Appendix A—List of end points for the active substance and the representative formulation

### Identity, Physical and Chemical Properties, Details of Uses, Further Information (Regulation (EU) N° 283/2013, Annex Part A, points 1.3 and 3.2)

| Active substance (ISO Common Name) | beta-cyfluthrin |
|------------------------------------|------------------|
| Function (e.g. fungicide)          | Insecticide      |

| Rapporteur Member State            | Germany          |
|------------------------------------|------------------|
| Co-rapporteur Member State         | Hungary          |

### Identity (Regulation (EU) N° 283/2013, Annex Part A, point 1)

| Chemical name (IUPAC) | a reaction mixture comprising the enantiomeric pair (R)-α-cyano-4-fluoro-3-phenoxybenzyl (1S,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (S)-α-cyano-4-fluoro-3-phenoxybenzyl (1R,3R)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate in ratio 1:2 with the enantiomeric pair (R)-α-cyano-4-fluoro-3-phenoxybenzyl (1S,3R)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (S)-α-cyano-4-fluoro-3-phenoxybenzyl (1R,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate |
|-----------------------|------------------|
| Chemical name (CA)    | cyano(4-fluoro-3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate |

| Diastereomer II       | cyclopropanecarboxylic acid, 3-(2,2-dichloroethenyl)-2,2-dimethyl-(R)-cyano(4-fluoro-3-phenoxyphenyl)methyl ester, (1S,3S)-rel- |
| Diastereomer IV       | cyclopropanecarboxylic acid, 3-(2,2-dichloroethenyl)-2,2-dimethyl-(R)-cyano(4-fluoro-3-phenoxyphenyl)methyl ester, (1S,3R)-rel- |

| CIPAC No              | 482              |
|-----------------------|------------------|
| CAS No                | Not existing for beta-cyfluthrin as defined by ISO 1750 |
| EC No (EINECS or ELINCS) | Not allocated (new) |
| FAO Specification (including year of publication) | 482/TC (2016) applicable to material from Bayer |
Beta-cyfluthrin  ≥ 965 g/kg
Diastereomer II  300 – 400 g/kg
Diastereomer IV  570 – 670 g/kg

Minimum purity of the active substance as manufactured

Minimum purity  965 g/kg
Diastereomer II  300 – 400 g/kg
Diastereomer IV  570 – 670 g/kg

Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured

None.

Molecular formula

C_{22}H_{18}Cl_{2}FNO_{3}

Molar mass

434.3 g/mol

Structural formula

Diastereomer II (isomer II)

Diastereomer IV (isomer IV)
### Physical and chemical properties (Regulation (EU) N° 283/2013, Annex Part A, point 2)

| Property                                | Beta-cyfluthrin (98.8 %): 82 - 96 °C | Isomer II (99.2 %): 80.7 °C | Isomer IV (99.8 %): 106.2 °C |
|-----------------------------------------|--------------------------------------|-----------------------------|------------------------------|
| **Melting point** (state purity)        |                                      |                             |                              |
| **Boiling point** (state purity)        | The test item showed no boiling point at atmospheric condition, because it decomposed first at a temperature of approximately 210 °C. | The test item showed no boiling point at atmospheric conditions because it decomposed first starting at a temperature of 260 °C (glass crucibles) and 270 °C (aluminium crucibles). | The test item showed no boiling point at atmospheric conditions because it decomposed first starting at a temperature of 255 °C (glass crucibles) and 260 °C (aluminium crucibles). |
| **Temperature of decomposition** (state purity) | Beta-cyfluthrin (98.8 %): approximately 210°C. | Isomer II (99.4 %): starting at a temperature of 260 °C (glass crucibles) and 270 °C (aluminium crucibles). | Isomer IV (99.2 %): starting at a temperature of 255 °C (glass crucibles) and 260 °C (aluminium crucibles). |
| **Appearance** (state purity)           | Beta-cyfluthrin (99.1 %): white powder | Isomer II (99.4 %): white powder | Isomer IV (99.2 %): white powder |
| **Vapour pressure** (state temperature, state purity) | Isomer II (99.4 %): 1.0 x 10^-6 Pa at 25 °C | Isomer IV (99.2 %): 4.6 x 10^-6 Pa at 25 °C |
| **Henry’s law constant**                | Isomer II (99.4 %): 9.3 x 10^-2 Pa m^3 mol^-1 | Isomer IV (99.2 %): 0.6 Pa m^3 mol^-1 |
| **Solubility in water** (state temperature, state purity and pH) | Isomer II (99.4 %): 2.1 µg/L at 20 °C (pH 6.4) | Isomer IV (99.2 %): 1.6 µg/L at 20 °C (pH 6.4) |
Solubility in organic solvents
(state temperature, state purity)

| Solubility of Isomer II at 20 °C in g/L (99.3 %) | Solubility of Isomer IV at 20 °C in g/L (98.9 %) |
|-----------------------------------------------|-----------------------------------------------|
| acetone > 250 | acetone > 250 |
| acetonitrile > 250 | acetonitrile 81 |
| dichloromethane > 250 | dichloromethane > 250 |
| dimethylsulfoxide > 250 | dimethylsulfoxide 204 |
| ethylacetate > 250 | ethylacetate > 250 |
| n-heptane 3.2 | n-heptane 1.2 |
| 1-octanol 7.1 | 1-octanol 2.8 |
| polyethylene glycol 55 | polyethylene glycol 27 |
| 2-propanol 9.3 | 2-propanol 4.3 |
| xylene > 250 | xylene 103 |

Surface tension
(state concentration and temperature, state purity)

Not applicable - water solubility of the test item is lower than 1 mg/L.

Partition coefficient
(state temperature, pH and purity)

| Isomer II (99.4 %): log P_{OW} = 5.9 at 25 °C (pH 5.6) |
|----------------------------------------------------------|
| Isomer IV (99.2 %): log P_{OW} = 5.8 at 25 °C (pH 5.6) |

Dissociation constant (state purity)

Not applicable; the substance does not have acid or alkaline properties. (Statement)
UV/VIS absorption (max.) incl. \( \varepsilon \) (state purity, pH)

| Isomer II (99.3 %): | \( \lambda_{\text{max}} \) [nm], \( \varepsilon \) [L mol\(^{-1}\) cm\(^{-1}\)], pH |
|---------------------|------------------------------------------|
| 204                 | 41366                                    | neutral |
| 269                 | 2129                                     | neutral |
| 276                 | 2008                                     | neutral |
| 291                 | 80                                       | neutral |
| 203                 | 44498                                    | acidic   |
| 269                 | 2129                                     | acidic   |
| 276                 | 2008                                     | acidic   |
| 291                 | 80                                       | acidic   |
| 220                 | 29639                                    | basic    |
| 295                 | 1486                                     | basic    |

| Isomer IV (99.2 %): | \( \lambda_{\text{max}} \) [nm], \( \varepsilon \) [L mol\(^{-1}\) cm\(^{-1}\)], pH |
|---------------------|------------------------------------------|
| 204                 | 42545                                    | neutral |
| 269                 | 2127                                     | neutral |
| 276                 | 2000                                     | neutral |
| 291                 | 85                                       | neutral |
| 204                 | 42503                                    | acidic   |
| 269                 | 2042                                     | acidic   |
| 276                 | 1957                                     | acidic   |
| 291                 | 43                                       | acidic   |
| 219                 | 28888                                    | basic    |
| 294                 | 1617                                     | basic    |

Flammability (state purity)

Beta-cyfluthrin technical is not flammable (99.1 %)

Explosive properties (state purity)

Beta-cyfluthrin technical is neither explosive when heated in a closed tube, nor it is sensitive to shock, nor to friction. (98.8 %)

Oxidising properties (state purity)

Beta-cyfluthrin technical has no oxidizing properties. (99.1 %)
| Crop and/or situation (a) | Member State or Country | Product name | FG or I (b) | Pests or Group of pests controlled (c) | Preparation | Application | Application rate per treatment | PHI (days) (m) | Remarks |
|--------------------------|--------------------------|--------------|-------------|---------------------------------------|-------------|------------|--------------------------------|----------------|---------|
| Beet                     | EU                       | Montur Forte | F           | Chaetocnema spp, Atomaria linears, Agriotes spp, Pegomyia hyoscyami Pegomyia betae Scutigerella immaculatae Blanilidus guttulatus Aphids Thrips | FS IMD: CYB: 80 Seed treatment | 00 1 na na na IMD: 19.5 CYB: 10.4 na | Sowing rate: 1.30 u/ha 1 u = 100 000 seeds Dose rate: 0.10 L Pdt/u 0.13 L Pdt/ha |
| Potato                   | North-Zone, Central Zone | Bulldock 25 EC F | Sucking and biting insects | EC CYB: 25 Foliar spray 10-49 2 14 days 1.5-5 150 - 500 CYB: 7.5 3 |
| Potato                   | South Zone               | Bulldock 25 EC F | Sucking and biting insects | EC CYB: 25 Foliar spray 10-49 2 14 days 1.25-4.16 300 - 1000 CYB: 12.5 3 |
| Wheat                    | North-Zone, Central Zone | Bulldock 25 EC F | Sucking and biting insects | EC CYB: 25 Foliar spray Winter cereals BBCH 11-29 (autumn) BBCH 49-75 (spring) Spring cereals BBCH 10-75 | 2 14 days 1.875-5 150 - 400 CYB: 7.5 21 |
| Crop and/or situation (a) | Member State or Country | Product name | FG or I (b) | Pests or Group of pests controlled (c) | Preparation | Application | Application rate per treatment | PHI (days) (m) | Remarks |
|--------------------------|-------------------------|--------------|-------------|----------------------------------------|-------------|------------|-------------------------------|---------------|---------|
| Wheat                    | South Zone              | Bulldock 25 EC | F           | Sucking and biting insects             | EC CYB: 25 Foliar spray | Winter cereals BBCH 11-29 (autumn) BBCH 49-75 (spring) Spring cereals BBCH 10-75 | g a.s./hl min-max (l) | Water L/ha min-max | g as/ha min-max (l) | 21 |
| Tomato                   | EU                      | Bulldock 25 EC | G           | Sucking and biting insects             | EC CYB: 25 Foliar spray | all BBCH up to PHI | 1.75-3.5 | 500-1000 | CYB: 17.5 | 3 |

Pdt = product, CYB = beta-Cyfluthrin; IMD = imidacloprid

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant; type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxyprpy). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).
(j) Growth stage range from first to 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
(k) Indicate the maximum number of applications possible under practical conditions of use
(l) The values should be given in g/kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval
Summary of additional intended uses for which MRL applications have been made, that in addition to the uses above, have also been considered in the consumer risk assessment (name of active substance or the respective variant)

Regulation (EC) No 1107/2009 Article 8.1(g))

Important note: efficacy, environmental risk and risk to humans by exposure other than via their diet have not been assessed for these uses

| Crop and/or situation (a) | Member State or Country | Product name | F G or I (b) | Pests or Group of pests controlled (c) | Preparation | Application | Application rate per treatment | Remarks |
|---------------------------|-------------------------|--------------|--------------|--------------------------------------|-------------|------------|-------------------------------|---------|
|                           |                         |              |              |                                      | Type (d-f)  | Conc. as (i) | method kind (f-h) | range of growth stages & season (j) | number min-max (k) | Interval between application (min) | kg as /hl | Water L/ha | kg as/ha min-max (l) | PHI (days) (m) |          |
|                           |                         |              |              |                                      |             |             |                              |                        |                           |                       |                        |                        |               |          |
| MRL Application           |                         |              |              |                                      |             |             |                              |                        |                           |                       |                        |                        |               |          |
|                           |                         |              |              |                                      |             |             |                              |                        |                           |                       |                        |                        |               |          |

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)

(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)

(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds

(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide

(f) All abbreviations used must be explained

(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench

(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant-type of equipment used must be indicated

(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).

(j) Growth stage range from first to 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

(k) Indicate the minimum and maximum number of applications possible under practical conditions of use

(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha

(m) PHI - minimum pre-harvest interval
Further information, Efficacy

Effectiveness (Regulation (EU) N° 284/2013, Annex Part A, point 6.2)

| Results of efficacy tests carried out for the registration in different European countries and several years of farmers use of products containing the active ingredients beta-cyfluthrin and imidacloprid gave proof of sufficient efficacy on relevant pest species in beet. Results of efficacy tests carried out for the registration in different European countries and several years of farmers use of beta-cyfluthrin gave proof of sufficient efficacy on a large number of biting and sucking pest species in several different crops like oilseed rape, potato, cereals, sugar beet. |

Adverse effects on field crops (Regulation (EU) N° 284/2013, Annex Part A, point 6.4)

| No important phytotoxic effects on treated crops have been observed in the long period of use of beta-cyfluthrin containing products in a wide range of different crops. No adverse effects on quality or yield of treated crops have been observed. |

Observations on other undesirable or unintended side-effects (Regulation (EU) N° 284/2013, Annex Part A, point 6.5)

| No undesirable or unintended side-effects of the product ‘Montur Forte FS 230’ or ‘Bulldock EC 25’ have been described. Experience from the long commercial use in several countries with a wide range of crops showed no adverse effects on quality or yield of adjacent crops or succeeding crops, or plants or plant products used for propagation. |

Groundwater metabolites: Screening for biological activity (SANCO/221/2000-rev.10-final Step 3 a Stage 1)

| Activity against target organism |

| Not relevant. |
Methods of Analysis

Analytical methods for the active substance (Regulation (EU) N° 283/2013, Annex Part A, point 4.1 and Regulation (EU) N° 284/2013, Annex Part A, point 5.2)

| Technical as (analytical technique) | HPLC-UV |
|------------------------------------|---------|
| Impurities in technical as (analytical technique) | HPLC-UV |
| Plant protection product (analytical technique) | HPLC-UV |

Analytical methods for residues (Regulation (EU) N° 283/2013, Annex Part A, point 4.2 & point 7.4.2)

Residue definitions for monitoring purposes

| Food of plant origin | cyfluthrin (cyfluthrin including other mixtures of constituent isomers (sum of isomers)) |
|----------------------|------------------------------------------------------------------------------------------|
| Food of animal origin| cyfluthrin (cyfluthrin including other mixtures of constituent isomers (sum of isomers)) |
| Soil                 | constituent isomers of beta-cyfluthrin                                                   |
| Sediment             | constituent isomers of beta-cyfluthrin                                                   |
| Water surface        | constituent isomers of beta-cyfluthrin                                                   |
| Drinking/ground      | constituent isomers of beta-cyfluthrin                                                   |
| Air                  | beta-cyfluthrin                                                                          |
| Body fluids and tissues| beta-cyfluthrin, sulphate conjugate of 4-OH-FPB acid                                    |

Monitoring/Enforcement methods

| Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes) | GC-MS multi residue method DFG S19 (with ions m/z 226, 206, 199 validated for confirmation); ILV available; applicable for all matrix groups, LOQ = 0.01 mg/kg |
|-------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes) | multi residue method DFG S19 GC-ECD (DB-1 column, applicable for all matrix groups); ILV available; confirmatory analysis by GC-ECD (DB-1701 column), LOQ = 0.01 mg/kg |
| Soil (analytical technique and LOQ) | multi residue method DFG S19 GC-ECD (DB-1 column); confirmatory analysis by NCI-GC-MS (HP-5ms column), LOQ = 0.01 mg/kg |
| Water (analytical technique and LOQ) | Drinking water: LC-MS/MS (with transitions m/z 451→191 and m/z 451→127 validated for confirmation), ILV available, LOQ = 0.01 µg/L  
Surface water: Data gap: primary and confirmatory methods which allow the determination of 0.0002 µg/L beta-cyfluthrin  |
### Classification and labelling with regard to physical and chemical data (Regulation (EU) N° 283/2013, Annex Part A, point 10)

| Substance | Beta-cyfluthrin |
|-----------|----------------|
| Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]¹: | None |
| Peer review proposal² for harmonised classification according to Regulation (EC) No 1272/2008: | None |

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1 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

2 It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.
Impact on Human and Animal Health

Absorption, distribution, metabolism and excretion (toxicokinetics) (Regulation (EU) N° 283/2013, Annex Part A, point 5.1)

| Rate and extent of oral absorption/systemic bioavailability | Cyfluthrin: > 80% (based on i.v. studies with excretion via urine, faeces and body without GIT; supported by oral and duodenal studies) - 50 % of the faecally excreted radioactivity is due to an absorbed and biliary eliminated amount. Cmax 1.0-1.5 µg/mL at 0.5 mg/kg bw and 18-27µg/mL at 10 mg/kg bw. Tmax 1.5-2.0 h at 0.5 mg/kg bw and 1.5-2.4 h at 10 mg/kg bw. Beta-cyfluthrin: 77 % (males) or 85% (females) (based on low dose experiments using 0.5 mg/kg bw beta-cyfluthrin; radioactivity detected in expired air, urine, cage wash, residues in carcass and tissues Cmax 0.1-0.3 µg/mL at 0.5 mg/kg bw and 1.4-1.5 µg/mL at 10 mg/kg bw. Tmax 0.5 h at 0.5 mg/kg bw and 6-8 h at 10 mg/kg bw |
| Distribution | Widely distributed (highest values in fatty tissue, adrenals, kidney and liver) Cyfluthrin: t1/2 plasma data depend on phase of elimination curve Beta-Cyfluthrin: t1/2 plasma (terminal) 10-14 h at 0.5 mg/kg bw and 42-50 h at 10 mg/kg bw |
| Potential for accumulation | No evidence for accumulation |
| Rate and extent of excretion | Rapid and extensive (> 90 % within 48 h), mainly via urine (55 %, 12 % via faeces, 33 % via bile) |
| Metabolism in animals | Extensively metabolised (> 95 %); main metabolites at radiolabelled cyclopropyl-moiety: cis/trans DCVA, DCVA acyl glucuronide; Radiolabelled fluorophenyl-moiety: sulfate conjugate of 4-OH-FPB, FPB acid. Parent compound only detected in faeces (up to 20 %). Cleavage of the ester bond, oxidation, hydroxylation and conjugation. |
| In vitro metabolism | Rat liver microsomes: beta-cyfluthrin is extensively metabolised (11 metabolite fractions) Human liver microsomes: limited metabolism rate (2 metabolite fractions) All metabolite fractions observed in human microsomes were also found in rats in similar portions. |
| Toxicologically relevant compounds (animals and plants) | Beta-cyfluthrin |
| Toxicologically relevant compounds (environment) | Beta-cyfluthrin |
### Acute Toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.2)

| Route | Value | Cat | Notes |
|-------|-------|-----|-------|
| Rat LD$_{50}$ oral | 14.3 mg/kg bw (cyfluthrin, cremophor/water) - 1189 mg/kg bw (cyfluthrin, PEG 400) | Cat 2 H300 | Non-irritant | Beta-cyfluthrin | Skin irritation | Not phototoxic (3T3 NRU-PT$^{(a)}$ with limitations) |
| Mouse LD$_{50}$ oral | 91 mg/kg bw (beta-cyfluthrin, PEG 400) - 609 mg/kg bw (cyfluthrin, PEG 400) | Cat 2 H330 | Non-irritant | Beta-cyfluthrin | Eye irritation | Non-irritant |
| Rat/Rabbit LD$_{50}$ dermal | Rat: >2000 mg/kg bw (beta-cyfluthrin, PEG 400) | Non-sensitizer | M&K | Cyfluthrin: | Skin sensitisation | Non-sensitizer (cyfluthrin, M&K) |
| Rat LC$_{50}$ inhalation | Aerosol (ethanol/PEG 400) 0.081 mg/L air (beta-cyfluthrin, 4h-exposure, head-nose only) >1.089 mg/L air (cyfluthrin, 1h-exposure, nose only) Dust 0.532 mg/L air (beta-cyfluthrin, 4h-exposure, head-nose only) 0.967 mg/L air (beta-cyfluthrin, 4h-exposure, head/nose) | Cat 2 H330 | It might not be appropriate to UVB absorbers like beta-cyfluthrin (data gap). |

### Short-term Toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.3)

| Category | Value |
|----------|-------|
| Target/critical effect | Mortality (rats) at 16 and 40 mg/kg bw per d; behavioural/motor disturbances, reduced body weight development, choreoathetotic signs (rats and dogs) |
| Relevant oral NOAELs | Beta-cyfluthrin: |
| | 1 mg/kg bw per d (28-day rat) |
| | 2.4 mg/kg bw per d (90-d dog) |
| | Cyfluthrin: |
| | 2.43 mg/kg bw per d (1-year dog) |
| Relevant dermal NOAEL | Cyfluthrin: |
| | 22/23-d, rat: |
| | - local effects: 113 mg/kg bw per d |
| | - systemic effects: 376 mg/kg bw per d |
| Relevant inhalation NOAEL | Cyfluthrin: |
| | 0.09 mg/L air (~0.02 mg/kg bw per d) |
| | Rat, 6 h/day, head-nose exposure, 13-week, aerosol, 5 days per week |
| | Beta-cyfluthrin: |
| | 0.2 mg/L air (~0.07 mg/kg bw per day) |
### Genotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.4)

#### In vitro studies

| Test Type | Substance | Results |
|-----------|-----------|---------|
| Ames tests | Beta-cyfluthrin | supplementary studies (3), negative |
| | Cyfluthrin | supplementary studies (3), negative |
| In vitro HPRT/MLA | Beta-cyfluthrin | 1 negative, 1 equivocal |
| | Cyfluthrin | supplementary, negative |
| In vitro CA | Cyfluthrin | 1 supplementary, negative |
| In vitro UDS | Beta-cyfluthrin | negative (no guideline requirement) |
| | Cyfluthrin | supplementary, negative |
| In vitro DNA strand breaks | Cyfluthrin | supplementary, positive |

#### In vivo studies

| Test Type | Substance | Results |
|-----------|-----------|---------|
| In vivo MN/CA | Beta-cyfluthrin | negative, supplementary |
| | Cyfluthrin | negative, supplementary |

- **Photomutagenicity**: No data, not required.
- **Potential for genotoxicity**: No genotoxic potential (beta-cyfluthrin and cyfluthrin).

### Long-term toxicity and carcinogenicity (Regulation (EU) N°283/2013, Annex Part A, point 5.5)

#### Long-term effects (target organ/critical effect)

| Organ/System | Description |
|--------------|-------------|
| Rat | Body weight reduction |
| Mouse | Ovary (organ weight changes) and Spleen (organ weight changes), skin findings due to scratching (paresthesia) |

#### Relevant long-term NOAELs

| Substance | Description |
|-----------|-------------|
| Cyfluthrin | 2.6 mg/kg bw per d (2-yr rat) |
| LOAEL | 32 mg/kg bw per d (18-mo, mouse) |

#### Carcinogenicity (target organ, tumour type)

| Substance | Description |
|-----------|-------------|
| Cyfluthrin | No evidence for carcinogenicity |

#### Relevant NOAEL for carcinogenicity

| Substance | Description |
|-----------|-------------|
| Cyfluthrin | Rat: 22.8 mg/kg bw per day (high dose) |
| Mouse: | 233 mg/kg bw per day (high dose) |
Reproductive toxicity (Regulation (EU) No 283/2013, Annex Part A, point 5.6)

| Reproduction target / critical effect | Lact H362 |
|--------------------------------------|-----------|
| Parental: splaying of hindlimbs, bw reduction | |
| Offspring: coarse tremors, bw reduction during lactation | |

Relevant parental NOAEL

| Cyfluthrin: 3.3 mg/kg bw per d |

Relevant reproductive NOAEL

| Cyfluthrin: 26.7 mg/kg bw per d |

Relevant offspring NOAEL

| Cyfluthrin: 3.3 mg/kg bw-per d |

Developmental toxicity

| Rat (oral studies): |
|---------------------|
| - maternal: mortality, bw reduction, reduced food consumption, clinical signs (hypoactivity, locomotor incoordination, salivation). |
| - developmental: bw reduction, retarded ossification/skeletal variations |

Inhalation studies with rats:

| - maternal: reduced food intake and bw development, hypothermia and bradypnoe |
| - developmental: increased incidence of microphthalmia, retarded development, retarded ossification |

Rabbit:

| - maternal: reduced food consumption and body weight loss |
| - developmental: post-implantative resorptions |

Relevant maternal NOAEL

| Beta-cyfluthrin+Cyfluthrin: |
|-----------------------------|
| Rat: 3 mg/kg bw per d |
| Rabbit: 20 mg/kg bw per d |

Inhalation study with cyfluthrin in rats:

| < 0.46 mg/m³ air |

Relevant developmental NOAEL

| Beta-cyfluthrin: |
|-----------------|
| Rat: 10 mg/kg bw per d |
| Rabbit: 20 mg/kg bw per d |

Inhalation study with cyfluthrin in rats:

| 0.46 mg/m³ air |

Neurotoxicity (Regulation (EU) No 283/2013, Annex Part A, point 5.7)

| Acute neurotoxicity | Beta-cyfluthrin: reversible clinical signs in Functional Observation Battery (FOB) (reduced motor and locomotor activity) NOAEL: 2 mg/kg bw |
|---------------------|----------------------------------------------------------------------------------------------------------------------------------|

Repeated neurotoxicity

| Beta-cyfluthrin: Clinical signs (paresthesia), decreased bw |
| Developmental neurotoxicity | **Beta-cyfluthrin:**  
Maternal: Lower bw development during gestation and lactation, no evidence for neurotoxicity  
Offspring: Reduced pup weight gain, FOB: minimal resistance during handling, reduced startle response  
NOAEL maternal and offspring: 11 mg/kg bw per d |
|-----------------------------|--------------------------------------------------------|
| Delayed neurotoxicity in laying hens | **Cyfluthrin** (6 studies): bw loss, clinical signs, mortality at doses > 4000 mg/kg bw.  
No evidence of delayed neurotoxic activity.  
Single and repeated oral (gavage) application.  
No NOAEL derived |
| Other toxicological studies (Regulation (EU) N° 283/2013, Annex Part A, point 5.8) | Supplementary studies on the active substance  
Cyfluthrin and some metabolites were less efficient inhibitors of Na⁺-, K⁺- or Mg²⁺-activated transport ATPases than other substances like ouabain or DDT.  
Exposure of rats to cyfluthrin led to reflectory respiratory changes associated with effects on thermoregulation and the acid-base status.  
Cyfluthrin aerosol (up to 101 mg/m³ air) had no relevant impact on the arterial blood gases of rats but led to hypothermia.  
Oral administration of up to 500 mg/kg bw cyfluthrin to rats (PEG 400) had no impact on body temperature.  
A reduced acute toxicity of cyfluthrin was observed in an antidote study with musaril.  
Combined administration of cyfluthrin with other insecticides (unless omethoate) resulted in sub-additive acute toxic effect.  
Beta-cyfluthrin led to lower LD₅₀ values than cyfluthrin following i.p. injection.  
The s.c. LD₅₀ for cyfluthrin in PEG 400 was >2500 mg/kg bw in mice.  
The RD₅₀ values for beta-cyfluthrin in PEG 400/ethanol were 38 and 37 mg/m³ air for rats and mice, respectively  
After cyfluthrin administration the RD₅₀ value in rat was a bit higher. |
| Mechanism studies | Cyfluthrin was detected in serum, fat and brain of rats following feed or gavage exposure.  
Cyfluthrin and beta-cyfluthrin exposure was associated with oxidative stress in vivo and in vitro, respectively.  
Cyfluthrin act as a PXR agonist *  
Cyfluthrin did not show AhR- or PPARα or PPARγ mediated transcriptional activity*. |

* The studies are considered supplementary.
### Immunotoxicity

**Human volunteer studies**

There is no evidence indicative of an immunotoxic effect.

1-h inhalation exposure to approx. 0.1 mg cyfluthrin/m³ air appeared to be in the range of an irritant threshold concentration for humans.

STOT-SE Cat. 3
May cause respiratory irritation (supported by developmental toxicity studies in rats).

### Indications for adverse effects on hormonal systems

The examined endpoints on reproduction did not indicate endocrine disrupting properties of beta-cyfluthrin.
Mechanistic transactivation assays indicate that cyfluthrin has both agonistic and antagonistic effects on oestrogen receptors, as well as antagonistic effects on both androgen and thyroid receptors.
Overall, beta-cyfluthrin is considered unlikely to be an endocrine disruptor.

### Studies performed on metabolites or impurities

**3-Phenoxy-4-fluorobenzyl alcohol (FPB-alcohol):**
Rat LD<sub>50</sub> oral: 1599 (male), 1600-1800 mg/kg bw (female), *
Ames test: negative

**3-Phenoxy-4-fluorobenzaldehyde (FPB-aldehyde):**
Rat LD<sub>50</sub> oral: 1248 (male), 1040 mg/kg bw (female),
Rat LD<sub>50</sub> (dermal): >5000 mg/kg bw
Rat acute inhalation (vapour: 50 g): no dead animal,
Rabbit skin/eye irritation: negative
Ames test: negative*

**3-Phenoxy-4-fluorobenzoic acid (FPB acid):**
Rat LD<sub>50</sub> oral: >5000 mg/kg bw (male, female)*

**3(4'-Hydroxyphenoxy)-4-fluorobenzoic acid (4-OH-FPB acid):**
Rat LD<sub>50</sub> oral: >1000 mg/kg bw (male, female)*
Ames test: negative*

**3-Phenoxy-4-fluorobenzoic acid amide (FPB amide):**
Rat LD<sub>50</sub> oral: >5000 mg/kg bw (male, female)
Ames test: negative*

FCR 2728: +,(R,S)-α-Carboxy-[3-phenoxy-4-fluorobenzyl-1-(R,S)-trans-3-(2,2'-dichloroethenyl1'-yl)-2,2-dimethylcyclo-propanecarboxylic acid ester:
Rat LD<sub>50</sub> oral: >2500 mg/kg bw (male, female)*

FCR 2978: +,(R,S)-α-Carboxamido-[3-phenoxy-4-fluorobenzyl-1-(R,S)-trans-3-(2,2'-dichloroethenyl1'-yl)-2,2-dimethyl-cyclopropanecarboxylic acid ester:
Rat LD<sub>50</sub> oral: >2500 mg/kg bw (male, female)*

FCR 1272-Phenoxyethylene: 2-phenoxyethyl 3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate
Rat LD<sub>50</sub> oral: >2500 mg/kg bw (male, female)
Ames test: negative*

* supplementary studies

### Other sources
Medical data (Regulation (EU) N° 283/2013, Annex Part A, point 5.9)

| No adverse effects in manufacturing personnel reported. Occupational medical surveillance of workers did not reveal any unwanted effects. Skin symptoms after dermal contact (paresthesia, pruritus, tautness, reddening of the facial skin) and signs of irritation in the oro-pharyngeal cavity or coughing after inhalative exposure to cyfluthrin in workers. | STOT-SE cat. 3 May cause respiratory irritation |

Summary3 (Regulation (EU) N° 1107/2009, Annex II, point 3.1 and 3.6)

| Value (mg/kg bw (per day)) | Study | Uncertainty factor |
|---------------------------|-------|--------------------|
| Acceptable Daily Intake (ADI**) | 0.01 | rat, 4-week | 100 |
| Acute Reference Dose (ARfD**) | 0.01 | rat, 4-week | 100 |
| Acceptable Operator Exposure Level (AOEL systemic)* | 0.000243 | Rat, 13-week inhalation | 100 |
| Acute Acceptable Operator exposure level (AAOEL) | 0.01 | rat, 4-week | 100 |

*From the first peer review, the ADI was 0.02 mg/kg bw per day based on the chronic rat study, revised to 0.003 mg/kg bw per day based on a pharmacological study in mice; the ARfD was 0.02 mg/kg bw based on the acute oral rat neurotoxicity study; and the AOEL was 0.02 mg/kg bw per day based on 90-day and acute oral rat neurotoxicity studies (European Commission, 2002b)

* Also applicable to DCVA, FPB acid (and its precursor FPB ald) and 4-OH-FPB acid.

Dermal absorption (Regulation (EU) N° 284/2013, Annex Part A, point 7.3)

| Representative formulation |
|---------------------------|
| Montur Forte FS 230 (beta-cyfluthrin 80 g/L): 0.1 % for the concentrate (80 g/L); 0.3 % for the intermediate dose (40 g/L), and 0.7 % for the low dose (11.4 g/L), applied dose approx. 0.1 L/cm² (exposure area 1 cm² skin); based on an in vitro dermal absorption study in human skin |
| Bulldock EC 25: Human skin: 13 % for the concentrate (26.5 g/L), applied dose approx. 0.268 ± 0.04 µg/cm² and 37 % for the dilution (0.013 g/L, applied dose approx. 0.13 µg/cm²); based on an in vitro dermal absorption study in rat and human skin membranes |

Exposure scenarios (Regulation (EU) N° 284/2013, Annex Part A, point 7.2)

Bulldock 25 EC (field). Use: potatoes and wheat, tractor mounted equipment

| Operators |
|------------|
| Bulldock 25 EC (field) |
| Use: potatoes and wheat, tractor mounted equipment, |
| Application rate 0.0125 kg as/ha (SEU) |

3 If available include also reference values for metabolites
### Exposures estimates:

| Model          | PPE/RPE                                      | %AOEL/AAOEL |
|----------------|----------------------------------------------|-------------|
| UK POEM        | Without PPE; with workwear                   | 99367/-     |
|                | Gloves during M/L and A, workwear           | 1510/-      |
| German model   | Without PPE                                  | 1570/-      |
|                | Gloves during M/L/A, coverall and sturdy footwear during A | 85.1/- |
| AOEM           | Workwear M/L and A (arms, body and legs covered) drift reducing nozzles | 3187/303 |
|                | M/L: workwear + gloves + hood and visor     | 72.7/13.0   |
|                | A: workwear + gloves                        |             |

**Bulldock 25 EC**

Use: potatoes and wheat, tractor mounted equipment, application rate 0.0125 kg as/ha

Exposure estimates:

| Model/ Data     | PPE                                      | %AOEL/AAOEL |
|-----------------|------------------------------------------|-------------|
| Krebs et al (2000) | workwear                                 | 317/-       |
|                 | workwear + gloves                        | 74/-        |
| EFSA (2014)     | Potential                                | 4101/-      |
|                 | workwear                                 | 459/-       |
|                 | Workwear + gloves                        | -/-         |

**Bulldock 25 EC**

Use: potatoes and wheat, tractor mounted equipment, application rate 0.0075 kg as/ha

Exposure estimates:

| Model/ Data     | PPE                                      | %AOEL/AAOEL |
|-----------------|------------------------------------------|-------------|
| Krebs et al (2000) | Workwear                                 | 190/-       |
|                 | workwear + gloves                        | 44/-        |
| EFSA (2014)     | potential                                | 2460/-      |
|                 | workwear                                 | 276/-       |
|                 | workwear + gloves                        | -/-         |
### Bystanders and residents

**Bulldock 25 EC**: field use, application rate 0.0125 kg as/ha (SEU)

| Exposure estimates: | Model | Category          | %AOEL/AAOEL |
|---------------------|-------|-------------------|--------------|
| Martin et al. (2008) | Bystander (adult) | 88/-             |
|                     | Bystander (child) | 69/-             |
|                     | Resident (adult)  | 11/-             |
|                     | Resident (child)  | 18/-             |

**EFSA (2014)**, 10m, drift reduction, high water volume

| Exposure estimates: | Model | Category | %AOEL/AAOEL |
|---------------------|-------|----------|--------------|
| Bystander (child):  |       |          | n.r./<1      |
| - Drift             |       |          | n.r./11      |
| - Vapour            |       |          | n.r./<1      |
| - Deposits          |       |          | n.r./13      |
| - Re-entry          |       |          | n.r./<1      |
| Bystander (adult):  |       |          | n.r./<1      |
| - Drift             |       |          | n.r./2       |
| - Vapour            |       |          | n.r./<1      |
| - Deposits          |       |          | n.r./8       |
| - Re-entry          |       |          | n.r./<1      |
| Resident (child):   |       |          | 14/n.r.      |
| - Drift             |       |          | 440/n.r.     |
| - Vapour            |       |          | 6/n.r        |
| - Deposits          |       |          | 554/n.r.     |
| - Re-entry          |       |          | 894/n.r.     |
| - Sum (mean)        |       |          |              |
| Resident (adult):   |       |          | 3/n.r.       |
| - Drift             |       |          | 95/n.r.      |
| - Vapour            |       |          | 3/n.r        |
| - Deposits          |       |          | 308/n.r.     |
| - Re-entry          |       |          | 343/n.r.     |
| - Sum (mean)        |       |          |              |

**Bulldock 25 EC**: field use, application rate 0.0075 kg as/ha (SEU)

| Exposure estimates: | Model | Category | %AOEL/AAOEL |
|---------------------|-------|----------|--------------|
| Martin et al. (2008) | Bystander (adult) | 53/-     |
|                     | Bystander (child) | 41/-     |
|                     | Resident (adult)  | 7/-       |
|                     | Resident (child)  | 11/-      |
| EFSA (2014); 10m distance, drift reduction, high water volume | Bystander (child): |  |
|---|---|---|
| | - Drift | n.r./< 1 |
| | - Vapour | n.r./1 |
| | - Deposits | n.r./1 |
| | - Re-entry | n.r./8 |

| Bystander (adult): |  |
|---|---|
| - Drift | n.r./< 1 |
| - Vapour | n.r./2 |
| - Deposits | n.r./< 1 |
| - Re-entry | n.r./4 |

| Resident (child): |  |
|---|---|
| - Drift | 8/n.r. |
| - Vapour | 440/n.r. |
| - Deposits | 4/n.r. |
| - Re-entry | 332/n.r. |
| - Sum (mean) | 713/n.r. |

| Resident (adult): |  |
|---|---|
| - Drift | 2/n.r. |
| - Vapour | 95/n.r. |
| - Deposits | 2/n.r. |
| - Re-entry | 185/n.r. |
| - Sum (mean) | 244/n.r. |

**Bulldock 25 EC (greenhouse): Use: tomatoes, hand-held equipment**

### Bulldock 25 EC (greenhouse)

**Use:** tomatoes, hand-held equipment, application rate 0.0175 kg as/ha

**Exposure estimates:**

**Operator**

| Model/ Data | PPE/RPE | %AOEL/AAOEL |
|---|---|---|
| German model (M/L) Mich, 1996 (A) | Without PPE (T-shirt and shorts) | 7536/na |
| | M/L: work wear + gloves + RPE A: protective suite + gloves + RPE | 278/na |

**Worker**

**Bulldock 25 EC**

**Use:** tomatoes, greenhouse, hand-held equipment, application rate 0.0175 kg as/ha

**Exposure estimates:** calculations performed with models for outdoor worker tasks (considered to be comparable since active substance is not volatile)
### Bystander and resident

**Bulldock 25 EC**

**Use:** tomatoes, greenhouse, handheld equipment, application rate 0.0175 kg as/ha

Exposure estimates: negligible for permanent greenhouse structures, for non-permanent structures models for outdoor application were used (see below)

| Model/ Data | Category | %AOEL/ AAOEL |
|-------------|----------|--------------|
| Krebs et al (2000) | workwear | 1776 / - |
| | workwear + gloves | 412 / - |
| EFSA (2014) | potential | 10655 / - |
| | workwear | 4593 / - |
| | workwear + gloves | 1066 / - |

| Model | Category | %AOEL/ AAOEL |
|-------|----------|--------------|
| Martin et al (2008); 10m distance | Bystander (adult) | 55 / - |
| | Bystander (child) | 44 / - |
| | Resident (adult) | 7 / - |
| | Resident (child) | 12 / - |
| EFSA (2014); 10m distance; high water volume | Bystander (adult): | |
| | - Drift | n.r./21 |
| | - Vapour | n.r./11 |
| | - Deposits | n.r./1 |
| | - Re-entry | n.r./19 |
| | Bystander (child): | |
| | - Drift | n.r./11 |
| | - Vapour | n.r./2 |
| | - Deposits | n.r./< 1 |
| | - Re-entry | n.r./11 |
| | Resident (adult): | |
| | - Drift | 370/n.r. |
| | - Vapour | 440/n.r. |
| | - Deposits | 18/n.r |
| | - Re-entry | 775/n.r. |
| | - Sum (mean) | 1316/n.r. |
| | Resident (child): | |
| | - Drift | 205/n.r. |
| | - Vapour | 95/n.r. |
| | - Deposits | 7/n.r |
| | - Re-entry | 431/n.r. |
| | - Sum (mean) | 578/n.r. |
Montur Forte FS 230 (seed): Use: beet, seed treatment,

Operator

Montur Forte FS 230 (seed)
Use: beet, seed treatment, application rate 0.0104 kg as/ha

Exposure estimates:

| Model/Data | PPE/RPE | %AOEL/AAOEL |
|------------|---------|--------------|
| Seed TROPEX | With gloves, coverall for all tasks (no gloves for bagging) | 12942/- |
|            | With additional RPE for all tasks | 1379/- |

Field studies for beet seed treatment:

Mixing/loading
Without RPE | 482/11.7 |
With RPE | 57.8/1.4 |

Seed coating
Without RPE | 656/33.0 |
With RPE | 76.7/3.6 |

Storage logistics
Without RPE | 115/2.8 |
With RPE | 13.0/0.3 |

Workers

Montur Forte FS 230
Workers loading and sowing the treated seed
Seed TROPEX (60 kg bw)

| Model/Data | PPE | %AOEL/AAOEL |
|------------|-----|--------------|
| Seed TROPEX | Coverall and gloves | 1301/- |

Bystander and resident

Bystanders and residents are not expected to be exposed significantly during seed treatment in professional plants

N/A: not applicable
n.a.: not available
n.r.: not relevant

Classification with regard to toxicological data (Regulation (EU) No 283/2013, Annex Part A, Section 10)

Substance:

Beta-cyfluthrin

Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]⁴:

Acute Tox. 2, H300*: Fatal if swallowed
Acute Tox. 2, H330*: Fatal if inhaled

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⁴ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJL 353, 31.12.2008, 1-1355.
Peer review proposal for harmonised classification according to Regulation (EC) No 1272/2008:

In addition to the harmonised classification:
- **Lact., H362**: May cause harm to breast-fed children
- **Irritant, STOT SE 3, H335**: May cause respiratory irritation
- **Repro. 2, H361d**: Suspected of damaging the unborn child

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5 It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.
### Residues in or on treated products food and feed

**Metabolism in plants (Regulation (EU) No 283/2013, Annex Part A, points 6.2.1, 6.5.1, 6.6.1 and 6.7.1)**

| Primary crops (Plant groups covered) | Crop groups | Crop(s) | Application(s) | DAT (days) |
|--------------------------------------|-------------|---------|----------------|------------|
| Fruit crops                          | Tomato<sup>a</sup>,<sup>d</sup> | Brushing (ca 1.75N) | 1,5,7,9,14,21,28,35 (fruit); 14,28,35 (leaves); 0,7,14,21,28 |
|                                      | Apple<sup>a</sup>,<sup>c</sup> | Fruit spraying | 0,42,52,80,98 (leaves and tubers) |
| Root crops                           | Potato<sup>a</sup>,<sup>c</sup> | Foliar spraying (4 N) | For 10 N: 56 (intermediate leaves); 117 to 119 (leaves, roots at maturity); For 1N: Mature samples (leaves, roots) |
|                                      | Sugar beet<sup>b</sup>,<sup>f</sup> | Seed treatment (1N and 10N) |  |
| Leafy crops                          | *            | *       | *              | *          |
| Cereals/grass crops                  | Wheat<sup>a</sup>,<sup>c</sup>,<sup>e</sup> | Foliar spraying (12N to 16N) | 1 and 21 |
| Pulses/Oilseeds                      | Soybean<sup>a</sup>,<sup>c</sup> | Foliar spraying | 4,19,33,48,62,84 (leaves only); 88 (leaves, stalks, seeds) |
|                                      | Cotton<sup>a</sup> | Foliar spraying (experiment 1/2/4); Cotton boll spraying (experiment 3) | Leaves: 0,7,14,21,35,49 and 63 (exp.1); 7,22 and 37 (exp.2); 85 (exp.4); Bolls: 53 (exp.3) |
| Miscellaneous                        |             |         |                |            |
Peer review of the pesticide risk assessment of the active substance beta-cyfluthrin

Metabolism studies after seed treatment fully acceptable. Metabolism data in crops after foliar application show coherent picture over all test systems investigated. Non-GLP and non-guideline compliant data are acceptable for risk assessment when considered altogether. Limitations of the data base are outlined in Vol.3, B.7 (Germany, 2018).

Rotational crops

| Metabolic pattern | Crop groups | Crop(s) | PBI (days) | Comments |
|-------------------|-------------|---------|-----------|----------|
| OECD Guideline 502 | Root/tuber crops | Red beet (root, leaf) | 36, 121, 285 | Limited efforts to identify the nature of residues in harvested crop (and soil) samples. Indications for incorporation of radioactivity into natural plant constituents. |
| Leafy crops | Kale | 36, 121, 285 | |
| Cereal (small grain) | Wheat (head, stalk foliage) | 36, 121, 285 | |
| Other | - | - | |

Rotational crop and primary crop metabolism similar?

Non-GLP study, not complying with OECD 502. Rotational crop studies are triggered by behaviour of parent in soil. Despite high residues at PBI 36 days in wheat stalks and heads identification and characterisation attempts were insufficient. The endpoint is not addressed therefore a data gap for a new rotational crop study is set.

Processed commodities

| Standard hydrolysis study | Conditions | Parent | FPBacid | FPBald | M7 | Others |
|--------------------------|------------|--------|---------|--------|----|--------|
| OECD Guideline 507       | 20 min, 90°C, pH 4 | 106.5 % | - | - | - | - |
|                          | 60 min, 100°C, pH 5 | 99.7 % | - | - | - | - |
|                          | 20 min, 120°C, pH 6 | 12.1 % | 4.9 % | 33.6 % | 21.9 % | 5 compounds 1.3-6.2 % |

Residue pattern in processed commodities similar to residue pattern in raw commodities?

GLP study, complying with OECD 507 using [Fluorophenyl-UL-14C]-beta-cyfluthrin. Residue pattern in processed commodities differs to RAC for conditions representative for sterilisation (relevant for tomato processing). No identification of major metabolite M7 performed (study outside data requirements). Due to low solubility of beta-cyfluthrin (ca 2 µg/kg) this endpoint is not triggered and therefore no data gap to identify M7 is set. Similar for other processes.

Plant residue definition for monitoring (RD-Mo)

OECD Guidance, series on pesticides No 31

Cyfluthrin, including other mixtures of constituent isomers (sum of isomers)

General residue definition (primary crops and provisional for rotational crops), foliar and seed treatment uses

Plant residue definition for risk assessment (RD-RA)

Cyfluthrin, including other mixtures of constituent isomers (sum of isomers)

General residue definition (primary crops and provisional for rotational crops), foliar and seed treatment uses
Conversion factor (monitoring to risk assessment) None.

Metabolism in livestock (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.2, 6.2.3, 6.2.4, 6.2.5, 6.7.1)

| OECD Guideline 503 and SANCO/11187/2013 rev. 3 (fish) | Animal | Dose (mg/kg bw/d) | Duration (days) | N rate/comment |
|------------------------------------------------------|--------|------------------|----------------|---------------|
| Animals covered                                      |        |                  |                |               |
|                                                      | **Animal** |                  |                |               |
| Laying hen                                           | 5<sup>c</sup> | 3000<sup>2</sup>  | 5              | Calculation of the N rate is pending the final values for feed commodities from valid field trials |
| Goat/Cow                                             | 0.5<sup>c</sup>; 0.5<sup>d</sup>; 0.11<sup>e</sup>; 1<sup>e</sup> | 5; 5; 7; 7     | Calculation of the N rate is pending the final values for feed commodities from valid field trials |
| Pig                                                  | -      | -                | -              |               |
| Fish                                                 | 11.7 mg/kg DM<sup>f</sup> [cyclopropane-1-14C]beta-cyfluthrin | 14             | -              |
|                                                      | 10.6 mg/kg DM [fluorophenyl-UL-14C]beta-cyfluthrin<sup>f</sup> |                  |                |

| <sup>a</sup> Livestock: Non-GLP study, not complying with OECD 503 with [phenyl-U-14C]cyfluthrin |
| <sup>b</sup> Livestock: Non-GLP study, not complying with OECD 503, not radiolabelled |
| <sup>c</sup> Livestock: Non-GLP study, not complying with OECD 503 with [phenyl-U-14C]cyfluthrin |
| <sup>d</sup> Livestock: GLP study, not complying with OECD 503 with [phenyl-U-14C]cyfluthrin |
| <sup>e</sup> Livestock: GLP study, complying with OECD 503 with [cyclopropane-1-14C]beta-cyfluthrin |
| <sup>f</sup> Fish: GLP study, complying with SANCO/11187/2013 rev. 3 with [cyclopropane-1-14C]beta-cyfluthrin and [fluorophenyl-UL-14C]beta-cyfluthrin |

Sufficient information available to allow for firm conclusions on livestock and fish metabolism:

Major metabolites besides parent (56 to 99% TRR) in the cow study were: FPB aldehyde in liver (14% TRR) and FPB alcohol in kidney (43% TRR).

In the goat study TRRs were below 0.01 mg/kg in all tissues.

In the poultry study cyfluthrin was predominant in all matrices (12 to 75% TRR) and to a minor extent FPB acid and 4-OH-FPB acid (up to 26% and 20% TRR, respectively).

In rainbow trouts parent was the major residue in liver (16% TRR for cyclopropyl label and 27% TRR for the fluorophenyl label) and muscle (82% TRR for cyclopropyl label and 86% TRR for the fluorophenyl label).
| Time needed to reach a plateau concentration in milk and eggs (days) | Eggs: >96 hours  
Milk: 2-3 days |
|---|---|
| Animal residue definition for monitoring (RD-Mo) OECD Guidance, series on pesticides No 31 | Cyfluthrin, including other mixtures of constituent isomers (sum of isomers) |
| Animal residue definition for risk assessment (RD-RA) | Cyfluthrin, including other mixtures of constituent isomers (sum of isomers) |
| Conversion factor (monitoring to risk assessment) | None |
| Metabolism in rat and ruminant similar (Yes/No) | Yes |
| Fat soluble residues (Yes/No) (FAO, 2009) | Yes |

**Residues in succeeding crops (Regulation (EU) N° 283/2013, Annex Part A, point 6.6.2)**

| Confined rotational crop study (Quantitative aspect) OECD Guideline 502 | Non-GLP study, not complying with OECD 502. A quantitative transfer of radioactivity from cyfluthrin treated soil into rotational crops is demonstrated after application of 988 g as/ha (28N rate). TRRs in samples were highest in cereals (up to 0.348 mg/kg in heads). While parent cyfluthrin was detected in soil organic extracts of early samples (90 % of TRR at day 0 and 55 % at days 36 and 106), no cyfluthrin or its metabolites were identified in any rotational crop sample. Indications for incorporation of radioactivity into natural plant constituents are presented. It is not clear, in which chemical structure the radioactivity is taken up by plants. The data package is not considered complete under conditions relevant for the assessment of representative uses and therefore a data gap was set (s. above “Rotational crops (metabolic pattern) OECD Guideline 502). Limitations of the data base are outlined in Vol.3, B.7, Germany, 2018. |
|---|---|
Field rotational crop study
OECD Guideline 504

GLP study, not complying with OECD 504.
The study, which is based on a targeted study design
(limiting number of crops, trials, PBI, samplings,
regional spread) and on fully validated analytical
methods for all matrices, supports the conclusions of
other studies (primary and rotational crop metabolism,
field trials, environmental fate), that no residues of beta-
cyfluthrin are expected in rotational crops after
treatment according to GAP.
Beta-cyfluthrin was applied twice by foliar spraying at
the GAP rate of 12.5 g a.s/ha, with application intervals
of 14 and 15 days. Ten days after harvesting of the
primary crop lettuce, one further application of beta-
cyfluthrin was performed directly to bare soil on the
treated plots at the target rate 12.5 g a.s/ha (0.5N rate
regarding lettuce GAP). Lettuce whole plant was
sampled at 11 DALA and at 41 DALA, lettuce heads at
60 DALA. Carrot whole plant was sampled at 76
DALA and carrotroot at 160 DALA and at 181 DALA.
Residues in plant parts were <0.01 mg/kg.
Non-GLP study, not complying with OECD 504.
One field rotational crop study on cereals was
conducted in winter wheat at ca 30 and 120 days plant-
back intervals. Samples were taken at the times of last
treatment (applications of cyfluthrin at about 0.12 kg
a.s/ha to bare soil) and planting (soil) and at forage stage
(1 trial) and harvest (wheat). Residues in plant parts
were <0.01 mg/kg.
The data package, although not comprising a stand-
alone-study, is considered complete under conditions
relevant for the assessment of representative uses
provided that metabolism in rotational crops is
confirmed (see data gap set above “Rotational crops
(metabolic pattern) OECD Guideline 502).
Limitations of the data base are outlined in Vol.3, B.7,
Germany, 2018.

Stability of residues (Regulation (EU) N° 283/2013, Annex Part A, point 6.1)
OECD Guideline 506

| Plant products (Category) | Commodity | T (°C) | Stability (Months) |
|--------------------------|-----------|--------|--------------------|
|                          |           |        | Cyfluthrin         |
| High water content 6      | Whole group except: Tomato sugar cane | -23    | 13                 |
|                          |           | -23    | 20                 |
|                          |           | -23    | 20                 |
| High oil content          |           | -      | -                  |
| High protein content      |           | -      | -                  |
| High starch content       |           | -      | -                  |
|                          | Potato tuber | -23    | Inconclusive for whole group |

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Wheat grain | -23 | 25
Maize grain | -23 | 13
High acid content\(^b\) | Oranges | -23 | Pending validation of the analytical method
Other | Peanut shells | -23 | 20
Processed products\(^b\) | Maize oil | -23 | Pending validation of the analytical method

\(^a\) Apple, cantaloupe, sugar cane, tomato and cucumber and the processed commodity sugar cane molasses were analysed in a GLP study, study design complying with OECD 506 in relevant points.

\(^b\) Cyfluthrin was analysed in maize green forage, head lettuce, and wheat green forage in a GLP compliant study. The analytical method (TLC) was only partly validated therefore data are supportive only (stability at \(-24\) °C up to 26 months).

\(^h\) Storage stability data for orange up to 25 months and maize oil up to 1 months are available but pending the validation of the analytical method. There is no representative use proposed for these two matrices in the current evaluation. However, in the light of future uses it is recommended to provide validation data for the analytical method.

Stability data for the roots of root and tuber vegetables within the high starch group are not available (data gap) and data in the other two commodity groups (grain and starchy root crops) are with 13/25 and 1 month, respectively too diverse in order to conclude on the whole group or to extrapolate to roots of root and tuber vegetables to which sugar beet belongs. Limitations of the data base are outlined in Vol.3, B.7.

| Animal | Animal commodity | T (°C) | Stability (Months) |
|---|---|---|---|
| Cow | Muscle | | |
| Cow | Liver\(^h,i\) | -18 to -23 | 3 |
| Cow | Kidney\(^h,i\) | -18 to -23 | 1 |
| Cow | Milk\(^h,i\) | Not reported | 11 |
| Cow | Fat | | |
| Hen | Egg | < -18°C | 12 |

\(^b\) non-GLP study, not complying with OECD 506.

\(^i\) Based on data with incurred residues

Stability in muscle and fat is not demonstrated as no residue data for point 0 are available but only one data point at 5 months (data gap).

Limitations of the data base are outlined in Vol.3, B.7 (Germany, 2018). Study in eggs was OECD 506 and GLP compliant.
### Summary of residues data from the supervised residue trials (Regulation (EU) No 283/2013, Annex Part A, point 6.3); OECD Guideline 509, OECD Guidance, series on pesticides No 66 and OECD MRL calculator

| Crop | Region/Indoor (a) | Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs (b) | Recommendations/comments (OECD calculations) | MRL proposals (mg/kg) | HR (mg/kg) (c) | STMR (mg/kg) (d) |
|------|-------------------|-------------------------------------------------------------------------------------------------|-----------------------------------------------|-----------------------|----------------|----------------|
| **Representative uses** | | | | | | |
| Sugar beet (root) | N+SEU | Combined data set fully acceptable, provided that storage stability data covering the storage period in the residue trials will be provided. | | open | open | open |
| Sugar beet (leaf) | N+SEU | Combined data set fully acceptable, provided that storage stability data covering the storage period in the residue trials will be provided. | | open | open | open |
| Tomato | Indoor | <0.01(3), 0.011(2), 0.012, 0.014, 0.016 | Two supporting residue trials in potato are required with storage ≤1 month according to the recommendations of the PRAS meeting 173 (Feb 2018). | 0.03 | 0.016 | 0.011 |
| Potato | NEU | Combined data set fully acceptable, provided that storage stability data covering the storage period in the residue trials will be provided. | | open | open | open |
| Potato | SEU | Combined data set fully acceptable, provided that storage stability data covering the storage period in the residue trials will be provided. | | open | open | open |
| Wheat (grain) | NEU | <0.01 (4) | Residue data set incomplete. | open | open | open |
| Wheat (grain) | SEU | <0.01 (4), 0.01 (2) | Residue data set incomplete. | open | open | open |
| Wheat (straw) | NEU | 0.31, 0.48, 0.50, 0.59 | Residue data set incomplete. | open | open | open |
| Wheat (straw) | SEU | 0.42, 0.43, 0.65, 0.69, 0.71, 0.78 | Residue data set incomplete. | open | open | open |

### Summary of the data on formulation equivalence; OECD Guideline 509

| Crop | Region | Residue data (mg/kg) | Recommendations/comments |
|------|--------|----------------------|-------------------------|
| Sugar beet | N+SEU | No comparative assessment required. | Representative FS formulation. |
| Tomato | Indoor | No comparative assessment required. | Representative EC formulation. |
| Potato | N+SEU | No comparative assessment required. | Representative EC formulation. |

### Summary of data on residues in pollen and bee products (Regulation (EU) No 283/2013, Annex Part A, point 6.10.1)

Data on residues in pollen and bee products are not provided (data gap)
Peer review of the pesticide risk assessment of the active substance beta-cyfluthrin

(a): **NEU** or **SEU** for northern or southern outdoor trials in EU member states (**N+SEU** if both zones), **Indoor** for glasshouse/protected crops, **Country** if non-EU location.

(b): Residue levels in trials conducted according to GAP reported in ascending order (e.g. 3x <0.01, 0.01, 6x 0.02, 0.04, 0.08, 3x 0.10, 2x 0.15, 0.17). When residue definition for monitoring and risk assessment differs, use **Mo/RA** to differentiate data expressed according to the residue definition for Monitoring and Risk Assessment.

(c): **HR**: Highest residue. When residue definition for monitoring and risk assessment differs, HR according to residue definition for monitoring reported in brackets (HRₘₐₜ).

(d): **STMR**: Supervised Trials Median Residue. When residue definition for monitoring and risk assessment differs, STMR according to definition for monitoring reported in brackets (STMRₘₐₜ).
## Inputs for animal burden calculations

| Feed commodity                        | Median dietary burden (mg/kg) | Maximum dietary burden (mg/kg) | Comment | Comment |
|---------------------------------------|------------------------------|-------------------------------|---------|---------|
| **Representative uses**               |                              |                               |         |         |
| Sugar beet leaves                     | 0.01                         | all values <LOQ               | 0.01    | all values <LOQ |
| Potato                                | 0.01                         | (a)                           | 0.01    | (a)     |
| Wheat grain                           | 0.01                         | (b)                           | 0.01    | (b)     |
| Wheat straw                           | 0.67                         | Provisional based on SEU data; incomplete data set for NEU and SEU | 0.78    | Provisional based on SEU data; incomplete data set for NEU and SEU |
| Beet, sugar dried pulp                | 0.01                         |                               |         |         |
| Beet, sugar ensiled pulp              | 0.01                         |                               |         |         |
| Beet, sugar molasses                  | 0.01                         |                               |         |         |
| Distiller's grain                     | 0.01                         | (b)                           |         |         |
| Potato process waste                  | 0.01                         | (a)                           |         |         |
| Potato dried pulp                     | 0.01                         | (a)                           |         |         |
| Wheat gluten meal                     | 0.01                         | (b)                           |         |         |
| Wheat milled by-products              | 0.01                         | (b)                           |         |         |

(a) Provisional, GAP compliant trials with analysis performed within max storage stability interval pending; current trial all values <LOQ  
(b) provisional; incomplete data set for NEU and SEU
Residues from livestock feeding studies (Regulation (EU) N° 283/2013, Annex Part A, points 6.4.1, 6.4.2, 6.4.3 and 6.4.4)
OECD Guideline 505 and OECD Guidance, series on pesticides No 73

Study designs follow largely OECD 505
The MRL and N rate calculations are provisional and pending the results from the residue trials for potato and wheat

| MRL calculations | Ruminant | Pig/Swine | Poultry | Fish |
|------------------|----------|-----------|---------|------|
| Highest expected intake (mg/kg bw/d) (mg/kg DM for fish) | Beef cattle: 0.021 | Ram/Ewe: 0.034 | Breeding: 0.008 | Broiler: 0.007 | Carp: - |
| | Dairy cattle: 0.027 | Lamb: 0.030 | Finishing: 0.003 | Layer: 0.011 | Trout: - |
| Intake > 0.004 mg/kg bw | Yes | Yes | No | Yes | No |
| Feeding study submitted | Yes | Yes | No | Yes | No |
| Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and N rates | Level: Beef: 8-218N | Level: Lamb: 6-151N | N rate Breed/Finish: 19-534N | Level: Turkey: n.r. | Level: N rate n.r. |
| | Level: Dairy: 6-169N | Level: Ewe: 5-131N | Level: Layer: 75-750N | Level: Carp/Tout |
| Meat(b) | Muscle | 0.049 | 0.05 | 0.063 | 0.07 | 0.15 | 0.15 | 0.015 | 0.015 |
| | Fat | <0.01 | 0.01* | <0.01 | 0.01* | <0.01 | 0.01* | <0.01 | 0.01* |
| Method of calculation(c) | Meat(b) | Tf | Tf | Tf |
| | Liver | <0.01 | 0.01* | <0.01 | 0.01* | <0.01 | 0.01* |
| | Kidney | <0.01 | 0.01* | <0.01 | 0.01* | <0.01 | 0.01* |
| | Milk(a) | <0.01 | 0.01* | <0.01 | 0.01* | <0.01 | 0.01* |
| | Eggs | <0.01 | 0.01* | <0.01 | 0.01* | <0.01 | 0.01* |

(a): Estimated HR calculated at 1N level (estimated mean level for milk).
(b): HR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry.
(c): The OECD guidance document on residues in livestock (series on pesticides 73) recommends three different approaches to derive MRLs for animal products; by applying a transfer factor (Tf), by intrapolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.
### STMR calculations

| Median expected intake (mg/kg bw/d) | Ruminant | Pig/Swine | Poultry | Fish |
|-----------------------------------|----------|-----------|---------|------|
| Beef cattle (mg/kg DM for fish)    | 0.020    | 0.033     | 0.008   | 0.007 |
| Dairy cattle                       | 0.026    | 0.028     | 0.003   | 0.010 |
| Ruminant                           |          |           |         |      |
| Pig/Swine                          |          |           |         |      |
| Poultry                            |          |           |         |      |
| Fish                               |          |           |         |      |

| Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and N rates | Level | Level | Level | Level |
|-------------------------------------------------------------------------|-------|-------|-------|-------|
| Muscle                                                                  | 0.163 mg/kg bw | 0.163 mg/kg bw | 0.163 mg/kg bw | 0.848 mg/kg bw |
| Fat                                                                     | 0.163 mg/kg bw | 0.163 mg/kg bw | 0.163 mg/kg bw | 0.848 mg/kg bw |
| Meat<sup>(a)</sup>                                                       |<0.01 mg/kg | <0.01 mg/kg |<0.01 mg/kg |<0.01 mg/kg |
| Fat                                                                     |<0.01 mg/kg |<0.01 mg/kg |<0.01 mg/kg |<0.01 mg/kg |
| Liver                                                                   |<0.01 mg/kg |<0.01 mg/kg |<0.01 mg/kg |<0.01 mg/kg |
| Kidney                                                                  |<0.01 mg/kg |<0.01 mg/kg |<0.01 mg/kg |<0.01 mg/kg |
| Milk                                                                    |<0.01 mg/kg |<0.01 mg/kg |<0.01 mg/kg |<0.01 mg/kg |
| Eggs                                                                    |<0.01 mg/kg |<0.01 mg/kg |<0.01 mg/kg |<0.01 mg/kg |

| Method of calculation<sup>(c)</sup> | Tf | Tf | Tf | Tf |

<sup>(a):</sup> STMR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry

<sup>(b):</sup> When the mean level is set at the LOQ, the STMR is set at the LOQ.

<sup>(c):</sup> The OECD guidance document on residues in livestock (series on pesticide 73) recommends three different approaches to derive MRLs for animal products; by applying a transfer factor (Tf), by intrapolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.
Conversion Factors (CF) for monitoring to risk assessment
Not relevant.

Processing factors (Regulation (EU) N° 283/2013, Annex Part A, points 6.5.2 and 6.5.3)
OECD Guideline 508 and OECD Guidance, series on testing and assessment No 96
Study compliant to OECD 508

| Crop (RAC)/Edible part or Crop (RAC)/Processed product | Number of studies(a) | Processing Factor (PF) | Conversion Factor (CF) for RA(b) |
|--------------------------------------------------------|----------------------|------------------------|---------------------------------|
|                                                        |                      | Individual values      | Mean PF                         |
| Canned tomatoes                                        | 2                    | 0.05, 0.12             | 0.08                            |
| Tomato wet pomace                                       | 2                    | 3.1, 3.2               | 3.14                            |
| Tomato raw juice                                        | 2                    | 0.45, 0.12             | 0.28                            |
| Tomato raw puree                                        | 2                    | 0.82, 0.47             | 0.64                            |

(a): Studies with residues in the RAC at or close to the LOQ should be disregarded (unless concentration)
(b): When the residue definition for risk assessment differs from the residue definition for monitoring

Provisional Consumer risk assessment (Regulation (EU) N° 283/2013, Annex Part A, point 6.9)
Representative uses
ADI 
0.01 mg/kg bw per day
TMDI according to EFSA PRIMo
Highest TMDI: 4.6 % ADI (NL children)
IEDI (% ADI), according to EFSA PRIMo
Not calculated
Factors included in the calculations
none

ARfD
0.01 mg/kg bw
IESTI (% ARfD), according to EFSA PRIMo
Highest IESTI: 17 % ARfD (NL children, tomato)
Factors included in IESTI and NESTI
Existing MRL input values

Proposed MRLs (Regulation (EU) No 283/2013, Annex Part A, points 6.7.2 and 6.7.3)

| Code(a) | Commodity/Group | MRL/Import tolerance(b) (mg/kg) and Comments |
|---------|-----------------|--------------------------------------------|
| Plant commodities |
| Code(a) | Commodity/Group | MRL/Import tolerance(b) (mg/kg) and Comments |
|---------------------------------------------------|
| 0900010  | Sugar beet      | Pending valid residue trials               |
| 0500090  | Wheat           | Pending valid residue trials               |
| 0231010  | Tomato          | 0.03                                       |
| 0211000  | Potato          | Pending valid residue trials               |

MRL application: No MRL application was submitted.

Animal commodities

| Code | Commodity/Group         | MRL proposals for animal commodities pending valid residue trials |
|------|-------------------------|-----------------------------------------------------------------|
| 1011000 | Swine products               |                                                                  |
| 1012040 | Bovine kidney               |                                                                  |
|       | Other bovine products      |                                                                  |
| 1013000 | Sheep products              |                                                                  |

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| Commodity code number | Commodity name     |
|-----------------------|--------------------|
| 1014000               | Goat products      |
| 1020000               | Milk               |

(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005
(b): MRLs proposed at the LOQ, should be annotated by an asterisk (*) after the figure.
Environmental fate and behaviour

Route of degradation (aerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.1)

| Parameter                                                                 | Mineralisation after 100 days | Non-extractable residues after 100 days |
|----------------------------------------------------------------------------|-------------------------------|-----------------------------------------|
| Mineralisation after 100 days                                             | 47.3 % after 94 d, [14C-fluorophenyl]-label (n = 1) | 33.4 % after 94 d, [14C-fluorophenyl]-label (n = 1) |
|                                                                           | 41.0 – 44.1 % after 91 d, [cyclopropyl-1-14C]-label (n = 3) | 29.2 – 45.7 % after 91 d, [cyclopropyl-1-14C]-label (n = 3) |

Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)

- FPB-acid: 12.7 % after 7 d, [14C-fluorophenyl]-label (n = 1)
- DCVA: 10.1 % after 3 d – 40.5 % after 7 d, [cyclopropyl-1-14C]-label (n = 3)

Route of degradation (anaerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.2)

| Parameter                                                                 | Mineralisation after 100 days | Non-extractable residues after 100 days |
|----------------------------------------------------------------------------|-------------------------------|-----------------------------------------|
| Mineralisation after 100 days                                             | 8.1 % after 91 d, [14C-fluorophenyl]-label (n = 1) | 8.7 % after 91 d, [14C-fluorophenyl]-label (n = 1) |
|                                                                           | 4.7 % after 91 d, [cyclopropyl-1-14C]-label (n = 1) | 4.4 % after 91 d, [cyclopropyl-1-14C]-label (n = 1) |

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)

- FPB-acid: 63.9 % at 91 d (n = 1)
- DCVA: 75.7 % at 120 d (n = 1)

Route of degradation (photolysis) on soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3)

| Parameter                                                                 | Mineralisation at study end | Non-extractable residues at study end |
|----------------------------------------------------------------------------|-------------------------------|-----------------------------------------|
| Mineralisation at study end                                               | 1.8 % after 18 d, [14C-fluorophenyl]-label (n = 1) | 16 % after 18 d, [14C-fluorophenyl]-label (n = 1) |
| Non-extractable residues at study end                                      |                               |                                         |
### Rate of degradation in soil (aerobic) laboratory studies active substance (Regulation (EU) No 283/2013, Annex Part A, point 7.1.2.1.1 and Regulation (EU) No 284/2013, Annex Part A, point 9.1.1.1)

| Beta-cyfluthrin | Dark aerobic conditions |
|-----------------|-------------------------|
| Soil type       | --                      |
|                 | pH<sup>a</sup>          |
|                 | t. °C / % MWHC          |
|                 | DT<sub>50</sub> / DT<sub>90</sub> (d) |
|                 | DT<sub>50</sub> (d) 20 °C pF2/10kPa<sup>b</sup> |
|                 | St. (χ²)                |
|                 | Method of calculation   |
| sandy clay loam | 4.9                     |
|                 | 20 °C / 30.9            |
|                 | 15.8 / 194              |
|                 | (k1 0.0848; k2 0.00682; g 0.625) |
|                 | 89.5                    |
|                 | 2.2                     |
|                 | DFOP<sup>c</sup>        |
| silt loam       | 5.5                     |
|                 | 20 °C / 26.3            |
|                 | 8.5 / 66                |
|                 | (α 1.145; β 10.196)     |
|                 | 17.7                    |
|                 | 3.1                     |
|                 | FOMC<sup>c</sup>        |
| sandy loam      | 7.1                     |
|                 | 20 °C / 11.2            |
|                 | 5.9 / 67                |
|                 | (α 0.841; β 4.608)      |
|                 | 16.7                    |
|                 | 2.8                     |
|                 | FOMC<sup>c</sup>        |
| sandy loam      | 6.9                     |
|                 | 20 °C / 13.2            |
|                 | 12.3 / 88               |
|                 | (α 1.251; β 16.602)     |
|                 | 23.4                    |
|                 | 1.6                     |
|                 | FOMC<sup>c</sup>        |

Geometric mean (if not pH dependent) 28.0

pH dependence: no

<sup>a</sup> Measured in calcium chloride solution

<sup>b</sup> Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

<sup>c</sup> For triggering and modelling

### Rate of degradation in soil (aerobic) laboratory studies transformation products (Regulation (EU) No 283/2013, Annex Part A, point 7.1.2.1.2 and Regulation (EU) No 284/2013, Annex Part A, point 9.1.1.1)

| Metabolite DCVA | Dark aerobic conditions - Metabolite dosed or the precursor from which the f.f. was derived was beta-cyfluthrin, metabolite-dosed if no f.f. is indicated |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------|
| Soil type       | --                                                                              |
|                 | pH (CaCl<sub>2</sub>)                                                          |
|                 | t. °C / % MWHC                                                                  |
|                 | DT<sub>50</sub> / DT<sub>90</sub> (d)                                           |
|                 | f. f. k<sub>f</sub> / k<sub>dp</sub>                                           |
|                 | DT<sub>50</sub> a 20 °C pF2 (all SFO)                                           |
|                 | St. (χ²)                                                                         |
|                 | Method of calculation<sup>b</sup>                                               |
| sandy clay loam<sup>1</sup> | 4.9                     |
|                 | 20/30.9                                                                          |
|                 | 4.7 / 16                                                                         |
|                 | 0.766                                                                            |
|                 | 4.2                                                                              |
|                 | 6.9                                                                              |
|                 | DFOP-SFO                                                                        |
| silt loam<sup>1</sup>       | 5.5                     |
|                 | 20/26.3                                                                          |
|                 | 1.7 / 5.5                                                                        |
|                 | 0.849                                                                            |
|                 | 1.5                                                                              |
|                 | 1.9                                                                              |
|                 | FOMC-SFO                                                                        |
| sandy loam<sup>1</sup>       | 7.1                     |
|                 | 20/11.2                                                                         |
|                 | 8.5 / 28                                                                         |
|                 | 1.0                                                                              |
|                 | 7.1                                                                              |
|                 | 20.6                                                                             |
|                 | FOMC-SFO                                                                        |
| Loamy sand<sup>2 3</sup>      | 5.8                     |
|                 | 20/45                                                                           |
|                 | 3.4/10<sup>2</sup>                                                              |
|                 | 3.6/10<sup>3</sup>                                                              |
|                 | 3.5<sup>3</sup>                                                                  |
|                 | 0.929<sup>c</sup>                                                                |
|                 | 0.815<sup>c</sup>                                                                |
|                 | SFO                                                                             |
| Loam<sup>2 3</sup>           | 7.1                     |
|                 | 20/45                                                                           |
|                 | 2.7/10<sup>2</sup>                                                              |
|                 | 3.1/10<sup>3</sup>                                                              |
|                 | 2.6<sup>3</sup>                                                                  |
|                 | 0.964<sup>c</sup>                                                                |
|                 | 0.972<sup>c</sup>                                                                |
|                 | SFO                                                                             |
| Clay loam<sup>2 3</sup>       | 6.8                     |
|                 | 20/45                                                                           |
|                 | 8.0/27<sup>2</sup>                                                               |
|                 | 11.0/35<sup>3</sup>                                                             |
|                 | 8.1<sup>3</sup>                                                                  |
|                 | 0.973<sup>c</sup>                                                                |
|                 | 0.948<sup>c</sup>                                                                |
|                 | SFO                                                                             |
Geometric mean (n = 11 \( a \)) | 3.9
---|---
Arithmetic mean (n = 8) | 0.872

pH dependence, Yes or No | No

1) Hiler, 2013a (parent-dosed study submitted for renewal of beta-cyfluthrin)
2) cis-DCVA in Class and Dorn, 2003 (metabolite-dosed study, accepted in EFSA conclusion regarding the peer review of the pesticide risk assessment of the active substance zeta-cypermethrin. EFSA Scientific Report (2008) 196, 1-119; DOI: 10.2903/j.efsa.2009.196r)
3) trans-DCVA in Class and Dorn, 2003 (metabolite-dosed study, accepted in EFSA conclusion regarding the peer review of the pesticide risk assessment of the active substance zeta-cypermethrin. EFSA Scientific Report (2008) 196, 1-119; DOI: 10.2903/j.efsa.2009.196r)
4) Geometric mean considering total DCVA, i.e. cis- and trans-DCVA considered as replicates
   a) Normalised using a Q10 of 2.58 and a Walker equation coefficient of 0.7
   b) First model refers to the parent, second to the metabolite for triggering and modelling
   c) Regression coefficient R²

### Rate of degradation in soil (aerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

| Metabolite FPB-acid | Dark aerobic conditions | Metabolite dosed or the precursor from which the f.f. was derived was beta-cyfluthrin |
|---------------------|-------------------------|----------------------------------------------------------------------------------|
| Soil type           | pH\(^b\) CaCl₂ | t. °C / gravimetric moisture % w/w | DT\(_{50}\)/DT\(_{90}\) (d) | f. f. kₜ / kₜp | DT\(_{50}\) (d) 20 °C pF2/10kPa\(^b\) | St. (χ²) | Method of calculation |
| sandy loam          | 6.9 | 20 °C / 13.2 | 2.9 / 9.8 | 0.812 | 2.6 | 9.2 | FOMC-SFO |
| silt loam           | 5.4 | 20 °C / 35.6 | 1.0 / 3.4 | - | 1.0 | 3.6 | SFO |
| silt loam           | 6.2 | 20 °C / 30.9 | 0.9 / 2.9 | - | 0.8 | 3.7 | SFO |
| clay loam           | 7.3 | 20 °C / 46.9 | 1.0 / 3.2 | - | 1.0 | 3.5 | SFO |

**Geometric mean (if not pH dependent)** | 1.2

| Arithmetic mean | 0.812 |
| pH dependence: no |

a) Measured in calcium chloride solution
b) Normalised using a Q10 of 2.58 and a Walker equation coefficient of 0.7

### Rate of degradation field soil dissipation studies (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.1)

| Beta-cyfluthrin | Aerobic conditions |
|-----------------|--------------------|
| Soil type (indicate if bare or cropped soil was used). | Location (country or USA state). | -- | pH\(^a\) | Depth (cm) | DT\(_{50}\) (d) actual | DT\(_{50}\) (d) actual | St. (χ²) | DT\(_{50}\) (d) Norm\(^b\), Method of calculation |
| loam            | S-France           | 7.4 | 0 - 10 | 45 | 258 | 10.9 | - | HS |
| loam            | N-France           | 8.3 | 0 - 10 | 29.7 | 99 | 17.4 | - | SFO |
| silty clay      | Spain              | 8.1 | 0 - 10 | 3.3 | 52 | 18 | - | FOMC |
| clay loam       | Germany            | 7.2 | 0 - 10 | 27.9 | 359 | 12.9 | - | HS |

**Geometric mean (if not pH dependent)**
Rate of degradation field soil dissipation studies (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.1)

| Beta-cyfluthrin | Aerobic conditions |
|-----------------|--------------------|
| Soil type (indicate if bare or cropped soil was used). | Location (country or USA state). |
| Soil type (indicate if bare or cropped soil was used). | Location (country or USA state). |
| pHe) | Depth (cm) | DT50 (d) actual | DT90 (d) actual | St. (χ²) | DT30 (d) Normb) | Method of calculation |
| pH dependence: as pH of all tested soils was >7, no conclusion can be derived (although on the basis of laboratory data pH-dependence is not expected). Field dissipation studies were performed on bare soil. |

a) Measured in water  
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7, values are DegT50matrix

| Metabolites | No data on metabolites from field dissipation studies. |
Combined laboratory and field kinetic endpoints for modelling (when not from different populations)

| Endpoint Description                                                                 | Note                                                                 |
|-------------------------------------------------------------------------------------|----------------------------------------------------------------------|
| Rate of degradation in soil active substance, normalised geometric mean (if not pH dependent) | As data from only two soils with temperature/moisture normalisation was provided for field studies, no combined endpoints for modelling can be derived. |
| Rate of degradation in soil transformation products, normalised geometric mean (if not pH dependent) |
| Kinetic formation fraction (f. f. \( k_f / k_{dp} \)) of transformation products, arithmetic mean |

**Soil accumulation (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.2)**

| Soil accumulation and plateau concentration | Not required. |

**Rate of degradation in soil (anaerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)**

| Beta-cyfluthrin | Dark anaerobic conditions |
|-----------------|---------------------------|
| Soil type       | pH\(^a\)                  |
| Madera sandy loam (CA, USA) (Total) | 7.8 |
| FL CY           | 20 ± 2°C / 11.2 at 1/3 bar | 23.4 / 216.5 |
|                 | 29.5 / 180.6              | –           |
|                 |                           | 1.499       |
|                 |                           | 4.661       |
|                 |                           | FOMC        |

\(^a\) Measured in water
\(^b\) Normalised using a Q10 of 2.58
### Rate of degradation in soil (anaerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.4 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

| Metabolites | No data provided. |

### Rate of degradation on soil (photolysis) laboratory active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3)

| Beta-cyfluthrin | Soil photolysis |
|-----------------|-----------------|
| Soil type       | pH<sup>a</sup>  | t. °C / % MWHC | DT<sub>50</sub> / DT<sub>90</sub> (d) calculated at 30-50°N | St. (χ²) | Method of calculation |
| Silt loam       | 6.7             | 19.4 ± 1.4 / pF2 at 31.7% (w/w) | 41.8 (at natural summer sunlight of locations 30 to 50°N) | 1.7% | SFO |

<sup>a</sup> Measured in [medium to be stated, usually calcium chloride solution or water]
### Soil adsorption active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

| Soil Type        | OC % | Soil pH | $K_d$ (mL/g) | $K_{dsc}$ (mL/g) | $K_F$ (mL/g) | $K_{Foc}$ (mL/g) | $1/n$ |
|------------------|------|---------|--------------|-----------------|-------------|----------------|-------|
| sandy loam       | 1.26 | 5.1     | 810          |                | 64286       |                |       |
| silt loam        | 0.9  | 7.3     | 1116         |                | 124000      |                |       |
| loamy sand       | 0.69 | 6.0     | 1244         |                | 180290      |                |       |
| clay loam        | 1.12 | 6.7     | 1321         |                | 117946      |                |       |
| Geometric mean   |      |         | 1216         |                | 104491      |                |       |
| Arithmetic mean  |      |         |              |                |             |                |       |
| pH dependence: no|      |         |              |                |             |                |       |

a) Measured in calcium chloride solution, except of last value for clay loam

### Soil adsorption transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

| Metabolite     | Soil Type     | OC % | Soil pH | $K_d$ (mL/g) | $K_{dsc}$ (mL/g) | $K_F$ (mL/g) | $K_{Foc}$ (mL/g) | $1/n$ |
|----------------|---------------|------|---------|--------------|-----------------|-------------|----------------|-------|
| FPB-acid       | sandy loam    | 1.0  | 5.3     | 1.23         | 123             | 0.749       |                |       |
|                | clay loam     | 2.1  | 5.7     | 1.80         | 86              | 0.60        |                |       |
|                | silt loam     | 2.07 | 6.5     | 1.03         | 50              | 0.595       |                |       |
|                | sandy loam    | 1.64 | 6.1     | 0.65         | 39              | 0.733       |                |       |
|                | loam          | 2.08 | 5.6     | 1.39         | 67              | 0.609       |                |       |
|                | sandy clay loam| 3.4 | 4.9 | 14.42 | 424 | 0.664 |
|                | sandy loam    | 0.5  | 7.1     | 0.62         | 124             | 0.799       |                |       |
|                | silt loam     | 1.0  | 5.5     | 1.76         | 176             | 0.561       |                |       |
| Geometric mean (if not pH dependent) | | | | 1.54 | 103.12 |
| Arithmetic mean (if not pH dependent) | | | | | 0.664 |
| pH dependence: no | | | | | |

a) Measured in [medium to be stated, usually calcium chloride solution or water]

### Soil adsorption transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

| Metabolite     | Soil Type     | OC % | Soil pH | $K_d$ (mL/g) | $K_{dsc}$ (mL/g) | $K_F$ (mL/g) | $K_{Foc}$ (mL/g) | $1/n$ |
|----------------|---------------|------|---------|--------------|-----------------|-------------|----------------|-------|
| DCVA           | Sand$^{1)}$   | 0.59 | 6.0     | 0.184        | 31.05           | 0.884       |                |       |
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| Soil Type       | pH  | EC50 | qPCR | pH Dependence |
|-----------------|-----|------|------|---------------|
| Clay loam 1)    | 1.6 | 7.5  | 0.224| no            |
| Sandy loam 1)   | 0.8 | 4.3  | 2.893| no            |
| Sandy loam 3)   | 2.0 | 5.1  | 1.4857| no           |
| Silt loam 2)    | 2.9 | 6.3  | 0.4331| no           |
| Loam 2)         | 4.4 | 7.3  | 0.3946| no           |
| Sandy loam 3)   | 0.98| 6.4  | 0.12 | no            |
| Clay 3)         | 1.75| 7.2  | 0.19 | no            |
| Silt loam 3)    | 1.3 | 6.6  | 0.17 | no            |
| Silty clay 4)   | 2.56| 6.4  | 0.46 | no            |
| Sandy loam 4)   | 0.83| 6.8  | 0.16 | no            |
| Sandy loam 4)   | 1.14| 5.6  | 0.54 | no            |

Geometric mean (pH > 5, n = 13) 21.6

Arithmetic mean (pH > 5, n = 13) 0.767

pH dependence: no (in a range of pH > 5)

1) DCVA in Slangen, 1999 (study submitted for renewal of beta-cyfluthrin)
2) DCVA in Hein and Dambrosio, 2013 (study submitted for renewal of beta-cyfluthrin)
3) DCVA in Hein, 2009 (accepted in EFSA conclusion on the peer review of the pesticide risk assessment of the active substance beta-cypermethrin. EFSA Journal 2014;12(6):3717; DOI: 10.2903/j.efsa.2014.3717)
4) trans-DCVA in Gravelle, 1994 (accepted in EFSA conclusion regarding the peer review of the pesticide risk assessment of the active substance zeta-cypermethrin. EFSA Scientific Report (2008) 196, 1-119; DOI: 10.2903/j.efsa.2009.196r)
### Mobility in soil column leaching active substance (Regulation (EU) No 283/2013, Annex Part A, point 7.1.4.1.1 and Regulation (EU) No 284/2013, Annex Part A, point 9.1.2.1)

| Type                        | Description                                                                 |
|-----------------------------|-----------------------------------------------------------------------------|
| Column leaching             | Information available in the DAR of beta-cyfluthrin; not transparently evaluated. The exposure assessment was finalised using the adsorption data coming from the available batch adsorption studies. |
| Aged column leaching        | Information available in the DAR of beta-cyfluthrin; not transparently evaluated. The exposure assessment was finalised using the adsorption data coming from the available batch adsorption studies. |

### Mobility in soil column leaching transformation products (Regulation (EU) No 283/2013, Annex Part A, point 7.1.4.1.2 and Regulation (EU) No 284/2013, Annex Part A, point 9.1.2.1)

| Type                        | Description                                                                 |
|-----------------------------|-----------------------------------------------------------------------------|
| Column leaching             | Information available in the DAR of beta-cyfluthrin; not transparently evaluated. The exposure assessment was finalised using the adsorption data coming from the available batch adsorption studies. |
Lysimeter / field leaching studies (Regulation (EU) N° 283/2013, Annex Part A, points 7.1.4.2 / 7.1.4.3 and Regulation (EU) N° 284/2013, Annex Part A, points 9.1.2.2 / 9.1.2.3)

| Lysimeter/field leaching studies | Information available in the DAR; not transparently evaluated. The exposure assessment was finalised using the adsorption data coming from the available batch adsorption studies. |

Hydrolytic degradation (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.1.1)

| Hydrolytic degradation of the active substance and metabolites > 10 % | pH 4: > 1 year at 20 °C  
| pH 7: 160 d (isomers III + IV) - 270 d (isomers I + II) at 20 °C  
| pH 9:  
| 33 h (isomers III + IV) - 42 h (isomers I + II) at 20 °C  
| metabolite DCVA: stable pH 4, 7, 9 |

Aqueous photochemical degradation (Regulation (EU) N° 283/2013, Annex Part A, points 7.2.1.2 / 7.2.1.3)

| Photolytic degradation of active substance and metabolites above 10 % | Natural light, 40 °N; DT_{50} 5.88 – 4.99 days (spring and summer)  
| Quantum yield of direct phototransformation in water at λ > 290 nm | 0.001149 mol · Einstein^{-1} |

‘Ready biodegradability’ (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.1)

| Readily biodegradable (yes/no) | No data, so considered not readily biodegradable |
Aerobic mineralisation in surface water (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.1)

Data gap: An aerobic mineralisation in surface water study or information to demonstrate that contamination of open water (freshwater, estuarine and marine) will not occur was not available for beta-cyfluthrin.

**Water / sediment study (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.2)**

| Test substance | Distribution (for cyfluthrin): max in water 40.14% after 0.5 h. Max. in sediment 68.36% after 6 h. |
|----------------|--------------------------------------------------------------------------------------------------|
| Water / sediment system | pH | pH | t. °C | DT50/DT90 | St. \( (\chi^2) \) | DT50/DT90 | St. \( (\chi^2) \) | DT50/DT90 | St. \( (\chi^2) \) | Method of calculation |
|-----------------|-----|-----|-------|-----------|----------------|-----------|----------------|-----------|----------------|--------------------------|
| Barmener        | 5.1-8.1 | 6.9 | 20    | 14.4/47.9 | 5.0 | 0.7/2.3 | 12.8 | 14.3/47.6 | 5.4 | DFOP decline fit |
| Genkel          | 4.6-8.0 | 4.6 | 20    | 53.0/103.7 | 9.8 | 0.4/1.3 | 19.6 | 81.5/180.8 | 11.8 | FOMC decline fit |

Geometric mean at 20°Cb) 27.6 0.5 34.1

\( a) \) Measured in [medium to be stated, usually calcium chloride solution or water]

\( b) \) Normalised using a Q10 of 2.58

| Metabolite | Distribution: in water maximum 36% applied at 2 d, in sediment maximum 23.7% applied at 100d kinetic formation fraction \( (k_f/k_{dp}) \): not determined |
|------------|----------------------------------------------------------------------------------------------------------------------------------------|
| Water / sediment system | pH | pH | t. °C | DT50/DT90 | St. \( (\chi^2) \) | DT50/DT90 | St. \( (\chi^2) \) | DT50/DT90 | St. \( (\chi^2) \) | Method of calculation |
|-----------------|-----|-----|-------|-----------|----------------|-----------|----------------|-----------|----------------|--------------------------|
| Genkel          | 4.6-8.0 | 4.6 | 20    | 113.8/378 | 10.5 | 4.8 | 2.2/7.3 | 5.6 | FOMC decline fit |

Geometric mean at 20°Cb) 6.6 5.0

\( a) \) Measured in [medium to be stated, usually calcium chloride solution or water]

\( b) \) Normalised using a Q10 of 2.58

| FPB-aldehyde | Distribution: in water maximum 1.1% applied at 1 d, in sediment maximum 15.7% applied at 1 d kinetic formation fraction \( (k_f/k_{dp}) \): not determined |
|--------------|----------------------------------------------------------------------------------------------------------------------------------------|
| Water / sediment system | pH | pH | t. °C | DT50/DT90 | St. \( (\chi^2) \) | DT50/DT90 | St. \( (\chi^2) \) | DT50/DT90 | St. \( (\chi^2) \) | Method of calculation |
|-----------------|-----|-----|-------|-----------|----------------|-----------|----------------|-----------|----------------|--------------------------|
| Lienden         | 7.0 – 8.3 | 7.8 | 22    | 10 | 23.1 | 11.2 / 37.1 | 15.1 | SFO decline fit |
| Ijzendoorn      | 7.0 – 8.3 | 6.8 | 22    | 4.3 | 4.8 | 2.2 / 7.3 | 5.6 | FOMC decline fit |

Geometric mean at 20°Cb) 6.6 5.0

\( c) \) Measured in [medium to be stated, usually calcium chloride solution or water]

\( d) \) Normalised using a Q10 of 2.58
FPB-acid

Distribution: in sediment maximum 24.3 % applied at 1 d, in water maximum 29.1 % applied at 11 d
kinetic formation fraction (k/f/kdp): not determined

| Water / sediment system | pH water phase | pH sed | t. °C | DT50 / DT90 whole sys. | St. (χ2) | DT50 / DT90 water | St. (χ2) | DT50 / DT90 sed | St. (χ2) | Method of calculation |
|-------------------------|---------------|--------|-------|------------------------|---------|-------------------|---------|-----------------|---------|---------------------|
| Lienden                 | 7.0 – 8.3     | 7.8    | 22    | 7.8 / 25.9 SFO          | 2.7     | 5.2 / 17.3        | 3.8     | FOFC decline fit |
| Ijzendoorn              | 7.0 – 8.3     | 6.8    | 22    | 4.0 / 13.3 SFO          | 4.1     | 5.5 / 18.4        | 7       | FOFC decline fit |

Geometric mean at 20°C(b)

| Method of calculation | 5.6 | 5.3 |

(a) Measured in [medium to be stated, usually calcium chloride solution or water]

(b) Normalised using a Q10 of 2.58

Mineralisation and non-extractable residues (from parent dosed experiments)

| Water / sediment system | pH water phase | pH sed | Mineralisation x % after n d. (end of the study) | Non-extractable residues in sed. max x % after n d | Non-extractable residues in sed. max x % after n d (end of the study) |
|-------------------------|---------------|--------|-------------------------------------------------|--------------------------------------------------|---------------------------------------------------------------------|
| Barmener                | 5.1 – 8.1     | 6.9    | 36.72% after 100 d                              | 28.7% after 14 d                                 | 12.19% after 100 d                                                  |
| Genkel                  | 4.6 – 8.0     | 4.6    | 14.2% after 100 d                              | 26.03% after 100 d                              | 26.03% after 100 d                                                  |

Fate and behaviour in air (Regulation (EU) N° 283/2013, Annex Part A, point 7.3.1)

Direct photolysis in air: no data

Photochemical oxidative degradation in air: DT50 of 17.8 hours derived by the Atkinson model (version 1.4). OH (24 h) concentration assumed = 5 × 10^5 OH/cm^3

Volatilisation: from plant surfaces (BBA guideline): 18 % after 24 h

from soil surfaces (BBA guideline): 9 % after 24 h

Metabolites: n.a.

Residues requiring further assessment (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.1)

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure

| Soil: | constituent isomers of beta-cyfluthrin, constituent isomers of DCVA, FPB-acid |
|-------|---------------------------------------------------------------------------------|
| Surface water: | constituent isomers of beta-cyfluthrin, constituent isomers of DCVA, FPB-acid, FPB-aldehyde |
| Sediment: | constituent isomers of beta-cyfluthrin, constituent isomers of DCVA, FPB-acid, FPB-aldehyde |
| Ground water: | constituent isomers of beta-cyfluthrin, constituent isomers of DCVA, FPB-acid |
| Air: | beta-cyfluthrin |
Definition of the residue for monitoring (Regulation (EU) No 283/2013, Annex Part A, point 7.4.2)

See section 5, Ecotoxicology

Monitoring data, if available (Regulation (EU) No 283/2013, Annex Part A, point 7.5)

| Type        | Available   |
|-------------|-------------|
| Soil        | Not available. |
| Surface water | Not available. |
| Ground water | Not available. |
| Air         | Not available. |
PEC soil (Regulation (EU) N° 284/2013, Annex Part A, points 9.1.3 / 9.3.1)

| Parent | Method of calculation | Application data |
|--------|-----------------------|------------------|
|        | HS-kinetic, k1 = 0.0249 (DT$_{50}$ 27.8 d), k2 = 0.00485 (DT$_{50}$ 143 d), tb = 28 d | Crop: potato |
|        | (maximum field)        | Depth of soil layer: 5 cm |
|        |                        | Soil bulk density: 1.5g/cm$^3$ |
|        |                        | % plant interception: 15 % |
|        |                        | Number of applications: 2 |
|        |                        | Interval(d): 14 |
|        |                        | Application rate(s): 12.5 g as/ha |

| PEC$_{soil}$ (mg/kg) | Single application | Single application | Multiple application | Multiple application |
|----------------------|--------------------|--------------------|----------------------|----------------------|
|                      | Actual             | Time weighted average | Actual             | Time weighted average |
| Initial              | 0.0242             |                     |                      |                     |
| Short term 24h       | 0.0241             | 0.0244             | 0.0241               | 0.0236               |
| 2d                   | 0.0235             | 0.0241             | 0.0241               | 0.0236               |
| 4d                   | 0.0224             | 0.0241             | 0.0241               | 0.0236               |
| Long term 7d         | 0.0208             | 0.0227             |                      |                     |
| 28d                  | 0.0142             | 0.0185             |                      |                     |
| 50d                  | 0.0128             | 0.0163             |                      |                     |
| 100d                 | 0.0102             | 0.0142             |                      |                     |
| Plateau concentration| n. a.              |                     |                      |                     |

Parent

Method of calculation

Application data

Crop: wheat
Depth of soil layer: 5 cm
Soil bulk density: 1.5g/cm$^3$
% plant interception: 25 %
Number of applications: 2
Interval(d): 14
Application rate(s): 12.5 g as/ha
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| **PEC**<sub>(s)</sub> (mg/kg) | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|-------------------------------|---------------------------|------------------------------------------|----------------------------|------------------------------------------|
| **Initial**                   |                           | 0.0213                                   |                            |                                          |
| **Short term**                |                           |                                          |                            |                                          |
| 24h                           |                           | 0.0213                                   | 0.0215                     |                                          |
| 2d                            |                           | 0.0208                                   | 0.0213                     |                                          |
| 4d                            |                           | 0.0198                                   | 0.0208                     |                                          |
| **Long term**                 |                           |                                          |                            |                                          |
| 7d                            |                           | 0.0184                                   | 0.0201                     |                                          |
| 28d                           |                           | 0.0125                                   | 0.0163                     |                                          |
| 50d                           |                           | 0.0113                                   | 0.0144                     |                                          |
| 100d                          |                           | 0.009                                    | 0.0125                     |                                          |
| **Plateau concentration**     |                           | n. a.                                    |                            |                                          |

Parent Method of calculation

**HS-kinetic.** \(k1 = 0.0249\) (DT<sub>50</sub> 27.8 d), \(k2 = 0.00485\) (DT<sub>50</sub> 143 d), \(tb = 28\) d

(maximum field)

Application data

Crop: tomato

Depth of soil layer: 5 cm

Soil bulk density: 1.5 g/cm³

% plant interception: 50%

Number of applications: 2

Interval (d): 14

Application rate(s): 17.5 g as/ha

| **PEC**<sub>(s)</sub> (mg/kg) | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|-------------------------------|---------------------------|------------------------------------------|----------------------------|------------------------------------------|
| **Initial**                   |                           | 0.0199                                   |                            |                                          |
| **Short term**                |                           |                                          |                            |                                          |
| 24h                           |                           | 0.0152                                   | 0.0154                     |                                          |
| 2d                            |                           | 0.0149                                   | 0.0152                     |                                          |
| 4d                            |                           | 0.0141                                   | 0.0149                     |                                          |
| **Long term**                 |                           |                                          |                            |                                          |
| 7d                            |                           | 0.0132                                   | 0.0143                     |                                          |
| 28d                           |                           | 0.0093                                   | 0.0118                     |                                          |
| 50d                           |                           | 0.0084                                   | 0.0109                     |                                          |
| 100d                          |                           | 0.0066                                   | 0.0094                     |                                          |
| **Plateau concentration**     |                           | n. a.                                    |                            |                                          |
Parent Method of calculation

HS-kinetic, $k_1 = 0.0249$ (DT$_{50} 27.8$ d), $k_2 = 0.00485$ (DT$_{50} 143$ d), $t_b = 28$ d
(maximum field)

Application data
Crop: sugar beet (seed treatment)
Depth of soil layer: 5 cm
Soil bulk density: 1.5 g/cm$^3$
% plant interception: 0%
Number of applications: 1
Application rate(s): 10.4 g as/ha

| PEC$_{(o)}$ (mg/kg) | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|---------------------|---------------------------|----------------------------------------|-----------------------------|------------------------------------------|
| Initial             |                           |                                        |                             | 0.0140                                    |
| Short term          |                           |                                        |                             |                                          |
| 24h                 |                           |                                        |                             | 0.014                                     |
| 2d                  |                           |                                        |                             | 0.0137                                    |
| 4d                  |                           |                                        |                             | 0.013                                     |
| Long term           |                           |                                        |                             |                                          |
| 7d                  |                           |                                        |                             | 0.0121                                    |
| 28d                 |                           |                                        |                             | 0.0073                                    |
| 50d                 |                           |                                        |                             | 0.0066                                    |
| 100d                |                           |                                        |                             | 0.0053                                    |
| Plateau concentration | n. a.                     |                                        |                             |                                          |

Metabolite DCVA
Method of calculation
Molecular weight relative to the parent: 209.1
DT$_{50}$ (d): 7.1, SFO, maximum lab*$
* The correct DT$_{50}$ is 8.5 d (not normalised worst case from the Lab)

Application data
Application rate assumed: appl. rate parent × maximum occurrence in soil (40.5%) × mol. weight correction factor

| PEC$_{(o)}$ (mg/kg) | potato | wheat | tomato | beet |
|---------------------|--------|-------|--------|------|
| Initial             | 0.0047 | 0.042 | 0.0029 | 0.0027 |

Metabolite FPB-acid
Method of calculation
Molecular weight relative to the parent: 232.2
DT$_{50}$ (d): 2.6, SFO, maximum lab*$
* The correct DT$_{50}$ is 2.9 d (not normalised worst case from the Lab)

Application data
Application rate assumed: appl. rate parent × maximum occurrence in soil (40.5%) × mol. weight correction factor
occurrence in soil (22.3 %) × mol. weight correction factor

|        | potato | wheat | tomato | beet |
|--------|--------|-------|--------|------|
| Initial| 0.0028 | 0.0025| 0.0014 | 0.0010|

PEC ground water (Regulation (EU) N° 284/2013, Annex Part A, point 9.2.4.1)

Method of calculation and type of study (e.g. modelling, field leaching, lysimeter)

For FOCUS gw modelling, values used –
Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance.
Model(s) used: FOCUS PEARL v4.4.4 and FOCUS PELMO v5.5.3
Crop: winter cereals

Active substance:
Crop uptake factor: 0.0
Water solubility (mg/L): 0.00185 at pH 7 and 20°C
Vapour pressure: 1.33 x 10^-6 Pa at 20°C
Geometric mean parent DT50lab 28 d
KOC: geometric mean 104491 mL/g, 1/n = 1.

Metabolites:

FPB-acid
Crop uptake factor: 0
Water solubility (mg/L): 24000 at pH 7 and 20°C
Vapour pressure: 4.2 x 10^-5 Pa at 20°C
Geometric mean parent DT50lab 1.2 d
KOC: geometric mean 103 mL/g, arithmetic mean 1/n = 0.664
Transformation fraction (from as): 0.812

DCVA
Crop uptake factor: 0
Water solubility (mg/L): 42000 at pH 7 and 20°C
Vapour pressure: 1.3 x 10^-2 Pa at 20°C
Geometric mean parent DT50lab 3.5 d*
KOC: geometric mean 16 / 68 mL/g (for pH > 6 and pH < 6 correspondingly), arithmetic mean 1/n *= 0.888
Transformation fraction (from as): 0.872
* updated DT50 3.9 d. Koc = 21.6 and 1/n = 0.767 values should be used for future evaluations

Application rate
Gross application rate: 2 x 12.5 g as/ha.
Crop growth stage: BBCH 11-29
Canopy interception %: 25
Application rate net of interception: 9.37 g as/ha.
No. of applications: 2
Time of application (absolute or relative application dates): emergence

PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m)

| Scenario                     | Parent (µg/L) | Metabolite (µg/L) |
|------------------------------|---------------|-------------------|
|                              | Parent        | Metabolite        |
|                              | (µg/L)        | FPB acid          | DCVA          |
| Chateaudun                   | < 0.001       | < 0.001           | < 0.001       |
| Hamburg                      | < 0.001       | < 0.001           | 0.002         |
| Jokioinen                    | < 0.001       | < 0.001           | 0.001         |
| Kremsmunster                 | < 0.001       | < 0.001           | < 0.001       |
| Okehampton                   | < 0.001       | < 0.001           | 0.002         |
| Piacenza                     | < 0.001       | < 0.001           | < 0.001       |
| Porto                        | < 0.001       | < 0.001           | 0.002         |
| Sevilla                      | < 0.001       | < 0.001           | < 0.001       |
| Thiva                        | < 0.001       | < 0.001           | < 0.001       |

In order to improve the readability of the document, no PEC_{gw} for other crops from GAP are provided here, as they are comparably low <0.001 µg/L to 0.003 for all scenarios.

PEC_{gw} From lysimeter/field studies

| No data                      |

PEC_{gw} surface water and PEC sediment (Regulation (EU) N° 284/2013, Annex Part A, points 9.2.5/9.3.1)

| Parent                       |
|------------------------------|
| Parameters used in FOCUSsw step 1 and 2 |

| FOCUS Step 1 and 2 calculator vs 3.2 |
|-------------------------------------|
| beta-Cyfluthrin                    |
| water solubility: 1.85 µg/L at 20°C (average between |
Isomers II and IV)
\( DT_{50} \) water/sediment system: 27.6 d
\( DT_{50} \) water: 1000d
\( DT_{50} \) sediment: 34.1 d
Koc: 104491
\( DT_{50} \) soil: 28 d

DCVA
Molar weight: 209.1
Water solubility: 42000 mg/L
\( DT_{50} \) water/sediment system: 113.8 d
\( DT_{50} \) water: 113.8 d
\( DT_{50} \) sediment: 113.8 d
Koc*: 16 / 68
\( DT_{50} \) soil*: 3.5 d
Max. occurrence in W/S system: 47.6 %
Max. occurrence in soil: 75.7 %
* Updated \( DT_{50} \) soil 3.9 d, Koc = 21.6 and 1/n = 0.767
Values should be used for future evaluations

FPB-Acid
Molar weight: 232.2
Water solubility: 24000 mg/L
\( DT_{50} \) water/sediment system: 5.6 d
\( DT_{50} \) water: 5.6 d
\( DT_{50} \) sediment: 5.6 d
Koc: 103
\( DT_{50} \) soil: 1.2 d
Max. occurrence in W/S system: 44.5 %
Max. occurrence in soil: 63.9 %

FPB-aldehyde
Molar weight: 216.2
Water solubility: 71207 mg/L (estimated with EpiSuite 4.1.1)
\( DT_{50} \) water/sediment system: 6.6 d
\( DT_{50} \) water: 6.6 d
\( DT_{50} \) sediment: 6.6 d
Koc: 238.8 d (estimated with EpiSuite 4.1.1 using KocWIN 2.0 model with MCI)
\( DT_{50} \) soil: 1000 d
Max. occurrence in W/S system: 15.7 %
Max. occurrence in soil: 1 %

Parameters used in FOCUSsw step 3

Version control no.'s of FOCUS software FOCUS
SWASH version 5.3, FOCUS SPIN 2.2, FOCUS
MACRO 5.5.4, FOCUS PRZM 4.3.1, FOCUS
TOXSWA 4.4.3, SWAN 4.0.1
### Application rate

| Parameter                                                                 | Value                                      |
|--------------------------------------------------------------------------|--------------------------------------------|
| beta-cyfluthrin                                                          |                                            |
| Water solubility (average between Isomers II and IV)                     | 1.85 μg/L                                  |
| Vapour pressure                                                          | $1.33 \times 10^{-6}$ Pa at 20°C           |
| Koc (mL/g)                                                               | 104491                                     |
| $1/n$: (Freundlich exponent general or for soil, susp. solids or sediment respectively) | 1.0                                        |
| $Q_{10}=2.58$, Walker equation coefficient 0.7                           |                                            |
| Crop uptake factor                                                       | 0                                          |
| Wash-off factor                                                          | $0.02 \text{ cm}^{-1}$                     |
| Crop: cereals, potatoes, tomatoes, beets                                 |                                            |
| Number of applications                                                   | 2 except for beets where 1 was simulated   |
| Interval (d)                                                             | 14                                         |
| Application rate(s):                                                     | see following results tables               |
### Beta-cyfluthrin, PECsw, µg/L

| Crop                  | Timing | Period  | Crop interception | Region        | Appl. rate | Step 1 | Step 2 | Step 2 |
|-----------------------|--------|---------|-------------------|---------------|------------|--------|--------|--------|
| Winter cereals        | Spring | Mar-May | Full canopy       | North Europe  | 7.5        | 0.17   | 0.07   | 0.06   |
| Winter cereals        | Spring | Mar-May | Full canopy       | South Europe  | 12.5       | 0.29   | 0.11   | 0.1    |
| Winter cereals        | Autumn | Oct-Feb | Minimal crop cover| North Europe  | 7.5        | 0.17   | 0.07   | 0.06   |
| Winter cereals        | Autumn | Oct-Feb | Minimal crop cover| South Europe  | 12.5       | 0.29   | 0.11   | 0.1    |
| Spring cereals        | -      | Mar-May | Minimal crop cover| North Europe  | 7.5        | 0.17   | 0.07   | 0.06   |
| Spring cereals        | -      | Mar-May | Minimal crop cover| South Europe  | 12.5       | 0.29   | 0.11   | 0.1    |
| Potatoes              | -      | Mar-May | Minimal crop cover| North Europe  | 7.5        | 0.17   | 0.07   | 0.06   |
| Potatoes              | -      | Mar-May | Minimal crop cover| South Europe  | 12.5       | 0.29   | 0.11   | 0.1    |
| Tomatoes              | -      | Mar-May | No interception   | North Europe  | 17.5       | 0.41   | 0.16   | 0.14   |
| Tomatoes              | -      | Mar-May | No interception   | South Europe  | 17.5       | 0.41   | 0.16   | 0.14   |

### Beta-cyfluthrin, PECsed, µg/kg

| Crop                  | Timing | Period  | Crop interception | Region        | Appl. rate | Step 1 | Step 2 | Step 2 |
|-----------------------|--------|---------|-------------------|---------------|------------|--------|--------|--------|
| Winter cereals        | Spring | Mar-May | Full canopy       | North Europe  | 7.5        | 37.31  | 1.48   | 2.46   |
| Winter cereals        | Spring | Mar-May | Full canopy       | South Europe  | 12.5       | 62.19  | 4.16   | 6.98   |
| Winter cereals        | Autumn | Oct-Feb | Minimal crop cover| North Europe  | 7.5        | 37.31  | 6.79   | 11.53  |
| Winter cereals        | Autumn | Oct-Feb | Minimal crop cover| South Europe  | 12.5       | 62.19  | 9.21   | 15.61  |
| Spring cereals        | -      | Mar-May | Minimal crop cover| North Europe  | 7.5        | 37.31  | 3      | 5.05   |
| Spring cereals        | -      | Mar-May | Minimal crop cover| South Europe  | 12.5       | 62.19  | 9.21   | 15.61  |
| Potatoes              | -      | Mar-May | Minimal crop cover| North Europe  | 7.5        | 37.31  | 3.34   | 5.63   |
| Potatoes              | -      | Mar-May | Minimal crop cover| South Europe  | 12.5       | 62.19  | 10.34  | 17.53  |
| Tomatoes              | -      | Mar-May | No interception   | North Europe  | 17.5       | 87.06  | 8.97   | 15.14  |
| Tomatoes              | -      | Mar-May | No interception   | South Europe  | 17.5       | 87.06  | 16.84  | 28.58  |

* Due to model’s specificities, some combination of substance’s features may lead to higher PEC values for single rather than for multiple applications.

### DCVA, Koc = 16 at pH > 6, worst-case for water

| PECsw, µg/L | Step 1 | Step 2 | Step 2 |
|------------|--------|--------|--------|
| Crop       | Appl. rate | 2x appl. | 1x appl. | 2x appl. |
| Winter cereals | Spring | Mar-May | Full canopy | North Europe | 7.5 | 37.31 | 1.48 | 2.46 |
| Winter cereals | Spring | Mar-May | Full canopy | South Europe | 12.5 | 62.19 | 4.16 | 6.98 |
| Winter cereals | Autumn | Oct-Feb | Minimal crop cover | North Europe | 7.5 | 37.31 | 6.79 | 11.53 |
| Winter cereals | Autumn | Oct-Feb | Minimal crop cover | South Europe | 12.5 | 62.19 | 9.21 | 15.61 |
| Spring cereals | - | Mar-May | Minimal crop cover | North Europe | 7.5 | 37.31 | 3 | 5.05 |
| Spring cereals | - | Mar-May | Minimal crop cover | South Europe | 12.5 | 62.19 | 9.21 | 15.61 |
| Potatoes | - | Mar-May | Minimal crop cover | North Europe | 7.5 | 37.31 | 3.34 | 5.63 |
| Potatoes | - | Mar-May | Minimal crop cover | South Europe | 12.5 | 62.19 | 10.34 | 17.53 |
| Tomatoes | - | Mar-May | No interception | North Europe | 17.5 | 87.06 | 8.97 | 15.14 |
| Tomatoes | - | Mar-May | No interception | South Europe | 17.5 | 87.06 | 16.84 | 28.58 |
| Winter cereals | Spring | Mar-May | full canopy | North Europe | 7.5 | 2.94 | 0.07 | 0.1 |
|----------------|--------|--------|-------------|--------------|-----|------|------|-----|
| Winter cereals | Spring | Mar-May | full canopy | South Europe | 12.5 | 4.9 | 0.21 | 0.3 |
| Winter cereals | Autumn | Oct-Feb | minimal crop cover | North Europe | 7.5 | 2.94 | 0.36 | 0.51 |
| Winter cereals | Autumn | Oct-Feb | minimal crop cover | South Europe | 12.5 | 4.9 | 0.48 | 0.69 |
| Spring cereals | - | Mar-May | minimal crop cover | North Europe | 7.5 | 2.94 | 0.15 | 0.22 |
| Spring cereals | - | Mar-May | minimal crop cover | South Europe | 12.5 | 4.9 | 0.48 | 0.69 |
| Potatoes | - | Mar-May | minimal crop cover | North Europe | 7.5 | 2.94 | 0.17 | 0.25 |
| Potatoes | - | Mar-May | minimal crop cover | South Europe | 12.5 | 4.9 | 0.54 | 0.78 |
| Tomatoes | - | Mar-May | no interception | North Europe | 17.5 | 6.85 | 0.46 | 0.67 |
| Tomatoes | - | Mar-May | no interception | South Europe | 17.5 | 6.85 | 0.89 | 1.27 |

**DCVA, Koc = 68 at pH < 6, worst-case for sediment**

| crop timing period | crop interception | region | appl. rate | Step 1 | Step 2 | Step 2 |
|--------------------|-------------------|--------|------------|--------|--------|--------|
| Winter cereals | Spring Mar-May | full canopy | North Europe | 7.5 | 1.86 | 0.04 | 0.07 |
| Winter cereals | Spring Mar-May | full canopy | South Europe | 12.5 | 4.59 | 0.2 | 0.28 |
| Winter cereals | Autumn Oct-Feb | minimal crop cover | North Europe | 7.5 | 1.86 | 0.23 | 0.32 |
| Winter cereals | Autumn Oct-Feb | minimal crop cover | South Europe | 12.5 | 3.1 | 0.3 | 0.44 |
| Spring cereals | - Mar-May | minimal crop cover | North Europe | 7.5 | 1.86 | 0.1 | 0.14 |
| Spring cereals | - Mar-May | minimal crop cover | South Europe | 12.5 | 3.1 | 0.3 | 0.44 |
| Potatoes | - Mar-May | minimal crop cover | North Europe | 7.5 | 1.86 | 0.11 | 0.16 |
| Potatoes | - Mar-May | minimal crop cover | South Europe | 12.5 | 3.1 | 0.34 | 0.49 |
| Tomatoes | - Mar-May | no interception | North Europe | 17.5 | 4.34 | 0.29 | 0.42 |
| Tomatoes | - Mar-May | no interception | South Europe | 17.5 | 4.34 | 0.56 | 0.8 |

**FPB-acid**

| PECsw, µg/L | crop timing period | crop interception | region | appl. rate | Step 1 | Step 2 | Step 2 |
|-------------|-------------------|-------------------|--------|------------|--------|--------|--------|
| Winter cereals | Spring Mar-May | full canopy | North Europe | 7.5 | 2.58 | 0.04 | 0.06 |
| Winter cereals | Spring Mar-May | full canopy | South Europe | 12.5 | 4.3 | 0.12 | 0.19 |
| Winter cereals | Autumn Oct-Feb | minimal crop cover | North Europe | 7.5 | 2.58 | 0.21 | 0.34 |
| Winter cereals | Autumn Oct-Feb | minimal crop cover | South Europe | 12.5 | 4.3 | 0.29 | 0.46 |
### Table 1: PECsed, µg/kg

| Crop                  | Timing   | Period       | Crop interception | Region     | Appl. Rate | 2x Appl. | 1x Appl. | 2x Appl. |
|-----------------------|----------|--------------|-------------------|------------|------------|----------|----------|----------|
| Winter cereals        | Spring   | Mar-May      | Full canopy       | North Europe | 7.5        | 2.58     | 0.09     | 0.14     |
| Winter cereals        | Spring   | Mar-May      | Full canopy       | South Europe | 12.5       | 4.3      | 0.29     | 0.46     |
| Potatoes              | Mar-May  | Mar-May      | Minimal crop cover| North Europe | 7.5        | 2.58     | 0.1      | 0.16     |
| Potatoes              | Mar-May  | Mar-May      | Minimal crop cover| South Europe | 12.5       | 4.3      | 0.33     | 0.46     |
| Tomatoes              | Mar-May  | No interception | North Europe | 17.5       | 6.02     | 0.28     | 0.43     |
| Tomatoes              | Mar-May  | No interception | South Europe | 17.5       | 6.02     | 0.53     | 0.85     |

### Table 2: PECsw, µg/L

| Crop                  | Timing   | Period       | Crop interception | Region     | Appl. Rate | 2x Appl. | 1x Appl. | 2x Appl. |
|-----------------------|----------|--------------|-------------------|------------|------------|----------|----------|----------|
| Winter cereals        | Spring   | Mar-May      | Full canopy       | North Europe | 7.5        | 0.33     | 0.01     | 0.02     |
| Winter cereals        | Spring   | Mar-May      | Full canopy       | South Europe | 12.5       | 0.54     | 0.03     | 0.05     |
| Winter cereals        | Autumn   | Oct-Feb      | Minimal crop cover| North Europe | 7.5        | 0.33     | 0.06     | 0.1      |
| Winter cereals        | Autumn   | Oct-Feb      | Minimal crop cover| South Europe | 12.5       | 0.54     | 0.08     | 0.13     |
| Spring cereals        | -        | Mar-May      | Minimal crop cover| North Europe | 7.5        | 0.33     | 0.02     | 0.04     |
| Spring cereals        | -        | Mar-May      | Minimal crop cover| South Europe | 12.5       | 0.54     | 0.08     | 0.13     |
| Potatoes              | Mar-May  | Mar-May      | Minimal crop cover| North Europe | 7.5        | 0.33     | 0.03     | 0.05     |
| Potatoes              | Mar-May  | Mar-May      | Minimal crop cover| South Europe | 12.5       | 0.54     | 0.09     | 0.15     |
| Tomatoes              | Mar-May  | No interception | North Europe | 17.5       | 0.76     | 0.07     | 0.12     |
| crop                | timing  | period     | crop interception      | region      | appl. rate | 2x appl. | 1x appl. * | 2x appl. |
|---------------------|---------|------------|------------------------|-------------|------------|-----------|------------|-----------|
| Winter cereals      | Spring  | Mar-May    | full canopy            | North Europe| 7.5        | 0.75      | 0.03       | 0.04      |
| Winter cereals      | Spring  | Mar-May    | full canopy            | South Europe| 12.5       | 1.25      | 0.08       | 0.13      |
| Winter cereals      | Autumn  | Oct-Feb    | minimal crop cover     | North Europe| 7.5        | 0.75      | 0.13       | 0.23      |
| Winter cereals      | Autumn  | Oct-Feb    | minimal crop cover     | South Europe| 12.5       | 1.25      | 0.18       | 0.3       |
| Spring cereals      | -       | Mar-May    | minimal crop cover     | North Europe| 7.5        | 0.75      | 0.06       | 0.09      |
| Spring cereals      | -       | Mar-May    | minimal crop cover     | South Europe| 12.5       | 1.25      | 0.18       | 0.3       |
| Potatoes            | -       | Mar-May    | minimal crop cover     | North Europe| 7.5        | 0.75      | 0.06       | 0.11      |
| Potatoes            | -       | Mar-May    | minimal crop cover     | South Europe| 12.5       | 1.25      | 0.2        | 0.34      |
| Tomatoes            | -       | Mar-May    | no interception        | North Europe| 17.5       | 1.76      | 0.17       | 0.29      |
| Tomatoes            | -       | Mar-May    | no interception        | South Europe| 17.5       | 1.76      | 0.33       | 0.56      |

* Due to model’s specificities, some combination of substance’s features may lead to higher PEC values for single rather than for multiple applications.
Maximum PEC_{SW} and PEC_{sed} values (FOCUS Steps 3) for beta-cyfluthrin

| Scenario | PEC_{sw}, max (µg/L) | PEC_{sed}, max (µg/kg) |
|----------|----------------------|------------------------|
| 1 x 7.5 g as/ha in autumn application in winter cereals * | |
| D1 | ditch | 0.0446 | 0.2554 |
| | stream | 0.0390 | 0.1368 |
| D2 | ditch | 0.0444 | 0.2139 |
| | stream | 0.0360 | 0.0458 |
| D3 | ditch | 0.0440 | 0.1345 |
| D4 | pond | 0.0015 | 0.0192 |
| | stream | 0.0381 | 0.0889 |
| D5 | pond | 0.0015 | 0.0203 |
| | stream | 0.0411 | 0.1048 |
| D6 | ditch | 0.0445 | 0.2401 |
| R1 | pond | 0.0015 | 0.0236 |
| | stream | 0.0290 | 0.1134 |
| R3 | stream | 0.0406 | 0.0879 |
| R4 | stream | 0.0291 | 0.0627 |
| 2 x 7.5 g as/ha (14 d) in autumn application in winter cereals | |
| D1 | ditch | 0.0434 | 0.42630 |
| | stream | 0.0336 | 0.13910 |
| D2 | ditch | 0.0386 | 0.20400 |
| | stream | 0.0309 | 0.03940 |
| D3 | ditch | 0.0382 | 0.13880 |
| D4 | pond | 0.0015 | 0.03100 |
| | stream | 0.0328 | 0.07650 |
| D5 | pond | 0.0016 | 0.03220 |
| | stream | 0.0354 | 0.09950 |
| D6 | ditch | 0.0386 | 0.20860 |
| R1 | pond | 0.0017 | 0.04070 |
| | stream | 0.0249 | 0.22750 |
| R3 | stream | 0.035 | 0.08990 |
| R4 | stream | 0.0251 | 0.10600 |
| 1 x 12.5 g as/ha in autumn application in winter cereals * | |
| D1 | ditch | 0.0741 | 0.4245 |
| | stream | 0.0650 | 0.2280 |
| D2 | ditch | 0.0737 | 0.3556 |
| | stream | 0.0599 | 0.0764 |
| D3 | ditch | 0.0730 | 0.2235 |
| D4 | pond | 0.0025 | 0.0324 |
| | stream | 0.0635 | 0.1482 |
| D5 | pond | 0.0025 | 0.0343 |
| | stream | 0.0685 | 0.1747 |
| D6 | ditch | 0.0739 | 0.3991 |
| R1 | pond | 0.0025 | 0.0398 |
| | stream | 0.0483 | 0.1890 |
| R3 | stream | 0.0677 | 0.1465 |
| R4 | stream | 0.0486 | 0.1045 |
| 2 x 12.5 g as/ha in autumn application in winter cereals | |
| D1 | ditch | 0.0724 | 0.7106 |
| | stream | 0.0563 | 0.2331 |
| D2 | ditch | 0.0643 | 0.3401 |
|             | stream | ditch | pond | stream |
|-------------|--------|-------|------|--------|
| D3          | 0.0519 | 0.0637| 0.0026| 0.0549 |
| D4          |        |       |      |        |
| D5          |        |       |      |        |
| R1          |        |       |      |        |
| R2          |        |       |      |        |
| R3          | 0.0586 | 0.0593| 0.0418| 0.0420 |
| R4          |        |       |      |        |

**1 x 7.5 g as/ha in spring application in winter cereals** *

|             | stream | ditch | pond | stream |
|-------------|--------|-------|------|--------|
| D1          | 0.0445 | 0.0380| 0.0447| 0.0397 |
| D2          |        |       |      |        |
| D3          |        |       |      |        |
| D4          |        |       |      |        |
| D5          |        |       |      |        |
| R1          |        |       |      |        |
| R2          |        |       |      |        |
| R3          | 0.0411 | 0.0352| 0.0436| 0.0291 |
| R4          |        |       |      |        |

**2 x 7.5 g as/ha (14 d) in spring application in winter cereals**

|             | stream | ditch | pond | stream |
|-------------|--------|-------|------|--------|
| D1          | 0.0412 | 0.0332| 0.039 | 0.0341 |
| D2          |        |       |      |        |
| D3          |        |       |      |        |
| D4          |        |       |      |        |
| D5          |        |       |      |        |
| R1          |        |       |      |        |
| R2          |        |       |      |        |
| R3          | 0.0353 | 0.029 | 0.0334| 0.025 |
| R4          |        |       |      |        |

**1 x 12.5 g as/ha in spring application in winter cereals** *

|             | stream | ditch | pond | stream |
|-------------|--------|-------|------|--------|
| D1          | 0.0740 | 0.0633| 0.0742| 0.0662 |
| D2          |        |       |      |        |
| D3          |        |       |      |        |
| D4          |        |       |      |        |
| D5          |        |       |      |        |
| R1          |        |       |      |        |
| R2          |        |       |      |        |
| R3          | 0.0353 | 0.0025| 0.0542| 0.0386 |
| R4          |        |       |      |        |
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|   | ditch | pond | stream |
|---|-------|------|--------|
| D6 | 0.0724 | 0.1834 | |
| R1 | 0.0025 | 0.0340 | |
| R3 | 0.0445 | 0.1032 | |
| R4 | 0.0684 | 0.1719 | |

2 x 12.5 g as/ha in spring application in winter cereals

|   | ditch | pond | stream |
|---|-------|------|--------|
| D1 | 0.0687 | 0.5983 | |
| D2 | 0.0651 | 0.4368 | |
| D3 | 0.0639 | 0.2493 | |
| D4 | 0.0026 | 0.0532 | |
| D5 | 0.0028 | 0.0517 | |
| D6 | 0.0643 | 0.2966 | |
| R1 | 0.0025 | 0.0489 | |
| R3 | 0.0592 | 0.1539 | |
| R4 | 0.0420 | 0.3649 | |

1 x 7.5 g as/ha spring application in spring cereals *

|   | ditch | pond | stream |
|---|-------|------|--------|
| D1 | 0.0443 | 0.1893 | |
| D3 | 0.0354 | 0.0408 | |
| D4 | 0.0440 | 0.1444 | |
| D5 | 0.0015 | 0.0190 | |
| R4 | 0.0346 | 0.0336 | |
| R1 | 0.0015 | 0.0195 | |
| R3 | 0.0350 | 0.0244 | |
| R4 | 0.0290 | 0.1033 | |

2 x 7.5 g as/ha (14 d) spring application in spring cereals

|   | ditch | pond | stream |
|---|-------|------|--------|
| D1 | 0.0393 | 0.1893 | |
| D3 | 0.0335 | 0.0408 | |
| D4 | 0.0384 | 0.1444 | |
| D5 | 0.0015 | 0.019 | |
| R4 | 0.031 | 0.0336 | |
| R1 | 0.0017 | 0.0195 | |
| R3 | 0.033 | 0.0244 | |
| R4 | 0.025 | 0.1033 | |

1 x 12.5 g as/ha (14 d) spring application in spring cereals *

|   | ditch | pond | stream |
|---|-------|------|--------|
| D1 | 0.0737 | 0.3147 | |
| D3 | 0.0591 | 0.0680 | |
| D4 | 0.0732 | 0.2400 | |
| D5 | 0.0025 | 0.0321 | |
| R4 | 0.0577 | 0.0560 | |
| R1 | 0.0025 | 0.0330 | |
| R3 | 0.0583 | 0.0406 | |
| R4 | 0.0483 | 0.1721 | |

2 x 12.5 g as/ha (14 d) spring application in spring cereals

|   | ditch | pond | stream |
|---|-------|------|--------|
| D1 | 0.0655 | 0.4262 | |
| D3 | 0.0562 | 0.1978 | |
| D3 | 0.0640 | 0.2626 | |
Due to model’s specificities, some combination of substance’s features may lead to higher PEC values for single rather than for multiple applications.

**PEC<sub>sw</sub> (μg/L)** for beta-cyfluthrin in tomato, 2 × 17.5 g as/ha (permanent glasshouses) 0.1% emission calculated as being deposited on the surface water body.

| Scenario | Step 3 |
|----------|--------|
| D4       | pond   | 0.0025 | 0.0463 |
|          | stream | 0.0520 | 0.0685 |
| D5       | pond   | 0.0028 | 0.0515 |
|          | stream | 0.0552 | 0.0679 |
| R4       | stream | 0.0419 | 0.3377 |

1 × 7.5 g as/ha (14 d) in potatoes *

| D3       | ditch  | 0.0365 | 0.1250 |
| D4       | pond   | 0.0015 | 0.0182 |
|          | stream | 0.0306 | 0.0342 |
| D6       | ditch  | 0.0360 | 0.0856 |
| D6       | ditch  | 0.0358 | 0.0775 |
| R1       | pond   | 0.0015 | 0.0228 |
|          | stream | 0.0248 | 0.1246 |
| R2       | stream | 0.0334 | 0.1781 |
| R3       | stream | 0.0356 | 0.0910 |

2 × 7.5 g as/ha (14 d) in potatoes

| D3       | ditch  | 0.0316 | 0.118  |
| D4       | pond   | 0.0015 | 0.026  |
|          | stream | 0.0262 | 0.029  |
| D6       | ditch  | 0.0315 | 0.101  |
| D6       | ditch  | 0.0313 | 0.087  |
| R1       | pond   | 0.0015 | 0.031  |
|          | stream | 0.0217 | 0.153  |
| R2       | stream | 0.0286 | 0.178  |
| R3       | stream | 0.0305 | 0.154  |

1 × 12.5 g as/ha (14 d) in potatoes *

| D3       | ditch  | 0.0605 | 0.2073 |
| D4       | pond   | 0.0025 | 0.0307 |
|          | stream | 0.0509 | 0.0568 |
| D6       | ditch  | 0.0596 | 0.1420 |
| D6       | ditch  | 0.0594 | 0.1285 |
| R1       | pond   | 0.0025 | 0.0383 |
|          | stream | 0.0412 | 0.2077 |
| R2       | stream | 0.0554 | 0.2967 |
| R3       | stream | 0.0591 | 0.1516 |

2 × 12.5 g as/ha (14 d) in potatoes

| D3       | ditch  | 0.0316 | 0.1184 |
| D4       | pond   | 0.0015 | 0.0260 |
|          | stream | 0.0262 | 0.0293 |
| D6       | ditch  | 0.0315 | 0.1012 |
| D6       | ditch  | 0.0313 | 0.0871 |
| R1       | pond   | 0.0015 | 0.0308 |
|          | stream | 0.0217 | 0.1525 |
| R2       | stream | 0.0286 | 0.1778 |
| R3       | stream | 0.0305 | 0.1537 |
### Maximum PEC\textsubscript{SW} and PEC\textsubscript{SED} values for beta-cyfluthrin in beet, 10.4 g as/ha (FOCUS Step 3 calculations)*

| Scenario       | PEC\textsubscript{sw} (μg/L) | PEC\textsubscript{sed} (μg/kg) |
|----------------|-------------------------------|-------------------------------|
| D3 (ditch)     | <0.000001                     | <0.000001                     |
| D4 (pond)      | 2.76 \times 10^{-10}         | 3.23 \times 10^{-7}          |
| D4 (stream)    | 4.01 \times 10^{-9}          | 3.09 \times 10^{-7}          |
| R1 (pond)      | <0.000001                     | <0.000001                     |
| R1 (stream)    | <0.000001                     | <0.000001                     |
| R3 (stream)    | <0.000001                     | <0.000001                     |

*For these calculations the following input parameters were used: Water solubility: 2.1 μg/L; Vapour pressure: 1.4 \times 10^{-8} Pa at 20°C; Wash-off factor: 0.05 cm\(^{-1}\); K\textsubscript{oc} (mL/g): 123930; 1/n: 1.0

### Estimation of concentrations from other routes of exposure (Regulation (EU) N° 284/2013, Annex Part A, point 9.4)

**Method of calculation**

Not performed.

### PEC

**Maximum concentration**

-
Ecotoxicology
Effects on birds and other terrestrial vertebrates (Regulation (EU) N° 283/2013, Annex Part A, point 8.1 and Regulation (EU) N° 284/2013, Annex Part A, point 10.1)

| Species                  | Test substance | Time scale | End point            | Toxicity (mg/kg bw per day) |
|--------------------------|----------------|------------|----------------------|-----------------------------|
| **Birds**                |                |            |                      |                             |
| *Serinus canaria,*       | beta-cyfluthrin| Acute      | LD₅₀                 | 170ᵃ                        |
| *Colinus virginianus*    | Preparation    | Acute      | LD₅₀                 | >2000 [> 58.6 mg as]         |
| *Anas platyrhynchos*     | beta-cyfluthrin| Long-term  | NOEC/NOAEL           | 21.5 mg a.s./kg dietᵇ        |
|                          |                |            |                      | 2.6 mg a.s./kg bwᶜ           |
| *Serinus canaria,*       | beta-cyfluthrin| Long-term  | LD₅₀/3ᵇ              | 56.7                        |
| **Mammals**              |                |            |                      |                             |
| (lowest value, male mice)| beta-cyfluthrin| Acute      | LD₅₀                 | 91.0                        |
| *rat (Rattus rattus)*    | Preparation    | Acute      | LD₅₀                 | > 300 (as: 8.79)             |
|                          | Bulldock EC 25 |            |                      | < 2000 (as:54.8)            |
| *rat (Rattus rattus)*    | beta-cyfluthrin| Long-term  | NOAEL                | 1.39 mg a.s./kg bwᶜ          |

Endocrine disrupting properties (Annex Part A, points 8.1.5)
Mammals: A detailed analysis of all the apical toxicological studies (developmental toxicity studies in rats and rabbits, reproductive toxicity study in rats, developmental neurotoxicity study in rats and long-term toxicity/carcinogenicity in mice and rats) on beta-cyfluthrin revealed no evidence of any reproducible endocrine effect. Therefore, based on a complete toxicological data set, it is concluded that beta-cyfluthrin is unlikely to have endocrine disrupting properties in mammals.

Birds: Insufficient information. No firm conclusion can be drawn regarding non-target organisms other than mammals.

Additional higher tier studies (Annex Part A, points 10.1.1.2): no studies submitted

Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3):

ᵃ Lowest endpoint of available acute avian toxicity data. This value should be used in the risk assessment together with an assessment factor of 3.
ᵇ For consideration of sublethal effects in adults impairing the reproductive capacity the acute LD₅₀ was divided by 3 to be in line with the assessment factor selected for the acute avian risk assessment.
ᶜ Since this endpoint is derived for cyfluthrin, an adjustment factor of 0.42 has been applied to the original endpoint. This is to account for the content of beta-cyfluthrin in cyfluthrin.
Toxicity/exposure ratios for terrestrial vertebrates (Regulation (EU) N° 284/2013, Part A, Annex point 10.1)

**Spray application of Bulldock EC 25 in wheat/potato at 7.5 g as/ha [x 2 (14 d)]**

| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|--------------|----------------------------|------------|------------------------|-----|---------|
| **Screening Step (Birds)** | | | | | |
| All          | Small omnivorous bird     | Acute      | 1.43                   | 118.9 | 3       |
| All          | Small omnivorous bird     | Long-term  | 0.36                   | 7.2 | 5       |
| **Screening Step (Mammals)** | | | | | |
| All          | Small herbivorous mammal  | Acute      | 1.07                   | 85.1 | 10      |
| All          | Small herbivorous mammal  | Acute      | 1.07                   | > 8.2<sup>a</sup> | 10 |
| All          | Small herbivorous mammal  | Long-term  | 0.27                   | 5.2 | 5       |
| **Tier 1 in winter/spring wheat<sup>1</sup>** | | | | | |
| BBCH 10-19   | Small insectivorous mammal "shrew" | Acute | 0.070                   | 125.0 | 10 |
| BBCH ≥ 20    | Small insectivorous mammal "shrew" | Acute | 0.050                   | 175.9 | 10 |
| BBCH ≥ 40    | Small herbivorous mammal "vole" | Acute | 0.378                   | 23.2 | 10 |
| Early shoots | Large herbivorous mammal "lagomorph" | Acute | 0.390                   | 22.6 | 10 |
| BBCH 10-29   | Small omnivorous mammal "mouse" | Acute | 0.159                   | 55.2 | 10 |
| BBCH 30-39   | Small omnivorous mammal "mouse" | Acute | 0.080                   | 110.5 | 10 |
| BBCH ≥ 40    | Small omnivorous mammal "mouse" | Acute | 0.048                   | 182.7 | 10 |
| **Tier 1 in potatoes<sup>1</sup>** | | | | | |
| BBCH 10-19   | Small insectivorous mammal "shrew" | Acute | 0.070                   | 125.0 | 10 |
| BBCH ≥ 20    | Small insectivorous mammal "shrew" | Acute | 0.050                   | 175.9 | 10 |
| BBCH ≥ 40    | Small herbivorous mammal "vole" | Acute | 0.378                   | 23.2 | 10 |
| BBCH 10-40   | Large herbivorous mammal "lagomorph" | Acute | 0.325                   | 27.1 | 10 |
| BBCH ≥ 40    | Large herbivorous mammal "lagomorph" | Acute | 0.097                   | 90.5 | 10 |
| BBCH 10-39   | Small omnivorous mammal "mouse" | Acute | 0.159                   | 55.2 | 10 |
### Growth stage, Indicator or focal species, Time scale, DDD (mg/kg bw per day), TER, Trigger

| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|--------------|----------------------------|------------|------------------------|-----|---------|
| BBCH ≥ 40    | Small omnivorous mammal "mouse" | Acute      | 0.048                  | 182.7 | 10      |

### Risk from bioaccumulation and food chain behaviour

| Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|----------------------------|------------|------------------------|-----|---------|
| Earthworm-eating birds     | Long-term  | 0.11<sup>b</sup>       | 23.6 | 5       |
| Earthworm-eating mammals   | Long-term  | 0.13<sup>b</sup>       | 10.3 | 5       |
| Fish-eating birds          | Long-term  | 0.021<sup>c</sup>      | 124  | 5       |
| Fish-eating mammals        | Long-term  | 0.019<sup>c</sup>      | 74.2 | 5       |

### Risk from consumption of contaminated water

| Scenarios                  | Indicator or focal species | Time scale   | PEC<sub>soil</sub>xDWR | TER | Trigger |
|----------------------------|----------------------------|--------------|-------------------------|-----|---------|
| Leaf scenario              | Since none of the representative crop uses falls into these categories, the leaf scenario does not apply to the use of Bulldock EC 25. | | | | |
| Puddle scenario, Screening step | Application rate (g as/ha)/relevant endpoint <3000 (koc≥500 L/kg), TER calculation not needed | | | | |

<sup>a</sup> Risk assessment based on the toxicity endpoint of the formulation Bulldock. LD<sub>50</sub> > 300 mg/kg bw (>8.79 mg as/kg bw)

<sup>b</sup> Risk assessment for earthworm-eating birds and mammals performed using the worst case initial PEC<sub>soil</sub> for representative uses (0.0242 mg a.s./kg soil dw, use to potato at 2 x 12.5 g a.s./ha), Koc=104491, and LogP=5.9.

<sup>c</sup> Risk assessment for fish-eating birds and mammals performed using the worst case initial FOCUS Step 3 PEC value for all representative uses (0.0724 µg a.s./L for d1 ditch for the representative use to wheat at 2 x 12.5 g a.s./ha) and a BCF of 1822.

### Spray application of Bulldock EC 25 in wheat/potato at 12.5 g as/ha [x 2 (14 d)]

| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|--------------|----------------------------|------------|------------------------|-----|---------|
| Screening Step (Birds) | | | | | |
| All          | Small omnivorous bird     | Acute      | 2.38                   | 71.4 | 3       |
| All          | Small omnivorous bird     | Long-term  | 0.60                   | 4.3  | 5       |
| Screening Step (Mammals) | | | | | |
| All          | Small herbivorous mammal  | Acute      | 1.78                   | 51.1 | 10      |
| All          | Small herbivorous mammal  | Acute      | 1.78                   | >4.93<sup>a</sup> | 10 |
| All          | Small herbivorous mammal  | Long-term  | 0.45                   | 3.1  | 5       |
| Tier 1 in winter/spring wheat<sup>a</sup> | Small insectivorous bird “passerine” | Long-term  | 0.20                   | 12.78 | 5 |

<sup>a</sup> Late post-emergence May-June

BBCH 71-89
| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|--------------|---------------------------|------------|------------------------|-----|---------|
| Early shoots | Large herbivorous bird "goose" | Long-term | 0.14 | 17.68 | 5 |
| BBCH 10-29   | Small omnivorous bird "lark" | Long-term | 0.10 | 26.27 | 5 |
| BBCH 30-39   | Small omnivorous bird "lark" | Long-term | 0.05 | 53.03 | 5 |
| BBCH ≥40     | Small omnivorous bird "lark" | Long-term | 0.03 | 86.78 | 5 |
| Late season   | Small granivorous/insectivorous bird "bunting" | Long-term | 0.11 | 22.91 | 5 |
| Seed heads   | Small insectivorous mammal "shrew" | Acute | 0.117 | 75.0 | 10 |
| BBCH 10-19   | Small insectivorous mammal "shrew" | Acute | 0.083 | 105.5 | 10 |
| BBCH ≥20     | Small herbivorous mammal "vole" | Acute | 0.631 | 13.9 | 10 |
| Early shoots | Large herbivorous mammal "lagomorph" | Acute | 0.694 | 13.5 | 10 |
| BBCH 10-29   | Small omnivorous mammal "mouse" | Acute | 0.265 | 33.1 | 10 |
| BBCH 30-39   | Small omnivorous mammal "mouse" | Acute | 0.133 | 66.3 | 10 |
| BBCH ≥40     | Small omnivorous mammal "mouse" | Acute | 0.080 | 109.6 | 10 |
| BBCH 10-19   | Small insectivorous mammal "shrew" | Long-term | 0.042 | 33.5 | 5 |
| BBCH ≥20     | Small insectivorous mammal "shrew" | Long-term | 0.019 | 74.0 | 5 |
| BBCH ≥40     | Small herbivorous mammal "vole" | Long-term | 0.215 | 6.5 | 5 |
| Early shoots | Large herbivorous mammal "lagomorph" | Long-term | 0.220 | 6.3 | 5 |
| BBCH 10-29   | Small omnivorous mammal "mouse" | Long-term | 0.077 | 18.0 | 5 |
| BBCH 30-39   | Small omnivorous mammal "mouse" | Long-term | 0.039 | 36.1 | 5 |
| BBCH ≥40     | Small omnivorous mammal "mouse" | Long-term | 0.023 | 61.1 | 5 |

* Tier 1 in potatoes*
| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|--------------|---------------------------|------------|------------------------|-----|---------|
| BBCH 10-19  | Small insectivorous mammal "shrew" | Acute      | 0.117                  | 75.0| 10      |
| BBCH ≥ 20   | Small insectivorous mammal "shrew" | Acute      | 0.083                  | 105.5| 10     |
| BBCH ≥ 40   | Small herbivorous mammal "vole"     | Acute      | 0.631                  | 13.9| 10      |
| BBCH 10-40  | Large herbivorous mammal "lagomorph" | Acute     | 0.541                  | 33.8| 10      |
| BBCH ≥ 40   | Large herbivorous mammal "lagomorph" | Acute     | 0.162                  | 54.3| 10      |
| BBCH 10-39  | Small omnivorous mammal "mouse"     | Acute      | 0.265                  | 33.1| 10      |
| BBCH ≥ 40   | Small omnivorous mammal "mouse"     | Acute      | 0.080                  | 109.6| 10     |
| BBCH 10-19  | Small insectivorous mammal "shrew" | Long-term  | 0.042                  | 33.5| 5       |
| BBCH ≥ 20   | Small insectivorous mammal "shrew" | Long-term  | 0.019                  | 74.0| 5       |
| BBCH ≥ 40   | Small herbivorous mammal "vole"     | Long-term  | 0.215                  | 6.5 | 5       |
| BBCH 10-40  | Large herbivorous mammal "lagomorph" | Long-term | 0.141                  | 9.8 | 5       |
| BBCH ≥ 40   | Large herbivorous mammal "lagomorph" | Long-term | 0.043                  | 32.7| 5       |
| BBCH 10-39  | Small omnivorous mammal "mouse"     | Long-term  | 0.077                  | 18.0| 5       |
| BBCH ≥ 40   | Small omnivorous mammal "mouse"     | Long-term  | 0.023                  | 61.1| 5       |

**Risk from bioaccumulation and food chain behaviour**

| Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|---------------------------|------------|------------------------|-----|---------|
| Earthworm-eating birds   | Long-term  | 0.11<sup>b</sup>       | 23.6| 5       |
| Earthworm-eating mammals | Long-term  | 0.13<sup>b</sup>       | 10.3| 5       |
| Fish-eating birds        | Long-term  | 0.021<sup>c</sup>      | 124 | 5       |
| Fish-eating mammals      | Long-term  | 0.019<sup>c</sup>      | 74.2| 5       |

**Risk from consumption of contaminated water**

| Scenarios              | Indicator or focal species | Time scale | PEC<sub>soil</sub>xDWR | TER | Trigger |
|------------------------|----------------------------|------------|-------------------------|-----|---------|
| Leaf scenario          | Since none of the representative crop uses falls into these categories, the leaf scenario does not apply to the use of Bulldock EC 25. |

**Puddle scenario, Screening step**

Application rate (g as/ha)/relevant endpoint <3000 (koc≥500 L/kg), TER calculation not needed

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<sup>a</sup> Risk assessment based on the toxicity endpoint of the formulation Bulldock. LD<sub>50</sub> > 300 mg/kg bw (>8.79 mg as/kg bw)

<sup>b</sup> Risk assessment for earthworm-eating birds and mammals performed using the worst case initial PECsoil for representative uses (0.0242 mg a.s./kg soil dw, use to potato at 2 x 12.5 g a.s./ha), Koc=104491, and LogP=5.9.
Spray application of Bulldock EC 25 in tomato (semi-protected) at 17.5 g as/ha [x 2 (14 d)].

| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|--------------|---------------------------|------------|------------------------|-----|---------|
| Screening Step (Birds) | | | | | |
| All | Small omnivorous bird | Acute | 3.33 | 51.1 | 3 |
| All | Small omnivorous bird | Long-term | 0.84 | **3.1** | 5 |
| Screening Step (Mammals) | | | | | |
| All | Small herbivorous mammal | Acute | 2.86 | >3.1<sup>a</sup> | 10 |
| All | Small herbivorous mammal | Acute | 2.86 | 32.3 | 10 |
| All | Small herbivorous mammal | Long-term | 0.94 | **1.5** | 5 |
| Tier 1 in tomato/fruiting vegetables (semi-protected)<sup>a</sup> | | | | | |
| Fruit stage BBCH 71-89 | Frugivorous bird “crow” | Long-term | 0.443 | 5.9 | 5 |
| BBCH 10-49 | Small granivorous bird “finch” | Long-term | 0.158 | 16.5 | 5 |
| BBCH ≥ 50 | Small granivorous bird “finch” | Long-term | 0.047 | 55.3 | 5 |
| BBCH 10-49 | Small omnivorous bird “lark” | Long-term | 0.151 | 17.2 | 5 |
| BBCH ≥ 50 | Small omnivorous bird “lark” | Long-term | 0.046 | 56.9 | 5 |
| Fruit stage BBCH 71-89 | Frugivorous bird “starling” | Long-term | 0.286 | 9.1 | 5 |
| BBCH 10-19 | Small insectivorous bird “wagtail” | Long-term | 0.156 | 16.6 | 5 |
| BBCH ≥ 20 | Small insectivorous bird “wagtail” | Long-term | 0.134 | 19.4 | 5 |
| BBCH 71-89 | Frugivorous mammal “rat” | Acute | 0.95 | **9.3** | 10 |
| BBCH 10-19 | Small insectivorous mammal “shrew” | Acute | 0.16 | 55.1 | 10 |
| BBCH ≥ 20 | Small insectivorous mammal “shrew” | Acute | 0.11 | 77.5 | 10 |
| BBCH 10-49 | Small herbivorous mammal “mouse” | Acute | 2.86 | **3.1** | 10 |
| BBCH ≥ 50 | Small herbivorous mammal “mouse” | Acute | 0.86 | 10.2 | 10 |
| BBCH 10-49 | Small omnivorous mammal “mouse” | Acute | 0.36 | 24.3 | 10 |
| BBCH ≥ 50 | Small omnivorous mammal “mouse” | Acute | 0.11 | 80.5 | 10 |

<sup>a</sup> Risk assessment for fish-eating birds and mammals performed using the worst case initial FOCUS Step 3 PEC value for all representative uses (0.0724 µg a.s./L for d1 ditch for the representative use to wheat at 2 x 12.5 g a.s./ha) and a BCF of 1822.
### Growth stage Indicator or focal species Time scale DDD (mg/kg bw per day) TER Trigger
BBCH 71-89 Frugivorous mammal “rat” Long-term 0.349 4.0 5
BBCH 10-19 Small insectivorous mammal “shrew” Long-term 0.058 23.9 5
BBCH ≥ 20 Small insectivorous mammal “shrew” Long-term 0.026 52.9 5
BBCH 10-49 Small herbivorous mammal “mouse” Long-term 1.001 1.4 5
BBCH ≥ 50 Small herbivorous mammal “mouse” Long-term 0.300 4.6 5
BBCH 10-49 Small omnivorous mammal “mouse” Long-term 0.108 12.9 5
BBCH ≥ 50 Small omnivorous mammal “mouse” Long-term 0.032 43.7 5

### Risk from bioaccumulation and food chain behaviour

| Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|---------------------------|------------|------------------------|-----|---------|
| Earthworm-eating birds    | Long-term  | 0.11\(^b\)             | 23.6| 5       |
| Earthworm-eating mammals  | Long-term  | 0.13\(^b\)             | 10.3| 5       |
| Fish-eating birds (PEC\(_{sw}\) much lower – 10-20x – therefore not relevant for semi-protected greenhouse) | Long-term |                      |     |         |
| Fish-eating mammals (PEC\(_{sw}\) much lower – 10-20x – therefore not relevant for semi-protected greenhouse) | Long-term |                      |     |         |

### Risk from consumption of contaminated water

| Scenarios                      | Indicator or focal species | Time scale | PEC\(_{dw}\)xDWR | TER | Trigger |
|-------------------------------|---------------------------|------------|-----------------|-----|---------|
| Leaf scenario                  | Since none of the representative crop uses falls into these categories, the leaf scenario does not apply to the use of Bulldock EC 25. |            |                 |     |         |

#### Puddle scenario, Screening step
Application rate (g as/ha)/relevant endpoint <3000 (Koc ≥ 500 L/kg), TER calculation not needed

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\(^a\) Risk assessment based on the toxicity endpoint of the formulation Bulldock. LD\(_{50}\) > 300 mg/kg bw (>8.79 mg as/kg bw)  
\(^b\) Risk assessment for earthworm-eating birds and mammals performed using the worst case initial PEC\(_{soil}\) for representative uses (0.0242 mg a.s./kg soil dw, use to potato at 2 x 12.5 g a.s./ha), Koc=104491, and LogP=5.9.

### Application of Montur Forte FS 230 as seed treatment in beet seeds at 10.4 g as/ha (beta-cyfluthrin) and 19.5 g as/ha (imidacloprid)

| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|--------------|----------------------------|------------|------------------------|-----|---------|
| BBCH0        | medium granivorous bird    | Acute      | 0.557\(^a\)            | 305 | 3       |

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(Birds) ingestion of beet seedlings

Data gap

Screening Step (Mammals) ingestion as grit

According to the EFSA GD (2009) chapter 5.2.1 a risk assessment for mammals is not required in case of pelleted seeds.

(Mammals) ingestion of beet seedlings

Data gap

### Risk from bioaccumulation and food chain behaviour

| Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|----------------------------|------------|------------------------|-----|---------|
| Earthworm-eating birds     | Long-term  | 0.11\(^b\)             | 23.6| 5       |
| Earthworm-eating mammals  | Long-term  | 0.13\(^b\)             | 10.3| 5       |
| Fish-eating birds          | Long-term  | 0.021\(^c\)            | 124 | 5       |
| Fish-eating mammals        | Long-term  | 0.019\(^c\)            | 74.2| 5       |

### Risk from consumption of contaminated water

| Scenarios             | Indicator or focal species | Time scale (Test type) | PEC\(_{soil}\) xDWR | TER | Trigger |
|-----------------------|---------------------------|------------------------|----------------------|-----|---------|
| Leaf scenario         | Since the representative crop use does not fall into these categories, the leaf scenario does not apply to the use of Montur Forte FS 230. | | |
| Puddle scenario, Screening step | | | |

\(^a\) based on beta-cyfluthrin only

\(^b\) Risk assessment for earthworm-eating birds and mammals performed using the worst case initial PEC\(_{soil}\) for representative uses (0.0242 mg a.s./kg soil dw, use to potato at 2 x 12.5 g a.s./ha), Koc=104491, and LogP=5.9.

\(^c\) Risk assessment for fish-eating birds and mammals performed using the worst case initial FOCUS Step 3 PEC value for all representative uses (0.0724 µg a.s./L for d1 ditch for the representative use to wheat at 2 x 12.5 g a.s./ha) and a BCF of 1822.

### Toxicity data for all aquatic tested species (Regulation (EU) N° 283/2013, Annex Part A, points 8.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.2)

| Group       | Test substance | Time-scale (Test type) | End point     | Toxicity \(^i\)           |
|-------------|----------------|------------------------|---------------|---------------------------|
| Laboratory tests |                  |                        |               |                           |
| Fish        |                 |                        |               |                           |
| *Oncorhynchus mykiss* | beta-cyfluthrin | Acute 96 hr (flow-through) | Mortality, LC\(_{50}\) | 0.068 µg a.s/L\(_{\text{IC}_{50}}\) (0.060–0.079) |
| *Oncorhynchus mykiss* | beta-cyfluthrin | Acute 96 hr (flow-through) | Mortality, LC\(_{50}\) | 0.089 µg a.s/L\(_{\text{IC}_{50}}\) |
| *Lepomis macrochirus* | beta-cyfluthrin | Acute 96 hr (flow-through) | Mortality, LC\(_{50}\) | 0.280 µg a.s/L\(_{\text{IC}_{50}}\) |
| Group                      | Test substance | Time-scale (Test type) | End point                  | Toxicity[^]          |
|---------------------------|----------------|------------------------|----------------------------|----------------------|
| Leuciscus idus melanotus  | beta-cyfluthrin| Acute 96 hr (flow-through) | Mortality, LC₅₀  | 0.331 µg as/L (mm)  |
| Oncorhynchus mykiss       | beta-cyfluthrin| Acute 96 hr (static)  | Mortality, LC₅₀  | 0.359 µg as/L (mm)  |
| Lepomis macrochirus       | beta-cyfluthrin| Acute 96 hr (static)  | Mortality, LC₅₀  | 0.870 µg as/L (mm)  |
| Gasterosteus aculeatus    | beta-cyfluthrin| Acute 96 hr (static)  | Mortality, LC₅₀  | 0.865 µg as/L (mm)  |
| Rutilus rutilus          | beta-cyfluthrin| Acute 96 hr (static)  | Mortality, LC₅₀  | 0.521 µg as/L (mm)  |
| Pimephales promelas       | beta-cyfluthrin| Acute 96 hr (static)  | Mortality, LC₅₀  | 0.921 µg as/L (mm)  |
| Cyprinus carpio           | beta-cyfluthrin| Acute 96 hr (static)  | Mortality, LC₅₀  | >1.25 µg as/L (mm)  |
| Oncorhynchus mykiss       | Bullock EC25   | Acute 96 hr (flow-through) | Mortality, LC₅₀  | 2.6 µg prep./L (mm) |
|                      |                |                        |                            | 0.08 µg as/L (mm)    |
| Oncorhynchus mykiss       | cyfluthrin     | Chronic (58d flow-through) | Growth, development, and behaviour NOEC | 0.010 µg cyf./L, adjusted 0.0042 µg as/L (mm) |
| Oncorhynchus mykiss       | cyfluthrin     | Chronic (307 d FLC flow-through) | Growth, development, and behaviour NOEC | 0.140 µg cyf./L, adjusted 0.0588 µg beta-cyf./L (mm) |
| Oncorhynchus mykiss       | beta-cyfluthrin| 72 d ELS Pulsed exposure | behaviour NOEC  | 0.032 µg /L (mm)    |
| Oncorhynchus mykiss       | FPB-acid       | 96 hr (static)        | Mortality, LC₅₀  | 4060 µg /L (mm)     |
| Oncorhynchus mykiss       | DCVA           | 96 hr (static)        | Mortality, LC₅₀  | >14700 (nom)        |

**Aquatic invertebrates**

| Daphnia magna            | beta-cyfluthrin| 48 h (flow-through) | Mortality, EC₅₀  | 0.290 µg as/L (mm) |
| Daphnia magna            | beta-cyfluthrin| 48 h (semi-static)  | Mortality, EC₅₀  | 0.105 µg as/L (mm) |
| Americamysis bahia       | beta-cyfluthrin| 96 h (flow-through) | Mortality, EC₅₀  | 0.0023 µg as/L (mm) |
| Americamysis bahia       | beta-cyfluthrin| 96 h (flow-through) | Mortality, EC₅₀  | 0.0022 µg as/L (mm) |
| Americamysis bahia       | cyfluthrin     | 96 h (flow-through) | Mortality, EC₅₀  | 0.0025 µg cyfluthrin/L (mm) |
| Group                  | Test substance          | Time-scale (Test type) | End point        | Toxicity₁ |
|-----------------------|-------------------------|------------------------|------------------|-----------|
| Hyalella azteca       | cyfluthrin              | 96 h (flow-through)    | Mortality, EC₅₀  | 0.00055 μg as/L (mm) (eq. to 0.000231 μg beta-cyfl/L (mm)) |
| Daphnia magna         | Bulklock EC 25          | 48 h (semi-static)     | Mortality, EC₅₀  | 2.9 μg prep./L (nom) 0.062 μg as/L (mm) |
| Daphnia magna         | Montur Forte FS 230     | 48 h (semi-static)     | Mortality, EC₅₀  | 4.2 μg prep./L (nom) |
| Daphnia magna         | beta-cyfluthrin         | 21 d (semi-static)     | Reproduction, NOEC EC₁₀ | 0.025 μg as/L (mm) 0.023 μg as/L (0.0017-0.034) (mm) |
| Americamysis bahia    | beta-cyfluthrin         | 28 d (flow-through)    | Development, NOEC EC₁₀ | 0.00041 μg as/L (mm) 0.00043 μg as/L (0.00006-0.00067) (mm) |
| Gammarus pulex        | Cyfluthrin as Cyfluthrin EC 050 | 21 d (static) | Behavior, NOEC EC₁₀ | 0.0018 μg cyfluthrin/L (estimate mm) (eq. to 0.00075 μg beta-cyfl/L (mm)) 0.0027 (mm) |
| Daphnia magna         | Cyfluthrin as Cyfluthrin EC 050 Xylol | 29 d (static) With sediment | NOEC EC₁₀ | 0.100 (nom.in) μg cyfluthrin/L = 0.026 (mm) μg cyfluthrin/L 0.137 (n.d.) (mm) |
| Daphnia magna         | ¹⁴C-Cyfluthrin           | 21 d (flow-through)    | NOEC EC₁₀        | 0.02 (mm) μg cyfluthrin/L 0.023 (0.011-0.031) (mm) μg cyfluthrin/L |
| Daphnia magna         | FPB-acid                | 48 h (static)          | Mortality, EC₅₀  | 39300 μg/L (nom) |
| Daphnia magna         | DCVA                    | 48 h (static)          | Mortality, EC₅₀  | 25000 μg/L (nom) |
### Sediment-dwelling organisms

| Group                     | Test substance | Time-scale (Test type) | End point          | Toxicity¹ |
|---------------------------|----------------|------------------------|--------------------|-----------|
| **Chironomus riparius**   | beta-cyfluthrin| 28 d (static, spiked water) | Development rate NOEC | 0.4 µg as/L (nom) | Estimated 0.0057 µg/L (mm) |
|                           |                |                        | NOEC               | 1.3 µg as/L (0.93 - 2.0) (nom) |
|                           |                |                        | EC₁₀               |                       |
| **Chironomus riparius**   | beta-cyfluthrin| 28 d (static, spiked-sediment) | Development rate NOEC | <125 µg as/kg dry sediment (nom) |
|                           |                |                        | NOEC               | 170 µg as/kg dry sediment (70-270) (nom and mm) |
|                           |                |                        | EC₁₀               |                       |
| **Chironomus riparius**   | Montur Forte   | 28 d (static)          | Development rate NOEC | <6.90 µg form/L (nom) |
|                           |                |                        | NOEC               | 17.5 µg form/L (nom) |
|                           |                |                        | EC₁₀               |                       |
|                           |                |                        | Emergence rate NOEC | 15.5 µg form/L (nom) |
|                           |                |                        | EC₁₀               | 18.8 µg form/L (nom) |

### Algae

| Group                     | Test substance       | Time-scale (Test type) | End point       | Toxicity¹ |
|---------------------------|----------------------|------------------------|-----------------|-----------|
| **Scenedesmus subspicatus** | beta-cyfluthrin     | 96 h (static)          | Growth rate: E₅₀ | > 2 µg as/L (nom) |
|                           |                      |                        |                 |           |
| **Pseudokirchneriella subcapitata** | Montur Forte FS 230 | 72 h (static)          | Growth rate: E₅₀ | > 100 mg form/L (nom) |
|                           |                      |                        |                 |           |

### Higher plant

| Group                     | Test substance | Time-scale (Test type) | End point | Toxicity¹ |
|---------------------------|----------------|------------------------|-----------|-----------|
| **Lemna gibba**           | beta-cyfluthrin | 7 d (semi-static)     | E₅₀       | > 0.84 µg as/L (mm) |

¹ (nom) nominal concentration; (mm) mean measured concentration; prep.: preparation; as: active substance
² As the study was conducted with cyfluthrin instead with beta-cyfluthrin the endpoint was multiplied with the factor 0.42.

### Summary of Tier 1 and higher tier data on aquatic organisms
### Fish:

| tier | acute | chronic |
|------|-------|---------|
| 1    | Oncorhynchus mykiss. LC$_{50}$ (4 d) = 0.068 µg/L; AF (assessment factor) = 100 | Oncorhynchus mykiss. NOEC (56 d ELS) = 0.0042 µg/L; AF = 10 |
|      | RAC$_{acute}$ = 0.68 ng/L | RAC$_{chronic}$ = 0.42 ng/L |
| 2    | SSD median HC$_3$ LC$_{50}$ = 0.158 µg/L; AF = 9 | Oncorhynchus mykiss. NOEC (72 d ELS, refined exposure test) = 0.032 µg/L; AF = 10 |
|      | Tier 2B- RAC$_{acute}$ = 17.5 ng/L | RAC$_{chronic}$ = 3.2 ng/L* |

*Only suitable if the exposure profile in the test covers for the predicted exposure profiles

### Aquatic invertebrates:

| tier | acute | chronic |
|------|-------|---------|
| 1    | Americamysis bahia. EC$_{50}$ (4 d, mm) = 2.225 ng/L; AF = 100 | Americamysis bahia. NOEC (21 d) = 0.41 ng/L; AF = 10 |
|      | RAC$_{acute}$ = 0.02225 ng/L. | RAC$_{chronic}$ = 0.041 ng/L |
| 2    | Geometric mean calculated on the basis of 3 species of invertebrates effect values [based on mean measured concentrations (ng/L)] | In a weight of evidence approach the lowest endpoint amongst the three species tested is selected. To account for the reduced uncertainties on species sensitivity, the AF is reduced to 8: |
|      | Daphnia magna: 2d LC$_{50}$ = 123 ng/L; (geomean LC$_{50}$ = 62 ng/L, 290 ng/L and 105 ng/L) | Daphnia magna: NOEC (21 d) = 25 ng/L |
|      | Americamysis bahia: 4d LC$_{50}$ = 2.225 ng/L; (mean of 2 values: 2.22 ng/L and 2.23 ng/L) | Americamysis bahia: NOEC (21 d) = 0.41 ng/L |
|      | Hyallela azteca: 4d LC$_{50}$ = 0.23 ng/L; Geomean LC$_{50}$: 3.9 ng/L; AF = 100 | Gammarus pulex: NOEC (21 d) = 0.43 ng/L |
|      | Tier 2A- RAC$_{acute}$ = 0.039 ng/L. | Relevant endpoint is 0.41 ng/L; AF = 8 |
|      | *Endpoints are suitable if the exposure profiles in the study cover for the predicted exposure profiles |

### Sediment dwellers

| tier | Chronic (µg/L) | chronic |
|------|----------------|---------|
|      | Water spiked   | Sediments spiked |
| 1    | Chironomus riparius NOEC (28 d) = 0.0057 µg/L; AF = 10 | Chironomus riparius: EC$_{10}$ (28 d) = 170 µg/kg; AF = 10 |
|      | RAC$_{acute}$ = 0.57 ng/L | RAC$_{chronic}$ = 17 µg/kg |
| 2    | Chironomus riparius NOEC (28 d) = 0.4 µg/L; AF = 10 |
**Potential endocrine disrupting properties (Annex Part A, point 8.2.3)**

Insufficient information. No firm conclusion can be drawn regarding non-target organisms other than mammals.

### Bioconcentration in fish (Annex Part A, point 8.2.2.3)

|                  | beta-Cyfluthrin | FPB-acid | DCVA | FPB-aldehyde |
|------------------|-----------------|----------|------|--------------|
| log\(P_{O/W}\)   | 5.9             | 2.6      | 2.5  | 2.6 (surrogate based on FPB-acid data) |
| Steady-state bioconcentration factor (BCF) (total wet weight/normalised to 5 % lipid content) | 2295 | - | - | - |
| Uptake/depuration kinetics BCF (total wet weight/normalised to 5 % lipid content) | 1822 | - | - | - |
| Annex VI Trigger for the bioconcentration factor | 2000 | - | - | - |
| Clearance time (days) \( (CT_{50}) \) | 8.66 d | | | |
| \( (CT_{90}) \) | 26.5 d | | | |
| Level and nature of residues (%) in organisms after the 28 day depuration phase | 0.017 \( \mu g/g \) | | | |

* based on measured concentration of the parent substance
Toxicity/exposure ratios for the most sensitive aquatic organisms (Regulation (EU) No 284/2013, Annex Part A, point 10.2)

FOCUS\textsubscript{sw} step 3 - Acceptability of risk (PEC/RAC < 1) after calculations based on RACs (from Tier 1 effect assessments for beta-cyfluthrin – autumn spray application of Bulldock EC 25 at 7.5 g as/ha in winter wheat

| FOCUS Scenario | PEC\textsubscript{sw} max (µg/L) | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Sed. dweller prolonged | Algae | Aquat. plant |
|----------------|---------------------------------|------------|--------------|-----------------------|-------------------------------|-----------------------|--------|--------------|
|                |                                 | Oncorhynchus mykiss | Oncorhynchus mykiss | Americamysis bahia | Americamysis bahia | Chironomus riparius | Pseudokirchn. subcapitata | Lemma gibba |
|                |                                 | LC\textsubscript{50} | NOEC | EC\textsubscript{50} | NOEC | NOEC | EC\textsubscript{50} | E\textsubscript{C50} |
|                |                                 | 0.068 µg/L | 0.0042 µg/L | 0.002225 µg/L | 0.00041 µg/L | 0.0057 µg/L | >2 µg/L | >0.84 |
|                | **RAC values (µg/L)** | **0.00068** | **0.00042** | **0.00002225** | **0.000041** | **0.00057** | >0.2 | >0.084 |

FOCUS Step 3

|                | D1/ditch | 0.0434 | 63.82 | 103.33 | 1950.56 | 1058.54 | 76.14 | <0.217 | <0.517 |
|                | D1/stream | 0.0336 | 49.41 | 80.00 | 1510.11 | 819.51 | 58.95 | <0.168 | <0.400 |
|                | D2/ditch | 0.0386 | 56.76 | 91.90 | 1734.83 | 941.46 | 67.72 | <0.193 | <0.460 |
|                | D2/stream | 0.0309 | 45.44 | 73.57 | 1388.76 | 753.66 | 54.21 | <0.155 | <0.368 |
|                | D3/ditch | 0.0382 | 56.18 | 90.95 | 1716.85 | 931.71 | 67.02 | <0.191 | <0.455 |
|                | D4/pond | 0.0015 | 2.21 | 3.57 | 67.42 | 36.59 | 2.63 | <0.008 | <0.018 |
|                | D4/stream | 0.0328 | 48.24 | 78.10 | 1474.16 | 800.00 | 57.54 | <0.164 | <0.390 |
|                | D5/pond | 0.0016 | 2.35 | 3.81 | 71.91 | 39.02 | 2.81 | <0.008 | <0.019 |
|                | D5/stream | 0.0354 | 52.06 | 84.29 | 1591.01 | 863.41 | 62.11 | <0.177 | <0.421 |
|                | D6/ditch | 0.0386 | 56.76 | 91.90 | 1734.83 | 941.46 | 67.72 | <0.193 | <0.460 |
|                | R1/pond | 0.0017 | 2.50 | 4.05 | 76.40 | 41.46 | 2.98 | <0.009 | <0.020 |
|                | R1/stream | 0.0249 | 36.62 | 59.29 | 1119.10 | 607.32 | 43.68 | <0.125 | <0.296 |
|                | R3/stream | 0.035 | 51.47 | 83.33 | 1573.03 | 853.66 | 61.40 | <0.175 | <0.417 |
|                | R4/stream | 0.0251 | 36.91 | 59.76 | 1128.09 | 612.20 | 44.04 | <0.126 | <0.299 |

Bold numbers indicate that acceptability criterion is not achieved: PEC/RAC ≥ 1
FOCUS step 3 - Acceptability of risk (PEC/RAC < 1) after calculations based on RACs (from Tier 1 effect assessments for beta-cyfluthrin – autumn spray application of Bulldock EC 25 at 12.5 g as/hain winter wheat [x2 (14 d)]

| FOCUS Scenario | PEC_{sw} max (µg/L) | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Sed. dweller prolonged | Algae | Aquat. plant |
|----------------|----------------------|------------|--------------|----------------------|---------------------------------|-----------------------|-------|-------------|
|                |                      | Oncorhynchus mykiss | Oncorhynchus mykiss | Americamysis bahia | Americamysis bahia | Chironomus riparius | Pseudokirchn. subcapitata | Lemna gibba |
| FOCUS Step 3   |                      | LC₅₀        | NOEC         | EC₅₀        | NOEC         | NOEC        | EC₅₀        | E₅₀        |
| D1/ditch       | 0.0724               | 0.068 µg/L | 0.00042 µg/L | 0.002225 µg/L | 0.000041 µg/L | 0.0057 µg/L | >2 µg/L     | >0.84      |
| D1/stream      | 0.0563               | 0.0464 µg/L | 0.00042 µg/L | 0.002225 µg/L | 0.000041 µg/L | 0.0057 µg/L | >2 µg/L     | >0.84      |
| D2/ditch       | 0.0643               | 0.0464 µg/L | 0.00042 µg/L | 0.002225 µg/L | 0.000041 µg/L | 0.0057 µg/L | >2 µg/L     | >0.84      |
| D2/stream      | 0.0519               | 0.0464 µg/L | 0.00042 µg/L | 0.002225 µg/L | 0.000041 µg/L | 0.0057 µg/L | >2 µg/L     | >0.84      |
| D3/ditch       | 0.0637               | 0.0464 µg/L | 0.00042 µg/L | 0.002225 µg/L | 0.000041 µg/L | 0.0057 µg/L | >2 µg/L     | >0.84      |
| D4/pond        | 0.0026               | 0.0464 µg/L | 0.00042 µg/L | 0.002225 µg/L | 0.000041 µg/L | 0.0057 µg/L | >2 µg/L     | >0.84      |
| D4/stream      | 0.0549               | 0.0464 µg/L | 0.00042 µg/L | 0.002225 µg/L | 0.000041 µg/L | 0.0057 µg/L | >2 µg/L     | >0.84      |
| D5/pond        | 0.0027               | 0.0464 µg/L | 0.00042 µg/L | 0.002225 µg/L | 0.000041 µg/L | 0.0057 µg/L | >2 µg/L     | >0.84      |
| D5/stream      | 0.0593               | 0.0464 µg/L | 0.00042 µg/L | 0.002225 µg/L | 0.000041 µg/L | 0.0057 µg/L | >2 µg/L     | >0.84      |
| D6/ditch       | 0.0644               | 0.0464 µg/L | 0.00042 µg/L | 0.002225 µg/L | 0.000041 µg/L | 0.0057 µg/L | >2 µg/L     | >0.84      |
| R1/pond        | 0.0029               | 0.0464 µg/L | 0.00042 µg/L | 0.002225 µg/L | 0.000041 µg/L | 0.0057 µg/L | >2 µg/L     | >0.84      |
| R1/stream      | 0.0418               | 0.0464 µg/L | 0.00042 µg/L | 0.002225 µg/L | 0.000041 µg/L | 0.0057 µg/L | >2 µg/L     | >0.84      |
| R3/stream      | 0.0586               | 0.0464 µg/L | 0.00042 µg/L | 0.002225 µg/L | 0.000041 µg/L | 0.0057 µg/L | >2 µg/L     | >0.84      |
| R4/stream      | 0.042                | 0.0464 µg/L | 0.00042 µg/L | 0.002225 µg/L | 0.000041 µg/L | 0.0057 µg/L | >2 µg/L     | >0.84      |

Bold numbers indicate that acceptability criterion is not achieved: PEC/RAC > 1
FOCUS Step 3 - Acceptability of risk (PEC/RAC < 1) after calculations based on RACs (from Tier 1 effect assessments for beta-cyfluthrin – spring spray application of Bulldock EC 25 at 7.5 g as/ha in winter wheat [x2 (14 d)]

| FOCUS Scenario | PECmax (µg/L) | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Sed. dweller prolonged | Algae | Aquat. plant |
|----------------|---------------|------------|--------------|-----------------------|---------------------------------|------------------------|-------|--------------|
|                |               | Oncorhynchus mykiss | Oncorhynchus mykiss | Americamysis bahia | Americamysis bahia | Chironomus riparius | Pseudokirchh. subcapitata | Lemma gibba |
|                |               | LC50       | NOEC         | EC50      | NOEC      | NOEC       | EC50 | EC50         |
| D1/ditch       | 0.0412        | 0.068 µg/L | 0.00042 µg/L | 0.000225 µg/L | 0.00041 µg/L | 0.00057 µg/L | >2 µg/L | >0.84 |
| D1/stream      | 0.0332        | 0.0412     | 0.068 µg/L   | 0.00042 µg/L | 0.000225 µg/L | 0.00041 µg/L | 0.00057 µg/L | >2 µg/L | >0.84 |
| D2/ditch       | 0.039         | 0.0412     | 0.068 µg/L   | 0.00042 µg/L | 0.000225 µg/L | 0.00041 µg/L | 0.00057 µg/L | >2 µg/L | >0.84 |
| D2/stream      | 0.0341        | 0.0412     | 0.068 µg/L   | 0.00042 µg/L | 0.000225 µg/L | 0.00041 µg/L | 0.00057 µg/L | >2 µg/L | >0.84 |
| D3/ditch       | 0.0383        | 0.0412     | 0.068 µg/L   | 0.00042 µg/L | 0.000225 µg/L | 0.00041 µg/L | 0.00057 µg/L | >2 µg/L | >0.84 |
| D4/pond        | 0.0015        | 0.0412     | 0.068 µg/L   | 0.00042 µg/L | 0.000225 µg/L | 0.00041 µg/L | 0.00057 µg/L | >2 µg/L | >0.84 |
| D4/stream      | 0.029         | 0.0412     | 0.068 µg/L   | 0.00042 µg/L | 0.000225 µg/L | 0.00041 µg/L | 0.00057 µg/L | >2 µg/L | >0.84 |
| D5/pond        | 0.0017        | 0.0412     | 0.068 µg/L   | 0.00042 µg/L | 0.000225 µg/L | 0.00041 µg/L | 0.00057 µg/L | >2 µg/L | >0.84 |
| D5/stream      | 0.0334        | 0.0412     | 0.068 µg/L   | 0.00042 µg/L | 0.000225 µg/L | 0.00041 µg/L | 0.00057 µg/L | >2 µg/L | >0.84 |
| D6/ditch       | 0.0386        | 0.0412     | 0.068 µg/L   | 0.00042 µg/L | 0.000225 µg/L | 0.00041 µg/L | 0.00057 µg/L | >2 µg/L | >0.84 |
| R1/pond        | 0.0015        | 0.0412     | 0.068 µg/L   | 0.00042 µg/L | 0.000225 µg/L | 0.00041 µg/L | 0.00057 µg/L | >2 µg/L | >0.84 |
| R1/stream      | 0.025         | 0.0412     | 0.068 µg/L   | 0.00042 µg/L | 0.000225 µg/L | 0.00041 µg/L | 0.00057 µg/L | >2 µg/L | >0.84 |
| R3/stream      | 0.0353        | 0.0412     | 0.068 µg/L   | 0.00042 µg/L | 0.000225 µg/L | 0.00041 µg/L | 0.00057 µg/L | >2 µg/L | >0.84 |
| R4/stream      | 0.0251        | 0.0412     | 0.068 µg/L   | 0.00042 µg/L | 0.000225 µg/L | 0.00041 µg/L | 0.00057 µg/L | >2 µg/L | >0.84 |

Bold numbers indicate that acceptability criterion is not achieved: PEC/RAC ≥ 1
FOCUS step 3 - Acceptability of risk (PEC/RAC < 1) after calculations based on RACs (from Tier 1 effect assessments for beta-cyfluthrin – spring spray application of Bulldock EC 25 at 12.5 g as/hain winter wheat [x2 (14 d)]

| FOCUS Scenario | PEC_{sw} max (µg/L) | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Sed. dweller prolonged | Algae | Aquat. plant |
|----------------|---------------------|------------|--------------|-----------------------|---------------------------------|------------------------|-------|-------------|
|                |                     | Oncorhynhus mykiss | Oncorhynhus mykiss | Americamysis bahia | Americamysis bahia | Chironomus riparius | Pseudokirchn. subcapitata | Lemma gibba |
|                |                     | LC₅₀        | NOEC         | EC₅₀                  | NOEC                            | NOEC                   | EC₅₀ | EC₅₀        |
| D1/ditch       | 0.0687              | 0.0628      | 0.00042      | 0.002225              | 0.00041                         | 0.0057                 | >2 µg/L | >0.84       |
| D1/stream      | 0.0556              | 0.0516      | 0.00038      | 0.00017               | 0.00032                         | 0.00027               | >2 µg/L | >0.84       |
| D2/ditch       | 0.0651              | 0.0601      | 0.00040      | 0.00191               | 0.00045                         | 0.00050               | >2 µg/L | >0.84       |
| D2/stream      | 0.0572              | 0.0527      | 0.00037      | 0.00013               | 0.00033                         | 0.00042               | >2 µg/L | >0.84       |
| D3/ditch       | 0.0639              | 0.0590      | 0.00040      | 0.00026               | 0.00042                         | 0.00054               | >2 µg/L | >0.84       |
| D4/pond        | 0.0026              | 0.0020      | 0.00012      | 0.00007               | 0.00014                         | 0.00017               | >2 µg/L | >0.84       |
| D4/stream      | 0.0485              | 0.0433      | 0.00034      | 0.00018               | 0.00031                         | 0.00044               | >2 µg/L | >0.84       |
| D5/pond        | 0.0028              | 0.0022      | 0.00012      | 0.00008               | 0.00013                         | 0.00015               | >2 µg/L | >0.84       |
| D5/stream      | 0.056               | 0.0506      | 0.00034      | 0.00018               | 0.00031                         | 0.00044               | >2 µg/L | >0.84       |
| D6/ditch       | 0.0643              | 0.0595      | 0.00037      | 0.00022               | 0.00042                         | 0.00054               | >2 µg/L | >0.84       |
| R1/pond        | 0.0025              | 0.0020      | 0.00012      | 0.00007               | 0.00014                         | 0.00017               | >2 µg/L | >0.84       |
| R1/stream      | 0.042               | 0.0365      | 0.00027      | 0.00016               | 0.00028                         | 0.00036               | >2 µg/L | >0.84       |
| R3/stream      | 0.0592              | 0.0532      | 0.00034      | 0.00018               | 0.00031                         | 0.00044               | >2 µg/L | >0.84       |
| R4/stream      | 0.042               | 0.0365      | 0.00027      | 0.00016               | 0.00028                         | 0.00036               | >2 µg/L | >0.84       |

Bold numbers indicate that acceptability criterion is not achieved: PEC/RAC ≥ 1
FOCUS<sub>sw</sub> step 3 - Acceptability of risk (PEC/RAC < 1) after calculations based on RACs (from Tier 1 effect assessment) for beta-cyfluthrin – spray application of Bulldock EC 25 at 7.5 g as/ha in spring wheat [x2 (14 d)]

| FOCUS Scenario | PEC<sub>sw</sub> max (µg/L) | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Sed. dweller prolonged | Algae | Aquat. plant |
|----------------|-----------------------------|------------|--------------|-----------------------|-----------------------------|------------------------|-------|-------------|
|                |                             | Oncorhynchus mykiss | Oncorhynchus mykiss | Americamysis bahia | Americamysis bahia | Chironomus riparius | Pseudokirchn. subcapitata | Lemna gibba |
|                |                             | LC<sub>50</sub> | NOEC | EC<sub>50</sub> | NOEC | NOEC | EC<sub>50</sub> | EC<sub>50</sub> |
|                |                             | 0.068 µg/L | 0.0042 µg/L | 0.002225 µg/L | 0.00041 µg/L | 0.0057 µg/L | >2 µg/L | >0.84 |
| RAC values (µg/L) |                             | 0.00068 | 0.00042 | 0.00002225 | 0.000041 | 0.00057 | >0.2 | >0.084 |

FOCUS Step 3

| Scenario | RAC<sub>sw</sub>  | PEC<sub>sw</sub> max (µg/L) | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Sed. dweller prolonged | Algae | Aquat. plant |
|----------|-------------------|-----------------------------|------------|--------------|-----------------------|-----------------------------|------------------------|-------|-------------|
| D1/ditch | 0.0393            | 57.79 | 93.57 | 1766.29 | 958.54 | 68.95 | <0.197 | <0.468 |
| D1/stream | 0.0335            | 49.26 | 79.76 | 1505.62 | 817.07 | 58.77 | <0.168 | <0.399 |
| D3/ditch | 0.0384            | 56.47 | 91.43 | 1725.84 | 936.59 | 67.37 | <0.192 | <0.457 |
| D4/pond  | 0.0015            | 2.21 | 3.57 | 67.42 | 36.59 | 2.63 | <0.008 | <0.018 |
| D4/stream | 0.031             | 45.59 | 73.81 | 1393.26 | 756.10 | 54.39 | <0.155 | <0.369 |
| D5/pond  | 0.0017            | 2.50 | 4.05 | 76.40 | 41.46 | 2.98 | <0.009 | <0.020 |
| D5/stream | 0.033             | 47.65 | 77.14 | 1456.18 | 790.24 | 56.84 | <0.162 | <0.386 |
| R4/stream | 0.025             | 36.76 | 59.52 | 1123.60 | 609.76 | 43.86 | <0.125 | <0.298 |

Bold numbers indicate that acceptability criterion is not achieved: PEC/RAC ≥ 1
FOCUS\textsubscript{sw} step 3 - Acceptability of risk (PEC/RAC < 1) after calculations based on RACs (from Tier 1 effect assessment) for beta-cyfluthrin – spray application of Bulldock EC \textsubscript{25} at 12.5 g as/hain spring wheat [x2 (14 d)]

| FOCUS Scenario | PEC\textsubscript{sw max} (µg/L) | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Sed. dweller prolonged | Algae | Aquat. plant |
|----------------|--------------------------------|------------|--------------|----------------------|---------------------------------|------------------------|-------|-------------|
|                |                                | \(\text{Onchorhyncus mykiss}\) | \(\text{Onchorhyncus mykiss}\) | \(\text{Americamysis bahia}\) | \(\text{Americamysis bahia}\) | \(\text{Chironomus riparius}\) | \(\text{Pseudokirchn. subcapitata}\) | \(\text{Lemna gibba}\) |
|                |                                | \(\text{LC}_{50}\) | \(\text{NOEC}\) | \(\text{EC}_{50}\) | \(\text{NOEC}\) | \(\text{NOEC}\) | \(\text{EC}_{50}\) | \(\text{EC}_{50}\) |
| D1/ditch       | 0.0655                         | 96.32      | 155.95       | 2493.82              | 1597.56                         | 114.91                 | <0.33 | <0.78       |
| D1/stream      | 0.0562                         | 82.65      | 133.81       | 2525.84              | 1370.73                         | 98.60                  | <0.28 | <0.67       |
| D3/ditch       | 0.064                          | 94.12      | 152.38       | 2876.40              | 1560.98                         | 112.28                 | <0.32 | <0.76       |
| D4/pond        | 0.0025                         | 3.68       | 5.95         | 112.36               | 60.98                           | 4.39                   | <0.01 | <0.03       |
| D4/stream      | 0.052                          | 76.47      | 123.81       | 2337.08              | 1268.29                         | 91.23                  | <0.26 | <0.62       |
| D5/pond        | 0.0028                         | 4.12       | 6.67         | 125.84               | 68.29                           | 4.91                   | <0.01 | <0.03       |
| D5/stream      | 0.0552                         | 81.18      | 131.43       | 2480.90              | 1346.34                         | 96.84                  | <0.28 | <0.66       |
| R4/stream      | 0.0419                         | 61.62      | 99.76        | 1883.15              | 1021.95                         | 73.51                  | <0.21 | <0.50       |

Bold numbers indicate that acceptability criterion is not achieved: PEC/RAC \(\geq\) 1
FOCUS\textsubscript{sw} step 3 - Acceptability of risk (PEC/RAC $< 1$) after calculations based on RACs (from Tier 1 effect assessment) for beta-cyfluthrin – spray application of Bulldock EC\textsubscript{25} at 7.5 g as/ha in potatoes [$x2$ (14 d)]

| FOCUS Scenario | PEC\textsubscript{sw} max (µg/L) | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Sed. dweller prolonged | Algae | Aquat. plant |
|----------------|-------------------------------|------------|--------------|-----------------------|-----------------------------|-----------------------|-------|-------------|
|                |                               | Oncorhynchus mykiss | Oncorhynchus mykiss | Americamysis bahia | Americamysis bahia | Chironomus riparius | Pseudokirchn. subcapitata | Lemna gibba |
|                |                               | LC\textsubscript{50} | NOEC | EC\textsubscript{50} | NOEC | NOEC | EC\textsubscript{50} | E\textsubscript{C50} |
|                |                               | 0.068 µg/L | 0.0042 µg/L | 0.00225 µg/L | 0.00041 µg/L | 0.0057 µg/L | >2 µg/L | >0.84 |

| FOCUS Step 3 | RAC values (µg/L) |
|--------------|-------------------|
| D3/ditch     | 0.00068           |
| D4/pond      | 0.00042           |
| D4/stream    | 0.00002225        |
| D6/ditch     | 0.000041          |
| D6/ditch     | 0.000057          |

Bold numbers indicate that acceptability criterion is not achieved: PEC/RAC $\geq 1$
FOCUS<sub>sw</sub> step 3 - Acceptability of risk (PEC/RAC &lt; 1) after calculations based on RACs (from Tier 1 effect assessment) for beta-cyfluthrin – spray application of Bulldock EC 25 at 12.5 g as/her in potatoes [x2 (14 d)]

| FOCUS Scenario | PEC<sub>sw</sub> max (µg/L) | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Sed. dweller prolonged | Algae | Aquat. plant |
|----------------|-----------------|-------------|--------------|-----------------------|--------------------------------|------------------------|-------|-------------|
|                |                 | Oncorhynchus mykiss | Oncorhynchus mykiss | Americamys bahia | Americamys bahia | Chironomus riparius | Pseudokirchn. subcapitata | Lemna gibba |
|                |                 | LC<sub>50</sub> | NOEC | EC<sub>50</sub> | NOEC | NOEC | EC<sub>50</sub> | E<sub>50</sub> | E<sub>50</sub> |
|                |                 | 0.068 µg/L | 0.0042 µg/L | 0.00225 µg/L | 0.00041 µg/L | 0.0057 µg/L | &gt;2 µg/L | &gt;0.84 |
| RAC values (µg/L) | 0.00068 | 0.00042 | 0.0002225 | 0.000041 | 0.00057 | &gt;0.2 | &gt;0.084 |

**FOCUS Step 3**

| Scenario | Value 1 | Value 2 | Value 3 | Value 4 | Value 5 | Value 6 | Value 7 |
|----------|---------|---------|---------|---------|---------|---------|---------|
| D3/ditch | 0.0316  | 46.47   | 75.24   | 1420.22 | 770.73  | 55.44   | &lt;0.16 |
| D4/pond  | 0.0015  | 2.21    | 3.57    | 67.42   | 36.59   | 2.63    | &lt;0.01 |
| D4/stream | 0.0262  | 38.53   | 62.38   | 1177.53 | 639.02  | 45.96   | &lt;0.13 |
| D6/ditch | 0.0315  | 46.32   | 75.00   | 1415.73 | 768.29  | 55.26   | &lt;0.16 |
| D6/ditch | 0.0313  | 46.03   | 74.52   | 1406.74 | 763.41  | 54.91   | &lt;0.16 |
| R1/pond  | 0.0015  | 2.21    | 3.57    | 67.42   | 36.59   | 2.63    | &lt;0.01 |
| R1/stream | 0.0217  | 31.91   | 51.67   | 975.28  | 529.27  | 38.07   | &lt;0.11 |
| R2/stream | 0.0286  | 42.06   | 68.10   | 1285.39 | 697.56  | 50.18   | &lt;0.14 |
| R3/stream | 0.0305  | 44.85   | 72.62   | 1370.79 | 743.90  | 53.51   | &lt;0.15 |

Bold numbers indicate that acceptability criterion is not achieved: PEC/RAC ≥ 1
### FOCUS<sub>sw</sub> Step 3 - Acceptability of risk (PEC/RAC < 1) after calculations based on RACs (from Tier 1 effect assessment for beta-cyfluthrin – spray application of Bulldock EC 25 at 17.5 g as/ha in tomatoes, permanent glasshouse [x2 (14 d)])

| FOCUS Scenario | PEC<sub>sw</sub> max (µg/L) | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Sed. dweller prolonged | Algae | Aquat. plant |
|----------------|----------------------------|------------|--------------|----------------------|--------------------------------|------------------------|-------|--------------|
|                |                            | Oncorhynchus mykiss | Oncorhynchus mykiss | Americamysis bahia | Americamysis bahia | Chironomus riparius | Pseudokirchn. subcapitata | Lemna gibba |
|                |                            | LC<sub>50</sub> µg/L | NOEC µg/L | EC<sub>50</sub> µg/L | NOEC µg/L | NOEC µg/L | E<sub>A</sub>C<sub>50</sub> µg/L | E<sub>E</sub>C<sub>50</sub> µg/L |
| R2             | 0.003                      | 4.41       | 7.14         | 134.83               | 73.17               | 5.26                   | <0.02             | <0.04          |
| R3             | 0.003                      | 4.41       | 7.14         | 134.83               | 73.17               | 5.26                   | <0.02             | <0.04          |
| R4             | 0.005                      | 7.35       | 11.90        | 224.72               | 121.95              | 8.77                   | <0.03             | <0.06          |
| D6             | 0.004                      | 5.88       | 9.52         | 179.78               | 97.56               | 7.02                   | <0.02             | <0.05          |

Bold numbers indicate that acceptability criterion is not achieved: PEC/RAC ≥ 1.
FOCUS<sub>sw</sub> step 3 - Acceptability of risk (PEC/RAC < 1) after calculations based on RACs (from Tier 1 effect assessment) for beta-cyfluthrin in Montur Forte, seed treatment application for beet.

| FOCUS Scenario | PEC<sub>sw</sub> max (µg/L) | Fish acute | Fish chronic | Invertebrates acute | Invertebrates chronic | Sed. dweller spiked water | Algae | Aquat. plant |
|----------------|----------------------------|------------|-------------|---------------------|-----------------------|--------------------------|-------|--------------|
|                |                            | Oncorhynchus mykiss | Oncorhynchus mykiss | Americamysis bahia | Americamysis bahia | Chironomus riparius | Pseudokirchn. subcapitata | Lemna gibba |
|                |                            | LC<sub>50</sub> | NOEC | EC<sub>50</sub> | NOEC | NOEC | E<sub>0</sub>C<sub>50</sub> | E<sub>r</sub>C<sub>50</sub> |
| RAC values (µg/L) | 0.00068                   | 0.00042 | 0.00002225 | 0.000041 | 0.00057 | >2.00 µg/L | >0.84 µg/L |

- Bold numbers indicate that acceptability criterion is not achieved: PEC/RAC ≥ 1
Acceptability of risk (PEC/RAC < 1) after calculations based on RACs (from Tier 2 and 3 effect assessments) and maximum PEC_{sw} values (FOCUS Step 3 for beta-cyfluthrin [2 x 7.5 g as/ha (14 d) in autumn application in winter cereals]

| FOCUS Scenario | PEC_{sw} max (µg/L) | Tier 2 RACs (µg/L) | Tier 3 RACs (µg/L) |
|----------------|----------------------|--------------------|--------------------|
|                | Fish acute |  | Fish chronic |  | Invert. acute |  | Invert. chronic |  | Sed. dweller |  | Overall assessment/mesocosm |
|                |            |  |              |  |              |  |                  |  |              |  | ETO-RAC | ERO-RAC |
| Step 3         |            |  |              |  |              |  |                  |  |              |  |          |          |
| D1 ditch       | 0.0434     | 2.48 | 13.56 | 1112.82 | 850.98 | 1.09 | 259.88 |
| D1 stream      | 0.0336     | 1.92 | 10.50 | 861.54 | 658.82 | 0.84 | 201.20 |
| D2 ditch       | 0.0386     | 2.21 | 12.06 | 989.74 | 756.86 | 0.97 | 231.14 |
| D2 stream      | 0.0309     | 1.77 | 9.66 | 792.31 | 605.88 | 0.77 | 185.03 |
| D3 ditch       | 0.0382     | 2.18 | 11.94 | 979.49 | 749.02 | 0.96 | 228.74 |
| D4 ditch       | 0.0015     | 0.09 | 0.47 | 38.46 | 29.41 | 0.04 | 8.98 |
| D4 stream      | 0.0328     | 1.87 | 10.25 | 841.03 | 643.14 | 0.82 | 196.41 |
| D5 pond        | 0.0016     | 0.09 | 0.50 | 41.03 | 31.37 | 0.04 | 9.58 |
| D5 stream      | 0.0354     | 2.02 | 11.06 | 907.69 | 694.12 | 0.89 | 211.98 |
| D6 ditch       | 0.0386     | 2.21 | 12.06 | 989.74 | 756.86 | 0.97 | 231.14 |
| D6 stream      | 0.0249     | 1.42 | 7.78 | 638.46 | 488.24 | 0.62 | 149.10 |
| R1 pond        | 0.0017     | 0.10 | 0.53 | 43.59 | 33.33 | 0.04 | 10.18 |
| R1 stream      | 0.0355     | 2.00 | 10.94 | 897.44 | 686.27 | 0.88 | 209.58 |
| R3 stream      | 0.0251     | 1.43 | 7.84 | 643.59 | 492.16 | 0.63 | 150.30 |

Bold numbers indicate that acceptability criterion is not achieved: PEC/RAC ≥ 1
*Only suitable if the exposure profile in the test covers for the predicted exposure profiles (comparison not performed)
**ND : NOAEC and thus ERO-RAC could not be derived
Acceptability of risk (PEC/RAC < 1) after calculations based on RACs (from Tier 2 and 3 effect assessments) and maximum PEC<sub>SW</sub> values (FOCUS Step 3 for beta-cyfluthrin [2 x 12.5 g as/ha (14 d) in autumn application in winter cereals]

| FOCUS Scenario | PEC<sub>SW</sub> max (µg/L) | Tier 2 RACs (µg/L) | Tier 3 RACs (µg/L) |
|----------------|-----------------------------|--------------------|--------------------|
|                |                             | Fish acute         | Fish chronic       | Inverte. acute | Inverte. chronic | Sed. dweller | ETO-RAC | ERO-RAC |
| Step 3         |                             |                    |                    |                |                  |             |         |
| D1             | ditch 0.0724                | 4.14               | 22.63              | 1856.41        | 1419.61          | 1.81        | 433.53  | -       |
|                | stream 0.0563               | 3.22               | 17.59              | 1443.59        | 1103.92          | 1.41        | 337.13  | -       |
| D2             | ditch 0.0643                | 3.67               | 20.09              | 1648.72        | 1260.78          | 1.61        | 385.03  | -       |
|                | stream 0.0519               | 2.97               | 16.22              | 1330.77        | 1017.65          | 1.30        | 310.78  | -       |
| D3             | ditch 0.0637                | 3.64               | 19.91              | 1633.33        | 1249.02          | 1.59        | 381.44  | -       |
| D4             | pond 0.0026                 | 0.15               | 0.81               | 66.67          | 50.98            | 0.07        | 15.57   | -       |
|                | stream 0.0549               | 3.14               | 17.16              | 1407.69        | 1076.47          | 1.37        | 328.74  | -       |
| D5             | pond 0.0027                 | 0.15               | 0.84               | 69.23          | 52.94            | 0.07        | 16.17   | -       |
|                | stream 0.0593               | 3.39               | 18.53              | 1520.51        | 1162.75          | 1.48        | 355.09  | -       |
| D6             | ditch 0.0644                | 3.68               | 20.13              | 1651.28        | 1262.75          | 1.61        | 385.63  | -       |
| R1             | pond 0.0029                 | 0.17               | 0.91               | 74.36          | 56.86            | 0.07        | 17.37   | -       |
|                | stream 0.0418               | 2.39               | 13.06              | 1071.79        | 819.61           | 1.05        | 250.30  | -       |
| R3             | stream 0.0586               | 3.35               | 18.31              | 1502.56        | 1149.02          | 1.47        | 350.90  | -       |
| R4             | stream 0.042                | 2.40               | 13.13              | 1076.92        | 823.53           | 1.05        | 251.50  | -       |

Bold numbers indicate that acceptability criterion is not achieved: PEC/RAC ≥ 1
* Only suitable if the exposure profile in the test covers for the predicted exposure profiles (comparison not performed)
** ND: NOAEC and thus ERO-RAC could not be derived

Acceptability of risk (PEC/RAC < 1) after calculations based on RACs (from Tier 2 and 3 effect assessments) and maximum PEC<sub>SW</sub> values (FOCUS Step 3 for beta-cyfluthrin [2 x 7.5 g as/ha (14 d) in spring application in winter cereals]
### Peer review of the pesticide risk assessment of the active substance beta-cyfluthrin

|    | Fish acute | Fish chronic | Invert. acute | Invert. chronic | Sed. dweller | ETO-RAC | ERO-RAC |    |
|----|------------|--------------|---------------|-----------------|--------------|----------|----------|----|
| Step 3 |            |              |               |                 |              |          |          |    |
| D1  | ditch      | 0.0412       | 2.35          | 12.88           | 1056.41      | 807.84   | 1.03     | 246.71 |
|     | stream     | 0.0332       | 1.90          | 10.38           | 851.28       | 650.98   | 0.83     | 198.80 |
| D2  | ditch      | 0.039        | 2.23          | 12.19           | 1000.00      | 764.71   | 0.98     | 233.53 |
|     | stream     | 0.0341       | 1.95          | 10.66           | 874.36       | 668.63   | 0.85     | 204.19 |
| D3  | ditch      | 0.0383       | 2.19          | 11.97           | 982.05       | 750.98   | 0.96     | 229.34 |
| D4  | pond       | 0.0015       | 0.09          | 0.47            | 38.46        | 29.41    | 0.04     | 8.98   |
|     | stream     | 0.029        | 1.66          | 9.06            | 743.59       | 568.63   | 0.73     | 173.65 |
| D5  | pond       | 0.0017       | 0.10          | 0.53            | 43.59        | 33.33    | 0.04     | 10.18  |
|     | stream     | 0.0334       | 1.91          | 10.44           | 856.41       | 654.90   | 0.84     | 200.00 |
| D6  | ditch      | 0.0386       | 2.21          | 12.06           | 989.74       | 756.86   | 0.97     | 231.14 |
| R1  | pond       | 0.0015       | 0.09          | 0.47            | 38.46        | 29.41    | 0.04     | 8.98   |
|     | stream     | 0.025        | 1.43          | 7.81            | 641.03       | 490.20   | 0.63     | 149.70 |
| R3  | stream     | 0.0353       | 2.02          | 11.03           | 905.13       | 692.16   | 0.88     | 211.38 |
| R4  | stream     | 0.0251       | 1.43          | 7.84            | 643.59       | 492.16   | 0.63     | 150.30 |

Bold numbers indicate that acceptability criterion is not achieved: PEC/RAC ≥ 1

*Only suitable if the exposure profile in the test covers for the predicted exposure profiles (comparison not performed)

**ND**: NOAEC and thus ERO-RAC could not be derived
Acceptability of risk (PEC/RAC < 1) after calculations based on RACs (from Tier 2 and 3 effect assessments) and maximum PEC_{sw} values (FOCUS Step 3 for beta-cyfluthrin [2 x 12.5 g as/ha (14 d) in spring application in winter cereals])

| FOCUS Scenario | PEC_{sw} max (µg/L) | Tier 2 RACs (µg/L) | Tier 3 RACs (µg/L) |
|----------------|---------------------|--------------------|--------------------|
|                |                     | Fish acute | Fish chronic | Inverte. acute | Inverte. chronic | Sed. dweller | ETO-RAC | ERO-RAC |
| Step 3         |                     |           |             |                |                 |              |         |         |
| D1 ditch       | 0.0687              | 3.93      | 21.47       | 1761.54        | 1347.06          | 1.72          | 411.38  | -        |
|                |                     | 3.18      | 17.38       | 1425.64        | 1090.20          | 1.39          | 332.93  | -        |
| D2 ditch       | 0.0651              | 3.72      | 20.34       | 1669.23        | 1276.47          | 1.63          | 389.82  | -        |
|                |                     | 3.27      | 17.88       | 1466.67        | 1121.57          | 1.43          | 342.51  | -        |
| D3 ditch       | 0.0639              | 3.65      | 19.97       | 1638.46        | 1252.94          | 1.60          | 382.63  | -        |
|                |                     | 0.15      | 0.81        | 66.67          | 50.98            | 0.07          | 15.57   | -        |
| D4 pond        | 0.0026              | 2.77      | 15.16       | 1243.59        | 950.98           | 1.21          | 290.42  | -        |
|                |                     | 0.16      | 0.88        | 71.79          | 54.90            | 0.07          | 16.77   | -        |
| D5 pond        | 0.0028              | 3.20      | 17.50       | 1435.90        | 1098.04          | 1.40          | 335.33  | -        |
|                |                     | 0.056     | 0.78        | 64.10          | 49.02            | 0.06          | 14.97   | -        |
| D6 ditch       | 0.0643              | 3.67      | 20.09       | 1648.72        | 1260.78          | 1.61          | 385.03  | -        |
| R1 pond        | 0.0025              | 0.14      | 0.78        | 64.10          | 49.02            | 0.06          | 14.97   | -        |
|                |                     | 0.042     | 13.13       | 1076.92        | 823.53           | 1.05          | 251.50  | -        |
| R3 stream      | 0.0592              | 3.38      | 18.50       | 1517.95        | 1160.78          | 1.48          | 354.49  | -        |
| R4 stream      | 0.042               | 2.40      | 13.13       | 1076.92        | 823.53           | 1.05          | 251.50  | -        |

Bold numbers indicate that acceptability criterion is not achieved: PEC/RAC \geq 1

*Only suitable if the exposure profile in the test covers for the predicted exposure profiles (comparison not performed)

**ND : NOAEC and thus ERO-RAC could not be derived

Acceptability of risk (PEC/RAC < 1) after calculations based on RACs (from Tier 2 and 3 effect assessments) and maximum PEC_{sw} values (FOCUS Step 3 for beta-cyfluthrin [2 x 7.5 g as/ha (14 d) in spring cereals])

| FOCUS Scenario | PEC_{sw} max (µg/L) | Tier 2 RACs (µg/L) | Tier 3 RACs (µg/L) |
|----------------|---------------------|--------------------|--------------------|
|                |                     | Fish acute | Fish chronic | Inverte. acute | Inverte. chronic | Sed. dweller | ETO-RAC | ERO-RAC |
|                |                     |           |             |                |                 |              |         |         |
| D1 ditch       | 0.0175              | 0.0032*   | 0.000039    | 0.000051       | 0.04*           | 0.000167*    | ND**    |         |
|                |                     |           |             |                |                 |              |         |         |
### Peer review of the pesticide risk assessment of the active substance beta-cyfluthrin

|           | Fish acute | Fish chronic | Invert. acute | Invert. chronic | Sed. dweller | ETO-RAC | ERO-RAC |
|-----------|------------|--------------|---------------|----------------|--------------|----------|---------|
| **Step 3**|            |              |               |                |              |          |         |
| D1        | ditch      | 0.0393       | 2.25          | 12.28          | 1007.69      | 770.59   | 0.98    | 235.33  |
|           | stream     | 0.0335       | 1.91          | 10.47          | 858.97       | 656.86   | 0.84    | 200.60  |
| D3        | ditch      | 0.0384       | 2.19          | 12.00          | 984.62       | 752.94   | 0.96    | 229.94  |
|           | stream     | 0.0015       | 0.09          | 0.47           | 38.46        | 29.41    | 0.04    | 8.98    |
| D4        | pond       | 0.0015       | 0.031         | 1.77           | 9.69         | 794.87   | 607.84  | 0.78    | 185.63  |
|           | stream     | 0.0017       | 0.10          | 0.53           | 43.59        | 33.33    | 0.04    | 10.18   |
| D5        | pond       | 0.033        | 1.89          | 10.31          | 846.15       | 647.06   | 0.83    | 197.60  |
|           | stream     | 0.025        | 1.43          | 7.81           | 641.03       | 490.20   | 0.63    | 149.70  |

Bold numbers indicate that acceptability criterion is not achieved: PEC/RAC ≥ 1

*Only suitable if the exposure profile in the test covers for the predicted exposure profiles (comparison not performed)

**ND**: NOAEC and thus ERO-RAC could not be derived
Acceptability of risk (PEC/RAC < 1) after calculations based on RACs (from Tier 2 and 3 effect assessments) and maximum PEC\textsubscript{sw} values (FOCUS Step 3 for beta-cyfluthrin [2 x 12.5 g as/ha (14 d) in spring cereals]

| FOCUS Scenario | PEC\textsubscript{sw} max (µg/L) | Tier 2 RACs (µg/L) | Tier 3 RACs (µg/L) |
|----------------|-------------------------------|-------------------|-------------------|
|                |                               | Fish acute | Fish chronic | Invert. acute | Invert. chronic | Sed. dweller | Overall assessment/mesocosm |
| Step 3         |                               |            |              |              |                |              | ETO-RAC | ERO-RAC |
| D1 ditch       | 0.0655                        | 3.74       | 20.47       | 1679.49      | 1284.31        | 1.64         | 392.22 | -       |
| stream         | 0.0562                        | 3.21       | 17.56       | 1441.03      | 1101.96        | 1.41         | 336.53 | -       |
| D3 ditch       | 0.064                         | 3.66       | 20.00       | 1641.03      | 1254.90        | 1.60         | 383.23 | -       |
| pond           | 0.0025                        | 0.14       | 0.78        | 64.10        | 49.02           | 0.06         | 14.97  | -       |
| stream         | 0.052                         | 2.97       | 16.25       | 1333.33      | 1019.61        | 1.30         | 311.38 | -       |
| D5 pond        | 0.0028                        | 0.16       | 0.88        | 71.79        | 54.90           | 0.07         | 16.77  | -       |
| stream         | 0.0552                        | 3.15       | 17.25       | 1415.38      | 1082.35        | 1.38         | 330.54 | -       |
| R4 stream      | 0.0419                        | 2.39       | 13.09       | 1074.36      | 821.57          | 1.05         | 250.90 | -       |

Bold numbers indicate that acceptability criterion is not achieved: PEC/RAC ≥ 1

*Only suitable if the exposure profile in the test covers for the predicted exposure profiles (comparison not performed)

**ND : NOAEC and thus ERO-RAC could not be derived
Acceptability of risk (PEC/RAC < 1) after calculations based on RACs (from Tier 2 and 3 effect assessments) and maximum PEC_{SW} values (FOCUS Step 3 for beta-cyfluthrin [2 x 7.5 g as/ha (14d) in potatoes]

| FOCUS Scenario | PEC_{SW} max (µg/L) | Tier 2 RACs (µg/L) | Tier 3 RACs (µg/L) |
|----------------|---------------------|--------------------|--------------------|
|                |                     | Fish acute | Fish chronic | Invert. acute | Invert. chronic | Sed. dweller | Overall assessment/mesocosm |
| Step 3         |                     |            |             |              |                |              | ETO-RAC | ERO-RAC |
| D3 ditch       | 0.0316              | 1.81       | 9.88        | 810.26       | 619.61         | 0.79         | 189.22 | -       |
| D4 pond        | 0.0015              | 0.09       | 0.47        | 38.46        | 29.41          | 0.04         | 8.98   | -       |
|                | stream              | 0.0262     | 1.50        | 8.19         | 671.79         | 0.66         | 156.89 | -       |
| D6 ditch       | 0.0315              | 1.80       | 9.84        | 807.69       | 617.65         | 0.79         | 188.62 | -       |
| D6 ditch       | 0.0015              | 0.09       | 0.47        | 38.46        | 29.41          | 0.04         | 8.98   | -       |
| R1 pond        | 0.0217              | 1.24       | 6.78        | 556.41       | 425.49         | 0.54         | 129.94 | -       |
|                | stream              | 0.0286     | 1.63        | 8.94         | 733.33         | 0.72         | 171.26 | -       |
| R2 stream      | 0.0305              | 1.74       | 9.53        | 782.05       | 598.04         | 0.76         | 182.63 | -       |
| R3 stream      | 0.0316              | 1.81       | 9.88        | 810.26       | 619.61         | 0.79         | 189.22 | -       |

Bold numbers indicate that acceptability criterion is not achieved: PEC/RAC ≥ 1
* Only suitable if the exposure profile in the test covers for the predicted exposure profiles (comparison not performed)
**ND : NOAEC and thus ERO-RAC could not be derived
Acceptability of risk (PEC/RAC < 1) after calculations based on RACs (from Tier 2 and 3 effect assessments) and maximum PEC_{sw} values (FOCUS Step 3 for beta-cyfluthrin [2 x 12.5 g as/ha (14 d) in potatoes]

| FOCUS Scenario | PEC_{sw} max (µg/L) | Tier 2 RACs (µg/L) | Tier 3 RACs (µg/L) |
|----------------|---------------------|-------------------|-------------------|
|                |                     | Fish acute        | Fish chronic      | Invert. acute | Invert. chronic | Sed. dweller | Overall assessment/mesocosm |
|                |                     |                   |                   |              |              |              |                      |
| Step 3         |                     |                   |                   |              |              |              |                      |
| D3  ditch      | 0.0605              | 3.46              | 18.91             | 1551.28      | 1186.27      | 1.51         | 362.28               |
| D4  pond       | 0.0025              | 0.14              | 0.78              | 64.10        | 49.02        | 0.06         | 14.97                |
| D4  stream     | 0.0509              | 2.91              | 15.91             | 1305.13      | 998.04       | 1.27         | 304.79               |
| D6  ditch      | 0.0596              | 3.41              | 18.63             | 1528.21      | 1168.63      | 1.49         | 356.89               |
| D6  ditch      | 0.0025              | 0.14              | 0.78              | 64.10        | 49.02        | 0.06         | 14.97                |
| R1  pond       | 0.0412              | 2.35              | 12.88             | 1056.41      | 807.84       | 1.03         | 246.71               |
| R1  stream     | 0.0554              | 3.17              | 17.31             | 1420.51      | 1086.27      | 1.39         | 331.74               |
| R2  stream     | 0.0591              | 3.38              | 18.47             | 1515.38      | 1158.82      | 1.48         | 353.89               |
| R3  stream     | 0.0605              | 3.46              | 18.91             | 1551.28      | 1186.27      | 1.51         | 362.28               |

Bold numbers indicate that acceptability criterion is not achieved: PEC/RAC ≥ 1

*Only suitable if the exposure profile in the test covers for the predicted exposure profiles (comparison not performed)

**ND**: NOAEC and thus ERO-RAC could not be derived
Acceptability of risk (PEC/RAC < 1) after calculations based on RACs (from Tier 2 and 3 effect assessments) and maximum PEC_sw values (FOCUS Step 3 for beta-cyfluthrin [2 x 17.5 g as/ha (14 d) in tomatoes, permanent glasshouse]

| FOCUS Scenario | PEC_sw max (µg/L) | Tier 2 RACs (µg/L) | Tier 3 RACs (µg/L) |
|----------------|------------------|-------------------|-------------------|
|                | Fish acute       | Fish chronic      | Invert. acute     | Invert. chronic | Sed. dweller | ETO-RAC | ERO-RAC  |
|                | Overall assessment/mesocosm |                        |                    |
| D6 ditch       | 0.004            | 0.229             | 1.250             | 101.8          | 78.4         | 0.100 | 24.0      | -         |
| R2 stream      | 0.003            | 0.171             | 0.938             | 76.3           | 58.8         | 0.075 | 18.0      | -         |
| R3 stream      | 0.003            | 0.171             | 0.938             | 76.3           | 58.8         | 0.075 | 18.0      | -         |
| R4 stream      | 0.005            | 0.286             | 1.563             | 127.2          | 98.0         | 0.125 | 29.9      | -         |

*Bold numbers indicate that acceptability criterion is not achieved: PEC/RAC ≥ 1

*Only suitable if the exposure profile in the test covers for the predicted exposure profiles (comparison not performed)

**ND : NOAEC and thus ERO-RAC could not be derived
### DCVA

| Crop          | Highest FOCUS Step 2 PEC (µg/L) | fish acute | invertebrate acute | algae |
|---------------|---------------------------------|------------|--------------------|-------|
|               |                                 | Oncorhynchus mykiss | Daphnia magna | E,C50 |
|               |                                 | LC₅₀       | LC₅₀               |       |
|               |                                 | >14700 µg/L | 25000 µg/L        |       |
| RAC values (µg/L) |                                 | >147       | 250                |       |
| Winter cereals| 0.69                            | <0.005     | 0.003              | -     |
| Spring cereals| 0.69                            | <0.005     | 0.003              | -     |
| Potatoes      | 0.78                            | <0.005     | 0.003              | -     |
| Tomatoes      | 1.27                            | <0.009     | 0.005              | -     |
| Beet          | 0.35                            | <0.002     | 0.001              | -     |

### FPB-acid

| Crop          | Highest FOCUS Step 2 PEC (µg/L) | fish acute | invertebrate acute | algae |
|---------------|---------------------------------|------------|--------------------|-------|
|               |                                 | Oncorhynchus mykiss | Daphnia magna | E,C50 |
|               |                                 | LC₅₀       | LC₅₀               |       |
|               |                                 | 4060 µg/L   | 39300 µg/L        |       |
| RAC values (µg/L) |                                 | 40.6       | 250                |       |
| Winter cereals| 0.44                            | 0.011      | 0.001              | -     |
| Spring cereals| 0.44                            | 0.011      | 0.001              | -     |
| Potatoes      | 0.49                            | 0.012      | 0.001              | -     |
| Tomatoes      | 0.8                             | 0.020      | 0.002              | -     |
| Beet          | 0.1                             | 0.002      | 0.000              | -     |
**FPB-aldehyde**

| Crop          | Highest FOCUS Step 2 PEC (µg/L) | fish acute | invertebrate acute | algae |
|---------------|---------------------------------|------------|--------------------|-------|
|               |                                 | *Oncorhynchus mykiss* | *Daphnia magna* | -     |
|               |                                 | LC₅₀       | LC₅₀               | E₅₀   |
|               |                                 | 792 µg/L*  | 1300 µg/L*        | -     |

| Crop          | RAC values (µg/L) |          |          |       |
|---------------|-------------------|----------|----------|-------|
| Winter cereals| 0.46              | 0.058    | 0.035    | -     |
| Spring cereals| 0.46              | 0.058    | 0.035    | -     |
| Potatoes      | 0.52              | 0.066    | 0.040    | -     |
| Tomatoes      | 0.85              | 0.107    | 0.065    | -     |
| Beet          | -                 | -        | -        | -     |

*Illustrative risk assessment, performed with invalid endpoints
**Effects on bees (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.1 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.1)**

| Species             | Test substance | Time scale/type of endpoint | End point toxicity          |
|---------------------|----------------|-----------------------------|-----------------------------|
| *Apis mellifera* L. | beta-cyfluthrin | acute                       | Oral toxicity (LD₅₀) 0.05 µg/bee |
| *Apis mellifera* L. | beta-cyfluthrin | acute                       | Contact toxicity (LD₅₀) 0.012 µg/bee |
| *Apis mellifera* L. | Bulldock 25 EC  | acute                       | Oral toxicity (LD₅₀) 0.0164 µg as/bee |
| *Apis mellifera* L. | Bulldock 25 EC  | acute                       | Contact toxicity (LD₅₀) 0.0337 µg as/bee |
| *Apis mellifera* L. | Monturforte 230 FS | acute                       | Oral toxicity (LD₅₀) 0.270 µg product/bee |
| *Apis mellifera* L. | Monturforte 230 FS | acute                       | Contact toxicity (LD₅₀) 0.201 µg product/bee |
| *Apis mellifera* L. | Bulldock 25 EC  | chronic                     | 10 d-LD₅₀ 0.019 µg as/bee/day |
| *Apis mellifera* L. | Bulldock 25 EC  | bee brood development       | NOEDₜₜₜₜₜ 0.007 µg as/larva* |
| *Apis mellifera* L. |               | Sub-lethal effects (behavioural and reproductive) | NOEC hypopharyngeal glands no data |

* single oral exposure

**Tier 1 Honey bee Risk assessment** for spray applications (tomato: 17.5 g as/ha; potato, wheat: 12.5 g as/ha).
Calculation performed according to SANCO (2002)

| Species             | Crop               | Test substance | Risk quotient | HQ  | Trigger |
|---------------------|--------------------|----------------|---------------|-----|---------|
| *Apis mellifera* L. | tomatoes           | beta-cyfluthrin | HQoral        | 519 | 50      |
| *Apis mellifera* L. | tomatoes           | beta-cyfluthrin | HQcontact     | 1067| 50      |
| *Apis mellifera* L. | wheat, potatoes    | beta-cyfluthrin | HQoral        | 371 | 50      |
| *Apis mellifera* L. | wheat, potatoes    | beta-cyfluthrin | HQcontact     | 762 | 50      |

**Honey bee Risk assessment** for seed treatment (beet: 10.4 g as/ha).
Data gap

**Risk assessment** for “wild pollinators” – screening step according to EFSA (2013) (acute contact and oral exposition, Bulldock EC 25)

| Field application rate (AR) [g a.s./ha] | Type of assessment | Type of bee | Formula screening step assessment [in-field] | Formula refined assessment [off-field] | Endpoint Acute contact LD50 [µg a.s./bee] | Trigger values (DW) | Risk yes = + no = - in-field / off-field |
|----------------------------------------|--------------------|-------------|---------------------------------------------|--------------------------------------|------------------------------------------|---------------------|----------------------------------------|
|                                       |                    |             | $HQ_{contact} = AR/LD_{50,contact}$           | $HQ_{contact} = f_{dep}/100 \times AR/LD_{50,contact}$ |                                           |                     |                                        |
|                | Acute contact exposure adults | Bumble bee | Solitary bee | LD50 oral [µg a.s./bee] | ETAR acute oral LD50 [µg a.s./bee] |
|----------------|------------------------------|------------|--------------|-------------------------|----------------------------------|
| **7.5 (tomato)** | 6250                         | 175        | 0.0012       | 7                       | +/+                              |
|                |                              | 6250       | 175          | 0.0012                  | 8                                |
| **12.5 (wheat)**| 10417                        | 292        | 0.0012       | 7                       | +/+                              |
|                |                              | 10417      | 292          | 0.0012                  | 8                                |
| **17.5 (greenhouse tomato)** | greenhouse/ indoor use 2 | 408        | 0.0012       | 7                       | na/+                             |
|                |                              | 408        | 0.0012       | 8                       | na/+                             |
| **17.5* (greenhouse tomato)** | greenhouse/ indoor use 2 | 10.08      | 0.0012       | 7                       | na/-                             |
|                |                              | 10.08      | 0.0012       | 8                       | na/-                             |

1 = this endpoint from honey bee is divided by 10
2 = here regarded as not relevant
3 = na = not available
4 = Concentration taken from Table 10 in Spickermann (2014), please see also B.9.6.2.2 and Table B.9.6-4 for details. Drift deposition with 0.1% drift [mg/m²] used for FOCUS Step 3 and Step 4 calculations, the STEP 3 for ditch was taken (0.001209 mg/m²) and no correction factor was used.

Field application rate (AR) [kg a.s./ha]

| Type of assessment | Type of bee | Formula screening step assessment [in-field] | ETAR acute adult oral = AR * SV/LD50oral | Shortcut value SV (DW) | Endpoint Acute contact LD50 [µg a.s./bee] | Trigger values (DW) | Risk yes = + no = - |
|--------------------|-------------|---------------------------------------------|------------------------------------------|------------------------|------------------------------------------|----------------------|---------------------|
| Acute oral exposure adult bees | Bumble bee | 16.8                                       | 11.2                                    | 0.005                  | 0.036                                   | +                    |
|                     | Solitary bee | 8.55                                      | 5.7                                    | 0.005                  | 0.04                                    | +                    |
| Acute oral exposure adult bees | Bumble bee | 28                                        | 11.2                                    | 0.005                  | 0.036                                   | +                    |
|                     | Solitary bee | 14.25                                     | 5.7                                    | 0.005                  | 0.04                                    | +                    |
| Acute oral exposure adult bees | Bumble bee | Unrealistic 2                              | 11.2                                    | 0.005                  | 0.036                                   | na 3                 |
|                     | Solitary bee | 5.7                                        | 0.005                                  | 0.04                   | na 3                                    |
| Acute oral exposure adult bees | Bumble bee | 0.0271 4                                  | 11.2                                    | 0.005                  | 0.036                                   | -                    |
|                     | Solitary bee | 0.013 4                                  | 5.7                                    | 0.005                  | 0.04                                    | -                    |

1 = this endpoint from honey bee is divided by 10
2 = here regarded as not relevant/ Unrealistic in greenhouse/indoor use
3 = na = not available
4 = Concentration taken from Table 10 in Spickermann (2014), please see also B.9.6.2.2 and Table B.9.6-4 for details. Drift deposition with 0.1% drift [mg/m²] used for FOCUS Step 3 and Step 4 calculations, the STEP 3 for ditch was taken (0.001209 mg/m²) and no correction factor was used.

With a more realistic scenario (from Focus SW calculations by Spickermann, 2014) for greenhouse use (17.5 g a.s./ha tomato) at least a risk for honey bees and “wild pollinators” for “off-crop” (drift only) is according screening step regarded as negligible.
Risk assessment for “wild pollinators” – screening step (acute contact and oral exposition, Montur Forte FS 230)

Acute contact toxicity screening step in risk assessment according dust drift exposure (scenario 4: field margin) for “wild” pollinators (Montur Forte FS 230)

| a.s.       | Species     | EU endpoint (contact) [µg a.s./bee] | PEC 3-D off-field 1m [g a.s./ha] | HQ\(_{\text{contact}}\) = PEC3-D/LD\(_{50}\)\(_{\text{contact}}\) | Trigger | Risk |
|------------|-------------|-------------------------------------|----------------------------------|-------------------------------------------------|---------|------|
| Beta-cyfluthrin | bumblebee  | 0.0012 \(^1\)                    | 0.09                           | 75                      | 2.3     | +    |
| Beta-cyfluthrin | solitary bee | 0.0012 \(^1\)                    | 0.09                           | 75                      | 2.6     | +    |

Acute oral toxicity screening step in risk assessment according dust drift exposure (scenario 4: field margin) for “wild” pollinators

| a.s.       | Species     | EU endpoint (oral) [µg a.s./bee] | PEC 3-D off-field 1m [g a.s./ha] | SV                  | ETR\(_{\text{oral}}\) = PEC3-D* SV/ LD\(_{50}\)\(_{\text{oral}}\) | Trigger | Risk |
|------------|-------------|----------------------------------|----------------------------------|---------------------|-------------------------------------------------|---------|------|
| Beta-cyfluthrin | bumblebee  | 0.005 \(^1\)                    | 0.09                           | 11.2                | 201.6                                         | 0.036   | +    |
| Beta-cyfluthrin | solitary bee | 0.005 \(^1\)                    | 0.09                           | 5.7                 | 102.6                                         | 0.04    | +    |

Potential for accumulative toxicity: no data

Higher tier data
Semi-field test (Cage and tunnel test)
Available tent studies indicate that spray application of beta-cyfluthrin to flowering *Phacelia* at 15 g a.s./ha after daily bee flight, there was a slight increase in bee mortality and a transient reduction in flight intensity under these confined conditions. Colony strength and brood were not affected. All studies mentioned above have been conducted according to the BBA-Guideline 23-1 methodology and have already been evaluated and accepted in the first EU evaluation of beta-cyfluthrin (2002). However, due to present requirements, these studies are taken into account as additional information for the current risk assessment.

In two newly submitted semi-field studies beta-cyfluthrin was applied once at 7.5 g a.s./ha on flowering oilseed rape after bee flight. The studies showed no long- or medium-term repellent effect on foraging behavior of honeybees. Residues of beta-cyfluthrin in manually sampled pollen from oilseed rape flowers were found to be up to 64 times higher compared to residues in pollen collected by foraging honeybees.

Field tests
In two studies on flowering *Phacelia*, each study included an application during bee flight at 15 g a.s./ha and an application during bee flight at 7.5 g a.s./ha. In both studies, there was an increase in mortality and a reduction in foraging activity, the latter being restricted to a period of 1-3 days. There were no effects on brood. In four studies, beta-cyfluthrin was sprayed at 15 g a.s./ha after bee flight. In all four studies, mortality was not increased, and flight intensity was transiently reduced. Colony strength and brood were not affected. All studies mentioned above have already been evaluated and accepted in the first EU evaluation of beta-cyfluthrin (2002). However, due to present requirements, these studies are taken into account as additional information for the current risk assessment.

Furthermore, for the current risk assessment, four new field studies were submitted. One of the studies considered residues only.

Two field studies, each including two applications at 17.5 g a.s./ha (first application: 6-7 days before colony set up; second application (after bee flight): 4 days after colony set up), have been submitted. In one study, foraging activity was reduced for one day, mortality was not increased, and the assessments of colony strength and brood area were inconclusive. In the other study, foraging activity was not reduced, mortality slightly increased for 2 days, colony strength and brood area were slightly decreased, and there were no biologically relevant effects on brood development. However, the distance between control and test item field was only 1.6
km in the study, which is considered insufficient, and thus reliability of the test is considered limited. In a third new study, beta-cyfluthrin was applied once at 7.5 g a.s./ha on flowering oilseed rape after bee flight. One study investigated possible effects on the behaviour and colony development, including wintering success, on honeybees. No statistically significant adverse effects on the flight activity, mortality rates of adult and immature bees, brood development or on the condition and development of the colonies or wintering success were found. However, due to unfavourable weather conditions on the days after application the flight and foraging activity was decreased in the control and treatment groups. Furthermore, on the day after application when the residues of beta-cyfluthrin were found to reach their highest level in oilseed rape flowers (0.36 mg/kg) and pollen (0.83 mg/kg) the pollen-loads of the control and treatment group contained limited amounts of 5-20 % oilseed rape pollen. These limitations reduced the exposure of foraging honeybees to beta-cyfluthrin. Nevertheless, the presence of residues in bee pollen and nectar from honey sacs and the results of the assessments on foraging activity in 1 m² patches of the treated areas of the study fields indicate an exposition to the product.

Therefore, on the basis of all studies with spray applications, effects on colony conditions cannot finally be excluded. However, it was concluded that for the applications at 7.5 g a.s./ha in the field there is sufficient information for concluding a low risk, provided that the application is performed after bee flight hours. In addition, the available data were sufficient to conclude a low risk to honeybees, for the foliar spray uses, from exposure to plants in the field margin and adjacent crop areas.

For seed treatment no valid data on the risk of dust drift on honeybees were available.

Effects on other arthropod species (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.2)

Laboratory tests with standard sensitive species

| Species                | Test Substance | End point          | Toxicity       |
|------------------------|----------------|--------------------|----------------|
| *Typhlodromus pyri*    | Bulldock EC 25| Mortality, LR₅₀    | 0.0025 g a.s/ha|
|                        |                | Reproduction, ER₅₀ | not tested     |
| *Aphidius rhopalosiphi*| Bulldock EC 25| Mortality, LR₅₀    | 0.163 g a.s/ha |
|                        |                | Reproduction, ER₅₀ | not tested     |

Additional species

| *Poecilus cupreus* (adult) | Bulldock EC 25 | Mortality, LR₅₀ | > 7.7 g a.s/ha |

First tier risk assessment for – Spray application in wheat and potato at 2 x 7.5 g a.s./ha and 2 x 12.5 g a.s./ha. Spray application to tomatoes at 2 x 17.5 g a.s./ha

| Test substance | Intended use    | Species               | Effect (LR₅₀ g/ha) | HQ in-field | HQ off-field¹ | Trigger |
|----------------|-----------------|-----------------------|--------------------|-------------|---------------|---------|
| Bulldock EC 25| Wheat, potato   | *Typhlodromus pyri*  | 0.0025 g a.s/ha    | 5100        | 121.38        | 2       |
| Bulldock EC 25| 7.5 g a.s/ha    | *Aphidius rhopalosiphi* | 0.163 g a.s/ha    | 78          | 1.86          | 2       |
| Bulldock EC 25| Wheat, potato   | *Typhlodromus pyri*  | 0.0025 g a.s/ha    | 8500        | 202.3         | 2       |
Peer review of the pesticide risk assessment of the active substance beta-cyfluthrin

Test substance | Intended use | Species | Effect (LR$_{50}$ g/ha) | HQ in-field | HQ off-field$^1$ | Trigger |
---|---|---|---|---|---|---|
Bulldock EC 25 | 12.5 g as/ha | *Aphidius rhopalosiphi* | 0.163 g as/ha | 130 | 3.10 | 2 |
Bulldock EC 25 | Fruiting vegetables (Tomato), 17.5 g as/ha | *Typhlodromus pyri* | 0.0025 g as/ha | 11900 | 4.34 | 2 |
Bulldock EC 25 | | *Aphidius rhopalosiphi* | 0.163 g as/ha | 182.5 | 4.34 | 2 |

Refined off-field risk assessment assuming 5 m buffer zone and 90% drift reduction
for – Spray application in wheat and potato at 2 x 7.5 g as/ha and 2 x 12.5 g as/ha. Spray application to tomatoes at 2 x 17.5 g a.s./ha

Test substance | Intended use | Species | Effect (LR$_{50}$ g/ha) | HQ off-field$^1$ | Trigger |
---|---|---|---|---|---|
Bulldock EC 25 | Wheat, potato 7.5 g as/ha | *Typhlodromus pyri* | 0.0025 g as/ha | 2.4 | 2 |
Bulldock EC 25 | Wheat, potato 12.5 g as/ha | *Typhlodromus pyri* | 0.0025 g as/ha | 4 | 2 |
Bulldock EC 25 | Fruiting vegetables, 17.5 g as/ha | *Typhlodromus pyri* | 0.0025 g as/ha | 5.59 | 2 |

$^1$PER off-field with risk mitigation: 5 m + 90% drift reduction (drift factor = 0.00047)

Extended laboratory tests, aged residue tests

| Species | Life stage | Test substance, substrate | Time scale | Dose (g/ha) | End point | % effect | ER$_{50}$ |
|---|---|---|---|---|---|---|---|
| *Poecilus cupreus* larvae | Bulldock EC 25 | 65 days | 0.04 mg as/kg dw (initial) | Mortality | 0 % effect on mortality | >0.04 mg as/kg dw (initial) |
| | | | 0.4 mg as/kg dw (initial) | Mortality | 100 % |
| *Poecilus cupreus* larvae | beta-cyfluthrin | 55 days | 0.014 mg as/kg dw | Mortality | 0 % (corrected) | > 0.014 mg/kg dw |

Aged residue tests

| Species | Life stage | Test substance, substrate | Time scale | Dose (g/ha) | End point | % effect | ER$_{50}$ |
|---|---|---|---|---|---|---|---|
| *Coccinella septempunctata* larvae | Bulldock EC 25 | 0-7 d | 0.3 as(initial) | Mortality | 91 - 87 | < 0.3 g as/ha |
| | | 14 d | 1.2 as (initial) | Mortality | 19 | > 1.2 g as/ha |
| | | 28 d | 25 as (initial) | Mortality | 46 | 25 g as/ha |

Risk assessment (in-field) for – Montur Forte FS 230, beet seed treatment at 10.4 g beta-cyfluthrin and 19.5 g as imidacloprid/ha based aged residue tests
Species & LR$_{50}$ & In-field rate, PEC$_{soil, max.}$ & Trigger value \\
--- & --- & --- & --- \\
*Poecilus cupreus* (larvae) & 0.041 & 0.014 & 1 \\

**Semi-field tests**
- 

**Field studies**

There are four field studies performed at application rates means to represent in-field conditions:
- Field study in an alfalfa field in Spain (Mack, 2013, R-8693, KIIIA1 10.5.4/05)
- Field study in a pome fruit orchard in northern Germany (Knäbe, 2013, R-28694, KIIIA1 10.5.4/06)
- Field study in cereals in southern England (Vinall, 2005, R-19598, KIIIA1 10.5.4/03)
- Field study in orchard in south-west France (Vinall, 2006, R-19592, KIIIA1 10.5.4/04)

There is one field study performed at application rates means to represent off-field conditions:
A Field Study on Meadow in Germany (Mack, 2014, R-30607, KIIIA1 10.5.4/07)

**Author/reference:** Mack, 2013, R-8693, KIIIA1 10.5.4/05  
**Conditions of the study:**
Locations: Spain  
Time of year: May-end of October  
Crop: Alfalfa  
Test item: Bulldock 25 EC (25 g beta-cyfluthrin/L)  
Application rate: 2 x 0.5 L prod/ha (2 x 12.5 g a.s./ha), 15 day interval between applications  
**Methodology:**  
Sampling methods: pitfall traps, visual control (beating), Vortis suction,  
Statistics: univariate with treatment vs control, multivariate with PCA and PRC (= Principal Response Curve)  
**Study appraisal:**  
- Generally, the abundance of organisms was rather low, so it was very difficult to discriminate true effects and related recovery.  
- Sampling just after application was not performed (only 8 days after the first application). Therefore, the study does not provide information on initial effects.  
- Only one plot used.  
- Arthropod dynamic possibly more influenced/covered up to an unknown extent by irrigation system than by application schedule, with insecticides used the three previous years and “alfalfa field was cut before the start of the study”.  
- Sampling methods unsuitable for certain guilds (e.g. pollinators).  
- Finally sampling was 1-40 days after 2nd application.  
- Sampling periods differing expressing differing effort (e.g. in pitfalls with 6-8 days).  
- Statistical power not determined but indicated to be low by lack of statistical differences identified.  
- Several statistical shortcomings  
- Acari were not present in study.  
- Spiders (Araneae) were detected in lower in pitfall traps in the treatment plot (than in the control) right from the beginning of the study.  
- Many taxa were not abundant in sufficient numbers to make any meaningful assessment.  
- Pooling of taxa for the statistical assessment.  

**Summary of results:**
There were no groups of taxa for which it could be concluded that there was clearly no recovery by the end of the study. However, the low numbers of many taxa do not allow for meaningful interpretation of the data.

**Conclusion of the RMS and peer review:**
Owing to the methodological shortcomings, the RMS concluded that the study should be considered as unreliable. The experts at the meeting agreed that little useful information could be gained from this study.

**Author/reference:** Knäbe, 2013, R-28694, KIIIA1 10.5.4/06

**Conditions of the study:**
Location: Spain
Time of year: May-end of November
Crop: pome fruit
Test item: Bulldock 25 EC (25 g beta-cyfluthrin/L)
Application: 2 x 0.7 L prod/ha (2x 17.5 g a.s./ha) with a 14 day interval between applications.

**Methodology:**
Sampling pitfall traps, visual assessments examining methodically upper and lower surfaces of leaves (to provide data on foliage-dwelling arthropods, e.g. predatory/parasitic arthropods), inventory sampling

Statistics: univariate with treatment vs control and control vs reference, multivariate with PCA and PRC.

**Study appraisal:**
- Sampling just after application was not performed (closest was 1 week after the application).
- Results of the visual sampling were not presented.
- For the inventory sampling the methodology was not clear (beating, knock-down, etc.)
- Results of the PRC are not presented.
- Some taxa were excluded in the repository sampling because part of the target species.
- Soil dwelling organisms were sampled by pitfall traps below the trees. Exposure to soil arthropods via drift only.
- Numbers of order (taxa) represented are low, some expected ones were missing (Neuroptera, Psocoptera, Acari
- Statistical shortcomings
- Pooling of taxa for the statistical assessment.
- Low numbers of some taxa prevent meaningful interpretations.
- Final sampling was 124 days after 2nd application.

**Summary of results:**

Pitfall traps:
No groups of taxa for which it could be concluded that there was clearly no recovery by the end of the study.

Inventory sampling:

| Taxa for which recovery was not demonstrated by the study end (124 days after 2nd application): | Comment |
|---|---|
| Chironomidae adults (Diptera) | Statistically significant difference on 124 DAT 2 only. |
| Total Auchenorrhyncha (includes sucking insects some of which are considered to be a target) | Numbers in control declined by final sampling date but clearly lower numbers in the treatment for the duration of the study. |
| Juvenile Auchenorrhyncha (includes sucking insects some of which are considered to be a target) | Clearly lower numbers at the study end. |

**Conclusion of the RMS and peer review:**
The RMS considered that the study was unreliable owing to the reliability issues highlighted above. The experts at the meeting agreed with the RMS’s concerns but considered that the study was not completely unreliable. The experts agreed that the study was not comparable to the representative uses.

**Author/reference:** Vinall, 2005, R-19598, KIIIA1 10.5.4/03

**Conditions of the study:**
Location: Southern England  
Time of year: mid-April to mid-June, 2 years  
Crop: Winter-sown barley  
Test item: Baythroid EC 50 (50 g cyfluthrin/L)  
Applications:  
2 x 500 mL prod/ha (2 x 25 g cyfluthrin as/ha ~ 2 x 10.5 g beta-cyfluthrin), interval 16 d  
2.85 mL prod. (2 x 0.1425 g cyfluthrin as/ha), interval 16 d  
Study design: Sixteen plots of approximately 1 ha were marked out and each treatment assigned to four replicate plots in a randomised block design  

Methodology:  
Sampling: pitfall traps, visual control (beating), Vortis suction, yellow sticky traps and sweep nets  
Statistics (univariate ANOVA, Dunett’s test for multiple testing for data 2004, t-test for unmatched pairs data of 2005 (with only two treatments), no multivariate with PRC).  

Study appraisal:  
- Some groups that showed no effects were only sampled for 33 days (sweep-net samples). This is problematic, because delayed effects could be masked.  
- Three additional traps (pitfall) were taken during May 2005 (the time in which a different crop than the original). Additionally, the final sample was taken within a year of the initial application (T1) which was 18 May 2004.  
- The reliability of the study is lowered due to the application of other PPPs during the experiment (missing information): According to the study report appendix II some other plant protection products were applied in the field during the experiment. For example, the product shogun (Propaquizafop) was applied at 02.09.04 and Centium (Clomazone) was applied at 14.03.05. It is not reported to which plots these products are applied (i.e., control, toxic or treatment plots). Furthermore, the direct and indirect effects of these applications on arthropods were not reported or investigated in the study.  
- An impact, of unknown intensity, is assumed by the (rather exceptional) crop rotation used in this experiment. The agricultural procedure is described as follows: “After the barley harvest in July 2004, stubble-turnip was sown which was subsequently grazed by cattle in the field from 1 Nov 2004 to 1 Feb 2005. In March 2005, the soil was ploughed and sown with peas, i.e. the May 2005 sampling was in peas (not barley)”.  
- Further the applicant stated that that “two species of rove beetle were no longer present in the control plots (and the treatment plots) in May 2005 (in the second year), which might have been due to the cattle, ploughing, the change of crop type, or other factors.”. Indeed, it remains unclear how strong the impact and in which direction the agricultural procedure worked onto the abundance of the missing rove beetle species. Still, it cannot be ruled out that the disappearance of some rove beetles is connected to exposure to the test item.  
- In cases where the numbers in the control are low, it cannot be assumed that recovery occurred i.e. recovery was not demonstrated.  
- Owing to the study design (small plots with a checkerboard design) it cannot be excluded that recolonization (rather than internal recovery) will have occurred.  
- Statistical shortcomings: Statistical power is unknown, which adds with a possible highly variable control sample a high level of uncertainty to this field study. No PRC with multivariate testing is available.  
- Study performed with cyfluthrin  
- Representativeness for off-field environments questionable.  

Summary of key results:  
2 x 25 g cyfluthrin as/ha ~ 2 x 10.5 g beta-cyfluthrin  

| Taxa for which recovery was not demonstrated 55 days after the second treatment (DAT2) (i.e. in 2004) | Recovery demonstrated within 1 year of 1st application (i.e. May 2005) |
|---|---|
| *Philonthus cognatus* (Coleoptera: Staphylinidae) | No, only detected 349 DAT2 and then numbers notably lower in treatment plots. |
| *Philonthus laminatus* (Coleoptera: Staphylinidae) | No, not detected in samples taken in 2005. |
### Study appraisal

- Not representative formulation and contains cyfluthrin.
- Crop (orchard) is not comparable to representative uses.
- No sampling directly after the applications (no info on direct effects immediately after the treatment).

### Methodology

- Sampling: pitfall traps, visual control (beating), Vortis suction
- Statistics: univariate with treatment vs control, multivariate with PCA and PRC

### Conditions of the study

- Location: South-west France
- Time of year: May 2005-end of February 2006
- Crop: Apple orchard
- Test item: Baythroid EC 50 (50 g/L Cyfluthrin)
- Application rate:
  - 2 x 500 mL prod/ha (2 x 25 g cyfluthrin as/ha), interval 14 d
  - 2 x 78.65 mL product/ha (3.9325 g as/ha), interval 14 d
  - 2 x 18 mL product/ha (0.9 g as/ha), interval 14 d
  - 2 x 5.45 mL product/ha (0.2725 g as/ha), interval 14 d
- Statistics (univariate with treatment vs control, multivariate with PCA and PRC)

### Conclusion

The study was reasonable in terms of representativeness for an in-field environment, even if low number of species for some groups (peer review). Several issues with the reliability were noted which the RMS considered to conclude that the study was not reliable. The experts at the peer review meeting agreed with the points noted by the RMS but considered that some information can still be gained from the study. Overall, both the RMS and the peer review concluded that recovery of the affected taxa was not clearly demonstrated within 1 year of the first application.

**Author/reference:** Vinall, 2006, R-19592, KIIIA1 10.5.4/04

| Test item | Results |
|-----------|---------|
| *Tachyporus hypnorum* (Coleoptera: Staphylinidae) | Yes, numbers in treatment plots > control 349 DAT2. |
| *Tachyporus chrysomelinus* (Coleoptera: Staphylinidae) | Questionable, only low numbers detected but numbers in treatment plots > control 349 DAT2. |
| *Tachyporus* spp. larvae (Coleoptera: Staphylinidae) | No, not detected in samples taken in 2005. Note results are for larvae. |
| *Tachinus rufipes* (Coleoptera: Staphylinidae) | No, not detected in samples taken in 2005. |
| Staphylinidae larvae (Coleoptera: Staphylinidae) | No, too few detected in samples taken in 2005. Note results are for larvae. |
| Total Linyphiidae (Araneae) | Yes, numbers in treatment plots are comparable to control 349 DAT2. |
| *Erigone* spp. (Araneae: Linyphiidae) | Questionable, only low numbers detected but numbers in treatment plots > control 349 DAT2. |
| *Erigone atrata* (Araneae: Linyphiidae) | No, too few detected in samples taken in 2005. |
| *Leptophantes tenuis* (Araneae: Linyphiidae) | No, too few detected in samples taken in 2005. |
| Total Lycosidae (Araneae: Lycosidae) | Yes, numbers in treatment plots are comparable to control 349 DAT2. |
| *Pardosa pullata* (Araneae: Lycosidae) | Yes, numbers in treatment plots are comparable to control 349 DAT2. |
| *Pachygnatha degeeri* (Araneae: Tetragnathidae) | Questionable, only low numbers detected. |
| Diptera – adults (sweep nets, 33 days after 2nd treatment) | No results included for 2005. |

2.85 mL prod (2 x 0.1425 g cyfluthrin as/ha), interval 16 d

No notable effects but the applicant and RMS assessment primarily focused on the in-field application rate.

**Peer review of the pesticide risk assessment of the active substance beta-cyfluthrin**

Peer review meeting: 19.04.05 (KIIIA1 10.5.4/04)

EFSA Journal 2006;4(3):349

KIIIA1 10.5.4/04
- Only one tree per sampling date was sampled.
- The type of sampling was also questioned (knock-down sampling with other insecticide, without preventing drift to other trees).
- The ground arthropods were not sampled. Leaf sampling only counted predatory mites.
- Lack of statistical power analysis (MDD): It was pointed out that in the de Jong guidance, the lack of the MDD does not automatically translate into rejection of the study, but just affects the reliability score. Nonetheless, such information would help understand and estimate if effects are possibly obscured by low statistical power (and e.g. high variability in the control).

**Summary of result:**
2 x Baythroid EC 50 at 500 mL prod/ha (2 x 25 g cyfluthrin as/ha), interval 14 d

| Taxa for which recovery was not demonstrated by the study end (149 days after 2nd application) | Comment |
|---|---|
| Lauxaniidae (Diptera) | Numbers in control declined. |
| Cicadellidae | Numbers in the treatment remained notable lower than the control. |
| Cimicidae | Numbers in control declined. |
| Cixiidae | Numbers in control declined. |
| Larval Coccinellidae (Coleoptera) | Numbers in control declined. Note, results are for larvae |
| Tachyporus spp. (Coleoptera: Staphylinidae) | Questionable, low numbers. |
| THYSANOPTERA | Unclear. 85 DAT2, the numbers in the treatment were higher than the control but for all other sample dates the numbers were notably higher in the control including a statistically significant difference on the final sampling date. |
| ACARI - Trombididae | Numbers in control declined. |

**Drift rates**
The results were not concluded on owing to the lack of representativeness for the off-field environments in arable crops.

**Conclusion of the RMS and peer review:**
According to the peer review and RMS, the study had methodological issues and therefore the results are not fully reliable. The experts agreed that the study was not comparable to the representative uses.

**Author/reference:** Mack, 2014, R-30607, KIIIA1 10.5.4/07

**Conditions of the study:**
Location: Germany
Time of year: end of June-beginning of August,
Crop: meadow
Test item: Bulldock 25 EC (25 g/L beta-cyfluthrin)
Application rate:
1 x 240 mL prod/ha (1 x 6 g as/ha)
1 x 64 mL product/ha (1.6 g as/ha)
1 x 16 mL product/ha (0.4 g as/ha)
1 x at 4 mL product/ha (0.1 g as/ha)

**Methodology:**
Sampling: pitfall traps, photoeclectors, Vortis suction
Statistics: univariate with treatment vs control applied on abundances on individual taxon level, higher taxonomic groups and total abundance for each sampling occasion, multivariate with PCA and PRC for community analysis

**Study appraisal:**
- Representative arthropod composition: There are important groups missing, but the spiders were present (most sensitive group) and sufficient for performing stats. Taxonomic resolution was
acceptable. Still, according to de Jong et al. (2010) a much higher number of taxa/orders should be available since it is supposedly to represent an off-crop habitat.

- Representativeness of the experimental area (mowed meadow) for off-field conditions is questionable.
- Low diversity of taxa and a low abundance of individuals per taxa were observed. The abundance of the sampled (statistically evaluated) taxa few days (-2 and -3 days) before treatment is very low for several species and rises during the study course (especially in the control). Therefore possible short-term effects right after application (typical for knock-out effects usually caused by pyrethroids) might stay undetectable.
- Several reasons for the low general diversity in the plots as well as for the relatively low abundance of sampled taxa before treatment start might be discussed.
- Agricultural measures are not in line with natural off-crops (like natural meadows).
- Concerns were also noted with the study design. For this reason it cannot distinguish between recolonisation and real recovery.
  - Plots are regarded as too small (0.09 ha/plot). In contrast de Jong et al. (2010) recommends a minimum plot area of 1 ha.
  - The distance between plots of 10 m is regarded as too close to exclude a recolonisation from less exposed plots and/or control plots to higher treated plots instead of a real recovery.

Summary of results:
At the population level several taxa were considered adversely affected by treatment with beta-cyfluthrin at the rates 1.6 g as/ha and 6.0 g as/ha. For both rates, respectively one taxon (Cicadellidae) did not recover within the sampling period.
No NOER for population effects demonstrated.

Conclusion of the RMS and peer review:
The RMS considered that the study should be considered as not reliable particularly because of the poor species composition and the low abundance of many taxa. The experts at the meeting agreed with the RMS’s concerns but did not consider that the study was totally unreliable.
Effects on non-target soil meso- and macro fauna; effects on soil nitrogen transformation (Regulation (EU) N° 283/2013, Annex Part A, points 8.4, 8.5, and Regulation (EU) N° 284/2013 Annex Part A, points 10.4, 10.5)

| Test organism | Test substance | Application method of test as/OM | Time scale | End point | Toxicity |
|---------------|----------------|----------------------------------|------------|-----------|----------|
| Earthworms    |                |                                  |            |           |          |
| *Eisenia fetida* | Bullock EC 25 | test item was mixed into soil/10% OM | Chronic | reproduction | NOEC: 60 mg product/kg soil EC<sub>10</sub>: 45.2 mg product/kg soil EC<sub>20</sub>: 67.8 mg product/kg soil NOEC: 1.65 mg a.s./kg soil NOEC<sub><sup>CORR</sup></sub>: 0.825 mg a.s./kg soil |
| *Eisenia fetida* | Montur Forte FS230 | test item was mixed into soil/5% OM | Chronic | reproduction | NOEC = 1.78 mg product/kg dw soil EC<sub>10</sub> = 1.88 mg product/kg dw soil EC<sub>20</sub> = 4.19 mg product/kg dw soil NOEC<sub><sup>CORR</sup></sub> = 0.89 mg product/kg dw soil |
| *Eisenia fetida* | FPB-acid       | test item was mixed into soil/10% OM | Chronic | reproduction | NOEC: 5.2 mg/kg soil<sup>+</sup> NOEC<sub><sup>CORR</sup></sub>: 2.6 mg/kg soil |
| *Eisenia fetida* | DCVA           | test item was mixed into soil/10% OM | Chronic | reproduction | NOEC: 5.2 mg/kg soil<sup>+</sup> NOEC<sub><sup>CORR</sup></sub>: 2.6 mg/kg soil |

Other soil macroorganisms
| Test organism   | Test substance | Application method of test as/OM | Time scale | End point          | Toxicity                                                                 |
|----------------|----------------|---------------------------------|------------|--------------------|--------------------------------------------------------------------------|
| Folsomia candida | beta-cyfluthrin | test item was mixed into soil/5% OM | Chronic    | reproduction       | NOEC = 56 mg/kg dw soil a NOEC<sub>CORR</sub> = 28 mg/kg dw soil          |
| Folsomia candida | Buldock EC 25  | test item was mixed into soil/5% OM | Chronic    | reproduction       | NOEC = 55.6 mg product/kg soil dw EC<sub>10</sub> = 6.1 mg product/kg soil dw EC<sub>20</sub> = 13.4 mg product/kg soil dw EC<sub>10</sub> = 0.1525 mg a.s./kg soil dw EC<sub>10</sub><sub>CORR</sub> = 0.076 mg a.s./kg soil dw |
| Folsomia candida | Montur Forte FS 230 | test item was mixed into soil/5% OM | Chronic    | reproduction       | NOEC: 4.6 mg product/kg soil EC<sub>10</sub>: 3.6 mg product/kg soil EC<sub>20</sub>: 4.8 mg product/kg soil EC<sub>10</sub><sub>CORR</sub>: 1.8 mg product/kg soil |
| Folsomia candida | FPB-acid       | test item was mixed into LUFA 2.1 soil/5% OM | Chronic    | reproduction       | NOEC = 28 mg/kg dw soil NOEC<sub>CORR</sub> = 14 mg/kg dw soil            |
| Folsomia candida | DCVA           | test item was mixed into soil/5% OM | Chronic    | reproduction       | NOEC = 18 mg/kg dw soil (EC<sub>10</sub> = 18.3 mg/kg dw soil, EC<sub>20</sub> = 24.1 mg/kg dw soil) NOEC<sub>CORR</sub> = 9 mg/kg dw soil |
| Test organism | Test substance | Application method of test as/OM | Time scale | End point | Toxicity |
|---------------|----------------|----------------------------------|------------|-----------|----------|
| Hypoaspis aculeifer | beta-cyfluthrin | test item was mixed into soil/5% OM | Chronic | reproduction | NOEC = 0.97 mg/kg dw soil (EC\textsubscript{10} = 1.62 mg/kg dw soil, EC\textsubscript{20} = 2.97 mg/kg dw soil) NOEC\textsubscript{CORR} = 0.485 mg/kg dw soil |
| Hypoaspis aculeifer | Bulldock EC 25 | test item was mixed into soil/5% OM | Chronic | reproduction | NOEC = 122.44 mg product/kg soil dw EC\textsubscript{10} > 122.44 mg product/kg soil dw NOEC = 3.159 mg a.s./kg soil NOEC\textsubscript{CORR} = 1.58 mg a.s./kg soil |
| Hypoaspis aculeifer | Montur Forte FS 230 | test item was mixed into soil/5% OM | Chronic | reproduction | NOEC = 32 mg/product/kg soil dw EC\textsubscript{10} > 32 mg product/kg soil dw NOEC\textsubscript{CORR} = 16 mg product/kg soil dw |
| Hypoaspis aculeifer | FPB-acid | test item was mixed into LUFA 2.1 soil/ < 5% OM assumed | Chronic | reproduction | NOEC = 297 mg/kg soil NOEC\textsubscript{CORR} = 148.5 mg/kg soil |
| Hypoaspis aculeifer | DCVA | test item was mixed into soil/5% OM | Chronic | mortality | NOEC = 100 mg/kg soil dw NOEC\textsubscript{CORR} = 100 mg/kg soil dw |

* EC\textsubscript{10}/EC\textsubscript{20} calculations not possible – could not be reliably estimated due to the lack of adequate concentration-response relationship

Higher tier testing (e.g. modelling or field studies) no studies

Nitrogen transformation | beta-cyfluthrin | max. field rate/soil concentration: | at 180 g/ha < 25% effect at day 0-28
### Nitrogen transformation

| Nitrogen transformation | Test item | max. field rate/soil concentration: | TER | Trigger |
|-------------------------|-----------|------------------------------------|-----|---------|
| Bulldock EC 25          | beta-cyfluthrin (Bulldock 25 EC) | 2 x 0.5 L prod./ha (2x 12.5 g as/ha) | 9.61 mg/kg dry soil, corresponding to 8.0 L test item/ha (200 mg as/ha) | < 25 % effect at day 0-28 |
| Montur Forte            | FPB-acid  | max. field rate/soil concentration: 0.196 mg product/kg dry soil | 0.98 mg/kg dry soil | < 25 % effect at day 0-28 |
| FPB-acid                | DCVA      | max. field rate/soil concentration: 0.0047 mg/kg dry soil (max. value for Bulldock EC 25) 0.001 mg/kg dry soil (Montur Forte FS 230) | 0.125 mg/kg dry soil corresponding to 94 g/ha | < 25 % at day 0-28 |
| DCVA                    |           | max. field rate/soil concentration: 0.0047 mg/kg dry soil (max. value for Bulldock EC 25) 0.001 mg/kg dry soil (Montur Forte FS 230) | 0.112 mg/kg dry soil | < 25 % at day 0-28 |

### Toxicity/exposure ratios for soil organisms

**Bulldock EC 25: wheat. 2x12.5 g as/ha, interception: 25%. 14 d**

| Species             | Test item          | Time scale | Max. PECsoil [mg/kg soil dw] | TER  | Trigger |
|---------------------|--------------------|------------|------------------------------|------|---------|
| *Eisenia fetida*    | beta-cyfluthrin    | Chronic    | 0.0213                       | 26.5 | 5       |
| FPB-acid            | Chronic            | 0.0025     | 1040                         |      |         |
| DCVA                | Chronic            | 0.042      | 61.9                         |      |         |
| *Folsomia candida*  | beta-cyfluthrin    | Chronic    | 0.0213                       | 1314.6 | 5   |
| FPB-acid            | Chronic            | 0.0025     | 11200                        |      |         |
| DCVA                | Chronic            | 0.042      | 214.3                        |      |         |
| *Hypoaspis aculeifer* | beta-cyfluthrin  | Chronic    | 0.0213                       | 3.6  | 5       |
| FPB-acid            | Chronic            | 0.0025     | 59400                        |      |         |
| DCVA | Chronic | 0.042 | 2381 | 5 |
| beta-cyfluthrin (Bulldock 25 EC) | Chronic | 0.0213 | 74.2 | 5 |

**Bulldock EC 25: potatoes, 2x12.5 g as/ha interception: 15 %. 14 d**

| Species | Test item | Time scale | Max. PEC_{SOIL} [mg/kg soil dw] | TER | Trigger |
|---------|-----------|------------|---------------------------------|------|---------|
| *Eisenia fetida* | beta-cyfluthrin (Bulldock 25 EC) | Chronic | 0.0242 | 23.3 | 5 |
| | FPB-acid | Chronic | 0.0028 | 929 | 5 |
| | DCVA | Chronic | 0.0047 | 553 | 5 |
| *Folsomia candida* | beta-cyfluthrin | Chronic | 0.0242 | 1157 | 5 |
| | FPB-acid | Chronic | 0.0028 | 10000 | 5 |
| | DCVA | Chronic | 0.0047 | 1914.9 | 5 |
| | beta-cyfluthrin (Bulldock 25 EC) | Chronic | 0.0242 | 3.1 | 5 |
| *Hypoaspis aculeifer* | beta-cyfluthrin | Chronic | 0.0242 | 20.0 | 5 |
| | FPB-acid | Chronic | 0.0028 | 53036 | 5 |
| | DCVA | Chronic | 0.0047 | 21277 | 5 |
| | beta-cyfluthrin (Bulldock 25 EC) | Chronic | 0.0242 | 65.3 | 5 |

**Bulldock EC 25: tomatoes greenhouse. 2 x 17.5 g as/ha, interception: 50 %. 14 d**

| Species | Test item | Time scale | Max. PEC_{SOIL} [mg/kg soil dw] | TER | Trigger |
|---------|-----------|------------|---------------------------------|------|---------|
| *Eisenia fetida* | beta-cyfluthrin (Bulldock 25 EC) | Chronic | 0.0199 | 28.4 | 5 |
| | FPB-acid | Chronic | 0.0014 | 1857 | 5 |
| | DCVA | Chronic | 0.0030 | 867 | 5 |
| *Folsomia candida* | beta-cyfluthrin | Chronic | 0.0199 | 1407 | 5 |
| | FPB-acid | Chronic | 0.0014 | 3286 | 5 |
| | DCVA | Chronic | 0.0030 | 3000 | 5 |
| | beta-cyfluthrin (Bulldock 25 EC) | Chronic | 0.0199 | 3.8 | 5 |
| *Hypoaspis aculeifer* | beta-cyfluthrin | Chronic | 0.0199 | 24.4 | 5 |
| | FPB-acid | Chronic | 0.0014 | 106071 | 5 |

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| Species               | Test item                                      | Time scale | Max. PEC_{SOIL} [mg/kg soil dw] | TER | Trigger |
|-----------------------|------------------------------------------------|------------|---------------------------------|-----|---------|
| *Eisenia fetida*      | beta-cyfluthrin + imidacloprid FS 230         | Chronic    | 0.196^A                         | 4.5 | 5       |
|                       | beta-cyfluthrin                               | Chronic    | 0.014                           | 40.4^B | 5     |
|                       | FBP-acid                                      | Chronic    | 0.003                           | 867 | 5       |
|                       | DCVA (permethrin acid)                        | Chronic    | <0.001                          | >2600 | 5     |
| *Folsomia candida*    | beta-cyfluthrin                               | Chronic    | 0.014                           | 2000 | 5       |
|                       | beta-cyfluthrin + imidacloprid FS 230         | Chronic    | 0.196^A                         | 9.2 | 5       |
|                       | FBP-acid                                      | Chronic    | 0.003                           | 9330 | 5     |
|                       | DCVA (permethrin acid)                        | Chronic    | <0.001                          | >9000 | 5     |
| *Hypoaspis aculeifer* | beta-cyfluthrin                               | Chronic    | 0.014                           | 34.6 | 5       |
|                       | beta-cyfluthrin + imidacloprid FS 230         | Chronic    | 0.196^A                         | 81.6 | 5     |
|                       | FBP-acid                                      | Chronic    | 0.003                           | 49500 | 5     |
|                       | DCVA (permethrin acid)                        | Chronic    | <0.001                          | >100000 | 5     |

^A Product PEC_{SOIL} based on a product density of 1.13 kg/L, a dose rate of product of 0.13 L/ha (considering a sowing rate of 130000 seeds/ha) and standard soil parameters (soil layer of 5 cm with a bulk density of 1.5 g/cm^3).

^B No toxicity data for the parent substance beta-cyfluthrin is available. Therefore a risk assessment was presented for illustrative purposes using the endpoint in terms of active substance from the product 'Bulldock 25 EC' (EC_{10} CORR: 0.565 mg a.s./kg soil).
Effects on terrestrial non target higher plants (Regulation (EU) N° 283/2013, Annex Part A, point 8.6 and Regulation (EU) N° 284/2013 Annex Part A, point 10.6)

Screening data

| Test substance | Species | ER$_{50}$ (g as/ha) vegetative vigour | ER$_{50}$ (g as/ha) emergence | Exposure (g as/ha) | TER | Trigger |
|----------------|---------|--------------------------------------|-----------------------------|-------------------|-----|---------|
| <60            | Green cabbage (Brassica oleracea var. sabellica) | >60  | 0.346 | >173 | 5   |
| >60            | Cucumber (Cucumis sativa) | >60  | 0.346 | >173 | 5   |
| >60            | Carrot (Daucus carota) | >60  | 0.346 | >173 | 5   |
| >60            | Lacy phacelia (Phacelia tanacetifolia) | >60  | 0.346 | >173 | 5   |
| >60            | Sunflower (Helianthus annuus) | >60  | 0.346 | >173 | 5   |
| >60            | Flax (Linum usitatissimum) | >60  | 0.346 | >173 | 5   |
| >60            | Onion (Allium cepa) | >60  | 0.346 | >173 | 5   |
| >60            | Rye grass (Lolium multiflorum) | >60  | 0.346 | >173 | 5   |
| >60            | Barley (Hordeum vulgare) | >60  | 0.346 | >173 | 5   |
| >60            | Erect brome (Bromus erectus) | >60  | 0.346 | >173 | 5   |

Extended laboratory studies:

Semi-field and field test:
Effects on biological methods for sewage treatment (Regulation (EU) N° 283/2013, Annex Part A, point 8.8)

| Test type/organism | end point                  |
|-------------------|----------------------------|
| Activated sludge  | 30 min EC$_{50} > 10000$mg/L |

Monitoring data (Regulation (EU) N° 283/2013, Annex Part A, point 8.9 and Regulation (EU) N° 284/2013, Annex Part A, point 10.8)

Available monitoring data concerning adverse effect of the as: no data available

Available monitoring data concerning effect of the PPP: no data available

Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2) Ecotoxicologically relevant compounds

| Compartment | constituent isomers of beta-cyfluthrin |
|-------------|---------------------------------------|
| soil        | constituent isomers of beta-cyfluthrin |
| water       | constituent isomers of beta-cyfluthrin |
| sediment    | constituent isomers of beta-cyfluthrin |
| groundwater | constituent isomers of beta-cyfluthrin |

1 metabolites are considered relevant when, based on the risk assessment, they pose a risk comparable or higher than the parent

Classification and labelling with regard to ecotoxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)

| Substance | beta-cyfluthrin |
|-----------|-----------------|
| Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]⁶: |
| GHS09     | Aquatic Acute 1 |
| H400      | Aquatic Chronic 1 |

Peer review proposal⁷ for harmonised classification according to Regulation (EC) No 1272/2008:

| GHS09     | Aquatic Acute 1 |
| H400      | M-factor acute = 100000 |
| H410      | Aquatic Chronic 1 |
|           | M-factor chronic = 100000 |

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⁶ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

⁷ It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.