Total exposure duration : 21 d |
| Test Vessel Loading | 1 daphnia / 60 mL |
| Feeding during test | Daily with green algae (*Desmodesmus subspicatus*). The approximate daily amounts of algal TOC/Daphnia/day were as follows: |

| | |
|---|---|
| | Days 0-3: 0.1 mg<br>Days 4-7: 0.15 mg<br>Days 8-20: 0.2 mg |
| Test conditions | Temperature: 19.4- 21.2° C in fresh medium, 18.9 – 20.4°C in aged medium.<br>Constant measurement: 18.7 – 20.0°C<br>Photoperiod: 16h light, 8 h dark<br>Light intensity: 670 – 1020 lux<br>pH: 7.7 – 7.9 in fresh medium, 7.7 – 8.9 in aged medium<br>Water hardness: 178 – 223 mg $CaCO_3$/L<br>Dissolved oxygen: 8.6 – 9.3 mg/L in fresh medium (98-103% of saturation), 8.6 – 10.6 mg/L in aged medium (98-120% of saturation)<br>Conductivity: 570-681 µS/cm |
| Parameters Measured / Observations | The pH-values, dissolved oxygen concentrations and water temperatures were measured in the freshly prepared test media at test start and at each water renewal and in the corresponding aged test media at each water renewal and test end. The parameter in the freshly prepared test media were measured from the bulk for each treatment, while the parameter of the aged test media were measured in two randomly chosen replicates. The temperature was measured additionally continuously in a vessel with test water treated like test replicates.<br>Water hardness, conductivity and alkalinity were measured at test start and test end and once in between in the bulk of the freshly prepared media of the control and the highest test concentration and in one replicate of the aged media. |
| Sampling for chemical analysis | Duplicate samples from the freshly prepared test media of all test concentrations and the control were taken at the test start (day 0) and at the test medium renewal periods on day 7, 14, 19. Duplicate samples of the respective aged test media and controls were sampled at days 3, 10, 17, and at test end (day 21). The replicate beakers were not pooled, but instead were sampled individually. To reduce the number of samples produced the first water renewal was sampled from beaker replicates 1 and 2 (day 3), the second sampling from beaker replicates 3 and 4 (day 10), the third sampling from beaker replicates 5 and 6 (day 17), and the fourth sampling from beaker replicates 7 and 8 (day 21).<br>BCS-AL58660 was measured by LC-MS/MS. |
| Data analysis | ToxRat software, version 3.3.0 was used for statistical analysis.<br>$EC_x$ values cannot be calculated because of the very low level of effects.<br>NOEC were determined by different methods depending on normality, variance homogeneity and linear trend of the data. |

**Results and discussion**

| Validity criteria of OECD 211 | Required | Obtained |
|---|---|---|
| Immobility of adult daphnia in the control | ≤ 20% | 10% |
| Mean number of live offspring in the control after 21 days | ≥ 60 | 130 |

<u>Analytical results</u>:

The measured concentrations from the fresh and aged samples are all in the range of 80-120% of nominal concentrations. No residues of the test substance were found in the control.

**Measured concentration of BCS-AL58660 (% of nominal) – LOD = 0.04 µg test item /L**

| Nominal Concentration (mg p.m./L) | Day 0 Fresh | Day 3 Aged | Day 7 Fresh | Day 10 Aged | Day 14 Fresh | Day 17 Aged | Day 19 Fresh | Day 21 Aged |
|---|---|---|---|---|---|---|---|---|

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Control | Not applicable (< LOD) | Not applicable (< LOD) | Not applicable (< LOD) | Not applicable (< LOD) | Not applicable (< LOD) | Not applicable (< LOD) | Not applicable (< LOD) | Not applicable (< LOD) |
| 0.254 | 103 | 108 | 98 | 95 | 103 | 101 | 106 | 104 |
| 0.635 | 103 | 97 | 99 | 98 | 107 | 103 | 103 | 102 |
| 1.59 | 106 | 116 | 106 | 115 | 109 | 113 | 104 | 106 |
| 3.97 | 98 | 106 | 103 | 98 | 108 | 109 | 99 | 106 |
| 9.92 | 109 | 106 | 104 | 94 | 94 | 107 | 105 | 107 |

Biological results:

Immobility

At the control and the test item concentration of 0.254 and 3.97 mg pure metabolite/L, one Daphnia was immobile. In the test concentrations of 0.635, 1.59 and 9.92 mg pure metabolite/L all Daphnia were mobile until test end. The Cochran-Armitage trend test revealed no significant trend in immobility.

Observations

Apart from the reported mortality, only very few Daphnia were reported to be small or pale. No dead offspring was observed.

Growth

The results of the growth parameters are presented in the table below, with the % of inhibition compared to the control.

| **Parameter** | **Control** | **0.254 mg p.m./L** | **0.635 mg p.m./L** | **1.59 mg p.m./L** | **3.97 mg p.m./L** | **9.92 mg p.m./L** |
|---|---|---|---|---|---|---|
| Mean length* | 4.38 | 4.35 | 4.39 | 4.45 | 4.33 | 4.23 |
| % of inhibition | - | 0.7 | -0.3 | -1.5 | 1.0 | 3.3 |
| Mean weight** | 1.36 | 1.31 | 1.38 | 1.36 | 1.39 | 1.52 |
| % of inhibition | - | 3.3 | -1.3 | 0.1 | -2.4 | -11.7 |

*No significant difference from the control (tested with Dunnett´s t-test, α = 0.05, one-sided).

**No significant difference from the control (tested with Williams t-test, α = 0.05, one-sided).

Reproduction

The results of the reproduction parameters are presented in the table below, with the % of inhibition compared to the control.

| **Parameter** | **Control** | **0.254 mg p.m./L** | **0.635 mg p.m./L** | **1.59 mg p.m./L** | **3.97 mg p.m./L** | **9.92 mg p.m./L** |
|---|---|---|---|---|---|---|
| Mean number of offspring per introduced adult* | 122.9 | 122.0 | 132.8 | 119.6 | 112.8 | 131.4 |
| % of inhibition | - | 0.7 | -8.1 | 2.7 | 8.2 | -6.9 |
| Mean number of offspring per surviving adult** | 129.6 | 126.1 | 132.8 | 119.6 | 125.2 | 131.4 |
| % of inhibition | - | 2.7 | -2.5 | 7.7 | 3.3 | -1.4 |

| | | | | | | |
|---|---|---|---|---|---|---|
| Mean number of offspring per adult per reproduction day* | 9.1 | 9.0 | 10.3 | 9.3 | 8.4 | 10.2 |
| % of inhibition | - | 0.75 | -14.5 | -2.6 | 6.7 | -12.5 |
| Production rate of 1st brood*** | 7.4 | 6.8 | 9.0 | 8.4 | 5.4 | 8.4 |
| % of inhibition | - | 8.1 | -21.6 | -14.1 | 27.0 | -13.5 |

*No significant difference from the control (tested with Multiple sequentially-rejective U-test after Bonferroni-Holm, α = 0.05, one-sided).

**No significant difference from the control (tested with Dunnett´s t-test, α = 0.05, one-sided).

***No significant difference from the control (tested with Welch t-test, α = 0.05, one-sided).

**Conclusion**

The study meets the validity criteria. The endpoints based on nominal concentrations are as follows (in mg p.m./L):

| Parameter | Reproduction per introduced adult | Reproduction per surviving adult | Reproduction per reproduction day | Production rate of 1st brood | Immobility of adults | Length of adults | Weight of adults |
|---|---|---|---|---|---|---|---|
| $EC_{20}$ | > 9.92 | > 9.92 | > 9.92 | > 9.92 | > 9.92 | > 9.92 | > 9.92 |
| $EC_{10}$ | > 9.92 | > 9.92 | > 9.92 | > 9.92 | > 9.92 | > 9.92 | > 9.92 |
| NOEC | 9.92 | 9.92 | 9.92 | 9.92 | 9.92 | 9.92 | 9.92 |
| LOEC | > 9.92 | > 9.92 | > 9.92 | > 9.92 | > 9.92 | > 9.92 | > 9.92 |

| | |
|---|---|
| Comments of zRMS: | The study is considered acceptable. All validity criteria were met.<br>**Agreed endpoints:;**<br><br>**NOEC = 98.4 mg CGA 321113/kg sed.**<br>**$NOEC_{corr}$ ( log Pow>2) = 49.2 mg CGA 321113/kg sed.** |

| | |
|---|---|
| Reference: | **KCA 8.2.5.2/02** |
| Title: | A study on the chronic toxicity to the sediment dweller Lumbriculus variegatus - AE 1344138, technical |
| Report: | Egeler, P.; Witte, A.; 2018; 18P6LA; M-630580-01-2 |
| Authority registration No: | |
| Guideline(s): | OECD Guideline 225, "Sediment-water Lumbriculus toxicity test using spiked sediment", October 2007 |
| Deviations: | None |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication (if vertebrate study): | |

**Material and methods:**

| | |
|---|---|
| Test material | AE 1344138<br>Synonym: CGA 321113<br>batch: AE 1344138-01-02<br>Specifications: not reported<br>Purity: 98.4% |
| Guideline(s) adaptation | None |
| Test species | *Lumbriculus variegatus*<br>Lab in-house culture |
| Organism age/size at study initiation | Adult worms<br>10 days before the start of the test, the worms were artificially fragmented ("synchronisation"). This synchronisation was performed to avoid "uncontrolled" regeneration and subsequent high variation in test results.<br>After regenerating, intact complete worms of similar size, which were actively swimming or crawling upon a gentle mechanical stimulus, were used for the test. |
| Preparation of spiked sediment | The peat was mixed with deionised water.<br>The pH of this mixture was adjusted with CaCO3 and left for conditioning during 2 d.<br>The amount of sand provided by the test-item-plus-sand mixture was taken into account when preparing the sediment (i.e. the sediment was prepared with less sand).<br>The sediment was topped with overlying water and conditioned for seven days.<br>After conditioning, the overlying water was discarded.<br>The food source (*Urtica* & cellulose powder) was mixed with the sediment.<br>The test item was spiked into the formulated, conditioned sediment: Each of the application solutions of the different concentration levels was spiked onto a defined quantity of the sediment. The spiked sand was left for evaporation of the solvent and was then mixed into the quantity of formulated sediment necessary for all replicates of one concentration level to achieve the desired nominal concentration levels in mg/kg dry sediment.<br>After spiking, analytical samples were taken. Sediment dry weight and TOC were determined. Subsequently the spiked sediment was equilibrated with the overlying water under a light and temperature regimen comparable to the test conditions for 2 days. This period is considered to allow for distribution of the test item in the sediment-water system while minimising the risk of degradation of the test item. |
| Test concentrations | 0.984 – 3.11 – 9.84 – 31.1 – 98.4 mg p.m./kg dry sediment<br>Control: Artificial sediment and reconstituted water but without test item<br>Solvent control: sediment was spiked with acetone without test item |
| Replication: | No. of vessels per concentration (replicates): 4<br>No. of vessels per control (replicates): 4<br>No. of vessels per solvent control (replicates): 6<br>Additional test vessels were set up for analytical purposes only (analysis of test concentrations at start and at end of exposure). |
| Organisms per replicate | No. of organisms per vessel: 10 at test start |
| Exposure | Static test<br>Total exposure duration: 28 days<br>Overlying water: OECD 203 medium |
| Feeding during test | *Urtica* powder (0.37%) and cellulose powder (0.13%) added to the sediment during sediment preparation. No further feeding during exposure. |
| Test conditions | Temperature: 19.2 – 20.3°C (manual measurements in test vessels), 18.9 – 20.6°C (automatic measurement in separate vessel) |

| | |
|---|---|
| | Photoperiod: 16h light, 8h dark<br>Light intensity: 326 – 368 lux<br>pH of overlying water: 7.6 – 8.3<br>Water hardness: 261 – 307 mg $CaCO_3$/L<br>Dissolved oxygen: ≥ 79% saturation<br>Ammonium content: < 0.099– 10.4 mg/L<br>Sediment amount: 74 g wet sediment<br>Overlying water volume: approx. 165 mL<br>Depth of sediment and overlying water: 1.5 cm approx.<br>Sediment water ratio approx. 1:3.5<br>Aeration: Gentle aeration during equilibration and exposure<br>Replacement of evaporated test water: yes |
| Sediment | Artificial sediment formulated according to the OECD guideline<br>% sand: 75-76%<br>% clay: 20% (kaolinite)<br>% peat: 5% of sediment dry weight<br>pH whole sediment: 6.2<br>Total organic carbon (%): 2.11% |
| Parameters Measured / Observations | The total number of worms per replicate (as a surrogate for reproduction) and the total dry weight of the worms per replicate were assessed at the end of the test. In order to estimate mortalities at 28 d, the numbers of worms that did not react to a gentle stimulus or showed signs of decomposition were considered to be dead. |
| Sampling for chemical analysis | Samples of sediment and overlaying water were taken on day 0 of exposure and at the end of the test from separate test vessels |
| Data analysis | With ToxRat version 2.10.<br>Statistically significant differences were observed between control and solvent control so the comparison of effects was performed against solvent control.<br>Probit analysis and Dunnett's tests were applied. |

**Results:**

| **Validity criteria** | **Required** | **Obtained** |
|---|---|---|
| Average increase factor of the number of living worms in the control replicates at the end of exposure: | 1.8 | 2.73 in control, 1.93 in solvent control |
| pH of overlying water | 6-9 | 7.6 – 8.3 |
| Dissolved oxygen concentration | ≥ 30% saturation | ≥ 79% saturation |

In 2 out of 6 replicates of the solvent control the replicate increase factor was slightly below the required minimum of 1.8 (1.6 and 1.7). Since the validity criterion is based on the average increase factor which is 19.3, and since the inter-replicate variability of worm numbers in the solvent control was within the ranges reported in Annex 6 of the test guideline, this study is considered valid

Analytical results:

The test substance was measured in sediment and overlying water on day 0 of exposure (i.e. day 2 after spiking). Distribution from sediment to overlying is observed, increasing with time. However, the mass balance (i.e. recovery in the whole system) shows that the substance is stable: recoveries in the range 80-120% of nominal. Therefore results will be expressed as nominal concentrations.

| **Nominal concentrations** | **Measured concentration in sediment** | **Measured concentration in overlying water** | **Recovery in whole system** | **Measured concentration in sediment** | **Measured concentration in overlying water** | **Recovery in whole system** |
|---|---|---|---|---|---|---|
| **mg p.m./kg dry sed.** | **mg p.m./kg dry sed.** | **µg p.m./L** | **% of nominal** | **mg p.m./kg dry sed.** | **µg p.m./L** | **% of nominal** |
| | **Day 0** | | | **Day 28** | | |
| Control | n.d. | n.d. | n.a. | n.d. | n.d. | n.a. |
| Solvent control | n.d. | n.d. | n.a. | n.d. | n.d. | n.a. |
| 0.984 | 0.733 | 78.5 | 96 | 0.366 | 164 | 88 |
| 3.11 | 2.30 | 217 | 93 | 1.12 | 532 | 87 |
| 9.84 | 6.96 | 884 | 97 | 3.08 | 1699 | 84 |
| 31.1 | 19.31 | 2641 | 86 | 9.40 | 5538 | 85 |
| 98.4 | 63.9 | 8565 | 90 | 27.0 | 20237 | 91 |

n.d. not detected (<0.03 mg/kg dry sediment or <1.5 µg/L for overlying water)
n.a. not applicable

Analytical findings
The applicability of an HPLC-MS/MS method for the analysis of AE 1344138 in water and sediment specimens was tested. The data presented in part B5 demonstrate that the method allows the determination of AE 1344138 with satisfactory accuracy, precision and repeatability according to guideline SANCO/3029/99. This method was used for analysis of AE 1344138 concentrations in specimens derived from an ecotoxicity study of Egeler, P.; Witte, A.; 2018; M-630580-01-1.

Biological results:

Survival

After 28 days of exposure, no mortality was observed up to the highest concentration level. In all replicates 10 or more worms were found. Therefore, the parameter survival was not affected up to the highest test item concentration level and no statistical evaluation was performed on worm survival.

Reproduction
The mean number of worms per replicate was higher in all test concentrations than in the solvent control.

| **Nominal concentrations (mg p.m./kg dry sed.)** | Mean number of worms per replicate | % of inhibition in comparison to solvent control |
|---|---|---|
| Control | 27.3 | -41.5 |
| Solvent control | 19.3 | - |
| 0.984 | 23.0 | -19.2 |
| 3.11 | 22.3 | -15.5 |
| 9.84 | 23.3 | -20.7 |
| 31.1 | 28.5 | -47.7 |
| 98.4 | 21.3 | -10.4 |

Biomass
No statistically significant effect on dry weight was observed between the test concentrations and the solvent control.

| **Nominal concentrations (mg p.m./kg dry sed.)** | Mean dry weight per replicate (mg) | % of inhibition in comparison to solvent control |
|---|---|---|

| | | |
|---|---|---|
| Control | 37.2 | 1.33 |
| Solvent control | 37.7 | - |
| 0.984 | 37.5 | 0.80 |
| 3.11 | 41.2 | -9.28 |
| 9.84 | 33.7 | 10.6 |
| 31.1 | 35.0 | 7.16 |
| 98.4 | 35.5 | 5.84 |

Observations
All worms were burrowed in the sediment as observed one hour after start of exposure. During the regular inspections (at least three times per week), concentration-dependent sediment avoidance or production of fecal pellets could not be observed in any of the treatments, which indicated similar feeding behaviour throughout these treatments. No worms were observed on the sediment surface.

<u>Conclusion</u>

The endpoints based on nominal concentrations are:

| **Parameter** | **NOEC (mg p.m./kg dry sediment)** |
|---|---|
| Survival | 98.4* |
| Reproduction | 98.4* |
| Dry weight | 98.4* |

*highest concentration tested

| | |
|---|---|
| Comments of zRMS: | The study is considered valid.<br>**Agreed endpoint:**<br><br>NOEC = 0.00259 mg p.m./$L_{mm}$ |

| | |
|---|---|
| Reference: | **KCA 8.2.5.2/03** |
| Title: | Metabolite of trifloxystrobin: BCS-AB39835 - Influence to Daphnia magna in a semi-static reproduction test - 1st final report amendment |
| Report: | Börschig, C.; Emnet, P.; 2019; 140431221; M-670321-02-1 |
| Authority registration No: | |
| Guideline(s): | Commission Regulation (EC) No 440/2008, Annex, Part C, C.20.: "Daphnia magna Reproduction Test", Official Journal of the European Union (EN), dated May 30, 2008<br>EPA Guideline 712-C-16-005: OCSPP 850.1300, "Daphnid Chronic Toxicity Test", October 2016<br>EPA Guideline 712-C-16-014: OCSPP 850.1000, "Background and Special Considerations-Tests with Aquatic and Sediment-Dwelling Fauna and Aquatic Microcosms", October 2016<br>OECD Guideline for Testing of Chemicals, No. 211: "Daphnia magna Reproduction Test", adopted October 02, 2012<br>OECD Series on Testing and Assessment, No. 23, "Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures", December 15, 2000<br>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: | |
| Duplication (if vertebrate study): | |

### Material and methods

| | |
|---|---|
| Test material | Name of substance BCS-AB39835, synonym: CGA 357276<br>lot/batch: BCOO 6204-3-3<br>purity:97.8% |
| Guideline(s) adaptation | none |
| Test species | Waterflea: *Daphnia magna*<br>Clone 5 |
| Culturing conditions | The Daphnia were bred in the laboratory under similar temperature and light conditions as in the test. The cultivation of the parental Daphnia was performed in Elendt M4 medium. The test organisms were not first brood progeny. The Daphnia in the stock culture were fed at least all working days with green algae (*Desmodesmus subspicatus*). |
| Acclimation | Not necessary |
| Organism age/size at study initiation | 2 to 20 hours old at test start |
| Test solutions | Test medium: Elendt M4<br>Nominal concentrations: 0.0013, 0.004, 0.012, 0.036, 0.108 mg test item/L<br>Time weighted average concentration : 0.000814, 0.00259, 0.00772, 0.0244, 0.0746 mg pm/L |

| | |
|---|---|
| | Controls: test medium<br>Solvent control: dimethylformamide (DMF), 100 µL/L<br>Evidence of undissolved material: no precipitation was observed in the test media |
| Replication | No. of vessels per concentration (replicates): 10<br>No. of vessels per control (replicates): 10<br>No. of vessels per solvent control (replicates): 10 |
| Organisms per replicate | No. of organisms per vessel: 1 |
| Exposure | Test type: semi-static, 3 renewals per week<br>Total exposure duration : 21 d |
| Test Vessel Loading | 1 daphnia / 60 mL |
| Feeding during test | Daily with green algae (*Desmodesmus subspicatus*). The approximate daily amounts of algal TOC/Daphnia/day were as follows:<br>Days 0-3: 0.1 mg<br>Days 4-7: 0.15 mg<br>Days 8-20: 0.2 mg |
| Test conditions | Temperature: 19.4- 20.5° C in fresh medium, 19.5 – 20.7°C in aged medium.<br>Constant measurement: 20.2 – 21.5°C<br>Photoperiod: 16h light, 8 h dark<br>Light intensity: 600 – 900 lux<br>pH: 7.6 – 7.9 in fresh medium, 7.8 – 8.8 in aged medium<br>Water hardness: 196 – 223 mg $CaCO_3$/L<br>Dissolved oxygen: 8.5 – 9.1 mg/L in fresh medium (97-101% of saturation), 8.6 – 10.8 mg/L in aged medium (98-125% of saturation)<br>Conductivity: 550-610 µS/cm |
| Parameters Measured / Observations | The pH-values, dissolved oxygen concentrations and water temperatures were measured in the freshly prepared test media at test start and at each water renewal and in the corresponding aged test media at each water renewal and test end. The parameter in the freshly prepared test media were measured from the bulk for each treatment, while the parameter of the aged test media were measured in two randomly chosen replicates. The temperature was measured additionally continuously.<br>Water hardness, conductivity and alkalinity were measured at test start and test end and once in between in the bulk of the freshly prepared media and in two replicates of the aged media of the controls and the highest test concentration. The light intensity was measured at test start and then once a week (Day 7 and Day 14). |
| Sampling for chemical analysis | Duplicate samples from the freshly prepared test media of all test concentrations and the control were taken at the test start (day 0) and at the test medium renewal periods on day 7, 14, 19. Duplicate samples of the respective aged test media and controls were sampled at days 3, 10, 17, and at test end (day 21). The replicate beakers were not pooled, but instead were sampled individually. To reduce the number of samples produced the first water renewal was sampled from beaker replicates 1 and 2 (day 3), the second sampling from beaker replicates 3 and 4 (day 10), the third sampling from beaker replicates 5 and 6 (day 17), and the fourth sampling from beaker replicates 7 and 8 (day 21).<br>BCS- AB39835 was measured by LC-MS/MS. |
| Data analysis | ToxRat software, version 3.3.0 was used for statistical analysis.<br>$EC_x$ values were calculated by Probit analysis.<br>NOEC were determined by different methods depending on normality, variance homogeneity and linear trend of the data. |

**Results and discussion**

| Validity criteria of OECD 211 | Required | Obtained |
|---|---|---|
| Immobility of adult daphnia in the control | ≤ 20% | 0% |
| Mean number of live offspring in the control after 21 days | ≥ 60 | 138 in both the water and solvent controls |

Analytical results:

The measured concentrations from the fresh and aged samples are not in the range of 80-120% of nominal concentrations, therefore time weighted average concentrations were calculated.
No residues of the test substance were found in the control.

**Measured concentration of BCS- AB39835 (% of nominal) – LOQ = 0.4 µg test item /L**

| Nominal Concentration (mg test item/L) | Day 0 Fresh | Day 3 Aged | Day 7 Fresh | Day 10 Aged | Day 14 Fresh | Day 17 Aged | Day 19 Fresh | Day 21 Aged |
|---|---|---|---|---|---|---|---|---|
| Control | Not applicable (< LOQ) | Not applicable (< LOQ) | Not applicable (< LOQ) | Not applicable (< LOQ) | Not applicable (< LOQ) | Not applicable (< LOQ) | Not applicable (< LOQ) | Not applicable (< LOQ) |
| Solvent control | Not applicable (< LOQ) | Not applicable (< LOQ) | Not applicable (< LOQ) | Not applicable (< LOQ) | Not applicable (< LOQ) | Not applicable (< LOQ) | Not applicable (< LOQ) | Not applicable (< LOQ) |
| 0.0013 | 83 | 56 | 69 | 56 | 78 | 44 | 87 | 49 |
| 0.004 | 85 | 62 | 87 | 58 | 74 | 42 | 78 | 49 |
| 0.012 | 82 | 59 | 80 | 52 | 84 | 42 | 87 | 52 |
| 0.036 | 83 | 60 | 88 | 58 | 79 | 55 | 75 | 58 |
| 0.108 | 85 | 65 | 86 | 57 | 84 | 47 | 88 | 64 |

Time weighted average concentrations:

| Nominal Concentration (mg test item/L) | Time weighted average concentrations (mg p.m./L) | % of nominal |
|---|---|---|
| 0.0013 | 0.000814 | 63 |
| 0.004 | 0.00259 | 65 |
| 0.012 | 0.00772 | 64 |
| 0.036 | 0.0244 | 68 |
| 0.108 | 0.0746 | 69 |

Biological results:

Immobility

No immobilisation was observed in the controls and all test item concentrations except at 0.00772 mg p.m./L, where 1 Daphnia was immobile. The Cochran-Armitage trend test revealed no significant trend in immobility.

Observations

Apart from the reported immobilisation and effects on reproduction, dead offspring and aborted eggs were reported at 0.00772 mg p.m./L and above.

Growth

The results of the growth parameters are presented in the table below, with the % of inhibition compared to the pooled controls.

| **Parameter** | **Pooled controls** | **0.000814 mg p.m./L** | **0.00259 mg p.m./L** | **0.00772 mg p.m./L** | **0.0244 mg p.m./L** | **0.0746 mg p.m./L** |
|---|---|---|---|---|---|---|
| Mean length | 4.27 | 4.27 | 4.28 | 4.25 | 4.09 | 3.17 |
| % of inhibition | - | 0.0 | -0.1 | 0.7 | 4.3* | 25.9* |
| Mean weight | 1.10 | 1.07 | 1.04 | 0.94 | 0.85 | 0.27 |
| % of inhibition | - | 2.7 | 5.8 | 14.5* | 22.6* | 75.9* |

*significant difference from the controls (tested with Williams' t-test, α = 0.05, one-sided).

Reproduction

The results of the reproduction parameters are presented in the table below, with the % of inhibition compared to the pooled controls.

| **Parameter** | **Pooled controls** | **0.000814 mg p.m./L** | **0.00259 mg p.m./L** | **0.00772 mg p.m./L** | **0.0244 mg p.m./L** | **0.0746 mg p.m./L** |
|---|---|---|---|---|---|---|
| Mean number of offspring per introduced adult | 138.0 | 129.2 | 135.0 | 115.5 | 102.0 | 15.9 |
| % of inhibition | - | 6.4 | 2.2 | 19.2* | 26.1* | 88.5* |
| Mean number of offspring per surviving adult | 138.0 | 129.2 | 135.0 | 118.3 | 102.0 | 15.9 |
| % of inhibition | - | 6.4 | 2.2 | 14.3** | 26.1** | 88.5** |
| Mean number of offspring per adult per reproduction day | 9.9 | 9.2 | 9.6 | 8.0 | 7.3 | 1.1 |
| % of inhibition | - | 6.4 | 2.2 | 18.4** | 26.1** | 88.5** |
| Production rate of 1st brood*** | 0.116 | 0.114 | 0.117 | 0.107 | 0.116 | 0.123 |
| % of inhibition | - | 1.3 | -0.8 | 7.3 | -0.2 | -6.2 |

* significant difference from the controls (tested with Step-down Jonckheer-Terpstra test, α = 0.05, one-sided).

**significant difference from the controls (tested with Williams t-test, α = 0.05, one-sided).

*** no significant difference from the controls (tested with Dunett's t-test, α = 0.05, one-sided).

## Conclusion

The study meets the validity criteria. The endpoints based on TWA concentrations are as follows (in mg p.m./L); 95% confidence interval is given in brackets:

| **Parameter** | **Reproduction per introduced adult** | **Reproduction per surviving adult** | **Reproduction per reproduction day** | **Production rate of 1st brood** | **Immobility of adults** | **Length of adults** | **Weight of adults** |
|---|---|---|---|---|---|---|---|
| $EC_{20}$ | 0.0192 (0.0140-0.0265) | 0.0207 (0.0160-0.0268) | 0.0196 (0.0145-0.0265) | > 0.0746 | > 0.0746 | 0.0777* (0.0506-0.114*) | 0.0194 (0.0121-0.0298) |
| $EC_{10}$ | 0.0140 (0.00918-0.0214) | 0.0155 (0.0110-0.0218) | 0.0143 (0.0096-0.0214) | > 0.0746 | > 0.0746 | 0.0156 (0.0119-0.0205) | 0.0126 (0.0068-0.0232) |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| NOEC | 0.00259 | 0.00259 | 0.00259 | 0.0746 | 0.0746 | 0.00772 | 0.00259 |
| LOEC | 0.00772 | 0.00772 | 0.00772 | > 0.0746 | > 0.0746 | 0.0244 | 0.00772 |

*extrapolated values

| | |
|---|---|
| Comments of zRMS: | The study is valid.<br>**Agreed endpoint:**<br>NOEC = 0.101 mg p.m./$L_{mm}$ |

| | |
|---|---|
| Reference: | **KCA 8.2.5.2/04** |
| Title: | Metabolite of trifloxystrobin: BCS-AR14200 - Influence to Daphnia magna in a semi-static reproduction test -1st final report amendment |
| Report: | Börschig, C.; Emnet, P.; 2019; 140441221; M-670322-02-1 |
| Authority registration No: | |
| Guideline(s): | Commission Regulation (EC) No 440/2008, Annex, Part C, C.20.: "Daphnia magna Reproduction Test", Official Journal of the European Union (EN), dated May 30, 2008<br>EPA Guideline 712-C-16-005: OCSPP 850.1300, "Daphnid Chronic Toxicity Test", October 2016<br>EPA Guideline 712-C-16-014: OCSPP 850.1000, "Background and Special Considerations-Tests with Aquatic and Sediment-Dwelling Fauna and Aquatic Microcosms", October 2016<br>OECD Guideline for Testing of Chemicals, No. 211: "Daphnia magna Reproduction Test", adopted October 02, 2012<br>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<br>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: | |
| Duplication<br>(if vertebrate study): | |

## Material and methods

| | |
|---|---|
| Test material | Name of substance BCS-AR14200, synonym: CGA 357261<br>lot/batch: BCOO6713-2-2<br>purity:92.3% |
| Guideline(s) adaptation | none |
| Test species | Waterflea: *Daphnia magna*<br>Clone 5 |
| Culturing conditions | The Daphnia were bred in the laboratory under similar temperature and light conditions as in the test. The cultivation of the parental Daphnia was performed in Elendt M4 medium. The test organisms were not first brood progeny. The Daphnia in the stock culture were fed at least all working days with green algae (*Desmodesmus subspicatus*). |
| Acclimation | Not necessary |

| | |
|---|---|
| Organism age/size at study initiation | 1.5 to 21.25 hours old at test start |
| Test solutions | Test medium: Elendt M4<br>Nominal concentrations: 0.064, 0.14, 0.31, 0.68, 1.5 mg test item/L<br>Time weighted average concentration : 0.048, 0.101, 0.215, 0.515, 0.972 mg pm/L<br>Control: test medium<br>Solvent control: dimethylformamide (DMF), 100 µL/L<br>Evidence of undissolved material: no precipitation was observed in the test media |
| Replication | No. of vessels per concentration (replicates): 10<br>No. of vessels per control (replicates): 10<br>No. of vessels per solvent control (replicates): 10 |
| Organisms per replicate | No. of organisms per vessel: 1 |
| Exposure | Test type: semi-static, 3 renewals per week<br>Total exposure duration : 21 d |
| Test Vessel Loading | 1 daphnia / 60 mL |
| Feeding during test | Daily with green algae (*Desmodesmus subspicatus*). The approximate daily amounts of algal TOC/Daphnia/day were as follows:<br>Days 0-3: 0.1 mg<br>Days 4-7: 0.15 mg<br>Days 8-20: 0.2 mg |
| Test conditions | Temperature: 19.4- 20.5° C in fresh medium, 19.7 – 20.6°C in aged medium.<br>Constant measurement: 18.7 – 20.0°C<br>Photoperiod: 16h light, 8 h dark<br>Light intensity: 600 – 1000 lux<br>pH: 7.9 – 8.0 in fresh medium, 7.9 – 8.8 in aged medium<br>Water hardness: 178 – 214 mg $CaCO_3$/L<br>Dissolved oxygen: 8.6 – 9.2 mg/L in fresh medium (97-105% of saturation), 8.6 – 10.6 mg/L in aged medium (98-119% of saturation)<br>Conductivity: 540-600 µS/cm |
| Parameters Measured / Observations | The pH-values, dissolved oxygen concentrations and water temperatures were measured in the freshly prepared test media at test start and at each water renewal and in the corresponding aged test media at each water renewal and test end. The parameter in the freshly prepared test media were measured from the bulk for each treatment, while the parameter of the aged test media were measured in two randomly chosen replicates. The temperature was measured additionally continuously.<br>Water hardness, conductivity and alkalinity were measured at test start and test end and once in between in the bulk of the freshly prepared media and in one replicate of the aged media of the controls and the highest test concentration. The light intensity was measured at test start and then once a week (Day 7 and Day 19). |
| Sampling for chemical analysis | Duplicate samples from the freshly prepared test media of all test concentrations and the control were taken at the test start (day 0) and at the test medium renewal periods on day 7, 14, 19. Duplicate samples of the respective aged test media and controls were sampled at days 3, 10, 17, and at test end (day 21). The replicate beakers were not pooled, but instead were sampled individually. To reduce the number of samples produced the first water renewal was sampled from beaker replicates 1 and 2 (day 3), the second sampling from beaker replicates 3 and 4 (day 10), the third sampling from beaker replicates 5 and 6 (day 17), and the fourth sampling from beaker replicates 7 and 8 (day 21).<br>BCS-AR14200was measured by LC-MS/MS. |

| | |
|---|---|
| Data analysis | ToxRat software, version 3.3.0 was used for statistical analysis.<br>$EC_x$ values were calculated by Probit analysis.<br>NOEC were determined by different methods depending on normality, variance homogeneity and linear trend of the data. |

**Results and discussion**

| **Validity criteria of OECD 211** | **Required** | **Obtained** |
|---|---|---|
| Immobility of adult daphnia in the control | ≤ 20% | 0% |
| Mean number of live offspring in the control after 21 days | ≥ 60 | 144.9 in water control<br>133.3 in solvent control |

Analytical results:

The measured concentrations from the fresh and aged samples are not in the range of 80-120% of nominal concentrations, therefore time weighted average concentrations were calculated.
No residues of the test substance were found in the control.
**Measured concentration of BCS-AR14200 (% of nominal) – LOD = 0.04 µg test item /L**

| **Nominal Concentration (mg test item/L)** | **Day 0 Fresh** | **Day 3 Aged** | **Day 7 Fresh** | **Day 10 Aged** | **Day 14 Fresh** | **Day 17 Aged** | **Day 19 Fresh** | **Day 21 Aged** |
|---|---|---|---|---|---|---|---|---|
| Control | Not applicable (< LOD) | Not applicable (< LOD) | Not applicable (< LOD) | Not applicable (< LOD) | Not applicable (< LOD) | Not applicable (< LOD) | Not applicable (< LOD) | Not applicable (< LOD) |
| Solvent control | Not applicable (< LOD) | Not applicable (< LOD) | Not applicable (< LOD) | Not applicable (< LOD) | Not applicable (< LOD) | Not applicable (< LOD) | Not applicable (< LOD) | Not applicable (< LOD) |
| 0.064 | 93 | 40 | 100 | 67 | 105 | 77 | 102 | 85 |
| 0.14 | 94 | 38 | 104 | 63 | 102 | 75 | 89 | 75 |
| 0.31 | 92 | 29 | 102 | 69 | 105 | 71 | 97 | 55 |
| 0.68 | 94 | 49 | 112 | 63 | 109 | 67 | 100 | 82 |
| 1.5 | 96 | 49 | - | - | - | - | - | - |

- no measurements, all daphnia were immobilised.

Time weighted average concentrations:

| **Nominal Concentration (mg test item/L)** | **Time weighted average concentrations (mg p.m./L)** | **% of nominal** |
|---|---|---|
| 0.064 | 0.048 | 75 |
| 0.14 | 0.101 | 72 |
| 0.31 | 0.215 | 69 |
| 0.68 | 0.515 | 76 |
| 1.5 | 0.972 | 65 |

Biological results:

Immobility

The Cochran-Armitage trend test revealed a significant trend in immobility. The effects on immobility are presented in the table below.

| Parameter | Water control | Solvent control | 0.048 mg p.m./L | 0.101 mg p.m./L | 0.215 mg p.m./L | 0.515 mg p.m./L | 0.972 mg p.m./L |
|---|---|---|---|---|---|---|---|
| Immobility | 0 | 0 | 1 | 0 | 0 | 2 | 10 |
| % mortality | 0 | 0 | 10 | 0 | 0 | 20 | 100* |

*significant difference from pooled controls (tested with Step-down Cochran Armitage test, α = 0.05, one-sided)

Observations

Apart from the reported immobility and the reduced reproduction, dead offspring were observed during the test at the concentrations of 0.215 and 0.515 mg pure metabolite/L. At 0.215 mg pure metabolite/L aborted eggs were observed.

Growth

The results of the growth parameters are presented in the table below, with the % of inhibition compared to the pooled controls.

| Parameter | Pooled controls | 0.048 mg p.m./L | 0.101 mg p.m./L | 0.215 mg p.m./L | 0.515 mg p.m./L | 0.972 mg p.m./L |
|---|---|---|---|---|---|---|
| Mean length | 4.26 | 4.27 | 4.20 | 4.16 | 3.89 | - |
| % of inhibition | - | -0.3 | 1.2 | 2.2 | 8.6* | - |
| Mean weight | 1.20 | 1.16 | 1.26 | 1.08 | 0.89 | - |
| % of inhibition | - | 3.3 | -5.0 | 9.8* | 26.0* | - |

*significant difference from the controls (tested with Williams' t-test, α = 0.05, one-sided).
- no daphnia survived

Reproduction

The results of the reproduction parameters are presented in the table below, with the % of inhibition compared to the pooled controls.

| Parameter | Pooled controls | 0.048 mg p.m./L | 0.101 mg p.m./L | 0.215 mg p.m./L | 0.515 mg p.m./L | 0.972 mg p.m./L |
|---|---|---|---|---|---|---|
| Mean number of offspring per introduced adult | 139.1 | 134.9 | 131.5 | 106.0 | 10.7 | 0.0 |
| % of inhibition | - | 3.0 | 5.5 | 23.8* | 92.3* | 100* |
| Mean number of offspring per surviving adult | 139.1 | 141.9 | 131.5 | 106 | 13.4 | - |
| % of inhibition | - | -2.0 | 5.5 | 23.8** | 90.4** | - |
| Mean number of offspring per adult per reproduction day | 9.9 | 10.2 | 9.4 | 7.6 | 0.8 | - |
| % of inhibition | - | -3.0 | 5.5 | 23.8** | 91.5** | - |
| Production rate of 1st brood*** | 0.120 | 0.119 | 0.122 | 0.117 | 0.108 | - |
| % of inhibition | - | 0.9 | -1.7 | 2.3 | 10.2** | - |

* significant difference from the pooled control (tested with Welch t-Test, α = 0.05, one-sided)
**significant difference from the pooled control (tested with Williams t-test, α = 0.05, one-sided).

- no daphnia survived

**Conclusion**

The study meets the validity criteria. The endpoints based on TWA concentrations are as follows (in mg p.m./L); 95% confidence interval is given in brackets:

| **Parameter** | **Reproduction per introduced adult** | **Reproduction per surviving adult** | **Reproduction per reproduction day** | **Production rate of 1st brood** | **Immobility of adults** | **Length of adults** | **Weight of adults** |
|---|---|---|---|---|---|---|---|
| $EC_{20}$ | 0.199 (0.162-0.245) | 0.197 (0.149-0.261) | 0.199 (0.153-0.258) | n.d. | n.d. | n.d. | 0.392 (0.235-0.653) |
| $EC_{10}$ | 0.165 (0.126-0.216) | 0.161 (0.112-0.232) | 0.163 (0.116-0.230) | 0.372 (0.020*-6.84*) | n.d. | 0.648 (0.277-1.52*) | 0.203 (0.096-0.429) |
| NOEC | 0.101 | 0.101 | 0.101 | 0.215 | 0.515 | 0.215 | 0.101 |
| LOEC | 0.215 | 0.215 | 0.215 | 0.515 | 0.972 | 0.515 | 0.215 |

*extrapolated values
n.d. not determined for mathematical reasons

## A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms

| | |
|---|---|
| Comments of zRMS: | This study from the literature is only used as supportive information for the aquatic risk assessment of metabolites. Therefore, no endpoint is determined. |

| | |
|---|---|
| Reference: | **KCP 10.2.3/01** |
| Title: | Predicting the environmental fate and ecotoxicological and toxicological effects of pesticide transformation products |
| Report: | Sinclair, C. J.; 2009; M-551653-01-1 |
| Authority registration No: | |
| Guideline(s): | none |
| Deviations: | none |
| GLP/GEP: | not applicable |
| Acceptability: | |
| Duplication (if vertebrate study): | |

The overall aim of this work was to investigate and develop pragmatic approaches for assessing the fate and effects of pesticides transformation products in the absence of experimentally determined data. Specific objectives were:
1. To identify relationships that exist between parent pesticides and their transformation products in terms of the physico-chemical properties, ecotoxicology and toxicology;
2. To identify and evaluate methods by which the most important physico-chemical properties and effects of transformation products can be estimated;
3. To develop approaches for assessing the ecotoxicity, toxicity and pesticidal activity (e.g. fungicidal activity) of transformation products to non-target organisms;
4. To develop methodologies for identifying and ranking those transformation products that could pose

the greatest risk to the public through exposure via drinking water.
The summary below will not address all these objectives but only those related to the identification of toxophores in pesticide active substances.

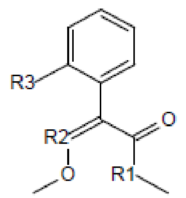
**Materials and methods**
Information on the identity, physico-chemical properties, ecotoxicity, and fate and behavior of both pesticides and their transformation products was gathered from multiple sources (open literature, databases, UK authority reports). Data quality was checked in the original citation according to the following rules: 1) when a large number of data points were available on a particular substance from a number of sources and where the values for one or more of the data points exhibited a large difference compared to the majority of the data points; and 2) when three or fewer data points were reported for a particular substance. If appropriate, the data were revised in light of the results of the quality assessment.

The ecotoxicity data for transformation products and their parent compound were compared to determine whether the transformation products had similar ecotoxicity or were more or less toxic.

Toxophores for each of the major classes of pesticides were identified by looking for sub-structural similarities within a pesticide class. The structure of each transformation product for which ecotoxicity data were available was then examined to determine whether or not it contained a pesticide toxophore.

**Results and discussions**
Using the search strategy, information was obtained on the transformation pathways of 60 active substances and based on these pathways; the structures of 485 transformation products were identified. The active substances examined covered a range of pesticide classes and included 27 herbicides, 20 insecticides, 12 fungicides and one compound used as an herbicide, fungicide and insecticide. All the major classes of pesticides were represented by at least one active substance.
The final database only comprised property and ecotoxicity values for 89 transformation products arising from 37 parent compounds. Twenty-three parent compounds with identified transformation pathways had either no corresponding data or only unsuitable data for their respective transformation products.
Fifty-four toxophores associated with a wide range of pesticide classes were identified. It was not possible to identify a toxophore for all the active compounds considered in the study. Some pesticide classes contained too few members for reasonable toxophore identification, whilst some compounds had an undefined mode of action and/or were not a member of a defined pesticide class.

**Conclusion**
For substance trifloxystrobin, the toxophore is:

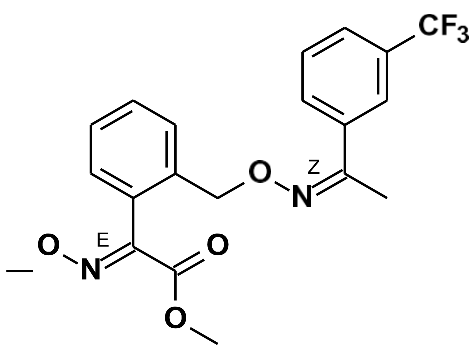


strobilurin analogue

| Comments of zRMS: | These values have already been accepted/used for the dossier EXTERIS STRESSGARD Central and Northern zones).The value from this study was also considerd in evaluation for ppp Flint (zRMS –BE).<br><br>**Agreed endpoints:** |
|---|---|

| Reference: | **KCP 10.2.3/02** |
|---|---|
| Title: | CGA 357261 (BCS-AR14200) - Estimation of bioconcentration factors |
| Report: | xxx |
| Authority registration No: | |
| Guideline(s): | none |
| Deviations: | none |
| GLP/GEP: | no |
| Acceptability: | |
| Duplication<br>(if vertebrate study): | No |

The bioconcentration factor (BCF) of compound CGA 357261 (BCS-AR14200) was calculated using the EPI Suite module BCFBAF v3.02. Two BCF estimation methods are implemented in BCFBAF: a Kow based regression model (Meylan model) and a physiology based mechanistic model (Arnot-Gobas model). Other models were considered, but were not adequate for the intended use in risk assessments.
Recommendations of the EFSA aquatic guidance document have been followed to evaluate these two models. Considering aspects from all three criteria (relevance, validity and applicability) leads to the conclusion that the Meylan model is more relevant for the intended purpose than the Arnot-Gobas model. Thus, it can be concluded that predictions of the Meylan model for molecules within the applicability domain are adequate for use in risk assessments (e.g. secondary poisoning), whereas results of the Arnot-Gobas model are considered as supplementary data. The Arnot-Gobas model predicts BCF for three trophic levels corresponding to lipid contents of 10.7; 6.85 and 5.98% for upper, middle and lower level respectively. The results of the lower level are reported here because they are more representative of the BCF normalised to 5% lipid content as recommended in the OECD 305 guideline.

| Compound | Results |
|---|---|
| CGA 357261 (BCS-AR14200)<br><br><br><br>SMILES code: FC(F)(F)c1cc(ccc1)/C(=N\OCc2c(cccc2)/C(=N\OC)/C(=O)OC)/C<br>logKow: 3.86 (Stulz 1997, M-078479-01-1) | Model Results (BCFBAF v3.02)<br><br>Meylan model:<br>log BCF: 2.21<br>BCF: 164 L/kg wet-wt<br>Within Applicability Domain?*<br>Yes – the parameters molecular weight, log Kow and calculated BCF are in the ranges determined by the training set molecules.<br>Predictions for similar molecules agree with experimental findings.<br><br>Arnot-Gobas model (for information only): log BCF: 2.47 (lower trophic level)<br>BCF: 293 L/kg wet-wt<br><br>Within Applicability Domain?*<br>No information on model training set available. However, |

| | |
|---|---|
| | the compound is within the domain of the $k_M$ submodel – the parameters molecular weight, log Kow and calculated $k_M$ are in the ranges determined by the training set molecules.<br>Adequacy<br>The results of the Arnot-Gobas model were considered less adequate for use in risk assessments than the Meylan model for the following reasons:<br>The training and validation sets are not available.<br>Thus, the applicability domain could not be clearly checked. (c) And, the predictive performance could not be strictly evaluated for compounds outside the training set. (d) Only the lower trophic level is representative for the lipid content of 5% recommended by OECD guideline 305. |

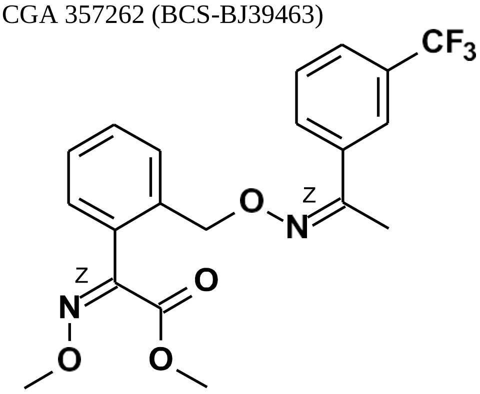
* EPISuite requires a manual check of the AD. The user has to assess whether the molecular weight, logP or $k_M$ of the target substance fall in the range of the training set.

| | |
|---|---|
| Comments of zRMS: | These values have already been accepted/used for the dossier EXTERIS STRESSGARD Central and Northern zones). The value from this study was also considerd in evaluation for ppp Flint (zRMS –BE).<br>**Agreed endpoints:**<br>**BCF: 807 L/kg wet-wt** |

| | |
|---|---|
| Reference: | **KCP 10.2.3/03** |
| Title: | CGA 357262 (BCS-BJ39463) - Estimation of bioconcentration factors |
| Report: | xxx |
| Authority registration No: | |
| Guideline(s): | none |
| Deviations: | none |
| GLP/GEP: | no |
| Acceptability: | |
| Duplication (if vertebrate study): | No |

The bioconcentration factor (BCF) of compound CGA 357262 (BCS-BJ39463) was calculated using the EPI Suite module BCFBAF v3.02. Two BCF estimation methods are implemented in BCFBAF: a Kow based regression model (Meylan model) and a physiology based mechanistic model (Arnot-Gobas model). Other models were considered, but were not adequate for the intended use in risk assessments.
Recommendations of the EFSA aquatic guidance document have been followed to evaluate these two models. Considering aspects from all three criteria (relevance, validity and applicability) leads to the conclusion that the Meylan model is more relevant for the intended purpose than the Arnot-Gobas model. Thus, it can be concluded that predictions of the Meylan model for molecules within the applicability domain are adequate for use in risk assessments (e.g. secondary poisoning), whereas results of the Arnot-Gobas model are considered as supplementary data. The Arnot-Gobas model predicts BCF for three trophic levels corresponding to lipid contents of 10.7; 6.85 and 5.98% for upper, middle and lower level respectively. The results of the lower level are reported here because they are more representative of the BCF normalised to 5% lipid content as recommended in the OECD 305 guideline.

| Compound | Results |
|---|---|

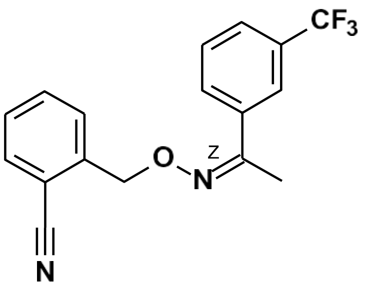
<table>
<tr><td>CGA 357262 (BCS-BJ39463)<br><br>SMILES code:<br>CO\N=C(/C(=O)OC)\c1ccccc1CO\N=<br>C(\C)/c2cccc(c2)C(F)(F)F<br>logKow: 4.91 (Stulz 1997, M-078525-01-1)</td><td>Model Results (BCFBAF v3.02)<br><br>Meylan model:<br>log BCF: 2.91<br>BCF: 807 L/kg wet-wt<br>Within Applicability Domain?*<br>Yes – the parameters molecular weight, log Kow and calculated BCF are in the ranges determined by the training set molecules. Predictions for similar molecules agree with experimental results.<br><br>Arnot-Gobas model (for information only): log BCF: 3.13 (lower trophic level)<br><br>BCF: 1866 L/kg wet-wt Within Applicability Domain?*<br>No information on model training set available. However, the compound is within the domain of the $k_M$ submodel – the parameters molecular weight, log Kow and calculated $k_M$ are in the ranges determined by the training set molecules.<br>Adequacy<br>The results of the Arnot-Gobas model were considered less adequate for use in risk assessments than the Meylan model for the following reasons:<br>The training and validation sets are not available.<br>Thus, the applicability domain could not be clearly checked. (c) And, the predictive performance could not be strictly evaluated for compounds outside the training set.<br>(d) Only the lower trophic level is representative for the lipid content of 5% recommended by OECD guideline 305.</td></tr>
</table>

* EPISuite requires a manual check of the AD. The user has to assess whether the molecular weight, logP or $k_M$ of the target substance fall in the range of the training set.

| | |
|---|---|
| Comments of zRMS: | These values have already been accepted/used for the dossier EXTERIS STRESSGARD Central and Northern zones). The value from this study was also considerd in evaluation for ppp Flint (zRMS –BE).<br>**Agreed endpoints:**<br>**BCF: 274 L/kg wet-wt** |

| | |
|---|---|
| Reference: | **KCP 10.2.3/04** |
| Title: | NOA 409480 (BCS-CR74871) - Estimation of bioconcentration factors |
| Report: | xxx |
| Authority registration No: | |
| Guideline(s): | none |
| Deviations: | none |
| GLP/GEP: | no |
| Acceptability: | |
| Duplication (if vertebrate study): | No |

The bioconcentration factor (BCF) of compound NOA 409480 (BCS-CR74871) was calculated using the EPI Suite module BCFBAF v3.02. Two BCF estimation methods are implemented in BCFBAF: a Kow based regression model (Meylan model) and a physiology based mechanistic model (Arnot-Gobas model). Other models were considered, but were not adequate for the intended use in risk assessments.
Recommendations of the EFSA aquatic guidance document have been followed to evaluate these two models. Considering aspects from all three criteria (relevance, validity and applicability) leads to the conclusion that the Meylan model is more relevant for the intended purpose than the Arnot-Gobas model. Thus, it can be concluded that predictions of the Meylan model for molecules within the applicability domain are adequate for use in risk assessments (e.g. secondary poisoning), whereas results of the Arnot-Gobas model are considered as supplementary data. The Arnot-Gobas model predicts BCF for three trophic levels corresponding to lipid contents of 10.7; 6.85 and 5.98% for upper, middle and lower level respectively. The results of the lower level are reported here because they are more representative of the BCF normalised to 5% lipid content as recommended in the OECD 305 guideline.

| Compound | Results |
| --- | --- |
| NOA 409480 (BCS-CR74871)<br><br><br>SMILES code:<br>C\C(=N\OCc1ccccc1C#N)\c2cccc(c<br>2)C(F)(F)F<br>logKow: 4.2 (Bogdoll and Peschke 2012, M-427343-01-1) | Model Results (BCFBAF v3.02)<br><br>Meylan model:<br>log BCF: 2.44<br>BCF: 274 L/kg wet-wt<br>Within Applicability Domain?*<br>Yes – the parameters molecular weight, log Kow and calculated BCF are in the ranges determined by the training set molecules. Predictions for similar molecules agree with experimental results.<br><br>Arnot-Gobas model (for information only):<br>log BCF: 2.90 (lower trophic level)<br>BCF: 792 L/kg wet-wt<br>Within Applicability Domain?*<br>No information on model training set available. However, the compound is within the domain of the $k_M$ submodel – the parameters molecular weight, log Kow and calculated $k_M$ are in the ranges determined by the training set molecules.<br>Adequacy<br>The results of the Arnot-Gobas model were considered less adequate for use in risk assessments than the Meylan model for the following reasons:<br>The training and validation sets are not available.<br>Thus, the applicability domain could not be clearly checked. (c) And, the predictive performance could not be strictly evaluated for compounds outside the training set.<br>(d) Only the lower trophic level is representative for the lipid content of 5% recommended by OECD guideline 305. |

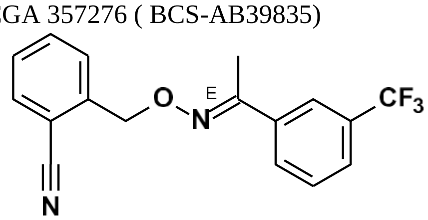
* EPISuite requires a manual check of the AD. The user has to assess whether the molecular weight, logP or $k_M$ of the target substance fall in the range of the training set.

| Comments of zRMS: | These values have already been accepted/used for the dossier EXTERIS STRESSGARD Central and Northern zones). The value from this study was also considerd in evaluation for ppp Flint (zRMS –BE).<br><br>**Agreed endpoints:** |
| --- | --- |

| | |
|---|---|
| | **BCF: 586 L/kg wet-wt** |

| | |
|---|---|
| Reference: | **KCP 10.2.3/05** |
| Title: | CGA 357276 ( BCS-AB39835) - Estimation of bioconcentration factors |
| Report: | xxx |
| Authority registration No: | |
| Guideline(s): | none |
| Deviations: | none |
| GLP/GEP: | no |
| Acceptability: | |
| Duplication (if vertebrate study): | No |

The bioconcentration factor (BCF) of compound CGA 357276 ( BCS-AB39835) was calculated using the EPI Suite module BCFBAF v3.02. Two BCF estimation methods are implemented in BCFBAF: a Kow based regression model (Meylan model) and a physiology based mechanistic model (Arnot-Gobas model). Other models were considered, but were not adequate for the intended use in risk assessments.
Recommendations of the EFSA aquatic guidance document have been followed to evaluate these two models. Considering aspects from all three criteria (relevance, validity and applicability) leads to the conclusion that the Meylan model is more relevant for the intended purpose than the Arnot-Gobas model. Thus, it can be concluded that predictions of the Meylan model for molecules within the applicability domain are adequate for use in risk assessments (e.g. secondary poisoning), whereas results of the Arnot-Gobas model are considered as supplementary data. The Arnot-Gobas model predicts BCF for three trophic levels corresponding to lipid contents of 10.7; 6.85 and 5.98% for upper, middle and lower level respectively. The results of the lower level are reported here because they are more representative of the BCF normalised to 5% lipid content as recommended in the OECD 305 guideline.

| Compound | Results |
|---|---|
| CGA 357276 ( BCS-AB39835)<br><br><br>SMILES code:<br>C\C(=N/OCc1ccccc1C#N)\c2cccc(c 2)C(F)(F)F<br>logKow: 4.7 (Bogdoll and Peschke 2012, M-428439-01-1) | Model Results (BCFBAF v3.02)<br><br>Meylan model:<br>log BCF: 2.77<br>BCF: 586 L/kg wet-wt<br>Within Applicability Domain?*<br>Yes – the parameters molecular weight, log Kow and calculated BCF are in the ranges determined by the training set molecules. Predictions for similar molecules agree with experimental results.<br><br>Arnot-Gobas model (for information only):<br>log BCF: 3.31 (lower trophic level)<br>BCF: 2056 L/kg wet-wt<br>Within Applicability Domain?*<br>No information on model training set available. However, the compound is within the domain of the $k_M$ submodel – the parameters molecular weight, log Kow and calculated $k_M$ are in the ranges determined by the training set molecules.<br>Adequacy<br>The results of the Arnot-Gobas model were considered less adequate for use in risk assessments than the Meylan model for the following reasons:<br>The training and validation sets are not available. |

| | |
|---|---|
| | Thus, the applicability domain could not be clearly checked. (c) And, the predictive performance could not be strictly evaluated for compounds outside the training set.<br>(d) Only the lower trophic level is representative for the lipid content of 5% recommended by OECD guideline 305. |

* EPISuite requires a manual check of the AD. The user has to assess whether the molecular weight, logP or $k_M$ of the target substance fall in the range of the training set.

| | |
|---|---|
| Comments of zRMS: | This study from the literature could be used as supportive information. |

| | |
|---|---|
| Reference: | **KCP 10.2.3/06** |
| Title: | Acute to chronic ratios in aquatic toxicity - Variation across trophic levels and relationship with chemical structure |
| Report: | Ahlers, J.; Riedhammer, C.; Vogliano, M.; Ebert, R.; Kuehne, R.; Schueuermann, G.; 2006; M-634467-01-1 |
| Authority registration No: | |
| Guideline(s): | not applicable |
| Deviations: | not applicable |
| GLP/GEP: | no |
| Acceptability: | |
| Duplication<br>(if vertebrate study): | |

**Material and methods:**

Acute to chronic ratio (ACR) have been derived for fish and daphnia. The dataset is based on ICS database of UBA, containing information on new and existing chemicals.
The studies selected were conducted according to OECD guidelines, and evaluated and validated by authorities.
To reduce uncertainty of the extrapolation, it was checked whether the quality of the fish data, the mode of action (MoA) according to Verhaar's scheme and Russom's classification, Kow values or the level of acute toxicity could be used to refine the extrapolation.
Alert structures for high ACR were also compiled.
The publication reports also on ACR for algae, data for 24-h studies for daphnia, an analysis of sensitivity ratios between trophic level and aquatic ecosystem ACR. This is not discussed further in this summary.

**Results:**

The calculated ACR for chemicals are shown in the table below:

| Parameter | Daphnia | Fish |
|---|---|---|
| Number of values | 102 | 39 |
| Minimum | 0.6 | 1.3 |
| Median | 7.0 | 10.5 |
| $90^{th}$ percentile | 41.5 | 198.2 |
| Maximum | 2222 | 4250 |

The ACR was > 100 for 12.8% of chemicals for fish and 6.9% of chemicals for daphnia.

<u>Quality of chronic fish data:</u>
The chronic fish data in the dataset were heterogenous both in terms of species and study types.
Therefore, subsets of ACR were calculated according to these 2 criteria:
ACR1 included data across all fish species and test types

ACR2 included all test types but was confined to data with acute and chronic results from the same fish species
ACR3 was restricted to chronic toxicity testing conducted according or equivalent to OECD 210 representing FELS studies, all species
ACR4 included FELS tests that were confined to data with acute and chronic results from the same species
ACR5 included all chronic studies that were not conducted according or equivalent to OECD 210
ACR6 was confined to ELS data for Pimephales promelas used in acute and chronic tests
The results are shown in the table below:

| Parameter | ACR1 | ACR2 | ACR3 | ACR4 | ACR5 | ACR6 |
|---|---|---|---|---|---|---|
| Number of values | 47 | 39 | 36 | 28 | 11 | 18 |
| Minimum | 1.3 | 1.3 | 1.6 | 2.1 | 1.3 | 3.4 |
| Median | 10.6 | 10.5 | 12.7 | 12.3 | 4.6 | 11.5 |
| $90^{th}$ percentile | 128.3 | 198.2 | 136.2 | 250.6 | 9.2 | 66.4 |
| Maximum | 4250 | 4250 | 4250 | 4250 | 29.6 | 1370 |

The fish species does not influence the median value but there is a factor 2 for the $90^{th}$ percentile.
For ACR 3 and 5, the study type has an impact on the ACR value. Fish ELS test is considered more conservative.

Kow
No relation could be established between the Kow value and the ACR.

Acute toxicity level
No relation could be established between substances having a high acute toxicity ($E(L)C_{50}$ < 1 mg/L) and the ACR values.

Mode of action of chemicals
Non-polar narcosis represents a predictor for lower ACR, whereas non-narcotic substances represents a predictor for increased ACR.

Analysis of chemical structures associated with high ACR
The following alerts have been deduced from the analysis of chemical structures:
For fish, primary aniline derivatives, nitrobenzene derivatives and compounds containing phosphorous are associated with high ACR.
For daphnia, carboxyl esters or carboxylate ion, $NH_2$ attached to an aromatic carbon, nitrobenzene derivatives and phenyl sulfonate derivatives were considered as alerts for high ACR.

| | |
|---|---|
| Comments of zRMS: | The reliability of the study was not fully assessed by zRMS –PL since not used to finalise the risk assessment in this specific case. |

| Reference: | **KCP 10.2.3/07** |
|---|---|
| Title: | Waiving chronic fish tests: possible use of acute-to-chronic relationships and interspecies correlations |
| Report: | Kienzler, A.; Halder, M.; Worth, A.; 2016; M-632126-01-1 |
| Authority registration No: | |
| Guideline(s): | -- |
| Deviations: | -- |
| GLP/GEP: | not applicable |
| Acceptability: | |
| Duplication (if vertebrate study): | |

**Material and methods:**

Acute to chronic ratio (ACR) have been derived for fish considering or not the mode of action (MoA) according to Verhaar scheme. The dataset is based on all the databases included in the OECD QSAR toolbox version 3.2.
The studies selected were conducted according to OECD guidelines, endpoints were $LC_{50}$ and NOEC. When several endpoints were available, the ACR were calculated either based on the lowest value or the geometric mean value.
A total of 240 organic substances were used, comprising chemicals and pesticides.
The publication reports also an analysis of sensitivity ratios between daphnia data and fish. This is not discussed further in this summary.

**Results:**

In general, the goodness of fit was better when geometric means rather than the lowest endpoint were used in the correlation.
There was a good correlation ($r^2 = 0.87$) when all MoA were pooled and geometric mean was considered, $r^2$ is 0.82 based on the lowest endpoint.
$R^2$ between 0.83 and 0.88 were obtained when the dataset was split by MoA.
Disregarding the MoA, the average ACR is 141.8, the median is 8.9, the 90$^{th}$ percentile is 70.85.
Some ACR were below 1; they are discussed in the publication.
The proportions of substances for a range of ACR are shown in the table below:

| ACR range | MoA1 | MoA2 | MoA3 | MoA4 | MoA5 | All MoA |
|---|---|---|---|---|---|---|
| < 1 | 4.8 | 2.3 | - | 2.0 | 3.7 | 2.9% |
| 1-10 | 53.2 | 50.0 | 56.7 | 47.1 | 48.1 | 50.4% |
| 10-100 | 32.3 | 40.9 | 43.3 | 41.2 | 42.6 | 39.6% |
| 100-1000 | 8.1 | 4.5 | - | 5.9 | 5.6 | 5.4% |
| 1000-10 000 | - | 2.3 | - | 3.9 | - | 1.3% |
| > 10 000 | 1.6 | - | - | - | - | 0.4% |
| Number of substances | 62 | 44 | 30 | 50 | 54 | 240 |

The ACR was below 100 for 85.5% of MoA1 substances, 90.9% for MoA2 substances, 100% for MoA3 substances, 88.2% of MoA 4 substances and 94.4% of MoA5 substances.

| Comments of zRMS: | The reliability of the study was not fully assessed by zRMS –PL since not used to finalise the risk assessment in this specific case. |
|---|---|

| Reference: | **KCP 10.2.3/08** |
|---|---|
| Title: | Evaluation of acute-to-chronic ratios of fish and Daphnia to predict acceptable no-effect levels |
| Report: | May, M.; Drost, W.; Germer, S.; Juffernholz, T.; Hahn, S.; 2016; M-634484-01-1 |
| Authority registration No: | |
| Guideline(s): | not applicable |
| Deviations: | not applicable |
| GLP/GEP: | no |
| Acceptability: | |
| Duplication (if vertebrate study): | |

**Material and methods:**

Acute to chronic ratio (ACR) have been derived for fish and daphnia. The dataset is based on ICS database of UBA, OECD eChemPortal and the dataset used by Ahlers et al, 2006 (M-634467-01-1).
The studies selected were conducted according to OECD guidelines, endpoints were $E(L)C_{50}$ and NOEC.
A total of 203 substances were found comprising 132 chemicals and 71 pesticides.
To reduce uncertainty of the extrapolation, it was checked whether the quality of the fish data, the mode of action (MoA) according to Verhaar scheme, Kow values or the level of acute toxicity could be used to refine the extrapolation.

**Results:**

There was a good correlation ($r^2 = 0.8$) for both fish and daphnia acute and chronic data.
The calculated ACR for chemicals and pesticides are shown in the table below:

| Parameter | Chemicals | | Pesticides | | Total | |
|---|---|---|---|---|---|---|
| | Daphnia | Fish | Daphnia | Fish | Daphnia | Fish |
| Number of values | 130 | 122 | 69 | 70 | 199 | 192 |
| Minimum | 1.0 | 1.1 | 1.2 | 1.7 | 1.0 | 1.1 |
| Median | 8.8 | 12.0 | 11.4 | 15.9 | 9.4 | 12.8 |
| $90^{th}$ percentile | 50.2 | 68.0 | 109.4 | 120.1 | 76.5 | 102.4 |
| Maximum | 1500.0 | 1370.6 | 1661.5 | 659.1 | 1661.5 | 1370.6 |

The ACR was > 100 for 11 chemicals (9%) for fish and 6 chemicals (4.6%) for daphnia.

Quality of chronic fish data:
The chronic fish data in the dataset were heterogenous both in terms of species and study types.
Therefore, subsets of ACR were calculated according to these 2 criteria:
ACR1 included data across all fish species and test types
ACR2 included all test types but was confined to data with acute and chronic results from the same fish species
ACR3 was confined to data from different fish species
ACR4 was restricted to chronic toxicity testing conducted according or equivalent to OECD 210 representing FELS studies
ACR5 included all chronic studies that were not conducted according or equivalent to OECD 210
ACR6 included FELS tests that were confined to data with acute and chronic results from the same species
The results are shown in the table below:

| Parameter | ACR1 | ACR2 | ACR3 | ACR4 | ACR5 | ACR6 |
|---|---|---|---|---|---|---|
| Number of values | 122 | 75 | 47 | 99 | 23 | 63 |
| Minimum | 1.1 | 1.8 | 1.1 | 1.1 | 1.8 | 1.9 |

| | | | | | | |
|---|---|---|---|---|---|---|
| Median | 12.0 | 10.8 | 12.8 | 12.7 | 7.3 | 12.2 |
| 90th percentile | 68.0 | 63.5 | 111.1 | 96.6 | 36.6 | 63.5 |
| Maximum | 1370.6 | 1370.6 | 514.0 | 1370.6 | 375.0 | 1370.6 |

For ACR1 to 3, same median values were calculated but the data variance is higher when different species are considered.
For ACR 4 and 5, the study type has an impact on the ACR value. Fish ELS test is considered more conservative.

Kow
No relation could be established between the Kow value and the ACR.

Acute toxicity level
Substances having a high acute toxicity ($E(L)C_{50}$ < 1 mg/L) have lower probability for high ACR values. The uncertainty of extrapolation is expected to be reduced for this kind of substances.

Mode of action of chemicals
Non-polar narcosis (MoA1) represents a predictor for lower ACR, whereas polar narcosis (MoA2) represents a predictor for increased ACR.
Details are shown in the table below:

| Parameter | MoA1 | MoA2 | MoA3 | MoA5 |
|---|---|---|---|---|
| Number of values | 23 | 18 | 12 | 30 |
| Minimum | 2.2 | 4.5 | 2.7 | 1.9 |
| Median | 7.6 | 51.9 | 9.6 | 10.8 |
| 90th percentile | 24.1 | 514.0 | 56.0 | 39.1 |
| Maximum | 40.1 | 1370.6 | 63.5 | 67.0 |

MoA3 represents a diverse group of chemicals with different unspecific reaction mechanisms that are assumed to result in enhanced toxicity compared to baseline toxicity
MoA4 are not included in this assessment, these are substances like pesticides having a specific mechanism.
MoA5 represents chemicals that cannot be classified in another group.

Correlation of ACRs of fish and daphnia
It was also concluded that it is generally not possible to conclude from a Daphnia ACR on fish ACR, and vice versa.

## 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: | The study previously evaluated.<br>**Agreed endpoints:**<br>$LD_{50}$> 200.0 µg product/bee (contact) and LD50 > 208.8 µg product/bee ( oral) |

| | |
|---|---|
| Reference: | **KCP 10.3.1.1/01** |
| Title: | Effects of AE C656948+trifloxystrobin SC 250+250 g/L (acute contact and oral) on honey bees (Apis mellifera L.) in the laboratory |
| Report: | Schmitzer, S.; 2007; 34491035; M-288193-01-1 |
| Authority registration No: | |
| Guideline(s): | OECD 213: OECD Guideline for the Testing of Chemicals, Honeybees, Acute Oral Toxicity Test, (adopted 21st September 1998) ; OECD 214: OECD Guideline for the Testing of Chemicals, Honeybees, Acute Contact Toxicity Test, (adopted 21st September 1998); Equivalent to US EPA OPPTS Guideline No. 850.3020 SUPP |
| Deviations: | none |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication (if vertebrate study): | |

**Executive summary**

Test item: AE C656948 + Trifloxystrobin SC 250 + 250 g/L, Batch ID: 2007-000441.

The acute oral and contact toxicity of AE C656948 + Trifloxystrobin SC 250 + 250 g/L, to bees (*Apis mellifera* L.; female worker bees) was studied in a limit test for 48h duration. 5 replicates, each consisting of 10 bees in one cage per test concentration, were assessed for mortality after 4, 24 and 48 hours. Reference item was Dimethoate 400 g/L (nominal). The test item concentration was 200 µg formulated product for the contact test and 208.8 µg for the oral test.

At the end of the contact toxicity test (48 hours after application), there was no mortality at 200.0 µg product/bee. 0.0 % mortality occurred in the control (water + 0.5 % Adhäsit).
In the oral toxicity test the maximum nominal test level of AE C656948+Trifloxystrobin SC 250+250 g/L (200 µg product/bee) corresponded to an actual intake of 208.8 µg product/bee. This dose level led to 6.0 % mortality after 48 hours. 2.0 % mortality occurred in the control (50 % sugar solution). No test item induced behavioral effects were observed at any time.

Thus, the $LD_{50}$ (48 h) was > 200.0 µg product/bee in the contact toxicity test and > 208.8 µg product/bee in the oral toxicity test.

**Materials and methods:**

A. Materials

| | |
|---|---|
| 1. Test material: | AE C656948 + Trifloxystrobin SC 250+250 G |
| TOX No. | TOX07851-00 |
| Batch ID: | 2007-0040441 |
| Visual appearance: | white fluid |
| Physical density: | 1.174 g/mL |
| Active substance 1: | AE C656948, fluopyram |
| Active ingredient 2: | CGA 279202, trifloxystrobin |
| Nominal content of active substance: | fluopyram: 250 g/L<br>trifloxystrobin: 250 g/L) |
| Analyzed content of active substance: | fluopyram: 21.4% (251.5 g/L)<br>trifloxystrobin: 21.6% (253.5 g/L) |
| Expiration date: | 2008-02-21 |
| 2. Vehicle and/or positive control | Tap water + 0.5% Adhäsit (100 g/L Marlopon) used to improve the adhesion of the droplet on the bee body.<br>Toxic reference item: Perfekthion EC, active substance: dimethoate, 414.4 g/L |
| 3. Test organism | |
| Species | Honeybee - Apis mellifera L. (Hymenoptera, Apoidea) Female worker bees of a colony in good health condition and queen-right |
| Source | Internal breeding of IBACON GmbH.<br>Bees were collected on the morning of use with glass tubes from the flight board without the use of smoke and without anesthetics. |

B. Study design and methods

| | |
|---|---|
| 1. In life dates | 2007-04-16 to 2004-04-19 (both studies) |
| 2. Experimental treatments | |
| Temperature | 25°C |
| Photoperiod | Constant darkness except during observations |
| Relative humidity | 26 to 46% |

Worker bees of the honeybee Apis mellifera L. were exposed to one dose (limit-test) of the test item and to a range of doses of the reference item (Perfekthion, a.s.: dimethoate 414.4 g/L). The treated bees were kept under controlled climatic conditions and assessed for toxic effects for up to 48 hours.
The cages (stainless steel cages with ventilation holes in the bottom and a glass plate in front for observation of the bees, dimensions inside: 10 cm × 8.5 cm × 5.5 cm) were aerated by the air-conditioning equipment of the incubators.
Two different routes of exposure were used permitting the evaluation of both toxic feeding effects and contact effects of the test and the reference items. For both routes of exposure control treatments were included in the test design. If appropriate, mortality values were used to provide a regression line and calculate the median lethal dose value ($LD_{50}$) expressed in µg of the test item per bee.
At the beginning of the test, 10 healthy worker bees per replicate (cage) (5 replicates/test item, control and reference item) were transferred individually in glass tubes from the hive.
Food: Commercial ready-to-use Apiinvert syrup containing 30% saccharose, 31% glucose and 39% fructose. Food was given ad libitum, immediately after applications.
Application in the contact test: Prior to application, bees were shortly anaesthetized with $CO_2$. One single 5 µL droplet of test item in carrier (water + 0.5% Adhäsit) was placed on the dorsal bee thorax using a Burkard – Applicator.
For the control one 5 µL droplet of tap water with 0.5 % Adhäsit, and toxic standard in same carrier

was used (a 5 µL droplet was chosen in deviation to the guideline recommendation of a 1 µL droplet, since a higher volume ensured a more reliable dispersion of the test item; Ibacon experience has proven that higher volumes are suitable and no adverse effects on the outcome of the study are to be expected).

Application in the oral test: Aqueous stock solutions were prepared and then mixed 1 + 1 with the ready-to-use syrup to achieve the required test concentrations and so that the final syrup solution was 50 %. The treated food was offered in syringes, which were weighed before and after introduction into the cages (duration of uptake was 1 hour 20 minutes for the test item treatments). After a maximum of 1 hour 20 minutes, the syringes containing the treated food were removed, weighed and replaced by ones containing fresh, untreated food.

The target dose levels (e.g. 200 µg product/bee nominal) would have been obtained if 20 mg/bee of the treated food was ingested. In practice, higher (or lower) dose levels were obtained as the bees had a higher or lower uptake of the test solutions than the nominal 20 mg/bee.

3. Observations

Endpoints

The number of dead and affected bees was counted at 4, 24 and 48 hours. During assessments times any behavioral abnormalities of the bees were also recorded: vomiting, apathy, intensive cleaning.

Statistical method

The contact and oral $LD_{50}$ of the toxic standard were estimated with Probit Analysis (according to Finney 1971). The software used to perform the statistical analysis was ToxRat Professional, Version 2.09, ToxRat Solutions GmbH.

**Results and discussions:**

A. Findings

Contact Toxicity Test

| | | | |
|---|---|---|---|
| Mortality:<br>(48 hours after application) | Test Item:<br>200.0 µg product/bee<br>Control:<br>$CO_2$/water control<br>Reference Item:<br>0.30 µg a.i./bee:<br>0.20 µg a.i./bee:<br>0.15 µg a.i./bee:<br>0.10 µg a.i./bee: | <br>0 of 50 bees (0.0 %)<br><br>0 of 50 bees (0.0 %)<br><br>36 of 50 bees (72.0 %)<br>17 of 50 bees (34.0 %)<br>10 of 50 bees (20.0 %)<br>3 of 50 bees (6.0 %) | |
| Behavioral Abnormalities: | No behavioral abnormalities attributed to exposure of the test item to the bees occurred during the experimental time of 48 hours.<br>There were behavioral abnormalities consistent with the observed toxicity in the reference item test. | | |
| Test Item Contact $LD_{50}$: | Since there was no mortality in the test item group at 200.0 µg product/bee, the contact $LD_{50}$ can be considered as > 200.0 µg product/bee. | | |
| Reference Item Contact $LD_{50}$: | 24 h | 48 h | |
| | 0.30 µg a.i./bee | 0.26 µg a.i./bee | |
| 95 %- Confidence limit (lower): | 0.13 µg a.i./bee | 0.17 µg a.i./bee | |
| 95 %- Confidence limit (upper): | 0.65 µg a.i./bee | 0.39 µg a.i./bee | |

Oral Toxicity Test

| | | |
|---|---|---|
| Mortality:<br>(48 hours after application) | Test Item:<br>208.8 µg product/bee<br>Control:<br>water/sugar control | <br>3 of 50 bees (6.0 %)<br><br>1 of 50 bees (2.0 %) |

| | | | |
|---|---|---|---|
| | Reference Item:<br>0.33 µg a.i./bee:<br>0.17 µg a.i./bee:<br>0.08 µg a.i./bee:<br>0.06 µg a.i./bee: | <br>49 of 50 bees (98.0 %)<br>47 of 50 bees (94.0 %)<br>9 of 50 bees (18.0 %)<br>0 of 50 bees (0.0 %) | |
| Behavioral Abnormalities: | No product related behavioral abnormalities occurred.<br>There were behavioral abnormalities consistent with the observed toxicity in the reference item test. | | |
| Test Item Oral $LD_{50}$: | Since the mortality was 6.0 % in the 208.8 µg product/bee group, the contact $LD_{50}$ can be considered as > 208.8 µg product/bee. | | |
| Reference Item Oral $LD_{50}$: | 24 h | 48 h | |
| | 0.14 µg a.i./bee | 0.13 µg a.i./bee | |
| 95 %- Confidence limit (lower): | 0.12 µg a.i./bee | 0.12 µg a.i./bee | |
| 95 %- Confidence limit (upper): | 0.16 µg a.i./bee | 0.15 µg a.i./bee | |

Toxicity of AE C656948 + trifloxystrobin SC 250+250 g/L to honey bees (*Apis mellifera* L.) in contact and oral toxicity (limit test)

| | **Contact Test [48 h]** | **Oral Test [48 h]** |
|---|---|---|
| $LD_{50}$ | > 200.0 µg product/bee | > 208.8 µg product/bee |

The contact and oral $LD_{50}$ (24 h) values of the reference item (dimethoate) were calculated to be 0.30 and 0.14 µg a.i./bee, respectively.

B. Observations
The results can be considered as valid, as all validity criteria of the test were met: control mortality is < 10% (2.0% in the oral and 0.0% in the contact test), the $LD_{50}$ (24 h) of the toxic standard in the oral test equals 0.14 µg/bee and the $LD_{50}$ (24 h) of the toxic standard in the contact test equals 0.30 µg/bee.

Behavioral abnormalities:
Contact Test:
No behavioral abnormalities attributed to exposure of the test item to the bees occurred during the experimental time of 48 hours.
There were behavioral abnormalities consistent with the observed toxicity in the reference item test.

Oral Test:
No test item related behavioral abnormalities occurred.
There were behavioral abnormalities consistent with the observed toxicity in the reference item test.

**Conclusion:**

The toxicity of AE C656948 + Trifloxystrobin SC 250 + 250 g/L was tested in both an acute contact and an oral toxicity test on honey bees. The $LD_{50}$ (48 h) was > 200.0 µg product/bee in the contact toxicity test. The $LD_{50}$ (48 h) was > 208.8 µg product/bee in the oral toxicity test.

| | |
|---|---|
| Comments of zRMS: | The study is valid.<br>The study was realized before the OECD Guideline 247 but the criteria of validity are fulfilled.<br>**Agreed endpoints:**<br>$LD_{50}$ > 115.9 µg a.s./bumble bee |

| | |
|---|---|
| Reference: | **KCP 10.3.1.1/02** |
| Title: | Trifloxystrobin tech.: Effects (acute oral) on bumble bees (Bombus terrestris L.) in the laboratory |
| Report: | Taenzler, V.; 2016; 99931105; M-557014-01-1 |
| Authority registration No: | |
| Guideline(s): | No specific guidelines available; study design based on OECD 213 (1998) Van der Steen (2001) and ICPPR non-apis group (2014); US EPA OCSPP not applicable |
| Deviations: | none |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication (if vertebrate study): | |

**Objective**

The purpose of this study was to determine the acute oral toxicity of trifloxystrobin tech. to the bumble bee (*Bombus terrestris* L.).
Mortality of the bumble bees was used as the endpoint. Sublethal effects, such as changes in behaviour, were also assessed.

**Material and methods**

Test item: trifloxystrobin tech. 95.7% w/w (analytical), Origin Batch No.: BCHR 1484-1-1, Customer Order No.: Tox-No.: 10866-00; Material: AE C642802, technical; LIMS No.: 1508873, Specification No.: 102000007792, Article No.: 05579724
Under laboratory conditions 50 female worker bumble bees (*Bombus terrestris*) per treatment group were exposed to 115.9 µg trifloxystrobin tech. per bumble bee by oral application (oral limit test) in 50% w/v sucrose solution containing maximum 5% acetone and 1% Tween80. Toxic reference item (dimethoate), water control (50% w/v sucrose solution) and solvent control (50% w/v sucrose solution containing 5% acetone and 1% Tween80) treatment groups were tested in parallel. Mortality and sublethal effects were assessed at 4, 24, and 48 hours after treatment.

The following food solutions were prepared:

- For the test item treatment, trifloxystrobin tech. was diluted in 50% w/v sucrose solution containing maximum 5% acetone and 1% Tween80.
- For the reference treatment, dimethoate was diluted in 50% w/v sucrose solution.
- For the water control, 50% w/v sucrose solution was used.
- For the solvent control, 50% w/v sucrose solution containing 5% acetone and 1% Tween80 was used.

The treated food was offered in syringes, which were weighed before and after introduction into the cages (duration of uptake was 6 hours for the test item treatment). After a maximum of 6 hours, the syringes containing the treated food were removed, weighed and replaced by ones containing fresh, untreated food. The mean target dose level (150 µg a.s./bumble bee) would have been obtained if exactly 40 mg/bumble bee of the treated food were ingested. In practice, uptake of the treated sugar solutions differed slightly from the nominal 40 mg/bumble bee and results are given based on the measured consumption.

Food: 50 % w/v sucrose solution *ad libitum;* was given directly after treatment using syringes.

During the experimental phase, the test organisms were kept in constant darkness except during the application and the assessments. The temperature during the test period was 25 ± 2°C, the relative humidity was between 60 ± 10 %, recorded with a data logger.

Results obtained from the bumble bees treated with the test item and the reference item were compared to those obtained from the solvent control and the control in the oral test.

The NOED was estimated using Fisher Exact Test (pairwise comparison, one-sided greater, α = 0.05), which is a distribution-free test and does not require testing for normality or homogeneity prior to analysis.

Dates of work: 2015-11-03 to 2015-11-05

**Results**

In the oral test the target dose level of 150 µg a.s./bumble bee would have been achieved if exactly 40 mg treated feeding solution per bumble bee were consumed. A test solution of 250 µg trifloxystrobin/mg sugar solution was prepared which was pre-determined in solubility testing to the highest concentration technically achievable. The measured consumption corresponded to an actual oral dose of 115.9 µg a.s./bumble bee. After 48 hours there was no mortality in the 115.9 µg trifloxystrobin tech./bumble bee test item group, in the control group (50 % w/v sucrose solution) and in the solvent control group (50 % w/v sucrose solution containing 5 % acetone and 1 % Tween80).

The target dose level of the reference item of 4 µg dimethoate a.s./bumble bee would have been achieved if exactly 40 mg treated feeding solution were consumed per bumble bee. The measured consumption corresponded to an actual oral dose of 3.7 µg a.s./bumble bee. The mortality in the reference item treatment group was 94.0 % (48 hours after application).

No test item related behavioural abnormalities or sublethal effects occurred at any time during the test.

| Treatment group | after 4 hours | | after 24 hours | | after 48 hours | |
|---|---|---|---|---|---|---|
| | **mortality mean %** | **beh. abnor. mean %** | **mortality mean %** | **beh. abnor. mean %** | **mortality mean %** | **beh. abnor. mean %** |
| Test item: 115.9 µg a.s./bumble bee | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Control | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Solvent control* | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Ref.: 3.7 µg dimethoate/bumble bee | 86.0 | 6.0 | 94.0 | 2.0 | 94.0 | 4.0 |

beh. abnor. = behavioural abnormalities
mean = mean of 50 individuals per treatment group (except solvent control treatment group (n=49))
control = 50% w/v sucrose solution; solvent control = 50% w/v sucrose solution with 1% Tween80 and 5% acetone
Ref. = Reference Item
*Considering bumble bees with a food uptake of > 10 mg/bumble bee (n=49)

Validity criteria:

No specific guidelines available. Study design based on OECD 213 (1998) Van der Steen (2001) and ICPPR non-apis group (2014). The validity criteria of the test were fulfilled.

| **Validity criteria** | **Recommended** | **Obtained** |
|---|---|---|
| Control mortality | ≤ 10% | 0% |
| $LD_{50}$ of reference item at test end | ≥ 50% | 94% |

**Conclusions:**

The toxicity of trifloxystrobin tech. was tested in an acute oral toxicity test on bumble bees. The oral NOED (No Observed Effect Dose) value was calculated to be ≥ 115.9 µg a.s./bumble bee. The oral $LD_{50}$ (lethal dose) value was > 115.9 µg a.s./bumble bee.
The concentration tested in this study was limited by the maximum solubility of the test item. Since this concentration caused no mortality, the generated end-points are limited by solubility of the test item.

| | |
|---|---|
| Comments of zRMS: | The study is valid.<br>The study was realized before the OECD Guideline 246 but the criteria of validity are fulfilled.<br>**Agreed endpoints:**<br>$LD_{50}$ > 100 µg a.s./bumble bee |

| | |
|---|---|
| Reference: | **KCP 10.3.1.1/03** |
| Title: | Trifloxystrobin (tech.): Acute contact toxicity to the bumble bee, Bombus terrestris L. under laboratory conditions |
| Report: | Kling, A.; 2014; S13-01491; M-480774-01-1 |
| Authority registration No: | |
| Guideline(s): | No specific guidelines are available. The test design is based on OEPP/EPPO 170 (4) (2010); OECD Guideline 214 (1998), and on the review article of VAN DER STEEN (2001) |
| Deviations: | not applicable |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication (if vertebrate study): | |

## Objective

The objectives of this study were to determine possible effects of trifloxystrobin (tech.) on the bumble bee, *Bombus terrestris* L., from contact exposure, and to determine whether the $LD_{50}$ value is greater than the tested dose.

## Material and methods

Test item: trifloxystrobin tech. 99.1% w/w (analytical), Origin Batch No.: EDFL006101, Tox-No.: 09277-01; Material: AE C642802-01-04, density: not applicable
The contact toxicity test was carried out as a limit test with one dose of trifloxystrobin (tech.), one dose of the reference item, as well as an acetone and a water control. Bumble bees were exposed to trifloxystrobin (tech.) by topical application. At each dose and treatment, respectively, three replicate groups of 10 bumble bees each were tested. Mortality and sub-lethal effects were regularly assessed after treatment.
In the laboratory, the bumble bees were exposed to 100 µg trifloxystrobin a.s./bumble bee by topical application. Mortality and sub-lethal effects were assessed 24 and 48 hours after treatment. The control groups were exposed for the same period of time under identical exposure conditions to tap water and acetone, respectively.
An aliquot of 2 µL of the control, test and reference item solutions were applied dorsally to the thorax of each bumble bee. After the application, the bumble bees were returned to the test cages and fed with a 50 % aqueous sucrose solution *ad libitum.*

During the experimental phase, the test organisms were kept in constant darkness except during the application and the assessments. The temperature during the test period was between 24.1 and 26.1°C, the relative humidity was between 54.3 % and 61.5 %, recorded with a data logger.
Sub-lethal effects as symptoms of poisoning or any abnormal behaviour in comparison to the control were recorded at each observation interval.

Fisher's Exact Test (Bonferroni-Holms corrected, one-sided, $p \leq 0.05$) was used to evaluate whether there are significant differences between the mortality data of the test item group and the control group and to determine the NOED value (No Observed Effect Dose) based on mortality.

Dates of work: 2013-09-24 to 2013-09-26

**Results**

In the test item treatment group, no mortality and no sub-lethal effects were observed until the final assessment 48 hours after start of the experimental phase. Thus, it can be concluded that the topical application of trifloxystrobin (tech.) on bumble bees at the treatment level of 100 µg trifloxystrobin a.s./bumble bee, caused no adverse effects regarding mortality, sub-lethal effects and behaviour.

| **Treatment level [µg a.s./bumble bee]** | **Mortality [%]** | |
|---|---|---|
| | **24 h** | **48 h** |
| Control (tap water) | 0.0 | 0.0 |
| Control (acetone) | 0.0 | 0.0 |
| **Test item: Trifloxystrobin (tech.)** | | |
| 100 | 0.0 | 0.0 |
| **Reference item: Perfekthion** | | |
| 11 | 60.0 | 66.7 |

Validity criteria:

No specific guidelines available. Study design based on OEPP/EPPO 170 (4) (2010), OECD Guideline No. 214 (1998) and on the review article of VAN DER STEEN (2001). The validity criteria of the test were fulfilled.

| **Validity criteria** | **Recommended** | **Obtained** |
|---|---|---|
| Control mortality | ≤ 10% | 0% |
| $LD_{50}$ of reference item at test end | ≥ 50% | 66.7% |

**Conclusions:**

The 48 hour contact $LD_{50}$ value for trifloxystrobin (tech.) was determined to be > 100 µg a.s./bumble bee.

| **Trifloxystrobin tech.** | **Contact toxicity test [µg a.s./bumble bee]** |
|---|---|
| $LD_{50}$ (24 h) | > 100 |
| $LD_{50}$ (48 h) | > 100 |
| NOED (No Observed Effect Dose) | 100 |

## A 2.3.1.2 KCP 10.3.1.2. Chronic toxicity to bees

## A 2.3.1.3 KCP 10.3.1.3 Effects on honey bee development and other honey bee

| | |
|---|---|
| Comments of zRMS: | According to the OECD Guidance 239, in the control plates, the adult emergence rate on D22 should be ≥70% across all replicates of the control. This means that at leat 70% of emergence has to be observed in each replicate of the control individually. The adult emergence at 22 days in blank control plate is 83.3% in replicate 1, 58.3% in replicate 2, 77.8% in replicate 3. Thus the criteria of validity for adult ermergence is not completely fulfil for blank control. The blank control is not valid and cannot be used to estimate the toxicity endpoint from this study.<br>For the solvent control, the adult emergence at 22 days is 83.3% in replicate 1, |

| | |
|---|---|
| | 66.7% in replicate 2, 83.3% in replicate 3. The replicate 2 is only slightly below the trigger of 70%. In opinion of zRMS this conditions, the solvent control is sufficient to assume that the study can be considered valid but the effects observed with the test item and the corresponding endpoints have to be compared only with the solvent control.<br><br>**Agreed endpoints:**<br>~~**NOED = 12.5 µg a.s./larva**~~<br>~~**NOEC = 79 mg a.s./kg food**~~<br><br>After commenting period the study was questioned by some MSs as validity criteria only fulfilled for solvent control. Therfore, the study is not recommend to use in the risk assessment. |

| | |
|---|---|
| Reference: | **KCP /01** |
| Title: | Trifloxystrobin tech. - Repeated exposure to honey bee (Apis mellifera) larvae under laboratory conditions (in vitro) |
| Report: | Kleebaum, K.; 2019; 18 48 BLC 0044; M-648913-01-1 |
| Authority registration No: | |
| Guideline(s): | Regulation (EC) No 1107/2009 (2009)<br>Directive 2003-01 (CANADA/PMRA)<br>US EPA OCSPP 850.SUPP<br>OECD Guidance Document 239 (2016) |
| Deviations: | None |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication (if vertebrate study): | |

**Objective:**

The purpose of this study was to determine the chronic toxicity (NOED, LOED, NOEC and LOEC for adult emergence up to Day 22, and $ED_{10}$, $ED_{20}$, $ED_{50}$ if possible) of the test item to the honey bee larvae, *Apis mellifera* L., in an *in vitro* test after repeated exposure.

**Material and methods:**

Test item: Trifloxystrobin tech., batch no.: BCHR 1484-1-1, certificate number: AZ 21455, TOX10866-01, specification no.: 102000007792, active ingredient (analysed purity): 95.7 % w/w trifloxystrobin. First instar honey bee larvae of *Apis mellifera* L. were transferred from brood combs to polystyrene grafting cells in 48-well cell culture plates 2 days before the start of the exposure period (D1, grafting). Larvae were exposed to 5 concentrations of trifloxystrobin tech. via the larval diet on 4 consecutive days (D3 to D6). No additional feeding of the larvae took place after D6.

Assessments of larval mortality were done on D4, D5, D6, D7 and D8. Additionally, other observations such as small body size or unconsumed food on D8 were noted. Pupal mortality was assessed on D15 and emergence of adults was evaluated at D22.

In the analytical phase of the study, the concentration of the active ingredient trifloxystrobin tech. was determined in the larval diet of each day of the exposure period.

A reference item (dimethoate tech. at a cumulative dose of 7.6 µg a.s./larva), a blank control (water), and a solvent control (0.5 % acetone) were included in the experimental design (in the following abbreviated as AR, AC and BC respectively).

Dates of work: 2018-09-03 to 2018-09-24

**Results:**

Chemical analysis

The concentrations of the active substance were determined in the diet samples. The mean recovery of trifloxystrobin ranged between 83 % and 90 % in the final diets.

Biological observations

On Day 8, larval mortalities of 5.6 and 8.3 % were observed in the controls AC and BC, respectively. In the test item group larval mortalities on Day 8 were 58.3 %, 16.7 %, 11.1 %, 2.8 % and 16.7 % following a treatment with 50, 25, 12.5, 6.3 and 3.1 µg a.s./larva, respectively. Mortality of the reference item treated group (AR) was above 50 % on Day 8.

Other observations:

On Day 8, 17.8 %, 3.0 %, 9.4 % and 5.6 % of the remaining larvae, which were treated with 50, 25, 12.5 and 6.3 µg a.s./larva, respectively, showed signs of abnormal development (remaining food). They were removed after the assessment.

Adult emergence:

In the final assessment on Day 22, adult emergence rates of 77.8 % were determined for the honey bees in both control groups. In the test item treated group the adult honey bees emerged at rates of 25.0 %, 50.0 %, 75.0 %, 77.8 % and 75.0 % exposed to a cumulative dose of 50, 25, 12.5, 6.3 and 3.1 µg a.s./larva, respectively, during the larval stages. On Day 22, larvae treated with 50 and 25 µg a.s./larva, respectively, showed an emergence rate, which was statistically significant different compared to the solvent control (BC).

**Mortality and other observations of larvae and adult emergence in the repeated exposure toxicity test**

| Treatment group | Test solution ID | Cummulative dose [µg a.s./larva] | Conc. [mg a.s./kg food] | On Day 8 | | | On Day 22 | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | Larval mortality D3 to D8 [%] | | Mean other observations [%] | Total mortality D3 to D22 [%] | | Adult emergence rate [%] |
| | | | | abs. | corr. | | abs. | corr. | abs. |
| Control | AC | --- | --- | 5.6 | 0.0 | 0.0 | 22.2 | 0.0 | 77.8 |
| | BC | --- | --- | 8.3 | 0.0 | 0.0 | 22.2 | 0.0 | 77.8 |
| Test item | AT | 50 | 317 | 58.3 | 54.5 | 17.8 | 75.0 | 67.9 | 25.0 |
| | BT | 25 | 158 | 16.7 | 9.0 | 3.0 | 50.0 | 35.7 | 50.0 |
| | CT | 12.5 | 79 | 11.1 | 3.0 | 9.4 | 25.0 | 3.6 | 75.0 |
| | DT | 6.3 | 40 | 2.8 | 0.0 | 5.6 | 22.2 | 0.0 | 77.8 |
| | ET | 3.1 | 20 | 16.7 | 9.1 | 0.0 | 25.0 | 3.6 | 75.0 |
| Reference item | AR | 7.6 | 48 | 86.1 | 85.3 | 0.0 | 97.2 | 96.4 | 2.8 |

Results are averages based on 3 replicates (hives), containing 12 larvae each; see Appendix 4 for details; corr.: corrected mortality (according to SCHNEIDER-ORELLI 1947): mortality in test and reference item treated groups were corrected by the mortality of the solvent (BC) and the blank control (AC), respectively; abs.: absolute mortality as counted from the results; calculation were performed with non-rounded values; OO: Other observations (e.g. remaining food) * Statistical significantly different if compared to the solvent control (Step-down Cochran-Armitage Test; α=0.05; one-sided greater)

Validity criteria:

| | **Recommended** | **Obtained** |
|---|---|---|
| Larval mortality between day 3 and day 8 for the controls | ≤ 15 % | 5.6 and 8.3 % |
| Adult emergence rate until day 22 for the controls | ≥ 70 % | 77.8 and 77.8 % |
| Larval mortality between day 3 and day 8 for the reference group | ≥ 50 % | 86.1 % |

**Conclusion:**

In a repeated exposure larval toxicity study performed in a dose-response design with trifloxystrobin tech., the NOED and LOED was determined to be 12.5 µg and 25 µg a.s./larva (based on adult emergence), respectively. The corresponding NOEC and LOEC were 79 mg and 158 mg a.s./kg food, respectively.
The $ED_{50}$, $ED_{20}$ and $ED_{10}$ values (based on adult emergence) were determined to be 37.2 µg, 20.0 µg and 13.2 µg a.s./larva, respectively. The corresponding $EC_{50}$, $EC_{20}$ and $EC_{10}$ values were determined to be 236 mg, 126 mg and 84 mg a.s./kg food, respectively.
The mean recovery for trifloxystrobin ranged between 83 % and 90 % in the final diets.

### A 2.3.1.4 KCP 10.3.1.4 Sub-lethal effects

### A 2.3.1.5 KCP 10.3.1.5 Cage and tunnel tests

### A 2.3.1.6 KCP 10.3.1.6 Field tests with honeybees

### A 2.3.2 KCP 10.3.2. Effects on non-target arthropods other than bees

### A 2.3.2.1 KCP 10.3.2.1. Standard laboratory testing for non-target arthropods

| | |
|---|---|
| Comments of zRMS: | The study was considered valid in the previous Registration for Luna Sensation. Validity criteria of the test were met. Results can be used for risk assessment.<br><br>**Agreed endpoints:**<br>$LR_{50}$ and the $ER_{50}$ > i.e. 3200 mL product/ha. |

| | |
|---|---|
| Reference: | **KCP 10.3.2.1/01** |
| Title: | Dose-response toxicity (LR50) of AE C656948 & trifloxystrobin SC 250 + 250 g/L to the parasitic wasp Aphidius rhopalosiphi (Destefani-Perez) under laboratory conditions |
| Report: | Roehlig, U.; 2007; 06 10 48 189; M-283599-01-1 |
| Authority registration No: | |
| Guideline(s): | IOBC (Mead-Briggs et al. 2000); Equivalent to US EPA OPPTS Guideline No. 850.SUPP |
| Deviations: | not specified |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication (if vertebrate study): | |

**Executive summary**
Test item: AE C656948 + Trifloxystrobin SC 250 + 250 g/L (analyzed active ingredients: 21.1 % w/w (246.1 g/L) AE C656948, 21.1 % w/w (245.8 g/L) CGA 279202 (trifloxystrobin), Specification No.: 102000012886, Batch ID: 2006-004983, TOX No.: 07762-00, density: 1.165 g/$cm^3$)

The aim of the test was to evaluate possible lethal and sublethal effects of the test item on the parasitic wasp under standardized, controlled worst case conditions during an exposure period of 48 hours and a subsequent reproduction phase.
The test item was tested under laboratory conditions after residual contact exposure of adults of the parasitic wasp *Aphidius rhopalosiphi* (DESTEFANI-PEREZ) to spray residues with rates of 200 – 400 – 800 – 1600 and 3200 mL product/ha in 200 L deionized water/ha applied on glass plates. The control was treated with deionized water (200 L/ha). Dimethoate EC 400 (0.3 mL product/ha in 200 L water/ha) was used as a toxic reference item.
Adults of *Aphidius rhopalosiphi* (DESTEFANI-PEREZ) were exposed in 3 replicates of 7 female and 3 male wasps (per treatment group) to the residues of the test item, reference item and control treatments, respectively. During the mortality test, the wasps were fed with aqueous fructose solution (25 % w/v). The number of surviving wasps and the number of parasitized aphids (mummies) were recorded over a period of 14 days.

From these data the endpoints mortality and fecundity were calculated.
The results of the control group indicated that the test organisms were in a good condition (mortality: 0 %, reproduction: 15.5 mummies per female). The results of the toxic standard group indicated that the test system was sensitive to harmful substances (corrected mortality: 100 %).
Statistical analysis (FISHER`s Exact Binomial-test, 1-sided, $p \leq 0.05$) revealed no significant differences concerning the mortality after 48 hours between the control and all test item treatment groups.
A calculation of the $LR_{50}$ (median lethal rate) was not possible. Therefore, the $LR_{50}$ is empirically estimated to exceed the highest tested application rate, i.e. 3200 mL product/ha.
There was no statistically significant effect of the test item on reproduction (mean number of mummies/female) at the tested rates, when compared to the control group (DUNNETT`S multiple t-test, 1-sided, $p \leq 0.05$).

**Materials and methods:**

A. Materials

| | |
|---|---|
| 1. Test material: | AE C656948 + Trifloxystrobin SC 250+250 G |
| Specification No. | 102000012886 |
| Batch ID: | 2006-004983 |
| Visual appearance: | white fluid |
| Physical density: | 1.165 g/mL |
| Active substance 1: | AE C656948, fluopyram |
| Active ingredient 2: | CGA 279202, trifloxystrobin |
| Nominal content of active substance: | fluopyram: 250 g/L<br>trifloxystrobin: 250 g/L) |
| Analyzed content of active substance: | fluopyram: 21.1% (246.1 g/L)<br>trifloxystrobin: 21.1% (245.8 g/L) |
| Expiration date: | 2007-10-24 |
| 2. Vehicle and/or positive control | No solvent used; deionized water was used as diluent for the test item and for the reference item<br>Reference substance: Dimethoate (408.7 g/L) |
| 3. Test organism | |
| Species | Parasitic wasps *Aphidius rhopalosiphi* |
| Age | < 48 hours following hatching |
| Source of test organism | *Aphidius rhopalosiphi* were taken in the stage of mummies from Katz Biotech AG, D – 15837 Baruth, Germany. |
| Source of host organism | *Rhopalosiphum padi* (aphids) was taken from the breeding of the testing facility. |

B. Study design and methods

| | |
|---|---|
| 1. In life dates | November 27, 2006 to December 11, 2006 |
| Test duration | Mortality test: 48 hours<br>Parasitation test: 12 days (24 hours for parasitation + 11 days for the development of wasps |
| 2. Environmental conditions | |
| Temperature | 19 - 22°C |
| Relative humidity | 64 – 73% |
| Photoperiod | 16 hours light / 8 hours dark; light intensity: |
| Light intensity | 2100 lux in the mortality phase<br>4400 lux in the parasitation phase |
| Test cage | 2 square glass plates (13 cm x 13 cm), held apart by an aluminum frame (13 cm x 13 cm x 1.4 cm) with gauze covered holes for forced air ventilation (blowing air; flow rate: 2.5 L/min) |
| Parasitation cage | acrylic cylinder (11 cm Ø, 20 cm high) with 20 wheat seedlings (8 days old) infested with > 100 adult and nymphal (II- to III-instar) aphids and covered at the top of the cylinder with gauze |
| 3. Experimental treatments | |
| Mortality test: | |
| Number of wasps/cage (= 1 replicate) | 7 females + 3 males |
| Number of replicates / treatment group | 3 |
| Number of wasps/treatment group | 30 |
| Parasitation test: | |
| Number of wasps/cage (= 1 replicate) | 1 female |
| Number of replicates / treatment group | 15 |
| Number of wasps/treatment group | 15 females |

Pupae of the parasitic wasp (i.e. aphid mummies) were placed in glass bottles for hatching. A cotton wool pad soaked with aqueous fructose solution as food supply was fixed at one opening of the hatching bottle. The test wasps were used within 48 hours after hatching. The wasps were not fed, but only provided with water for 12-18 hours prior to exposure initiation.
Per replicate two glass plates were sprayed with water, the test or the reference item at the stated rates. The test solution was sprayed to a defined area (= "test arena") on one side of the glass plates. Following drying of the spray deposits (at room temperature for about 1 hour), the glass plates with the test arena to the inside were assembled with an aluminium frame containing holes. Thereafter, 7 females and 3 males of Aphidius impartially selected were confined in each cage and the holes were closed.
25 % fructose solution was added as food and watering supply and was offered to the parasitic wasps with a cotton wool thread using the capillary force. Dark paper had been fixed to the glass plates from the outside, leaving the treated area blank. The incoming light attracts the wasps ("positive phototaxis") to stay on the test arena.
Subsequently, the test units were placed in a climatic test room and connected via a water bottle with an aquarium pump for ventilation with humid air.
For the subsequent fecundity assessment, a series of pots of aphid-infested wheat was prepared. Each pot contained 20 seedlings (8 days old) infested with >100 cereal aphids (both adult and nymphal *Rhopalosiphum padi*). For the assessment of the effects on the relative fecundity of surviving wasps, 15 females per treatment group were taken from the test units after 48 h. They were individually confined to an acrylic cylinder containing untreated aphid-infested wheat plants. After 24 hours, the wasps were removed and the plants were maintained under controlled conditions for further 11 days before the number of aphid mummies was assessed (for each individual wasp).

4. Observations

The condition of the wasps in the treated arenas was assessed 2, 24 and 48 hours after start of

| |
|---|
| exposure. It was recorded as being:<br>Alive: alive and apparently unaffected<br>Affected: still upright and attempting to walk; but showing signs of reduced co-ordination; or generally inactive with respect to the insects in the control treatment<br>Moribund: on their back or side, still twitching, but generally unable to right themselves<br>Dead: no longer moving and the mortality was assessed.<br>During the fecundity assessment, mortality was observed after 24 hours of exposure and the parasitation rate was determined by counting the number of mummies for each individual wasp at the end of the parasitation test. |
| 5. Statistics |
| The software ToxRat Professional, Version 2.09 (RATTE, 2006) was used to perform the statistical analyses.<br>For statistical calculation FISHER`s Exact Binomial-test with BONFERRONI Correction (mortality) and DUNNETT`s multiple t-test (parasitisation) were used. The accepted significance level was $p \leq 0.05$.<br>A calculation of the $LR_{50}$ (median lethal rate) was not possible due to a lack of mortality. |

**Results and discussions:**

A. Findings

Mortality and reproduction after exposure of *Aphidius rhopalosiphi* to freshly dried residues of AE C656948 + Trifloxystrobin SC 250 + 250 g/L.

| **Test item** | AE C656948 + Trifloxystrobin SC 250 + 250 g/L | | | |
|---|---|---|---|---|
| **Test object** | *Aphidius rhopalosiphi* (Destefani-Perez) | | | |
| **Exposure** | Dried spray deposits on glass plates | | | |
| **Treatment** | **Mortality after 48 hours [%]** | **Reproduction** | | |
| | | **Mean number of mummies/ female** | **Relative to control [%]** | **Reduction relative to control [%]** |
| Control | 0 | 15.5 | - | - |
| Application rate [mL product/ha] | Corrected mortality [%] | | | |
| 200 | 0 | 15.5 | 100 | 0 |
| 400 | 0 | 14.7 | 94.8 | 5.2 |
| 800 | 3.3 | 14.1 | 91.0 | 9.0 |
| 1600 | 0 | 13.3 | 85.8 | 14.2 |
| 3200 | 3.3 | 12.0 | 77.4 | 22.6 |
| $LR_{50}$ | > 3200 mL product/ha | | | |
| Reference item Dimethoate EC 400 0.3 mL product/ha | 100 | - | - | - |

B. Observations

All validity criteria were met. The mortality was 0 % and the number of mummies per female was 15.5 in the control. Thus, the test accomplished the validity criteria (control group: ≤ 12.5 % (48 h) mortality and ≥ 5 mummies per female).

The mortality in the reference item group was 100 %. Thus, the test accomplished the validity criterion (mortality > 50 %).

The results of the control group indicated that the test organisms were in a good condition (mortality: 0 %, reproduction: 15.5 mummies per female).

The results of the toxic standard group indicated that the test system was sensitive to harmful substances (corrected mortality: 100 %).

Statistical analysis (FISHER`s Exact Binomial-test, 1-sided, $p \leq 0.05$) revealed no significant differences concerning the mortality after 48 hours between the control and all test item treatment groups.

**Conclusion:**

The $LR_{50}$ and the $ER_{50}$ were empirically estimated to exceed the highest tested application rate, i.e. 3200 mL product/ha.

| | |
|---|---|
| Comments of zRMS: | The study was considered valid in the previous Registration for Luna Sensation.<br>• Validity criteria of the test were met. Results can be used for risk assessment.<br>**Agreed endpoints:**<br>$LR_{50}$ and the $ER_{50}$ > i.e. 3200 mL product/ha. |

| | |
|---|---|
| Reference: | **KCP 10.3.2.1/02** |
| Title: | Dose-response toxicity (LR50) of AE C656948 & trifloxystrobin SC 250 + 250 g/L to the predatory mite Typhlodromus pyri (Scheuten) under laboratory conditions |
| Report: | Roehlig, U.; 2007; 06 10 48 190; M-283552-01-1 |
| Authority registration No: | |
| Guideline(s): | IOBC (Bluemel et al. 2000); Equivalent to US EPA OPPTS Guideline No. 850.SUPP |
| Deviations: | not specified |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication (if vertebrate study): | |

**Executive summary**

Test item: AE C656948 + Trifloxystrobin SC 250 + 250 g/L; analyzed active ingredients: 21.1 % w/w (246.1 g/L) AE C656948, 21.1 % w/w (245.8 g/L) CGA 279202 (trifloxystrobin), Specification No.: 102000012886, Batch ID: 2006-004983, TOX No.: 07762-00, density: 1.165 $g/cm^3$.
The aim of the test was to evaluate possible lethal and sublethal effects and to determine the median lethal rate ($LR_{50}$), i.e. the rate of the test item which kills 50 % of the initial number of test organisms.
The test item was tested under laboratory conditions after exposure of protonymphs of the predatory mite *Typhlodromus pyri* (SCHEUTEN) to spray residues with rates of 200 – 400 – 800 – 1600 and 3200 mL product/ha in 200 L deionized water/ha applied onto glass plates. The control was treated with deionized water (200 L/ha). Dimethoate EC 400 (10 mL product/ha in 200 L water/ha) was used as a toxic reference item.
Protonymphs of *T. pyri* were exposed in 5 replicates of 20 mites (per treatment group) to the spray residues of the test item, reference item and control treatments, respectively. During the assessments the predatory mites were fed with pollen (*Pinus nigra* and *Betula pendula*). The number of surviving, dead and escaped predatory mites and the number of eggs laid per viable female per evaluation period as well as behavioural impacts were recorded over a period of 14 days. From these data the endpoints mortality and effect on reproduction were calculated.

Statistical analysis (FISHER`S Exact Binomial-test, 1-sided**,** $p \leq 0.05$) revealed no significant differences concerning the mortality after 7 days between the control and all test item treatment groups.
A calculation of the $LR_{50}$ (median lethal rate) was not possible. Therefore, the $LR_{50}$ is empirically estimated to exceed the highest tested application rate, i.e. 3200 mL product/ha.
There was no statistically significant effect of the test item on reproduction at all tested rates (DUNNETT`s Multiple t-test, 1-sided, $p \leq 0.05$) compared to the control group.

**Material and methods:**

A. Material

| | |
|---|---|
| 1. Test material: | AE C656948 + Trifloxystrobin SC 250+250 G |
| Specification No. | 102000012886 |
| Batch ID: | 2006-004983 |
| Visual appearance: | white fluid |

| | |
|---|---|
| Physical density: | 1.165 g/mL |
| Active substance 1: | AE C656948, fluopyram |
| Active ingredient 2: | CGA 279202, trifloxystrobin |
| Nominal content of active substance: | fluopyram: 250 g/L<br>trifloxystrobin: 250 g/L) |
| Analyzed content of active substance: | fluopyram: 21.1% (246.1 g/L)<br>trifloxystrobin: 21.1% (245.8 g/L) |
| Expiration date: | 2007-10-24 |
| Testing rates (spray application) | Equivalent to 200 – 400 – 800 – 1600 – 3200 mL product/ha in 200 L/ha of deionized water |
| 2. Vehicle and/or positive control | Toxic reference item: Perfekthion EC 400, active substance: dimethoate, 408.7 g/L |
| 3. Test organism | |
| Species | predatory mite - *Typhlodromus pyri* (SCHEUTEN) (Acari: Phytoseiidae) |
| Source | purchased from "PK Nützlingszuchten<br>An der Birkenpfuhlheide 10, D-15837 Baruth,<br>on November 24, 2006 in the developmental stage of eggs |
| Age | ≤ 24 hours old protonymphs (from a synchronized cohort) |

B. Study design and methods

| | |
|---|---|
| 1. In life dates | November 28, 2006 to December 12, 2006 |
| Test duration | 14 days |
| 2. Environmental conditions | |
| Temperature | 23 - 26°C |
| Relative humidity | 73 – 79% |
| Ventilation | By air conditioning equipment of the climatic chamber |
| Photoperiod | 16 hours light / 8 hours dark; light intensity: |
| Light intensity | 2200 lux |
| Test cage | 2 glass plates (cover glasses: 50 mm x 22 mm stuck together along their longitudinal sides) with a barrier of sticky material on moistened filter paper on a sponge placed in a cage of Bellaplast (183 mm x 136 mm x 64 mm) filled with tap water;<br>refuges were provided using 2 glass cover slips (10 mm x 10 mm) placed on the glass plates within the glue enclosed area |
| 3. Experimental treatments and observations | |
| Mortality phase | |
| Number of predatory mites/test unit (1 replicate) | 20 |
| Number of replicates / treatment group | 5 |
| Number of predatory mites /treatment group | 100 |
| Fecundity phase | |
| Number of predatory/test unit | All surviving mites |
| Number of replicates / treatment group | 5 |
| Number of wasps/treatment group | All surviving mites |
| Food | Pollen: pine (Pinus nigra) and birch (Betula pendula), 1:1 (collected near |

| | |
|---|---|
| | the test facility in the spring of 2006) |
| Feeding during the test | At each assessment day |

Per replicate two cover glass plates (50 mm x 22 mm) and two glass coverslips (10 mm x 10 mm) were sprayed with the test solutions at the stated concentrations. After air-drying of the spray deposit (at room temperature for about 1 hour) the cover glasses were laid along their longitudinal side parallel to one another and touching. The treated surface was placed upwards on moistened filter paper in Bellaplast cages. A band of sticky insect glue was applied round the edges of the arena to form a barrier to prevent the mites from escaping. A shelter made of 2 glass coverslips (10 mm x 10 mm) treated on both sides was put on the top of the test arena. Then the protonymphs were put in the test arena by means of a moistened brush.
Pollen was supplied as food source. The mites obtained the necessary moisture by the upward capillary movement of water in the space between the two adjacent cover glass plates. Subsequently, the test units were placed in a climatic test room.
On day 3, 7, 9, 11 and 14 after the application, the number of surviving predatory mites was counted (from 7th day onward differentiated according to the sex), dead mites were recorded and removed. The males were differentiated from the females by their smaller and flatter phenotype. The number of laid eggs was determined on days 9, 11 and 14. Any eggs found on day 7 were removed and not counted in the fecundity assessment.
The final assessment for mortality was performed on day 7 after treatment and the final assessment for reproduction was made on day 14 after treatment.
From these data the cumulative juvenile mortality on day 7 (in %) corrected according to Abbott (1925) and the cumulative mean reproduction per female (during 7 days) were calculated.

4. Statistics

The software ToxRat Professional 2.09 was used to perform the statistical analyses.
For statistical calculation FISHER`S Exact Binomial-test with BONFERRONI Correction (mortality) and DUNNETT`s multiple t-test (fecundity) were used. The accepted significance level was $p < 0.05$.
A calculation of the LR50 (median lethal rate) was not possible due to a lack of mortality.

**Results and discussions:**

A. Findings
A 14-day exposure to five application rates of AE F656948 + trifloxystrobin SC 250 + 250 g/L caused the following effects:

| | | | | |
|---|---|---|---|---|
| **Test item** | AE C656948 + trifloxystrobin SC 250 + 250 g/L | | | |
| **Test object** | *Typhlodromus pyri* (SCHEUTEN) | | | |
| **Exposure** | Dried spray deposits on glass plates | | | |
| **Treatment** | **Mortality after 7 days [%]** | **Reproduction** | | |
| | | **Mean number of eggs/female** | **Relative to control [%]** | **Reduction relative to control [%]** |
| Control | 3 | 7.27 | - | - |
| Application rate [mL product/ha] | Corrected mortality [%] | | | |
| 200 | 2.1 | 7.21 | 99.2 | 0.8 |
| 400 | 1.0 | 7.33 | 100.8 | 0 (+ 0.8) |
| 800 | 3.1 | 7.72 | 106.2 | 0 (+ 6.2) |
| 1600 | 6.2 | 7.25 | 99.7 | 0.3 |

| | | | | |
|---|---|---|---|---|
| 3200 | 13.4 | 7.20 | 99.0 | 1.0 |
| $LR_{50}$ | > 3200 mL product/ha | | | |
| Reference item Dimethoate EC 400 10 mL product/ha | 79.4 | - | - | - |

B. Observations
All validity criteria according to BLÜMEL et al. (2000) for conducting the laboratory test with *Typhlodromus pyri* were met (control group: ≤ 20 % mortality, ≥ 4 eggs/female; reference group: 50-100 % corrected mortality).

7 days after testing was started, 3 out of 100 predatory mites were recorded as dead in the control replicates (= 3 %). By the end of the fecundity phase (day 14) the mean oviposition in the control was 7.27 eggs/female. After 7 days of exposure, 80 % of the mites were dead in the reference group (corrected mortality compared to control group: 79.4 %).

The results of the control group indicated that the test organisms were in a good condition (mortality: 3 %, reproduction: 7.27 eggs/female).
The results of the toxic standard group indicated that the test system was sensitive to harmful substances (corrected mortality: 79.4 %).

Statistical analysis (FISHER`S Exact Binomial-test, 1-sided**,** $p \leq 0.05$) revealed no significant differences concerning the mortality after 7 days between the control and all test item treatment groups.
A calculation of the $LR_{50}$ (median lethal rate) was not possible. Therefore, the $LR_{50}$ is empirically estimated to exceed the highest tested application rate, i.e. 3200 mL product/ha.

There was no statistically significant effect of the test item on reproduction at any tested rates (DUNNETT`s Multiple t-test, 1-sided, $p \leq 0.05$) compared to the control group.

**Conclusion:**

The $LR_{50}$ and the $ER_{50}$ were empirically estimated to exceed the highest tested application rate, i.e. 3200 mL product/ha.

## A 2.3.2.2 KCP 10.3.2.2. Extended laboratory testing, aged residue studies with non-target arthropods

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|---|---|
| Comments of zRMS: | The study was considered valid in the previous Registration for Luna Sensation.<br>• Validity criteria of the test were met. Results can be used for risk assessment.<br><br>**Agreed endopints:**<br>The $LR_{50}$ > 2340 mL/ha<br>At the highest test rate of 2340 mL/ha (1154 g total a.s./ha) no effect on reproduction was observed. |

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| Reference: | **KCP 10.3.2.2/01** |
| Title: | Effects of fluopyram + trifloxystrobin SC 500 (250+250 g/L) on the green lacewing Chrysoperla carnea (STEPH.) under extended laboratory conditions |
| Report: | Roehlig, U.; 2014; 14 10 48 022 A; M-482453-01-1 |
| Authority registration No: | |
| Guideline(s): | US EPA OCSPP Guideline No. 850.SUPP<br>IOBC (VOGT et al. 2000), modified for the exposure on natural substrate (extended laboratory test) |
| Deviations: | none |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication (if vertebrate study): | |

### Executive summary

The test item Fluopyram + Trifloxystrobin SC 500 (250+250 g/L) [analysed active ingredients: 21.1 % w/w (246.2 g/L) fluopyram (AE C656948); 21.2 % w/w (246.8 g/L) trifloxystrobin (CGA 279202); Specification No.: 102000012886 - 03, Batch ID: NP65CX4182, Sample description: TOX10120-00, Material No.: 06033007, density: 1.167 g/mL (according to CoA)] was tested under extended laboratory conditions after contact exposure of larvae of the green lacewing *Chrysoperla carnea* Steph. to dried spray residues of the test item with rates of 300 – 500 – 840 – 1400 – 2340 mL product/ha in 200 L deionised water/ha applied on bean leaves. The control was treated with deionised water (200 L/ha). Dimethoate EC 400 (40 mL product/ha, nominally equivalent to 16 g a.i./ha, in 200 L deionised water/ha) was used as a toxic reference item.
Larvae of *Chrysoperla carnea* Steph. were exposed in 40 replicates per treatment group and 1 larva per replicate to the residues of the test item, reference item and control treatments, respectively. During the assessments the larvae were fed with UV-sterilized eggs of *Sitotroga cereallela*. The number of dead larvae and pupae and hatched adults as well as the number of eggs laid and larvae hatched ($F_1$) were recorded over a period of 36 days. From these data the endpoint mortality was calculated. Additionally, effects on reproduction were investigated.

All validity criteria according to VOGT *et al.* (2000) for conducting the laboratory test with *Chrysoperla carnea* were met.

The aim of the test was to evaluate lethal and sublethal effects of the test item on the green lacewing and to estimate the $LR_{50}$. The reproductive ability of the hatched adults was determined at those rates in which a sufficient number of test organisms survived the exposure phase.

A calculation of the $LR_{50}$ (median lethal rate) was not possible, since the corrected mortality of the test item groups did not exceed 10.0 %. Therefore, the $LR_{50}$ is empirically estimated to exceed the highest tested application rate, 2340 mL/ha.
The NOER (no observed effect rate) for pre-imaginal mortality was the highest tested application rate, 2340 mL/ha.

**Materials and methods:**

A. Material

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| 1. Test material: | Fluopyram + Trifloxystrobin SC 500 (250 + 250 g/L) |
| Specification No. | 102000012886-03 |
| Batch ID: | NP65CX4182 |
| Visual appearance: | white suspension |
| Physical density: | 1.167 g/mL |
| Active substance 1: | AE C656948, fluopyram |
| Active ingredient 2: | CGA 279202, trifloxystrobin |
| Nominal content of active substance: | fluopyram: 250 g/L<br>trifloxystrobin: 200 g/L |
| Analyzed content of active substance: | fluopyram: 21.1% (246.2 g/L)<br>trifloxystrobin: 21.2% (246.8 g/L) |
| Expiration date: | 2015-04 |
| Testing rates (spray application) | 300, 500, 840, 1400 and 2340 mL product/ha applied in 200 L water |
| 2. Vehicle and/or positive control | Toxic reference item: EC formulation of Dimethoate: (Dimethoate = BAS 152 I: 414.4 g/L), 40 mL product/ha in 200 L water |
| 3. Test organism | |
| Species | *Chrysoperla carnea* |
| Source | Neudorff GmbH, 31860 Emmerthal |
| Age | 2-3 day old larvae |

B. Study design and methods

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| 1. In life dates | 2014-02-06 to 2014-03-14 |
| Test duration | 37 days |
| 2. Environmental conditions | |
| Temperature | 23.0 – 27.0°C |
| Relative humidity | 66 – 74%. |
| Photoperiod | 16:8 hours |
| Light intensity | 1270 Lux |
| Test cage | Mortality test: glass cylinder (4 cm Ø, 4 cm high) with gauze cover; with a treated bean leaf on moistened filter paper as bottom, fixed to a glass plate and an acrylic plate (both 25 cm x 25 cm and untreated)<br>Oviposition test: 4 L glass beaker (16 cm ∅, 22 cm height); covered with cotton gauze (mesh size 1 mm x 1 mm) providing a suitable substrate for oviposition, the gauze was held in place using an elastic band) Hatching unit for F1 larvae: plastic cage (Bellaplast) with a clear cover (inside dimensions about 16.5 cm x 12 cm x 6 cm). |
| Test plant: | Detached bean leaves (*Phaseolus vulgaris*) |
| 3. Experimental treatments and observations | |

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| Number of larvae/replicate | 1 |
| Number of replicates / treatment group | 40 |
| Number of larvae /treatment group | 40 |
| Food | **Larvae:** *ad libitum* 3 times a week, *Sitotroga cerealella* eggs (UV sterilised), stored in a refrigerator; eggs purchased from: AMW Nützlinge GmbH, 64319 Pfungstadt, Germany<br>**Adults:** each day of assessment, synthetic diet (according to the guideline) was provided as viscous pulp placed in small amounts on the inner wall (thin layer approx. 1 cm x 5 cm near the upper edge of the test unit);<br>water was provided through a piece of cotton wool which was continuously moistened by the water from a small bottle; the water bottle being placed inside the holding vessel |

The test consisted of two phases. In the exposure phase of the test, mortality of the larvae and pupae and adult emergence was determined following exposure to dried spray deposits on bean leaves. In the reproduction phase, the sublethal effects on reproductive performance (egg laying and hatching success) were assessed. In the exposure phase, 40 replicates each containing 1 larva (2-3 days old) was established for each treatment group. In the reproduction phase of the test, all hatched adults were set up for each treatment group.
In the exposure phase of the test, undamaged bean leaves from untreated plants with a diameter of about 4 cm were used as substrate. Only the most vital leaves were used and were cut shortly before application.

The test solutions were applied on the upper side of detached bean leaves in an automatic application cabin at the stated rates. After air drying of the spray deposits (at room temperature within 1 hour after application) the leaves were placed, with the treated side upward, on moistened filter paper on glass plates. Acrylic plates with drill holes (4.2 cm Ø) were placed on top of the glass plates. Glass cylinders (4 cm Ø, 4 cm high) were then fitted into the holes over the treated leaves as confinements for the green lacewing larvae during the test. One impartially selected larva (2-3 days old) and a small quantity of UV-sterilized eggs of *Sitotroga cerealella* were transferred to each confinement. The inner walls of the glass cylinders were coated with Fluon to prevent green lacewing larvae from climbing, thus warranting full exposure to the dried spray deposits over the entire test period. The test units were placed in a well-ventilated climatic chamber.
The larvae were continuously exposed to the spray residues on the bean leaves until pupation. Pupae were collected before hatching of the adults, but not earlier than 5 days after formation in order to avoid damaging the young pupae. All pupae from a treatment group were put together in a rearing box.
The mortality was recorded for larvae and pupae and was summed up for an overall pre-imaginal mortality until hatch of the adults.
The reproductive performance of the lacewings was assessed for the control and the test item treatment groups, in which a sufficient number of test organisms survived the exposure phase and successfully completed their metamorphosis.

The reproduction phase started with adults from a treatment hatched within a period of up to seven days and without deformations. These adults were sexed and put together in one oviposition unit. The oviposition started about one week after the first egg laying had been observed because the last hatched adults needed some days to mature (pre-oviposition period).
For assessment of sublethal effects two egg samples were taken within one week. Each sample covered an egg laying period of 24 hours, i.e. the oviposition units were covered with new cotton gauze for 24 hours. Eggs, which were laid on the walls of the oviposition unit, were counted as well. The number of eggs was counted after renewal of the gauze. After 2-3 days of incubation of

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| the eggs on the gauze in a hatching box, food (*Sitotroga cerealella* eggs) was added. The larvae hatched from the eggs on the gauze only were counted after 4 days. No unusual observations were noted.<br>Because egg production was > 15 eggs per female and day and viability of the eggs (= hatching rate) was > 70 % in both egg samples taken in the control and the test item treatment groups during the 1st week of the test, the assessment of the reproduction was finished after one week of egg laying and 4 additional days for larval hatch.<br>To calculate the mortality, the total number of dead larvae and dead pupae were summed up for an overall mortality of the exposure phase. The mean number of eggs per female per day (fecundity) and the mean hatching rate (fertility) were calculated for each treatment group. |
| 4. Statistics |
| Statistical analysis of mortality was performed with a Fisher`s Exact test, two-sided. P-values were adjusted according to Bonferroni-Holm. |

**Results and discussions:**

A. Findings

| **Test item** | Fluopyram + Trifloxystrobin SC 500 (250+250 g/L) | | | |
|---|---|---|---|---|
| **Test object** | *Chrysoperla carnea* STEPH. | | | |
| **Exposure** | Dried spray deposits on detached bean leaves | | | |
| **Treatment** | **Mortality [2)]** | **Corrected mortality [3)]** | **Reproduction** | |
| | | | **Fecundity** | **Fertility** |
| | **[%]** | **[%]** | **Average number of eggs/female/day (number)** | **Hatching rate [%]** |
| Control | 2.5 | | 19.9 | 72.4 |
| Application rate [1)] [mL/ha] | | | | |
| 300 | 5.0 (n.s.) | 2.6 | 19.5 | 73.5 |
| 500 | 7.5 (n.s.) | 5.1 | 20.2 | 72.8 |
| 840 | 7.5 (n.s.) | 5.1 | 19.4 | 72.6 |
| 1400 | 10.0 (n.s.) | 7.7 | 20.0 | 73.2 |
| 2340 | 7.5 (n.s.) | 5.1 | 19.6 | 72.8 |
| $LR_{50}$ | > 2340 mL/ha | | | |
| Reference item Dimethoate EC 400 40 mL product/ha | 70.0* | 69.2 | n.d. | n.d. |

1) Application rate in 200 L water/ha
2) Mortality after exposure to residues on treated bean leaves. The results for mortality in individual treatments were compared to that in the control using FISHER´S Exact Binomial test (α = 0.05).
3) Corrected mortality according to ABBOTT (1925)
(n.s.) not statistically significantly different compared to the control
* statistically significantly different compared to the control

n.d. not determined

Validity
All validity criteria were met. The mortality in the water control was ≤ 20%, the corrected mortality of the reference item was between ≥ 50%, the number of eggs per female and day in the water control was ≥ 15 and the mean hatching rate of the eggs in the water control was ≥ 70%.

**Conclusion:**

The $LR_{50}$ is empirically estimated to exceed the highest tested application rate, 2340 mL/ha.
The reproductive output was above the lower limit given as validity criteria (average number of fertile eggs per viable female per day ≥ 15 and mean hatching rate ≥ 70 % in the control group) according to the historical database of the ring testing group (VOGT *et al.* 2000). According to that, this parameter was considered as not impacted by the treatment.

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| Comments of zRMS: | The study was considered valid in the previous Registration for Luna Sensation.<br>• Validity criteria of the test were met. Results can be used for risk assessment<br>**Agreed endpoints:**<br>The $LR_{50}$ = 139.0 mL/ha (95% confidence limits 113.2 – 170.7 mL/ha).<br>The $ER_{50}$ > 100 mL/ha. |

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| Reference: | **KCP 10.3.2.2/02** |
| Title: | Dose-response toxicity of AE C656948 & Trifloxystrobin SC 250 + 250 to the predatory bug Orius laevigatus (FIEBER) (Heteroptera: Anthocoridae) under extended laboratory conditions |
| Report: | Barth, M.; 2007; 07 10 48 049 A; M-297476-01-1 |
| Authority registration No: | |
| Guideline(s): | IOBC (BAKKER et al. 2000) modified for the exposure on natural substrate (excised leaf discs); Equivalent to US EPA OPPTS Guideline No. 850.SUPP |
| Deviations: | natural substrate was used instead of glass plates |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication (if vertebrate study): | |

**Executive summary**

Test item: AE C656948 + Trifloxystrobin SC 250 + 250 (analyzed content: 246.1 g/L AE C656948 + 245.8 g/L trifloxystrobin (CGA 279202); specification No.: 102000012886, Batch ID.: 2006-004983, TOX No.: 07762-00.

The test item was tested under extended laboratory conditions on the predatory bug *Orius laevigatus* after contact exposure to spray residues on excised grape-vine leaf discs. Endpoints were the mortality of exposed nymphs and the reproductive performance of adult bugs compared to control on day 10 and on day 23, respectively, after application.
After 10 days of exposure, mortality of 15.0, 11.7, 30.0, 45.0, 65.0 and 93.3 % was recorded in the control and at 25, 50,100, 200 and 400 mL/ha, respectively. The corrected mortality according to Abbott was 0.0, 17.6, 35.3, 58.8 and 92.2 % in the 25, 50, 100, 200 and 400 mL/ha treatments, respectively.

The $LR_{50}$ (the application rate causing 50 % corrected mortality) of AE C656948 + trifloxystrobin SC 250 + 250 to *Orius laevigatus* was calculated to be 139.0 mL/ha (95% confidence limits 113.2 – 170.7 mL/ha).
The mean daily oviposition was 6.1, 6.4, 5.4 and 5.0 eggs per female and day in the control and at the 25,

50 and 100 mL/ha treatment levels, respectively. The mean percent hatching rate of eggs laid during the oviposition periods of the test was 89.2, 88.4, 88.6 and 90.1 % in the control and at the 25, 50 and 100 mL/ha treatment levels, respectively.
Overall, the mean number of viable eggs produced per reproductive female during the 4-day egg laying period was 5.4, 5.6, 4.8 and 4.5 in the control and the 25, 50 and 100 mL/ha treatment group, respectively. The differences between control and test item treatments were not statistically significant.
The relative effect on reproductive performance was +3.7, -11.0 and -16.8 % at the application rates of 25, 50 and 100 mL/ha, respectively. These values indicating no decreased reproductive performance compared to the control and no significant effects on reproductive performance were visible up to a treatment level of 100 mL/ha.
No reproduction phase test was conducted with the test item rates > 100 mL/ha or with the reference item, due to the mortality observed at these rates during the exposure phase.

**Materials and methods:**

A. Material

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| 1. Test material: | AE C656948 + Trifloxystrobin SC 250+250 G |
| Specification No. | 102000012886 |
| Batch ID: | 2006-004983 |
| Visual appearance: | white fluid |
| Physical density: | 1.165 g/mL |
| Active substance 1: | AE C656948, fluopyram |
| Active ingredient 2: | CGA 279202, trifloxystrobin |
| Nominal content of active substance: | fluopyram: 250 g/L<br>trifloxystrobin: 250 g/L) |
| Analyzed content of active substance: | fluopyram: 21.1% (246.1 g/L)<br>trifloxystrobin: 21.1% (245.8 g/L) |
| Expiration date: | 2007-10-24 |
| Testing rates | based upon results of a range finding test: 25, 50, 100, 200 and 400 mL product/ha in 200 L/ha each applied in a single application on excised grape-vine leaf discs |
| 2. Vehicle and/or positive control | Toxic reference item: Perfekthion EC 400, active substance: dimethoate, 386.9 g/L |
| 3. Test organism | |
| Species | predatory bug - *Orius laevigatus* (FIEBER) / nymphs (Heteroptera: Anthocoridae) |
| Source | Syngenta Bioline Production Ltd.; Telstar Nursery; Holland Road, Little Clacton, Essex CO16 9QG, United Kingdom |
| Age | II-instar nymphs (4 days after hatching) |
| Acclimatization/pre culturing: | *O. laevigatus* (eggs/nymphs) were held under the following conditions:<br>temperature: 23 – 24 °C<br>relative humidity: 67 - 71 %<br>light intensity: 800 lux<br>photoperiod: 16 hours light and 8 hours dark |

B. Study design and methods

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| 1. In life dates | October 18, 2007 to November 10, 2007 |
| Test duration | Exposure phase: 10d; mating phase: 4d, reproduction phase 4 days + 5 additional days for hatching after 1st and 2nd egg counting |

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|---|---|---|
| | Total duration: 23d | |
| 2. Environmental conditions | | |
| Temperature | 24.7 – 27°C | |
| Relative humidity | 53 – 65 % | |
| Ventilation | By air conditioning equipment of the climatic chamber | |
| Photoperiod | 16 hours light / 8 hours dark; light intensity: | |
| Light intensity | 800 lux | |
| 3. Experimental treatments and observations | | |
| Number of insects/ test cage (1 replicate): | exposure phase: | 10 |
| | reproduction phase: | 1 female |
| Number of replicates/ treatment group: | exposure phase: | 6 |
| | reproduction phase: | 15 |
| Number of insects/ treatment group: | exposure phase: | 60 (nymphs) |
| | reproduction phase: | 15 females |
| Food: | before and during the test, the insects (nymphs and adults) were fed ad libitum with untreated Sitotroga cerealella eggs (fresh eggs (UV sterilized) stored at 2-4 °C); during the test fresh untreated food added every 2-3 days<br>Sitotroga-eggs were purchased from: AMW Nützlinge GmbH, D-64319 Pfungstadt, Germany | |
| Test cage | exposure phase:<br>small plastic Petri dish (∅ 3.5 cm, 1.2 cm high; thin agar layer; treated grape-vine leaf disc) covered with a lid (with a hole ∅ 1.5 cm covered with metal gauze)<br>mating phase:<br>2 L glass cylinder (for each treatment group) covered with a gauze lid<br>reproduction phase:<br>small plastic petri dish (∅ 3.5 cm, 1.2 cm high; thin agar layer; untreated bean leaf disc) covered with a clear Petri dish lid | |
| Test plant: | untreated grape vine, "Weißer Gutedel" (genus Vitis Mitschurinski) | |
| Test plant cultivation: | grape-vine of about 1.0 - 1.5 m height with 40–70 leaves per tree cultivated in pots (Ø 19 cm, 15 cm height) (cultivated under semi-field conditions without use of plant protection products during the actual growing season) | |

Procedures:
In the exposure phase, pre-imaginal mortality of *O. laevigatus* was determined following exposure to dried residues on grape-vine leaf discs.
In the reproduction phase, the sublethal effects of the test item on reproductive parameters (egg laying and hatching success) were assessed.

The test consisted of 7 treatment groups: control, 5 test item application rates and a reference item rate. In the exposure phase, 6 replicates each containing 10 second-instar nymphs were established for each treatment group.
In the reproduction phase of the test, 15 replicates each containing one mated *O. laevigatus* female were set up. For treatment groups in which the number of surviving *O. laevigatus* was not high enough (≥ 50 % corrected mortality) to ensure a correct assessment of the reproduction, no reproduction phase was performed.

In the exposure phase of the test, 2nd instar nymphs (4 days after hatching) were exposed to treated plants (leaf discs) for 10 days. The treatments were applied onto the upper (dorsal) surface of the grape-vine leaf discs using a SCHACHTNER track-sprayer.
Before the Petri dish was covered with the lid, the 2nd -instar *O. laevigatus* were taken from holding vessels and transferred into the test cages. Thereafter, the food was added and the test cages were placed in a climatic chamber. Only untreated food was supplied on the first day and thereafter every 2-3 days.
The exposure phase was terminated when all control insects reached at least the last (5th) nymphal stage and approximately 80 % of the insects were adults (after 10 days after exposure).

At completion of the mortality assessment phase (exposure phase), the surviving nymphs or adults within each treatment group were transferred in a 2 L glass cylinder for 4 additional days until all insects had reached the adult stage and had an opportunity to mate. After this period, 15 single females were selected, placed singularly in the reproduction test cages and food was added. The sex was determined by observing the ventral side of the abdomen through a transparent pipette tip under a microscope. After every 2 days, the single females were transferred to a new oviposition cage for a second oviposition period. The egg assessment was terminated on reproduction day 4. The cages including leaves with eggs (of the 1st and 2nd egg assessment) were stored for 5 additional days for assessment of the hatching success (successfully hatched: eggs with opened caps and empty shell).
For the toxic reference no reproduction phases were conducted because there were insufficient organisms that survived the exposure phase (the number of surviving females was < 15).

Observations/Assessments:
The surviving nymphs or adults were recorded on day 10 of the exposure phase. The test cages were examined individually and the number of dead and surviving nymphs or adults was recorded. The day of transfer of the females to the oviposition cages was designated as reproduction day 0. The number of eggs was inspected first after 2 days of the reproduction test. One additional inspection was made on reproduction day 4. Each test cage was inspected for the number of eggs laid on the bean leaf disc and for surviving, dead or missing females.
The oviposition phase of the test was terminated on reproduction day 4. The number of successfully hatched nymphs was determined after 5 additional days of the 1st and 2nd egg counting.

Statistical analyses:
The $LR_{50}$ with respect to the mortality was calculated by Probit analysis according to the maximum likelihood method (FINNEY 1971). The goodness-of-fit of the model was evaluated by Pearson's $Chi^2$ test.
The mortality and fecundity results were analyzed using the $Chi^2$ test with Bonferroni correction and the Dunnett-test, respectively. The accepted significance level was $p \leq 0.05$.
The calculation of statistical significance and the $LR_{50}$ was performed using the computer program ToxRat Professional 2.09 (2006).

**Results and discussions:**

A. Findings

Survival of *Orius laevigatus* FIEBER (pre-imaginal mortality)

| **Treatment group** | | **Survivors** | | | | | | **Mortality (%)** | **Corrected mortality (ABBOTT) (%)** |
|---|---|---|---|---|---|---|---|---|---|
| | | **Nymphs** | ♀ | ♂ | Σ | **Mean/ replicate** | **SD** | | |
| Control | | 5 | 27 | 19 | 51 | 8.5 | 1.05 | 15.0 | - |
| Reference item | | 1 | 0 | 0 | 1 | 0.2 | 0.41 | 98.3* | 98.0 |
| Test | 25 | 16 | 23 | 14 | 53 | 8.8 | 0.98 | 11.7 | 0 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| item | mL/ha | | | | | | | | |
| Test item | 50 mL/ha | 16 | 11 | 15 | 42 | 7.0 | 1.79 | 30.0* | 17.6 |
| Test item | 100 mL/ha | 13 | 8 | 12 | 33 | 5.5 | 1.22 | 45.0* | 35.2 |
| Test item | 200 mL/ha | 10 | 6 | 5 | 21 | 3.5 | 0.84 | 65.0* | 58.8 |
| Test item | 400 mL/ha | 4 | 0 | 0 | 4 | 0.7 | 0.82 | 93.3* | 92.2 |

* Statistically significant difference (Chi$^2$ test with Bonferroni correction, $p \leq 0.05$)
SD: standard deviation

Reproduction test of *Orius laevigatus* FIEBER (with 15 females surviving the exposure phase)

| **Treatment group** | | **Mean eggs/female/day (number)** | **Mean viable eggs/reproductive female/day** | **Mean hatched nymphs/egg (%)** | **Reduction in** | |
|---|---|---|---|---|---|---|
| | | | | | **fecundity (%)** | **fertility (%)** |
| Control | | 6.1 | 89.2 | 5.4 | - | - |
| Test item | 25 mL/ha | 6.4 | 88.4 | 5.6 | -4.6 | -3.7 |
| Test item | 50 mL/ha | 5.4 | 88.6 | 4.8 | 10.7 | 11.0 |
| Test item | 100 mL/ha | 5.0 | 90.1 | 4.5 | 17.6 | 16.8 |

Negative values indicate a better performance than observed in the control.

B. Observations

Validity:
The mortality was 15.0 % in the control and 98.3 % in the toxic reference group; 6.1 eggs/female/day were laid in the control group with a mean hatching rate of 89.2 %. One female produced no eggs within the 4-day reproduction phase in the control treatment group. Thus, the validity criteria (control group: ≤ 25 % mortality, toxic reference group: > 40 % mortality, control group: number of eggs/female/day ≥ 2, number of females producing no eggs < 5 and hatching success (control) ≥ 70 %) were accomplished.

Behavior:
No abnormal nymphal behavior was observed in any treatment group during the test for surviving individuals.

Mortality:
No statistically significant effects on survival were found for the application rate of 25 mL/ha. All test item application rates including and above 50 mL/ha resulted in a statistically significant effect on survival if compared to control assessed on day 10 after exposure of nymphs on treated leaf discs.
The mean percentage mortality in the control, test item at 25, 50, 100, 200 and 400 mL/ha and toxic reference treatment were 15.0, 11.7, 30.0, 45.0, 65.0, 93.3 and 98.3 %, respectively.
The $LR_{50}$ (the application rate causing 50 % reduction of Orius-survival after correction of mortalities according to ABBOTT) of AE C656948 + trifloxystrobin SC 250 + 250 to *Orius laevigatus* was calculated to be 139.0 mL/ha (95% confidence limits 113.2 – 170.7 mL/ha).

Fecundity:
No statistically significant differences in the average number of eggs/female/day were observed in the 25, 50 and 100 mL/ha treatment groups when compared to the control group.
The mean number of eggs per female per day was 6.1, 6.4, 5.4 and 5.0 for the control and the application rates of 25, 50 and 100 mL/ha, respectively.

Nymph hatch:
No significant differences for the hatching success (% of eggs from which nymphs had hatched, i.e. the

number of viable eggs per reproductive female) were observed in the 25, 50 and 100 mL/ha treatment groups when compared to control group. The mean hatching rate was 89.2, 88.4, 88.6 and 90.1 % for the control and the application rates of 25, 50 and 100 mL/ha, respectively.

The mean number of viable eggs produced per reproductive female during the 4-day egg laying period was 5.4, 5.6, 4.8 and 4.5 in the control and the 25, 50 and 100 mL/ha treatment group, respectively. The differences were not statistically significant. The relative effect on reproductive performance was -3.7, +11.0 and 16.8 % at the application rates of 25, 50 and 100 mL/ha, respectively.

Based on these values no negative effects on reproductive performance were visible up to a treatment level of 100 mL/ha.

**Conclusion:**

The $LR_{50}$ (the application rate causing 50 % reduction of *Orius*-survival after correction of mortalities according to ABBOTT) of AE C656948 + Trifloxystrobin SC 250 + 250 to *Orius laevigatus* was calculated to be 139.0 mL/ha (95% confidence limits 113.2 – 170.7 mL/ha). The $ER_{50}$ exceeded 100 mL/ha.

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| Comments of zRMS: | The study was considered valid in the previous Registration for Luna Sensation. The exposure to 14 days aged residues of Fluopyram + Trifloxystrobin SC 250 + 250 applied on grape-vine leaves resulted in 51.9% mortality of *Orius laevigatus* nymphs until adulthood (corrected according to Abbott). No fecundity and fertility test was performed due to less numbers of surviving adults.<br><br>The exposure to 21 days aged residues of Fluopyram + Trifloxystrobin SC 250 + 250 applied on grape-vine leaves resulted in 7.0% mortality of *Orius laevigatus* nymphs until adulthood (corrected according to Abbott). The fecundity and fertility of the surviving adults were reduced by 2.9% and increased by 1.8%, respectively, relative to control.<br><br>The exposure to 28 days aged residues of Fluopyram + Trifloxystrobin SC 250 + 250 applied on grape-vine leaves resulted in 7.3% mortality of *Orius laevigatus* nymphs until adulthood (corrected according to Abbott). The fecundity and fertility of the surviving adults were increased by 5.6% and 2.1%, respectively, relative to control.<br><br>In conclusion, potential for recovery can be considered after 14 days following the last application but was evident 21 days following the last application, with exposure to aged residues resulting effects on survival and reproduction below 50%.<br>**Agreed endpoints:**<br>Fresh residues, 7-days aged residues and 14-days aged residues: >50% mortality<br>21 and 28 days aged residues: mortality <10%, reproduction not affected |

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|---|---|
| Reference: | **KCP 10.3.2.2/03** |
| Title: | Toxicity of AE C656948 & Trifloxystrobin SC 250 + 250 to the predatory bug Orius laevigatus (FIEBER) (Heteroptera: Anthocoridae) under extended laboratory conditions using semi-field-aged residues on grape-vine |
| Report: | Barth, M.; 2008; 07 10 48 005 A; M-297471-01-1 |
| Authority registration No: | |
| Guideline(s): | IOBC (BAKKER et al. 2000) modified for the exposure on natural substrate; Equivalent to US EPA OPPTS Guideline No. 850.SUPP |
| Deviations: | under semi-field conditions applied and aged residues on natural substrate were used instead of glass plates |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication (if vertebrate study): | |

**Materials and methods:**

Test item: Fluopyram + Trifloxystrobin SC 250 + 250 (246.1 g/L fluopyram (AE C656948) + 245.8 g/L trifloxystrobin; Specification No.: 102000012886, Batch ID: 2006-004983, TOX No.: 07762-00).

Fresh and aged residues of the test item Fluopyram + Trifloxystrobin SC 250 + 250 (2 x 0.8 L product/ha, 7 days interval) were tested under extended laboratory conditions with the predatory bug *Orius laevigatus* after contact exposure on leaf discs prepared from grape-vines sprayed under semi-field conditions. Endpoints were the mortality of exposed nymphs and the reproductive performance of adult bugs compared to control after exposure on day 0, 7, 14, 21 and 28 after last application.
Five bioassays were conducted with an exposure period of 10 days each, initiated on the day of the 2nd (last) application (DAT 0, bioassay 1), 7 days after the last application (DAT 7, bioassay 2), 14 days after the last application (DAT 14, bioassay 3), 21 days after last application (DAT 21, bioassay 4) and 28 days after the last application (DAT 28, bioassay 5).

During these successive bioassays, mortalities of 15.0, 11.7, 13.3, 5.0 and 8.3% and 96.7, 90.0, 58.3, 11.7 and 15.0% were recorded for the control and the test item in bioassay 1, 2, 3, 4 and 5, respectively.
The corresponding corrected mortality (according to Abbott) in these five bioassays was calculated at 96.1, 88.7, 51.9, 7.0 and 7.3%, respectively.
No reproduction phase was conducted in bioassays 1, 2 and 3, due to the high mortality. In bioassays 4 and 5 (started on DAT 21 and 28) the relative effect on reproductive performance was -1.8% (increased) and -2.1% (increased), respectively, in the test item treatment group.

**Results and discussions:**

A. Findings
The test endpoints were mortality and the effect on reproduction in comparison with the control group. Exposure to 0, 7, 14, 21 and 28 days aged residues of the test item Fluopyram + Trifloxystrobin SC 250 + 250 gave the following results:

| **Treatment group** | **Surviving nymphs/ adults (no.)** | **Mortality** | | **Eggs/ female/ day (mean no)** | **Viable eggs/ female/ day (mean no)** | **Hatched nymphs/ egg (%)** | **Reduction in** | |
|---|---|---|---|---|---|---|---|---|
| | | **Absolute (%)** | **Corrected (according to Abbott) (%)** | | | | **Fecundity (%)** | **Fertility (%)** |
| 1st bioassay (DAT 0) | | | | | | | | |
| Control | 51 | 15.0 | - | - | - | - | - | - |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Toxic reference | 0 | 100* | 100 | - | - | - | - | - |
| Test item | 2 | 96.7* | 96.1 | - (a) | - | - | - | - |
| 2nd bioassay (DAT 7) | | | | | | | | |
| Control | 53 | 11.7 | - | - | - | - | - | - |
| Toxic reference | 0 | 100* | 100 | - | - | - | - | - |
| Test item | 6 | 90.0* | 88.7 | - (a) | - | - | - | - |
| 3rd bioassay (DAT 14) | | | | | | | | |
| Control | 52 | 13.3 | - | - | - | - | - | - |
| Toxic reference | 0 | 100* | 100 | - | - | - | - | - |
| Test item | 25 | 58.3* | 51.9 | - (a) | - | - | - | - |
| 4th bioassay (DAT 21) | | | | | | | | |
| Control | 57 | 5.0 | - | 6.8 | 5.7 | 89.7 | - | - |
| Toxic reference | 0 | 100* | 100 | - | - | - | - | - |
| Test item | 53 | 11.7 | 7.0 | 6.6 | 5.8 | 93.7 | 2.9 | -1.8 |
| 5th bioassay (DAT 28) | | | | | | | | |
| Control | 55 | 8.3 | - | 5.4 | 4.8 | 91.4 | - | - |
| Toxic reference | 1 | 98.3* | 98.2 | - | - | - | - | - |
| Test item | 51 | 15.0 | 7.3 | 5.7 | 4.9 | 91.3 | -5.6 | -2.1 |
| * Statistically significant ($p \leq 0.05$)<br>(a) no reproduction phase conducted due to high mortality during the exposure period<br>(negative values indicating an increase compared to control) | | | | | | | | |

B. Observations

Validity:
The validity criteria for the control group and the toxic standard were accomplished

| | |
|---|---|
| - Mortality in the control group: | ≤ 25% (being 15.0, 11.7, 13.3, 5.0 and 8.3% during 1st, 2nd , 3rd, 4th and 5th bioassay) |
| - Mortality in the reference item: | > 40% (being 100, 100, 100, 100 and 98.3% during 1st, 2nd , 3rd, 4th and 5th bioassay) |
| - Number of eggs/female/day in the control: | ≥ 2.0 (being 6.8 and 5.4 during 4th and 5th bioassay) |
| - Number of females in the control producing no eggs: | < 5 (being 1 during 4th and 5th bioassay) |
| - Hatching rate in the control: | ≥ 70% (being 89.7 and 91.4% during 4th and 5th bioassay) |

Nymphal behavior:
No abnormal nymphal behavior was observed in any treatment group during the test for surviving individuals.

**Conclusion:**

The exposure to 14 days aged residues of Fluopyram + Trifloxystrobin SC 250 + 250 applied on grape-vine leaves resulted in 51.9% mortality of *Orius laevigatus* nymphs until adulthood (corrected according to Abbott). No fecundity and fertility test was performed due to less numbers of surviving adults.

The exposure to 21 days aged residues of Fluopyram + Trifloxystrobin SC 250 + 250 applied on grape-vine leaves resulted in 7.0% mortality of *Orius laevigatus* nymphs until adulthood (corrected according to Abbott). The fecundity and fertility of the surviving adults were reduced by 2.9% and increased by 1.8%, respectively, relative to control.

The exposure to 28 days aged residues of Fluopyram + Trifloxystrobin SC 250 + 250 applied on grape-vine leaves resulted in 7.3% mortality of *Orius laevigatus* nymphs until adulthood (corrected according to Abbott). The fecundity and fertility of the surviving adults were increased by 5.6% and 2.1%, respectively, relative to control.

In conclusion, potential for recovery can be considered after 14 days following the last application but was evident 21 days following the last application, with exposure to aged residues resulting effects on survival and reproduction below 50%.

## A 2.3.2.3 KCP 10.3.2.3. Semi-field studies with non-target arthropods

## A 2.3.2.4 KCP 10.3.2.4. Field studies with non-target arthropods

## A 2.3.2.5 KCP 10.3.2.5. Other routes of exposure for non-target arthropods

## A 2.4 KCP 10.4 Effects on non-target soil meso- and macrofauna

## A 2.4.1 KCP 10.4.1 Earthworms

### A 2.4.1.1 KCP 10.4.1.1 Earthworms - sub-lethal effects

| | |
|---|---|
| **Comments of zRMS**: | The study was considered valid in the previous Registration for Luna Sensation. According to the guideline, the weight of the worms should be 300-600 mg. However, the weight of some of the worms exposed was less than 300 mg. Since this can be considered as a minor deviation, the study is acceptable. Validity criteria of the test were met. Results can be used for risk assessment.14d LC50 > 1000 mg product/kg dry weight soil, which is equivalent to 422 mg total a.s./kg soil dw.<br><br>**Agreed endpoints:**<br>The overall NOEC is determined to be 5.0 L product/ha, corresponding to 23.3 mg product/kg dry weight artificial soil. Thus, the overall LOEC is determined to be 8.0 L product/ha.<br><br>The NOEC related to growth ≥ 18.0 L product/ha (corresponding to ≥ 83.9 mg product/kg dry weight artificial soil). The LOEC related to growth > 18.0 L product/ha.<br>The NOEC related to reproduction is 5.0 L product/ha (corresponding to 23.3 mg product/kg dry weight artificial soil). corresponding to 9.83 mg total a.s./kg soil dw.<br>The LOEC related to reproduction is 8.0 L product/ha. |

| | |
|---|---|
| Reference: | **KCP 10.4.1.1/01** |
| Title: | AE C656948 & trifloxystrobin SC 250 & 250 G: effects on survival, growth and reproduction on the earthworm Eisenia fetida tested in artificial soil with 5 percent peat |
| Report: | Leicher, T.; 2007; LRT-RG-R-28/06; M-283637-01-1 |
| Authority registration No: | |
| Guideline(s): | International Standards ISO 11268-2: 1998(E): „Soil quality - Effects of pollutants on earthworms (Eisenia fetida) Part 2: Determination of effects on reproduction, July 1998. OECD 222: April 13, 2004: "OECD Guideline for the Testing of Chemicals Earthworm Reproduction Test (Eisenia fetida / Eisenia andrei)"; Equivalent to US EPA OPPTS Guideline No. 850.6200 SUPP |
| Deviations: | none |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication (if vertebrate study): | |

### Executive summary

Test item: AE C656948 + Trifloxystrobin SC 250 + 250 G; (Specification No.: 102000012886; Material No.:06033007; Batch no.: 2006-004983; content of a.s. (analyzed): AE C656948: 246.1 g/L (21.1 % w/w) + trifloxystrobin: 245.8 g/L (21.1 % w/w); density: 1.165 g/mL.

Adult *Eisenia fetida* (approx. 8 months old, 8 × 10 animals for the control group and 4 × 10 animals per application rate of the treatment group) were exposed in an artificial soil to the application rates of 3.0 – 5.0 – 8.0 – 12.0 – 18.0 L product/ha, corresponding to 14.0 – 23.3 – 37.3 – 55.9 – 83.9 mg product/kg dry weight artificial soil under the conditions of the test. After 28 days the number of surviving animals and their weight alteration was determined. They were then removed from the artificial soil. After further 28 days, the number of offspring was determined.

No mortality of adult earthworms was observed after 28 days of exposure at any application rate of the test item in this study.
No statistically significant different values for the growth relative to the control were observed at any application rate including the highest application rate of 18.0 L product/ha. No statistically significant different values for the number of juveniles per test vessel relative to the control were observed at the application rates of 3.0 and 5.0 L test item/ha. Statistically significant different values for the number of juveniles per test vessel relative to the control were observed at the application rates of 8.0, 12.0 and 18.0 L product/ha.

The overall NOEC is determined to be 5.0 L product/ha, corresponding to 23.3 mg product/kg dry weight artificial soil. Thus, the overall LOEC is determined to be 8.0 L product/ha.

**Materials and methods:**

A. Materials

| | |
|---|---|
| 1. Test material: | AE C656948 + Trifloxystrobin SC 250+250 G |
| Specification No. | 102000012886 |
| Batch ID: | 2006-004983 |
| Visual appearance: | white fluid |
| Physical density: | 1.165 g/mL |
| Active substance 1: | AE C656948, fluopyram |
| Active ingredient 2: | CGA 279202, trifloxystrobin |
| Nominal content of active substance: | fluopyram: 250 g/L<br>trifloxystrobin: 250 g/L) |
| Analyzed content of active substance: | fluopyram: 21.1% (246.1 g/L)<br>trifloxystrobin: 21.1% (245.8 g/L) |
| Expiration date: | 2007-10-24 |
| 2. Vehicle and/or positive control | Reference substance: Derosal flüssig (active substance: carbendazim 360 g/L) is tested at least once a year in a dose response study (sprayed onto soil). |
| 3. Test organism | |
| Species | *Eisenia fetida andrei* |
| Age | Adult worms (ca. 8 months, with clitellum)<br>Weight: 0.25 g – 0.45 g/worm at the start of the study |
| Source | Strain of Prof. Graff, Forschungsanstalt für Landwirtschaft, Braunschweig, Germany held in the laboratory for several years |
| Breeding conditions | The breeding substrate consists of about 55 % by weight of natural soil, 34 % peat and 4.2 % straw and 6.8% animal manure (dry weight in each case). The animals are fed on ground, animal manure at 14 day intervals. At the same time, the substrate is also replenished with water. In order to obtain a synchronized culture of earthworms, 100 adult earthworms were kept in a rearing vessel with substrate and food for a period of 4 weeks. After this time, the adult earthworms were picked out of the substrate again and the offspring hatched from the cocoons. The age of the worms from the synchronized |

| | |
|---|---|
| | culture differed by not more than 4 weeks |
| Environmental breeding conditions | |
| Temperature | 22 ± 2°C |
| Acclimation period | For 4 days prior to the test start, the test organisms were acclimated to the artificial soil and test temperature. |

B. Study design and methods

| | |
|---|---|
| 1. In life dates | October 16, 2006 to December 18, 2006 |
| Test duration | The study consisted of 2 parts. Adult earthworms were exposed to the test item for a period of 4 weeks (first part): after this period, the adults were removed from the test vessels and the cocoons and juvenile earthworms remained in the test vessels for additional 4 weeks (second part). The total duration of each run of the study was 8 weeks. |
| 2. Experimental treatments | |
| Temperature (room) | 20 + 2°C |
| Photoperiod | 16-hour light – 8-hour darkness photoperiod |
| Light intensity | 400 - 800 lux |
| Test container | Non re-usable plastic boxes of size: 16.5 x 12 x 6 cm, surface around 200 cm2, containing an amount of about 500 g artificial soil (dry weight) to obtain a depth of approximately 5 cm soil in the test vessels.<br>The test vessels were covered with transparent lids to prevent earthworms from escaping and to reduce evaporation during the test period. The lids were perforated to allow air exchange. |
| Test substrate | Artificial soil with the following composition (percentage distribution on dry weight basis):<br>Sphagnum peat (With respect to the properties of the ingredients of the test item (log $P_{OW}$ ≥ 2) 5% peat instead of 10% peat was used considering the influence on bioavailability (EPPO 2002).),<br>Kaolinite clay (20%, content of Kaolinite ($Al_2Si_2O_5$ $(OH)_4$) = 56%),<br>industrial quartz sand (Sort: F 36), 73.85%, particle size: 0.20 mm – 0.05 mm = 89.5%),<br>calcium carbonate ($CaCO_3$): 0.15%, for the adjustment to pH 6.0 ± 0.5.<br>Food (air dried and finely shredded cow manure) 1%<br>The moisture of the artificial soil was adjusted to nominal 30.0 % corresponding to approximately 58 % of the maximum water holding capacity of the artificial soil. At day 0; the mean soil moisture was 21.91% and at day 56 it was 20.4%. |
| pH of the soil during the test | 6.72 to 6.87 |
| 3. Experimental treatments | |
| Number of earthworm/replicate | Ten earthworms were placed in a randomized procedure in each test container. The average weight was 0.25 – 0.45 g. |
| Number of replicates | 4 per treatment group,<br>8 for the control group |

| | |
|---|---|
| Feeding | The adult earthworms were fed once per week during the test period with approximately 5 g food / vessel. The offspring were fed only once at the start of the second 4 weeks exposure period by mixing the food into the soil |
| AE C656948 + trifloxystrobine SC 250 + 250 G was sprayed at application rates of 3.0 – 5.0 – 8.0 – 12.0 – 18.0 L product/ha, corresponding to 14.0 – 23.3 – 37.3 – 55.9 – 83.9 mg product/kg dry weight artificial soil containing earthworms *Eisenia fetida*. | |
| 3. Observations | |
| Endpoints and Statistical method<br>The endpoints were mortality, change of biomass (difference in fresh weight of surviving worms between test start and four weeks after treatment) and reproduction (the number of juveniles present). The arithmetic mean and the standard deviation per treatment and per control for reproduction and biomass were calculated.<br>The statistical analysis was performed with the software ToxRat Professional 2.09. The reproduction of the surviving test organisms per test vessel at the end of the study was compared to the control values.<br>The homogeneity of variances of the data was checked by Cochran's test. The homogeneity hypothesis was accepted.<br>The normal distribution of the data was tested by Kolmogorov-Smirnov test.<br>The normality hypothesis of the data was accepted.<br>The data showed a monotonous decrease of responses in the sample populations. Therefore, the data were statistically evaluated by means of a Williams multiple sequential t-test.<br><br>Soil quality data<br>Physico-chemical parameters of the artificial soil (water content, pH; analyzed from mixed samples for each test group) were measured at the start and at the end of the test.<br><br>Analytical verification<br>The analytical concentrations of the active substances were not determined, since an analytical check of the test concentrations for this reproduction test was not specified in the test guideline. | |

**Results and discussions:**

A. Findings

Reproduction of the earthworms (Values in this table are rounded values)

| **Application rate (L product/ha)** | **Box No.** | **Reproduction rate (per surviving adult)** | | **Juvenile earthworms per test box** | | | | **Statistical evaluation*** |
|---|---|---|---|---|---|---|---|---|
| | | | **Mean ± SD** | | **Mean ± SD** | **CV (%)** | **% of control** | |
| Control | 1 | 26.3 | 23.5 ± 2.4 | 263 | 234.8 ± 24.5 | 10.4 | 100.0 | --- |
| | 2 | 25.8 | | 258 | | | | |
| | 3 | 19.9 | | 199 | | | | |
| | 4 | 22.5 | | 225 | | | | |
| | 5 | 26.3 | | 263 | | | | |
| | 6 | 22.7 | | 227 | | | | |
| | 7 | 21.0 | | 210 | | | | |
| | 8 | 23.3 | | 233 | | | | |
| 3.0 | 1 | 23.7 | 23.0 | 237 | 230.0 | 8.1 | 98.0 | n.s. |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 2 | 25.0 | ± 1.9 | 250 | ± 18.6 | | | |
| | 3 | 20.6 | | 206 | | | | |
| | 4 | 22.7 | | 227 | | | | |
| 5.0 | 1 | 22.0 | 21.8 ± 1.9 | 220 | 217.5 ± 19.3 | 8.9 | 92.7 | n.s. |
| | 2 | 24.1 | | 241 | | | | |
| | 3 | 21.5 | | 215 | | | | |
| | 4 | 19.4 | | 194 | | | | |
| 8.0 | 1 | 17.2 | 19.0 ± 2.9 | 172 | 190.0 ± 29.1 | 15.3 | 80.9 | s. |
| | 2 | 15.9 | | 159 | | | | |
| | 3 | 20.9 | | 209 | | | | |
| | 4 | 22.0 | | 220 | | | | |
| 12.0 | 1 | 21.1 | 17.5 ± 3.5 | 211 | 174.8 ± 34.6 | 19.8 | 74.4 | s. |
| | 2 | 12.9 | | 129 | | | | |
| | 3 | 17.1 | | 171 | | | | |
| | 4 | 18.8 | | 188 | | | | |
| 18.0 | 1 | 17.4 | 16.0 ± 1.1 | 174 | 159.8 ± 10.5 | 6.6 | 68.1 | s. |
| | 2 | 15.0 | | 150 | | | | |
| | 3 | 15.4 | | 154 | | | | |
| | 4 | 16.1 | | 161 | | | | |

* Statistical comparison of mean reproduction per test vessel:
Result of a Williams Multiple Sequential t-test, one-sided smaller, $\alpha = 0.05$
n.s.: mean value not statistically significantly different compared to the control ($p \geq 0.05$)
s.: mean value statistically significantly different compared to the control ($p < 0.05$)

B. Observations

No mortality of adult earthworms was observed after 28 days test duration in the control group and at any application rate, including the highest rate of 18.0 L test item/ha of AE C656948 + trifloxystrobin SC 250 + 250 G.

The mean body weight of the adult earthworms in the control group had increased during the 4 weeks exposure. The mean body weight was 0.49 g per worm (+ 50.4 % of the mean initial weight).

No statistically significant different values for the growth relative to the control were observed at the application rates of 3.0, 5.0, 8.0, 12.0 and 18.0 L test item/ha. Increase in the mean initial weight was + 54.1 %, + 52.8 %, + 54.8 %, + 45.2 % and + 52.7 %, respectively.

In the control group, on average 234.8 juvenile earthworms per test vessel were found (corresponding to a mean reproduction rate of 23.5 juveniles per surviving adult).
For the product treatment groups exposed to AE C656948 + Trifloxystrobin SC 250 + 250 G up to and including the highest application rate of 18.0 L product/ha, the mean reproduction rate was in the range of 68.1 % to 98.0 % of the control value.

No statistically significant different values for the number of juveniles per test vessel relative to the control were observed at the application rates of 3.0 and 5.0 L product/ha. Statistically significant different values for the number of juveniles per test vessel relative to the control were observed at the application rates of 8.0, 12.0 and 18.0 L product/ha.

**Conclusion:**

The overall NOEC is determined to be 5.0 L product/ha, corresponding to 23.3 mg product/kg dry weight artificial soil. Thus, the overall LOEC is determined to be 8.0 L product/ha.

The NOEC related to growth is ≥ 18.0 L product/ha (corresponding to ≥ 83.9 mg product/kg dry weight artificial soil). The LOEC related to growth is > 18.0 L product/ha.
The NOEC related to reproduction is 5.0 L product/ha (corresponding to 23.3 mg product/kg dry weight artificial soil). The LOEC related to reproduction is 8.0 L product/ha.

### 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)

Comments of zRMS:

The study was considered valid in the previous Registration for Luna Sensation.
At the highest test rate of 1000 mg test item/kg dry weight artificial soil (426 mg total a.s./kg dry weight artificial soil) no effect on mortality was observed.
At the test rate of 316 mg test item/kg dry weight artificial soil (135 mg total a.s./kg dry weight artificial soil) no effect on reproduction was observed.

**Agreed endpoints:**

**Effects on mortality and reproduction of *Hypoaspis aculeifer***

| Test item<br>Test object<br>Exposure | **Fluopyram + Trifloxystrobin SC 500 G**<br>*Hypoaspis aculeifer*<br>Artificial soil | |
|---|---|---|
| | **Adult mortality** | **Reproduction** |
| | **[mg test item/kg soil d.w.]** | |
| NOEC | ≥ 1000<br>(426 mg a.s./kg dws) | 316<br>(135 mg total a.s./kg dws) |
| LOEC | > 1000 | 562 |
| $EC_{10}$ 1)<br>(95% confidence limits) | | 457<br>(25 – 645) |
| $EC_{20}$ 1)<br>(95% confidence limits) | | 702<br>(275 – 998) |

Calculations were done with un-rounded values.
1) Probit analysis

| Reference: | **KCP 10.4.2/01** |
|---|---|
| Title: | Fluopyram + trifloxystrobin SC 500 (250+250) G: Influence on mortality and reproduction of the soil mite species Hypoaspis aculeifer tested in artificial soil |
| Report: | Larnaudie Lopez, M. I.; 2016; E 428 4844-4; M-548820-01-1 |
| Authority registration No: | |
| Guideline(s): | OECD 226 from October 03, 2008: OECD guideline for the Testing of Chemicals - Predatory mite (Hypoaspis (Geolaelaps) aculeifer) reproduction test in soil; US EPA OCSPP: not applicable |
| Deviations: | none |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication (if vertebrate study): | |

**Objective:**

The purpose of this study was to assess the effect of Fluopyram + Trifloxystrobin SC 500 (250+250) G on mortality and reproduction of the soil mite species *Hypoaspis aculeifer* tested during an exposure of 14 days in artificial soil by comparing control and treatment.

**Materials and methods:**

Fluopyram + Trifloxystrobin SC 500 (250+250) G (analytical findings: 21.1 % w/w fluopyram (AE C656948) equivalent to 246.2 g/L; 21.5 % w/w trifloxystrobin (CGA 279202) equivalent to 250.8 g/L; density: 1.165 g/mL (20°C); supplier batch no.: PAIS005173; sample description: REG40032-00; specification no.: 102000012886)

Ten adult, fertilized female *Hypoaspis aculeife*r per replicate (8 replicates for the control group and 4 replicates for each treatment group) were exposed to control and treatments. Concentrations of 100, 178, 316, 562 and 1000 mg test item/kg dry weight artificial soil were mixed into the artificial soil. During the test, the *Hypoaspis aculeife*r were fed with nematodes bred on watered oat flakes. During the study a temperature of 20 ± 2 °C and light regime of 400 – 800 Lux, 16 h light : 8 h dark were applied. The artificial soil was prepared according to the guideline with the following constituents (percentage distribution on dry weight basis): 75 % fine quartz sand, 5 % Sphagnum peat, air dried and finely ground, 20 % Kaolin clay.
After a period of 14 days, the surviving adults and the living juveniles were extracted by applying a temperature gradient using a MacFadyen-apparatus. Extracted mites were collected in a fixing solution (20 % ethylene glycol, 80 % deionised water; 2 g detergent/L fixing solution were added). All *Hypoaspis aculeifer* were counted under a binocular.

Reference item (Dimethoate): 1.00, 1.80, 3.2, 5.6 and 10.0 mg/kg soil d.w.; control: untreated, solvent control: none.

Dates of work: November 25 – December 21, 2015

**Results and discussions:**

Biological findings:

| test item<br>test object<br>exposure | Fluopyram + trifloxystrobin SC 500 (250+250) G<br>*Hypoaspis aculeifer*<br>artificial soil | | | | |
|---|---|---|---|---|---|
| mg test item/kg dry weight artificial soil | adult mortality (%) | significance (*) | mean number of juveniles per test vessel ± standard dev. | reproduction (% of control) | significance (**) |

| | | | | | | |
|---|---|---|---|---|---|---|
| Control | 1.3 | --- | 265.6 ± | 21.2 | --- | --- |
| 100 | 2.5 | - | 320.8 ± | 27.5 | 120.8 | - |
| 178 | 2.5 | - | 319.5 ± | 13.1 | 120.3 | - |
| 316 | 2.5 | - | 267.8 ± | 14.8 | 100.8 | - |
| 562 | 7.5 | - | 214.8 ± | 22.0 | 80.8 | + |
| 1000 | 2.5 | - | 186.0 ± | 30.1 | 70.0 | + |

Calculations were done with un-rounded values.
(*) = Fisher´s exact Binomial Test with Bonferroni Correction, one-sided greater, α=0.05, "-": non-significant; "+": significant
(**) = William's t-test, one sided smaller; α=0.05; "-": non-significant; "+": significant

Mortality:
In the control group 1.3 of the adult *Hypoaspis aculeifer* died which is below the allowed maximum of ≤ 20 % mortality.
Concerning the mortality of the adult test organisms statistical analysis (Fisher´s Exact Binomial Test with Bonferroni Correction, one-sided greater, α = 0.05) revealed no significant difference between control and any treatment group.
Therefore the No-Observed-Effect-Concentration (NOEC) for mortality is ≥1000 mg test item/kg dry weight artificial soil. The Lowest-Observed-Effect-Concentration (LOEC) for mortality is >1000 mg test item/kg dry weight artificial soil.

Reproduction:
Concerning the number of juveniles statistical analysis (William's t-test, one-sided smaller, α = 0.05) revealed a significant difference between control and treatment groups with 562 and 1000 mg test item /kg dry weight artificial soil.
Therefore the No-Observed-Effect-Concentration (NOEC) for reproduction is 316 mg test item/kg dry weight artificial soil. The Lowest-Observed-Effect-Concentration (LOEC) for reproduction is 562 mg test item/kg dry weight artificial soil.

**Effects on mortality and reproduction of *Hypoaspis aculeifer***

| Test item<br>Test object<br>Exposure | **Fluopyram + Trifloxystrobin SC 500 G**<br>*Hypoaspis aculeifer*<br>Artificial soil | |
|---|---|---|
| | **Adult mortality** | **Reproduction** |
| | **[mg test item/kg soil d.w.]** | |
| NOEC | ≥ 1000 | 316 |
| LOEC | > 1000 | 562 |
| $EC_{10}$ 1)<br>(95% confidence limits) | | 457<br>(25 – 645) |
| $EC_{20}$ 1)<br>(95% confidence limits) | | 702<br>(275 – 998) |

Calculations were done with un-rounded values.
1) Probit analysis

Validity criteria:

| | **Recommended** | **Obtained** |
|---|---|---|
| Mean mortality of adult females | ≤ 20% | 1.3% |
| Mean number of juveniles per replicate | ≥ 50 | 265.6 |
| Coefficient of variation (mean number of juveniles per replicate) | ≤ 30% | 8.0% |

All validity criteria were met. Therefore this study is valid.

**Conclusion:**

The test item Fluopyram + Trifloxystrobin SC 500 (250+250) G showed no statistically significantly adverse effects on adult mortality of the predatory mite *Hypoaspis aculeifer* at all tested concentrations. The test item showed statistically significantly adverse effects on reproduction of *Hypoaspis aculeifer* in the treatment groups with 562 and 1000 mg test item /kg dry weight artificial soil. 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 316 and 562 mg test item/kg soil d.w., respectively. The $EC_{10}$ and $EC_{20}$ value for reproduction were calculated to be 457 and 702 mg test item/kg soil dry weight, respectively.

| | |
|---|---|
| Comments of zRMS: | The study was considered valid. All validity criteria were met.<br>**Agreed endpoints:**<br>NOEC for mortality and reproduction =562 mg test item/kg soil d.w. corresponding to 240. 2 mg total a.s./mg dws)<br>LOEC for reproduction =1000 mg test item/kg soil d.w.<br>The $EC_{10}$ and the $EC_{20}$ for reproduction = 605 mg test item/kg soil d.w. and 887 mg test item/kg soil d.w., respectively. |

| | |
|---|---|
| Reference: | **KCP 10.4.2/02** |
| Title: | Fluopyram + trifloxystrobin SC 500 (250+250) G: Effects on mortality and reproduction of the collembolan species Folsomia candida tested in artificial soil |
| Report: | Friedrich, S.; 2017; 16 10 48 273 S; M-576685-01-1 |
| Authority registration No: | |
| Guideline(s): | EU Directive 91/414/EEC; Regulation (EC) No 1107/2009 (2009); US EPA OCSPP Not Applicable |
| Deviations: | none |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication (if vertebrate study): | |

**Objective:**

The purpose of this study was to determine potential effects of the test item on the reproductive output of the collembolan *Folsomia candida* as a representative of soil micro-arthropods during a test period of 28 days. After 4 weeks the number of offspring (juveniles) and surviving parental collembolans were counted.

**Materials and methods:**

Test item: Fluopyram + trifloxystrobin SC 500 (250+250) G, Short name: FLU+TFS SC 500 (250+250) G, Supplier batch No.: PAIS005173, Sample description: REG40032-00, Specification No.: 102000012886, active ingredients (analysed content): 246.2 g/L (21.1 % w/w ) fluopyram (AE C656948), 250.8 g/L (21.5 % w/w) trifloxystrobin (CGA 279202), Density (20 °C): 1.165 g/mL, water solubility: dispersible.

Collembola (9-12 days old, reared in the laboratory) were exposed to a control treatment and 18 – 32 – 56 – 100 – 178 – 316 – 562 – 1000 mg test item/kg dry weight mixed into artificial soil containing 74.7 % quartz sand, 20 % kaolin clay, 5 % sphagnum peat and 0.3 % $CaCO_3$. The control group and treatment group consisted of 8 replicates (+ 2 replicates without collembolans for measurement purposes) and 4 replicates (+ 2 replicates without collembolans for measurement purposes), respectively. Test units were

glass container (approximately 150 mL) covered with a lid and surface area of soil 18.9 cm².
Collembola were exposed at 18.6 – 19.9 °C and a photoperiod: light : dark = 16 h : 8 h (580 lux) and were fed weekly with granulated dry yeast. Mortality and reproduction were determined after 28 days.
The statistical analysis was performed with the software ToxRat Professional.

The reference item boric acid (100 % analysed) was tested in a separate study at concentrations of 44, 67, 100, 150 and 225 mg/kg soil dry weight.

**Results and discussions:**

Biological findings:

| **Test item**<br>**Test object**<br>**Exposure** | **Fluopyram + Trifloxystrobin SC 500 (250+250) G**<br>***Folsomia candida***<br>**Artificial soil** | | | | |
|---|---|---|---|---|---|
| **mg test item/kg dry weight artificial soil (nominal concentrations)** | **Adult mortality (%)** | **Significance (**)** | **Mean number of juveniles per test vessel ± standard deviation** | **Reproduction (% of control)** | **Significance (*)** |
| Control | 2.5 | | 686 ± 57 | - | |
| 18 | 2.5 | - | 704 ± 56 | 103 | - |
| 32 | 2.5 | - | 685 ± 83 | 100 | - |
| 56 | 2.5 | - | 685 ± 144 | 100 | - |
| 100 | 2.5 | - | 667 ± 53 | 97 | - |
| 178 | 2.5 | - | 681 ± 154 | 99 | - |
| 316 | 5.0 | - | 686 ± 33 | 100 | - |
| 562 | 15.0 | - | 616 ± 90 | 90 | - |
| 1000 | 32.5 | + | 521 ± 63 | 76 | + |
| | | | | **Mortality** | **Reproduction** |
| NOEC (mg test item/kg dry weight artificial soil)<br>LOEC (mg test item/kg dry weight artificial soil) | | | | 562<br>1000 | 562<br>1000 |
| | | | | **Reproduction** | |
| $EC_{10}$ (mg test item/kg dry weight artificial soil)1)<br>95% confidence limits<br>$EC_{20}$ (mg test item/kg dry weight artificial soil)1)<br>95% confidence limits | | | | 605<br>(511 – 715)<br>887<br>(808 – 973) | |

The calculations were performed with unrounded values
1) Logit analysis for reproduction
(*) = (Williams-t-test, one-sided-smaller, α = 0.05, + = significant, - = not significant)
(**) = (Multiple Sequentially-rejective Fisher Test After Bonferroni-Holm, one-sided-greater, α = 0.05, + = significant, - = not significant)

Mortality rates of 2.5 % - 32.5 % were recorded in the test item treatment groups. 2.5 % parental mortality was observed in the control. Statistically significant effects on mortality compared to the control were observed at a concentration of 1000 mg test item/kg soil dry weight (Multiple Sequentially-rejective Fisher Test After Bonferroni-Holm, α = 0.05, one-sided greater). No effects on behaviour of the collembolans were observed during the test.
The mean number of juvenile collembolans counted four weeks after introduction of the parental collembolans into the test vessels was 686 in the control and 704, 685, 685, 667, 681, 686, 616 and 521 at concentrations of 18, 32, 56, 100, 178, 316, 562 and 1000 mg test item/kg soil d.w., respectively. Statistically significant effects (Williams-t-test, α = 0.05, one-sided smaller) on the number of juveniles compared to the control group were recorded at a concentration of 1000 mg test item/kg soil d.w.

Reference test:

In a separate study (BioChem project No. R 16 10 48 003 S, dated 2016-08-08), the $EC_{50}$ (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:

| | **Recommended** | **Obtained** |
|---|---|---|
| Mean adult mortality | ≤ 20 % | 2.5 % |
| Mean number of juveniles per replicate | ≥ 100 | 686 |
| Coefficient of variation (mean number of juveniles per replicate) | < 30 % | 8.4 % |

All validity criteria were met. Therefore this study is valid.

**Conclusion:**

The test item Fluopyram + Trifloxystrobin SC 500 G showed statistically significantly adverse effects on adult mortality of the collembolan *Folsomia candida* in artificial soil at a concentration of 1000 mg test item/kg d.w. The test item caused a significant reduction of reproduction of the collembolan *Folsomia candida* in artificial soil at a concentration of 1000 mg test item/kg d.w. Therefore, the No-Observed-Effect-Concentration (NOEC) for mortality and reproduction was determined to be 562 mg test item/kg soil d.w. and the Lowest-Observed-Effect-Concentration (LOEC) for reproduction was determined to be 1000 mg test item/kg soil d.w.
The $EC_{10}$ and the $EC_{20}$ for reproduction were determined to be 605 mg test item/kg soil d.w. and 887 mg test item/kg soil d.w., respectively.

### A 2.4.2.1 KCP 10.4.2.1 Species level testing

### A 2.4.2.2 KCP 10.4.2.2 Higher tier testing

### A 2.5 KCP 10.5 Effects on soil nitrogen transformation

| | |
|---|---|
| Comments of zRMS: | The study was considered valid in the previous Registration for Luna Sensation.<br>**Agreed endpoints:**<br>During the 56-day test, 1.07 µL Fluopyram + Trifloxystrobin SC 500 (250+250) G had no relevant influence on nitrogen transformation in a soil amended with lucerne-grass-green meal.<br>The 10-fold dose of Fluopyram + trifloxystrobin SC 500 (250+250) G caused a temporary stimulation of the daily nitrate rates at the time interval 0-7 days, 14-28 days and 28-42 days after treatment At the end of the experiment (42-56 day interval), differences in the nitrate-N rates between control soil samples and treated soil samples are below the trigger value of 25%. |

| | |
|---|---|
| Reference: | **KCP 10.5/01** |
| Title: | Fluopyram + trifloxystrobin SC 500 (250+250) G: Determination of effects on nitrogen transformation in soil |
| Report: | Leicher, T.; 2007; LRT-N-91/07; M-295282-01-1 |
| Authority registration No: | |
| Guideline(s): | OECD 216; adopted January 21, 2000, OECD Guideline for the Testing of Chemicals, Soil Microorganisms: Nitrogen Transformation Test; Equivalent to US EPA OPPTS Guideline No. 850.SUPP |
| Deviations: | At day 42 the soil moisture was below the demanded minimum of 40 of the maximum water holding capacity (36.1 %). |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication (if vertebrate study): | |

**Executive summary**

Test item: Fluopyram + Trifloxystrobin SC 500 (250+250) G; analytical findings: Fluopyram, 251.5 g/L, trifloxystrobin, 253.5 g/L; specification No.: 102000012886, batch No.: 2007-000441, Master recipe ID: 0036845-001, TOX-No.: 07851-00.

The objective of the test was to determine the influence of the product on nitrogen transformation in an agricultural soil.
A loamy sand soil was exposed for 56 d to 1.07 µL and 10.67 µL product/kg dry weight soil. Application rates were equivalent to 0.8 L and 8 L product/ha. Lucerne-grass-green meal was added to the soil (5 g/kg dry weight soil) to stimulate nitrogen transformation.
Individual values and the mean values for the rates of nitrate-N formation for 5 respective time intervals (0-7 days, 7-14 days, 14-28 days, 28-42 days, 42-56 days) were determined.
The product did not cause a change in the soil pH.

During the 56-day test, 1.07 µL Fluopyram + Trifloxystrobin SC 500 (250+250) G had no relevant influence on nitrogen transformation in a soil amended with lucerne-grass-green meal. The 10-fold dose of Fluopyram + Trifloxystrobin SC 500 (250+250) G caused a temporary stimulation of the daily nitrate rates at the time interval 0-7 days, 14-28 days and 28-42 days after treatment. At the end of the experiment (42-56 day interval), differences in the nitrate-N rates between control soil samples and treated soil samples are < 25 %. Since the values are <25% the study was terminated at 56 days per aforementioned guideline.

**Materials and methods:**

A. Materials

| | |
|---|---|
| 1. Test material: | AE C656948 + Trifloxystrobin SC 250+250 G |
| Material number: | 06033007 |
| Batch ID: | 2007-000441 |
| Visual appearance: | white fluid |
| Physical density: | 1.174 g/mL |
| Active substance 1: | AE C656948, fluopyram |
| Active ingredient 2: | CGA 279202, trifloxystrobin |
| Nominal content of active substance: | fluopyram: 250 g/L<br>trifloxystrobin: 250 g/L) |
| Analyzed content of active substance: | fluopyram: 21.4% (251.5 g/L)<br>trifloxystrobin: 21.6% (253.5 g/L) |
| Expiration date: | 2008-02-21 |
| 2. Vehicle and/or positive control | Quartz sand |
| 3. Test substrate | |

| | |
|---|---|
| Soil | Loamy sand soil |
| Collection | The soil was collected on June 05, 2007 at a depth of 0-20 cm, passed through a 2 mm sieve and stored at 4 ± 2°C until used. |
| Source | The soil used is from field plot E1 on the Bayer CropScience AG's experimental farm Laacher Hof, Germany, located at latitude 51°4'N and longitude 6°55'E. |
| Soil history | Plant protection chemicals have not been used on this field since 2000. The plot has been under grass and has not been treated with fertilizers since 2000. |
| Characterization of the soil (particle size) – measured annually | Particle Size Distribution (µm) in Weight % was 2000-630 µm (4.7%), 630-200 µm (50.9%), 200-63 µm (18.8%), 63-20 µm (6.7%), 20-6.3 µm (6.2%), 6.3-2.0 µm (4.1%) and 2.0-0 µm (8.7%). |
| Characterization of the soil (% of soil organic carbon content) | 0.94% – measured annually |
| Characterization of the soil (carbon content of the metabolically active microbial biomass) | Biomass (mg microbial C/kg dry weight soil) = 384 Carbon content = 4.1 mg/kg calculated as 384/(0.94 x 100) – measured at the start of the test |
| Characterization of the soil (nitrogen content) | 0.09% – measured annually |
| Characterization of the soil (Cation Exchange Capacity) | 6.0 meq/100 g dry weight soil – measured annually |
| Organic substrate | Lucerne-grass-green meal (containing 40.6% $C_{total}$, 0.05% $C_{inorg}$ and 2.5% N) |
| Environmental conditions: | |
| Temperature | 20 ± 2°C |
| Photoperiod | permanent dark |

B. Study design and methods

| | |
|---|---|
| 1. In life dates | August 21, 2007 – October 17, 2007 |
| 2. Experimental treatments | |
| 900 g dry weight sieved soil (2 mm) was treated with either 10 g ground quartz sand/kg dry weight soil (control) or a mixture of quartz sand and Fluopyram + trifloxystrobin SC 500 (250+250) G (1.07 µL or 10.67 µL/kg dry weight soil). The samples were mixed with pulverized Lucerne-grass-green meal (5 g/kg dry weight soil) and quartz sand in 3 litre polyethylene containers.<br>After mixing, soil samples equivalent to 300 g dry weight were poured into 500 mL brown glass bottles and these were closed with parafilm. Three replicates were prepared per treatment. The soil was held in the dark at 20 ± 2°C and at about 40-60% of the maximum water holding capacity ($WHC_{max}$). | |
| 3. Observations | |
| The soil moisture and the maximum water holding capacity were determined on day 1, 7, 14, 28, 42 and 56.<br>Immediately after treatment and after 7, 14, 28, 42 and 56 days, a moist sample, corresponding to 10 g dry weight, was removed and extracted with 50 ml 1 M-KCl. Subsequently, soil particles were removed by filtration and the extracts analyzed for their content of ammonium-N, nitrite-N and nitrate-N.<br>The measured values of ammonium, nitrate and nitrite were divided by their molecular weight and expressed as ammonium-N, nitrate-N and nitrite-N respectively.<br>The pH-values were measured at the beginning and end of the tests.<br>The % differences in the quantities of nitrate-N formed between control soils and treated soils were expressed as absolute values and determined as follows:<br>((treatment rates – control rates)/control rates) x 100% = % difference.<br>Homogeneity of variances was determined by Cochran's test, α = 0.05. | |

Depending on the results the appropriate t-tests were performed.
In the t-test, the values of nitrate-N/kg dry weight soil/time interval/day (Table 5) from control soils and treated soils were compared. The statistical calculations were carried out using ToxRatPro 2.09).

**Results and discussions:**

A. Findings
The pH values at the beginning and the end of the study in untreated and treated samples were between 5.83 and 6.14, so the test item did not cause a change in the soil pH.
The soil moisture remained between 40 and 60% of the maximum water holding capacity. At day 42 the soil moisture was below the demanded minimum of 40 % of the maximum water holding capacity. The test vessels were rewetted.

Nitrogen Transformation:

Nitrogen transformation in a loamy sand soil treated with Fluopyram + trifloxystrobin SC 500 (250+250) G and amended with lucerne-grass-green meal (mean value of 3 soil replicates ± standard deviation)

| **Days after treat-ment** | **Application rate [mg Fluopyram + Trifloxystrobin SC 500 (250+250) G /kg d.wt.s.]** | | | | | |
|---|---|---|---|---|---|---|
| | **0** | | **1.07 µL** | | **10.67 µL** | |
| | **mg Nitrogen (N)/kg d.wt.s.** | | **mg Nitrogen (N)/kg d.wt.s.** | | **mg Nitrogen (N)/kg d.wt.s.** | |
| | **Ammonium-N** | **Nitrate-N** | **Ammonium-N** | **Nitrate-N** | **Ammonium-N** | **Nitrate-N** |
| 0 | 4.16 ± 0.08 | 18.39 ± 0.56 | 3.89 ± 0.28 | 17.34 ± 0.21 | 4.07 ± 0.21 | 17.06 ± 0.06 |
| 7 | 2.20 ± 0.29 | 3.99 ± 0.26 | 1.98 ± 0.35 | 5.87 ± 2.06 | 1.91 ± 0.29 | 9.02 ± 1.62 |
| 14 | 1.82 ± 0.16 | 8.39 ± 0.03 | 2.04 ± 0.46 | 9.73 ± 1.31 | 2.05 ± 0.23 | 13.23 ± 1.14 |
| 28 | 1.98 ± 0.18 | 23.00 ± 0.36 | 1.91 ± 0.10 | 25.68 ± 0.72 | 2.00 ± 0.16 | 31.70 ± 0.93 |
| 42 | 2.04 ± 0.26 | 41.93 ± 1.05 | 1.84 ± 0.21 | 44.74 ± 1.87 | 1.98 ± 0.16 | 55.57 ± 0.95 |
| 56 | 2.44 ± 0.34 | 51.26 ±1.29 | 1.92 ± 0.51 | 52.99 ± 2.30 | 1.74 ± 0.23 | 62.95 ± 0.45 |

B. Observations
All validity criteria were met. In this study, the highest coefficient of variation (CV) between nitrate-N concentrations in replicate control samples was 7 % (7 days after treatment) and thus did not exceed the recommended limit $\leq$ 15 %.

Nitrite formation was not detected in any of the soil samples.
The highest difference between nitrate-N rates per day of control and the one-fold-treated soil samples was 20 % (0-7 days after soil treatment).
The highest difference between nitrate-N rates per day of control and of the 10-fold-treated soil samples was 44 % (0-7 days after soil treatment).

Effects on non-target soil micro-organisms (nitrogen transformation):

| **Test item** | Fluopyram + Trifloxystrobin SC 500 (250+250) G | |
|---|---|---|
| **Test object** | Soil Micro-organisms<br>Nitrogen-Transformation (loamy sand soil) | |
| **Exposure** | 56 days | |
| **µL product/kg dry weight soil** | 1.07 | 10.67 |
| **L test item/ha (equivalent)** | 0.8<br>(recommended field rate) | 8.0<br>(10 times recommended field rate) |
| **Final result: Difference in rates of nitrogen formation between control and treatment groups** | Difference to control:<br>12% (<25%) | Difference to control:<br>21% (<25%) |

**Conclusion**

During the 56-day test, 1.07 µL Fluopyram + Trifloxystrobin SC 500 (250+250) G had no relevant influence on nitrogen transformation in a soil amended with lucerne-grass-green meal. The 10-fold dose of Fluopyram + trifloxystrobin SC 500 (250+250) G caused a temporary stimulation of the daily nitrate rates at the time interval 0-7 days, 14-28 days and 28-42 days after treatment At the end of the experiment (42-56 day interval), differences in the nitrate-N rates between control soil samples and treated soil samples are below the trigger value of 25%.

## 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

No additional studies are submitted.

### A 2.6.2 KCP 10.6.2 Testing on non-target plants

| | |
|---|---|
| Comments of zRMS: | The study was considered valid in the previous Registration for Luna Sensation.<br>**Agreed endpoints:** |

| **Fluopyram + Trifloxystrobin SC 500** | | | | |
|---|---|---|---|---|
| **Test design** | **Test species** | **Ecotoxicological endpoint** | | |
| | | **application rate** | **effects** | **parameter** |
| Tier 1 test glasshouse vegetative vigor test 21 days | 7 dicotyledonous plant species from 7 different families<br><br>3 monocotyledonous plant species from 2 families | 0.75 L/ha | < 50% | Survival, visual phytotoxicity and shoot dry weight |

| | |
|---|---|
| Reference: | **KCP 10.6.2/01** |
| Title: | Non-target terrestrial plants: an evaluation of the effects of AE C656948 + Trifloxystrobin SC 250 + 250 g/L in the vegetative vigour test (Tier 1) |
| Report: | Gosch, H.; Nguyen, D. H.; 2007; VV07/03; M-289527-01-1 |
| Authority registration No: | |
| Guideline(s): | OECD 227 (July 200): vegetative vigour test (Tier 1); Equivalent to US EPA OPPTS Guideline No. 850.4150 |
| Deviations: | none |
| GLP/GEP: | no |
| Acceptability: | |
| Duplication (if vertebrate study): | |

**Executive summary**

Test item: Fluopyram + Trifloxystrobin SC 250 + 250 g/L, sample description: TOX07851-00, master recipe ID: 0036845-001, batch ID: 2007-000441, appearance: white suspension, expiry date: 21.02.2008

The purpose of this specific study was to evaluate the effect of AE C656948 + Trifloxystrobin SC 250 + 250 g/L on the vegetative vigour of ten plant species representing a broad range of both dicotyledonous and monocotyledonous plant families over a 21 day period.
Ten species of terrestrial non-target plants (3 monocots and 7 dicots) were treated at an application rate of 0.75 L product (AE C656948 + Trifloxystrobin SC 250 + 250 g/L) / ha. Plants were treated at the 2-4-leaf stage with foliar spray application. Spray treatments were applied once, at test initiation, with a sprayer set at the nominal spray volume of 200 litres/ha. Control pots were sprayed with deionized water. Four to five replicates with four to five plants per pot for each species were tested. All pots were individually contained in saucers and retained on benches within a greenhouse.
Plants were assessed for survival and phytotoxicity on days 7, 14 and 21. At study termination, endpoint determinations were performed for plant dry weights.

A nominal product application rate of 0.75 L/ha Fluopyram + Trifloxystrobin SC 250 + 250 g/L showed no adverse effect (i.e. greater than 50%) for any tested species in the vegetative vigor test.

**Materials and methods:**

A. Materials

| | |
|---|---|
| 1. Test material: | Fluopyram + Trifloxystrobin SC 250 + 250 G |
| Material number: | 06033007 |
| Batch ID: | 2007-000441 |
| Visual appearance: | white fluid |
| Physical density: | 1.174 g/mL |
| Active substance 1: | AE C656948, fluopyram |
| Active ingredient 2: | CGA 279202, trifloxystrobin |
| Nominal content of active substance: | fluopyram: 250 g/L<br>trifloxystrobin: 250 g/L |
| Analyzed content of active substance: | fluopyram: 21.4% (251.5 g/L)<br>trifloxystrobin: 21.6% (253.5 g/L) |
| Expiration date: | 2008-02-21 |
| 2. Vehicle and/or positive control | Deionized water |
| 3. Test organisms | |
| Species | 7 dicotyledonous plant species from 7 different families:<br>cucumber (*Cucumis sativus*), oilseed rape (*Brassica napus*), soybean (*Glycine max*), sugar beet (*Beta vulgaris*), sunflower (*Helianthus annuus* L.), tomato (*Lycopersicon esculentum*) and buckwheat (*Fagopyrum esculentum*);<br>3 monocotyledonous plant species from 1 family:<br>oat (*Avena sativa*), onion (*Allium cepa*) and corn (*Zea mays*) |
| Plant growth stage at application | Plants were grown from seed to the 2 to 4-leaf stage. |
| Source | Seeds used on the study had not been treated with pesticides or repellents prior to test initiation. Seeds were supplied from commercial sources via Bayer CropScience AG, Horticulture, H 872, 65926 Frankfurt am Main. Routine germination tests were carried out on the seeds to ensure their viability. Seeds |

| | |
|---|---|
| | were stored in plastic box in refrigerator. |
| Acclimation period | Greenhouse conditions |
| Environmental conditions: | |
| Temperature | Regulated at 23 ± 8°C day, 18 ± 8°C night |
| Photoperiod | 16:8 hours light/dark<br>Natural daylight supplemented by artificial lighting to provide the required photoperiod. >15000 lux lamps turn off, >50000 lux shading closing. |

B. Study design and methods

| | |
|---|---|
| 1. Experimental Dates | 12 April 2007-14 May 2007 |
| 2. Experimental treatments | |
| Plants were grown from seed to the 2 to 4-leaf stage in commercial plastic flower pots (10-13 cm diameter) before application of test substance. Four to five replicates with four to five plants per pot for each species were tested. All pots were individually contained in saucers and retained on benches within a greenhouse.<br>Test soil was standard soil (sandy-silt loam) sterilized with 120 degrees vapor for about 30 minutes, fertilized with 2.4 g Blaukorn per liter and sieved to 2 mm. Soil composition: 16.7% sand, 24.2% clay and 59.1% silt; pH 7.31; organic carbon content 1.3%; lime content 1.2%.<br>Bottom watering was performed via saucers standing below each pot. Water was given in the saucer according to the need of the plants in order to have an optimal water supply for plant growth.<br>The spray solution was applied to the plant foliage. The blank control spray solution was deionized water. The test item was dissolved in deionized water and was applied once with 200 L/ha using a spray chamber equipped with an overhead nozzle (Teejet 8001EVSV), with nozzle height set at 35 cm above the sprayed surface. The spray chamber volume was calibrated by weighing the amount of water applied to a known surface area. | |
| 3. Observations | |
| <u>Analytical verification</u>: No analytical verification of the stock solution was conducted.<br><br>Assessment:<br>Survival: Number of plants that survived after application was recorded at the final assessment (day 21).<br>Phytotoxicity: Visual phytotoxicity ratings were recorded (e.g. chlorosis, necrosis, stunting, abnormal growth) at days 7, 14 and 21.<br>Growth stages: Growth stages at day 21 were recorded according to BBCH-Monograph - Growth stages.<br>Biomass: The dry weights were determined at the final assessment (day 21).<br><br>Calculation and statistics:<br>Statistical analysis of biomass data: Statistical analysis was carried out using the Pairwise Mann-Whitney-U-test (one sided smaller). | |

**Results and discussions:**

Findings

The following table summarizes the findings from this study:

| **Species** | **Survival (% inhibition)** | **Dry Weight * (% inhibition)** | **Phytotoxicity (%)** | **Growth stages **** |
|---|---|---|---|---|
| Cucumber | 0 | 20.3 | 0 | 61 (61) |
| Oilseed rape | 0 | 12.6 | 0 | 26-28 (26-28) |
| Soybean | 0 | - 4.6 | 0 | 61 (61) |
| Sugar beet | 0 | 31.3 | 0 | 41 (41) |
| Sunflower | 0 | 0.3 | 0 | 51 (51) |
| Tomato | 0 | 22.5 | 0 | 61 (61) |
| Buckwheat | 0 | - 30.9 | 0 | 61 (61) |
| Corn | 0 | - 10.7 | 0 | 16 (16) |
| Oat | 0 | 7.9 | 0 | 41 (41) |
| Onion | 0 | - 118 | 0 | 41 (41) |

* An increase in dry weight is given as negative values.
** growth stages of the control in parentheses

Treatment with the product did not cause any visible phytotoxicity symptoms in any species at the rate tested in this study

Validity criteria:
- Seedling emergence at least 70%: not documented in report but without influence on study outcome as more seeds were sown than needed and the surplus was later thinned out
- Plants in control do not exhibit visible phytotoxic effects: fulfilled
- Plants in control exhibit only normal variation in growth and morphology: fulfilled
- Mean plant survival in control at least 90%: Survival was 100% for all species in this study.

**Conclusion:**

A nominal product application rate of 0.75 L/ha Fluopyram + Trifloxystrobin SC 250 + 250 g/L showed no adverse effect (i.e. greater than 50%) for all the tested species in the vegetative vigor test.

| | |
|---|---|
| Comments of zRMS: | The study was considered valid in the previous Registration for Luna Sensation.<br><br>**Agreed endpoints:** |

| **Test design** | **Test species** | **Ecotoxicological endpoint** | | |
|---|---|---|---|---|
| **Fluopyram + Trifloxystrobin SC 500** | | | | |
| Tier 1 test glasshouse vegetative vigor test 21 days | 7 dicotyledonous plant species from 7 different families<br><br>3 monocotyledonous plant species from 2 families | application rate | effects | parameter |
| | | 2 × 0.80 L/ha | < 50% | Survival, visual phytotoxicity and shoot dry weight |

| | |
|---|---|
| Reference: | **KCP 10.6.2/02** |
| Title: | Fluopyram + trifloxystrobin SC 500 (250 + 250 g/L) - Effects on the vegetative vigour of ten species of non-target terrestrial plants (Tier 1) |
| Report: | Koehler, P.; 2013; VV13/033; M-464310-01-1 |
| Authority registration No: | |
| Guideline(s): | EU Directive 91/414/EEC; Regulation (EC) No. 1107/2009; US EPA OCSPP 850.4150; OECD 227 guideline for the testing of chemicals, Terrestrial Plant Test: Vegetative vigour (July 2006) and considers the recommendations of US EPA Ecological Effects Test Guideline OCSPP 850.4150 |
| Deviations: | not specified |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication (if vertebrate study): | |

**Executive summary**

Test item (product): Fluopyram + Trifloxystrobin SC 500 (250 + 250 g/L), sample description: TOX 0053-00, batch ID: EM4L011075, appearance: white suspension, expiry date: 2015-03-08.

The purpose of this specific study was to evaluate the effect of Fluopyram + Trifloxystrobin SC 500 on the vegetative vigour of ten non-target terrestrial plant species following two consecutive post-emergence applications of the test item onto the foliage of plants at the 2-4 leaf stage.
A total of ten species, 7 dicotyledonous species and 3 monocotyledonous, were tested in this vegetative vigour test representing 9 plant families. The plants were grown in a greenhouse in 13 cm pots and were treated at the 2-4 leaf stage (first application). The used soil was a silt loam.
There were 4 plants per pot and 5 replicate pots, giving a total of 20 plants per treatment and the water control.
The test item was dissolved in deionized water for the preparation of the test item solution with the rate of 0.8 L product/ha and was applied twice, at test initiation and one week later, onto the leaves and above ground portions of the plants using a laboratory track sprayer at a volume rate of 200 L/ha. Control pots were sprayed with 200 L/ha of deionised water.
Following application, the pots with plants were maintained under greenhouse conditions with a

temperature regulation at 23ºC during day and 18ºC at night with a 16 h photoperiod and relative humidity of 70%.
Assessments were made 7, 14 and 21 days after the second application.
Final assessments were made for plant survival, visual phytotoxicity, plant growth stage (BBCH, see Appendix 4) and shoot dry weight.
Statistical analysis of shoot dry weight data was carried out with the Mann-Whitney-U-Test (one sided smaller; $p \leq 0.05$), included in ToxRat statistics.
No adverse effects on survival, visual phytotoxicity, growth stage development and shoot dry weight above the 50% effect level were observed. No statistically significant differences between treated plants and plants in the control were found.

**Materials and methods:**

A. Materials

| | |
|---|---|
| 1. Test material: | Fluopyram + trifloxystrobin SC 500 (250 + 250 g/L) |
| Specification No. | 102000012886-03 |
| Batch ID: | EM4L011075 |
| Visual appearance: | white suspension |
| Physical density: | 1.167 g/mL |
| Active substance 1: | AE C656948, fluopyram |
| Active ingredient 2: | CGA 279202, tebuconazole |
| Nominal content of active substance: | fluopyram: 250 g/L<br>trifloxystrobin: 250 g/L |
| Analyzed content of active substance: | fluopyram: 20.7% (241.7 g/L)<br>trifloxystrobin: 21.1% (246.5 g/L) |
| Expiration date: | 2015-03-8 |
| Testing rates: | 0.8 L product / ha |
| 2. Vehicle and/or positive control | Deionized water |
| 3. Test organisms | |
| Species | 7 dicotyledonous plant species from 7 different families:<br>cucumber (*Cucumis sativus*), oilseed rape (*Brassica napus*), soybean (*Glycine max*), sugar beet (*Beta vulgaris*), sunflower (*Helianthus annuus* L.), tomato (*Lycopersicon esculentum*) and buckwheat (*Fagopyrum esculentum*);<br>3 monocotyledonous plant species from 1 family:<br>oat (*Avena sativa*), ryegrass (*Lolium perenne*) and corn *(Zea mays*) |
| Plant growth stage at application | Plants were grown from seed to the 2 to 4-leaf stage |
| Source | Seeds used in the study had not been treated with pesticides or repellents prior to test initiation. Routine germination tests were carried out on the seeds to ensure their viability. Seeds were stored in plastic box in refrigerator. |
| Acclimation period | Greenhouse conditions |
| Environmental conditions: | |
| Temperature | Regulated at 23°C day, 18°C night |
| Photoperiod | 16:8 hours light/dark<br>Natural daylight supplemented by artificial lighting to provide the required photoperiod. >15000 lux lamps turn off, >50000 lux shading closes. |

B. Study design and methods

| 1. Experimental Dates | 2013-05-22 to 2013-06-25 |
|---|---|
| 2. Experimental treatments | |
| Plants were grown from seed to the 2 to 4-leaf stage in commercial plastic flower pots (13 cm diameter) before the first application of test substance. Five replicates with four plants per pot for each species were tested.<br>Test soil was standard soil (sandy-silt loam) sterilized with 120 degrees vapor for about 30 minutes, fertilized with 2.4 g Blaukorn per liter and sieved to 2 mm. Soil composition: 14.1% sand, 21.4% clay and 64.5% silt; pH 6.91; organic carbon content 0.86%; lime content 0.4%.<br>Bottom watering was performed via saucers standing below each pot. Water was given in the saucer according to the need of the plants in order to have an optimal water supply for plant growth.<br><br>The spray solution was applied to the plant foliage. The blank control spray solution was deionized water. The test item was dissolved in deionized water and was applied twice, at test initiation (2013-05-22) and one week later (2013-05-29) with 200 L/ha using a spray chamber equipped with an overhead nozzle (Teejet 8001EVS), with nozzle height set at 30 cm above the sprayed surface. The spray chamber volume was calibrated by weighing the amount of water applied to a known surface area. | |
| 3. Observations | |
| <u>Assessment</u>:<br>Survival: Number of plants that survived after application was recorded on day 7, 14 and 21 days after the second application.<br>Phytotoxicity: Visual phytotoxicity ratings were recorded (e.g. chlorosis, necrosis, stunting, abnormal growth) at days 7, 14 and 21 after the second application.<br>Growth stages: Growth stages at the final assessment (day 21) were recorded according to BBCH-Monograph - Growth stages.<br>Biomass: The dry weights were determined at the final assessment (day 21).<br><br><u>Calculation and statistics</u>:<br>Statistical analysis of biomass data: Statistical analysis was carried out using the Pairwise Mann-Whitney-U-test (one sided).<br><br><u>Analytical verification</u>: The spray solutions were analysed for the content of Trifloxystrobin (94.4% of nominal for the first and 94.4% for the second application) | |

**Results and discussions:**

Findings

All ten species in this study met the validity criteria for survival according to the OECD guideline (OECD 227) and US EPA guideline (OCSPP 850.4150), respectively.

The analysis of Trifloxystrobin content in the application rate revealed measured concentrations of 94.4% for the first and 94.4% for the second application of nominal.

As a result of the foliar application of Fluopyram + Trifloxystrobin SC 500 on ten species of non-target terrestrial plants, this study revealed no adverse effect on the survival and the growth stage development in comparison to the control. The plants exhibited normal variation in the growth stage development.

Slight phytotoxic symptoms were observed sporadically for *Brassica napus* and *Lycopersicon esculentum* that was stunting. For *Cucumis sativus, Fagopyrum esculentum and Glycine max,* there were mostly slight to moderate phytotoxic symptoms observed i.e. chlorosis and/or necrosis and/or stunting.

Shoot dry weight for *Fagopyrum esculentum, Helianthus annuus* and *Lolium perenne* was reduced by 14.9%, 4.0% and 3.7%, respectively. Shoot dry weight for *Beta vulgaris*, *Brassica napus*, *Cucumis sativus, Glycine max, Lycopersicon esculentum, Avena sativa* and *Zea mays* was increased by 4.2%, 0.2%, 1.2%, 0.3%, 9.8%, 5.3% and 0.6%, respectively. None of the shoot dry weight differences was statistically significant or biologically meaningful.

The following table summarizes the effect on survival, phytotoxicity, shoot dry weight and growth stages (BBCH):

| **Plant Species** | **Survival (% inhibition)** | **Phyto-toxicity** | **Shoot Dry Weight (% inhibition)*** | **Growth stage (BBCH) control min - max** | **Growth stage (BBCH) treated min - max** |
|---|---|---|---|---|---|
| *Beta vulgaris* | 0.0 | 0 | -4.2 | 18-19 | 18-19 |
| *Brassica napus* | 0.0 | 0-Ae | -0.2 | 17-30 | 15[a]-30 |
| *Cucumis sativus* | 0.0 | A-B[#]ab | -1.2 | 69 | 69 |
| *Fagopyrum esculentum* | 0.0 | A-Bbe | 14.9 | 65 | 65 |
| *Glycine max* | 0.0 | Aabe | -0.3 | 51-59 | 51-59 |
| *Helianthus annuus* | 0.0 | 0 | 4.0 | 53-55 | 51[b]-55 |
| *Lycopersicon esculentum* | 0.0 | 0-A[~]e | -9.8 | 61-62 | 61-62 |
| *Avena sativa* | 0.0 | 0 | -5.3 | 31-32 | 31-32 |
| *Lolium perenne* | 0.0 | 0 | 3.7 | 29 | 27[c]-29 |
| *Zea mays* | 0.0 | 0 | -0.6 | 30-31 | 30-31 |

*: Negative values indicate an increase compared to the control.
[#]: Only one replicate was affected, the other replicates showed only slight phytotoxic symptoms.
[~]: Only one replicate was affected, the other replicates showed no phytotoxic symptoms.
[a]: One plant was BBCH 15, the majority of the plants was BBCH 18-30.
[b]: Only one plant BBCH 51, the majority of the plants was BBCH 53-55.
[c]: Only one replicate affected, the majority of the plants was BBCH 29.

Key:
0 no injury or effect
A slight symptom (s)
B moderate symptom (s)
C severe symptom (s)
D total plant symptom (s)
E moribund
Any plant considered as being dead was not rated for phytotoxicity.
Phytotoxicity symptoms:
a = chlorosis (yellowing of green shoot tissue)
b = necrosis (brown shoot tissue)
c = bleaching (shoot tissue without pigmentation)
d = leaf deformation (leaf curl. abnormal leaf shape)
e = stunting (plant height reduced with shorter internode length)

**Conclusion:**

In a Tier 1 vegetative vigour and growth study, Fluopyram + Trifloxystrobin SC 500 applied at 2 x 0.8 L product/ha in 200 L/ha deionized water (application interval 7 days) was tested under greenhouse conditions for effects on the vegetative vigour and growth of ten non-target terrestrial plant species, following a foliar application of the test item at the 2 - 4 leaf stage. No adverse effects on survival, visual phytotoxicity, growth stage development and shoot dry weight above the 50% effect level were observed. No statistically significant differences between treated plants and plants in the control were found.

<table>
<tr><td>Comments of zRMS:</td><td>The study is considred valid. All validity criteria were met.<br><br>Agreed endpoints:<br>

| Species | Substance | Exposure System | Results |
|---|---|---|---|
| *Zea mays* [1] m<br>*Lolium perenne* [1] m<br>*Avena sativa* [1] m<br>*Allium cepa* [1] m<br>*Brassica napus* [1] d<br>*Glycine max* [1] d<br>*Fagopyrum esculentum* [2] d | FLU + TFS SC 500 | 21 d<br>Vegetative vigour<br>Tier 1 | [1] $ER_{50}$ > 1.0 L prod./ha<br>[2] $ER_{50}$ < 1.0 L prod./ha (52% reduction of sdw) |

m: monocotyledonous; d: dicotyledonous<br><br>Visual injuries (mean effect of 10 %) and differences in the BBCH growth stage (BBCH 67 in the control group in comparison to BBCH 65 in the test item group) occurred in Fagopyrum esculentum.<br>A statistically significant difference in shoot height compared to the control group was observed for Glycine max (31.4%).</td></tr>
</table>

| | |
|---|---|
| Reference: | **KCP 10.6.2/03** |
| Title: | Fluopyram + trifloxystrobin SC 500 (250+250 g/L): Effects on the vegetative vigour of seven non-target terrestrial plant species under greenhouse conditions (Tier 1) |
| Report: | Ripperger, D.; 2020; S19-22936; M-681185-01-1 |
| Authority registration No: | |
| Guideline(s): | EU Directive 91/414/EEC<br>Regulation (EC) no. 1107/2009<br>US EPA OCSPP 850.4150 (2012)<br>OECD 227 (2006) |
| Deviations: | Yes (see report) |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication (if vertebrate study): | |

**Executive summary**

Test item (product): Fluopyram + Trifloxystrobin SC 500 (250 + 250 g/L), sample description: TOX21159-00, batch ID: EV57002709, appearance: liquid, whitish, expiry date: 2022-01-16.

The study objective was to determine the effects of Fluopyram + Trifloxystrobin SC 500 (250+250 g/L) on early growth of seven non-target terrestrial plant species.
In this limit test, 3 dicotyledonous species and 4 monocotyledonous species in the 2-3 leaf stage (BBCH growth stages 12-13) were treated with Fluopyram + Trifloxystrobin SC 500 at a single rate of 1.0 L product/ha for all plant species. Deionised water was used for the control treatment. Each test group consisted of a total of 20 plants which were treated by spray application with a spray volume of 200 L/ha. The plants were assessed for mortality and signs of visual injuries 7, 14 and 21 days after application. BBCH growth stage, shoot height and shoot dry weight were assessed for day 21 (termination of study).

A nominal product application rate of 1.0 L Fluopyram + Trifloxystrobin SC 500/ha showed no adverse effect (i.e. greater than 50%) for any tested species in the vegetative vigor test.

**Materials and methods:**

A. Materials

| | |
|---|---|
| 1. Test material: | Fluopyram + Trifloxystrobin SC 500 (250+250 g/L) |
| Specification number: | 102000012886 |
| Batch ID: | EV57002709 |
| Visual appearance: | Liquid / whitish |
| Physical density: | 1.169 g/mL |
| Active substance 1: | fluopyram (AE C656948) |
| Active ingredient 2: | trifloxystrobin (CGA 279202) |
| Nominal content of active substance: | fluopyram: 250 g/L<br>trifloxystrobin: 250 g/L |
| Analyzed content of active substance: | fluopyram: 21.1% (246.6 g/L)<br>trifloxystrobin: 21.3% (248.6 g/L) |
| Expiration date: | 2022-01-16 |
| 2. Vehicle and/or positive control | Deionized water |
| 3. Test organisms | |
| Species | 3 dicotyledonous plant species from 3 different families:<br>*Brassica napus* (oil seed rape), *Fagopyrum esculentum* (buckwheat), *Glycine max* (soybean);<br>4 monocotyledonous plant species from 2 families:<br>*Allium cepa* (onion), *Avena sativa* (oat), *Lolium perenne* (perennial ryegrass), *Zea mays* (corn) |
| Plant growth stage at application | 2-3 leaf stage (BBCH growth stage 12-13) |
| Source | Untreated seeds from commercial suppliers were used in this study. |
| Acclimation period | Greenhouse conditions |
| Environmental conditions: | Relative humidity (min/max) [%]: 54.25 / 87.96<br>Light intensity (min/max) [µmol/m$^2$/s]: 240 / 330 |
| Temperature | 14.72 / 26.98 °C (min/max) |
| Photoperiod | 16:8 hours light/dark |

B. Study design and methods

| | |
|---|---|
| 1. Experimental Dates | 19 Nov 2019 - 16 Dec 2019 |
| 2. Experimental treatments | |
| Plants were grown from seed to the 2-3 leaf stage (BBCH growth stage 12-13) in commercial plastic flower pots (15 cm diameter) before application of test substance. Ten (docotyledonous species and *Zea mays*) or five replicates (monocotyledonous species except for corn) with two or four plants per replicate were tested, respectively.Test soil was a specially mixed soil substrate (loamy sand) composed of 76.7 % sand, 20.2 % silt and 3.1 % clay, with a pH of 7.97, an electrical conductivity of 77.6 µS/cm and a total organic carbon content of 0.17 % (0.29 % organic matter).<br>Bottom watering was done to the plant soucer of each pot. Water was replenished regularly.<br>The blank control spray solution was deionized water. The test item was dissolved in deionized water and was applied once with 200 L/ha using a laboratory track-sprayer (Company Schachtner, Ludwigsburg, Germany) with 80015 EVS, TeeJet as spray nozzle. | |
| 3. Observations | |
| <u>Analytical verification</u>: Immediately before application two samples were taken from the test item solution and the water control. Analysis of the test item solution and the control solution was done by LC-UV.<br><br>Assessment:<br>Mortality: Number of dead plants was recorded on day 7, 14 and 21.<br>Visual injury: Visual phytotoxicity (necrosis, deformation and change in colour (e.g. chlorosis, bleaching, reddening)) was recorded on day 7, 14 and 21.<br>Growth stages: Growth stages at day 21 were recorded (BBCH stage according to MEIER, 2001).<br>Shoot height: The height of the above-ground vegetation was measured for each surviving plant at the | |

last assessment day (day 21)
Shoot dry weight: The dry weights were determined at the final assessment (day 21).

Calculation and statistics:
As no mortality occurred, no statistical evaluation was performed for this endpoint.
The data of shoot height and shoot dry weight were tested for normal distribution and homoscedasticity using Shapiro-Wilk`s Test and Levene-Test, respectively. For all species tested both requirements were fulfilled, therefore Student t-test was conducted. The significance level was set to α = 0.05 for all tests.
In case of an increase in the test item group compared to the control group for shoot height and shoot dry weight, no statistical evaluation was conducted.
Statistical analysis was performed using the program ToxRat Professional Version 3.3.0.

**Results and discussions:**

Analytical Rate Verification:
The analysed concentration of fluopyram in the test item solution corresponded to 102.8 % of the target concentration.

Biological findings:

**Summary of the effects of the test item at 1.0 L product/ha 21 days after application**

| **Plant species** | **Cumulative mortality [%]** | **Visual Injury [Mean in %/ Symptoms] [1]** | **BBCH growth stage [Min/Max]** | | **Inhibition [%] [#]** | |
|---|---|---|---|---|---|---|
| | | | **C** | **T** | **Shoot height** | **Shoot dry weight** |
| | **Dicotyledonous Species** | | | | | |
| *Brassica napus* | 0.0 | 0 / - | 15 / 15 | 15 / 15 | 4.6 | -3.1 |
| *Fagopyrum esculentum* | 0.0 | 10 / NE, CC | 67 / 67 | 65 / 65 | -7.3 | **52.0** * |
| *Glycine max* | 0.0 | 0 / - | 62 / 62 | 62 / 62 | **31.4** * | 7.3 |
| | **Monocotyledonous Species** | | | | | |
| *Allium cepa* | 0.0 | 0 / - | 15 / 15 | 15 / 15 | -18.1 | -3.0 |
| *Avena sativa* | 0.0 | 0 / - | 55 / 55 | 55 / 55 | 3.1 | **23.4** * |
| *Lolium perenne* | 0.0 | 0 / - | 26 / 26 | 26 / 26 | -3.5 | 7.2 |
| *Zea mays* | 0.0 | 0 / - | 16 / 16 | 16 / 16 | -3.8 | 1.1 |

C: Control, T: Test item
1 Visual symptoms: None (-), CC = change in colour, NE = necrosis
\# Negative values indicate that there was an increase compared to the control
* Statistically significantly different compared to the control (Student's t-test; one-sided smaller, α = 0.05)

Validity criteria:
All validity criteria were fulfilled for all species tested according to OECD 227:
- Seedling emergence: The seedling emergence was ≥ 70% for all species included in this test.
- Visual injury: The control seedlings of each species did not exhibit visible visual injuries and control plants exhibited normal variation in growth and morphology for that particular species.
- Mean survival: The mean survival of emerged control seedlings was ≥ 90% for all species included in this test (actually 100%).
- Cultivation conditions: 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.

**Conclusion:**

This Tier 1 vegetative vigour and growth study evaluating effects of Fluopyram + Trifloxystrobin SC 500 (250+250 g/L) was conducted at a single application rate of 1.0 L product/ha on seven non-target terrestrial plant species under greenhouse conditions.

No mortality occurred for any of the plant species tested.

Visual injuries (mean effect of 10 %) and differences in the BBCH growth stage (BBCH 67 in the control group in comparison to BBCH 65 in the test item group) occurred in *Fagopyrum esculentum*.
A statistically significant difference in shoot height compared to the control group was observed for *Glycine max* (31.4%).

An adverse effect on shoot dry weight above the 50% effect level occurred in *Fagopyrum esculentum* (52.0%) which was also statistically significant. An additional statistically significant difference in shoot dry weight compared to the control group was observed for *Avena sativa* (23.4%).

Comments of zRMS:

The study is considred valid. All validity criteria were met.

**Agreed endpoints:**

| **Species** | **Substance** | **Exposure System** | **Results** |
|---|---|---|---|
| *Beta vulgaris* [1] d<br>*Cucumis sativus* [1] d<br>*Solanum lycopersicum* [1] d | FLU + TFS SC 500 | 21 d<br>Vegetative vigour<br>Tier 2 | [1] $ER_{50}$ > 2.0 L prod./ha |

m: monocotyledonous; d: dicotyledonous

No adverse effects on visual phytotoxicity, growth stage development, above the 50% effect level.

| | |
|---|---|
| Reference: | **KCP 10.6.2/04** |
| Title: | Effects on the vegetative vigor of three species of non-target terrestrial plants (Tier 2) fluopyram + trifloxystrobin SC 500 (250 + 250 g/L) |
| Report: | Nöding, S.; 2018; VV17/038; M-612774-01-1 |
| Authority registration No: | |
| Guideline(s): | EU Directive 91/414/EEC<br>Regulation (EC) No. 1107/2009<br>US EPA OCSPP 850.4150 (2012)<br>OECD 227 (2006) |
| Deviations: | Yes (see report) |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication (if vertebrate study): | |

**Objective:**

The objective of this specific study was to evaluate the potential effect of Fluopyram + Trifloxystrobin SC 500 (250 + 250 g/L) on the vegetative vigor of three non-target terrestrial plant species following a post-emergence application of the test item onto the foliage of plants at the 2-4 leaf stage.

**Materials and methods:**

Test item (product): Fluopyram + Trifloxystrobin SC 500 (250 + 250 g/L), sample description: FAR30164-00, active substances: fluopyram (AE C656948): 21.1% w/w (246.7 g/L), trifloxystrobin (CGA 279202): 21.6% w/w (251.9 g/L), specification no.: SP102000012886, supplier batch no.: PAIS005241, density: 1.167 g/mL, white dispersion, expiry date: 2020-01-31.

Three dicotyledonous plant species were tested in this vegetative vigor test representing 3 different plant families. The plants were grown in a greenhouse in 15 cm pots (filled with approx. 1.2 L soil). The used soil was a silt loam. Planting density included 2 plants per pot with 16 replicate pots, for a total of 32 plants per treatment level. The plant species were treated at the 2-4 leaf stage with five test item rates and a water control. The stock and application solutions were prepared in the laboratory and transported to the application site immediately before application. Serial dilutions of Fluopyram + Trifloxystrobin SC 500 (250 + 250 g/L) were sprayed onto the foliage and above-ground portions of plants using a calibrated laboratory track sprayer at a volume rate of 200 L/ha. Details of the range of test item rates per species are summarized in the following table:

| **Species name** | **EPPO CODE** | **Common name** | **Test item rates in L product/ha** | | | | |
|---|---|---|---|---|---|---|---|
| | | | **S1** | **S2** | **S3** | **S4** | **S5** |
| | | | **0.06** | **0.144** | **0.346** | **0.832** | **2.0** |
| *Beta vulgaris* | BEAVA | Sugar beet | X | X | X | X | X |
| *Cucumis sativus* | CUMSA | Cucumber | X | X | X | X | X |
| *Solanum lycopersicum* | LYPES | Tomato | X | X | X | X | X |

X: Test item rate tested.

Control pots were sprayed with 200 L/ha of deionized water. After application, the plants were transferred back to the greenhouse and placed on the tables in a randomized design with all pots of one species arranged together in a species plot. During the course of the experimental study part the pots of each plant species were rearranged within these species plots on the tables. Following application, the pots with plants were maintained under greenhouse conditions, natural daylight was supplemented by artificial lighting. The temperature was regulated to maintain 19°C to 31°C during the light cycle (16 h) and 14°C to 26°C during the dark cycle (8 h). The relative humidity was regulated to maintain 55% to 85%. Assessments were made 7, 14 and 21 days after application. On day 7 and 14, only plant survival and visual phytotoxicity were recorded. Final assessments on day 21 were made for plant survival, visual phytotoxicity, plant growth stage, shoot length and shoot dry weight. Statistical analysis of the data were performed to obtain $ER_{50}$ (Effect Rate producing 50% effect) for survival, $IR_{50}$ (Inhibition Rate producing 50% effect) for shoot length and shoot dry weight, using ToxRat statistical software.

**Results and discussions:**

The germination rate of the seeds used in this study was ≥ 70%. All plant species in this study met the validity criterion for survival in the controls (at least 90%). In accordance with US EPA guideline (OCSPP 850.4150) and OECD guideline (OECD 227), there was no visible phytotoxicity, and normal growth occurred in the controls of the 3 species tested. The control plants of each species showed normal variation in growth, plant development and morphology. The environmental conditions during the test time were kept identical within each species. The pots used for all species of this study were filled in equal manner with the same soil. The analysis of trifloxystrobin content in the initial test item stock solution revealed measured concentrations of 101.6% of nominal. Typical symptoms observed at the final assessment (on day 21 after application) in vegetative vigor testing include chlorosis, necrosis, deformation and stunting of the plants. In this study, the severity and occurrence of phytotoxic symptoms differed among species and test item rates. The $ER_{50}$ for survival, $IR_{50}$ values for shoot length and shoot dry weight expressed in L product/ha are summarized for each of the plant species in the following tables for the final assessment (on day 21 after application).

| **Survival** | | | |
|---|---|---|---|
| **Plant Species** | **$ER_{50}$ (L product/ha)** | **95% Confidence Limits** | |
| | | **Lower** | **Upper** |
| *Beta vulgaris* | **>2**[b] | n.d. | n.d. |
| *Cucumis sativus* | **>2**[b] | n.d. | n.d. |
| *Solanum lycopersicum* | **>2**[b] | n.d. | n.d. |

n.d.: Confidence limits not determined (outside the range tested)
[b] No effects were observed up to the highest concentration tested.

| **Shoot Length** | | | |
|---|---|---|---|
| **Plant Species** | **$IR_{50}$* (L product/ha)** | **95% Confidence Limits** | |
| | | **Lower** | **Upper** |
| *Beta vulgaris* | **>2**[a] | n.d. | n.d. |
| *Cucumis sativus* | **>2**[a] | n.d. | n.d. |
| *Solanum lycopersicum* | **>2**[a] | n.d. | n.d. |

*: IR corresponds to ER.
n.d.: Confidence limits not determined (outside the range tested)
[a]: Not calculated (outside the range tested).
[c] : Calculated with Dunnett's multiple t-test procedure

| **Shoot Dry Weight** | | | |
|---|---|---|---|
| **Plant Species** | **$IR_{50}$* (L product/ha)** | **95% Confidence Limits** | |
| | | **Lower** | **Upper** |
| *Beta vulgaris* | **>2**[a] | n.d. | n.d. |
| *Cucumis sativus* | **>2**[a] | n.d. | n.d. |
| *Solanum lycopersicum* | **>2**[a] | n.d. | n.d. |

*: IR corresponds to ER.
n.d.: Confidence limits not determined (outside the range tested)
[a]: Not calculated (outside the range tested).

| **Plant species** | **Growth stage (BBCH) Min-Max at test item rates (in L product/ha) at the final assessment** | | | | | |
|---|---|---|---|---|---|---|
| | **Control** | **0.06** | **0.144** | **0.346** | **0.832** | **2** |
| *Beta vulgaris* | 19 | 19 | 18-19 | 19 | 19 | 19 |
| *Cucumis sativus* | 66-69 | 69 | 65-69 | 64-69 | 69 | 68-69 |
| *Solanum lycopersicum* | 51-52 | 51-52 | 51-52 | 51-52 | 51-52 | 51-52 |

| **Plant species** | **Phytotoxicity summary (mean damage in %) (in L product/ha) at the final assessment** | | | | | |
|---|---|---|---|---|---|---|
| | **Control** | **0.06** | **0.144** | **0.346** | **0.832** | **2** |
| *Beta vulgaris* | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| *Cucumis sativus* | 0.0 | 1.3 ab | 3.1 abe | 5.0 abe | 9.4 abe | 14.4abe |
| *Solanum lycopersicum* | 0.0 | 0.0 | 3.8 de | 1.3 de | 1.9 e | 0.0 |

Codes for phytotoxic symptoms:
a: chlorosis (yellowing of green shoot tissue)
b: necrosis (e.g. brown shoot tissue, parts of the plant die)

d: deformation (e.g. leaf curl, abnormal leaf shape, abnormal plant habitus)
e: stunting (e.g. plant height reduced with shorter internode length, plant growth reduction)
Any plant considered as being dead was not rated for phytotoxicity.

**Conclusion:**

This vegetative vigor and growth study, in which the effect of Fluopyram + Trifloxystrobin SC 500 (250 + 250 g/L) on three non-target terrestrial plant species was tested under greenhouse conditions, resulted in no adverse effects on survival, visual phytotoxicity, growth stage development, shoot length and shoot dry weight above the 50% effect level.
In the absence of effects, $IR_{50}$ values could not be calculated and are reported as >2 L product/ha for all species tested.
For shoot length and shoot dry weight the $IR_{50}$ values could not be calculated for the three species tested and are reported as >2 L product/ha.

<table>
<tr><td>Comments of zRMS:</td><td>The study was considered valid in the previous Registration for Luna Sensation.<br><br>Agreed endpoints:
<table>
<tr><th>Test design</th><th>Test species</th><th colspan="3">Ecotoxicological endpoint</th></tr>
<tr><td colspan="5">Fluopyram + Trifloxystrobin SC 500</td></tr>
<tr><td rowspan="2">Tier 1 test glasshouse seedling emergence and growth test<br>21 days</td><td rowspan="2">7 dicotyle-donous plant species from 7 different families<br><br>3 monocotyle-donous plant species from 2 families</td><td>application rate</td><td>effects</td><td>parameter</td></tr>
<tr><td>0.75 L/ha</td><td>< 50%</td><td>Emergence, survival, visual phyto-toxicity and shoot dry weight</td></tr>
</table>
</td></tr>
</table>

| | |
|---|---|
| Reference: | **KCP 10.6.2/05** |
| Title: | Non-target terrestrial plants: an evaluation of the effects of AE C656948 + trifloxystrobin SC 250 + 250 g/L in the seedling emergence and growth test (Tier 1) |
| Report: | Gosch, H.; Nguyen, D. H.; 2007; SE07/03; M-289525-01-1 |
| Authority registration No: | |
| Guideline(s): | OECD 208 (July 2006): seedling emergence and growth test (Tier 1); Equivalent to US EPA OPPTS Guideline No. 850.4100 |
| Deviations: | none |
| GLP/GEP: | no |
| Acceptability: | |
| Duplication (if vertebrate study): | |

**Executive summary**

Test item: AE C656948 + Trifloxystrobin SC 250 + 250 g/L, sample description: TOX07851-00, master recipe ID: 0036845-001, batch ID: 2007-000441, appearance: white suspension, expiry date: 21.02.2008.

The purpose of this specific study was to evaluate the effect of Fluopyram + Trifloxystrobin SC 250 + 250 g/L on the seedling emergence and seedling growth of ten plant species representing a broad range of both dicotyledonous and monocotyledonous plant families over a 21 day period.
Ten species of terrestrial non-target plants (3 monocots and 7 dicots) were treated at an application rate of 0.75 L product (AE C656948 + Trifloxystrobin SC 250 + 250 g/L)/ha. All seeds were planted one day before application and test duration was 14 days after 70% emergence of the seedling in the controls for each species.
Spray treatments were applied once, at test initiation, with a sprayer set at the nominal spray volume of 200 L/ha. Control pots were sprayed with deionized water. Four replicates with five seeds per pot for each species were tested. All pots were individually contained in saucers and retained on benches within a greenhouse.

Plants were assessed for emergence, survival and rated for phytotoxicity on days 7 and 14. At study termination, biomass endpoint determinations were performed for plant dry weights.

A nominal product application rate of 0.75 L/ha Fluopyram + Trifloxystrobin SC 250 + 250 g/L showed no adverse effect (i.e. greater than 50%) for any of the tested species in the seedling emergence test.

**Materials and methods:**

A. Materials

| | |
|---|---|
| 1. Test material: | Fluopyram + Trifloxystrobin SC 250 + 250 G |
| Material number: | 06033007 |
| Batch ID: | 2007-000441 |
| Visual appearance: | white fluid |
| Physical density: | 1.174 g/mL |
| Active substance 1: | AE C656948, fluopyram |
| Active ingredient 2: | CGA 279202, trifloxystrobin |
| Nominal content of active substance: | fluopyram: 250 g/L<br>trifloxystrobin: 250 g/L) |
| Analyzed content of active substance: | fluopyram: 21.4% (251.5 g/L)<br>trifloxystrobin: 21.6% (253.5 g/L) |
| Expiration date: | 2008-02-21 |
| 2. Vehicle and/or positive control | Deionized water |
| 3. Test organisms | |
| Species | 7 dicotyledonous plant species from 7 different families: cucumber (*Cucumis sativus*), oilseed rape (*Brassica napus*), soybean (Glycine max), sugar beet (*Beta vulgaris*), sunflower (*Helianthus annuus* L.), tomato (*Lycopersicon esculentum*) and buckwheat (*Fagopyrum esculentum*);<br>3 monocotyledonous plant species from 1 family: oat (*Avena sativa*), ryegrass (*Lolium perenne*) and corn (*Zea mays*) |
| Plant growth stage at application | Seeds |
| Source | Seeds used on the study had not been treated with pesticides or repellents prior to test initiation. Seeds were supplied from commercial sources via Bayer CropScience AG, Horticulture, H 872, 65926 Frankfurt am Main. Routine germination tests were carried out on the seeds to ensure their viability. Seeds were stored in plastic box in refrigerator. |
| Acclimation period | Greenhouse conditions |
| Environmental conditions | |
| Temperature | Regulated at 23 ± 8°C day, 18 ± 8°C night |
| Photoperiod | 16:8 hours light/dark<br>Natural daylight supplemented by artificial lighting to provide the required photoperiod. >15000 lux lamps turn off, >50000 lux shading closing. |

B Study design and methods

| | |
|---|---|
| 1. Experimental dates | 21 March 2007-17 April 2007 |
| 2. Experimental treatments | |
| The day before application the seeds were introduced manually in the soil. They were covered by about 2 - 5 mm of soil. Each pot contained 5 seeds. 4 pots per treatment group were used. All seeds were planted one day before application and test duration was 14 days after 70% emergence of the seedling in the controls for each species.<br>After sowing the pots were top watered. Later, bottom watering was performed via saucers standing below each pot. Water was given in the saucer according to the need of the plants in order to have an optimal water supply for plant growth.<br>The soil used is a mixture of 90% sandy-silt loam and 10% washed sand sterilized with 120 degrees vapor for about 30 minutes, fertilized with 2.4 g Blaukorn per liter and sieved to 2 mm. Soil composition: 39.7% sand, 43.1% silt and 17.2% clay; pH 7.3; organic carbon content 0.81%; lime content 2.0%.<br>The spray solution was applied to the soil surface. The blank control spray solution was deionized water. The product was dissolved in deionized water and was applied once with 200 L/ha using an | |

| |
|---|
| spray chamber equipped with an overhead nozzle (Teejet 8001EVSV), with nozzle height set at 35 cm above the sprayed surface. The spray chamber volume was calibrated by weighing the amount of water applied to a known surface area. |
| 3. Observations |
| Analytical verification: No analytical verification of the stock solution was conducted.<br>Assessment:<br>Emergence (germination): Daily checks were made to identify the date when 70% of the seedlings emerged in the control for each species. Numbers of plants were counted after 7 and 14 days.<br>Survival: Numbers of plants that survived after application were recorded at the final assessment.<br>Phytotoxicity: Visual phytotoxicity ratings were recorded (e.g. chlorosis, necrosis, stunting, abnormal growth) 7 and 14 days after the emergence of 70% of seeds in the controls.<br>Growth stages: Growth stages were recorded at the final assessment according to BBCH-Monograph - Growth stages.<br>Biomass: The dry weights were determined at the final assessment (day 14 after 70% emergence in the untreated control).<br><br>Calculation and statistics:<br>Statistical analysis of biomass data was carried out using the Pairwise Mann-Whitney-U-test (one sided smaller). |

**Results and discussions:**

Findings

The following table summarizes the findings from this study:

| **Species** | **Emergence *<br>(% inhibition)** | **Survival<br>(% inhibition)** | **Phytotoxicity** | **Dry Weight **<br>(% inhibition)** | **Growth stages<br>***** |
|---|---|---|---|---|---|
| Cucumber | 5.6 | 0 | 0 | - 13.5 | 12-14 (12-14) |
| Oilseed rape | 11.1 | 0 | 0 | 14.8 | 12-14 (12-14) |
| Soybean | 0 | 0 | 0 | -17.0 | 12-14 (12-14) |
| Sugar beet | - 11.1 | 0 | 0 | - 9.7 | 12-14 (12-14) |
| Sunflower | 10 | 0 | 0 | - 32.5 | 12-14 (12-14) |
| Tomato | - 5.9 | 0 | 0 | - 16.4 | 12 (10-12) |
| Buckwheat | - 20 | 0 | 0 | 12.5 | 12-14 (12-14) |
| Corn | 10 | 0 | 0 | - 10.0 | 13 (13) |
| Oat | - 11.8 | 0 | 0 | - 17.2 | 12-14 (12-14) |
| Ryegrass | - 11.1 | 0 | 0 | 15.2 | 12-14 (12-14) |

* An increase in dry weight is given as negative values.
** inhibition is expressed on a per plant basis. An increase in dry weight is given as negative values.
*** growth stages of the control in parentheses

Treatment with the test item did not cause any effects on germination, survival, phytotoxicity and biomass that exceeded the 50% trigger for further testing.

Validity criteria:
- Seedling emergence at least 70%: Emergence ranged from 75-100% in the controls of this study
- Plants in control do not exhibit visible phytotoxic effects: fulfilled
- Plants in control exhibit only normal variation in growth and morphology: fulfilled
- Mean plant survival in control at least 90%: Survival was 90-100% for all species in this study.

**Conclusion:**

A nominal product application rate of 0.75 L/ha AE C656948 + Trifloxystrobin SC 250 + 250 g/L showed no adverse effect (i.e. greater than 50%) for all the tested species in the seedling emergence test.

<table>
<tr><td>Comments of zRMS:</td><td>The study is considered valid.<br>**Agreed endpoints:**

| Species | Substance | Exposure System | Results |
|---|---|---|---|
| *Zea mays* [1] m<br>*Lolium perenne* [1] m<br>*Avena sativa* [1] m<br>*Allium cepa* [1] m<br>*Brassica napus* [1] d<br>*Glycine max* [1] d<br>*Fagopyrum esculentum* [2] d | FLU + TFS SC 500 | 21 d<br>Vegetative vigour<br>Tier 1 | [1] $ER_{50}$ > 1.0 L prod./ha<br>[2] $ER_{50}$ < 1.0 L prod./ha (52% reduction of sdw) |

Visual injuries occurred only in *Fagopyrum esculentum* with a mean effect of 3% compared to the control group.<br><br>No differences in the growth stages between the test item and the control group of all ten plant species tested were observed.</td></tr>
</table>

| | |
|---|---|
| Reference: | **KCP 10.6.2/06** |
| Title: | Fluopyram + trifloxystrobin SC 500 (250+250 g/L): Effects on the seedling emergence and seedling growth of ten non-target terrestrial plant species under greenhouse conditions (tier 1) |
| Report: | Ripperger, D.; 2020; S19-22935; M-681165-01-1 |
| Authority registration No: | |
| Guideline(s): | EU Directive 91/414/EEC<br>Regulation (EC) no. 1107/2009<br>US EPA OCSPP 850.4100 (2012)<br>OECD 208 (2006) |
| Deviations: | Yes (see report) |
| GLP/GEP: | yes |
| Acceptability: | |
| Duplication (if vertebrate study): | |

**Executive summary**

Test item (product): Fluopyram + Trifloxystrobin SC 500 (250 + 250 g/L), sample description: TOX21159-00, batch ID: EV57002709, appearance: liquid, whitish, expiry date: 2022-01-16.

The study objective was to determine the effects of Fluopyram + Trifloxystrobin SC 500 (250+250 g/L) on seedling emergence and early growth of ten non-target terrestrial plant species.

In this limit test, seeds of 6 dicotyledonous species and 4 monocotyledonous species were sown in pots filled with soil. The soil surface was treated with fluopyram + trifloxystrobin SC 500 (250+250 g/L) after sowing. The test item was applied at a single rate of 1.0 L product/ha. Deionised water was used for the control treatment. Each test group consisted of a total of 20 seeds which were treated by spray application to the soil surface.

The plants were evaluated for effects of the test item for seedling emergence, post-emergence mortality and signs of visual injuries 7, 14 and 21 days after at least 50% emergence in the control group. Additionally, BBCH growth stages, shoot height and shoot dry weight were assessed on day 21 (termination of study) for all species.

A nominal product application rate of 1.0 L Fluopyram + Trifloxystrobin SC 500/ha showed no adverse effect (i.e. greater than 50%) on emergence, post-emergence mortality, shoot height and shoot dry weight for any tested species.

**Materials and methods:**

A. Materials

| | |
|---|---|
| 1. Test material: | Fluopyram + Trifloxystrobin SC 500 (250+250 g/L) |
| Specification number: | 102000012886 |
| Batch ID: | EV57002709 |
| Visual appearance: | Liquid / whitish |
| Physical density: | 1.169 g/mL |
| Active substance 1: | fluopyram (AE C656948) |
| Active ingredient 2: | trifloxystrobin (CGA 279202) |
| Nominal content of active substance: | fluopyram: 250 g/L<br>trifloxystrobin: 250 g/L |
| Analyzed content of active substance: | fluopyram: 21.1% (246.6 g/L)<br>trifloxystrobin: 21.3% (248.6 g/L) |
| Expiration date: | 2022-01-16 |
| 2. Vehicle and/or positive control | Deionized water |
| 3. Test organisms | |
| Species | 6 dicotyledonous plant species from 6 different families:<br>*Beta* vulgaris (sugar beet), *Brassica napus* (oil seed rape), *Cucumis sativus* (cucumber), *Fagopyrum esculentum* (buckwheat), *Glycine max* (soybean), *Helianthus annuus* (sunflower);<br>4 monocotyledonous plant species from 2 families:<br>*Allium cepa* (onion), *Avena sativa* (oat), *Lolium perenne* (perennial ryegrass), *Zea mays* (corn) |
| Plant growth stage at application | Seeds |
| Source | Untreated seeds from commercial suppliers were used in this study. |
| Acclimation period | Greenhouse conditions |
| Environmental conditions: | Relative humidity (min/max) [%]: 51.25 / 87.96<br>Light intensity (min/max) [µmol/m$^2$/s]: 260 / 400 |
| Temperature | 14.72 / 26.98 °C (min/max) |
| Photoperiod | 16:8 hours light/dark |

B. Study design and methods

| | |
|---|---|
| 1. Experimental Dates | 20 Nov 2019 - 23 Dec 2019 |
| 2. Experimental treatments | |
| Untreated seeds of six dicotyledonous and four monocotyledonous plant species were sown in soil in commercial plastic flower pots (15 cm diameter) and treated with fluopyram + trifloxystrobin SC 500 (250+250 g/L) at a single rate of 1.0 L product/ha. In each treatment group a total number of 20 seeds were sown. Ten (docotyledonous species and *Zea mays*) or five replicates (monocotyledonous species except for corn) with two or four plants per replicate were tested, respectively. Test soil was a specially mixed soil substrate (loamy sand) composed of 76.7% sand, 20.2% silt and 3.1% clay, with a pH of 7.97, an electrical conductivity of 77.6 µS/cm and a total organic carbon content of 0.17% (0.29% organic matter).<br>Bottom watering was done to the plant soucer of each pot. Water was replenished regularly.<br>The blank control spray solution was deionized water. The test item was dissolved in deionized water and was applied once with 200 L/ha using a laboratory track-sprayer (Company Schachtner, Ludwigsburg, Germany) with 80015 EVS, TeeJet as spray nozzle. | |
| 3. Observations | |

Analytical verification: Immediately before application two samples were taken from the test item solution and the water control. Analysis of the test item solution and the control solution was done by LC-UV.

Assessment:
Seedling emergence: The emergence rate was determined 8 days after sowing for *Allium cepa* and 5 days after sowing for all further species tested. The number of emerged seeds per replicate (pot) was assessed 7, 14 and 21 days after at least 50% seedling emergence in the control group.
Post-emergence mortality: Number of dead plants was recorded 7, 14 and 21 days after at least 50% seedling emergence in the control group.
Visual injury: Visual phytotoxicity (necrosis, deformation and change in colour (e.g. chlorosis, bleaching, reddening)) was recorded 7, 14 and 21 days after at least 50% seedling emergence in the control group.
Growth stages: Growth stages (BBCH stage according to MEIER, 2001) were recorded at the last assessment day (21 days after at least 50% seedling emergence in the control)
Shoot height: The height of the above-ground vegetation was measured for each surviving plant at the last assessment day (21 days after at least 50% seedling emergence in the control)
Shoot dry weight: The dry weights were determined at the final assessment (21 days after at least 50% seedling emergence in the control).

Calculation and statistics:
The data of seedling emergence were tested with Fisher`s exact test.
As no mortality occurred, no computations were performed.
The data of shoot height and 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. The significance level was set to $\alpha = 0.05$ for all hypothesis tests.
In case of an increase in the test item group compared to the control group for seedling emergence, shoot height and shoot dry weight, no statistical evaluation was conducted.
Statistical analysis was performed using the program ToxRat Professional Version 3.3.0.

**Results and discussions:**

Analytical Rate Verification:
The analysed concentration of fluopyram in the test item solution corresponded to 99.8 % of the target concentration.

Biological findings:

**Summary of the effects of the test item at 1.0 L product/ha for the last assessment day (21 days after at least 50% seedling emergence in the control)**

| Plant species | Inhibition of seedling emergence [%] # | Cumulative mortality [%] | Visual Injury [Mean in %/ Symptoms] [1] | BBCH growth stage [Min/Max] | | Inhibition [%] # | |
|---|---|---|---|---|---|---|---|
| | | | | C | T | Shoot height | Shoot dry weight |
| **Dicotyledonous Species** | | | | | | | |
| *Beta vulgaris* | -5.3 | 0.0 | 0 / -- | 13/13 | 13/13 | 6.7 | 10.7 |
| *Brassica napus* | -5.3 | 0.0 | 0 / -- | 13/13 | 13/13 | **11.5 *** | 11.7 |
| *Cucumis sativus* | -11.1 | 0.0 | 0 / -- | 12/12 | 12/12 | -2.7 | 12.4 |
| *Fagopyrum esculentum* | 0.0 | 0.0 | 3 / CC, DE | 51/51 | 51/51 | 1.1 | -22.3 |
| *Glycine max* | 0.0 | 0.0 | 0 / -- | 21/21 | 21/21 | **14.3 *** | 2.2 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| *Helianthus annuus* | -11.8 | 0.0 | 0 / -- | 16/16 | 16/16 | -1.5 | -7.3 |
| **Monocotyledonous Species** | | | | | | | |
| *Allium cepa* | -11.1 | 0.0 | 0 / -- | 12/12 | 12/12 | **19.7 *** | **45.5 *** |
| *Avena sativa* | -17.6 | 0.0 | 0 / -- | 14/14 | 14/14 | -3.9 | 9.7 |
| *Lolium perenne* | 5.6 | 0.0 | 0 / -- | 21/21 | 21/21 | 7.5 | **37.5 *** |
| *Zea mays* | -11.1 | 0.0 | 0 / -- | 15/15 | 15/15 | 5.7 | 9.8 |

C: Control, T: Test item
[1] Visual symptoms: None (--), CC = change in colour, DE = deformation
# Negative values indicate that there was an increase compared to the control
* Statistically significantly different compared to the control (Student's t-test; one-sided smaller, α = 0.05

<u>Validity criteria</u>:
All validity criteria were fulfilled for all species tested according to OECD 208:
- Seedling emergence: The seedling emergence of control plants was ≥ 70% (actually between 80% and 100%).
- Visual injury: The control seedlings of each species did not exhibit visible visual injuries and control plants exhibited normal variation in growth and morphology for that particular species.
- Mean survival: The mean survival of emerged control seedlings was ≥ 90% (actually 100%) 21 days after at least 50% emergence in the control.
- Cultivation conditions: 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.

**Conclusion:**

This Tier 1 seedling emergence and growth study evaluating effects of Fluopyram + Trifloxystrobin SC 500 (250+250 g/L) was conducted at a single rate of 1.0 L product/ha on ten non-target terrestrial plant species under greenhouse conditions. No adverse effects on emergence, post-emergence mortality, shoot height and shoot dry weight above the 50% effect level occurred.

No statistically significant effects on the parameter seedling emergence were observed for any of the plant species tested. The highest inhibition occurred for *Lolium perenne* with 5.6% compared to the control group.

No post-emergence mortality occurred during the course of this study.

Visual injuries occurred only in *Fagopyrum esculentum* with a mean effect of 3% compared to the control group.

No differences in the growth stages between the test item and the control group of all ten plant species tested were observed.

Statistically significant differences in shoot height compared to the control group were observed for *Brassica napus* (11.5%), *Glycine max* (14.3%) and *Allium cepa* (19.7%).
Statistically significant differences in shoot dry weight compared to the control group were observed for *Allium cepa* (45.5%) and *Lolium perenne* (37.5%).

### A 2.6.3 KCP 10.6.3 Extended laboratory studies on non-target plants

No additional studies are submitted.

### A 2.6.4 KCP 10.6.4. Semi-field and field tests on non-target plants

No additional studies are submitted.

### A 2.7 KCP 10.7 Effects on other terrestrial organisms (flora and fauna)

No additional studies are submitted.

### A 2.8 KCP 10.8 Monitoring data

No additional studies are submitted.