Appendix to:

EFSA (European Food Safety Authority), 2017. Conclusion on the peer review of the pesticide risk assessment of the active substance etoxazole. EFSA Journal 2017;15(15):4988, 31 pp. doi:10.2903/j.efsa.2017.4988

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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) No 283/2013, Annex Part A, points 1.3 and 3.2)

| Active substance (ISO Common Name) | Etoxazole (BSI, ISO) |
|-----------------------------------|---------------------|
| Function (e.g. fungicide)         | Acaricide           |
| Rapporteur Member State           | Greece              |
| Co-rapporteur Member State        | United Kingdom      |

Identity (Regulation (EU) No 283/2013, Annex Part A, point 1)

| Chemical name (IUPAC)            | (RS)-5-tert-butyl-2-[2-(2,6-difluorophenyl)-4,5-dihydro-1,3-oxazol-4-yl]phenetole |
|----------------------------------|-------------------------------------------------------------------------------|
| Chemical name (CA)               | 2-(2,6-difluorophenyl)-4-[4-(1,1-dimethylethyl)-2-ethoxyphenyl]-4,5-dihydrooxazole |
| CIPAC No                         | 623                                                                           |
| CAS No                           | 153233-91-1                                                                  |
| EC No (EINECS or ELINCS)         | Not allocated                                                                 |
| FAO Specification (including year of publication) | None                                                                          |
| Minimum purity of the active substance as manufactured | min. 948g/kg                                                                 |
| Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured | None                                                                          |
| Molecular formula                | C_{21}H_{23}F_{2}NO_{2}                                                      |
| Molar mass                       | 359.42 g/mol                                                                 |
| Structural formula               | ![Structural formula](image)                                                |
### Physical and chemical properties (Regulation (EU) No 283/2013, Annex Part A, point 2)

| Property                                           | Value/Description                                                                 |
|----------------------------------------------------|-----------------------------------------------------------------------------------|
| **Melting point (state purity)**                   | 101.5 - 102.5°C (99.85% pure)                                                    |
| **Boiling point (state purity)**                   | The boiling point cannot be determined due to decomposition of etoxazole.        |
| **Temperature of decomposition (state purity)**    | Decomposed (as indicated by discoloration), at about 293°C (99.86% pure)         |
| **Appearance (state purity)**                      | Pure: White, free flowing, crystalline powder at 20°C (99.85% pure)              |
|                                                    | Active substance as manufactured: white lumpy powder at 20°C (95.4 %, technical)  |
| **Vapour pressure (state temperature, state purity)** | 7.0 x 10^{-6} Pa at 25°C (99.85% pure)                                           |
| **Henry’s law constant (state temperature)**       | 3.6 x 10^{-2} Pa.m^3/mole at 20 – 25°C                                          |
| **Solubility in water (state temperature, state purity and pH)** | 7.04 x 10^{-5} g/l in distilled water at 20°C (99.85% pure)                     |
|                                                    | 6.69 x 10^{-5} g/l in distilled water at 30°C (99.85% pure)                     |
|                                                    | The effect of pH was not determined as the test material has no ionisable groups or dissociation constant. |
| **Solubility in organic solvents** (state temperature, state purity) | Acetone: 309 g/l at 20°C                                                        |
|                                                    | 1,2-dichloroethane: 402 g/l at 20°C                                              |
|                                                    | Ethyl acetate: 249 g/l at 20°C                                                   |
|                                                    | n-heptane: 18.7 g/l at 20°C                                                      |
|                                                    | Methanol: 104 g/l at 20°C                                                       |
|                                                    | Xylene: 252 g/l at 20°C                                                         |
|                                                    | (95.4 %, technical)                                                              |
| **Surface tension** (state concentration and temperature, state purity) | Not applicable (solid with low water solubility).                               |
| **Partition coefficient** (state temperature, pH and purity) | Log Pow = 5.52 ± 0.58 at 20°C (99.85% pure)                                    |
|                                                    | The effect of pH was not determined as the test material has no ionisable groups or dissociation constant. |
| **Dissociation constant (state purity)**           | Not measurable (99.85 % pure)                                                   |
UV/VIS absorption (max.) incl. \( \varepsilon \) (state purity, pH)

| Solution Type                          | \( \lambda_{\text{max}} \) (\( \varepsilon \)) | \( \lambda_{\text{max}} \) (\( \varepsilon \)) |
|----------------------------------------|-----------------------------------------------|-----------------------------------------------|
| Neutral solution (methanol)            | 220 nm (17379 L mol\(^{-1}\) cm\(^{-1}\))     | 222.5 nm (16670 L mol\(^{-1}\) cm\(^{-1}\))    |
| Acidic solution (methanol/HCl)         |                                               |                                               |
| Alkaline solution (methanol/NaOH)      |                                               |                                               |

No absorption between 300 and 350 nm.

* RMS EL has noticed that in the UV spectrum in alkaline solution in the study of DAR (Betteley, 1997), a peak (the highest) at about 219nm was observed in the spectrum, however, this peak was not mentioned in the study results (neither data on its molar extinction coefficient (\( \varepsilon \)) were provided).

UV/vis spectra (recorded between 190-750 nm) (99.64% pure):

| Solution Type                          | \( \lambda_{\text{max}} \) (\( \varepsilon \)) | \( \lambda_{\text{max}} \) (\( \varepsilon \)) |
|----------------------------------------|-----------------------------------------------|-----------------------------------------------|
| Unadjusted solution (methanol)         | 219.33 nm (18351 L mol\(^{-1}\) cm\(^{-1}\)) |                                               |
| At \( \lambda = 290 \) nm, \( \varepsilon \) = 387 L mol\(^{-1}\) cm\(^{-1}\) |                                               |                                               |
| Acidic solution (methanol/HCl)         | 224.66 nm (25789 L mol\(^{-1}\) cm\(^{-1}\)) |                                               |
| At \( \lambda = 290 \) nm, \( \varepsilon \) = 3859 L mol\(^{-1}\) cm\(^{-1}\) |                                               |                                               |
| Basic solution (methanol/NaOH)         | 221.19 nm (20195 L mol\(^{-1}\) cm\(^{-1}\)) |                                               |
| At \( \lambda = 290 \) nm, \( \varepsilon \) = 390 L mol\(^{-1}\) cm\(^{-1}\) |                                               |                                               |

Flammability (state purity) Not flammable (95.4% technical)

Explosive properties (state purity) Not explosive (95.4% technical)

Oxidising properties (state purity) It is not considered as an oxidising substance (95.4% technical)
### Summary of representative uses evaluated, for which all risk assessments needed to be completed (name of active substance or the respective variant)
(Regulation (EU) No 284/2013, Annex Part A, points 3, 4)

| Crop and/or situation (a)       | Memb er State or Countr y | Product name | F G or I (b) | Pests or Group of pests controlled (c) | Preparation | Application | Application rate per treatment | PHI (day s) (m) | Remarks |
|---------------------------------|---------------------------|--------------|--------------|----------------------------------------|-------------|------------|--------------------------------|----------------|---------|
| Pome fruit                      | SEU/NEU                   | ETOX AZOLE 11 SC' | F           | mites                                  | SC          | Foliar application from infestation | 1 Not applicable | 0.0027-0.011 | 500-1500 | Max 0.055 | 28 | - |
| Plum                            | SEU/NEU                   | ETOX AZOLE 11 SC' | F           | mites                                  | SC          | Foliar application from infestation until BBCH 77 | 1 Not applicable | 0.0027-0.005 | 500-1500 | Max 0.055 | 42 (N), 3(S) | - |
| Peach, nectarine, apricot       | SEU                       | ETOX AZOLE 11 SC' | F           | mites                                  | SC          | Foliar application from infestation | 1 Not applicable | 0.0027-0.0011 | 500-1500 | Max 0.055 | 14 | - |
| Cherry                          | SEU                       | ETOX AZOLE 11 SC' | F           | mites                                  | SC          | Foliar application from infestation | 1 Not applicable | 0.0025-0.0055 | 1000-1400 | Max 0.055 | 3 | - |
| Citrus                          | SEU                       | ETOX AZOLE 11 SC' | F           | mites                                  | SC          | Foliar application from infestation | 1 Not applicable | 0.0014-0.0092 | 600-3000 | Max 0.055 | 14 | - |
| Grape                           | SEU/NEU                   | ETOX AZOLE    | F           | mites                                  | SC          | Foliar application from infestation | 1 Not applicable | 0.0027-0.00275 | 150-1000 | Max 0.0275 | 28 | - |
| Plant | Origin | Active substance | Formulation | Active concentration | Application timing | FRAC code | Crop protection | Max application rate | Comments |
|-------|--------|------------------|-------------|----------------------|-------------------|------------|----------------|------------------|----------|
| Grape | SEU/NEU | ETOX AZOL E 11 SC’ | F mites SC 110 g/L | Foliar application from infestation until BBCH 79 | 1 | Not applicable | 0.0027 - 0.0366 | 150-200 Max 0.055 | 110 |
| Cotton | SEU | ETOX AZOL E 11 SC’ | F mites SC 110 g/L | Foliar application before boll opening, upon appearance of the first mobile stages | 1 | Not applicable | 0.0033 - 0.00825 | 500-800 Max 0.04125 | 35 |
| Tomato/Eggplant | SEU | ETOX AZOL E 11 SC’ | F mites SC 110 g/L | Foliar application from infestation - until BBCH 89 | 1 | Not applicable | 0.0027 - 0.0275 | 200-1500 Max 0.055 | 3 |
| Cucumber edible peel | SEU | ETOX AZOL E 11 SC’ | F mites SC 110 g/L | Foliar application from infestation - until BBCH 89 | 1 | Not applicable | 0.0027 - 0.0275 | 200-1000 Max 0.055 | 3 |
| Strawberry | SEU/NEU | ETOX AZOL E 11 SC’ | F mites SC 110 g/L | Foliar application from infestation - until BBCH 89 | 1 | Not applicable | 0.0027 - 0.0275 | 200-1500 Max 0.055 | 3 |
| Ornamental plants | SEU/NEU | ETOX AZOL E 11 SC’ | F mites SC 110 g/L | Foliar application from infestation | 1 | Not applicable | 0.0037 - 0.0055 | 1000-1500 max 0.055 | n.a. |
| Tomato/Eggplant | NEU/SEU | ETOX AZOL | G mites SC 110 g/L | Foliar application from infestation | 1 | Not applicable | 0.0027 - 0.0275 | 200-2000 max 0.055 | 3 |
| Fruit        | NEU/SEU | E 11 SC’ | SC | 110 g/L | Foliar application | until BBCH 89 | 1 | Not applicable | 0.0027 | 200-1500 | max 0.055 | 3 | - |
|--------------|---------|----------|----|---------|--------------------|--------------|---|----------------|--------|---------|----------|---|---|
| Strawberry   | NEU/SEU | ETOXAZOLE 11 SC’ | G  mites | SC | 110 g/L | Foliar application | from infestation - until BBCH 89 | 1 | Not applicable | 0.0027 | 200-1500 | max 0.055 | 3 | - |
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) N° 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 or G or I (b) | Pests or Group of pests controlled (c) | Preparation | Application | Application rate per treatment | PHI (days) (m) | Remarks |
|--------------------------|-------------------------|--------------|----------------|--------------------------------------|-------------|------------|-------------------------------|---------------|---------|
|                          |                         |              |                |                                      | Type (d-f)  | Conc. a.s. (i) | method kind (f-h) | range of growth stages & season (j) | number min-max (k) | Interval between application (min) | kg a.s./ha min-max (l) | Water L/ha min-max | kg a.s./ha min-max (l) | |
| **MRL Application** (according to Article 8.1(g) of Regulation (EC) No 1107/2009) |                          |              |                |                                      |             |             |                               |               |         |
| **Not relevant**         |                         |              |                |                                      |             |             |                               |               |         |

(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. fluoroxypyr). 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)

| Considering that the substance is approved and also that plant protection products containing etoxazole have been evaluated according to Uniform Principles, no other efficacy documentation is deemed to be necessary at this stage. |
| More detailed evaluation will be made in the context of subsequent applications for products authorisation. |

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

| No data were submitted. However, considering that the substance is approved and also that plant protection products containing etoxazole have been evaluated according to Uniform Principles, no other efficacy documentation is deemed to be necessary at this stage. |
| More detailed evaluation will be made in the context of subsequent applications for products authorisation. |

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

| No data were submitted. However, considering that the substance is approved and also that plant protection products containing etoxazole have been evaluated according to Uniform Principles, no other efficacy documentation is deemed to be necessary at this stage. |
| More detailed evaluation will be made in the context of subsequent applications for products authorisation. |

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

| Activity against target organism |
| For representative uses, no metabolites trigger consideration. |
| - |
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 a.s. (analytical technique) | Validated method VAM-15o-001: int. std HPLC-UV 254 nm |
|---------------------------------------|----------------------------------------------------------|
| Impurities in technical a.s. (analytical technique) | Validated method VAM-15p-001 for the specified impurities: HPLC-UV and GC-FID |
| Plant protection product (analytical technique) | Validated HPLC/UV 270nm |

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 | Etoxazole (sum of isomers) – restricted to fruit crops, pulses and oilseeds - Foliar application. |
|----------------------|--------------------------------------------------------------------------------------------------|
| Food of animal origin| Not proposed and not required for the representative uses. |
| Soil                | Etoxazole |
| Sediment            | Etoxazole |
| Water surface       | Etoxazole |
| drinking/ground     | Etoxazole |
| Air                 | Etoxazole (sum of isomers) |
| Body fluids and tissues| Etoxazole (sum of isomers) |

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)

| GC/MS method [based on the multi residue method L 00.00-34 (extented and revised version of the DFG method S19)] |
|---------------------------------------------------------------------------------------------------------------|
| Substrates: melon (with extraction module E1) |
| Analysis: GC-MS (m/z 204) |
| Determined analyte: etoxazole |
| LOQ: 0.01mg/kg for melon |
| Method fully validated (reference CA 4.2/02) |
| Confirmation by monitoring two additional ions with m/z>100 (m/z 141 & m/z 300) in melon, providing also their validation data. (reference CA 4.2/02) |
| ILV submitted for apples (with extraction module E3 instead of E1 i.e. with addition of sodium hydrogen carbonate prior to extraction to adjust the pH at least 8): |
| Substrates: apples |
**Analysis:** GC-MS (m/z 204)

**Determined analyte:** etoxazole

**LOQ:** 0.01 mg/kg for apples

Method fully validated (reference CA 4.2/04)

Confirmation by monitoring two additional ions with m/z > 100 (m/z 300 & m/z 187) in apples, providing also their validation data (reference CA 4.2/04)

NOTE: As declared/clarified by the applicant, although not included in the validation using melon, *the pH adjustment using sodium hydrogen carbonate should be included in the enforcement method for crops with high water content as a precaution*, as a number of crops in this group are also acidic. The acceptable recoveries from the study demonstrate that the pH adjustment was not necessary for melon, but the pH adjustment was included in the high water ILV (apple).

**GC-MS method**

[based on the multi residue method L 00.00-34 (extended and revised version of the DFG method S19)]:

**Substrates:** mandarin pulp and peel (with extraction module E3)

**Analysis:** GC-MS (m/z 204)

**Determined analyte:** etoxazole

**LOQ:** 0.01 mg/kg for mandarin pulp and peel

Method fully validated (reference CA 4.2/03)

Confirmation: For the confirmation ions m/z 141, m/z 187 and m/z 300 no validation data were provided within the study CA 4.2/03.

However, the validation data in the study conducted with apple (using m/z 300 & m/z 187 as confirmatory) (reference CA 4.2/04) can be acceptable as confirmatory data for high acid content matrices, given that the watery matrix (apple) was extracted at a controlled pH (pH ≥ 8) (extraction module E3).

ILV submitted for mandarin pulp (with extraction module E3):

**Analysis:** GC-MS (m/z 204)

**Determined analyte:** etoxazole

**LOQ:** 0.01 mg/kg for mandarin pulp

Method fully validated (reference CA 4.2/05)

**LC-MS/MS method**

[based on the multi residue analytical method L 00.00-115 (QuEChERS)]:

### Substrates

- **hops (dry cones) and wheat grain.**

#### Analysis

- LC-MS/MS (m/z → m/z: 360→141)

#### Determined analyte

- etoxazole

#### LOQ: 0.01mg/kg for hops (dry cones) and wheat grain.

- Method fully validated (reference CA 4.2/01)

- Confirmation by monitoring a second mass transition, (m/z → m/z: 360→113), providing also validation data. (reference CA 4.2/01)

### ILV submitted for hops (dry cones) and wheat grain:

- **Analysis:** LC-MS/MS (m/z → m/z: 360→141)

- **Determined analyte:** etoxazole

- **LOQ:** 0.01mg/kg for hops (dry cones) and wheat grain

- Method fully validated (reference CA 4.2/04)

- A fully validated monitoring method for high oil content commodities should be submitted (included confirmatory and ILV data) (data gap).

### Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)

#### LC-MS/MS method

- (Derived from the multi residue analytical method QuEChERS (EN 15662)):

#### Substrates: milk, meat, liver, egg and fat.

#### Analysis

- LC-MS/MS (m/z → m/z: 360→141)

#### Determined analyte: etoxazole

#### LOQ: 0.01mg/kg for milk, meat, liver, egg and fat.

- Method fully validated (reference CA 4.2/06)

- Confirmation for milk, meat, liver, egg and fat by monitoring a second mass transition, (m/z → m/z: 360→113), providing also validation data. (reference CA 4.2/06)

### ILV submitted for liver and fat:

- **Analysis:** LC-MS/MS (m/z → m/z: 360→141)

- **Determined analyte:** etoxazole

- **LOQ:** 0.01mg/kg for liver and fat.

- Method fully validated (reference CA 4.2/07)

### Soil (analytical technique and LOQ)

#### LC-MS/MS method:

#### Substrate: soil

#### Analysis

- LC-MS/MS (m/z → m/z: 360→113)

#### Determined analyte: etoxazole

#### LOQ: 0.004 mg/kg for soil

- Method fully validated (reference CA 4.2/08)

- Confirmation for soil by monitoring a second mass transition, (m/z → m/z: 360→141), providing also validation data. (reference CA 4.2/08)
### Water (analytical technique and LOQ)

| ILV not required for soil |
|---------------------------|
| **LC-MS/MS method:**     |
| Substrate: surface water  |
| Analysis: LC-MS/MS (m/z → m/z: 360 → 113) |
| Determined analyte: etoxazole |
| **LOQ:** 0.1µg/L in surface water |
| Method fully validated (reference CA 4.2/09) |
| Confirmation for surface water by monitoring a second mass transition, (m/z → m/z: 360 → 141), providing also validation data. (reference CA 4.2/09) |

| ILV submitted for surface water: |
|----------------------------------|
| **Analysis:** LC-MS/MS (m/z → m/z: 360 → 113) |
| **Determined analyte:** etoxazole |
| **LOQ:** 0.1µg/L in surface water |
| Method fully validated (reference CA 4.2/10) |
| Given that the method has been acceptable validated for surface water at the LOQ required for drinking water (LOQ 0.1µg/L), the method is considered acceptable (without further validation) also for drinking water. |

### Air (analytical technique and LOQ)

| **GC-NPD method:** |
|---------------------|
| **Substrate:** air |
| **Analysis:** GC/NPD |
| **Determined analyte:** etoxazole |
| **LOQ:** 0.4 µg/m³ in air |
| Method fully validated (reference CA 4.2/11) |

No confirmatory method is required for the determination of etoxazole in air (given that sufficient confirmatory methods are available for its determination in soil and water).

### Body fluids and tissues (analytical technique and LOQ)

A fully validated analytical method for monitoring purpose for analysis of the active substance and relevant metabolites in body fluids should be submitted (included confirmatory data) (data gap).

The requirement for body tissues is considered covered by the method in products of animal origin.

### Classification and labelling with regard to physical and chemical data (Regulation (EU) N° 283/2013, Annex Part A, point 10)

| Substance |
|-----------|
| Etoxazole |
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:

|                         | No classification |
|-------------------------|-------------------|

Peer review proposal ² 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 | Rapidly, 52% based on recovery in bile, urine and carcass within 48 h after single dose administration. Correction is considered appropriate for the AOEL. |
|------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Toxicokinetics                                             | Widely and rapidly distributed; Peak plasma concentrations 2-4 hrs after administration of 5 mg/kg of [14C-t-butylphenyl]etoxazole or [14C-oxazole] etoxazole. Terminal half-lives of 52.9 hours and 61.3 hours for male and female rats, respectively after administration of [14C-t-butylphenyl] etoxazole. Terminal half-lives of 71.4 hours and 88.8 hours for male and female rats, respectively after administration of [14C-oxazole] etoxazole. |
| Distribution                                               | Highest residues in the liver, GI tract and fat after 7 days |
| Potential for bioaccumulation                             | Low evidence for accumulation |
| Rate and extent of excretion                               | Rapidly excreted within 48 h, mainly via faeces |

[^14C-t-butylphenyl]etoxazole: 7.55-8.49% via urine, 86.8-88.3% via faeces within 7 days (single low dose 5 mg/kg bw);
[^14C-oxazole]etoxazole: 14.2-16.6% via urine, 77% via faeces, within 7 days (single low dose 5 mg/kg bw)
[^14C-t-butylphenyl]etoxazole (bile-cannulated rats): 40.25-53.95% via bile, 12.13-13.53% via urine, 33.99-46.55% via faeces, within 48 hrs (single low dose 5 mg/kg bw)
[^14C-oxazole]etoxazole (bile-cannulated rats): 29.80-36.80% via bile, 18.37-24.11% via urine, 39.14-50.46% via faeces, within 48 hrs (single low dose 5 mg/kg bw)

Metabolism in animals

Extensively metabolised, principally by hydroxylation of the 4,5-dihydrooxazole ring followed by cleavage of the molecule and hydroxylation of the tertiary-butyl side chain.

In vitro metabolism

M9 (R-2) major metabolite in humans and male rats. Minor metabolites in humans also detected in rats. M10 major metabolite in male and female rats. The major metabolic pathway of humans was similar to that of rats. No unique metabolites detected in humans.

Toxicologically relevant compounds (animals and plants)

Parent compound.

Toxicologically relevant compounds (environment)

Parent compound.
Peer review of the pesticide risk assessment of the active substance etoxazole

Acute toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.2)

|                          | Value                                           |
|--------------------------|-------------------------------------------------|
| Rat LD₅₀ oral            | >5000 mg/kg bw                                  |
| Rat LD₅₀ dermal          | >2000 mg/kg bw                                  |
| Rat LC₅₀ inhalation      | >1.09 mg/l (whole body, max. attainable concentration) |
| Skin irritation          | Non-irritant                                    |
| Eye irritation           | Non-irritant                                    |
| Skin sensitisation      | Non-Sensitising                                 |
| Phototoxicity           | Not phototoxic under the examined conditions*   |

* The 3T3 NRU-PT test might not be appropriate test for UVB absorbers as etoxazole.

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

| Target organ / critical effect | Value                                           |
|-------------------------------|-------------------------------------------------|
| Dog, rat, mouse: Liver        | (indications of liver toxicity)                 |
| Relevant oral NOAEL           | Dog: 90-d & 1-yr, dog: 5 mg/kg bw per day        |
|                               | Rat: 6.1 mg/kg bw per day (male).               |
|                               | Mouse:55.1 mg/kg bw per day (male).             |
| Relevant dermal NOAEL         | 28-d, rat: 100 mg/kg bw per day                 |
| Relevant inhalation NOAEL     | No data (no study required)                      |

Genotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.4)

**In vitro** studies

- Reverse gene mutation assay (*Salmonella typhimurium* and *Escherichia coli*): negative
- Mammalian cell gene mutation (Mouse lymphoma L5178Y cells): Positive (+ S9)
- *In vitro* chromosome aberration assay (Chinese hamster lung cells): negative

**In vivo** studies

- Mouse micronucleus chromosome aberration assay: negative
- Unscheduled DNA Synthesis (rat): negative
- Comet assay in rat liver and glandular stomach: negative

Photomutagenicity

No study regarding photomutagenicity submitted – not required

Potential for genotoxicity

Non-genotoxic *in vivo*

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

| Long-term effects (target organ/critical effect) | Value                                           |
|--------------------------------------------------|-------------------------------------------------|
| Rat, mouse: Liver (indications of liver toxicity)|                                                |
### Relevant long-term NOAEL

|          |            |
|----------|------------|
|          | 2-year, rat: 4 mg/kg bw per day |
|          | 18-month, mouse: 242 mg/kg bw per day |

### Carcinogenicity (target organ, tumour type)

|          |            |
|----------|------------|
|          | Rat: no tumours |
|          | Mouse: no tumours |
|          | Etoxazole is unlikely to pose a carcinogenic hazard to humans |

### Relevant NOAEL for carcinogenicity

|          |            |
|----------|------------|
|          | 2 years rat: 400 mg/kg bw per day |
|          | 18-month, mouse: 480 mg/kg bw per day |

### Reproductive toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.6)

#### Reproduction toxicity

| Reproduction target / critical effect | Parental toxicity: increased relative liver weight. |
|--------------------------------------|---------------------------------------------------|
|                                      | Reproductive toxicity: none.                      |
|                                      | Offspring toxicity: Decreased viability and slight decrease in body weight of pups. |

| Relevant parental NOAEL | 24.5 mg/kg bw per day |
|-------------------------|-----------------------|
| Relevant reproductive NOAEL | 140 mg/kg bw per day (highest dose level) |
| Relevant offspring NOAEL | 24.5 mg/kg bw per day |

### Developmental toxicity

| Developmental target / critical effect | Rat: |
|---------------------------------------|------|
|                                       | Maternal toxicity: ↓ food consumption |
|                                       | Developmental toxicity: no effects |
| Rabbit:                               | Maternal toxicity: ↓ body weight & body weight gain, ↓ food consumption; liver enlargement |
|                                       | Developmental toxicity: statistically significant increased incidence of 27 presacral vertebrae with 13th ribs |

| Relevant maternal NOAEL | Rat: 200 mg/kg bw/day |
|-------------------------|-----------------------|
| Rabbit:                 | 200 mg/kg bw/day |
| Relevant developmental NOAEL | Rat: 1000 mg/kg bw/day |
|                         | Rabbit: 200 mg/kg bw/day |

* Preliminary teratology study, rabbit

### Neurotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.7)

|          |          |
|----------|----------|
|          | Acute neurotoxicity: NOAEL rat: 2000 mg/kg b.w. |
|          | Repeated neurotoxicity: NOAEL rat: 858 mg/kg per day (males) |
|          | Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity): Not submitted; not required |


Other toxicological studies (Regulation (EU) N° 283/2013, Annex Part A, point 5.8)

**Supplementary studies on the active substance**

| Effects on immunotoxicity: |
|---------------------------|
| 4-week oral (dietary) immunotoxicity study, rat: no immuno-toxicological effects |

**Endocrine disrupting properties**

The only evidence of potential endocrine disruption properties was coming from studies in dogs where the effects on prostate were observed at the highest dose level tested; however no further evidence from other species were observed. Results from ToxCast showed no exhibit androgenic, estrogenic and thyroid activities.

**Studies performed on metabolites or impurities**

**Metabolite R-3:** acute oral toxicity in rats (LD₅₀ >5000 mg/kg bw), bacterial reverse mutation test (negative).

**Metabolite R-7 (HCl salt):** acute oral toxicity in rats (LD₅₀ >5000 mg/kg bw), bacterial reverse mutation test (negative).

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

No findings of adverse effects at the periodical examinations considered related to etoxazole production. No reports of any health problems related to the manufacturing/packaging operations from the workers, and no incident of intoxication.

Summary (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) (a) | 0.04 | rat, 2-year | 100 |
| Acute Reference Dose (ARID) (a) | Not allocated-not necessary | - | - |
| Acceptable Operator Exposure Level (AOEL) (a) | 0.03(b) | dog, 90-day and 1-year study | 100 |
| Acute Acceptable Operator Exposure Level (AAOEL) | Not allocated-not necessary | - | - |
(a) Same as previously set by EC (2004)
(b) Including correction by oral absorption of 52%.

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

Representative formulation (Etoxazole 11SC, 110 g/L).

| Etoxazole 11SC: |
|----------------|
| **In vitro human skin data (1st Tier):** |
| 0.6% for the concentrated commercial formulation (110 g/L) & |
| 26.7% for the in-use spray dilution (1:8000 – 0.014 g/L) |
| **Triple-pack in vivo rat-in vitro rat/human (2nd Tier):** |
| 0.04% for the concentrated commercial formulation (110 g/L) & |
| 5% for the in-use spray dilution (1:8000 – 0.014 g/L) |

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

Operators

| Use: |
|----------------|
| **Outdoor**: pome fruit, plum, peach, nectarine, apricot, cherry, citrus, grapes, strawberry, tomato/eggplant, cucurbit, cotton, ornamentals |
| • Tractor mounted broadcast air-assisted sprayer application outdoors to high crops: |
| German model (No PPE): 65% |
| UKPOEM (PPE): 141% |
| UKPOEM (0.04 % & 5% dermal absorption as refinement, No PPE): 39% |
| • Hand-held sprayer application outdoors to high crops: |
| German model (No PPE): 32% |
| • Tractor mounted broadcast air-assisted sprayer application outdoors to grapes: |
| German model (No PPE): 65% |
| EUROPOEM database (No PPE): 68% |
| • Hand-held sprayer application outdoors grapes: |
| German model (No PPE): 32% |
| • Tractor boom sprayer application outdoors to low crops: |
| German model (No PPE): 29% |
| UKPOEM (PPE: gloves during M&L): 28% |
| • Hand-held sprayer application outdoors to low crops: |
| UKPOEM (PPE: Gloves during M&L & gloves and impermeable coverall during A): 79% |
| **Indoor**: tomato, eggplant, strawberry |
| • Hand-held application indoors to high crops: |
| NL Glasshouse model (PPE: gloves & coverall): 17% |
Workers

| EUROPOEM II: | % of AOEL |
|-------------|-----------|
| Without PPE |           |
| (5% dermal absorption as refinement): | 44.37 |

Bystanders and residents

| Martin et al. (2008): | % of AOEL |
|-----------------------|-----------|
|                       | 10 m      |
|                       | 5 m       |
|                       | 3 m       |
| Bystander (adult):    | 9.6       |
| Bystander (child):    | 7.5       |
| Resident (adult):     | 0.7       |
| Resident (child):     | 1.0       |

| UK Approach: | % of AOEL |
|--------------|-----------|
| Bystander exposure to vapour (adult) | 13 |
| Bystander exposure to vapour (child) | 28 |
| Bystander exposure to spray drift (adult) | 20 |
| Children’s/Residents’ exposure to fallout (grapes) | 1 |
| Children’s/Residents’ exposure to fallout (pome fruits) | 2 |

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

| Substance: |
|------------|
| Etoxazole  |

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]³:

|                |
|----------------|
| None           |

Peer review proposal ⁴ for harmonised classification according to Regulation (EC) No 1272/2008:

|                |
|----------------|
| None           |

---
³ 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.
⁴ 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) N° 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) |
|--------------------------------------|-------------|---------|----------------|------------|
| **OECD Guideline 501**               | Fruit crops |         |                |            |
|                                      |             |         |                |            |
|                                      |             | Apples  | Foliar spray, 1x 0.15 kg a.s./ha. | 0, 14, 15, 21, 30 |
|                                      |             | Oranges | Foliar spray, 1x 0.4 kg a.s./ha. | 0, 21, 30, 60, 90 |
|                                      |             | Aubergines | Foliar spray, 1x 0.2 kg a.s./ha. | 0, 1, 14, 27 |
|                                      | Pules/Oilseeds | Cotton | Foliar spray, 1x 0.113 kg a.s./ha + 1x0.115 kg a.s./ha | 42, 21 relative to the first and second applications respectively |
|                                      |             | Citrus, Cotton and Eggplants | Foliar spray, 1x 0.055 kg a.s./ha | 0, 7, 14, 28, 42 |

Metabolism data submitted on the leafy parts of the fruits and pulses and oilseeds crops cannot be used as a surrogate to metabolism data on representative leafy crops.

| Rotational crops (metabolic pattern) | Crop groups | Crop(s) | PBI (days) | Comments |
|--------------------------------------|-------------|---------|------------|----------|
| **OECD Guideline 502**               | Root/tuber crops | radish | 30 | 1x112 g a.s./ha to bare soil. (ca. 2.7 N rate) |
|                                      | Leafy crops | lettuce | 30 | |
|                                      | Cereals (small grain) | wheat | 30 | |
|                                      | Other |         |            | |

Rotational crop and primary crop metabolism similar?

| Processed commodities (standard hydrolysis study) | Conditions | Total Recovery | Etoxazole | R-7 | R-13 | R-4 |
|---------------------------------------------------|------------|----------------|-----------|-----|------|-----|
| **OECD Guideline 507**                            | 20 min, 90°C, pH 4 | 97.4 | 72.2 | 23.7 | 1.6 | - |
|                                                   | 60 min, 100°C, pH 5 | 97.4 | 62.8 | 28.7 | 1.3 | 1.5 |
|                                                   | 20 min, 120°C, pH 6 | 88.2 | 59.5 | - | 1.2 | 26.4 |

Residue pattern in processed commodities similar to residue pattern in raw commodities? No

| Plant residue definition for monitoring (RD-Mo) | Etoxazole (sum of isomers) – restricted to fruit crops, pulses and oilseeds - Foliar application. | OECD Guidance, series on pesticides No 31 |

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Plant residue definition for risk assessment (RD-RA)

Primary crops: Etoxazole (sum of isomers) – restricted to fruit crops, pulses and oilseeds – Foliar application. Processed commodities: Etoxazole, R-4 and R-7 (provisional) Rotational crops: open

Conversion factor (monitoring to risk assessment)

Open

### Metabolism in livestock (Regulation (EU) No 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) | Duratio n (days) | N rate/comment                                                                 |
|-------------------------------------------------------|-------------|-------------------|------------------|--------------------------------------------------------------------------------|
| Animals covered                                       | Laying hen  | 5.8 ([14C-difluorophenyl]-etoxazole) | 4.5              | Not triggered based on the representative uses.                               |
|                                                       |             | 6.3 ([14C-t-butylphenyl]-etoxazole)  |                  |                                                                                  |
|                                                       | Goat/Cow    | 0.3 (both labelled compounds)        | 4                |                                                                                  |
|                                                       | Pig         | -                               |                  | Not required – Metabolism in rat and ruminants is similar.                     |
|                                                       | Fish        | -                               |                  | Not required                                                                     |

| Time needed to reach a plateau concentration in milk and eggs (days) | Eggs: Plateau not reached Milk: Dosing day 2, 0.002 mg/kg |
|---------------------------------------------------------------------|----------------------------------------------------------|
| Animal residue definition for monitoring (RD-Mo)                     | Not proposed; not required                                 |
| OECD Guidance, series on pesticides No 31                           |                                                          |
| Animal residue definition for risk assessment (RD-RA)               | Not proposed; not required                                 |
| Conversion factor (monitoring to risk assessment)                   | Not applicable                                            |
| Metabolism in rat and ruminant similar (Yes/No)                     | Yes                                                      |
| Fat soluble residues (Yes/No) (FAO, 2009)                           | Yes (Log P<sub>ow</sub> = 5.52 at 20°C) Total residues higher in fat compared to fat free muscle. |

### Residues in succeeding crops (Regulation (EU) No 283/2013, Annex Part A, point 6.6.2)

Confined rotational crop study (Quantitative aspect) OECD Guideline 502

In the different crops investigated with [14C-etoxazole and at 30 days PBI, the total radioactive residues were <0.01 mg/kg and no further analysis were conducted. Data gap: Confined rotational crops metabolism studies addressing the fate of R-3, R-7 and R-8 in leafy crops, small grains crops and root crops are required.
| Field rotational crop study | Not provided. |
|-----------------------------|---------------|
| OECD Guideline 504          |               |
### Stability of residues (Regulation (EU) No 283/2013, Annex Part A, point 6.1)
OECD Guideline 506

| Plant products (Category) | Commodity | T (°C) | Stability (Months) |
|--------------------------|-----------|--------|--------------------|
|                          |           |        | Etoxazole | R-4 | R-7 | R-3 |
| **High water content**   |           |        |           |     |     |     |
| Cucumber                 | -20°C     |        | 5         |     |     |     |
| Tomato                   | -20°C     |        | 7         |     |     |     |
| Apple                    | -18°C     |        | 4         |     |     |     |
| Apricot                  | -18°C     |        | 6         |     |     |     |
| **High oil content**     |           |        |           |     |     |     |
| Cotton seed              |           |        | 17        |     |     |     |
| **High acid content**    |           |        |           |     |     |     |
| Mandarin Peel            | -18°C     |        | 12        |     |     |     |
| Mandarin Pulp            | -18°C     |        | 6         |     |     |     |
| Grape (berries)          | -20°C     |        | 8         |     |     |     |
| Strawberry               | -18°C     |        | 3         |     |     |     |
| **Processed commodities**|           |        |           |     |     |     |
| Grape (juice)            | -20°C     |        | 5         |     |     |     |
| Raisin                   | -20°C     |        | 3         |     |     |     |
| Apple (juice)            | -18°C     |        | 1.5       |     |     |     |
| Apple (purée)            | -18°C     |        | 1.5       |     |     |     |
| Apple (dry pomace)       | -18°C     |        | 1.5       |     |     |     |
| Tomato (juice)           | -18°C     |        | 3         |     |     |     |
| Tomato (paste)           | -18°C     |        | 6         |     |     |     |
| Tomato (canned)          | -18°C     |        | 3         |     |     |     |
| Tomato paste             | -18°C     |        | Not stable | 5 | 5 |     |
| Cotton gin trash         | -20°C     |        |           |     | 6 |     |

No storage stability data available for animal products.
## 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) |
|------|-------------------|--------------------------------------------------------------------------------------------------------|---------------------------------------------|----------------------|----------------|-----------------|
| Citrus fruits | SEU | Mandarins: 1x 0.01, 2x 0.02, 2x 0.04, 3x 0.05 Oranges: 3x 0.01, 4x 0.02, 0.05 | MRL, STMR and HR derived from the merged datasets on mandarins and oranges. | 0.1 | 0.05 | 0.02 |
| Pome fruits | SEU | Apples: 5x <0.01, 0.04 Pears: 2x <0.01 | Extrapolation to the whole group of pome fruits. | 0.05 | 0.04 | 0.01 |
| | NEU | Apples: 4x <0.01, 2x 0.01 Pears: 2x <0.01 | MRL, STMR and HR derived from the merged NEU and SEU datasets on apples and pears. | | | |
| Peaches, apricots, nectarines | SEU | Peaches: 2x <0.01, 5x 0.02, 2x 0.04, 0.06 Apricots: <0.01, 0.02, 0.03, 0.04 | Extrapolation to the peaches, apricots and nectarines | 0.09 | 0.06 | 0.02 |
| Cherries (sweet) | SEU | 0.03, 2x 0.04, 0.11 | | 0.2 | 0.11 | 0.04 |
| Plums | SEU | 6x <0.01, 0.01, 0.02, 0.03, 0.07 | | 0.1 | 0.07 | 0.01 |
| | NEU | 8x <0.01, 0.01 | | 0.02 | 0.01 | 0.01 |
| Table grapes ** Wine grapes | SEU | 10x <0.01, 0.02 | MRL, STMR and HR derived from the merged NEU and SEU datasets | 0.04 | 0.03 | 0.01 |
| | NEU | 7x <0.01, 0.01, 0.03 | | | | |
| | SEU | 8x <0.01 | | | | |
| | NEU | 8x <0.01 | | | | |
| Strawberries | SEU | 0.01, 3x 0.03, 2x 0.04, 2x 0.05, 0.06, 0.10, 0.16 | | 0.3 | 0.16 | 0.04 |
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#### Summary of the data on formulation equivalence OECD Guideline 509

| 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) |
|------|------------------|------------------------------------------------------------------|---------------------------------------------|----------------------|----------------|----------------|
| NEU  | 2x 0.01, 2x 0.02, 2x 0.03, 2x 0.04 | Residue trials on tomatoes extrapolated to aubergines/eggplants | 0.08 | 0.04 | 0.03 |
| Indoor | 2x 0.01, 0.04, 2x 0.05, 0.06, 0.07, 0.09 | | 0.2 | 0.09 | 0.05 |

#### Crop Region/Indoor (a) Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs (b) |

| Tomatoes/aubergines | SEU | Tomatoes: 4x <0.01, 2x 0.01, 2x 0.02, 0.03, 0.04 | Residue trials on tomatoes extrapolated to aubergines/eggplants | 0.06 | 0.04 | 0.01 |

| Indoor | Tomatoes: 0.01, 0.02, 6x 0.03, 0.06 | | 0.09 | 0.06 | 0.03 |

| Cucurbits inedible peel | SEU | Melon: 4x <0.01, 2x 0.02, 2x 0.03 | Extrapolation to the whole group of cucurbits inedible peel | 0.06 | 0.03 | 0.02 |

| Cotton seeds | SEU | 4x <0.01 | 0.01* | 0.01 | 0.01 |

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

Data gap: Determination of the residues in pollen and bee products for human consumption resulting from residues taken up by honeybees from crops at blossom with regard to etoxazole and metabolites residues

| Product(s) | Region | Residue data (mg/kg) | Recommendations/comments |
|------------|--------|----------------------|-------------------------|

(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 (HR<sub>Mo</sub>):

(d): STMR: Supervised Trials Median Residue. When residue definition for monitoring and risk assessment differs, STMR according to definition for monitoring reported in brackets (STMR<sub>Mo</sub>).

(*) Indicates that the MRL is set at the limit of analytical quantification.
## Inputs for animal burden calculations

| Feed commodity          | Median dietary burden (mg/kg) | Maximum dietary burden (mg/kg) |
|-------------------------|-------------------------------|-------------------------------|
|                         | Comment                       | Comment                       |
| Citrus (dried pulp)     | 0.022 STMR * PF<sup>1</sup>   | 0.022 STMR * PF<sup>1</sup>   |
| Apple pomace, wet       | 0.033 STMR * PF<sup>2</sup>   | 0.033 STMR * PF<sup>2</sup>   |
| Cotton seed meal        | 0.0005 STMR * PF<sup>3</sup> | 0.0005 STMR * PF<sup>3</sup> |

1. Processing trials on citrus not available. Default PF (10).
2. Median PF for apple pomace, wet: 3.6.
3. Mean PF for cotton seed meal: 0.05.
4. Provisional livestock dietary burden calculation considering etoxazole residues only in processed feed commodities and should be finalised once the magnitude of R-4 and R-7 residues in relevant processed commodities has been addressed and their toxicological profile (data gap).
# Residues from livestock feeding studies

Regulation (EU) No 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

## MRL Calculations

| Ruminant | Pig/Swine | Poultry | Fish |
|----------|-----------|---------|------|
| Beef cattle | 0.00040 | 0.0003 | Breeding | 0.001 |
| Dairy cattle | 0.002 | Lamb | 0.0004 | Finishing | 0.00000 |

### Highest Expected Intake

| (mg/kg bw/d) | Beef cattle | Ram/Ewe | Ewe/Breeding | Broiler | Layer | Turkey |
|--------------|-------------|---------|--------------|---------|-------|--------|
| (mg/kg DM for fish) | 0.00040 | 0.0003 | 0.001 | 0.00000 | 0.00000 | 0.00000 |

### Intake >0.004 mg/kg bw

- No
- No
- No
- No
- No

### Feeding Study Submitted

- Not required
- Not required
- Not required
- Not required
- Not required
- Not required

### Representative Feeding Level

| Level | Beef: N | Lamb: N | Broiler: N |
|-------|--------|--------|------------|
| Level | N | N | N |

### N Rates

- Estimated HR at 1N
- MRL proposals

### Method of Calculation

- Estimated HR calculated at N level (estimated mean level for milk).
- HR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry.
- 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 extrapolation (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 bw/d)          | 0.00040  | Breeding  | 0.001   | Broiler 0.00000 |
| Dairy cattle (mg/kg DM for fish)  | 0.0017   | Finishing | 0.00000 | Layer 0.00000 |
| Ruminant                          |          |           |         | Turkey 0.00000 |
| Pig/Swine                         |          |           |         | Fish 0.00000   |
| Poultry                           |          |           |         |                 |
| Fish                              |          |           |         |                 |

| Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and N rates | Level | Beef: N | Level | Lamb : N | Level | N rate | Level | B or T: N | Level | N rate |
|------------------------------------------------------------------------|-------|---------|-------|----------|-------|--------|-------|-----------|-------|--------|
| Mean level in feeding level                                            |       | Estimated STMR\(^{(b)}\) at 1N | Mean level in feeding level | Estimated STMR\(^{(b)}\) at 1N | Mean level in feeding level | Estimated STMR\(^{(b)}\) at 1N | Mean level in feeding level | Estimated STMR\(^{(b)}\) at 1N | Mean level in feeding level | Estimated STMR\(^{(b)}\) at 1N |
| Muscle                                                                  |       |         |       |         |       |        |       |           |       |        |
| Fat                                                                     | -      | -       | -     | -       | -     | -      | -     | -         | -     | -      |
| Meat\(^{(a)}\)                                                          | -      | -       | -     | -       | -     | -      | -     | -         | -     | -      |
| Liver                                                                   | -      | -       | -     | -       | -     | -      | -     | -         | -     | -      |
| Kidney                                                                  | -      | -       | -     | -       | -     | -      | -     | -         | -     | -      |
| Milk                                                                    | -      | -       | -     | -       | -     | -      | -     | -         | -     | -      |
| Eggs                                                                    | -      | -       | -     | -       | -     | -      | -     | -         | -     | -      |

Method of calculation\(^{(c)}\):

\(^{(a)}\): STMR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry.

\(^{(b)}\): When the mean level is set at the LOQ, the STMR is set at the LOQ.

\(^{(c)}\): 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.
### Processing factors (Regulation (EU) N° 283/2013, Annex Part A, points 6.5.2 and 6.5.3)(5)

OECD Guideline 508 and OECD Guidance, series on testing and assessment No 96

| Crop (RAC)/Edible part or Crop (RAC)/Processed product | Number of studies | Processing Factor (PF) | Conversion Factor (CF<sub>P</sub>) for RA |
|--------------------------------------------------------|-------------------|------------------------|----------------------------------------|
|                                                        |                   | Individual values | Median PF |                              |
| **Representative uses**                                |                   |                       |            |                              |
| Apple washed<sup>a</sup>                               | 2                 | 1.2, 0.33             | -          |                              |
| Apple juice                                            | 4                 | <0.05, <0.08, 0.009, 0.012 | <0.038   |                              |
| Apple puree                                            | 2                 | <0.05, <0.08          | <0.07     |                              |
| Canned apples (canned after pasteurisation)            | 2                 | <0.05, <0.08          | <0.07     |                              |
| Apple baby puree                                       | 1                 | <0.08                 | <0.08     |                              |
| Apples dried                                           | 1                 | 1.1                   | 1.1       |                              |
| Apple wet poamce                                       | 2                 | 5.8, 5.6              | 5.7       |                              |
| Tomato (washed)                                        | 2                 | 0.25, 0.83            | 0.54      |                              |
| Tomato juice (finished)                               | 2                 | <0.25, <0.18          | <0.22     |                              |
| Tomato puree                                           | 2                 | <0.25, <0.18          | <0.22     |                              |
| Tomato paste                                           | 2                 | <0.25, <0.18          | <0.22     |                              |
| Tomato (canned)                                        | 2                 | <0.25, <0.18          | <0.22     |                              |
| Tomato (sun-dried)<sup>1)</sup>                        | 2                 | 1.0, 4.7              | -         |                              |
| Tomato ketchup                                         | 2                 | <0.25, <0.18          | <0.22     |                              |
| Cotton meal                                            | 2                 | 0.04, 0.06            | 0.05      |                              |
| Cotton hulls<sup>1)</sup>                              | 2                 | 0.32, 0.12            | -         |                              |
| Cotton oil                                             | 2                 | 0.20, 0.12            | 0.16      |                              |

<sup>a</sup>Due to the significant difference of the 2 two values no robust processing factor can be derived for washed apples, sun-dried tomatoes and cotton hulls.

(5): Provisional processing factors to be reconsidered pending the finalisation of the residue definition for risk assessment for processed commodities.

### Consumer risk assessment (Regulation (EU) N° 283/2013, Annex Part A, point 6.9)(6)

Including all uses (representative uses and uses related to an MRL application).

| Factor                        | Value |
|-------------------------------|-------|
| **ADI**                       | 0.04 mg/kg bw per day |
| TMIDI according to EFSA PRIMo | Highest TMIDI: 3.8% ADI (DE child) |
| NTMIDI, according to (to be specified) | Not applicable |
| IEDI (% ADI), according to EFSA PRIMo | Calculation not triggered (TMIDI well below 100% ADI) |
| NEDI (% ADI), according to (to be specified) | Not applicable |
| Factors included in the calculations | none |

| Factor                        | Value                  |
|-------------------------------|------------------------|
| **ARfD**                      | Not applicable – Not allocated |
| IESTI (% ARfD), according to EFSA PRIMo | Not applicable |
| NESTI (% ARfD), according to (to be specified) | Not applicable |
| Factors included in IESTI and NESTI | none |
A provisional consumer dietary risk assessment can only be conducted considering the outstanding data to finalise the residue definition for risk assessment for processed commodities and the fate of high persistent soil metabolites in rotational crops.

Proposed MRLs (Regulation (EU) No 283/2013, Annex Part A, points 6.7.2 and 6.7.3)\(^{(7)}\)

| Code\(^{(a)}\) | Commodity/Group                     | MRLs\(^{(b)}\) (mg/kg) and Comments |
|--------------|------------------------------------|----------------------------------|
| **Plant commodities** |                                      |                                  |
| 0110000     | Citrus fruits                      | 0.1                              |
| 0130000     | Pome fruit                         | 0.05                             |
| 0140020     | Cherries (sweet)                   | 0.2                              |
| 0140010     | Apricots                           | 0.09                             |
| 0140030     | Peaches                            | 0.09                             |
| 0140040     | Plums                              | 0.1                              |
| 0151010     | Table grapes                       | 0.04                             |
| 0151020     | Wine grapes                        | 0.04                             |
| 0152000     | Strawberries                       | 0.3                              |
| 0231010     | Tomatoes                           | 0.09                             |
| 0231030     | Aubergines/eggplants               | 0.09                             |
| 0233000     | Cucurbits with inedible peel       | 0.06                             |
| 0401090     | Cotton seeds                       | 0.01*                            |
| **MRL application** |                                     |                                  |
| 0140040     | Plums                              | 0.1                              |
| 0152000     | Strawberries                       | 0.3                              |
| 0231010     | Tomatoes                           | 0.09                             |
| 0231030     | Aubergines/eggplants               | 0.09                             |
| 0233000     | Cucurbits with inedible peel       | 0.06                             |
| **Animal commodities** |                                 |                                  |
| 1000000     | Products of animal origin -Terrestrial animals | Not relevant based on the representative uses. |

\(\text{a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005}
\(\text{b): MRLs proposed at the LOQ, should be annotated by an asterisk (*) after the figure.}
\(\text{(7): Provisional proposed MRLs.}\)
### Environmental fate and behaviour

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

| Mineralisation after 100 days | 5.7-12.8 % after 120 d, [14C-butyphenyl]-label (n=3)  
50.34 % after 120 d, [14C-difluorophenyl]-label (n=1) |
|---|---|
| Non-extractable residues after 100 days | 10.2-32.9 % after 120 d, [14C-butyphenyl]-label (n=6)  
25.66 % after 120 d, [14C-difluorophenyl]-label (n=1) |
| Metabolites requiring further consideration  
- name and/or code, % of applied (range and maximum) |  
- R-3 (max. 1.5-10.4% butylphenyl)  
- R-4 (max. 2.6-12.4% butylphenyl)  
- R-7 (max. 8.1-24% butylphenyl, max. 21.6% difluorophenyl)  
- R-8 (max. 33.0-44.8% butylphenyl)  
- R-12 (max. 4-8.5% butylphenyl)  
- R-13 (max. 11.7-23.1%, butylphenyl, max. 10.9% difluorophenyl) |

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

| Mineralisation after 100 days | 2.16 % after 120 d, [13C- butyphenyl]-label (n=1)  
aqueous layer  
22.39 % after 120 d, [13C- difluorophenyl]-label (n=1) |
|---|---|
| Non-extractable residues after 100 days | 12.45 % after 120 d, [13C- butyphenyl]-label (n=1)  
4.24 % after 120 d, [13C- difluorophenyl]-label (n=1) |
| Metabolites that may require further consideration  
for risk assessment - name and/or code, % of applied (range and maximum) |  
- R-8 (max 24.6% butylphenyl)  
- R-11 (max 38.2% difluorophenyl)  
- R-7 (max 5.2% difluorophenyl) |

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

| Metabolites that may require further consideration  
for risk assessment - name and/or code, % of applied (range and maximum) |  
- R-3 (max. 9% butylphenyl, max. 11.7% difluorophenyl)  
- R-11 (max. 12% difluorophenyl)  
- R-12 (max. 7.9% butylphenyl) |
|---|---|
| Mineralisation at study end | 6.6 % after 294 h, [13C- butyphenyl]-label (n=1)  
8.7 % after 295 h, [13C- difluorophenyl]-label (n=1) |
| Non-extractable residues at study end | 13.05 % after 294 h, [13C- butyphenyl]-label (n=1)  
12.35 % after 295 h, [13C- difluorophenyl]-label (n=1) |
### Rate of degradation in soil (aerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

| Parent | Dark aerobic conditions |
|--------|-------------------------|
| Soil type | pH\(^a\) | t. °C / % MWHC | DT\(_{50}\)/DT\(_{90}\) (d) | alpha/beta or \(k_1, k_2, g\) | DT\(_{50}\) (d) | St. (\(\chi^2\)) | Method of calculation |
| Aldhams 20°C Sandy loam | 5.1 | 20 °C / 40% MWHC | 10.4 / 34.5 | - | 9.3 | 5.97 | SFO |
| Speyer 2.1 Sand | 6.7 | 20 °C / 40% MWHC | 18.6 / 61.75 | - | 15.1 | 12.68 | SFO |
| Speyer 2.2 Loamy sand | 6.7 | 20 °C / 40% MWHC | 24.5 / 81.3 | - | 24.5 | 9.25 | SFO |
| Evesham 3 Clay loam | 7.4 | 20 °C / 40% MWHC | 47.7\(^e\) / 158.6 | - | 30.5 | 3 | SFO |
| Aldhams 10°C Sandy loam | 5.1 | 10 °C / 40% MWHC | 31.9 / 105.8 | - | 11 | 10.1 | SFO |
| Aldhams 30°C Sandy loam | 5.1 | 30 °C / 40% MWHC | 1.8 / 19.88 | 0.77485 (alpha) 0.0.06633 (beta) | 13.2\(^d\) | 3.36 | FOMC |
| Chelmorton Silt loam | 5.9 | 20 °C / pF2 | 10.8 / 35.8 | - | 10.8 | 4.6 | SFO |
| Speyer 5M Sandy loam | 7.0 | 20 °C / pF2 | 74.1\(^f\) / 246.2 | - | 74.1 | 4.5 | SFO |

**Geometric mean (if not pH dependent):** 19.31\(^f\)

**pH dependence, Yes or No:** No

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\(\alpha\) Measured in water

\(\beta\) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

\(\chi\) For Aldhams soils (at 10° and 30° C) geometric mean has been derived first before the calculation of geometric mean for the whole data set

\(\delta\) DT90/3.32 (normalised)

\(\epsilon\) Normalised using a Q10 of 2.58 to 12 °C the DT50 in Speyer 5M Sandy loam is 157.4 days. When normalised to 12 °C the DT50 of all the other soils are < that of Evesham 3 clay loam which is 101.3 days. For the purpose of the application of Guidance on Information Requirements and Chemical Safety Assessment. Chapter R11: PBT/vPvB assessment (ECHA, November 2014 & June 2017) values at 12°C are considered.
**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)**

| Soil type          | pH\(^a\) | t. °C / % MWHC | DT\(_{50}\)/ DT\(_{90}\) (d) | alpha/ beta or k\(_1\), k\(_2\), k\(_g\) | f. f. k\(_{\ell}\) / k\(_{dp}\) | DT\(_{50}\) (d) 20 °C pF2/10kPa\(^b\) | St. (\(\chi^2\)) | Method of calculation |
|--------------------|----------|----------------|-------------------------------|---------------------------------|--------------------------------|---------------------------------|------------------|---------------------|
| **Longwoods**      | 7.7      | 20°C/38.9%     | 9.25/91.94                   | 0.9226 (alpha) 8.2612 (beta)   | 27.7 \(^c\)                     | 5.285                           | FOMC             |
| Loamy sand         |          |                |                               |                                 |                                 |                                 |                  |
| **Farditch**       | 6.5      | 20°C/68%       | 18.29/107.8                  | 1.6163 (alpha) 34.1473 (beta)  | 32.5 \(^c\)                     | 4.758                           | FOMC             |
| Silt loam          |          |                |                               |                                 |                                 |                                 |                  |
| **Warsop**         | 4.8      | 20°C/30.1%     | 89.14/296.1                  | -                               | 89.1                            | 3.202                           | SFO              |
| Sand               |          |                |                               |                                 |                                 |                                 |                  |
| Geometric mean (if not pH dependent)                              |         |                |                               |                                 |                                 | **43.1**                       |                   |
| Arithmetic mean                                             |         |                |                               |                                 |                                 | **I**                           |                   |

| pH dependence, Yes or No                                  |
|----------------------------------------------------------|
| a) Measured in water                                       |
| b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7 |
| c) DT\(_{90}\)/3.32 (normalised)                          |

| Soil type          | pH\(^a\) | t. °C / % MWHC | DT\(_{50}\)/ DT\(_{90}\) (d) | alpha/beta or k\(_1\), k\(_2\), k\(_g\) | f. f. k\(_{\ell}\) / k\(_{dp}\) | DT\(_{50}\) (d) 20 °C pF2/10kPa\(^b\) | St. (\(\chi^2\)) | Method of calculation |
|--------------------|----------|----------------|-------------------------------|---------------------------------|--------------------------------|---------------------------------|------------------|---------------------|
| **Longwoods**      | 7.7      | 20°C/38.9%     | 7.09/23.57                   | -                               | 7.1                            | 11.02                           | SFO              |
| Loamy sand         |          |                |                               |                                 |                                 |                                 |                  |
| **Farditch**       | 6.5      | 20°C/68%       | 10.49/34.84                  | -                               | 10.5                           | 5.434                           | SFO              |
| Silt loam          |          |                |                               |                                 |                                 |                                 |                  |
| **Warsop**         | 4.8      | 20°C/30.1%     | 1.03502 (alpha) 8.01403 (beta) | 19.9 \(^f\)                     | 1.9                            | FOMC                            |
| Sand               |          |                |                               |                                 |                                 |                                 |                  |
| Geometric mean (if not pH dependent)                              |         |                |                               |                                 |                                 | **11.4**                       |                   |
| Arithmetic mean                                             |         |                |                               |                                 |                                 | **I**                           |                   |

| pH dependence, Yes or No                                  |
|----------------------------------------------------------|
| a) Measured in water                                       |
| b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7 |
| f) DT\(_{90}\)/3.32 (normalised)                          |
### R-13

| Soil type       | pH<sup>a</sup> | t. ºC / % MWHC | DT<sub>50</sub>/DT<sub>x0</sub> (d) | alpha/beta or k<sub>1</sub>, k<sub>2</sub>, g | f. f. k<sub>f</sub>/k<sub>dp</sub> | DT<sub>50</sub> (d) 20 ºC pF2/10kPa<sup>b</sup> | St. (χ<sup>2</sup>) | Method of calculation |
|-----------------|----------------|----------------|-------------------------------|------------------------------------------|-------------------------------|-----------------------------|----------------------|----------------------|
| Longwoods Loamy sand | 7.7            | 20ºC/38.9%     | 205.7/812.4                  | 0.07783 (k<sub>1</sub>) 0.002653 (k<sub>2</sub>) 0.136965 (g) | 261.3<sup>i</sup>       | 1.866                       | DFOP                 |
| Farditch Silt loam | 6.5            | 20ºC/68%       | 41.7/444.3                   | 0.114 (k<sub>1</sub>) 0.00398 (k<sub>2</sub>) 0.414 (g) | 174.2<sup>i</sup>      | 3.314                       | DFOP                 |
| Warsop Sand      | 4.8            | 20ºC/30.1%     | 95.8/318.2                   | -                                         | 95.8                        | 4.248                       | SFO                  |

| Geometric mean (if not pH dependent) | **163.4** |
| Arithmetic mean | 1 |

**pH dependence. Yes or No**

- a)Measured in water
- b)Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
- i)Ln2/k<sub>slow</sub> (normalised)

### R-12

| Soil type       | pH<sup>a</sup> | t. ºC / % MWHC | DT<sub>50</sub>/DT<sub>90</sub> (d) | alpha/beta or k<sub>1</sub>, k<sub>2</sub>, g | f. f. k<sub>f</sub>/k<sub>dp</sub> | DT<sub>50</sub> (d) 20 ºC pF2/10kPa<sup>b</sup> | St. (χ<sup>2</sup>) | Method of calculation |
|-----------------|----------------|----------------|-------------------------------|------------------------------------------|-------------------------------|-----------------------------|----------------------|----------------------|
| Chelmorton Silt loam | 5.9            | 20ºC/44.7%     | 1.33/4.43                     | -                                         | 1.33                          | 4.135                       | SFO                  |
| Speyer 2.2 Loamy sand | 5.9            | 20ºC/20.3%     | 1.13/3.75                     | -                                         | 1.13                          | 7.8                          | SFO                  |
| Speyer 5M Sandy loam | 7.0            | 20ºC/21.2%     | 3.69/26.77                    | 1.23131 (alpha) 4.878 (beta)             | 8.07<sup>ii</sup>         | 3.366                       | FOMC                 |

| Geometric mean (if not pH dependent) | **2.3** |
| Arithmetic mean | 1 |

**pH dependence. Yes or No**

- a)Measured in water
- b)Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
- i)DT90/3.32 (normalised)

### R-8

| Soil type       | pH<sup>a</sup> | t. ºC / % MWHC | DT<sub>50</sub>/DT<sub>90</sub> (d) | alpha/beta or k<sub>1</sub>, k<sub>2</sub>, g | f. f. k<sub>f</sub>/k<sub>dp</sub> | DT<sub>50</sub> (d) 20 ºC pF2/10kPa<sup>b</sup> | St. (χ<sup>2</sup>) | Method of calculation |
|-----------------|----------------|----------------|-------------------------------|------------------------------------------|-------------------------------|-----------------------------|----------------------|----------------------|
|                  |                |                |                               |                                          |                               |                             |                      |                      |
### Dark aerobic conditions Metabolite dosed study (ff from parent aerobic degradation studies)

| Soil type                | pH   | t. °C / % MWHC | DT50/DT90 (d) | alpha/beta or k1, k2, g | f. f. kf/kdp | DT50 (d) 20 °C pF2/10kPab | St. (χ²) | Method of calculation |
|--------------------------|------|---------------|---------------|-------------------------|-------------|---------------------------|----------|----------------------|
| Chelmorton Silt loam     | 5.9  | 20°C/44.7%    | 5.75/167.4    | 0.2397 (k1) 0.007505 (k2) 0.6486 (g) |            | 92.36⁰i 4.972          | DFOP     |
| Speyer 2.2 Loamy sand    | 5.9  | 20°C/20.3%    | 6.53/71.77    | 0.8568 (alpha) 5.2410 (beta) |            | 21.62⁰i 4.674          | FOMC     |
| Speyer 5M Sandy loam     | 7.0  | 20°C/21.2%    | 2.17/7.21     | -                      |            | 3.11 7.174              | SFO      |

| Geometric mean (if not pH dependent) | 18.4 |
| Arithmetc mean              | 1    |

pH dependence, Yes or No

- a) Measured in water
- b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
- o) Ln2/k_{slow} (normalised)
- p) DT90/3.32 (normalised)
| Soil type          | pH<sup>a</sup> | 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> (d) 20 °C pF2/10kPa<sup>b</sup> | St. (χ<sup>2</sup>) | Method of calculation |
|-------------------|----------------|----------------|-----------------------------------|--------------------------------|---------------------------------------------|-------------------|----------------------|
| Tollebeek sandy clay | 7.3            | 24 °C/n.r.     | 14.5/48                           |                               | 20.8                                       | 4.32              | SFO                  |
| Heino humous sand  | 4.8            | 24 °C/n.r.     | 7.91/26.3                         |                               | 11.4                                       | 4.75              | SFO                  |

Geometric mean (if not pH dependent)  
Arithmetic mean  
PpH dependence, Yes or No

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<sup>a</sup>Measured in [medium to be stated, usually calcium chloride solution or water]
<sup>b</sup>Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
### Field studies

| Parent | Aerobic conditions | Soil type (indicate if bare or cropped soil was used). | Location (country or USA state). | pH | Depth (cm) | DT$_{50}$ (d) actual | DT$_{90}$(d) actual | St. $(\chi^2)$ | Method of calculation |
|--------|-------------------|-------------------------------------------------------|----------------------------------|----|------------|----------------------|---------------------|----------------|----------------------|
| Silty clay loam | | St Martin des Bois, Tours | 4.2 | 0-10 | 8.13 (9.4)* | 31.1 | 12.6 | DFOP K1 0.09091 K2 3.51x10$^{-12}$ g 0.9569 |
| Clay loam | | Montech, Montauban | 7.1 | 0-10 | 7.89 (8.7)* | 28.8 | 1.81 | DFOP K1 0.09213 K2 2.37x10$^{-2}$ g 0.9682 |
| Clay loam | | Senas, Provence | 7.2 | 0-10 | 3.14 (7.56)* | 25.1 | 3.64 | FOMC $(\alpha$: 1.111, $\beta$: 3.618) |
| Silt loam | | Schleithal, Alsace | 5.4 | 0-10 | 9.26 | 30.8 | 10.4 | SFO |
| Sandy loam | | California | 6.9 | 0-7.5 | 4.02 (18.6 d)* | 61.8 | 7.41 | FOMC $(\alpha$: 0.6978, $\beta$: 2.367) |
| Sandy loam | | Idaho | 7.2 | 0-7.5 | 11.1 (12.3)* | 41 | 8.57 | DFOP K1 0.06579 K2 6.32x10$^{-4}$ g 0.9648 |
| Silt loam | | Mississippi | 6.4 | 0-7.5 | 0.479 (2.53 d)* | 8.4 | 6.51 | FOMC $(\alpha$: 0.6516, $\beta$: 0.2526) |
| Sandy silt loam | | UK | 6.7 | 0-10 | 23.2 | 77.2 | 14.6 | SFO |
| Silt loam | | Belgium | 6.8 | 0-10 | 5.9 | 19.7 | 15.3 | SFO |
| Clay loam | | Spain | 7.6 | 0-10 | 5.97 (17.1)* | 56.7 | 7.53 | FOMC $(\alpha$: 0.9564, $\beta$: 1.659) |
| Sandy silt loam | | Italy | 5.0 | 0-10 | 1.64 (4.8)* | 15.8 | 9.64 | HS K1 0.423 K2 0.07753 Tb 3.128 |

Geometric mean (if not pH dependent)

pH dependence, Yes or No

No

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* Measured in calcium chloride solution

* DT$_{90}$/3.32
### 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)

#### Parent

| Soil type   | pH<sup>a</sup> | t. °C / % MWHC | DT<sub>50</sub> / DT<sub>90</sub> (d) | St. (%<sup>2</sup>) | Method of calculation |
|-------------|----------------|----------------|-------------------------------|-------------------|----------------------|
| Sandy loam  | 5.6            | 20°C/40.4% water content at 0 bar | 105/349                    | 1.7               | SFO                  |

<sup>a</sup> Measured in water
Rate of degradation on soil (photolysis) laboratory active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3)

| Parent | Soil photolysis |
|--------|-----------------|
| Soil type | pH | t. °C / % MWHC | DT50 / DT90 (d) calculated at 40°N | St. (χ²) | Method of calculation |
| Clay loam | 7.8 | 20/57.5% MWHC | 23.2/77.1 (mean value from the two labels) | n.r. | n.r. |

*a) Measured in 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)

| Parent | Soil Type | OC % | Soil pH | Kd (mL/g) | Kdoc (mL/g) | KF (mL/g) | KFoc (mL/g) | 1/n |
|--------|-----------|------|---------|-----------|------------|----------|-----------|-----|
| Speyer 2.1 (Sand) | 0.6 | 5.1 | - | - | 66 | 11000 | 1.01 |
| Speyer 2.2 (Loamy sand) | 2.1 | 7.4 | - | - | 103 | 4910 | 0.91 |
| Evesham 3 (Clay loam) | 1.3 | 6.7 | - | - | 68 | 5230 | 0.94 |
| Aldhams Farm (Sandy loam) | 2.4 | 6.7 | - | - | 131 | 5460 | 0.87 |
| Geometric mean (if not pH dependent)* | | | | | 6267 | | |
| Arithmetic mean (if not pH dependent) | | | | | 0.933 | | |

*a) Measured in water
* Only relevant after implementation of the published EFSA guidance.

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)

| Parent | Soil Type | OC % | Soil pH | Kd (mL/g) | Kdoc (mL/g) | KF (mL/g) | KFoc (mL/g) | 1/n |
|--------|-----------|------|---------|-----------|------------|----------|-----------|-----|
| Aldhams farm (Sandy loam) | 2.4 | 5.1 | | | | | | |
| Evesham 3 (Clay loam) | 1.3 | 7.4 | 877 | 36540 | 0.84 |
| Speyer 2.1 (Sand) | 0.6 | 6.7 | 1082 | 83230 | 1.00 |
| Geometric mean (if not pH dependent)* | | | | | 34642 | | |
| Arithmetic mean (if not pH dependent) | | | | | 0.853 | | |

*a) Measured in water
* Only relevant after implementation of the published EFSA guidance.

R-8

| Parent | Soil Type | OC % | Soil pH | Kd (mL/g) | Kdoc (mL/g) | KF (mL/g) | KFoc (mL/g) | 1/n |
|--------|-----------|------|---------|-----------|------------|----------|-----------|-----|
| Aldhams farm (Sandy loam) | 2.4 | 5.1 | 2.48 | 103 | 0.79 | | | |
Peer review of the pesticide risk assessment of the active substance etoxazole

| Soil Type                | OC % | Soil pH | $K_d$ (mL/g) | $K_{soc}$ (mL/g) | $K_F$ (mL/g) | $K_{Foc}$ (mL/g) | 1/n  |
|-------------------------|------|---------|--------------|------------------|--------------|------------------|------|
| Evesham 3 (Clay loam)  | 1.3  | 7.4     | 4.56         | 351              | 0.86         |                  |      |
| Speyer 2.1 (Sand)       | 0.6  | 6.7     | 1.24         | 207              | 0.84         |                  |      |

Geometric mean (if not pH dependent)* 196

Arithmetic mean (if not pH dependent) 0.83

pH dependence, Yes or No

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R-7

| Soil Type                | OC % | Soil pH | $K_d$ (mL/g) | $K_{soc}$ (mL/g) | $K_F$ (mL/g) | $K_{Foc}$ (mL/g) | 1/n  |
|-------------------------|------|---------|--------------|------------------|--------------|------------------|------|
| Aldhams farm (Sandy loam) | 2.4  | 5.1     | 27           | 1125             | 0.87         |                  |      |
| Evesham 3 (Clay loam)   | 1.3  | 7.4     | 98           | 7540             | 0.91         |                  |      |
| Speyer 2.1 (Sand)        | 0.6  | 6.7     | 14           | 2330             | 0.93         |                  |      |

Geometric mean (if not pH dependent)* 2704

Arithmetic mean (if not pH dependent) 0.903

pH dependence, Yes or No

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R-11

| Soil Type                | OC % | Soil pH | $K_d$ (mL/g) | $K_{soc}$ (mL/g) | $K_F$ (mL/g) | $K_{Foc}$ (mL/g) | 1/n  |
|-------------------------|------|---------|--------------|------------------|--------------|------------------|------|
| Farditch Farm (Silt loam) | 3.4  | 6.5     | 1.336        | 46.1             | 0.671        |                  |      |
| Warsop (Sand)            | 1.4  | 4.8     | 0.975        | 28.7             | 0.649        |                  |      |
| Lockington (Clay loam)   | 2.9  | 6.6     | 0.320        | 22.9             | 0.909        |                  |      |

Geometric mean (if not pH dependent)* 31

Arithmetic mean (if not pH dependent) 0.743

pH dependence, Yes or No

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* Measured in water
* Only relevant after implementation of the published EFSA guidance.
### R-3

| Soil Type                  | OC % | Soil pH<sup>a</sup> | K_d (mL/g) | K_doc (mL/g) | K_F (mL/g) | K_Foc (mL/g) | l/n  |
|---------------------------|------|---------------------|------------|--------------|------------|--------------|------|
| Farditch Farm (Silt loam)| 3.4  | 6.5                 | 178        | 6143         | 0.927      |
| Warsop (Sand)             | 1.4  | 4.8                 | 47         | 3359         | 0.957      |
| Lockington (Clay loam)    | 2.9  | 6.6                 | 183        | 6295         | 0.921      |
| Geometric mean (if not pH dependent)* | | | | 5064 | | |
| Arithmetic mean (if not pH dependent) | | | | 0.935 |

**pH dependence, Yes or No**

* Measured in water
* Only relevant after implementation of the published EFSA guidance.

### R-4

| Soil Type                  | OC % | Soil pH<sup>a</sup> | K_d (mL/g) | K_doc (mL/g) | K_F (mL/g) | K_Foc (mL/g) | l/n  |
|---------------------------|------|---------------------|------------|--------------|------------|--------------|------|
| Farditch Farm (Silt loam)| 3.4  | 6.5                 | 10.45      | 307          | 0.917      |
| Warsop (Sand)             | 1.4  | 4.8                 | 3.02       | 216          | 0.935      |
| Lockington (Clay loam)    | 2.9  | 6.6                 | 10.40      | 360          | 0.901      |
| Geometric mean (if not pH dependent)* | | | | 288 | | |
| Arithmetic mean (if not pH dependent) | | | | 0.918 |

**pH dependence, Yes or No**

* Measured in water
* Only relevant after implementation of the published EFSA guidance.

### R-12

| Soil Type     | OC % | Soil pH<sup>a</sup> | K_d (mL/g) | K_doc (mL/g) | K_F (mL/g) | K_Foc (mL/g) | l/n  |
|---------------|------|---------------------|------------|--------------|------------|--------------|------|
| SK961089      | 5    | 7.5                 | 0.28       | 6            | 0.9362     |
| SK104691      | 2.5  | 5.9                 | 0.6        | 24           | 0.9418     |
| SK179618      | 3.7  | 5                   | 3.52       | 95           | 0.9936     |
| Geometric mean (if not pH dependent)* | | | | 24 | | |
| Arithmetic mean (if not pH dependent) | | | | 0.957 |

**pH dependence, Yes or No**

* Measured in calcium chloride solution
* Only relevant after implementation of the published EFSA guidance.
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)

| Column leaching |
|----------------|
| No column leaching study was conducted |

Lysimeter / field leaching studies (Regulation (EU) No 283/2013, Annex Part A, points 7.1.4.2 / 7.1.4.3 and Regulation (EU) No 284/2013, Annex Part A, points 9.1.2.2 / 9.1.2.3)

| Lysimeter/ field leaching studies |
|----------------------------------|
| No lysimeter study was conducted |

Hydrolytic degradation (Regulation (EU) No 283/2013, Annex Part A, point 7.2.1.1)

| Hydrolytic degradation of the active substance and metabolites > 10 % |
|------------------------------------------------------------------|
| pH 5: 9.57 d at 20 °C |
| R-7: 65.6 % AR (21 d) |
| R-13: 5.7 % AR (14 d) |
| pH 7: 147-161 d at 20 °C (n=2) |
| R-4/R-7 (could not be separated): 13.9 % AR (30 d) |
| pH 9: 165-217 d at 20 °C (n=2) |
| R-4/R-7 (could not be separated): 16.9 % AR (30 d) |

Aqueous photochemical degradation (Regulation (EU) No 283/2013, Annex Part A, points 7.2.1.2 / 7.2.1.3)

| Photolytic degradation of active substance and metabolites above 10 % |
|------------------------------------------------------------------|
| DT₅₀: 130.1 h (mean of two radiolabels) |
| Natural light, 40°N; DT₅₀ 16.7 days (mean of two radiolabels) |
| - R-11: max. 64 % AR (38.24 d equiv.) |
| - R-3: max. 12.1 % AR (47 d equiv.) |
| - R-12: max. 30.6 % AR (47 d equiv.) |
| - R-15: max. 29.5 % AR (47 d equiv.) |
| Quantum yield of direct phototransformation in water at Σ > 290 nm |
| 0.026 mol · Einstein⁻¹ |

‘Ready biodegradability’ (Regulation (EU) No 283/2013, Annex Part A, point 7.2.2.1)

| Readily biodegradable (yes/no) |
|--------------------------------|
| Not readily biodegradable (no evidence of biodegradation after 28 days of the experiment) |
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)

| System identifier (indicate fresh, estuarine or marine) | pH water phase | pH sed | t. °C | DT50 / DT90 whole sys. (suspended sediment test) | St. (χ²) | DT50 / DT90 Water | St. (χ²) | Method of calculation |
|----------------------------------------------------------|----------------|--------|-------|-------------------------------------------------|----------|-------------------|----------|---------------------|
| Rhine (fresh water) High (30 μg/L)                        | 8.06           | 21     | 37.1/123 | 86.4/286.3                                      | 9.66     |                   |          | SFO                 |
| Rhine (fresh water) Low (10 μg/L)                         | 8.06           | 21     | 35.2/117 | 81.9/272.3                                      | 11.6     |                   |          | SFO                 |
| Rhine (fresh water) Combined (30 and 10 μg/L)             | 8.06           | 21     | 36.1/120 | 84/279.3                                        | 10.4     |                   |          | SFO                 |

Mineralisation and non extractable residues (for parent dosed experiments)

| System identifier (indicate fresh, estuarine or marine) | pH water phase | pH sed | Mineralisation x % after n d. (end of the study). | Non-extractable residues. max x % after n d (suspended sediment test) | Non-extractable residues. max x % after n d (end of the study) (suspended sediment test) |
|----------------------------------------------------------|----------------|--------|--------------------------------------------------|---------------------------------------------------------------------|----------------------------------------------------------------------------------|
| Rhine (fresh water) High (30 μg/L)                        | 8.06           | /      | Max 3% at the end of the study (difluorophenyl label)/0.1% (tert-butylphenyl label) | 13% after 28 d (tert-butylphenyl label)                                  | 11.4% at the end of the study                                                    |
| Rhine (fresh water) Low (10 μg/L)                         | 8.06           | /      | Max 2.3% at the end of the study (difluorophenyl label)/0.1% (tert-butylphenyl label) | 10.2% after 28 days/13.7% after 28 d (tert-butylphenyl label)             |                                                                                  |

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)

| Water / sediment system | pH water phase | pH sed | t. °C | DT50 / DT90 whole sys. | St. (χ²) | DT50 / DT90 water | St. (χ²) | Method of calculation |
|-------------------------|----------------|--------|-------|------------------------|----------|-------------------|----------|---------------------|
| Water / sediment system |                |        |       |                        |          |                   |          |                     |

Measured in water

Temperature of incubation

Normalised using a Q10 of 2.58 to 12 °C for the purpose of the application of Guidance on Information Requirements and Chemical Safety Assessment. Chapter R11: PBT/vPvB assessment (ECHA, November 2014 & June 2017)
Bury pond

| pH | Water phase | pH | Sediment | Mineralisation | Non-extractable residues | Non-extractable residues in sed. max x % after n.d. (end of the study) |
|----|-------------|----|----------|----------------|--------------------------|---------------------------------------------------------------------|
| 7.12 | 8 | 20 | 60.1/199.8 | 3.3 | 3.4/27.8 | 7.4 | SFO (system) DFOP (water) |

Houghton meadow

| pH | Water phase | pH | Sediment | Mineralisation | Non-extractable residues | Non-extractable residues in sed. max x % after n.d. (end of the study) |
|----|-------------|----|----------|----------------|--------------------------|---------------------------------------------------------------------|
| 7.58 | 7.5 | 20 | 107.5/357.3 | 2.5 | 1.8/42.7 | 21.2 | SFO (system) FOMC (water) |

Geometric mean at 20°C

|          |          |          |
|----------|----------|----------|
| 80.4     | 1000 (default) |          |

Metabolites

- R13 Distribution: Max. 13.2% in sediment (100 days) Max 1.7% in water (day 0)
- R4 Distribution: Max. 2.9% in sediment (100 days) Max 3.4% in water (100 days)

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

| Water / sediment system | pH water phase | pH sediment | 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) |
|-------------------------|----------------|-------------|-----------------------------------------------|--------------------------------------------------|---------------------------------------------------------------------|
| Bury pond               | 7.12           | 8           | 6.8% after 60 d (butylphenyl label)/13.8% at the end of the study (difluorophenyl label) | 11.3% at the end of the study (butylphenyl label)/12% at the end of the study (difluorophenyl label) |
| Houghton meadow         | 7.58           | 7.5         | 2.4% after the end of the study (butylphenyl label)/13.9% at the end of the study (difluorophenyl label) | 8.6% at the end of the study (butylphenyl label)/11.5% at the end of the study (difluorophenyl label) |

Fate and behaviour in air (Regulation (EU) No 283/2013, Annex Part A, point 7.3.1)

- Direct photolysis in air: Not studied - no data requested
- Photochemical oxidative degradation in air: DT₅₀ of 1.7 hours (Atkinson model-AOPWIN version 1.92). OH (12h) concentration assumed = 1.5x10⁶
- Volatilisation: VP < 10⁵ Pa (trigger value), no volatilisation expected
- Metabolites: -

Residues requiring further assessment (Regulation (EU) No 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: Parent (etoxazole), R-3, R-7, R-8, R-11 and R-13
  - Surface water: Parent (etoxazole), R-3, R-4, R-7, R-8, R-11, R-12, R-13 and R-15
  - Sediment: Parent (etoxazole), R-3, R-4, R-7, R-8, R-11, R-12, R-13 and R-15
  - Ground water: Parent (etoxazole), R-3, R-7, R-8, R-11, R-4, R-12 and R-13
  - Air: Parent (etoxazole)
Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2)

See section 5, Ecotoxicology

Monitoring data, if available (Regulation (EU) N° 283/2013, Annex Part A, point 7.5)

| Location Type                        | Data 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 | DT<sub>50</sub> (d): 74.1 days |
|-----------------------|---------------------------------|
|                      | Kinetics: SFO                   |
| Field or Lab:         | worst case lab                  |

Application data

| Crop:                      | strawberry (worst case scenario) |
|---------------------------|----------------------------------|
| Depth of soil layer:      | 5cm                              |
| Soil bulk density:        | 1.5 g/cm<sup>3</sup>             |
| % plant interception:     | 30% (BBCH 10-from infestation)   |
| Number of applications:   | 1                                |
| Interval (d):             | -                                |
| Application rate(s):      | 55 g a.s./ha                     |

PEC(s) (mg/kg)

| PEC(s) (mg/kg) | Single application | Single application | Multiple application | Multiple application |
|----------------|--------------------|--------------------|----------------------|----------------------|
|                | Initial Actual     | Time weighted average | Actual Time weighted average |
| Initial        | 0.051              | -                   | -                    |
| Short term     | 24h 0.051          | 0.051               | -                    |
|                | 2d 0.050           | 0.051               | -                    |
|                | 4d 0.049           | 0.050               | -                    |
| Long term      | 7d 0.048           | 0.050               | -                    |
|                | 28d 0.040          | 0.045               | -                    |
|                | 50d 0.032          | 0.041               | -                    |
|                | 100d 0.020         | 0.033               | -                    |
| Plateau        | concentration      | 0.002 mg/kg (5 cm)  |                      |
| after 2 yr     |                    | after 2 yr          |                      |

Metabolite R-3

| Method of calculation | Molecular weight relative to the parent: 361.38/359.4 |
|-----------------------|--------------------------------------------------------|
|                       | DT<sub>50</sub> (d): 89.1 days                         |
|                       | Kinetics: SFO                                         |
|                       | Field or Lab: worst case lab                           |

Application data

| Application rate assumed | 5.75 g/ha (assumed R-3 is |
formed at a maximum of 10.4% of the applied dose

| PEC(s) (mg/kg) | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|---------------|---------------------------|----------------------------------------|-----------------------------|----------------------------------------|
| Initial       | 0.0054                    | -                                      | -                           | -                                      |
| Short term    | 24h                       | 0.0053 0.005                           | -                           | -                                      |
|               | 2d                        | 0.0053 0.005                           | -                           | -                                      |
|               | 4d                        | 0.0052 0.005                           | -                           | -                                      |
| Long term     | 7d                        | 0.0051 0.005                           | -                           | -                                      |
|               | 28d                       | 0.0043 0.005                           | -                           | -                                      |
|               | 50d                       | 0.0036 0.004                           | -                           | -                                      |
|               | 100d                      | 0.0025 0.004                           | -                           | -                                      |
| Plateau       | concentration             | 0.0003 mg/kg (5 cm) after 2 yr         | -                           | -                                      |
Metabolite R-7
Method of calculation

| PEC(s) (mg/kg) | Single application | Single application | Multiple application | Multiple application |
|---------------|--------------------|--------------------|----------------------|----------------------|
|               | Actual             | Time weighted average | Actual               | Time weighted average |
| Initial       | 0.0129             | -                  | -                    | -                    |
| Short term 24h| 0.0106             | 0.012              | -                    | -                    |
| 2d            | 0.0086             | 0.011              | -                    | -                    |
| 4d            | 0.0058             | 0.009              | -                    | -                    |
| Long term 7d  | 0.0031             | 0.007              | -                    | -                    |
| 28d           | 0.0000             | 0.002              | -                    | -                    |
| 50d           | 0.0000             | 0.001              | -                    | -                    |
| 100d          | 0.0000             | 0.001              | -                    | -                    |

Plateau concentration -

Molecular weight relative to the parent: 377.4/359.4
DT50 (d): 3.43 days
Kinetics: SFO
Field or Lab: worst case lab

Application rate assumed: 13.86 g/ha (assumed R-7 is formed at a maximum of 24% of the applied dose)
### Metabolite R-8

#### Method of calculation

- Molecular weight relative to the parent: 237.17/359.4
- DT50 (d): 92.36 days
- Kinetics: SFO
- Field or Lab: worst case lab

#### Application data

Application rate assumed: 16.26 g/ha (assumed R-8 is formed at a maximum of 44.8% of the applied dose)

| PEC(s)          | Single application Actual | Single application Time weighted average | Multiple application Actual | Multiple application Time weighted average |
|-----------------|--------------------------|----------------------------------------|----------------------------|------------------------------------------|
| (mg/kg)         |                          |                                        |                            |                                          |
| Initial         | 0.0152                   | -                                      | -                          |                                          |
| Short term      |                          |                                        |                            |                                          |
| 24h             | 0.0151                   | 0.015                                  | -                          | -                                        |
| 2d              | 0.0149                   | 0.015                                  | -                          | -                                        |
| 4d              | 0.0147                   | 0.015                                  | -                          | -                                        |
| Long term       |                          |                                        |                            |                                          |
| 7d              | 0.0144                   | 0.015                                  | -                          | -                                        |
| 28d             | 0.0123                   | 0.014                                  | -                          | -                                        |
| 50d             | 0.0104                   | 0.013                                  | -                          | -                                        |
| 100d            | 0.0072                   | 0.011                                  | -                          | -                                        |
| Plateau         |                          |                                        |                            |                                          |
| concentration   | 0.001 mg/kg (5 cm) after 2 yr |                                        |                            |                                          |
Molecular weight relative to the parent: 158.02/359.4
DT50 (d): 20.8 days
Kinetics: SFO
Field or Lab: worst case lab

Application rate assumed: 2.92 g/ha (assumed R-11 is formed at a maximum of 12% of the applied dose)

| PEC(s)     | Single application | Single application | Multiple application | Multiple application |
|------------|--------------------|--------------------|----------------------|----------------------|
|            | Actual             | Time weighted average | Actual             | Time weighted average |
| Initial    | 0.0027             | -                  | -                    | -                    |
| Short term |                    |                    |                      |                      |
| 24h        | 0.0026             | 0.003              | -                    | -                    |
| 2d         | 0.0025             | 0.003              | -                    | -                    |
| 4d         | 0.0024             | 0.003              | -                    | -                    |
| Long term  |                    |                    |                      |                      |
| 7d         | 0.0021             | 0.002              | -                    | -                    |
| 28d        | 0.0011             | 0.002              | -                    | -                    |
| 50d        | 0.0005             | 0.001              | -                    | -                    |
| 100d       | 0.0001             | 0.001              | -                    | -                    |

Plateau concentration -
Metabolite R-13

Method of calculation

- Molecular weight relative to the parent: 357.4/359.4
- DT50 (d): 261.3 days
- Kinetics: SFO
- Field or Lab: worst case lab

Application data

Application rate assumed: 12.63 g/ha (assumed R-13 is formed at a maximum of 23.1% of the applied dose)

| PEC(s)       | Single application | Single application | Multiple application | Multiple application |
|--------------|---------------------|--------------------|----------------------|----------------------|
|              | Actual              | Time weighted average | Actual              | Time weighted average |
| Initial      | 0.0118              |                     | -                    | -                    |
| Short term   |                     |                     |                      |                      |
| 24h          | 0.0118              | 0.012              | -                    | -                    |
| 2d           | 0.0117              | 0.012              | -                    | -                    |
| 4d           | 0.0117              | 0.012              | -                    | -                    |
| Long term    |                     |                     |                      |                      |
| 7d           | 0.0116              | 0.012              | -                    | -                    |
| 28d          | 0.0109              | 0.011              | -                    | -                    |
| 50d          | 0.0103              | 0.011              | -                    | -                    |
| 100d         | 0.0090              | 0.010              | -                    | -                    |
| Plateau concentration | 0.007 mg/kg (5 cm) after 5 yr |                     |                      |                      |
PEC ground water (Regulation (EU) N° 284/2013, Annex Part A, point 9.2.4.1)

Method of calculation and type of study (modelling)

| Scenario | Parent | Metabolites (µg/L) |
|----------|--------|--------------------|
|          |        |                    |

Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance.

Model(s) used: FOCUS PELMO 5.5.3 & FOCUS PEARL 4.4.4

Crop: Pome/Stone fruits, Citrus, Grapes, Fruiting Vegetables, Strawberries, Cotton

Crop uptake factor: 0

Water solubility (mg/L): 0.07 (parent), 1000 (default for all metabolites) at pH 7 and 20°C

Vapour pressure: 7*10^{-6} Pa at 20°C (parent), 1*10^{-8} Pa (for metabolites)

Geometric mean parent DT_{50,lab} 19.3 d (normalisation to 10kPa or pF2, 20 °C with Q_{10} of 2.58 and Walker equation coefficient 0.7).

Metabolites:
- R-3: 43.1 d,
- R-7: 1.5 d,
- R-8: 18.4 d,
- R-11: 20.8 d,
- R-13: 163.4 d,
- R-4: 11.4 d,
- R-12: 2.3 d

K_{OC}: 6267 L/kg (geometric mean), 1/n= 0.933

Metabolites:
- R-3: 5064 L/kg, 1/n= 0.935,
- R-7: 2704 L/kg, 1/n=0.903,
- R-8: 196 L/kg, 1/n=0.83,
- R-11: 31 L/kg, 1/n=0.743,
- R-13: 34642 L/kg, 1/n=0.853,
- R-4: 288 L/kg, 1/n=0.918,
- R-12: 24 L/kg, 1/n=0.957

Kinetic formation fractions for all metabolites were set to 1. In the modelling, the precursor for all metabolites was the parent compound.

Application rate

Gross application rate: 55 g/ha.

Crop growth stage: from infestation

Canopy interception %: model estimated

No. of applications: 1

Time of application (absolute or relative application dates): 15 April

PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m)
| Scenario       | Parent (µg/L) | Metabolites (µg/L) |
|---------------|--------------|--------------------|
|               | R-3 | R-7 | R-8 | R-11 | R-13 | R-4 | R-12 |
| Chateaudun    | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 |
| Hamburg       | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 |
| Jokioinen     | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 |
| Kremsmunster  | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 |
| Okehampton    | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 |
| Piacenza      | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 |
| Porto         | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 |
| Sevilla       | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 |
| Thiva         | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 |

### All crops/scenarios PELMO

| Scenario       | Parent (µg/L) | Metabolites (µg/L) |
|---------------|--------------|--------------------|
|               | R-3 | R-7 | R-8 | R-11 | R-13 | R-4 | R-12 |
| Chateaudun    | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 |
| Hamburg       | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 |
| Jokioinen     | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 |
| Kremsmunster  | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 |
| Okehampton    | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 |
| Piacenza      | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 |
| Porto         | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 |
| Sevilla       | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 |
| Thiva         | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 | <0.0005 |
### PEC 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 | Version control no. of FOCUS calculator: Step 1-2, v.3.2 |
|----------------------------------------|-----------------------------------------------------------|
| Molecular weight (g/mol): 359.4        |                                                           |
| KOC/KOM (mL/g): 6650/3857              |                                                           |
| $\text{DT}_{50}$ soil (d): 19.3 days (Lab geometric. In accordance with FOCUS SFO) | |
| $\text{DT}_{50}$ water/sediment system (d): 1000 d (default) | |
| $\text{DT}_{50}$ water (d): 1000 d (default) | |
| $\text{DT}_{50}$ sediment (d): 80.4 d (geometric from sediment water studies) | |
| Crop interception (%): minimal crop cover | |

#### Parameters used in FOCUSsw step 3/4

| Version control no.’s of FOCUS software: FOCUS SWASH version 5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, TOXSWA v4.4 and SWAN 4.0.1 |
|---------------------------------------------------------------------------------------------------------------------------------------|
| Water solubility (mg/L): 0.07                                                                                                           |
| Vapour pressure: $7 \times 10^{-6}$ Pa at 20°C                                                                                           |
| Kom/Koc (mL/g): 6267/3635                                                                                                               |
| $1/n$: 0.933                                                                                                                             |
| $Q_{10} = 2.58$, Walker equation coefficient 0.7                                                                                       |
| Crop uptake factor: 0                                                                                                                   |

#### Application rate

| Crop and growth stage: Pome/Stone fruits - BBCH 10 |
|---------------------------------------------------|
| Number of applications: 1                         |
| Interval (d): -                                    |
| Application rate(s): 55 g a.s./ha                  |
| Application window: 14 days before emergence to 16 days after emergence (early or late)       |

| Crop and growth stage: Citrus - BBCH 10          |
|---------------------------------------------------|
| Number of applications: 1                         |
| Interval (d): -                                    |
| Application rate(s): 55 g a.s./ha                  |
| Application window: 14 days before emergence to 16 days after emergence       |

| Crop and growth stage: Vines - BBCH 8             |
|---------------------------------------------------|
| Number of applications: 1                         |
| Interval (d): -                                    |
| Application rate(s): 55 g a.s./ha                  |
| Application window: 1 June-1 July                 |

| Crop and growth stage: Fruiting vegetables - BBCH 10 |
|-------------------------------------------------------|
| Number of applications: 1                             |
| Interval (d): -                                      |
| Application rate(s): 55 g a.s./ha                     |
| Application window: 14 days before emergence to 16 days after emergence |
Crop and growth stage: *Legume (surrogate crop for tomatoes, eggplant)* - BBCH 10
Number of applications: 1
Interval (d): -
Application rate(s): 55 g a.s./ha
Application window: 14 days before emergence to 16 days after emergence

Crop and growth stage: *Cotton* - BBCH 10
Number of applications: 1
Interval (d): -
Application rate(s): 41.25 g a.s./ha
Application window: 14 days before emergence to 16 days after emergence
### PECsw/sed for Etoxazole calculated with STEP 3 and STEP 4

**Etoxazole**

**Pome/stone fruit early applications**

| Water-body | Application date | Main route of entrance at STEP 3 | Initial PECsw (µg/l) | Initial PECsed (µg/kg) |
|------------|------------------|---------------------------------|----------------------|------------------------|
|            |                  | Step 3                          | Step 4: 10 m no spray Buffer | Step 4: 20 m no spray Buffer | Step 4: 25 m no spray Buffer | Step 4: 10 m no spray Buffer | Step 4: 15 m no spray Buffer | Step 4: 25 m no spray Buffer |
| D3 Ditch   | 4 April          | Drift                           | 4.240                | 2.045                  | 0.467                  | 0.276                  | 3.012                | 1.459                  | 0.336                  | 0.199                  |
| D4 Pond    | 18 April         | Drift                           | 0.258                | 0.159                  | 0.051                  | 0.035                  | 2.205                | 1.374                  | 0.454                  | 0.309                  |
| D4 Stream  | 18 April         | Drift                           | 3.987                | 2.103                  | 0.481                  | 0.283                  | 0.144                | 0.076                  | 0.017                  | 0.010                  |
| D5 Pond    | 8 April          | Drift                           | 0.258                | 0.159                  | 0.051                  | 0.035                  | 2.264                | 1.411                  | 0.466                  | 0.317                  |
| D5 Stream  | 8 April          | Drift                           | 4.208                | 2.219                  | 0.507                  | 0.299                  | 0.130                | 0.068                  | 0.016                  | 0.009                  |
| R1 Stream  | 26 April         | Drift                           | 0.258                | 0.159                  | 0.051                  | 0.035                  | 2.076                | 1.296                  | 0.430                  | 0.293                  |
| R1 Pond    | 26 April         | Drift                           | 3.430                | 1.809                  | 0.413                  | 0.244                  | 0.443                | 0.234                  | 0.053                  | 0.038                  |
| R2 Stream  | 1 March          | Drift                           | 4.544                | 2.397                  | 0.548                  | 0.323                  | 0.284                | 0.150                  | 0.086                  | 0.082                  |
| R3 Stream  | 28 March         | Drift                           | 4.830                | 2.548                  | 0.582                  | 0.343                  | 0.980                | 0.517                  | 0.120                  | 0.101                  |
| R4 Stream  | 05 March         | Drift                           | 3.430                | 1.809                  | 0.414                  | 0.244                  | 0.446                | 0.235                  | 0.096                  | 0.093                  |

**Etoxazole**

**Pome/stone fruit late applications**

| Water-body | Application date | Main route of entrance at STEP 3 | Initial PECsw (µg/l) | Initial PECsed (µg/kg) |
|------------|------------------|---------------------------------|----------------------|------------------------|
|            |                  | Step 3                          | Step 4: 10 m no spray Buffer | Step 4: 15 m no spray Buffer |
| D3 Ditch   | 4 April          | Drift                           | 1.999                | 0.602                  | 0.304                  | 1.426                | 0.433                  | 0.219                  |
| D4 Pond    | 18 April         | Drift                           | 0.090                | 0.057                  | 0.036                  | 0.785                | 0.502                  | 0.324                  |
| D4 Stream  | 18 April         | Drift                           | 1.777                | 0.620                  | 0.313                  | 0.064                | 0.022                  | 0.011                  |
| D5 Pond    | 8 April          | Drift                           | 0.090                | 0.057                  | 0.036                  | 0.806                | 0.515                  | 0.333                  |
| D5 Stream  | 8 April          | Drift                           | 1.876                | 0.654                  | 0.330                  | 0.058                | 0.020                  | 0.010                  |
| R1 Stream  | 26 April         | Drift                           | 0.090                | 0.057                  | 0.036                  | 0.742                | 0.475                  | 0.308                  |
| R1 Pond    | 26 April         | Drift                           | 1.529                | 0.533                  | 0.269                  | 0.198                | 0.069                  | 0.039                  |
| R2 Stream  | 1 March          | Drift                           | 2.026                | 0.706                  | 0.357                  | 0.127                | 0.089                  | 0.083                  |
**Peer review of the pesticide risk assessment of the active substance etoxazole**

### Citrus

| Water-body | Application date | Main route of entrance at STEP 3 | Initial PECsw (µg/l) | Initial PECsed (µg/kg) |
|------------|------------------|---------------------------------|----------------------|------------------------|
| R3 Stream  | 28 March         | Drift                           | 2.153                | 0.751                  |
| R4 Stream  | 05 March         | Drift                           | 1.529                | 0.533                  |

### Vines late applications

| Water-body | Application date | Main route of entrance at STEP 3 | Initial PECsw (µg/l) | Initial PECsed (µg/kg) |
|------------|------------------|---------------------------------|----------------------|------------------------|
| D6 Ditch   | 14 January       | Drift                           | 2.016                | 0.608                  |
| R4 Stream  | 05 March         | Drift                           | 1.525                | 0.532                  |

### Fruiting Vegetables

| Water-body | Application date | Main route of entrance at STEP 3 | Initial PECsw (µg/l) | Initial PECsed (µg/kg) |
|------------|------------------|---------------------------------|----------------------|------------------------|
| R2 Stream  | 04 Jun           | Drift                           | 0.921                | 0.243                  |
| R3 Stream  | 02 Jun           | Drift                           | 0.965                | 0.255                  |
| R4 Stream  | 08 Jun           | Drift                           | 0.687                | 0.181                  |

### Cotton

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### Etoxazole

**Legumes (surrogate for strawberries, cucurbits and ornamentals)**

| Water-body | Application date | Main route of entrance at STEP 3 | Step 3 | Initial PECsw (µg/l) | Initial PECsed (µg/kg) |
|------------|------------------|----------------------------------|--------|----------------------|------------------------|
| D3 Ditch   | 4 Apr            | Drift                            |        | 0.286                | 0.186                  |
| D4 Pond    | 18 Apr           | Drift                            |        | 0.012                | 0.104                  |
| D4 Stream  | 18 Apr           | Drift                            |        | 0.229                | 0.008                  |
| D5 Pond    | 7 Mar            | Drift                            |        | 0.012                | 0.108                  |
| D5 Stream  | 7 Mar            | Drift                            |        | 0.238                | 0.007                  |
| D6 Ditch   | 9 Mar            | Drift                            |        | 0.286                | 0.231                  |
| R1 Pond    | 26 Apr           | Drift                            |        | 0.012                | 0.127                  |
| R1 Stream  | 26 Apr           | Drift                            |        | 0.198                | 0.251                  |
| R2 Stream  | 22 Apr           | Drift                            |        | 0.263                | 0.300                  |
| R3 Stream  | 11 Apr           | Drift                            |        | 0.280                | 7.135                  |
| R4 Stream  | 8 Apr            | Drift                            |        | 0.198                | 4.590                  |
The input parameters used for SW modelling are summarized below:

| Compound | Molar mass | Soil DT$_{50}$ (d) | Koc (L/kg) | Max. % in soil | Max. % in water |
|----------|------------|------------------|-----------|---------------|---------------|
| R-3      | 361.38     | 43.1             | 5266      | 10.4          | 12.1          |
| R-4      | 377.4      | 11.4             | 288       | 12.4          | 8.4           |
| R-7      | 377.4      | 1.5              | 2704      | 24.0          | not observed*|
| R-8      | 237.17     | 19.0             | 220       | 44.8          | not observed*|
| R-11     | 158.02     | 20.8             | 31        | 12.0          | 64.0          |
| R-12     | 222.3      | 2.3              | 24        | 8.5           | 30.6          |
| R-13     | 357.4      | 163              | 44480     | 23.1          | 16.7          |
| R-15     | 221.3      | 1000 (default*)  | 10        | not observed*| 29.5          |

n.r. = not required

* A default DT50 in water/sediment (days) of 1000 days and a default water solubility of 1000 mg/L was used for all metabolites

* For modelling purposes a value of 0.01 was used.

Parameters used in FOCUSsw step 3 (if performed)

No step 3-4 modelling conducted.

Application rate

Crop and growth stage: Pome/Stone fruits (worst case) BBCH 10 (minimal crop cover 20% interception)

Number of applications: 1

Interval (d): -

Application rate(s): 55 g a.s./ha (transformed according to the molar fraction and max. occurrence)

Application window: June-Sept (STEP2)

Main routes of entry

Drift
FOCUS Step 1 PECsw and PECsed for R-3 following etoxazole application on Pome fruit, early applications (1 x 55 g a.s./ha)

| Time (d) | PECsw (µg/L) | PECsed (µg/kg dry sediment) |
|----------|--------------|-------------------------------|
|          | Actual       | TWA                           | Actual       | TWA                           |
| 0        | 0.8903       |                               | 12.5862      |
| 1        | 0.3200       | 0.6051                        | 16.8500      | 14.7181                       |
| 2        | 0.3198       | 0.4625                        | 16.8383      | 15.7811                       |
| 4        | 0.3193       | 0.3910                        | 16.8150      | 16.3039                       |
| 7        | 0.3186       | 0.3601                        | 16.7801      | 16.5155                       |
| 14       | 0.3171       | 0.3390                        | 16.6989      | 16.6275                       |
| 21       | 0.3156       | 0.3315                        | 16.6180      | 16.6378                       |
| 28       | 0.3140       | 0.3273                        | 16.5376      | 16.6228                       |
| 42       | 0.3110       | 0.3224                        | 16.3779      | 16.5677                       |
| 50       | 0.3093       | 0.3204                        | 16.2873      | 16.5301                       |
| 100      | 0.2988       | 0.3122                        | 15.7325      | 16.2692                       |

FOCUS Step 1 PECsw and PECsed for R-4 following etoxazole application on Pome fruit, early applications (1 x 55 g a.s./ha)

| Time (d) | PECsw (µg/L) | PECsed(µg/kg) |
|----------|--------------|---------------|
|          | Actual       | TWA           | Actual       | TWA           |
| 0        | 3.3654       | --            | 8.3327       |
| 1        | 3.2322       | 3.2988        | 9.3087       | 8.8207        |
| 2        | 3.2300       | 3.2650        | 9.3023       | 9.0631        |
| 4        | 3.2255       | 3.2463        | 9.2894       | 9.1795        |
| 7        | 3.2188       | 3.2360        | 9.2701       | 9.2225        |
| 14       | 3.2032       | 3.2235        | 9.2252       | 9.2351        |
| 21       | 3.1877       | 3.2141        | 9.1806       | 9.2243        |
| 28       | 3.1723       | 3.2056        | 9.1362       | 9.2078        |
| 42       | 3.1416       | 3.1894        | 9.0479       | 9.1692        |
| 50       | 3.1243       | 3.1803        | 8.9979       | 9.1458        |
| 100      | 3.0178       | 3.1255        | 8.6914       | 8.9948        |

FOCUS Step 2 PECsw and PECsed for R-4 following etoxazole application on Pome fruit, early applications (1 x 55 g a.s./ha)

| Time (d) | North EU (June-Sept) | South EU (June-Sept) |
|----------|-----------------------|----------------------|
|          | PECsw (µg/L) | PECsed(µg/kg) | PECsw (µg/L) | PECsed(µg/kg) |
|          | Actual       | TWA           | Actual       | TWA           |
|          | Actual       | TWA           | Actual       | TWA           |
| 0        | 0.7532       | --            | 0.9424       | --            |
| 1        | 0.7180       | 0.7356        | 2.0679       | 2.0672        |
| 2        | 0.7175       | 0.7267        | 2.0651       | 2.0651        |
| 4        | 0.7165       | 0.7219        | 2.0622       | 2.0651        |

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### FOCUS Step 1 PECsw and PECsed for R-7 following etoxazole application on Pome fruit, early applications (1 x 55 g a.s./ha)

| Time (d) | PECsw (µg/L) | PECsed (µg/kg dry sediment) |
|----------|--------------|-------------------------------|
|          | Actual       | TWA                           | Actual       | TWA                           |
| 0        | 1.0042       |                               | 27.1396      |                               |
| 1        | 1.0031       | 1.0037                        | 27.1241      | 27.1318                       |
| 2        | 1.0024       | 1.0032                        | 27.1053      | 27.1232                       |
| 4        | 1.0010       | 1.0025                        | 27.0677      | 27.1049                       |
| 7        | 0.9989       | 1.0014                        | 27.0115      | 27.0769                       |
| 14       | 0.9941       | 0.9990                        | 26.8808      | 27.0115                       |
| 21       | 0.9893       | 0.9965                        | 26.7506      | 26.9462                       |
| 28       | 0.9845       | 0.9941                        | 26.6212      | 26.8811                       |
| 42       | 0.9750       | 0.9893                        | 26.3641      | 26.7515                       |
| 50       | 0.9696       | 0.9866                        | 26.2183      | 26.6779                       |
| 100      | 0.9366       | 0.9698                        | 25.3252      | 26.2235                       |

### FOCUS Step 2 PECsw and PECsed for R-7 following etoxazole application on Pome fruit, early applications (1 x 55 g a.s./ha)

| Time (d) | North EU (June-Sept) | South EU (June-Sept) |
|----------|----------------------|----------------------|
|          | PECsw (µg/L)        | PECsed (µg/kg)       | PECsw (µg/L) | PECsed (µg/kg) |
|          | Actual   | TWA      | Actual   | TWA      | Actual   | TWA      | Actual   | TWA      |
| 0        | 0.0255   | ---      | 0.6881   | ---      | 0.0382   | ---      | 1.0307   | ---      |
| 1        | 0.0254   | 0.0255   | 0.6880   | 0.6880   | 0.0381   | 0.0381   | 1.0303   | 1.0305   |
| 2        | 0.0254   | 0.0255   | 0.6875   | 0.6879   | 0.0381   | 0.0381   | 1.0296   | 1.0302   |
| 4        | 0.0254   | 0.0254   | 0.6865   | 0.6875   | 0.0380   | 0.0381   | 1.0282   | 1.0296   |
| 7        | 0.0253   | 0.0254   | 0.6851   | 0.6868   | 0.0379   | 0.0380   | 1.0260   | 1.0285   |
| 14       | 0.0252   | 0.0253   | 0.6818   | 0.6851   | 0.0378   | 0.0379   | 1.0211   | 1.0260   |
| 21       | 0.0251   | 0.0253   | 0.6785   | 0.6835   | 0.0376   | 0.0379   | 1.0161   | 1.0235   |
| 28       | 0.0250   | 0.0252   | 0.6752   | 0.6818   | 0.0374   | 0.0378   | 1.0112   | 1.0211   |
| 42       | 0.0247   | 0.0251   | 0.6687   | 0.6785   | 0.0370   | 0.0376   | 1.0014   | 1.0162   |
| 50       | 0.0246   | 0.0250   | 0.6650   | 0.6767   | 0.0368   | 0.0375   | 0.9959   | 1.0134   |
| 100      | 0.0238   | 0.0246   | 0.6423   | 0.6651   | 0.0356   | 0.0368   | 0.9620   | 0.9961   |
FOCUS Step 1 PECsw and PECsed for R-8 following etoxazole application on Pome fruit, early applications (1 x 55 g a.s./ha)

| Time (d) | PECsw (µg/L) | PECsed (µg/kg dry sediment) |
|----------|--------------|-----------------------------|
|          | Actual       | TWA                        | Actual       | TWA                        |
| 0        | 4.1911       | 9.2196                     |
| 1        | 4.1881       | 9.2138                     |
| 2        | 4.1852       | 9.2075                     |
| 4        | 4.1794       | 9.1947                     |
| 7        | 4.1707       | 9.1756                     |
| 14       | 4.1505       | 9.1312                     |
| 21       | 4.1304       | 9.0870                     |
| 28       | 4.1105       | 9.0430                     |
| 42       | 4.0708       | 8.9557                     |
| 50       | 4.0483       | 8.9062                     |
| 100      | 3.9104       | 8.6028                     |

FOCUS Step 1 PECsw and PECsed for R-11 following etoxazole application on Pome fruit, early applications (1 x 55 g a.s./ha)

| Time (d) | PECsw (µg/L) | PECsed (µg/kg) |
|----------|--------------|----------------|
|          | Actual       | TWA            | Actual       | TWA            |
| 0        | 2.2785       | ---            | 0.6998       | ---            |
| 1        | 2.2575       | 2.2680         | 0.6994       | 0.6996         |
| 2        | 2.2560       | 2.2624         | 0.6989       | 0.6994         |
| 4        | 2.2529       | 2.2584         | 0.6979       | 0.6989         |

FOCUS Step 2 PECsw and PECsed for R-11 following etoxazole application on Pome fruit, early applications (1 x 55 g a.s./ha)

| Time (d) | North EU (June-Sept) | South EU (June-Sept) |
|----------|-----------------------|-----------------------|
|          | PECsw (µg/L)         | PECsed(µg/kg)         | PECsw (µg/L) | PECsed(µg/kg) |
|          | Actual            | TWA                  | Actual       | TWA            | Actual       | TWA                  |
| 0        | 2.2785           | ---                  | ---          | 0.6998         | ---          | 0.8263                |
| 1        | 2.2575           | 2.2680               | 0.6994       | 0.6996         | 2.6656       | 2.6762               |
| 2        | 2.2560           | 2.2624               | 0.6989       | 0.6994         | 2.6637       | 2.6704               |
| 4        | 2.2529           | 2.2584               | 0.6979       | 0.6989         | 2.6601       | 2.6662               |
### FOCUS Step 1 PECsw and PECsed for R-12 following etoxazole application on Pome fruit, early applications (1 x 55 g a.s./ha)

| Time (d) | PECsw (µg/L) | PECsed (µg/kg dry sediment) |
|---------|--------------|-----------------------------|
|         | Actual       | TWA                         | Actual       | TWA                         |
| 0       | 5.3095       | 1.0311                      |              |                             |
| 1       | 5.2744       | 5.2919                      | 1.2659       | 1.1485                      |
| 2       | 5.2707       | 5.2823                      | 1.2650       | 1.2070                      |
| 4       | 5.2634       | 5.2747                      | 1.2632       | 1.2355                      |
| 7       | 5.2525       | 5.2675                      | 1.2606       | 1.2468                      |
| 14      | 5.2271       | 5.2537                      | 1.2545       | 1.2522                      |
| 21      | 5.2018       | 5.2406                      | 1.2484       | 1.2520                      |
| 28      | 5.1766       | 5.2277                      | 1.2424       | 1.2503                      |
| 42      | 5.1266       | 5.2023                      | 1.2304       | 1.2457                      |
| 50      | 5.0983       | 5.1880                      | 1.2236       | 1.2427                      |
| 100     | 4.9246       | 5.0994                      | 1.1819       | 1.2227                      |

### FOCUS Step 2 PECsw and PECsed for R-12 following etoxazole application on Pome fruit, early applications (1 x 55 g a.s./ha)

| Time (d) | North EU (June-Sept) | South EU (June-Sept) |
|---------|-----------------------|----------------------|
|         | PECsw (µg/L)         | PECsed(µg/kg)       | PECsw (µg/L)          | PECsed(µg/kg)       |
|         | Actual | TWA   | Actual | TWA   | Actual | TWA   | Actual | TWA   |
| 0       | 1.5000 | ---   | 0.3573 | ---   | 1.7553 | ---   | 0.4185 | ---   |
| 1       | 1.4887 | 1.4943 | 0.3570 | 0.3572 | 1.7439 | 1.7496 | 0.4182 | 0.4184 |
| 2       | 1.4877 | 1.4913 | 0.3568 | 0.3570 | 1.7427 | 1.7465 | 0.4180 | 0.4182 |
| 4       | 1.4856 | 1.4890 | 0.3563 | 0.3568 | 1.7403 | 1.7440 | 0.4174 | 0.4180 |
| 7       | 1.4825 | 1.4869 | 0.3556 | 0.3564 | 1.7367 | 1.7416 | 0.4165 | 0.4175 |
| 14      | 1.4754 | 1.4829 | 0.3538 | 0.3556 | 1.7283 | 1.7370 | 0.4145 | 0.4165 |
| 21      | 1.4682 | 1.4792 | 0.3521 | 0.3547 | 1.7199 | 1.7327 | 0.4125 | 0.4155 |
| 28      | 1.4611 | 1.4756 | 0.3504 | 0.3538 | 1.7116 | 1.7285 | 0.4105 | 0.4145 |
| 42      | 1.4470 | 1.4684 | 0.3470 | 0.3521 | 1.6950 | 1.7201 | 0.4065 | 0.4125 |
| 50      | 1.4390 | 1.4643 | 0.3451 | 0.3512 | 1.6857 | 1.7153 | 0.4043 | 0.4114 |
| 100     | 1.3900 | 1.4393 | 0.3334 | 0.3452 | 1.6283 | 1.6861 | 0.3905 | 0.4044 |
FOCUS Step 1 PECsw and PECsed for R-13 following etoxazole application on Pome fruit, early applications (1 x 55 g a.s./ha)

| Time (d) | PECsw (µg/L) | PECsed (µg/kg dry sediment) |
|---------|--------------|-----------------------------|
|         | Actual       | TWA | Actual | TWA |
| 0       | 0.9588       |     | 31.0620 |
| 1       | 0.0845       | 0.5216 | 37.5924 | 34.3272 |
| 2       | 0.0845       | 0.3031 | 37.5664 | 35.9533 |
| 4       | 0.0843       | 0.1937 | 37.5143 | 36.7468 |
| 7       | 0.0842       | 0.1468 | 37.4364 | 37.0591 |
| 14      | 0.0838       | 0.1154 | 37.2552 | 37.2024 |
| 21      | 0.0834       | 0.1048 | 37.0749 | 37.1899 |
| 28      | 0.0829       | 0.0994 | 36.8954 | 37.1387 |
| 42      | 0.0821       | 0.0938 | 36.5391 | 36.9981 |
| 50      | 0.0817       | 0.0919 | 36.3371 | 36.9085 |
| 100     | 0.0789       | 0.0861 | 35.0993 | 36.3116 |

FOCUS Step 1 PECsw and PECsed for R-15 following etoxazole application on Pome fruit, early applications (1 x 55 g a.s./ha)

| Time (d) | PECsw (µg/L) | PECsed (µg/kg dry sediment) |
|---------|--------------|-----------------------------|
|         | Actual       | TWA | Actual | TWA |
| 0       | 0.9734       |     | 0.0001 |
| 1       | 0.9600       | 0.9667 | 0.0960 | 0.0481 |
| 2       | 0.9593       | 0.9632 | 0.0959 | 0.0720 |
| 4       | 0.9580       | 0.9609 | 0.0958 | 0.0839 |
| 7       | 0.9560       | 0.9592 | 0.0956 | 0.0890 |
| 14      | 0.9514       | 0.9564 | 0.0951 | 0.0922 |
| 21      | 0.9467       | 0.9540 | 0.0947 | 0.0931 |
| 28      | 0.9422       | 0.9516 | 0.0942 | 0.0934 |
| 42      | 0.9331       | 0.9469 | 0.0933 | 0.0935 |
| 50      | 0.9279       | 0.9443 | 0.0928 | 0.0935 |
| 100     | 0.8963       | 0.9282 | 0.0896 | 0.0923 |
Estimation of concentrations from other routes of exposure (Regulation (EU) N° 284/2013, Annex Part A, point 9.4)

Method of calculation

Etoxazole has a low vapour pressure ($7.0 \times 10^{-6} \text{ Pa at } 25^\circ\text{C}$) and has a DT50 in air of 0.140 day. Therefore it is considered that predicted concentrations from airborne transport will be negligible. No other route of exposure is also expected to occur.

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 |
|---------|----------------|------------|-----------|----------|
| **Birds** | | | | |
| Mallard duck *(Anas platyrhynchos)* | Etoxazole | Acute | LD₅₀ | > 2000 mg/kg bw |
| Bobwhite quail *(Colinus virginianus)* | Etoxazole | Short-term | LC₅₀ | > 5200 ppm (equivalent to 1268 mg/kg bw/day) |
| Mallard duck *(Anas platyrhynchos)* | Etoxazole | Long-term | LD₅₀/10 | > 200 mg/kg bw/day |
| Bobwhite quail *(Colinus virginianus)* | Etoxazole | Long-term | NOEC | 300 ppm (equivalent to 28.6 mg/kg bw/day) |
| **Mammals** | | | | |
| Rat | Etoxazole | Acute | LD₅₀ | > 5000 mg/kg bw |
| Rat | Etoxazole 11SC | Acute | LD₅₀ | > 5000 mg/kg bw |
| Rat | Etoxazole | Long-term | NOAEL | 24.5 mg/kg bw/day |

Endocrine disrupting properties (Annex Part A, points 8.1.5)

With regard to the endocrine disruption potential, as discussed in Section 2, it is unlikely that etoxazole is an endocrine disruptor in mammals; however, no firm conclusion can be drawn regarding fish, birds and amphibians.

Additional higher tier studies (Annex Part A, points 10.1.1.2):

No additional higher-tier studies were submitted.

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

No additional studies on other terrestrial vertebrates are required. The literature search carried out by the applicant did not reveal any additional studies on terrestrial vertebrates including reptiles and amphibians.
Toxicity/exposure ratios for terrestrial vertebrates (Regulation (EU) No 284/2013, Part A, Annex point 10.1)

### Orchards at 1 x 55 g a.s./ha (from infestation)

| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|--------------|---------------------------|------------|------------------------|-----|---------|
| **Screening Step (Birds) – Active substance etoxazole** | | | | | |
| All | Small insectivorous bird | Acute | 2.57 | > 777 | 10 |
| All | Small insectivorous bird | Long-term | 0.53 | 54 | 5 |
| **Screening Step (Birds) – Metabolite DFB (2,6-difluorobenzamide)** | | | | | |
| All | Small insectivorous bird | Acute | 1.13 | > 178 | 10 |
| All | Small insectivorous bird | Long-term | 0.23 | 12 | 5 |
| **Screening Step (Mammals) – Active substance etoxazole** | | | | | |
| All | Small herbivorous mammal | Acute | 7.50 | > 666 | 10 |
| All | Small herbivorous mammal | Long-term | 2.11 | 12 | 5 |
| **Screening Step (Mammals) – Metabolite DFB (2,6-difluorobenzamide)** | | | | | |
| All | Small herbivorous mammal | Acute | 3.28 | > 152 | 10 |
| All | Small herbivorous mammal | Long-term | 0.92 | 2.7 | 5 |
| **Tier 1 (Mammals) – Metabolite DFB (2,6-difluorobenzamide)** | | | | | |
| < 10 | Large herbivorous mammal “lagomorph” | Long-term | 0.182 | 14 | 5 |
| < 10 | Small herbivorous mammal “vole” | Long-term | 0.921 | 2.7 | 5 |
| < 10 | Small insectivorous mammal “shrew” | Long-term | 0.024 | 102 | 5 |
| < 10 | Small omnivorous mammal “mouse” | Long-term | 0.099 | 25 | 5 |
| 10-19 | Large herbivorous mammal “lagomorph” | Long-term | 0.147 | 17 | 5 |
| 10-19 | Small herbivorous mammal “vole” | Long-term | 0.737 | 3.3 | 5 |
| 10-19 | Small omnivorous mammal “mouse” | Long-term | 0.079 | 31 | 5 |
| 20-40 | Large herbivorous mammal “lagomorph” | Long-term | 0.110 | 22 | 5 |
| 20-40 | Small herbivorous mammal “vole” | Long-term | 0.553 | 4.4 | 5 |
| 20-40 | Small omnivorous mammal “mouse” | Long-term | 0.060 | 41 | 5 |
| ≥ 40 | Large herbivorous mammal “lagomorph” | Long-term | 0.055 | 45 | 5 |
| ≥ 40 | Small herbivorous mammal “vole” | Long-term | 0.277 | 9 | 5 |
| ≥ 40 | Small omnivorous mammal “mouse” | Long-term | 0.029 | 85 | 5 |
| 71-79 | Frugivorous mammal “dormouse” | Long-term | 0.289 | 9 | 5 |

**Higher tier (Mammals) – Metabolite DFB (2,6-difluorobenzamide)**

No higher-tier data were available to address the long-term risk to wild mammals from etoxazole metabolite DFB (2,6-difluorobenzamide).
Risk from bioaccumulation and food chain behaviour

The log octanol-water partition coefficients (log $P_{ow}$) for etoxazole and its metabolites R-3, R-4, R-7 and R-13 exceed the trigger of 3 indicating that the potential for accumulation via the aquatic and terrestrial food chain should be assessed for these substances.

The risk assessment for earthworm- and fish-eating predators (including birds and mammals) has been conducted on the basis of the worst-case soil and surface water exposure estimations resulting from the proposed use pattern of the formulated product Etoxazole 11SC.

| Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|---------------------------|------------|------------------------|-----|---------|
| **Active substance etoxazole** |            |                        |     |         |
| Earthworm-eating birds    | Long-term  | 0.877                  | 33  | 5       |
| Earthworm-eating mammals  | Long-term  | 1.07                   | 23  | 5       |
| Fish-eating birds         | Long-term  | 1.92                   | 11  | 5       |
| Fish-eating mammals       | Long-term  | 1.71                   | 11  | 5       |
| **Metabolite R-3**         |            |                        |     |         |
| Earthworm-eating birds    | Long-term  | 0.0036                 | 784 | 5       |
| Earthworm-eating mammals  | Long-term  | 0.0044                 | 557 | 5       |
| Fish-eating birds         | Long-term  | 0.0353                 | 81  | 5       |
| Fish-eating mammals       | Long-term  | 0.0316                 | 94  | 5       |
| **Metabolite R-4**         |            |                        |     |         |
| Earthworm-eating birds    | Long-term  | 0.0139                 | 206 | 5       |
| Earthworm-eating mammals  | Long-term  | 0.0170                 | 144 | 5       |
| Fish-eating birds         | Long-term  | 0.158                  | 18  | 5       |
| Fish-eating mammals       | Long-term  | 0.141                  | 223 | 5       |
| **Metabolite R-7**         |            |                        |     |         |
| Earthworm-eating birds    | Long-term  | 0.0149                 | 192 | 5       |
| Earthworm-eating mammals  | Long-term  | 0.0182                 | 135 | 5       |
| Fish-eating birds         | Long-term  | 0.220                  | 13  | 5       |
| Fish-eating mammals       | Long-term  | 0.196                  | 54.4| 5       |
| **Metabolite R-13**        |            |                        |     |         |
| Earthworm-eating birds    | Long-term  | 0.588                  |     |         |
| Earthworm-eating mammals  | Long-term  | 0.717                  |     |         |
| Fish-eating birds         | Long-term  | 0.182                  |     |         |
| Fish-eating mammals       | Long-term  | 0.163                  |     |         |
| **Higher tier:**          |            |                        |     |         |
|                          |            |                        |     |         |
| No higher-tier data to address the risk to earthworm-eating birds and mammals from metabolite R-13 via secondary poisoning were available.

Risk from consumption of contaminated water

| Scenarios          | Indicator or focal species | Time scale | $\text{PEC}_{\text{dw}} \times \text{DWR}$ | TER | Trigger |
|--------------------|----------------------------|------------|----------------------------------------|-----|---------|
| Leaf scenario      | Birds                      | leaf scenario does not apply to the use of Etoxazole 11SC |     |         |
| **Puddle scenario, Screening step** | | | | | |
| Application rate (g a.s./ha)/relevant endpoint <3000 (koc≥500 L/kg), TER calculation not needed | | | | |
Ornamental plants at 1 x 55 g a.s./ha (from infestation)

| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|--------------|---------------------------|------------|------------------------|-----|---------|
| Screening Step (Birds) – Active substance etoxazole | All | Small insectivorous bird | Acute | 2.57 | > 777 | 10 |
| | All | Small insectivorous bird | Long-term | 0.53 | 54 | 5 |
| Screening Step (Birds) – Metabolite DFB (2,6-difluorobenzamide) | All | Small insectivorous bird | Acute | 1.13 | > 178 | 10 |
| | All | Small insectivorous bird | Long-term | 0.23 | 12 | 5 |
| Screening Step (Mammals) – Active substance etoxazole | All | Small herbivorous mammal | Acute | 7.50 | > 666 | 10 |
| | All | Small herbivorous mammal | Long-term | 2.11 | 12 | 5 |
| Screening Step (Mammals) – Metabolite DFB (2,6-difluorobenzamide) | All | Small herbivorous mammal | Acute | 3.28 | > 152 | 10 |
| | All | Small herbivorous mammal | Long-term | 0.92 | 2.7 | 5 |
| Tier 1 (Mammals) – Metabolite DFB (2,6-difluorobenzamide) | Application to crop – exposure to underlying ground | Small insectivorous mammal “shrew” | Long-term | 0.024 | 102 | 5 |
| | 10-49 | Small omnivorous mammal “mouse” | Long-term | 0.099 | 25 | 5 |
| | 40-49 | Small herbivorous mammal “vole” | Long-term | 0.050 | 49 | 5 |
| | ≥ 50 | Small omnivorous mammal “mouse” | Long-term | 0.460 | 5.3 | 5 |
| | ≥ 50 | Small herbivorous mammal “vole” | Long-term | 0.921 | 2.7 | 5 |
| Higher tier (Mammals) – Metabolite DFB (2,6-difluorobenzamide) | | | | | |

No higher-tier data were available to address the long-term risk to wild mammals from etoxazole metabolite DFB (2,6-difluorobenzamide).

Risk from bioaccumulation and food chain behaviour

The log octanol-water partition coefficients (log P_{ow}) for etoxazole and its metabolites R-3, R-4, R-7 and R-13 exceed the trigger of 3 indicating that the potential for accumulation via the aquatic and terrestrial food chain should be assessed for these substances.

The risk assessment for earthworm- and fish-eating predators (including birds and mammals) has been conducted on the basis of the worst-case soil and surface water exposure estimations resulting from the proposed use pattern of the formulated product Etoxazole 11SC. Please refer to the calculations presented above for orchards.

Risk from consumption of contaminated water

| Scenarios | Indicator or focal species | Time scale | PEC_{dw}xDWR | TER | Trigger |
|-----------|---------------------------|------------|--------------|-----|---------|
| Leaf scenario | Birds | leaf scenario does not apply to the use of Etoxazole 11SC | | | |
| Puddle scenario, Screening step | | | | | |

Application rate (g a.s./ha)/relevant endpoint <3000 (koc≥500 L/kg), TER calculation not needed
## Vineyard at 1 x 55 g a.s./ha (from infestation)

| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|--------------|---------------------------|------------|------------------------|-----|---------|
|              |                           |            |                        |     |         |
| Screening Step (Birds) – Active substance etoxazole | | | | | |
| All          | Small omnivorous bird     | Acute      | 5.24                   | > 382 | 10      |
| All          | Small omnivorous bird     | Long-term  | 1.13                   | 25   | 5       |
| Screening Step (Birds) – Metabolite DFB (2,6-difluorobenzamide) | | | | | |
| All          | Small omnivorous bird     | Acute      | 2.29                   | > 87  | 10      |
| All          | Small omnivorous bird     | Long-term  | 0.50                   | 5.8   | 5       |
| Screening Step (Mammals) – Active substance etoxazole | | | | | |
| All          | Small herbivorous mammal  | Acute      | 7.50                   | > 666 | 10      |
| All          | Small herbivorous mammal  | Long-term  | 2.11                   | 12   | 5       |
| Screening Step (Mammals) – Metabolite DFB (2,6-difluorobenzamide) | | | | | |
| All          | Small herbivorous mammal  | Acute      | 3.28                   | > 152 | 10      |
| All          | Small herbivorous mammal  | Long-term  | 0.92                   | 2.7  | 5       |
| Tier 1 (Mammals) – Metabolite DFB (2,6-difluorobenzamide) | | | | | |
| 10-19        | Small herbivorous mammal  | Long-term  | 0.553                  | 4.4  | 5       |
| 10-19        | Small omnivorous mammal   | Long-term  | 0.60                   | 41   | 5       |
| 10-19        | Small insectivorous mammal| Long-term  | 0.054                  | 45   | 5       |
| 10-19        | Large herbivorous mammal  | Long-term  | 0.085                  | 29   | 5       |
| ≥ 20         | Small insectivorous mammal| Long-term  | 0.024                  | 102  | 5       |
| 20-39        | Small herbivorous mammal  | Long-term  | 0.460                  | 5.3  | 5       |
| 20-39        | Small omnivorous mammal   | Long-term  | 0.050                  | 49   | 5       |
| 20-39        | Large herbivorous mammal  | Long-term  | 0.070                  | 35   | 5       |
| ≥ 40         | Large herbivorous mammal  | Long-term  | 0.042                  | 58   | 5       |
| ≥ 40         | Small herbivorous mammal  | Long-term  | 0.277                  | 9    | 5       |
| ≥ 40         | Small omnivorous mammal   | Long-term  | 0.029                  | 85   | 5       |

## Risk from bioaccumulation and food chain behaviour

The log octanol-water partition coefficients (log $P_{ow}$) for etoxazole and its metabolites R-3, R-4, R-7 and R-13 exceed the trigger of 3 indicating that the potential for accumulation via the aquatic and terrestrial food chain should be assessed for these substances.

The risk assessment for earthworm- and fish-eating predators (including birds and mammals) has been conducted on the basis of the worst-case soil and surface water exposure estimations resulting from the proposed use pattern of the formulated product Etoxazole 11SC. Please refer to the calculations presented above for orchards.

## Risk from consumption of contaminated water

| Scenarios       | Indicator or focal species | Time scale | PEC$_{in}$×DWR | TER | Trigger |
|-----------------|----------------------------|------------|----------------|-----|---------|
| Leaf scenario   | Birds                      | leaf scenario does not apply to the use of Etoxazole 11SC | | | 5 |

**Puddle scenario, Screening step**

Application rate (g a.s./ha)/relevant endpoint <3000 (koc≥500 L/kg), TER calculation not needed
**Fruiting vegetables at 1 x 55 g a.s./ha (from infestation until BBCH 89)**

| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|--------------|---------------------------|------------|------------------------|-----|---------|
| **Screening Step (Birds) – Active substance etoxazole** | | | | | |
| All | Small omnivorous bird | Acute | 8.73 | > 229 | 10 |
| All | Small omnivorous bird | Long-term | 1.89 | 15 | 5 |
| **Screening Step (Birds) – Metabolite DFB (2,6-difluorobenzamide)** | | | | | |
| All | Small omnivorous bird | Acute | 3.82 | > 52 | 10 |
| All | Small omnivorous bird | Long-term | 0.83 | 3.5 | 5 |
| **Tier 1 (Birds) – Metabolite DFB (2,6-difluorobenzamide)** | | | | | |
| 10-19 | Small insectivorous bird “wagtail” | Long-term | 0.144 | 20 | 5 |
| 10-49 | Small granivorous bird “finch” | Long-term | 0.145 | 20 | 5 |
| 10-49 | Small omnivorous bird “lark” | Long-term | 0.139 | 21 | 5 |
| ≥ 20 | Small insectivorous bird “wagtail” | Long-term | 0.124 | 23 | 5 |
| ≥ 50 | Small granivorous bird “finch” | Long-term | 0.043 | 66 | 5 |
| ≥ 50 | Small omnivorous bird “lark” | Long-term | 0.042 | 68 | 5 |
| 71-89 | Frugivorous bird “crow” | Long-term | 0.408 | 7.0 | 5 |
| 71-89 | Frugivorous bird “Starling” | Long-term | 0.264 | 11 | 5 |
| **Screening Step (Mammals) – Active substance etoxazole** | | | | | |
| All | Small herbivorous mammal | Acute | 7.50 | > 666 | 10 |
| All | Small herbivorous mammal | Long-term | 2.11 | 12 | 5 |
| **Screening Step (Mammals) – Metabolite DFB (2,6-difluorobenzamide)** | | | | | |
| All | Small herbivorous mammal | Acute | 3.28 | > 152 | 10 |
| All | Small herbivorous mammal | Long-term | 0.92 | 2.7 | 5 |
| **Tier 1 (Mammals) – Metabolite DFB (2,6-difluorobenzamide)** | | | | | |
| 10-19 | Small insectivorous mammal “shrew” | Long-term | 0.054 | 45 | 5 |
| 10-49 | Small herbivorous mammal “vole” | Long-term | 0.921 | 2.7 | 5 |
| 10-49 | Small omnivorous mammal “mouse” | Long-term | 0.099 | 25 | 5 |
| ≥ 20 | Small insectivorous mammal “shrew” | Long-term | 0.024 | 102 | 5 |
| ≥ 50 | Small herbivorous mammal “vole” | Long-term | 0.277 | 9 | 5 |
| ≥ 50 | Small omnivorous mammal “mouse” | Long-term | 0.029 | 85 | 5 |
| 71-89 | Frugivorous mammal “rat” | Long-term | 0.321 | 8 | 5 |
| **Higher tier (Mammals) – Metabolite DFB (2,6-difluorobenzamide)** | | | | | |
| No higher-tier data were available to address the long-term risk to wild mammals from etoxazole metabolite DFB (2,6-difluorobenzamide). |
Risk from bioaccumulation and food chain behaviour

The log octanol-water partition coefficients (log $P_{ow}$) for etoxazole and its metabolites R-3, R-4, R-7 and R-13 exceed the trigger of 3 indicating that the potential for accumulation via the aquatic and terrestrial food chain should be assessed for these substances. The risk assessment for earthworm- and fish-eating predators (including birds and mammals) has been conducted on the basis of the worst-case soil and surface water exposure estimations resulting from the proposed use pattern of the formulated product Etoxazole 11SC. Please refer to the calculations presented above for orchards.

Strawberry at 1 x 55 g a.s./ha (from infestation until BBCH 89)

Risk from consumption of contaminated water

| Scenarios       | Indicator or focal species | Time scale | PEC$_{dw} \times$DWR | TER | Trigger |
|-----------------|---------------------------|------------|-----------------------|-----|---------|
| Leaf scenario   | Birds                     | leaf scenario does not apply to the use of Etoxazole 11SC |

Puddle scenario, Screening step

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

Risk from bioaccumulation and food chain behaviour

The log octanol-water partition coefficients (log $P_{ow}$) for etoxazole and its metabolites R-3, R-4, R-7 and R-13 exceed the trigger of 3 indicating that the potential for accumulation via the aquatic and terrestrial food chain should be assessed for these substances. The risk assessment for earthworm- and fish-eating predators (including birds and mammals) has been conducted on the basis of the worst-case soil and surface water exposure estimations resulting from the proposed use pattern of the formulated product Etoxazole 11SC. Please refer to the calculations presented above for orchards.
### Risk from consumption of contaminated water

| Scenarios                     | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|-------------------------------|---------------------------|------------|------------------------|-----|---------|
| Leaf scenario                 | Birds                     |            | leaf scenario does not apply to the use of Etoxazole 11SC |     |         |

**Puddle scenario, Screening step**

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

### Cotton at 1 x 41.25 g a.s./ha (before boll opening, upon appearance of the first mobile stages)

| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|---------------|---------------------------|------------|------------------------|-----|---------|
| Screening Step (Birds) – Active substance etoxazole | All | Small omnivorous bird | Acute | 6.61 | > 302 | 10 |
|               | All | Small omnivorous bird | Long-term | 1.43 | 20 | 5 |
| Screening Step (Birds) – Metabolite DFB (2,6-difluorobenzamide) | All | Small omnivorous bird | Acute | 2.89 | > 69 | 10 |
|               | All | Small omnivorous bird | Long-term | 0.63 | 4.6 | 5 |
| Tier 1 (Birds) – Metabolite DFB (2,6-difluorobenzamide) | 10-19 | Medium insectivorous bird “pranticole” | Long-term | 0.022 | 130 | 5 |
|               | 10-49 | Small omnivorous bird “sparrow” | Long-term | 0.107 | 27 | 5 |
|               | ≥ 20 | Medium insectivorous bird “pranticole” | Long-term | 0.011 | 272 | 5 |
|               | ≥ 50 | Small omnivorous bird “sparrow” | Long-term | 0.027 | 107 | 5 |
| Screening Step (Mammals) – Active substance etoxazole | All | Small herbivorous mammal | Acute | 5.63 | > 889 | 10 |
|               | All | Small herbivorous mammal | Long-term | 1.58 | 16 | 5 |
| Screening Step (Mammals) – Metabolite DFB (2,6-difluorobenzamide) | All | Small herbivorous mammal | Acute | 2.46 | > 203 | 10 |
|               | All | Small herbivorous mammal | Long-term | 0.69 | 4 | 5 |
| Tier 1 (Mammals) – Metabolite DFB (2,6-difluorobenzamide) | ≥ 20 | Small insectivorous mammal “shrew” | Long-term | 0.018 | 136 | 5 |
|               | ≥ 50 | Small herbivorous mammal “vole” | Long-term | 0.174 | 14 | 5 |
|               | ≥ 50 | Small omnivorous mammal “mouse” | Long-term | 0.018 | 136 | 5 |
| 10-19 | Small insectivorous mammal “shrew” | Long-term | 0.040 | 61 | 5 |
| 10-49 | Small omnivorous mammal “mouse” | Long-term | 0.075 | 33 | 5 |
Higher tier (Mammals) – Metabolite DFB (2,6-difluorobenzamide)

No higher-tier data were available to address the long-term risk to wild mammals from etoxazole metabolite DFB (2,6-difluorobenzamide).

Risk from bioaccumulation and food chain behaviour

The log octanol-water partition coefficients (log $P_{ow}$) for etoxazole and its metabolites R-3, R-4, R-7 and R-13 exceed the trigger of 3 indicating that the potential for accumulation via the aquatic and terrestrial food chain should be assessed for these substances.

The risk assessment for earthworm- and fish-eating predators (including birds and mammals) has been conducted on the basis of the worst-case soil and surface water exposure estimations resulting from the proposed use pattern of the formulated product Etoxazole 11SC. Please refer to the calculations presented above for orchards.

Risk from consumption of contaminated water

Toxicity data for all aquatic tested species (Regulation (EU) Nº 283/2013, Annex Part A, points 8.2 and Regulation (EU) Nº 284/2013 Annex Part A, point 10.2)*
### Group

| Test substance | Time-scale | End point | Toxicity $^*$ |
|----------------|------------|-----------|---------------|
| **Lepomis macrochirus** | Metabolite R-4 | Acute 96 h – static-renewal | Mortality, LC$_{50}$ | $>0.99$ mg metab/L (nom) |
| **Lepomis macrochirus** | Metabolite R-7 | Acute 96 h – static-renewal | Mortality, LC$_{50}$ | $>0.96$ mg metab/L (nom) |
| **Lepomis macrochirus** | Metabolite R-8 | Acute 96 h – static-renewal | Mortality, LC$_{50}$ | $>0.99$ mg metab/L (nom) |
| **Lepomis macrochirus** | Metabolite R-13 | Acute 96 h – static-renewal | Mortality, LC$_{50}$ | $>1$ mg metab/L (nom) |
| **Oncorhynchus mykiss** | Etoxazole | Chronic 89 d – flow-through, ELS | Mortality, NOEC | 0.015 mg a.s./L (mm) |

### Aquatic invertebrates

| Test substance | Time-scale | End point | Toxicity $^*$ |
|----------------|------------|-----------|---------------|
| **Daphnia magna** | Etoxazole | Acute 48 h – flow-through | Immobilization, EC$_{50}$ | 0.0071 mg a.s./L (mm) |
| **Daphnia magna** | R-isomer of Etoxazole | Acute 48 h – static | Immobilization, EC$_{50}$ | 0.026 mg a.s./L (mm) |
| **Daphnia magna** | S-isomer of Etoxazole | Acute 48 h – static | Immobilization, EC$_{50}$ | 0.005 mg a.s./L (mm) |
| **Americamysis bahia** | Etoxazole | Acute 96 h – flow-through | Mortality, LC$_{50}$ | 0.0044 mg a.s./L (mm) |
| **Crassostrea virginica** | Etoxazole | Acute 96 h – flow-through | Mortality, LC$_{50}$ | 0.0043 mg a.s./L (mm) |
| **Daphnia magna** | Metabolite R-3 | Acute 48 h – static | Immobilization, EC$_{50}$ | $>1$ mg metab/L (nom) |
| **Daphnia magna** | Metabolite R-4 | Acute 48 h – static | Immobilization, EC$_{50}$ | $>1.3$ mg metab/L (mm) |
| **Daphnia magna** | Metabolite R-7 | Acute 48 h – static | Immobilization, EC$_{50}$ | $>7.4$ mg metab/L (nom) |
| **Daphnia magna** | Metabolite R-8 | Acute 48 h – static | Immobilization, EC$_{50}$ | $>0.99$ mg metab/L (nom) |
| **Daphnia magna** | Metabolite R-11 | Acute 48 h – static | Immobilization, EC$_{50}$ | $>11$ mg metab/L (mm) |
| **Daphnia magna** | Metabolite R-12 | Acute 48 h – static | Immobilization, EC$_{50}$ | $>9.3$ mg metab/L (mm) |
| **Daphnia magna** | Metabolite R-13 | Acute 48 h – static | Immobilization, EC$_{50}$ | $>1$ mg metab/L (nom) |
| **Daphnia magna** | Metabolite R-15 | Acute 48 h – static | Immobilization, EC$_{50}$ | $>2.7$ mg metab/L (mm) |
| Group                          | Test substance | Time-scale (Test type) | End point         | Toxicity $^1$                                                                 |
|-------------------------------|----------------|-----------------------|-------------------|-------------------------------------------------------------------------------|
| **Daphnia magna**             | Etixazole 11SC | Acute 48 h – static   | Immobilization, EC$_{50}$ | 0.015 mg prep./L (0.0016 mg a.s./L) (mm)                                      |
|                               | $[^{14}]$etixazole | Chronic 21 d – flow-through | NOEC              | 0.0002 mg a.s./L (mm)                                                        |
|                               | $[^{14}]$etixazole | Chronic 21 d – flow-through | NOEC              | 0.00013 mg a.s./L (mm)                                                       |
| **Americamysis bahia**        | $[^{14}]$etixazole | Chronic 28 d – flow-through | NOEC              | 0.00032 mg a.s./L (mm)                                                       |
| **Sediment-dwelling organisms** |                |                       |                   |                                                                               |
| **Chironomus riparius**       | $[^{14}]$etixazole | Chronic 10 d – static-renewal | NOEC              | 25 mg a.s./kg dry sediment (mm)                                               |
|                               | Etixazole       | Chronic 28 d – static  | NOEC              | 26 mg a.s./kg dry sediment (mm) (0.28 mg a.s./L in pore water and 0.016 mg a.s./L in overlying water) |
|                               | Etixazole       | Chronic 10 d – static-renewal | NOEC              | 11 mg a.s./kg dry sediment (mm)                                               |
| **Leptochaerus plumulosus**   | Etixazole       | Chronic 28 d – static-renewal | NOEC              | 0.86 mg a.s./kg dry sediment (mm)                                             |
| **Chironomus riparius**       | Metabolite R-13 | Chronic 28 d – static  | NOEC              | 75 mg metab/kg dry sediment (mm) (0.079 mg/L in pore water and 0.073 mg/L in overlying water) |
| **Algae**                     |                |                       |                   |                                                                               |
| **Selenastrum capricornutum** | Etixazole       | Chronic 72 d – static  | Growth rate: $E_{C_{50}}$ (NOEC) [Biomass: $E_{B_{C_{50}}}$ (NOEC)] | >10 mg a.s./L (mm)                                                          |
|                               | Metabolite R-3  | Chronic 72 d – static  | Growth rate: $E_{C_{50}}$ (NOEC) [Biomass: $E_{B_{C_{50}}}$ (NOEC)] | >0.84 mg metab/L (mm)                                                       |
| Group | Test substance | Time-scale (Test type) | End point | Toxicity $^1$ |
|-------|----------------|------------------------|-----------|---------------|
| *Selenastrum capricornutum* | Metabolite R-4 | Chronic 72 d – static | Growth rate: $E_rC_{50}$ (NOEC) [Biomass: $E_bC_{50}$ (NOEC)] | $>$0.98 mg metab/L (mm) |
| *Selenastrum capricornutum* | Metabolite R-13 | Chronic 72 d – static | Growth rate: $E_rC_{50}$ (NOEC) [Biomass: $E_bC_{50}$ (NOEC)] | $>$0.81 mg metab/L (mm) |

Further testing on aquatic organisms: Mesocosm (indoor) study for Etoxazole 11SC

The microcosm could be used for refining the risk assessment only for SEU due to the high temperatures (Pesticides Peer Review meeting July 2017). To further consider this study, the exposure profile in the microcosm should be compared with the FOCUS scenarios. This comparison should rely on the concentration of the active substance and on the water temperature. The representativeness of study by Schanné and Gries (2004) should be considered further at MS level.

**Potential endocrine disrupting properties (Annex Part A, point 8.2.3)**

With regard to the endocrine disruption potential, as discussed in Section 2, it is unlikely that etoxazole is an endocrine disruptor in mammals; however, no firm conclusion can be drawn regarding fish, birds and amphibians.

$^1$: (nom) nominal concentration; (mm) mean measured concentration; prep.: preparation; a.s.: active substance; metab: metabolite
### Bioconcentration in fish (Annex Part A, point 8.2.2.3)

|                         | Active substance | R-3 metabolite |
|-------------------------|------------------|----------------|
| logP<sub>OW</sub>       |                  |                |
|                         |                  |                |
| Steady-state bioconcentration factor (BCF) (total wet weight/normalised to 5% lipid content) | *2500-3300 (whole fish); 1100-1600 (edible tissue); 4100-4700 (non-edible tissue) | *202.4 |
|                         |                  |                |
| Annex VI Trigger for the bioconcentration factor | 100 |                |
|                         |                  |                |
| Clearance time (days) (CT<sub>50</sub>) | 5.0-6.3 days (whole fish) 2.6-2.6 days (edible) 4.6-6.2 days (non-edible) | - |
|                         |                  |                |
| (CT<sub>90</sub>) | 7.6-9.3 days (whole fish) 4.5-7.0 days (edible) 10.3-13.1 days (non-edible) | - |
|                         |                  |                |
| Level and nature of residues (%) in organisms after the 14 day depuration phase | 70-80% radioactivity (after 5 days) 94-96% radioactivity (after 20 days) | - |
|                         |                  |                |
|                          |                  | * based on total <sup>14</sup>C or on specific compounds |
|                          |                  | BCF<sub>fish</sub> estimated via QSAR analysis (EpiSuite BCFBAF 3.01 calculation program) |
| Metabolite | Description | Value |
|------------|-------------|-------|
| R-4 metabolite | log $P_{OW}$ | R-4 metabolite | log $P_{OW}$ | *28.2 |
| Steady-state bioconcentration factor (BCF) (total wet weight/normalised to 5% lipid content) | 100 |
| Clearance time (days) ($CT_{50}$) | - |
| ($CT_{90}$) | - |
| Level and nature of residues (%) in organisms after the 14 day depuration phase | *BCF$_{fish}$ estimated via QSAR analysis (EpiSuite BCFBAF 3.01 calculation program) |
| R-7 metabolite | log $P_{OW}$ | *407.1 |
| Steady-state bioconcentration factor (BCF) (total wet weight/normalised to 5% lipid content) | 100 |
| Clearance time (days) ($CT_{50}$) | - |
| ($CT_{90}$) | - |
| Level and nature of residues (%) in organisms after the 14 day depuration phase | *BCF$_{fish}$ estimated via QSAR analysis (EpiSuite BCFBAF 3.01 calculation program) |
| R-13 metabolite | log $P_{OW}$ | *10920 |
| Steady-state bioconcentration factor (BCF) (total wet weight/normalised to 5% lipid content) | 100 |
| Clearance time (days) ($CT_{50}$) | - |
| ($CT_{90}$) | - |
| Level and nature of residues (%) in organisms after the 14 day depuration phase | *BCF$_{fish}$ estimated via QSAR analysis (EpiSuite BCFBAF 3.01 calculation program) |
Toxicity/exposure ratios for the most sensitive aquatic organisms (Regulation (EU) N° 284/2013, Annex Part A, point 10.2)

FOCUSsw step 1 and 2 - PEC/RAC for etoxazole for the use of Etoxazole 11SC in Pome/stone fruit (early application) at 55 g a.s./ha (worst case Step 1 and 2 values)

| Group          | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae          | Sed. dwell. prolonged |
|----------------|------------|----------------|-----------------|---------------------|----------------|---------------------|
| Test species   | Cyprinodon variegatus | Oncorhynchus mykiss | Crassostrea virginica | Daphnia magna     | Pseudokirchn. subcapitata | Leptocheirus plumulosus |
| Endpoint       | LC50       | NOEC           | LC50            | NOEC                | EC50/EyEC50    | NOEC                |
| (µg/L)         | 160        | 15             | 4.3             | 0.13                | > 10000        | 860                 |
| AF             | 100        | 10             | 100             | 10                  | 10             | 10                  |
| RAC (µg/L)     | 1.6        | 1.5            | 0.043           | 0.013               | 1000           | 86                  |

FOCUS Scenario PECgl-max (µg/L) PECgl-max (µg/kg)

| Step 1 | PECgl-max (µg/L) | PECgl-max (µg/kg) |
|--------|------------------|-------------------|
|        | 7.31             | 157.3             |
|        | 4.56             | 1.83              |
|        | 4.87             |                    |
|        | 170              |                    |
|        | 562              |                    |
|        | 0.007            |                    |

Step 2 Northern Europe

| PECgl-max (µg/L) | PECgl-max (µg/kg) |
|------------------|-------------------|
| 5.35             | 157.3             |
| 3.34             | 1.83              |
| 3.57             |                    |
| 124              |                    |
| 411              |                    |
| 0.005            |                    |
| 51.48            |                    |
| 0.60             |                    |

Step 2 Southern Europe

| PECgl-max (µg/L) | PECgl-max (µg/kg) |
|------------------|-------------------|
| 5.35             | 157.3             |
| 3.34             | 1.83              |
| 3.57             |                    |
| 124              |                    |
| 411              |                    |
| 0.005            |                    |
| 68.35            |                    |
| 0.79             |                    |

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

FOCUSsw step 3 - PEC/RAC for etoxazole for the use of Etoxazole 11SC in Pome/stone fruit (late application) at 55 g a.s./ha, single application

| Group          | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae          | Sed. dwell. prolonged |
|----------------|------------|----------------|-----------------|---------------------|----------------|---------------------|
### Peer review of the pesticide risk assessment of the active substance etoxazole

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| Group | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sed. dwell. prolonged |
|-------|------------|----------------|-----------------|---------------------|-------|-----------------------|
| Test species | Cyprinodon variegatus | Oncorhynchus mykiss | Crassostrea virginica | Daphnia magna | Pseudokirchn. subcapitata | Leptocheirus plumulosus |
| Endpoint | LC₅₀ | NOEC | LC₅₀ | NOEC | LC₅₀ | NOEC |
| (µg/L) | 160 | 15 | 4.3 | 0.13 | > 10000 | 860 |
| AF | 100 | 10 | 100 | 10 | 10 | 10 |

| RAC (µg/L) | PEC₉₅/µL | 1.6 | 1.5 | 0.043 | 0.013 | 1000 |
|------------|---------|-----|-----|-------|-------|------|

| FOCUS Scenario | PEC₉₅ (µg/L) | PEC₉₅ (µg/kg) |
|----------------|-------------|---------------|
| Step 3 D3/ditch | 1.999 | 1.2 | 1.3 | 46.5 | 153.8 | < 0.002 | 1.426 | < 0.02 |
| D4/pond | 0.090 | 0.1 | 0.1 | 2.1 | 6.9 | < 0.002 | 0.785 | < 0.02 |
| D4/stream | 1.777 | 1.1 | 1.2 | 41.3 | 136.7 | < 0.002 | 0.064 | < 0.02 |
| D5/pond | 0.090 | 0.1 | 0.1 | 2.1 | 6.9 | < 0.002 | 0.806 | < 0.02 |
| D5/stream | 1.876 | 1.2 | 1.3 | 43.6 | 144.3 | < 0.002 | 0.058 | < 0.02 |
| R1/ stream | 0.090 | 1.0 | 1.0 | 2.1 | 6.9 | < 0.002 | 0.742 | < 0.02 |
| R1/pond | 1.529 | 0.1 | 0.1 | 35.6 | 117.6 | < 0.002 | 0.198 | < 0.02 |
| R2/stream | 2.026 | 1.3 | 1.4 | 47.1 | 155.8 | < 0.002 | 0.127 | < 0.02 |
| R3/stream | 2.153 | 1.3 | 1.4 | 50.1 | 165.6 | < 0.002 | 0.437 | < 0.02 |
| R4/stream | 1.529 | 1.0 | 1.0 | 35.6 | 117.6 | < 0.002 | 0.199 | < 0.02 |

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

**FOCUS_{sw} step 3 - PEC/RAC for etoxazole for the use of Etoxazole 11SC in Pome/stone fruit (early application) at 55 g a.s./ha, single application**
## Peer review of the pesticide risk assessment of the active substance etoxazole

### Table: Test Species and Endpoint Data

| Group                  | Fish acute  | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae                  | Sed. dwell. prolonged |
|------------------------|-------------|----------------|-----------------|--------------------|------------------------|-----------------------|
| Test species           | Cyprinodon variegatus | Oncorhynchus mykiss | Crassostrea virginica | Daphnia magna | Pseudokirch. subcapitata | Leptocheirus plumulosus |
| Endpoint (µg/L)        | LC$_{50}$   | NOEC           | LC$_{50}$       | NOEC               | E$_{10}$/E$_{10}$/C$_{50}$ | NOEC |
|                        | 160         | 15             | 4.3             | 0.13               | > 10000                | 860 |
| AF                     | 100         | 10             | 100             | 10                 | 10                     | 10       |
| RAC (µg/L)             | 1.6         | 1.5            | 0.043           | 0.013              | 1000                   | 86       |

### FOCUS Scenario

| Step 3 | PEC$_{gl}$-max (µg/L) | PEC$_{gl}$-max (µg/kg) |
|--------|------------------------|-----------------------|
| D3/ditch | 4.240 | 2.7 | 2.8 | 98.6 | 326.2 | < 0.005 | 3.012 | < 0.03 |
| D4/pond | 0.258 | 0.2 | 0.2 | 6.0 | 19.8 | < 0.005 | 2.205 | < 0.03 |
| D4/stream | 3.987 | 2.5 | 2.7 | 92.7 | 306.7 | < 0.005 | 0.144 | < 0.03 |
| D5/pond | 0.258 | 0.2 | 0.2 | 6.0 | 19.8 | < 0.005 | 2.264 | < 0.03 |
| D5/stream | 4.208 | 2.6 | 2.8 | 97.9 | 323.7 | < 0.005 | 0.130 | < 0.03 |
| R1/ stream | 0.258 | 0.2 | 0.2 | 6.0 | 19.8 | < 0.005 | 2.076 | < 0.03 |
| R1/pond | 3.430 | 2.1 | 2.3 | 79.8 | 263.8 | < 0.005 | 0.443 | < 0.03 |
| R2/stream | 4.544 | 2.8 | 3.0 | 105.7 | 349.5 | < 0.005 | 0.284 | < 0.03 |
| R3/stream | 4.830 | 3.0 | 3.2 | 112.3 | 371.5 | < 0.005 | 0.980 | < 0.03 |
| R4/stream | 3.430 | 2.1 | 2.3 | 79.8 | 263.8 | < 0.005 | 0.446 | < 0.03 |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold.
### FOCUS\textsubscript{sw} step 3 - PEC/RAC for etoxazole for the use of Etoxazole 11SC in Citrus at 55 g a.s./ha, single application

| Group          | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae   | Sed. dwell. prolonged |
|----------------|------------|----------------|-----------------|---------------------|---------|----------------------|
| Test species   |            |                |                 |                     |         |                      |
| Cyprinodon variegatus | Oncorhynchus mykiss | Crassostrea virginica | Daphnia magna | Pseudokirchner. subcapitata | Leptocheirus plumulosus |
| Endpoint       | LC\textsubscript{50} NOEC | LC\textsubscript{50} NOEC | E\textsubscript{C}\textsubscript{50}/E\textsubscript{C}\textsubscript{50} NOEC | NOEC |
| (µg/L)         | 160 15 4.3 0.13 | > 10000 | 860 |
| AF             | 100 10 10 | 10 | 10 |
| RAC (µg/L)     | 1.6 1.5 0.043 0.013 | 1000 | 86 |

**PEC/RAC Scenario**

| Step 3 | PEC \textsubscript{gl-max} (µg/L) | PEC \textsubscript{gl-max} (µg/kg) | FOCUS Scenario |
|--------|-------------------------------|---------------------------------|----------------|
| D6/ditch | 2.016 1.26 1.34 46.9 155 < 0.002 5.866 <0.002 | PEC \textsubscript{gl-max} (µg/kg) |
| R4/stream | 1.525 0.95 0.95 35.5 117 < 0.002 0.1855 0.002 | FOCUS Scenario |

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

### FOCUS\textsubscript{sw} step 3 - PEC/RAC for etoxazole for the use of Etoxazole 11SC in Vines at 27.5 g a.s./ha, single application

| Group          | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae   | Sed. dwell. prolonged |
|----------------|------------|----------------|-----------------|---------------------|---------|----------------------|
| Test species   |            |                |                 |                     |         |                      |
| Cyprinodon variegatus | Oncorhynchus mykiss | Crassostrea virginica | Daphnia magna | Pseudokirchner. subcapitata | Leptocheirus plumulosus |
| Endpoint       | LC\textsubscript{50} NOEC | LC\textsubscript{50} NOEC | E\textsubscript{C}\textsubscript{50}/E\textsubscript{C}\textsubscript{50} NOEC | NOEC |
| (µg/L)         | 160 15 4.3 0.13 | > 10000 | 860 |
| AF             | 100 10 10 | 10 | 10 |
| RAC (µg/L)     | 1.6 1.5 0.043 0.013 | 1000 | 86 |
### FOCUS Scenario step 3 - PEC/RAC for etoxazole for the use of Etoxazole 11SC in Legumes (surrogate for strawberries, cucurbits and ornamentals) at 55 g a.s./ha, single application

| Group   | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sed. dwell. prolonged |
|---------|------------|----------------|-----------------|---------------------|-------|----------------------|
| Test species | Cyprinodon variegatus | Oncorhynchus mykiss | Crassostrea virginica | Daphnia magna | Pseudokirchn. subcapitata | Leptocheirus plumulosus |
| Endpoint | LC<sub>50</sub> | NOEC | LC<sub>50</sub> | NOEC | E<sub>C50</sub>/E<sub>y</sub>C<sub>50</sub> | NOEC |
| (µg/L)   | 160        | 15            | 4.3            | 0.13              | > 10000 | 860 |
| AF       | 100        | 10            | 100            | 10                | 10     | 10       |
| RAC (µg/L)| 1.6        | 1.5           | 0.043          | 0.013             | 1000   | 86       |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold.
### FOCUS_sw step 3 - PEC/RAC for etoxazole for the use of Etoxazole 11SC in Fruiting Vegetables (surrogate for tomato, eggplant) at 55 g a.s./ha, single application

| Group | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sed. dwell. prolonged |
|-------|------------|----------------|-----------------|--------------------|-------|----------------------|
| D3/ditch | 0.286 | 0.18 | 0.19 | 6.65 | 22.0 | < 0.0003 | 0.186 | <0.08 |
| D4/pond | 0.012 | 0.01 | 0.01 | 0.28 | 0.9 | < 0.0003 | 0.104 | <0.08 |
| D4/stream | 0.229 | 0.14 | 0.15 | 5.33 | 17.6 | < 0.0003 | 0.008 | <0.08 |
| D5/pond | 0.012 | 0.01 | 0.01 | 0.28 | 0.9 | < 0.0003 | 0.108 | <0.08 |
| D5/stream | 0.238 | 0.15 | 0.16 | 5.53 | 18.3 | < 0.0003 | 0.007 | <0.08 |
| D6/ditch | 0.286 | 0.18 | 0.19 | 6.65 | 22.0 | < 0.0003 | 0.231 | <0.08 |
| R1/pond | 0.012 | 0.01 | 0.01 | 0.28 | 0.9 | < 0.0003 | 0.127 | <0.08 |
| R1/stream | 0.198 | 0.12 | 0.13 | 4.60 | 15.2 | < 0.0003 | 0.251 | <0.08 |
| R2/stream | 0.263 | 0.16 | 0.18 | 6.12 | 20.2 | < 0.0003 | 0.300 | <0.08 |
| R3/stream | 0.280 | 0.18 | 0.19 | 6.51 | 21.5 | < 0.0003 | 7.135 | <0.08 |
| R4/stream | 0.198 | 0.12 | 0.13 | 4.60 | 15.2 | < 0.0003 | 4.590 | <0.08 |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold.
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| Group          | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sed. dwell. prolonged |
|----------------|------------|----------------|------------------|---------------------|-------|----------------------|
| FOCUS Scenario | PEC gl-max (µg/L) | PEC gl-max (µg/kg) |                  |                     |       |                      |
| Step 3         |            |                |                  |                     |       |                      |
| D6/ditch       | 0.343      | 0.21           | 0.23             | 7.98                | 26.4  | < 0.0003            |
|                |            |                |                  |                     |       | 0.141                |
|                |            |                |                  |                     |       | <0.02               |
| R2/stream      | 0.302      | 0.19           | 0.20             | 7.02                | 23.2  | < 0.0003            |
|                |            |                |                  |                     |       | 5.525               |
|                |            |                |                  |                     |       | 0.06                |
| R3/stream      | 0.322      | 0.20           | 0.21             | 7.49                | 24.8  | < 0.0003            |
|                |            |                |                  |                     |       | 0.210               |
|                |            |                |                  |                     |       | <0.01               |
| R4/stream      | 0.228      | 0.14           | 0.15             | 5.30                | 17.5  | < 0.0003            |
|                |            |                |                  |                     |       | 4.594               |
|                |            |                |                  |                     |       | 0.05                |

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

### FOCUS<sub>sw</sub> step 3 - PEC/RAC for etoxazole for the use of Etoxazole 11SC in Cotton at 41.25 g a.s./ha, single application

| Group          | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sed. dwell. prolonged |
|----------------|------------|----------------|------------------|---------------------|-------|----------------------|
| Test species   | Cyprinodon variegatus | Oncorhynchus mykiss | Crassostrea virginica | Daphnia magna | Pseudokirchn. subcapitata | Leptochirus plumulosus |
| Endpoint       | LC<sub>50</sub> | NOEC           | LC<sub>50</sub> | NOEC               | E<sub>1</sub>C<sub>50</sub>/E<sub>2</sub>C<sub>50</sub> | NOEC |
| (µg/L)         | 160        | 15             | 4.3              | 0.13               | > 10000 | 860 |
| AF             | 100        | 10             | 100              | 10                 | 10     | 10 |
| RAC (µg/L)     | 1.6        | 1.5            | 0.043            | 0.013              | 1000   | 86 |
| FOCUS Scenario | PEC gl-max (µg/L) | PEC gl-max (µg/kg) |                  |                     |       |                      |
| Step 3         |            |                |                  |                     |       |                      |
| D6/ditch       | 0.2145     | 0.13           | 0.14             | 4.99                | 16.5  | <0.0002            |
|                |            |                |                  |                     |       | 0.1739               |
|                |            |                |                  |                     |       | 0.002               |
AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold.

**FOCUS \(_{sw}\) step 4 (10m buffer zone) - PEC/RAC for etoxazole for the use of Etoxazole 11SC in Pome/stone fruit (late application) at 55 g a.s./ha, single application**

| Group | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sed. dwell. prolonged |
|-------|------------|----------------|-----------------|---------------------|-------|----------------------|
| Test species | Cyprinodon variegatus | Oncorhynchus mykiss | Crassostrea virginica | Daphnia magna | Pseudokirchn. subcapitata | Leptocheirus plumulosus |
| Endpoint | LC\(_{50}\) | NOEC | LC\(_{50}\) | NOEC | E\(_{1C_{50}}\)/E\(_{2C_{50}}\) | NOEC |
| (µg/L) | | | | | | 860 |
| AF | 100 | 10 | 100 | 10 | 10 | 10 |
| RAC (µg/L) | 1.6 | 1.5 | 0.043 | 0.013 | 1000 | 86 |

**FOCUS Scenario**

| Scenario | PEC \(_{gl-max}\) (µg/L) | PEC \(_{gl-max}\) (µg/kg) |
|----------|-----------------|-----------------|

**Step 4: 10 m buffer zone (BZ)**

| Scenario | PEC \(_{gl-max}\) (µg/L) | PEC \(_{gl-max}\) (µg/kg) |
|----------|-----------------|-----------------|

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold.
FOCUS<sub>sw</sub> step 4 (10m buffer zone) - PEC/RAC for etoxazole for the use of Etoxazole 11SC in Pome/stone fruit (early application) at 55 g a.s./ha, single application

| Group          | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae                  | Sed. dwell. prolonged |
|----------------|------------|----------------|-----------------|---------------------|------------------------|-----------------------|
| Test species   | Cyprinodon variegatus | Oncorhychinus mykiss | Crassostrea virginica | Daphnia magna | Pseudokirchn. subcapitata | Leptocheirus plumulosus |
| Endpoint       | LC<sub>50</sub> | NOEC | LC<sub>50</sub> | NOEC | E<sub>1</sub>C<sub>50</sub>/E<sub>2</sub>C<sub>50</sub> | NOEC |
| (µg/L)         | 160        | 15    | 4.3             | 0.13            | > 10000                | 860                   |
| AF             | 100        | 10    | 100             | 10              | 10                     | 10                    |
| RAC (µg/L)     | 1.6        | 1.5   | 0.043           | 0.013           | 1000                   | 86                    |

FOCUS Scenario

| PEC<sub>gl-max</sub> (µg/L) | PEC<sub>gl-max</sub> (µg/kg) |
|-----------------------------|------------------------------|

Step 4: 10 m buffer zone

| Scenario | PEC<sub>gl-max</sub> (µg/L) |
|----------|-----------------------------|
| D3/ditch | 2.045 1.3 1.4 47.6 157.3    |
| D4/pond  | 0.159 OK at Step 3 3.7 12.2 1.374 OK at Step 3 |
| D4/stream| 2.103 1.3 1.4 48.9 161.8 0.076 OK at Step 3 |
| D5/pond  | 0.159 OK at Step 3 3.7 12.2 1.411 OK at Step 3 |
| D5/stream| 2.219 1.4 1.5 51.6 170.7 0.068 OK at Step 3 |
| R1/ stream| 0.159 OK at Step 3 3.7 12.2 1.296 OK at Step 3 |
| R1/pond  | 1.809 1.1 1.2 42.1 139.2 0.234 OK at Step 3 |
| R2/stream| 2.397 22:00 1.6 55.7 184.4 0.150 OK at Step 3 |
| R3/stream| 2.548 1.6 1.7 59.3 196.0 0.517 OK at Step 3 |
| R4/stream| 1.809 1.1 1.2 42.1 139.2 0.235 OK at Step 3 |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold.
FOCUS \textsubscript{sw} step 4 (20 m buffer zone) - PEC/RAC for etoxazole for the use of Etoxazole 11SC in Pome/stone fruit (early application) at 55 g a.s./ha, single application

| Group       | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae          | Sed. dwell. prolonged |
|-------------|------------|----------------|-----------------|---------------------|----------------|----------------------|
| Test species | Cyprinodon variegatus | Oncorhynchus mykiss | Crassostrea virginica | Daphnia magna      | Pseudokirchn. subcapitata | Leptocirhus plumulosus |
| Endpoint    | LC\textsubscript{50} | NOEC           | LC\textsubscript{50} | NOEC                | E\textsubscript{C_{50}}/E\textsubscript{C_{50}} | NOEC                |
| (µg/L)      | 160        | 15             | 4.3             | 0.13                | > 10000        | 860                  |
| AF          | 100        | 10             | 100             | 10                  | 10             | 86                   |
| RAC (µg/L)  | 1.6        | 1.5            | 0.043           | 0.013               | 1000           | 86                   |
| FOCUS Scenario | PEC \textsubscript{gl-max} (µg/L) | PEC \textsubscript{gl-max} (µg/kg) |
| Step 4: 20 m buffer zone |
| D3/ditch    | 0.467      | 0.3            | 0.3             | 10.9                | 35.9           | OK at Step 3 - OK at Step 3 |
| D4/pond     | 0.051      | OK at Step 3   | OK at Step 3    | 1.2                 | 3.9            | OK at Step 3 - OK at Step 3 |
| D4/stream   | 0.481      | 0.3            | 0.3             | 11.2                | 37.0           | OK at Step 3 - OK at Step 3 |
| D5/pond     | 0.051      | OK at Step 3   | OK at Step 3    | 1.2                 | 3.9            | OK at Step 3 - OK at Step 3 |
| D5/stream   | 0.507      | 0.3            | 0.3             | 11.8                | 39.0           | OK at Step 3 - OK at Step 3 |
| R1/ stream  | 0.051      | OK at Step 3   | OK at Step 3    | 1.2                 | 3.9            | OK at Step 3 - OK at Step 3 |
| R1/pond     | 0.413      | 0.3            | 0.3             | 9.6                 | 31.8           | OK at Step 3 - OK at Step 3 |
| R2/stream   | 0.548      | 0.3            | 0.4             | 12.7                | 42.2           | OK at Step 3 - OK at Step 3 |
| R3/stream   | 0.582      | 0.4            | 0.4             | 13.5                | 44.8           | OK at Step 3 - OK at Step 3 |
| R4/stream   | 0.414      | 0.3            | 0.3             | 9.6                 | 31.8           | OK at Step 3 - OK at Step 3 |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold.
## FOCUS step 4 (25 m buffer zone) - PEC/RAC for etoxazole for the use of Etoxazole 11SC in Pome/stone fruit (early application) at 55 g a.s./ha, single application

| Group          | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae                     | Sed. dwell. prolonged |
|----------------|------------|----------------|-----------------|---------------------|---------------------------|----------------------|
| Test species   | Cyprinodon variegatus | Oncorhynchus mykiss | Crassostrea virginica | Daphnia magna | Pseudokirchn. subcapitata | Leptochaerus plumulosus |
| Endpoint       | LC₅₀       | NOEC           | LC₅₀            | NOEC                | E₅₀/E₅₀                  | NOEC                 |
| (µg/L)         | 160        | 15             | 4.3             | 0.13                | > 10000                   | 860                  |
| AF             | 100        | 10             | 100             | 10                  | 10                        | 10                   |
| RAC (µg/L)     | 1.6        | 1.5            | 0.043           | 0.013               | 1000                      | 86                   |

| FOCUS Scenario | PEC gl-max (µg/L) | PEC gl-max (µg/kg) |
|----------------|-------------------|--------------------|
| Step 4: 25 m buffer zone |
| D3/ditch       | 0.276             | OK at Step 3       |
|                | (20 m)            | OK at Step 3       |
|                | 6.4               | OK at Step 3       |
|                | 21.2              | OK at Step 3       |
| D4/pond        | 0.035             | OK at Step 3       |
|                | 0.8               | OK at Step 3       |
| D4/stream      | 0.283             | OK at Step 3       |
|                | 6.6               | OK at Step 3       |
| D5/pond        | 0.035             | OK at Step 3       |
|                | 0.8               | OK at Step 3       |
| D5/stream      | 0.299             | OK at Step 3       |
|                | 7.0               | OK at Step 3       |
| R1/ stream     | 0.035             | OK at Step 3       |
|                | 0.8               | OK at Step 3       |
| R1/pond        | 0.244             | OK at Step 3       |
|                | 5.7               | OK at Step 3       |
| R2/stream      | 0.323             | OK at Step 3       |
|                | 7.5               | OK at Step 3       |

*Step 3 is passed if the PEC is at least 4 times lower than the RAC.*
### FOCUS<sub>sw</sub> step 4 (10m buffer zone) - PEC/RAC for etoxazole for the use of Etoxazole 11SC in Citrus at 55 g a.s./ha, single application

| Group     | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sed. dwell. prolonged |
|-----------|------------|----------------|-----------------|---------------------|-------|-----------------------|
| R3/stream | 0.343      | OK at Step 4 (20 m) | OK at Step 4 (20 m) | 8.0 | 26.4 | OK at Step 3 | - | OK at Step 3 |
| R4/stream | 0.244      | OK at Step 4 (20 m) | OK at Step 4 (20 m) | 5.7 | 18.8 | OK at Step 3 | - | OK at Step 3 |

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

### FOCUS<sub>sw</sub> step 4 (10m buffer zone) - PEC/RAC for etoxazole for the use of Etoxazole 11SC in Vines at 27.5 g a.s./ha, single application

| Group     | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sed. dwell. prolonged |
|-----------|------------|----------------|-----------------|---------------------|-------|-----------------------|
| Test species | Cyprinodon variegatus | Oncorhynchus mykiss | Crassostrea virginica | Daphnia magna | Pseudokirchn. subcapitata | Leptocheirus plumulosus |
| Endpoint (μg/L) | 160 | 15 | 4.3 | 0.13 | > 10000 | 860 |
| AF         | 100        | 10             | 100             | 10                  | 10    | 10                    |
| RAC (μg/L) | 1.6        | 1.5            | 0.043           | 0.013               | 1000  | 86                    |

**FOCUS Scenario**  
PEC<sub>gl-max</sub> (μg/L):  
PEC<sub>gl-max</sub> (μg/kg): 

**Step 4: 10 m buffer zone (BZ)**

| D6/ditch | 0.608 | 0.38 | 0.40 | 14.1 | 46.69 | OK at Step 3 | 1.798 | OK at Step 3 |
| R4/stream | 0.532 | OK at Step 3 | OK at Step 3 | 12.4 | 40.9 | OK at Step 3 | 0.1547 | OK at Step 3 |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold.
### Peer review of the pesticide risk assessment of the active substance etoxazole

| Group            | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae       | Sed. dwell. prolonged |
|------------------|------------|----------------|-----------------|---------------------|-------------|----------------------|
| Test species     | Cyprinodon variegatus | Oncorhynchus mykiss | Crassostrea virginica | Daphnia magna | Pseudokirchn. subcapitata | Leptocheirus plumulosus |
| Endpoint (µg/L)  | LC₅₀       | NOEC           | LC₅₀            | NOEC                | E₅₀/C₅₀/E₅₀/C₅₀ | NOEC                |
|                  | 160        | 15             | 4.3             | 0.13                | > 10000      | 860                  |
| AF               | 100        | 10             | 100             | 10                  | 10          | 10                   |
| RAC (µg/L)       | 1.6        | 1.5            | 0.043           | 0.013               | 1000        | 86                   |

| FOCUS Scenario  | PEC gl-max (µg/L) | PEC gl-max (µg/kg) |
|-----------------|-------------------|--------------------|
| Step 4: 10 m buffer zone (BZ) |
| D6/ditch        | 0.205             | OK at Step 3       |
|                 | 4.8               | OK at Step 3       |
|                 | 15.8              | OK at Step 3       |
|                 | 0.580             | OK at Step 3       |
| R1/pond         | 0.021             | OK at Step 3       |
|                 | 0.189             | OK at Step 3       |
| R1/stream        | 0.181             | OK at Step 3       |
|                 | 0.259             | OK at Step 3       |
| R2/stream        | 0.243             | OK at Step 3       |
|                 | 0.5               | OK at Step 3       |
|                 | 1.6               | OK at Step 3       |
|                 | 0.189             | OK at Step 3       |
| R3/stream        | 0.254             | OK at Step 3       |
|                 | 4.2               | OK at Step 3       |
|                 | 13.9              | OK at Step 3       |
|                 | 0.259             | OK at Step 3       |
| R4/stream        | 0.181             | OK at Step 3       |
|                 | 4.2               | OK at Step 3       |
|                 | 13.9              | OK at Step 3       |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold.
### FOCUS\textsubscript{sw} step 1 (worst case application scenario) - PEC/RAC for etoxazole metabolite R-3 for the use of Etoxazole 11SC

| Group                  | Fish acute | Inverteb. acute | Algae                  | Sed. dwell. prolonged |
|------------------------|------------|-----------------|------------------------|----------------------|
| Test species           | Lepomis macrochirus | Daphnia magna | Pseudokirchn. subcapitata | Chironomus riparius |
| Endpoint               | LC\textsubscript{50} | EC\textsubscript{50} | E\textsubscript{r}C\textsubscript{50}/E\textsubscript{y}C\textsubscript{50} | NOEC                |
| (µg/L)                 | > 1000     | > 1000          | > 840                  | n.r.                |
| AF                     | 100        | 100             | 10                     | 10                  |
| RAC (µg/L)             | 10         | 10              | 84                     | n.r.                |
| FOCUS Scenario         | PEC\textsubscript{gl-max} (µg/L) | | | PEC\textsubscript{gl-max} (µg/kg) |
| Step 1                 | 0.8903     | 0.089           | 0.089                  | 0.01                | 12.5862 | n.r. |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold; n.r.: not relevant

### FOCUS\textsubscript{sw} step 1 (worst case application scenario) - PEC/RAC for etoxazole metabolite R-4 for the use of Etoxazole 11SC

| Group                  | Fish acute | Inverteb. acute | Algae                  | Sed. dwell. prolonged |
|------------------------|------------|-----------------|------------------------|----------------------|
| Test species           | Lepomis macrochirus | Daphnia magna | Pseudokirchn. subcapitata | Chironomus riparius |
| Endpoint               | LC\textsubscript{50} | EC\textsubscript{50} | E\textsubscript{r}C\textsubscript{50}/E\textsubscript{y}C\textsubscript{50} | NOEC                |
| (µg/L)                 | > 990      | > 1300          | > 980                  | n.r.                |
| AF                     | 100        | 100             | 10                     | 10                  |
| RAC (µg/L)             | 9.9        | 13              | 98                     | n.r.                |
| FOCUS Scenario         | PEC\textsubscript{gl-max} (µg/L) | | | PEC\textsubscript{gl-max} (µg/kg) |
| Step 1                 |            |                 |                        |                     |
| Group             | Fish acute | Inverteb. acute | Algae   | Sed. dwell. prolonged |
|------------------|------------|-----------------|---------|----------------------|
|                  | 3.3654     | 0.34            | 0.26    | 0.034                |
|                  |            |                 |         | 8.3327               |
|                  |            |                 |         | n.r.                 |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold; n.r.: not relevant

**FOCUS**<sub>sw</sub> step 1 (worst case application scenario) - PEC/RAC for etoxazole metabolite R-7 for the use of Etoxazole 11SC

| Group             | Fish acute       | Inverteb. acute | Algae       | Sed. dwell. prolonged |
|------------------|------------------|-----------------|-------------|----------------------|
| Test species     | *Lepomis macrochirus* | *Daphnia magna* | *Pseudokirchn. subcapitata* | *Chironomus riparius* |
| Endpoint         | LC<sub>50</sub>  | EC<sub>50</sub> | E<sub>C</sub><sub>50</sub>/E<sub>y</sub>C<sub>50</sub> | NOEC               |
| (µg/L)           | > 960            | > 7400          | > 990       | n.r.                |
| AF               | 100              | 100             | 10          | 10                  |
| RAC (µg/L)       | 9.6              | 74              | 99          | n.r.                |

**FOCUS**<sub>sw</sub> Scenario

| PEC<sub>gl-max</sub> (µg/L) | PEC<sub>gl-max</sub> (µg/kg) |
|-----------------------------|-----------------------------|
| 1.0042                      | 27.1396                     |

| Step 1                      |
|-----------------------------|
| 0.105                       |
| 0.013                       |
| 0.010                       |
| 27.1396                     |
| n.r.                        |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold; n.r.: not relevant

**FOCUS**<sub>sw</sub> step 1 (worst case application scenario) - PEC/RAC for etoxazole metabolite R-8 for the use of Etoxazole 11SC

| Group             | Fish acute       | Inverteb. acute | Algae       | Sed. dwell. prolonged |
|------------------|------------------|-----------------|-------------|----------------------|
| Test species     | *Lepomis macrochirus* | *Daphnia magna* | *Pseudokirchn. subcapitata* | *Chironomus riparius* |
| Endpoint         | LC<sub>50</sub>  | EC<sub>50</sub> | E<sub>C</sub><sub>50</sub>/E<sub>y</sub>C<sub>50</sub> | NOEC               |
| (µg/L)           | > 990            | > 990           | > 1000      | n.r.                |
### Peer review of the pesticide risk assessment of the active substance etoxazole

| Group            | Fish acute | Inverteb. acute | Algae | Sed. dwell. prolonged |
|------------------|------------|-----------------|-------|----------------------|
| AF               | 100        | 100             | 10    | 10                   |
| RAC (µg/L)       | 9.9        | 9.9             | 100   | n.r.                 |
| FOCUS Scenario   | PEC gl-max (µg/L) |                 |       |                      |
| Step 1           | 4.1911     | 0.42            | 0.42  | 0.0419               | 9.2196   | n.r.     |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold; n.r.: not relevant

### FOCUS_sw step 1 (worst case application scenario) - PEC/RAC for etoxazole metabolite R-11 for the use of Etoxazole 11SC

| Group            | Fish acute | Inverteb. acute | Algae | Sed. dwell. prolonged |
|------------------|------------|-----------------|-------|----------------------|
| Test species     | Lepomis macrochirus | Daphnia magna | Pseudokirchn. subcapitata | Chironomus riparius |
| Endpoint         | LC₅₀       | EC₅₀            | E₁C₅₀/E₂C₅₀ | NOEC                 |
| (µg/L)           | n.r.       | > 11000         | n.r.    | n.r.                 |
| AF               | 100        | 100             | 10     | 10                   |
| RAC (µg/L)       | n.r.       | 110             | n.r.    | n.r.                 |
| FOCUS Scenario   | PEC gl-max (µg/L) |                 |       |                      |
| Step 1           | 7.3892     | n.r.            | 0.067  | n.r.                 | 1.8237   | n.r.     |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold; n.r.: not relevant
### FOCUS sw step 1 (worst case application scenario) - PEC/RAC for etoxazole metabolite R-12 for the use of Etoxazole 11SC

| Group                  | Fish acute         | Inverteb. acute | Algae                    | Sed. dwell. prolonged |
|------------------------|--------------------|-----------------|--------------------------|----------------------|
| Test species           | *Lepomis macrochirus* | *Daphnia magna* | *Pseudokirchn. subcapitata* | *Chironomus riparius* |
| Endpoint               | LC₃₀               | EC₃₀            | E₅ₐ×₅/O₅ₐ×₅₀             | NOEC                 |
| (µg/L)                 | n.r.               | > 9300          | n.r.                     | n.r.                 |
| AF                     | 100                | 100             | 10                       | 10                   |
| RAC (µg/L)             | n.r.               | 93              | n.r.                     | n.r.                 |
| FOCUS Scenario         | PEC gl-max (µg/L)  |                 |                          | PEC gl-max (µg/kg)   |
| Step 1                 | 5.3095             | n.r.            | 0.057                    | 1.0311               | n.r. |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold; n.r.: not relevant

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### FOCUS sw step 1 (worst case application scenario) - PEC/RAC for etoxazole metabolite R-13 for the use of Etoxazole 11SC

| Group                  | Fish acute         | Inverteb. acute | Algae                    | Sed. dwell. prolonged |
|------------------------|--------------------|-----------------|--------------------------|----------------------|
| Test species           | *Lepomis macrochirus* | *Daphnia magna* | *Pseudokirchn. subcapitata* | *Chironomus riparius* |
| Endpoint               | LC₃₀               | EC₃₀            | E₅ₐ×₅/O₅ₐ×₅₀             | NOEC                 |
| (µg/L)                 | > 1000             | > 1000          | > 810                    | 75000                |
| AF                     | 100                | 100             | 10                       | 10                   |
| RAC (µg/L)             | 10                 | 10              | 81                       | 7500                 |
| FOCUS Scenario         | PEC gl-max (µg/L)  |                 |                          | PEC gl-max (µg/kg)   |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold; n.r.: not relevant
| Group | Fish acute | Inverteb. acute | Algae | Sed. dwell. prolonged |
|-------|------------|----------------|-------|---------------------|
| Step 1 | 0.9588     | 0.096          | 0.096 | 0.01                | 31.062   | 0.004 |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold; n.r.: not relevant

**FOCUS step 1 (worst case application scenario) - PEC/RAC for etoxazole metabolite R-15 for the use of Etoxazole 11SC**

| Group | Fish acute | Inverteb. acute | Algae | Sed. dwell. prolonged |
|-------|------------|----------------|-------|---------------------|
| Test species | *Lepomis macrochir* | *Daphnia magna* | *Pseudokirchn. subcapitata* | *Chironomus riparius* |
| Endpoint | LC$_{50}$ | EC$_{50}$ | E$_{C_{50}}$/E$_{J_{C_{50}}}$ | NOEC |
| ($\mu$g/L) | n.r. | > 2700 | n.r. | n.r. |
| AF | 100 | 100 | 10 | 10 |
| RAC ($\mu$g/L) | n.r. | 27 | n.r. | n.r. |
| FOCUS Scenario | PEC$_{gl-max}$ ($\mu$g/L) | | | |
| Step 1 | 0.9734 | n.r. | 0.036 | n.r. | 0.0001 | n.r. |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold; n.r.: not relevant
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)*

* This section does reflect the new EFSA Guidance Document on bees (EFSA, 2013) which has not yet been noted by the Standing Committee on Plants, Animals, Food and Feed.

| Species          | Test substance | Time scale/type of endpoint | End point | Toxicity                        |
|------------------|----------------|-----------------------------|-----------|---------------------------------|
| Apis mellifera   | a.s.           | Acute                       | Oral toxicity (LD₅₀) | > 200 µg/beeᵃ                   |
|                  |                |                             | Contact toxicity (LD₅₀) | > 200 µg/beeᵃ                   |
| Apis mellifera   | Etoxazole 11SC | Chronic                     | 10 d-LC₅₀; 10 d-LDD₅₀ | 1504 mg a.s./kg food > 32.9 µg a.s./bee/day |
|                  |                |                             | NOEC      | 752 mg a.s./kg food 18.8 µg a.s./bee/day |
| Apis mellifera   | Etoxazole 11SC | Bee brood development       | NOECᵇ,c   | 110 mg a.s./L (application solution of 55 g a.s./ha in 500L/ha) |
| Bombus terrestris| Etoxazole 11SC | Oralᵈ                      | LC₅₀      | 4.4 mg a.s./L                   |
| Bombus terrestris| Etoxazole 11SC | Reproduction               | NOEC      | 0.55 mg a.s./L                  |

a  Endpoint included in the Review Report for etoxazole, 2004 (SANCO/4054/2001 – rev.3)
b  Endpoint included in the DAR (2005)
c  NOEC for toxic effects on egg/larvae and pupae; effects on adults were recorded at this dose level
d  Oral exposure via drinking treated sugar water; the exposure period is not clearly defined in the report

Semi-field test (Cage and tunnel test)
Tunnel test (Flowering Phacelia, France) 1st Trial: Increase in mean daily mortality of honeybees from D+3 up to D+5. Decrease of the foraging activity at D+3 and D+4. 2nd Trial: No toxicity and no effect on foraging activity. The toxic reference Zolone Flo (phosalone) did not demonstrate any lethal or sub-lethal effects on honeybees and colony development.
Tunnel test (Spring rape; France) No toxicity observed. Transient effect on foraging activity just after treatment. The toxic reference Zolone Flo (phosalone) did not demonstrate any lethal or sub-lethal effects on honeybees and colony development.
Tunnel test (Spring rape; France) No toxicity and no effect on foraging activity. The toxic reference Zolone Flo (phosalone) did not demonstrate any lethal or sub-lethal effects on honeybees and colony development.

Risk assessment for orchards, grape, field crops, grape and ornamentals, at 55 g a.s./ha

| Species          | Test substance | Risk quotient | HQ    | Trigger |
|------------------|----------------|---------------|-------|---------|
| Apis mellifera   | a.s.           | HQcontact     | < 0.275 | 50      |
| Apis mellifera   | a.s.           | HQoral        | < 0.275 | 50      |
| Apis mellifera   | Etoxazole 11SC | HQcontact     | < 0.550 | 50      |
| Apis mellifera   | Etoxazole 11SC | HQoral        | < 0.550 | 50      |

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
### Peer review of the pesticide risk assessment of the active substance etoxazole

#### Species, Test Substance, End point, and Toxicity

| Species                      | Test Substance | End point             | Toxicity                                           |
|------------------------------|----------------|-----------------------|---------------------------------------------------|
| Typhlodromus pyri           | Etoxazole SC 110 | Mortality, LR<sub>50</sub> | > 0.05 L/hL                                       |
|                             |                | Mortality, LR<sub>50</sub> | > 55 g a.s./ha                                     |
|                             |                | Reproduction          | 100% reduction in reproduction at 55 g a.s./ha     |
|                             |                | Reproduction          | 0% offspring viability at 55 g a.s./ha            |
| Aphidius rhopalosiphi       | Etoxazole SC 110 | Mortality, LR<sub>50</sub> | > 55 g a.s./ha                                     |
|                             |                | Mortality             | 18.4% mortality                                   |
|                             |                | Reproduction          | No effects on fecundity                           |

#### Additional species

| Species                  | Test Substance | End point            | Toxicity                                           |
|--------------------------|----------------|----------------------|---------------------------------------------------|
| N. californicus          | Etoxazole SC 110 | Mortality, Reproduction | 23.75% corrected mortality at 0.05 L f.p./hL No effects on fecundity at 0.05 L f.p./hL |
| Chrysoperla carnea       | Etoxazole SC 110 | Mortality            | 85% corrected mortality at 55 g a.s./ha            |
| A. bilineata             | Etoxazole SC 110 | Mortality, Reproduction | 10% corrected mortality at 55 g a.s./ha 14% reduction in reproduction at 55 g a.s./ha |
| Orius laevigatus         | Etoxazole SC 110 | Mortality, Reproduction | 79.9% corrected mortality at 55 g a.s./ha 100% reduction in fecundity at 55 g a.s./ha |

### First tier risk assessment for orchards, grape, field crops, grape and ornamentals, at 55 g a.s./ha

| Test substance | Species                | Effect<sup>a</sup> (LR<sub>50</sub> g/ha) | HQ in-field | Trigger |
|----------------|------------------------|------------------------------------------|-------------|---------|
| Etoxazole SC 110 | Typhlodromus pyri     | > 55                                      | < 1         | 2       |
| Etoxazole SC 110 | Aphidius rhopalosiphi | > 55                                      | < 1         | 2       |

<sup>a</sup> Only lethal effects are considered

### Extended laboratory tests, aged residue tests

| Species                  | Life stage | Test substance, substrate                  | Dose (g/ha) | End point | % effect |
|--------------------------|------------|--------------------------------------------|-------------|-----------|----------|
| **Extended laboratory studies** |            |                                            |             |           |          |
| Typhlodromus pyri       | Protonymphs | (R)-Etoxazole/ vine leaves                | Dose Response Test (0.010, 0.030, 0.10, 0.30 and 1.0 g a.s./ha) | Mortality Reproduction | LR<sub>50</sub> > 1.0 g a.s./ha 54.3% effect on reproduction at 0.30 g a.s./ha |
|                         | Protonymphs | (S)-Etoxazole/ vine leaves                | Dose Response Test (0.010, 0.030, 0.10, 0.30 and 1.0 g a.s./ha) | Mortality Reproduction | LR<sub>50</sub> 0.020 g a.s./ha 58.0% effect on reproduction at 0.010 g a.s./ha |
|                         | Protonymphs | Etoxazole 11SC/ bean leaves                | Dose Response Test (0.014, 0.035, 0.088, 0.22 and 0.55 g a.s./ha) | Mortality Reproduction | LR<sub>50</sub> 0.27 g a.s./ha ER<sub>50</sub> 0.10 g a.s./ha |

### Aged residue studies
| Insect Family                  | Life Stage | Active Substance | Application Details | Corrected Mortality | Effect on Reproduction |
|-------------------------------|------------|------------------|---------------------|---------------------|------------------------|
| *Aphidius rhopalosiphi*       | Adults     | Etoxazole 11SC/  | 10 g a.s./ha, 55 g a.s./ha | 3.3%                | 25.1%                  |
|                              |            | barley plants    | 0 DAT               |                     |                        |
|                              |            |                  | 10 g a.s./ha, 55 g a.s./ha |                     |                        |
| *Typhlodromus pyri*           | Protonymphs| Etoxazole 11SC/  | 10 g a.s./ha, 55 g a.s./ha | 95.2%               | 63.6%                  |
|                              |            | vine plants      | 0 DAT               |                     |                        |
|                              |            |                  | 10 g a.s./ha, 55 g a.s./ha | 57.6%               | 10.3%                  |
|                              |            |                  | 28 DAT              |                     |                        |
|                              |            |                  | 10 g a.s./ha, 55 g a.s./ha | 59.8%               |                        |
| *Orius laevigatus*            | Nymphs     | Etoxazole 11SC/  | 10 g a.s./ha, 55 g a.s./ha | 2.2%                | -                      |
|                              |            | vine plants      | 0 DAT               |                     |                        |
|                              |            |                  | 10 g a.s./ha, 55 g a.s./ha | 20.0%               | -                      |
| *Chrysoperla carnea*          | Larvae     | Etoxazole 11SC/  | 10 g a.s./ha, 55 g a.s./ha | 2.5%                | -                      |
|                              |            | vine plants      | 0 DAT               |                     |                        |
|                              |            |                  | 10 g a.s./ha, 55 g a.s./ha | 7.5%                | -                      |
|                              |            |                  | 0 DAT               |                     |                        |
Risk assessment for pome fruit, plum, peach, nectarine, apricot, cherry, citrus, at 55 g a.s./ha based on extended lab test or aged residue tests

| Species | ER<sub>50</sub> (g/ha) | In-field rate | Off-field rate (2-D)<sup>a</sup> |
|---------|----------------|---------------|-----------------------------|
| *Typhlodromus pyri* | 0.10 | 55 | 8.03 @ 3 m 0.08 @ 50 m |

*correction factor of 2

Risk assessment for grapevine, at 55 g a.s./ha based on extended lab test or aged residue tests

| Species | ER<sub>50</sub> (g/ha) | In-field rate | Off-field rate (2-D)<sup>a</sup> |
|---------|----------------|---------------|-----------------------------|
| *Typhlodromus pyri* | 0.10 | 55 | 2.21 @ 3 m 0.06 @ 30 m |

*correction factor of 2

Risk assessment for strawberry, tomato, aubergine, cucurbit with inedible peel, ornamentals, at 55 g a.s./ha based on extended lab test or aged residue tests

| Species | ER<sub>50</sub> (g/ha) | In-field rate | Off-field rate (2-D)<sup>a</sup> |
|---------|----------------|---------------|-----------------------------|
| *Typhlodromus pyri* | 0.10 | 55 | 0.76 @ 1 m 0.08 @ 10 m |

*correction factor of 2

Risk assessment for cotton, at 55 g a.s./ha based on extended lab test or aged residue tests

| Species | ER<sub>50</sub> (g/ha) | In-field rate | Off-field rate (2-D)<sup>a</sup> |
|---------|----------------|---------------|-----------------------------|
| *Typhlodromus pyri* | 0.10 | 41.25 | 0.57 @ 1 m 0.06 @ 10 m |

*correction factor of 2

Field studies

-
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 a.s./OM | Time scale | End point       | Toxicity                                      |
|------------------------|----------------|------------------------------------|------------|-----------------|-----------------------------------------------|
| **Earthworms**         |                |                                    |            |                 |                                               |
| *Eisenia fetida andrei*| Etoxazole      | Mixed into soil 10 % peat          | Acute, 14 d| mortality       | LC50 > 1000 mg a.s./kg d.w.soil               |
| *Eisenia fetida andrei*| Metabolite R-3 | Mixed into soil 10 % peat          | Acute, 14 d| mortality       | LC50 > 9.8 mg a.s./kg d.w.soil                |
| *Eisenia fetida andrei*| Metabolite R-4 | Mixed into soil 10 % peat          | Acute, 14 d| mortality       | LC50 > 9.9 mg a.s./kg d.w.soil                |
| *Eisenia fetida andrei*| Metabolite R-7 | Mixed into soil 10 % peat          | Acute, 14 d| mortality       | LC50 > 9.6 mg a.s./kg d.w.soil                |
| *Eisenia fetida andrei*| Metabolite R-8 | Mixed into soil 10 % peat          | Acute, 14 d| mortality       | LC50 > 9.9 mg a.s./kg d.w.soil                |
| *Eisenia fetida andrei*| Metabolite R-13| Mixed into soil 10 % peat          | Acute, 14 d| mortality       | LC50 > 9.9 mg a.s./kg d.w.soil                |
| *Eisenia fetida andrei*| Etoxazole      | Mixed into soil 5 % peat           | Chronic, 56 d| reproduction body weight | NOEC = 5 mg a.s./kg d.w.soil NOEC = 10 mg a.s./kg d.w.soil |
| *Eisenia fetida andrei*| Metabolite R-3 | Mixed into soil 5 % peat           | Chronic, 56 d| reproduction body weight | NOEC = 10 mg a.s./kg d.w.soil NOEC = 10 mg a.s./kg d.w.soil |
| *Eisenia fetida andrei*| Metabolite R-4 | Mixed into soil 5 % peat           | Chronic, 56 d| reproduction body weight | NOEC = 10 mg a.s./kg d.w.soil NOEC = 10 mg a.s./kg d.w.soil |
| *Eisenia fetida andrei*| Metabolite R-7 | Mixed into soil 5 % peat           | Chronic, 56 d| reproduction body weight | NOEC = 10 mg a.s./kg d.w.soil NOEC = 10 mg a.s./kg d.w.soil |
| *Eisenia fetida andrei*| Metabolite R-8 | Mixed into soil 5 % peat           | Chronic, 56 d| reproduction body weight | NOEC = 10 mg a.s./kg d.w.soil NOEC = 10 mg a.s./kg d.w.soil |
| Test organism          | Test substance | Application method of test a.s./OM¹ | Time scale | End point          | Toxicity                                    |
|------------------------|----------------|-------------------------------------|------------|--------------------|---------------------------------------------|
| *Eisenia fetida andrei*| Metabolite R-11| Mixed into soil 5 % peat            | Chronic, 56 d | reproduction body weight | NOEC = 10 mg a.s./kg d.w.soil NOEC = 10 mg a.s./kg d.w.soil |
| *Eisenia fetida andrei*| Metabolite R-12| Mixed into soil 5 % peat            | Chronic, 56 d | reproduction body weight | NOEC = 0.8 mg a.s./kg d.w.soil NOEC = 10 mg a.s./kg d.w.soil |
| *Eisenia fetida andrei*| Metabolite R-13| Mixed into soil 5 % peat            | Chronic, 56 d | reproduction body weight | NOEC = 10 mg a.s./kg d.w.soil NOEC = 10 mg a.s./kg d.w.soil |
| **Other soil macroorganisms** | | | | | |
| *Folsomia candida*     | Etoxazole      | Mixed into soil 5 % peat            | Chronic, 28 d | Reproduction        | NOEC = 1.0 mg a.s./kg d.w.soil EC₁₀ = 0.60 mg a.s./kg d.w.soil |
| *Folsomia candida*     | Metabolite R-3 | Mixed into soil 5 % peat            | Chronic, 28 d | Reproduction        | NOEC = 10 mg/kg d.w.soil                    |
| *Folsomia candida*     | Metabolite R-4 | Mixed into soil 5 % peat            | Chronic, 28 d | Reproduction        | NOEC = 1.0 mg/kg d.w.soil                    |
| *Folsomia candida*     | Metabolite R-7 | Mixed into soil 5 % peat            | Chronic, 28 d | Reproduction        | NOEC = 10 mg/kg d.w.soil                    |
| *Folsomia candida*     | Metabolite R-8 | Mixed into soil 5 % peat            | Chronic, 28 d | Reproduction        | NOEC = 10 mg/kg d.w.soil                    |
| *Folsomia candida*     | Metabolite R-11| Mixed into soil 5 % peat            | Chronic, 28 d | Reproduction        | NOEC = 10 mg/kg d.w.soil                    |
| *Folsomia candida*     | Metabolite R-12| Mixed into soil 5 % peat            | Chronic, 28 d | Reproduction        | NOEC = 10 mg/kg d.w.soil                    |
| *Folsomia candida*     | Metabolite R-13| Mixed into soil 5 % peat            | Chronic, 28 d | Reproduction        | NOEC = 10 mg/kg d.w.soil                    |
| *Hypoaspis aculeifer*  | Etoxazole      | Mixed into soil 5 % peat            | Chronic, 14 d | Reproduction        | NOEC = 0.2 mg a.s./kg d.w.soil              |
| *Hypoaspis aculeifer*  | Metabolite R-3 | Mixed into soil 5 % peat            | Chronic, 14 d | Reproduction        | NOEC = 10 mg/kg d.w.soil                    |
### Test organism

| Test organism | Test substance | Application method of test a.s./OM<sup>1</sup> | Time scale | End point | Toxicity |
|---------------|----------------|----------------------------------|-------------|-----------|----------|
| *Hypoaspis aculeifer* | Metabolite R-4 | Mixed into soil 5 % peat | Chronic, 14 d | Reproduction | NOEC = 1.0 mg/kg d.w.soil |
| *Hypoaspis aculeifer* | Metabolite R-7 | Mixed into soil 5 % peat | Chronic, 14 d | Reproduction | NOEC = 10 mg/kg d.w.soil |
| *Hypoaspis aculeifer* | Metabolite R-8 | Mixed into soil 5 % peat | Chronic, 14 d | Reproduction | NOEC = 10 mg/kg d.w.soil |
| *Hypoaspis aculeifer* | Metabolite R-11 | Mixed into soil 5 % peat | Chronic, 14 d | Reproduction | NOEC = 10 mg/kg d.w.soil |
| *Hypoaspis aculeifer* | Metabolite R-12 | Mixed into soil 5 % peat | Chronic, 14 d | Reproduction | NOEC = 10 mg/kg d.w.soil |
| *Hypoaspis aculeifer* | Metabolite R-13 | Mixed into soil 5 % peat | Chronic, 14 d | Reproduction | NOEC = 1.0 mg/kg d.w.soil |

<sup>1</sup>To indicate whether the test substance was oversprayed/to indicate the organic content of the test soil (e.g. 5 % or 10 %).

### Higher tier testing (e.g. modelling or field studies)

- Nitrogen transformation
  
  **Etoxazole**
  
  Maximum tested rate of 0.07 mg a.s./kg d.w. soil (equivalent to 52.5 g/ha with no foliage interception)
  
  No significant effects (> 25 %) on N transformation at day 28 at a concentration of 0.07 mg a.s./kg dry soil

### Toxicity/exposure ratios for soil organisms*<sup>2</sup>

*<sup>2</sup>A correction factor of 2 was applied to the acute and chronic endpoints of etoxazole and metabolites R-3, R-7, R-8 and R-13.

[Use in grapes, tomatoes /cucurbit and ornamentals at 55 g a.s./ ha]

| Test organism | Test substance | Time scale | Soil PEC<sup>1</sup> | TER | Trigger |
|---------------|----------------|------------|----------------------|-----|---------|
| *Eisenia fetida andrei* | Etoxazole | Acute | 0.037 mg a.s./d.w. soil initial | 13513.5 | 10 |
| *Eisenia fetida andrei* | Metabolite R-3 | Acute | 0.0038 mg a.s./d.w. soil initial | 1289.5 | 10 |
| *Eisenia fetida andrei* | Metabolite R-7 | Acute | 0.0092 mg a.s./d.w. soil initial | 521.7 | 10 |
| *Eisenia fetida andrei* | Metabolite R-8 | Acute | 0.0108 mg a.s./d.w. soil initial | 458.3 | 10 |
| Test organism                    | Test substance | Time scale | Soil PEC$^1$                       | TER  | Trigger |
|---------------------------------|----------------|------------|-----------------------------------|------|---------|
| *Eisenia fetida andrei*         | Metabolite R-13| Acute      | 0.0084 mg a.s./d.w. soil initial   | 589.3| 10      |
| *Eisenia fetida andrei*         | Etoxazole      | Chronic    | 0.037 mg a.s./d.w. soil initial    | 67.6 | 5       |
| *Eisenia fetida andrei*         | Metabolite R-3 | Chronic    | 0.0038 mg a.s./d.w. soil initial   | 1315.8| 5       |
| *Eisenia fetida andrei*         | Metabolite R-7 | Chronic    | 0.0092 mg a.s./d.w. soil initial   | 543.5| 5       |
| *Eisenia fetida andrei*         | Metabolite R-8 | Chronic    | 0.0108 mg a.s./d.w. soil initial   | 462.9| 5       |
| *Eisenia fetida andrei*         | Metabolite R-11| Chronic    | 0.0019 mg a.s./d.w. soil initial   | 5263.2| 5       |
| *Eisenia fetida andrei*         | Metabolite R-13| Chronic    | 0.0084 mg a.s./d.w. soil initial   | 595.2| 5       |
| **Other soil macroorganisms**   |                |            |                                   |      |         |
| *Folsomia candida*              | Etoxazole      | Chronic    | 0.037 mg a.s./d.w. soil initial    | 8.1  | 5       |
| *Folsomia candida*              | Metabolite R-3 | Chronic    | 0.0038 mg a.s./d.w. soil initial   | 1315.8| 5       |
| *Folsomia candida*              | Metabolite R-7 | Chronic    | 0.0092 mg a.s./d.w. soil initial   | 543.5| 5       |
| *Folsomia candida*              | Metabolite R-8 | Chronic    | 0.0108 mg a.s./d.w. soil initial   | 462.9| 5       |
| *Folsomia candida*              | Metabolite R-11| Chronic    | 0.0019 mg a.s./d.w. soil initial   | 5263.2| 5       |
| *Folsomia candida*              | Metabolite R-13| Chronic    | 0.0084 mg a.s./d.w. soil initial   | 595.2| 5       |
| *Hypoaspis aculeifer*           | Etoxazole      | Chronic    | 0.037 mg a.s./d.w. soil initial    | 2.7  | 5       |
| *Hypoaspis aculeifer*           | Metabolite R-3 | Chronic    | 0.0038 mg a.s./d.w. soil initial   | 1315.8| 5       |
| *Hypoaspis aculeifer*           | Metabolite R-7 | Chronic    | 0.0092 mg a.s./d.w. soil initial   | 543.5| 5       |
| *Hypoaspis aculeifer*           | Metabolite R-8 | Chronic    | 0.0108 mg a.s./d.w. soil initial   | 462.9| 5       |
| *Hypoaspis aculeifer*           | Metabolite R-11| Chronic    | 0.0019 mg a.s./d.w. soil initial   | 5263.2| 5       |
| *Hypoaspis aculeifer*           | Metabolite R-13| Chronic    | 0.0084 mg a.s./d.w. soil initial   | 59.5 | 5       |

$^1$indicate which PEC soil was used (e.g. plateau PEC)

In **bold** the TER values that do not meet the trigger of 5.
[Use in pome/stone fruit at 55 g a.s./ha]

| Test organism          | Test substance | Time scale | Soil PEC[^1]  | TER   | Trigger |
|------------------------|----------------|------------|---------------|-------|---------|
| **Earthworms**          |                |            |               |       |         |
| *Eisenia fetida andrei* | Etoxazole      | Acute      | 0.029 mg a.s./d.w. soil initial | 17241.4 | 10      |
| *Eisenia fetida andrei* | Metabolite R-3 | Acute      | 0.0031 mg a.s./d.w. soil initial | 1580.6  | 10      |
| *Eisenia fetida andrei* | Metabolite R-7 | Acute      | 0.0074 mg a.s./d.w. soil initial | 648.6   | 10      |
| *Eisenia fetida andrei* | Metabolite R-8 | Acute      | 0.0087 mg a.s./d.w. soil initial | 568.9   | 10      |
| *Eisenia fetida andrei* | Metabolite R-13| Acute      | 0.0067 mg a.s./d.w. soil initial | 738.8   | 10      |
| **Other soil macroorganisms** | | | | | |
| *Folsomia candida*     | Etoxazole      | Chronic    | 0.029 mg a.s./d.w. soil initial | 86.2   | 5       |
| *Folsomia candida*     | Metabolite R-3 | Chronic    | 0.0031 mg a.s./d.w. soil initial | 1612.9 | 5       |
| *Folsomia candida*     | Metabolite R-7 | Chronic    | 0.0074 mg a.s./d.w. soil initial | 675.7  | 5       |
| *Folsomia candida*     | Metabolite R-8 | Chronic    | 0.0087 mg a.s./d.w. soil initial | 574.7  | 5       |
| *Folsomia candida*     | Metabolite R-11| Chronic    | 0.0015 mg a.s./d.w. soil initial | 6666.7 | 5       |
| *Folsomia candida*     | Metabolite R-13| Chronic    | 0.0067 mg a.s./d.w. soil initial | 746.3  | 5       |
| *Hypoaspis aculeifer*  | Etoxazole      | Chronic    | 0.029 mg a.s./d.w. soil initial | **3.5** | 5       |
| *Hypoaspis aculeifer*  | Metabolite R-3 | Chronic    | 0.0031 mg a.s./d.w. soil initial | 1612.9 | 5       |
| *Hypoaspis aculeifer*  | Metabolite R-7 | Chronic    | 0.0074 mg a.s./d.w. soil initial | 675.7  | 5       |
| *Hypoaspis aculeifer*  | Metabolite R-8 | Chronic    | 0.0087 mg a.s./d.w. soil initial | 574.7  | 5       |
| *Hypoaspis aculeifer*  | Metabolite R-11| Chronic    | 0.0015 mg a.s./d.w. soil initial | 6666.7 | 5       |
| *Hypoaspis aculeifer*  | Metabolite R-13| Chronic    | 0.0067 mg a.s./d.w. soil initial | 74.6   | 5       |

[^1]: indicate which PEC soil was used (e.g. plateau PEC)

In **bold** the TER values that do not meet the trigger of 5.
[Use in citrus at 55 g a.s./ha]

| Test organism     | Test substance | Time scale | Soil PEC\(^1\) | TER   | Trigger |
|-------------------|----------------|------------|----------------|-------|---------|
| **Earthworms**    |                |            |                |       |         |
| *Eisenia fetida andrei* | Etoxazole | Acute      | 0.015 mg a.s./d.w. soil initial | 3333.3 | 10      |
| *Eisenia fetida andrei* | Metabolite R-3 | Acute     | 0.0015 mg a.s./d.w. soil initial | 3266.7 | 10      |
| *Eisenia fetida andrei* | Metabolite R-7 | Acute     | 0.0037 mg a.s./d.w. soil initial | 1297.3 | 10      |
| *Eisenia fetida andrei* | Metabolite R-8 | Acute     | 0.0043 mg a.s./d.w. soil initial | 1151.2 | 10      |
| *Eisenia fetida andrei* | Metabolite R-13 | Acute   | 0.0034 mg a.s./d.w. soil initial | 1455.9 | 10      |
| *Eisenia fetida andrei* | Etoxazole | Chronic   | 0.015 mg a.s./d.w. soil initial | 166.7  | 5       |
| *Eisenia fetida andrei* | Metabolite R-3 | Chronic | 0.0015 mg a.s./d.w. soil initial | 3333.3 | 5       |
| *Eisenia fetida andrei* | Metabolite R-7 | Chronic | 0.0037 mg a.s./d.w. soil initial | 1351.4 | 5       |
| *Eisenia fetida andrei* | Metabolite R-8 | Chronic | 0.0043 mg a.s./d.w. soil initial | 1162.8 | 5       |
| *Eisenia fetida andrei* | Metabolite R-11 | Chronic | 0.0008 mg a.s./d.w. soil initial | 12500  | 5       |
| *Eisenia fetida andrei* | Metabolite R-13 | Chronic | 0.0034 mg a.s./d.w. soil initial | 1470.6 | 5       |
| **Other soil macroorganisms** |          |            |                |       |         |
| *Folsomia candida* | Etoxazole | Chronic   | 0.015 mg a.s./d.w. soil initial | 20     | 5       |
| *Folsomia candida* | Metabolite R-3 | Chronic | 0.0015 mg a.s./d.w. soil initial | 3333.3 | 5       |
| *Folsomia candida* | Metabolite R-7 | Chronic | 0.0037 mg a.s./d.w. soil initial | 1351.4 | 5       |
| *Folsomia candida* | Metabolite R-8 | Chronic | 0.0043 mg a.s./d.w. soil initial | 1162.8 | 5       |
| *Folsomia candida* | Metabolite R-11 | Chronic | 0.0008 mg a.s./d.w. soil initial | 12500  | 5       |
| *Folsomia candida* | Metabolite R-13 | Chronic | 0.0034 mg a.s./d.w. soil initial | 1470.6 | 5       |
| *Hypoaspis aculeifer* | Etoxazole | Chronic   | 0.015 mg a.s./d.w. soil initial | 6.7    | 5       |
| *Hypoaspis aculeifer* | Metabolite R-3 | Chronic | 0.0015 mg a.s./d.w. soil initial | 3333.3 | 5       |
| *Hypoaspis aculeifer* | Metabolite R-7 | Chronic | 0.0037 mg a.s./d.w. soil initial | 1351.4 | 5       |
| *Hypoaspis aculeifer* | Metabolite R-8 | Chronic | 0.0043 mg a.s./d.w. soil initial | 1162.8 | 5       |
| *Hypoaspis aculeifer* | Metabolite R-11 | Chronic | 0.0008 mg a.s./d.w. soil initial | 12500  | 5       |
| *Hypoaspis aculeifer* | Metabolite R-13 | Chronic | 0.0034 mg a.s./d.w. soil initial | 147.1  | 5       |

\(^1\) indicate which PEC soil was used (e.g. plateau PEC)

In **bold** the TER values that do not meet the trigger of 5.
[Use in strawberry at 55 g a.s./ha]

| Test organism                  | Test substance | Time scale | Soil PEC\(^1\)      | TER   | Trigger |
|-------------------------------|----------------|------------|---------------------|-------|---------|
| **Earthworms**                |                |            |                     |       |         |
| *Eisenia fetida andrei*       | Etoxazole      | Acute      | 0.051 mg a.s./d.w. soil initial | 9803.9 | 10      |
|                               | Metabolite R-3 | Acute      | 0.0054 mg a.s./d.w. soil initial | 907.4  | 10      |
|                               | Metabolite R-7 | Acute      | 0.0129 mg a.s./d.w. soil initial | 372.1  | 10      |
|                               | Metabolite R-8 | Acute      | 0.0152 mg a.s./d.w. soil initial | 325.7  | 10      |
|                               | Metabolite R-13 | Acute      | 0.0118 mg a.s./d.w. soil initial | 419.5  | 10      |
|                               | Etoxazole      | Chronic    | 0.051 mg a.s./d.w. soil initial | 49.0   | 5       |
|                               | Metabolite R-3 | Chronic    | 0.0054 mg a.s./d.w. soil initial | 925.9  | 5       |
|                               | Metabolite R-7 | Chronic    | 0.0129 mg a.s./d.w. soil initial | 387.6  | 5       |
|                               | Metabolite R-8 | Chronic    | 0.0152 mg a.s./d.w. soil initial | 328.9  | 5       |
|                               | Metabolite R-11 | Chronic    | 0.0027 mg a.s./d.w. soil initial | 3703.7 | 5       |
|                               | Metabolite R-13 | Chronic    | 0.0118 mg a.s./d.w. soil initial | 423.7  | 5       |
| **Other soil macroorganisms** |                |            |                     |       |         |
| *Folsomia candida*            | Etoxazole      | Chronic    | 0.051 mg a.s./d.w. soil initial | 5.9    | 5       |
|                               | Metabolite R-3 | Chronic    | 0.0054 mg a.s./d.w. soil initial | 925.9  | 5       |
|                               | Metabolite R-7 | Chronic    | 0.0129 mg a.s./d.w. soil initial | 387.6  | 5       |
|                               | Metabolite R-8 | Chronic    | 0.0152 mg a.s./d.w. soil initial | 328.9  | 5       |
|                               | Metabolite R-11 | Chronic    | 0.0027 mg a.s./d.w. soil initial | 3703.7 | 5       |
|                               | Metabolite R-13 | Chronic    | 0.0118 mg a.s./d.w. soil initial | 423.7  | 5       |
| *Hypoaspis aculeifer*         | Etoxazole      | Chronic    | 0.051 mg a.s./d.w. soil initial | 1.96   | 5       |
|                               | Metabolite R-3 | Chronic    | 0.0054 mg a.s./d.w. soil initial | 925.9  | 5       |
|                               | Metabolite R-7 | Chronic    | 0.0129 mg a.s./d.w. soil initial | 387.6  | 5       |
|                               | Metabolite R-8 | Chronic    | 0.0152 mg a.s./d.w. soil initial | 328.9  | 5       |
|                               | Metabolite R-11 | Chronic    | 0.0027 mg a.s./d.w. soil initial | 3703.7 | 5       |
|                               | Metabolite R-13 | Chronic    | 0.0118 mg a.s./d.w. soil initial | 42.4   | 5       |

\(^1\) indicate which PEC soil was used (e.g. plateau PEC)
In **bold** the TER values that do not meet the trigger of 5.
[Use in cotton 41.2 g a.s./ha]

| Test organism | Test substance | Time scale | Soil PEC | TER | Trigger |
|---------------|----------------|------------|----------|-----|---------|
| **Earthworms**|                |            |          |     |         |
| *Eisenia fetida andrei* | Etoxazole | Acute | 0.039 mg a.s./d.w. soil initial | 12820.5 | 10 |
| *Eisenia fetida andrei* | Metabolite R-3 | Acute | 0.0040 mg a.s./d.w. soil initial | 1225 | 10 |
| *Eisenia fetida andrei* | Metabolite R-7 | Acute | 0.0097 mg a.s./d.w. soil initial | 494.9 | 10 |
| *Eisenia fetida andrei* | Metabolite R-8 | Acute | 0.0114 mg a.s./d.w. soil initial | 434.2 | 10 |
| *Eisenia fetida andrei* | Metabolite R-13 | Acute | 0.0088 mg a.s./d.w. soil initial | 562.5 | 10 |
| *Eisenia fetida andrei* | Etoxazole | Chronic | 0.039 mg a.s./d.w. soil initial | 64.1 | 5 |
| *Eisenia fetida andrei* | Metabolite R-3 | Chronic | 0.0040 mg a.s./d.w. soil initial | 1250 | 5 |
| *Eisenia fetida andrei* | Metabolite R-7 | Chronic | 0.0097 mg a.s./d.w. soil initial | 515.5 | 5 |
| *Eisenia fetida andrei* | Metabolite R-8 | Chronic | 0.0114 mg a.s./d.w. soil initial | 438.6 | 5 |
| *Eisenia fetida andrei* | Metabolite R-11 | Chronic | 0.0020 mg a.s./d.w. soil initial | 5000 | 5 |
| *Eisenia fetida andrei* | Metabolite R-13 | Chronic | 0.0088 mg a.s./d.w. soil initial | 568.2 | 5 |
| **Other soil macroorganisms** | | | | | |
| *Folsomia candida* | Etoxazole | Chronic | 0.039 mg a.s./d.w. soil initial | 7.7 | 5 |
| *Folsomia candida* | Metabolite R-3 | Chronic | 0.0040 mg a.s./d.w. soil initial | 1250 | 5 |
| *Folsomia candida* | Metabolite R-7 | Chronic | 0.0097 mg a.s./d.w. soil initial | 515.5 | 5 |
| *Folsomia candida* | Metabolite R-8 | Chronic | 0.0114 mg a.s./d.w. soil initial | 438.6 | 5 |
| *Folsomia candida* | Metabolite R-11 | Chronic | 0.0020 mg a.s./d.w. soil initial | 5000 | 5 |
| *Folsomia candida* | Metabolite R-13 | Chronic | 0.0088 mg a.s./d.w. soil initial | 568.2 | 5 |
| *Hypoaspis aculeifer* | Etoxazole | Chronic | 0.039 mg a.s./d.w. soil initial | 2.6 | 5 |
| *Hypoaspis aculeifer* | Metabolite R-3 | Chronic | 0.0040 mg a.s./d.w. soil initial | 1250 | 5 |
| *Hypoaspis aculeifer* | Metabolite R-7 | Chronic | 0.0097 mg a.s./d.w. soil initial | 515.5 | 5 |
| *Hypoaspis aculeifer* | Metabolite R-8 | Chronic | 0.0114 mg a.s./d.w. soil initial | 438.6 | 5 |
| *Hypoaspis aculeifer* | Metabolite R-11 | Chronic | 0.0020 mg a.s./d.w. soil initial | 5000 | 5 |
| *Hypoaspis aculeifer* | Metabolite R-13 | Chronic | 0.0088 mg a.s./d.w. soil initial | 56.8 | 5 |

1indicates which PEC soil was used (e.g. plateau PEC)
In bold the TER values that do not meet the trigger of 5.
### Toxicity/exposure ratios for soil organisms for use in strawberries considering PEC\textsubscript{plateau} calculations.

| Test organism               | Test substance | Time scale | Soil PEC\textsuperscript{1} | TER    | Trigger |
|-----------------------------|----------------|------------|------------------------------|--------|---------|
| **Earthworms**              |                |            |                              |        |         |
| *Eisenia fetida andrei*     | Etoxazole      | Acute      | 0.0527 mg a.s./d.w. soil accumulation | 9487.7 | 10      |
| *Eisenia fetida andrei*     | Metabolite R-3 | Acute      | 0.0057 mg a.s./d.w. soil accumulation | 859.6  | 10      |
| *Eisenia fetida andrei*     | Metabolite R-8 | Acute      | 0.0162 mg a.s./d.w. soil accumulation | 305.6  | 10      |
| *Eisenia fetida andrei*     | Metabolite R-13| Acute      | 0.0188 mg a.s./d.w. soil accumulation | 263.3  | 10      |
| *Eisenia fetida andrei*     | Etoxazole      | Chronic    | 0.0527 mg a.s./d.w. soil accumulation | 47.4   | 5       |
| *Eisenia fetida andrei*     | Metabolite R-3 | Chronic    | 0.0057 mg a.s./d.w. soil accumulation | 877.2  | 5       |
| *Eisenia fetida andrei*     | Metabolite R-8 | Chronic    | 0.0162 mg a.s./d.w. soil accumulation | 308.6  | 5       |
| *Eisenia fetida andrei*     | Metabolite R-13| Chronic    | 0.0188 mg a.s./d.w. soil accumulation | 265.9  | 5       |
| **Other soil macroorganisms**|                |            |                              |        |         |
| *Folsomia candida*          | Etoxazole      | Chronic    | 0.0527 mg a.s./d.w. soil accumulation | 5.7    | 5       |
| *Folsomia candida*          | Metabolite R-3 | Chronic    | 0.0057 mg a.s./d.w. soil accumulation | 877.2  | 5       |
| *Folsomia candida*          | Metabolite R-8 | Chronic    | 0.0162 mg a.s./d.w. soil accumulation | 308.6  | 5       |
| *Folsomia candida*          | Metabolite R-13| Chronic    | 0.0188 mg a.s./d.w. soil accumulation | 265.9  | 5       |
| *Hypoaspis aculeifer*       | Etoxazole      | Chronic    | 0.0527 mg a.s./d.w. soil accumulation | 1.9    | 5       |
| *Hypoaspis aculeifer*       | Metabolite R-3 | Chronic    | 0.0057 mg a.s./d.w. soil accumulation | 877.2  | 5       |
| *Hypoaspis aculeifer*       | Metabolite R-8 | Chronic    | 0.0162 mg a.s./d.w. soil accumulation | 308.6  | 5       |
| *Hypoaspis aculeifer*       | Metabolite R-13| Chronic    | 0.0188 mg a.s./d.w. soil accumulation | 26.6   | 5       |

\textsuperscript{1}Indicate which PEC soil was used (e.g. plateau PEC). For PEC accumulation, strawberries have been considered for PEC\textsubscript{plateau} calculations at 5 cm soil depth.

In **bold** the TER values that do not meet the trigger of 5.

### 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**

Not required for herbicides or plant growth regulators as ER\textsubscript{50} tests should be provided

**Laboratory dose response tests**

| Species        | Test substance | ER\textsubscript{50} (g/ha)\textsuperscript{2} vegetative vigour | ER\textsubscript{50} (g/ha)\textsuperscript{2} emergence | Exposure\textsuperscript{1} (g/ha)\textsuperscript{2} | TER | Trigger |
|----------------|----------------|---------------------------------------------------------------|----------------------------------------------------------|--------------------------------------------------|------|---------|
|                |                |                                                              |                                                          |                                                  |      |         |
| Species | Test substance | $\text{ER}_{50}$ (g/ha)$^2$ vegetative vigour | $\text{ER}_{50}$ (g/ha)$^2$ emergence | Exposure$^1$ (g/ha)$^3$ | TER | Trigger |
|---------|----------------|--------------------------------------------|--------------------------------------|--------------------------|-----|---------|
| Pome fruit and citrus: 55 g a.s./ha (drift rate = 15.73% at 3m) | Etoxazole | $> 67.2$ | $> 67.2$ | 8.65 | $> 7.77$ | 5 |
| Glycine max | Lactuca sativa | | | | | |
| Raphanus sativus | Lycopersicon | | | | | |
| esculentum | Cucumis sativus | | | | | |
| Brassica oleracea | Avena sativa | | | | | |
| Lolium perenne | Zea mays | | | | | |
| Allium cepa | | | | | | |
| Pome fruit and citrus: 55 g a.s./ha (drift rate = 29.2% at 3m) | Etoxazole | $> 67.2$ | $> 67.2$ | 16.06 | $> 4.18$ | 5 |
| Glycine max | Lactuca sativa | | | | | |
| Raphanus sativus | Lycopersicon | | | | | |
| esculentum | Cucumis sativus | | | | | |
| Brassica oleracea | Avena sativa | | | | | |
| Lolium perenne | Zea mays | | | | | |
| Allium cepa | | | | | | |
| Pome fruit and citrus: 55 g a.s./ha (drift rate = 29.2% at 3m with 50% drift reduction) | Etoxazole | $> 67.2$ | $> 67.2$ | 8.03 | 8.37 | 5 |
| Glycine max | Lactuca sativa | | | | | |
| Raphanus sativus | Lycopersicon | | | | | |
| esculentum | Cucumis sativus | | | | | |
| Brassica oleracea | Avena sativa | | | | | |
| Lolium perenne | Zea mays | | | | | |
| Allium cepa | | | | | | |
| Pome fruit and citrus: 55 g a.s./ha (drift rate = 29.2% at 5m) | Etoxazole | $> 67.2$ | $> 67.2$ | 10.94 | $> 6.1$ | 5 |
| Glycine max | Lactuca sativa | | | | | |
| Raphanus sativus | Lycopersicon | | | | | |
| esculentum | Cucumis sativus | | | | | |
| Brassica oleracea | Avena sativa | | | | | |
| Lolium perenne | Zea mays | | | | | |
| Allium cepa | | | | | | |
| Grape: 55 g a.s./ha (drift rate = 8.02% at 3m) | Etoxazole | $> 67.2$ | $> 67.2$ | 4.41 | $> 15.2$ | 5 |
| Species                        | Test substance | ER\textsubscript{50} (g/ha)\textsuperscript{2} | ER\textsubscript{50} (g/ha)\textsuperscript{2} | Exposure\textsuperscript{1} (g/ha)\textsuperscript{2} | TER | Trigger |
|-------------------------------|----------------|---------------------------------|---------------------------------|---------------------------------|-----|---------|
| *esculentum*                  |                |                                 |                                 |                                 |     |         |
| *Cucumis sativus*             |                |                                 |                                 |                                 |     |         |
| *Brassica oleracea*           |                |                                 |                                 |                                 |     |         |
| *Avena sativa*                |                |                                 |                                 |                                 |     |         |
| *Lolium perenne*              |                |                                 |                                 |                                 |     |         |
| *Zea mays*                    |                |                                 |                                 |                                 |     |         |
| *Allium cepa*                 |                |                                 |                                 |                                 |     |         |
| Vegetable: 55 g a.s./ha (drift rate = 2.77% at 1m) | Etoxazole | > 67.2 | > 67.2 | 1.52 | > 44.1 | 5 |
| *Glycine max*                 |                |                                 |                                 |                                 |     |         |
| *Lactuca sativa*              |                |                                 |                                 |                                 |     |         |
| *Raphanus sativus*            |                |                                 |                                 |                                 |     |         |
| *Lycopersicon esculentum*     |                |                                 |                                 |                                 |     |         |
| *Cucumis sativus*             |                |                                 |                                 |                                 |     |         |
| *Brassica oleracea*           |                |                                 |                                 |                                 |     |         |
| *Avena sativa*                |                |                                 |                                 |                                 |     |         |
| *Lolium perenne*              |                |                                 |                                 |                                 |     |         |
| *Zea mays*                    |                |                                 |                                 |                                 |     |         |
| *Allium cepa*                 |                |                                 |                                 |                                 |     |         |
| Cotton: 41.2 g a.s./ha (drift rate = 2.77% at 1m) | Etoxazole | > 67.2 | > 67.2 | 1.14 | > 58.8 | 5 |
| *Glycine max*                 |                |                                 |                                 |                                 |     |         |
| *Lactuca sativa*              |                |                                 |                                 |                                 |     |         |
| *Raphanus sativus*            |                |                                 |                                 |                                 |     |         |
| *Lycopersicon esculentum*     |                |                                 |                                 |                                 |     |         |
| *Cucumis sativus*             |                |                                 |                                 |                                 |     |         |
| *Brassica oleracea*           |                |                                 |                                 |                                 |     |         |
| *Avena sativa*                |                |                                 |                                 |                                 |     |         |
| *Lolium perenne*              |                |                                 |                                 |                                 |     |         |
| *Zea mays*                    |                |                                 |                                 |                                 |     |         |
| *Allium cepa*                 |                |                                 |                                 |                                 |     |         |

Extended laboratory studies: not required.
Semi-field and field test: not required.

\textsuperscript{1} explanation of how exposure has been estimated should be provided (e.g. based on Ganzelmeier drift data)

\textsuperscript{2} for preparations indicate whether dose is expressed in units of a.s. or preparation

**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  | NOEC = 1000 mg Etoxazole/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)**

No monitoring data available concerning adverse effect of the a.s. or the preparation.
**Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2) Ecotoxicologically relevant compounds**

| Compartment |  |
|-------------|---|
| soil        | Parent (etoxazole) |
| water       | Parent (etoxazole) |
| sediment    | Parent (etoxazole) |
| groundwater | Parent (etoxazole) |

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) No 283/2013, Annex Part A, Section 10)

Substance

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)\(^5\):

Peer review proposal\(^6\) for harmonised classification according to Regulation (EC) No 1272/2008:

| Substance | Aquatic Acute 1 – H400 (M=100) | Aquatic Chronic 1 – H410 (M=100) |
|-----------|-------------------------------|----------------------------------|
| Etoxazole  |                               |                                  |
|           | Aquatic Acute 1 – H400 (M=100) | Aquatic Chronic 1 – H410         |

\(^5\) 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.

\(^6\) It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.