Appendix III: Listing of end points

Appendix III.1: Chapter 1 (identity, physical and chemical properties, details of uses, further information, classification and labelling)

| Active substance (ISO Common Name) ‡ | Spiroxamine |
|--------------------------------------|-------------|
| Function (e.g. fungicide)            | fungicide   |
| Rapporteur Member State              | Federal Republic of Germany |
| Co-rapporteur Member State           | Hungary     |

Identity (Annex IIA, point 1)

| Chemical name (IUPAC) ‡ | 8-tert-butyl-1,4-dioxaspiro[4.5]decan-2-ylmethyl(ethyl)(propyl)amine (ISO) |
|-------------------------|------------------------------------------------------------------|
| Chemical name (CA) ‡    | 1,4-Dioxaspiro[4.5]decan-2-methanamine, 8-(1,1-dimethylethyl)-N-ethyl-N-propyl-|
| CIPAC No ‡             | 572                                              |
| CAS No ‡               | 118134-30-8 (unstated stereochemistry)                     |
| EC No (EINECS or ELINCS) ‡ | none                                        |
| FAO Specification (including year of publication) ‡ | none |
| Minimum purity of the active substance as manufactured ‡ | 950 g/kg |
| Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured | none |
| Molecular formula ‡     | C_{18}H_{35}NO_{2}                                      |
| Molecular mass ‡        | 297.5 g/mol                                            |
| Structural formula ‡    | ![Structural formula](image)                          |

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles
### Physical and chemical properties (Annex IIA, point 2)

| Property                                                                 | Value                                                                 |
|--------------------------------------------------------------------------|----------------------------------------------------------------------|
| Melting point (state purity) ‡                                            | < - 170 °C °C (> 98.6 %)                                              |
| Boiling point (state purity) ‡                                            | Not applicable                                                       |
| Temperature of decomposition (state purity)                              | Starts at 120 °C (99 %)                                               |
| Appearance (state purity) ‡                                              | Faintly yellowish liquid (98.7 %)                                     |
| Vapour pressure (state temperature, state purity) ‡ Diastereomer A      | 4.0 x 10⁻³ Pa at 20 °C (98.6 %)                                        |
| Vapour pressure (state temperature, state purity) ‡ Diastereomer B      | 6 x 10⁻³ Pa at 20 °C (99.3 %)                                         |
| Henry’s law constant ‡ Diastereomer A                                    | 2.5 x 10⁻³ Pa m³ mol⁻¹                                               |
| Henry’s law constant ‡ Diastereomer B                                    | 5.0 x 10⁻³ Pa m³ mol⁻¹                                               |
| Solubility in water (state temperature, state purity and pH) ‡ Diastereomer A | >200 g/L at 20 °C (pH 3) (99 %)                                      |
| Solubility in water (state temperature, state purity and pH) ‡ Diastereomer B | 470 mg/L at 20 °C (pH 5) (99 %)                                      |
| Solubility in water (state temperature, state purity and pH) ‡ Diastereomer B | 14 mg/L at 20 °C (pH 9) (99 %)                                      |
| Solubility in organic solvents ‡ (state temperature, state purity)      |                                                                 |
|                            | n-hexane > 200 g/L at 20 °C                                           |
|                            | toluene > 200 g/L at 20 °C                                            |
|                            | dichloromethane > 200 g/L at 20 °C                                   |
|                            | 2-propanol > 200 g/L at 20 °C                                         |
|                            | 1-octanol > 200 g/L at 20 °C                                          |
|                            | PEG > 200 g/L at 20 °C                                                |
|                            | PEG + ethanol > 200 g/L at 20 °C                                      |
|                            | acetone > 200 g/L at 20 °C                                            |
|                            | dimethylformamide > 200 g/L at 20 °C                                 |
|                            | ethylacetate > 200 g/L at 20 °C                                      |
|                            | acetonitril > 200 g/L at 20 °C                                        |
| Surface tension ‡ (state concentration and temperature, state purity)   |                                                                 |
|                            | Concentration [mg/L] surface tension [mN/m]                          |
|                            | 2                                                                       | 57                                                                   |
|                            | 20                                                                      | 53                                                                   |
|                            | 200                                                                     | 47                                                                   |
|                            | at 20 °C (pH 7)                                                        |
| Partition co-efficient ‡ (state temperature, pH and purity)              | log PŒW at 20 °C                                                      |
|                            | diastereomer A                                                         |
|                            | pH 5                                                                    | 1.28                                                                 |
|                            | pH 7                                                                    | 2.79                                                                 |
|                            | pH 9                                                                    | 4.88                                                                 |
|                            | diastereomer B                                                         |
|                            | pH 5                                                                    | 1.41                                                                 |
|                            | pH 7                                                                    | 2.98                                                                 |
|                            | pH 9                                                                    | 5.08                                                                 |

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles
| Property                                      | Value                                                                 |
|----------------------------------------------|                                                                     |
| Dissociation constant (state purity)‡        | $pK_a = 6.9 \ (99\%) \ in \ water$                                |
|                                              | $pK_a = 7.9 \ (99\%) \ in \ water/40\% \ 2\text{-propanol}$       |
| UV/VIS absorption (max.) incl. $\varepsilon$‡ | The UV-Spectrum shows no maximum of absorbance in the range of 200 nm – 400 nm for both isomers. |
| (state purity, pH)                           | $\varepsilon$ at 290 nm: $< 10$                                    |
| Flammability‡ (state purity)                 | 147 °C (flash point) (97.2 %)                                      |
| Explosive properties‡ (state purity)         | None (A 14) (97.2 %)                                               |
| Oxidising properties‡ (state purity)         | None (A 21) (97.0 %)                                               |

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles
1) Summary of representative uses evaluated (*name of active substance or the respective variant*) Spiproxamine 500 g/L.*

| Crop and/or situation (a) | Member State or Country | Product Name | F G or I (b) | Pests or Group of pests controlled (c) | Preparation | Application | Application rate per treatment (for explanation see the text in front of this section) | PHI (days) | Remarks |
|--------------------------|-------------------------|--------------|--------------|---------------------------------------|-------------|------------|------------------------------------------------------------------------------------|-----------|---------|
| Grape                    | France                  | HOGGAR PROSPER | F            | Powdery mildew (*Uncinula necator*)   | EC          | spraying   | BBCH 13 - 85 1 - 3 10 - 12 75 - 200 150 - 400 300 35 | 1000      | 2 x 100 – 3 x 300 - 400 | table 1/4 wine 35 |
| Grape                    | Italy                   | PROSPER 500 EC | F            | Powdery mildew (*Uncinula necator*)   | EC          | spraying   | BBCH 13 - 19 79 - 85 1 - 2 2 - 3 7 10 - 14 20 30 - 40 1000 1000 1 - 2 x 200 – 3 x 300 - 400 | 1000      | 20 - 3 x 300 - 400 75 35 | table grapes: 120-180 % of acute dietary reference values! |

* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).
(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) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(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. fluoroxypry). 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 at 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 application 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

2) Summary of representative uses evaluated (*name of active substance or the respective variant*)*Prothioconazole + Spiproxamine EC 460 (160 + 300) g/L

| Crop and/ | Member | Product Name | F G | Pests or Group of | Preparation | Application | Application rate per treatment (for explanation see the text in front of this section) | PHI** (days) |
|-----------|--------|--------------|-----|------------------|-------------|------------|------------------------------------------------------------------------------------|-----------|

† Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles
### Peer review of the pesticide risk assessment of the active substance spiroxamine

#### Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

| or situation | State or Country | or I | pests controlled | Type | Conc. of as (d-f) | method kind | growth stage & season | number min/max (k) | interval between applications (min) | g as/hL min - max (l) | water L/ha min - max (l) | g as/ha min - max (l) | Remarks |
|--------------|-----------------|-----|------------------|------|------------------|-------------|---------------------|-----------------|----------------------------------|------------------|-----------------|------------------|---------|
| Wheat & Triticale | EU - N EU - S | Input, Helix | F | Foliar & ear diseases | EC | 160 + 300 g/L | Field crop sprayer | BBCH 30 to BBCH 69 | 2 | 14 to 21 days | 50-100 (Prothio.) + 93,75-187,5 (Spirox.) | 200 - 400 | 200 + 375 | ** depending on national request: either PHI in days or growth stage at the latest application |
| Rye | EU - N EU - S | Input, Helix | F | Foliar & ear diseases | EC | 160 + 300 g/L | Field crop sprayer | BBCH 30 to BBCH 61 – 69 | 2 | 14 to 21 days | 50-100 (Prothio.) + 93,75-187,5 (Spirox.) | 200 - 400 | 200 + 375 | # may vary according to national conditions |
| Barley & Oat | EU - N EU - S | Input, Helix | F | Foliar & ear diseases | EC | 160 + 300 g/L | Field crop sprayer | BBCH 30 to BBCH 61 | 2 | 14 to 21 days | 50-100 (Prothio.) + 93,75-187,5 (Spirox.) | 200 - 400 | 200 + 375 | |

* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).

(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) GCPF Codes - GIFAP Technical Monograph No 2, 1989

(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 at 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 application 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

† Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles
Appendix III.3: Chapter 3 (impact on human and animal health)

Absorption, distribution, excretion and metabolism (toxicokinetics) (Annex IIA, point 5.1)

| Rate and extent of oral absorption ‡ | Rapid, about 60 % within 48 h, based on urinary excretion |
| Distribution ‡ | Wide, highest residues in liver, thymus, adrenals (high dose: fat) |
| Potential for accumulation ‡ | No evidence for accumulation |
| Rate and extent of excretion ‡ | > 80 % within 48 h (urine: > 60 %, faeces: > 20 %) |
| Metabolism in animals ‡ | Extensively metabolised (oxidation, sulphate conjugation, dealkylation) |
| Toxicologically relevant compounds ‡ (animals and plants) | Spiroxamine |
| Toxicologically relevant compounds ‡ (environment) | Spiroxamine and metabolites |

Acute toxicity (Annex IIA, point 5.2)

| Rat LD₅₀ oral ‡ | ~ 500 mg/kg bw | H302 |
| Rat LD₅₀ dermal ‡ | 1068 mg/kg bw | H312 |
| Rat LC₅₀ inhalation ‡ | 2 mg/L air; slight pulmonary irritation (4-h exposure, nose-only) | H332 |
| Skin irritation ‡ | Severe irritant | H315 |
| Eye irritation ‡ | Non-irritant |
| Skin sensitisation ‡ | Sensitiser (M&K; Buehler) | H317 |

Short term toxicity (Annex IIA, point 5.3)

| Target / critical effect ‡ | Oral: Liver (histological findings, wt ↑, clinical chemistry), clinical signs, effects on mucosal epithelium of oesophagus and fore-stomach; additionally in dogs: eye (cataracts), STOT RE 2 (eye) |
| Relevant oral NOAEL ‡ | 28-day, rat: 3.4 mg/kg bw/day |
| 90-day, rat: 1.9 mg/kg bw/day |
| 90-day, dog: 15.1 mg/kg bw/day |
| 1-year, dog: 2.5 mg/kg bw/day |
| 90-day, mouse: 25 mg/kg bw/day |
| Relevant dermal NOAEL ‡ | 21-day, rabbit: local effects: 0.2 mg/kg bw/day systemic effects: 5 mg/kg bw/day highest dose tested |
| Relevant inhalation NOAEL ‡ | 28-day, rat: 14.3 mg/m³ air (6-h exposure, nose only, 3.9 mg/kg bw/day) |

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles
Genotoxicity ‡ (Annex IIA, point 5.4)

| No genotoxic potential |

Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

| Target/critical effect ‡ | Both species: acanthosis & hyperkeratosis of oesophagus mucosa; bw ↓; 
Additionally in rats: hyperplasia of urinary bladder; mortality ↑; uterus (masses, distension) 
Additionally in mice: ovaries (cyst); acanthosis & hyperkeratosis of tail; acanthosis of auricles; liver (histological changes) |
| Relevant NOAEL ‡ | 2-year, rat: 4.2 mg/kg bw/day 
18-month, mouse: 4.5 mg/kg bw/day |
| Carcinogenicity ‡ | No evidence for carcinogenicity |

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

| Reproduction target / critical effect ‡ | Adult: bw and feed intake ↓; APTT ↑ 
Reproduction and fertility: no evidence for impairment of fertility and reproduction 
Offspring: bw gain ↓, delayed development |
| Relevant parental NOAEL ‡ | 5.5 mg/kg bw/day |
| Relevant reproductive NOAEL ‡ | 21 mg/kg bw/day |
| Relevant offspring NOAEL ‡ | 5.5 mg/kg bw/day |

Developmental toxicity

| Developmental target / critical effect ‡ | Maternal: 
Rat: bw gain and feed intake ↓ 
Rat, dermal: bw gain ↓ 
Rabbit: bw gain and feed intake ↓, clinical signs, mortality 
Developmental: 
Rat: delayed ossification, wt ↓, cleft palate 
Rat, dermal: wavy ribs 
Rabbit: wt ↓, spontaneous skeletal malformations slightly ↑ (hydrocephalus internus + caudal displacement of ears, chicken breast) |
| Relevant maternal NOAEL ‡ | Rat: 30 mg/kg bw/day 
Rat, dermal: 20 mg/kg bw/day / <5 mg/kg bw/day (systemic / local effects) 
Rabbit: 20 mg/kg bw/day |
| Relevant developmental NOAEL ‡ | Rat: 30 mg/kg bw/day 
Rat, dermal: 20 mg/kg bw/day 
Rabbit: 20 mg/kg bw/day |

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles
### Neurotoxicity (Annex IIA, point 5.7)

| Type of Neurotoxicity       | Description                                                                 |
|-----------------------------|-----------------------------------------------------------------------------|
| Acute neurotoxicity ‡       | Signs of acute toxicity related to general toxicity of spiroxamine          |
|                             | NOAEL: 10 mg/kg bw/day                                                      |
| Repeated neurotoxicity ‡    | No evidence for neurotoxicity up to 50 mg/kg bw/day, systemic toxicity (bw ↓, clinical chemistry findings, histological findings in the oesophagus) |
|                             | NOAEL: 2.4 mg/kg bw/day                                                    |
| Delayed neurotoxicity ‡     | No data – not required                                                     |

### Other toxicological studies (Annex IIA, point 5.8)

| Mechanism studies ‡        | Description                                                                 |
|-----------------------------|-----------------------------------------------------------------------------|
|                             | Lung function was depressed upon inhalatory exposure in rats and mice; tolerated air concentrations were 450 mg/m³ or 16 mg/m³, respectively |
|                             | Spiroxamine did not inhibit aromatase or steroidogenesis in vitro          |

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles
Studies performed on metabolites or impurities ‡

Metabolite KWG 4168 N-oxide (M03)

Rat LD$_{50}$ oral: ~707 mg/kg bw (f)  
H302  
No genotoxic potential in vitro  
- Ames test: negative  
- Hypoxanthine-Guanine Phospho Ribosyl Transferase gene mutation assay: negative  
- In vitro chromosome aberration assay: negative  
28-day, rat: bw ↓, liver (slight enzyme induction), hyperkeratosis in oesophagus and fore stomach, urinary bladder (hyperplasia); NOAEL: 12.9 mg/kg bw/day  
90-day, rat: bw ↓, liver (clinical chemistry, enzyme induction), hyperkeratosis in oesophagus and fore stomach; NOAEL: 8.8 mg/kg bw/day  
The toxicological reference values of the spiroxamine are applicable to metabolite M03.

Metabolites M20 and M21

Metabolites M20 and M21 are glucosides of metabolite M03 and the reference values of spiroxamine are also applicable to these metabolites.

Metabolite KWG 4168-aminodiol (M28)

Genotoxicity
- Bacterial reverse mutation assay: negative  
- Hypoxanthine-Guanine Phospho Ribosyl Transferase gene mutation assay: negative  
- In vitro micronucleus test: negative  
No genotoxic potential in vitro

General toxicity
Rat: LD$_{50}$ oral: 550 < LD$_{50}$ < 2000 mg/kg bw (females only)
28-day, rat (supplementary):
There were no treatment-related effects up to the high dose tested. NOAEL: 28.4/31.4 mg/kg bw/day in males/females (highest dose tested)
Developmental toxicity, rat (supplementary):
Maternal NOAEL: 150 mg/kg bw/d based on mortality, clinical observations (gasping and rales), gaseous contents and gas filled parts of the gastrointestinal tract and individual body weight decreases at 500 mg/kg bw/day.
Developmental NOAEL: 30 mg/kg bw/d, changes in ossification at 150 mg/kg bw/day.

ADI: 0.03 mg/kg bw per day (dev tox rat, UF 1000)
based on the developmental NOAEL of 30 mg/kg bw per day (top dose) supported by the 28-d rat.

ARfD: 0.5 mg/kg bw, based on the maternal NOAEL of

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles
Metabolite 4-tert-butylocyclohexanol (PTBCOL) (M13)

150 mg/kg bw per day from the dev tox study in rats, UF 300)

Genotoxicity
- Bacterial reverse mutation assay: negative
- In vitro chromosomal aberration (supplementary): negative
- (Q)SAR models: negative and read-cross: no new alerts;

Metabolite M13 is predicted as negative by all (Q)SAR models and no new alerts are identified by read-across; hence, they are not of concern for genotoxicity (EFSA PPR Panel, 2016).

No genotoxic potential in vitro

General toxicity
Rat LD₅₀ oral: 4200 mg/kg bw/day
Rabbit LD₅₀ dermal: >5000 mg/kg bw/day
28-day, rat: 2 weeks recovery
NOAEL: 50 mg/kg bw per day (m/f) based on clinical signs & transient signs of neurotoxicity at the LOAEL of 150 mg/kg bw par day. At 300 mg/kg bw/d in addition: reduced body weights & increased motor activity, changes in organ weights and clinical chemistry/haematology values.

ADI = 0.03 mg/kg bw per day (dev tox study in rat performed with M13 acetate, UF 1000) based on the NOAEL of 31.5 mg/kg bw per day based on clinical signs

ARfD = 0.1 mg/kg bw (dev tox study in rat with M13 acetate, based on clinical signs, in addition, transient signs of neurotoxicity were observed in the 28-d study in rat with M13, UF 300)

The point of departure for both the ADI and ARfD is 31.5 mg/kg bw per day from the developmental toxicity study (40 mg/kg bw per day *156 g/mol /198 g/mol to calculate the amount of M13 from the amount of M13 acetate).

Developmental toxicity, rat:
Maternal NOAEL: 40 mg/kg bw per day based on clinical signs at 160 mg/kg bw per day. Mortality, clinical signs, significantly reduced body weight gains, body weight losses and food consumption at 640 mg/kg bw per day.

Developmental NOAEL: 160 mg/kg bw per day, based on reduced foetal weights, increased incidences of dilatation of the renal pelvis and reduced ossification sites at 640 mg/kg bw per day.

Impurity AE 1344320

4-tert-butylocyclohexyl acetate (M 13 acetate)

Skin & eye irritant H315-H318

Ames test: negative

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles
Peer review of the pesticide risk assessment of the active substance spiroxamine

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

| Impurity AE 1344300 | Rat oral: 500 < LD$_{50}$ < 710 mg/kg bw (M) 212 < LD$_{50}$ < 500 mg/kg bw (F) H302 |
|---------------------|----------------------------------------------------------------------------------|
|                     | Rat LC$_{50}$ inhalative (4-h exp., nose only, vapour): ~13825/16303 mg/m$^3$ air (M/F) H332 |
|                     | Skin and eye corrosive H314-H318 |
|                     | Skin sensitisation: non-sensitiser (M&K) Ames test: negative |

| Impurity AE 2077192 | Rat LD$_{50}$ oral: > 2000 mg/kg bw Ames test: negative |

| Impurity AE 2074422 | Ames test: negative |

| Impurity AE 1344301 | Ames test: negative |

| Impurity AE 2078647 | Rat oral: 300 < LD$_{50}$ < 500 mg/kg bw H302 |
|---------------------|-------------------------------------------------|
|                     | Ames test: negative |

Medical data ‡ (Annex IIA, point 5.9)

No adverse effects in manufacturing personnel reported. Clinical cases/case reports were submitted, correlation between spiroxamine and the observed symptoms is unclear, besides findings of skin and eye irritation from splashes with spiroxamine-containing products.

Summary (Annex IIA, point 5.10)

| Value               | Study                        | Safety factor |
|---------------------|------------------------------|---------------|
| ADI ‡               | 0.025 mg/kg bw/day           | 1 year, dog   | 100 |
| AOEL sys.‡          | 0.015 mg/kg bw/day           | 1 year, dog   | overall 167 100 + 60* |
| ARfD ‡              | 0.1 mg/kg bw                 | Acute neurotoxicity, rat | 100 |

*correction for limited oral absorption

Dermal absorption ‡ (Annex IIIA, point 7.3)

| Spiroxamine (a.s.) | 100 % (default) considering physico-chemical properties (molecular mass: 297.5; log P$_{ow}$: 1.28-5.08) |
|--------------------|--------------------------------------------------------------------------------------------------|
| Impulse EC 500, KWG 4168 500 EC | 15 % for the concentrate (applied dose appr. 5 mg/cm$^2$) and 35 % or 40 % for the dilutions (applied dose appr. 0.02 mg/cm$^2$ or 0.008 mg/cm$^2$, respectively) based on in vitro human skin (supported by human in vivo) |

www.efsa.europa.eu/efsajournal 11 EFSA Journal 2020;19(2):6385
### Exposure scenarios (Annex IIIA, point 7.2)

#### Operator

| Scenario                        | Spiroxamine EC 500 (application rate 0.4 kg spiroxamine/ha) | Prothioconazole & spiroxamine EC 460 (application rate 0.375 kg spiroxamine/ha) |
|---------------------------------|-------------------------------------------------------------|---------------------------------------------------------------------------------|
|                                 | German model                                               | German model                                                                   |
| **High crop tractor mounted equipment** | % of AOEL                                                    | % of AOEL                                                                       |
| Without PPE                     | 1517.3                                                     | 841.1                                                                          |
| With PPE (gloves – M&L + applic., protective garment, sturdy footwear, hood & visor – applic.) | 73.4                                                        | 44.8                                                                          |
| **High crop hand held sprayer** | % of AOEL                                                    | % of AOEL                                                                       |
| Without PPE                     | 1800.4                                                     |                                                                                |
| With PPE (gloves – M&L + applic., protective garment, sturdy footwear, hood & visor – applic.) | 49.4                                                        |                                                                                |
| **UK POEM**                     | Not calculated                                             |                                                                                |

#### Workers

| Scenario                        | Spiroxamine EC 500                                        | Prothioconazole & spiroxamine EC 460                                          |
|---------------------------------|-----------------------------------------------------------|---------------------------------------------------------------------------------|
|                                 | % of AOEL                                                  | % of AOEL                                                                       |
| Without PPE                     | 2488.7                                                     | 2488.7                                                                         |
| With PPE (gloves, long sleeved shirt & long trousers) | 124.7                                                      | 124.7                                                                          |

#### Bystanders

| Scenario                        | Spiroxamine EC 500                                        | Prothioconazole & spiroxamine EC 460                                          |
|---------------------------------|-----------------------------------------------------------|---------------------------------------------------------------------------------|
|                                 | % of AOEL                                                  | % of AOEL                                                                       |
| Bystanders                      | max. 22.1 %                                                | max. 4.8 %                                                                      |
| Residents                       | max. 57.5 %                                                | max. 52.3 %                                                                     |
| (children, after three applications using a drift value of 1.02 %) |                                        | (children, after two applications using a drift value of 0.24 %)                |

*values agreed during the written procedure according to the agreed AOEL and re-calculation of the residential exposure considering three/two applications scenario as applicable, as reported in the final addendum.*

† Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles
Classification and proposed labelling with regard to toxicological data (Annex IIA, point 10)

| Substance classified (Spiroxamine) | RMS/peer review proposal |
|-----------------------------------|--------------------------|
|                                   | Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation):  |
|                                   | Acute Tox. 4, H302: Harmful if swallowed  |
|                                   | Acute Tox. 4, H312: Harmful in contact with skin  |
|                                   | Skin Irr. 2, H315: Causes skin irritation  |
|                                   | Skin Sens. 1, H317: May cause an allergic skin reaction  |
|                                   | Acute Tox. 4, H332: Harmful if inhaled  |
|                                   | Repr. 2, H361d: Suspected of damaging the unborn child  |
|                                   | STOT RE 2, H373: May cause damage to organs through prolonged or repeated exposure (eye)  |

† Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles
Appendix III.4: Chapter 4 (residues)

Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

| Plant groups covered | Fruits (grapes, banana), cereals (wheat) |
|----------------------|-----------------------------------------|
| Rotational crops     | Cereals (wheat), leafy crops (Swiss chard, turnip leaves) and root crops (turnip root) |
| Metabolism in rotational crops similar to metabolism in primary crops? | Yes |
| Processed commodities | Under conditions simulating industrial and household processing conditions, the main portion of spiroxamine (≥ 75%) is stable. Hydrolysis rate increases at decreasing pH. The main hydrolysis product is metabolite M28 (spiroxamine-aminodiol) for the dioxolane label and metabolite M15 (tert. butyl-cyclohexanone) for the cyclohexyl label. |
| Residue pattern in processed commodities similar to residue pattern in raw commodities? | Yes |
| Plant residue definition for monitoring | Spiroxamine (parent only) |
| Plant residue definition for risk assessment | **Fruits:** |
| Conversion factor (monitoring to risk assessment) | Grapes: pending reassessment |

Summary of residues data according to the representative uses on raw agricultural commodities and feedingstuffs (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Residue input data for dietary risk assessment are pending acceptable residue data for each of the individual groups A, B and C. Provisionally, a non-standard approach for estimating residue values for the different groups from measured total residues in lieu of group specific residue data has been used to refine the risk assessment (see Vol.3 B.7), however these figures are not considered agreed final assessment endpoints and are therefore not presented in this list of endpoints.

† Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles
**Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)**

The consumer risk assessment is surrounded by non-standard uncertainties. A conservative assessment, considering total residues, indicated an exceedance of the ARfD for table grapes. A refinement is justified based on the different toxicological properties and TRVs set for the major residues occurring in fruit, but would require additional quantitative residue data to enable a consumer risk assessment in the conventional way for each of the groups of residues. Provisionally, a non-standard approach has been used by RMS to refine the consumer risk assessment for grapes (see Vol.3 B.7.15).
### Appendix III.5: Chapter 5 (fate and behaviour in the environment)

#### Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

**Laboratory studies ‡**

| Parent | Aerobic conditions |
|--------|--------------------|
| Soil type | pH | t. °C / % MWHC | DT_{50}/DT_{90} (d) | DT_{50} (d) 20 °C pF2/10kPa | St. (r²) | Method of calculation |
| silt loam | - | 8.1 | 20 °C / 40 % MWHC | * | - | |
| sandy loam | - | 6.5 | 20 °C / 40 % MWHC | * | - | |
| sandy loam | - | 7.1 | 20 °C / 48 % MWHC | * | - | |
| loamy sand | - | 6.3 | 20 °C / 40 % MWHC | * | - | |
| loam | - | 8.7 | 20 °C / 15 % MWHC (75 % of 1/3 bar) | * | - | |
| silt loam | - | 7.0 | 20 °C / 55 % MWHC | 22.1 / 73** | - | Chi²: 13.2 1st order |

Geometric mean/median

* data available but not fully validated because of the lacking of information on the goodness of fit (visual and statistical assessment) of the kinetic analysis.

** calculated (DT_{90} = DT_{50}*3.32)

** Field studies (normalised data for use in modelling)‡**

| Parent | Aerobic conditions |
|--------|--------------------|
| Soil type (indicate if bare or cropped soil was used). | Location (country or USA state). | X1 | pH | Depth (cm) | DT_{50} (d) actual | DT_{50}(d) actual | St. (chi2) | DT_{50} (d) Norm. | Method of calculation |
| Northern Europe | silt loam (bare soil) | Höfchen, DE, 30122/1 | 6.5 | 0-10 | - | - | 11.3 | 36.5* | SFO |
| | loam (vegetation) | Laacher Hof, DE, 30124/8 | 6.8 | 0-10 | - | - | 7.0 | 38.7* | SFO |
| | sandy loam (vegetation) | Thurston, UK, 30262/7 | 7.5 | 0-10 | - | - | 6.8 | 54.2* | SFO |
| | loamy sand (vegetation) | Pakenham, UK, 30263/5 | 7.3 | 0-10 | - | - | 8.9 | 51.7* | SFO |
| | silt loam (bare soil) | Höfchen, DE, 40006/8 | 6.4 | 0-10 | - | - | 5.2 | 68.6* | SFO |
| | sandy loam (bare soil) | Laacher Hof, DE, 40007/6 | 6.6 | 0-10 | - | - | 9.8 | 29.9* | SFO |

1 X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

---

www.efsa.europa.eu/efsajournal 16 EFSA Journal 2020;19(2):6385
Peer review of the pesticide risk assessment of the active substance spiroxamine

Field studies (normalised data for use in modelling)‡

| 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_{50} (d) actual | St. (chi2) | DT_{50} (d) Norm. | Method of calculation |
| sandy loam (bare soil) | An der Scheune, DE, 40008/4 | 5.9 | 0-10 | - | - | 9.1 | 70.0* | SFO |
| silt loam (bare soil) | Swisttal-Hohn, DE, 40009/2 | 6.7 | 0-10 | - | - | 8.2 | 39.4* | SFO |
| clay loam / silt loam (bare soil) | Albig, DE, 40010/6 | 7.8 | 0-10 | - | - | 7.4 | 36.7* | SFO |
| sandy loam (spring barley) | Thurston, UK, 40097/1 | 7.4 | 0-10 | - | - | 5.8 | 88.0* | SFO |
| sandy loam (spring barley) | Thurston, UK, 40100/5 | 7.4 | 0-10 | - | - | 6.5 | SFO |
| sandy loam (spring barley) | Pakenham, UK, 40099/8 | 7.0 | 0-10 | - | - | 7.8 | 53.1* | SFO |
| sandy loam (spring barley) | Pakenham, UK, 40101/3 | 7.0 | 0-10 | - | - | 9.2 | SFO |
| silt loam (spring wheat) | Touffreville, FR, 40193/5 | 7.2 | 0-10 | - | - | 3.6 | 24.2* | SFO |
| Southern Europe | | | | | | | | |
| silty loamy sand (wine) | Laudun, FR, 50135/2 | 7.7 | 0-10 | - | - | 6.3 | 36.1+ | SFO |
| weak loamy sand (bare soil) | Nogarole Rocca, IT, 50136/0 | 7.7 | 0-10 | - | - | 4.6 | 25.4+ | SFO |
| silty loamy sand (bare soil) | Laudun, FR, 40198/6 | 7.7 | 0-10 | - | - | 18.5 | 72.2* | SFO |
| silt loam (wine) | Filetto, IT, 40424/1 | 7.6 | 0-10 | - | - | 14.3 | 46.5* | SFO |
| Geometric mean/median | | | - | - | - | 45.0 / 43.0 | |

+ = slow-phase DFOP;
1) = calculated as replicates

Soil adsorption/desorption (Annex IIA, point 7.1.2)

| Parent ‡‡ | OC % | Soil pH | Kd (mL/g) | Koc (mL/g) | Kf (mL/g) | Kfo (mL/g) | l/n |
|------------|------|---------|-----------|-----------|-----------|-----------|-----|
| loamy sand | 1.8  | 7.0     | 12.78     | 710       | 0.7851    |           |     |
| silt loam  | 2.4  | 6.0     | 44.98     | 1874      | 0.8310    |           |     |
| silty clay | 0.64 | 7.6     | 41.07     | 6417      | 0.8854    |           |     |

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

www.efsa.europa.eu/efsajournal 17 EFSA Journal 2020;19(2):6385
Peer review of the pesticide risk assessment of the active substance spiroxamine

‡ Endpoints identified by the EU Commission as relevant for Member States when applying the Uniform Principles

| Soil Type  | pH  | Water Solubility (mg/L) | K_{OC}/K_{OM} (L/kg) | DT_{50} soil (d) |
|------------|-----|-------------------------|----------------------|------------------|
| loamy sand | 0.3 | 7.7                     | 7.25                 | 2415             | 0.8333 |
| sand       | 0.7 | 5.9                     | 4.61                 | 659              | 0.7682 |
| sand       | 0.2 | 6.7                     | 8.552                | [4276]*          | 1.063  |
| sandy loam | 0.45 | 5.8                    | 14.47                | [3216]*          | 1.055  |
| sandy loam | 1.12 | 6.7                    | 15.09                | [1347]*          | 1.025  |
| loam       | 0.97 | 7.8                     | 381.7                | [39346]*         | 1.024  |
| silty clay | 1.05 | 5.1                     | 892.6                | [85008]*         | 1.013  |

**Arithmetic mean/median**

|                      | 2415 / 1874 | 0.8206 / 0.8324 |

| pH dependence, Yes or No | No. Due to the basic properties (amine) of spiroxamine, a significant absorption was observed in all soils. The pH range of natural soils used in agriculture is expected to have only a very minor influence because spiroxamine was also relatively stable in hydrolysis experiments conducted at different pH values. |

* U.S. soil not considered for calculating the mean (worst case approach)

**Route and rate of degradation in water (Annex IIA, point 7.2.1)**

**Degradation in water / sediment**

| Parent          | Distribution (e.g. max in water 75.5 % after 6 h. Max. sed. 60 % after 2 d) |
|-----------------|----------------------------------------------------------------------------|
| Water / sediment system | pH water phase | pH sed. | t °C | DT_{50} - DT_{90} whole sys. (d) | St. (chi^2) | DT_{50} - DT_{90} water (d) | St. (chi^2) | DT_{50} - DT_{90} sed. (d) | St. (chi^2) | Method of calculation |
| Hönninger Weiher | 7.2 | 6.2 | 20 | 346** | 13.4 | 0.6 – 2.0 * | 6.6 | 310 – 1028 * | 2.9 | SFO/ Level PI |
| Stillwell        | 8.5 | 7.8 | 20 | 247 – 820 ** | 7.8 | 1.3 – 4.3 * | 7.3 | - | - | SFO/ Level PI |
| Anglerweiher     | 7.1 | 7.2 | 20 | 16.4 – 54.3 | 12.6 | 0.8 | 10.5 | 39.3 | 17.3 | SFO/ Level PI |
| Hönninger Weiher | 7.2 | 5.5 | 20 | 51.6 – 171 | 18.4 | 0.7 | 11.7 | 152.9 | 13.1 | SFO/ Level PI |
| Geometric mean/median | 66.2 / 71.6 | 0.8 | 123 |

* DisT50 / DisT90 (Level PI evaluation)
** SFO kinetics derived from slow Phase DFOP

PEC surface water and PEC sediment (Annex IIIA, point 9.2.3)

**Parent**

Parameters used in FOCUS_{sw} step 1 and 2

Version control no. of FOCUS calculator:
Molecular weight (g/mol): 297.5
Water solubility (mg/L): 470
K_{OC}/K_{OM} (L/kg): 2415 / 1400
DT_{50} soil (d):
Peer review of the pesticide risk assessment of the active substance spiroxamine

Calculations Notifier: 30.3 days (geometric mean, field n=18)
Re-calculations RMS: with the geometric mean DT_{50} in soil of 45.0 d derived from the slow phase of DFOP kinetics observed in the 18 field dissipation studies, showed only minor changes to the original values provided by the notifier (concentrations in surface water after use of spiroxamine in cereals and vine is mainly affected by spray drift entries).

DT_{50} water/sediment system (d): -
DT_{50} water (d): 3.1 (geom. mean) of level P-II DegT50
DT_{50} sediment (d): 1000 (worst case)

Maximum occurrence observed in sediment (%): 50.7 (this represents not the worst case, which was determined to 60.1 % (dioxane labelled))

Parent

Parameters used in FOCUS_{sw} step 3 and step 4

Version control no. of FOCUS software: SWASH 2.1
Vapour pressure: 0.00972 Pa
K_{ow}/K_{oc}: 2415 / 1400
1/n: (Freundlich exponent general or for soil, susp. solids or sediment respectively) 0.82

Main routes of entry

Application rate

Crop: vines, variation 1
Crop interception: 40 /50 /60
Number of applications: 3
Interval (d): 10
Application rate(s): 3 * 300 g as/ha
Application window: BBCH 13-85

Application rate

Crop: vines, variation 2
Crop interception: 50 /50
Number of applications: 2
Interval (d): 7
Application rate(s): 2 * 200 g as/ha
Application window: BBCH 13-19

Application rate

Crop: vines, variation 3
Crop interception: 85 / 85 /85
Number of applications: 3
Interval (d): 10
Application rate(s): 3 * 400 g as/ha
Application window: BBCH 79-85

Application rate

Crop: vines, variation 4
Crop interception: 50 / 50 / 85 / 85 /85
Number of applications: 2 + 3
Interval (d): 10 / 10
Application rate(s): 2 * 200 + 3 * 400 g as/ha
Application window: BBCH 13-19 and BBCH 79-85

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles
Application rate

Crop: cereals, variation 1
Crop interception: 50 /50
Number of applications: 2
Interval (d): 14
Application rate(s): 2 * 375 g as/ha
Application window: BBCH 30

Application rate

Crop: cereals, variation 2
Crop interception: 70 /70
Number of applications: 2
Interval (d): 14
Application rate(s): 2 * 375 g as/ha
Application window: BBCH 30-69 (wheat, rye triticale)
BBCH 30-61 (barley)

FOCUS STEP 1 simulations were generally not performed.

| Crop | Compound | FOCUS STEP 2 PEC_{sw, max} (µg/L) | FOCUS STEP 2 PEC_{sed, max} (µg/kg) |
|------|----------|----------------------------------|-----------------------------------|
| Vines, variation 1, South Europe | Spiroxamine | 1 x 300 g as/ha | 3 x 300 g as/ha |
| | | 5.71 | 13.48 |
| | Spiroxamine | 1 x 300 g as/ha | 3 x 300 g as/ha |
| | | 136.62 | 323.63 |
| Vines early, variation 2, South Europe | Spiroxamine | 1 x 200 g as/ha | 2 x 200 g as/ha |
| | | 3.80 | 6.93 |
| | Spiroxamine | 1 x 200 g as/ha | 2 x 200 g as/ha |
| | | 91.08 | 166.16 |
| Vines late, variation 3, South Europe | Spiroxamine | 1 x 400 g as/ha | 3 x 400 g as/ha |
| | | 10.70 | 11.03 |
| | Spiroxamine | 1 x 400 g as/ha | 3 x 400 g as/ha |
| | | 107.72 | 222.43 |
| Vines variation 4, early + late, South Europe | Spiroxamine | 1 x 400 g as/ha | 5 x 400 g as/ha |
| | | 10.70 | 17.86 |
| | Spiroxamine | 1 x 400 g as/ha | 5 x 400 g as/ha |
| | | 149.47 | 424.11 |
| cereals, variation 1*, North Europe | Spiroxamine | 1 x 375 g as/ha | 2 x 375 g as/ha |
| | | 3.45 | 5.49 |
| | Spiroxamine | 1 x 375 g as/ha | 2 x 375 g as/ha |
| | | 79.76 | 130.74 |
| cereals, variation 1*, South Europe | Spiroxamine | 1 x 375 g as/ha | 2 x 375 g as/ha |
| | | 6.07 | 10.15 |
| | Spiroxamine | 1 x 375 g as/ha | 2 x 375 g as/ha |
| | | 145 | 243.33 |

* Simulations with variation 2 are not reported since they do not represent worst case conditions
‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles
### Peer review of the pesticide risk assessment of the active substance spiroxamine

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

www.efsa.europa.eu/efsajournal
21
EFSA Journal 2020;19(2):6385

| FOCUS STEP 3 | Scenario | Water body | PEC<sub>sw, max</sub> (µg/L) | 1 x 300 g as/ha | 3 x 300 g as/ha |
|--------------|----------|------------|-------------------------------|----------------|----------------|
| Vines, variation 1 | D6 (Thiva) | Ditch | 5.090 | 4.654 |
| R1 (Weiherbach) | Pond | 0.182 | 0.177 |
| R1 (Weiherbach) | Stream | 3.671 | 3.194 |
| R2 (Porto) | Stream | 5.018 | 4.277 |
| R3 (Bologna) | Stream | 5.275 | 4.515 |
| R4 (Roujan) | Stream | 3.684 | 3.141 |

| PEC<sub>sed, max</sub> (µg/kg) | 1 x 300 g as/ha | 3 x 300 g as/ha |
|-----------------------------|----------------|----------------|
| D6 (Thiva) | Ditch | 5.125 | 15.109 |
| R1 (Weiherbach) | Pond | 0.636 | 1.17 |
| R1 (Weiherbach) | Stream | 0.585 | 1.941 |
| R2 (Porto) | Stream | 1.133 | 2.56 |
| R3 (Bologna) | Stream | 1.216 | 2.224 |
| R4 (Roujan) | Stream | 2.318 | 2.564 |

| FOCUS STEP 3 | Scenario | Water body | PEC<sub>sw, max</sub> (µg/L) | 1 x 200 g as/ha | 3 x 200 g as/ha |
|--------------|----------|------------|-------------------------------|----------------|----------------|
| Vines early, variation 2 | D6 (Thiva) | Ditch | 1.126 | 1.044 |
| R1 (Weiherbach) | Pond | 0.038 | 0.037 |
| R1 (Weiherbach) | Stream | 0.808 | 0.732 |
| R2 (Porto) | Stream | 1.104 | 1.000 |
| R3 (Bologna) | Stream | 1.161 | 1.056 |
| R4 (Roujan) | Stream | 0.811 | 0.734 |

| PEC<sub>sed, max</sub> (µg/kg) | 1 x 200 g as/ha | 2 x 200 g as/ha |
|-----------------------------|----------------|----------------|
| D6 (Thiva) | Ditch | 1.184 | 2.740 |
| R1 (Weiherbach) | Pond | 0.148 | 0.215 |
| R1 (Weiherbach) | Stream | 0.344 | 0.664 |
| R2 (Porto) | Stream | 0.676 | 1.452 |
| R3 (Bologna) | Stream | 0.270 | 0.459 |
| R4 (Roujan) | Stream | 1.449 | 1.447 |

| FOCUS STEP 3 | Scenario | Water body | PEC<sub>sw, max</sub> (µg/L) | 1 x 400 g as/ha | 3 x 400 g as/ha |
|--------------|----------|------------|-------------------------------|----------------|----------------|
| Vines late, variation 3 | D6 (Thiva) | Ditch | 6.834 | 6.052 |
| R1 (Weiherbach) | Pond | 0.243 | 0.212 |
| R1 (Weiherbach) | Stream | 4.875 | 4.272 |
| R2 (Porto) | Stream | 6.720 | 5.728 |
| R3 (Bologna) | Stream | 7.066 | 6.026 |
| R4 (Roujan) | Stream | 5.011 | 4.272 |

| PEC<sub>sed, max</sub> (µg/kg) | 1 x 400 g as/ha | 3 x 400 g as/ha |
|-----------------------------|----------------|----------------|
| D6 (Thiva) | Ditch | 10.088 | 17.682 |
| R1 (Weiherbach) | Pond | 0.622 | 1.142 |
| R1 (Weiherbach) | Stream | 0.467 | 1.078 |
| R2 (Porto) | Stream | 0.757 | 1.404 |
| R3 (Bologna) | Stream | 1.823 | 5.814 |
| R4 (Roujan) | Stream | 0.784 | 1.476 |
Peer review of the pesticide risk assessment of the active substance spiroxamine

| FOCUS STEP 3 | Vines late, variation 4 (only multiple applications) | PEC_{sw, max} (µg/L) | 2 x 200 g as/ha + 3 x 400 g as/ha |
|--------------|------------------------------------------------------|----------------------|---------------------------------|
| D6 (Thiva)   | Ditch                                                | 5.968                |
| R1 (Weiherbach) | Pond                                                | 0.237                |
| R1 (Weiherbach) | Stream                                              | 4.112                |
| R2 (Porto)  | Stream                                              | 5.489                |
| R3 (Bologna) | Stream                                              | 5.799                |
| R4 (Roujan) | Stream                                              | 4.111                |

| PEC_{sed, max} (µg/kg) | 2 x 200 g as/ha + 3 x 400 g as/ha |
|------------------------|---------------------------------|
| D6 (Thiva)             | Ditch                           |
| R1 (Weiherbach)        | Pond                             |
| R1 (Weiherbach)        | Stream                           |
| R2 (Porto)             | Stream                           |
| R3 (Bologna)           | Stream                           |
| R4 (Roujan)            | Stream                           |

| Water body | FOCUS STEP 3 spring cereals 3 | FOCUS STEP 3 winter cereals 3 |
|------------|--------------------------------|--------------------------------|
| D1 (Lanna) | ditch 2.392 5.621 0.648 2.309 8.013 0.868 | ditch 2.392 5.621 0.648 2.309 8.013 0.868 |
| stream     | 2.092 1.253 0.085 1.810 1.667 0.143       | stream 2.092 1.253 0.085 1.810 1.667 0.143 |
| D3 (Vredepeel) | ditch 2.364 1.514 0.106 2.072 2.412 0.209 | ditch 2.364 1.572 0.110 2.069 2.198 0.192 |
| D4 (Skousbo) | pond 0.081 0.222 0.020 0.071 0.329 0.028 | pond 0.081 0.270 0.025 0.072 0.387 0.030 |
| stream     | 2.040 0.408 0.026 1.768 0.595 0.046       | stream 2.013 0.283 0.018 1.766 0.512 0.039 |
| D5 (La Jaillière) | pond 0.081 0.308 0.029 0.076 0.427 0.036 | pond 0.081 0.344 0.033 0.083 0.524 0.043 |
| stream     | 2.001 0.093 0.006 1.783 0.169 0.013       | stream 1.903 0.059 0.004 1.793 0.162 0.011 |
| R4 (Roujan) | stream 1.563 6.488 0.139 1.353 6.624 0.144 | ditch 2.332 0.674 0.045 2.076 2.691 0.214 |
| D1 (Lanna) | ditch 2.392 5.621 0.648 2.309 8.013 0.868 | pond 0.081 0.479 0.031 0.103 1.072 0.056 |
| stream     | 2.092 1.253 0.085 1.810 1.667 0.143       | stream 1.557 3.422 0.033 1.346 8.947 0.103 |
| D3 (Vredepeel) | ditch 2.364 1.572 0.110 2.069 2.198 0.192 | stream 2.187 3.159 0.029 1.902 6.801 0.085 |
| D4 (Skousbo) | pond 0.081 0.270 0.025 0.072 0.387 0.030 | stream 1.557 3.947 0.097 1.726 9.594 0.250 |

† Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles
### FOCUS STEP 4
**Vines, variation 1**

| Scenario   | Water body | PEC\(_{\text{sw, max}}\) (µg/L) | 5 m buffer zone | 10 m buffer zone | PEC\(_{\text{sed, max}}\) (µg/kg) |
|------------|------------|----------------------------------|-----------------|------------------|-------------------------------|
|            |            |                                  | 1 x 300 g as/ha | 3 x 300 g as/ha | 1 x 300 g as/ha | 3 x 300 g as/ha |
| D6 (Thiva) | Ditch      | 3.076                            | 2.790           | 1.113            | 0.993            |
| R1 (Weih)  | Pond       | a)                               | a)              | 0.116            | 0.112            |
| R1 (Weih)  | Stream     | 2.675                            | 2.317           | 0.968            | 0.828            |
| R2 (Porto) | Stream     | 3.656                            | 3.103           | 1.323            | 1.108            |
| R3 (Bolog) | Stream     | 3.843                            | 3.276           | 1.391            | 1.170            |
| R4 (Rouj)  | Stream     | 2.684                            | 2.279           | 0.971            | 0.814            |

| Scenario   | Water body | PEC\(_{\text{sw, max}}\) (µg/L) | 5 m buffer zone | 10 m buffer zone | PEC\(_{\text{sed, max}}\) (µg/kg) |
|------------|------------|----------------------------------|-----------------|------------------|-------------------------------|
|            |            |                                  | 1 x 300 g as/ha | 3 x 300 g as/ha | 1 x 300 g as/ha | 3 x 300 g as/ha |
| D6 (Thiva) | Ditch      | 3.145                            | 9.366           | 1.171            | 3.558            |
| R1 (Weih)  | Pond       | a)                               | a)              | 0.415            | 0.748            |
| R1 (Weih)  | Stream     | 0.556                            | 1.802           | 0.181            | 0.586            |
| R2 (Porto) | Stream     | 1.083                            | 2.452           | 0.224            | 0.505            |
| R3 (Bolog) | Stream     | 0.888                            | 1.809           | 0.323            | 0.611            |
| R4 (Rouj)  | Stream     | 2.254                            | 2.426           | 0.701            | 0.762            |

| Scenario   | Water body | PEC\(_{\text{sw, max}}\) (µg/L) | 1 x 300 g as/ha | 3 x 300 g as/ha | 1 x 300 g as/ha | 3 x 300 g as/ha |
|------------|------------|----------------------------------|-----------------|------------------|-----------------|----------------|
| D6 (Thiva) | Ditch      | 0.390                            | 0.342           | 0.421            | 1.306            |
| R1 (Weih)  | Pond       | 0.058                            | 0.056           | 0.216            | 0.390            |
| R1 (Weih)  | Stream     | 0.339                            | 0.286           | 0.084            | 0.264            |
| R2 (Porto) | Stream     | 0.463                            | 0.383           | 0.085            | 0.191            |
| R3 (Bolog) | Stream     | 0.487                            | 0.404           | 0.114            | 0.257            |
| R4 (Rouj)  | Stream     | 0.340                            | 0.281           | 0.327            | 0.348            |

a) not provided by the applicant

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles
**FOCUS STEP 4**

**Vines early, variation 2**

| Scenario | Water body | PEC$_{sw,\text{max}}$ (µg/L) | 5 m buffer zone | 10 m buffer zone |
|----------|------------|-------------------------------|-----------------|-----------------|
|          |            | 1 x 200 g as/ha | 2 x 200 g as/ha | 1 x 200 g as/ha | 2 x 200 g as/ha |
| D6 (Thiva) | Ditch | 0.671 | 0.611 | 0.236 | 0.207 |
| R1 (Weiherbach) | Pond | a) | a) | 0.024 | 0.023 |
| R1 (Weiherbach) | Stream | 0.583 | 0.523 | 0.205 | 0.178 |
| R2 (Porto) | Stream | 0.797 | 0.714 | 0.280 | 0.243 |
| R3 (Bologna) | Stream | 0.838 | 0.754 | 0.295 | 0.256 |
| R4 (Roujan) | Stream | 0.606 | 0.609 | 0.275 | 0.276 |

| Scenario | Water body | PEC$_{sed,\text{max}}$ (µg/kg) | 5 m buffer zone | 10 m buffer zone |
|----------|------------|-------------------------------|-----------------|-----------------|
|          |            | 1 x 200 g as/ha | 2 x 200 g as/ha | 1 x 200 g as/ha | 2 x 200 g as/ha |
| D6 (Thiva) | Ditch | 0.715 | 1.648 | 0.257 | 0.588 |
| R1 (Weiherbach) | Pond | a) | a) | 0.094 | 0.133 |
| R1 (Weiherbach) | Stream | 0.337 | 0.648 | 0.104 | 0.198 |
| R2 (Porto) | Stream | 0.662 | 1.426 | 0.123 | 0.268 |
| R3 (Bologna) | Stream | 0.195 | 0.330 | 0.069 | 0.115 |
| R4 (Roujan) | Stream | 1.433 | 1.432 | 0.423 | 0.423 |

| Scenario | Water body | PEC$_{sw,\text{max}}$ (µg/L) | 20 m buffer zone |
|----------|------------|-------------------------------|-----------------|
|          |            | 1 x 200 g as/ha | 2 x 200 g as/ha | 2 x 200 g as/ha |
| D6 (Thiva) | Ditch | 0.080 | 0.068 | 0.090 | 0.202 |
| R1 (Weiherbach) | Pond | 0.012 | 0.011 | 0.050 | 0.066 |
| R1 (Weiherbach) | Stream | 0.070 | 0.091 | 0.049 | 0.093 |
| R2 (Porto) | Stream | 0.095 | 0.080 | 0.046 | 0.101 |
| R3 (Bologna) | Stream | 0.100 | 0.084 | 0.024 | 0.039 |
| R4 (Roujan) | Stream | 0.144 | 0.144 | 0.198 | 0.198 |

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles
| FOCUS STEP 4 | Vines late, variation 3 | PEC\textsubscript{cw, max} (µg/L) | 5 m buffer zone | 10 m buffer zone |
|--------------|-------------------------|-------------------------------|----------------|----------------|
| Scenario     | Water body              |                               |                |                |
| D6 (Thiva)   | Ditch                   | 4.130                         | 3.632          | 1.495          | 1.295          |
| R1 (Weiherbach) | Pond            | a) 0.155                      | a) 0.134       |                |                |
| R1 (Weiherbach) | Stream              | 3.550                         | 3.098          | 1.285          | 1.107          |
| R2 (Porto)   | Stream                  | 4.894                         | 4.154          | 1.771          | 1.484          |
| R3 (Bologna) | Stream                  | 5.146                         | 4.371          | 1.862          | 1.561          |
| R4 (Roujan)  | Stream                  | 3.649                         | 3.098          | 1.320          | 1.106          |

| PEC\textsubscript{sed, max} (µg/kg) | 5 m buffer zone | 10 m buffer zone |
|-------------------------------------|----------------|----------------|
| Scenario                            | Water body     |                |
| D6 (Thiva)                          | Ditch          | 6.227          | 10.982         | 2.343          | 4.190          |
| R1 (Weiherbach)                     | Pond           | a) 0.404       | a) 0.745       |                |                |
| R1 (Weiherbach)                     | Stream         | 0.387          | 0.821          | 0.133          | 0.292          |
| R2 (Porto)                          | Stream         | 0.644          | 1.352          | 0.194          | 0.302          |
| R3 (Bologna)                        | Stream         | 1.331          | 5.531          | 0.484          | 1.439          |
| R4 (Roujan)                         | Stream         | 0.571          | 1.319          | 0.207          | 0.513          |

| 20 m buffer zone | PEC\textsubscript{cw, max} (µg/L) | PEC\textsubscript{sed, max} (µg/kg) | 5 m buffer zone | 10 m buffer zone |
|------------------|-----------------------------------|-----------------------------------|----------------|----------------|
| D6 (Thiva)       | Ditch                             | 0.523                             | 0.447          | 0.850          | 1.544          |
| R1 (Weiherbach)  | Pond                              | 0.078                             | 0.067          | 0.209          | 0.389          |
| R1 (Weiherbach)  | Stream                            | 0.450                             | 0.382          | 0.054          | 0.109          |
| R2 (Porto)       | Stream                            | 0.620                             | 0.513          | 0.075          | 0.111          |
| R3 (Bologna)     | Stream                            | 0.652                             | 0.540          | 0.171          | 0.619          |
| R4 (Roujan)      | Stream                            | 0.462                             | 0.382          | 0.073          | 0.237          |

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles
### Peer review of the pesticide risk assessment of the active substance spiroxamine

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

---

#### FOCUS STEP 4, Vines early + late (only multiple applications)

| Scenario | Water body | PEC<sub>sw, max</sub> (µg/L) |
|-----------|------------|-----------------|
|           |            | 5 m | 10 m | 20 m |
| D6 (Thiva) | Ditch | 3.583 | 1.278 | 0.441 |
| R1 (Weiherbach) | Pond | a) 0.150 | 0.074 |
| R1 (Weiherbach) | Stream | 2.983 | 1.066 | 0.369 |
| R2 (Porto) | Stream | 3.982 | 1.424 | 0.492 |
| R3 (Bologna) | Stream | 4.207 | 1.504 | 0.520 |
| R4 (Roujan) | Stream | 2.982 | 1.066 | 0.369 |

#### PEC<sub>sed, max</sub> (µg/kg)

| Scenario | Water body | PEC<sub>sw, max</sub> (µg/L) |
|-----------|------------|-----------------|
|           |            | 5 m | 10 m | 20 m |
| D6 (Thiva) | Ditch | 14.493 | 5.555 | 2.060 |
| R1 (Weiherbach) | Pond | a) 1.091 | 0.569 |
| R1 (Weiherbach) | Stream | 1.991 | 0.656 | 0.275 |
| R2 (Porto) | Stream | 3.271 | 0.712 | 0.268 |
| R3 (Bologna) | Stream | 4.055 | 1.408 | 0.627 |
| R4 (Roujan) | Stream | 3.914 | 0.951 | 0.402 |

---

No TWA reported for FOCUS STEP 2 simulations.

---

Due to big number of scenarios only worst case combinations are reported on level FOCUS STEP 4

#### Scenario | Day | PEC<sub>act, sw</sub> (µg/L) | TWAC<sub>sw</sub> (µg/L) | PEC<sub>act, sed</sub> (µg/kg) | TWAC<sub>sed</sub> (µg/kg) |
|----------------|-----|-----------------|-----------------|-----------------|-----------------|
| FOCUS STEP 4, vines, variation 1 | | | | | |
| Single application 1 x 300 g as/ha to vines at 5 m buffer zone |
| D6 (ditch) | 21 | 0.021 | 0.275 | 1.830 | 2.511 |
| R1 (stream) | 21 | < 0.001 | 0.029 | 0.430 | 0.485 |
| R2 (stream) | 21 | < 0.001 | 0.023 | 0.941 | 1.002 |
| R3 (stream) | 21 | < 0.001 | 0.057 | 0.429 | 0.610 |
| R4 (stream) | 21 | < 0.001 | 0.086 | 1.530 | 1.812 |

---

Multiple application 3 x 300 g as/ha to vines at 5 m buffer zone

| Scenario | Day | PEC<sub>act, sw</sub> (µg/L) | TWAC<sub>sw</sub> (µg/L) | PEC<sub>act, sed</sub> (µg/kg) | TWAC<sub>sed</sub> (µg/kg) |
|----------------|-----|-----------------|-----------------|-----------------|-----------------|
| D6 (ditch) | 21 | 0.056 | 0.897 | 5.897 | 7.951 |

---

* EFSA Journal 2020;19(2):6385

www.efsa.europa.eu/efsajournal
### Scenario Details

#### FOCUS STEP 4, vines, variation 1

| Scenario | Day | PEC<sub>act, sw</sub> (µg/L) | TWAC<sub>sw</sub> (µg/L) | PEC<sub>act, sed</sub> (µg/kg) | TWAC<sub>sed</sub> (µg/kg) |
|----------|-----|------------------------------|-----------------|-----------------|-----------------|
| R1 (stream) | 21 | < 0.001 | 0.063 | 1.236 | 1.462 |
| R2 (stream) | 21 | < 0.001 | 0.044 | 2.260 | 2.287 |
| R3 (stream) | 21 | 0.001 | 0.110 | 1.582 | 1.689 |
| R4 (stream) | 21 | < 0.001 | 0.112 | 1.735 | 2.017 |

Single application 1 x 300 g as/ha to vines at 10 m buffer zone

#### FOCUS STEP 4, vines, variation 1

| Scenario | Day | PEC<sub>act, sw</sub> (µg/L) | TWAC<sub>sw</sub> (µg/L) | PEC<sub>act, sed</sub> (µg/kg) | TWAC<sub>sed</sub> (µg/kg) |
|----------|-----|------------------------------|-----------------|-----------------|-----------------|
| D6 (ditch) | 21 | 0.008 | 0.098 | 0.722 | 0.964 |
| R1 (pond) | 21 | 0.011 | 0.040 | 0.324 | 0.396 |
| R1 (stream) | 21 | < 0.001 | 0.011 | 0.131 | 0.153 |
| R2 (stream) | 21 | < 0.001 | 0.009 | 0.184 | 0.202 |
| R3 (stream) | 21 | < 0.001 | 0.021 | 0.171 | 0.234 |
| R4 (stream) | 21 | < 0.001 | 0.037 | 0.425 | 0.537 |

Multiple application 3 x 300 g as/ha to vines at 10 m buffer zone

#### FOCUS STEP 4, vines, variation 3

| Scenario | Day | PEC<sub>act, sw</sub> (µg/L) | TWAC<sub>sw</sub> (µg/L) | PEC<sub>act, sed</sub> (µg/kg) | TWAC<sub>sed</sub> (µg/kg) |
|----------|-----|------------------------------|-----------------|-----------------|-----------------|
| D6 (ditch) | 21 | 0.021 | 0.316 | 2.309 | 3.062 |
| R1 (pond) | 21 | 0.006 | 0.051 | 0.570 | 0.711 |
| R1 (stream) | 21 | < 0.001 | 0.026 | 0.371 | 0.460 |
| R2 (stream) | 21 | < 0.001 | 0.017 | 0.467 | 0.463 |
| R3 (stream) | 21 | < 0.001 | 0.039 | 0.567 | 0.536 |
| R4 (stream) | 21 | < 0.001 | 0.046 | 0.504 | 0.613 |

### Additional Details

- **PEC<sub>act, sw</sub>** and **PEC<sub>act, sed</sub>** represent the predicted environmental concentrations (active substance in water and sediments, respectively).
- **TWAC<sub>sw</sub>** and **TWAC<sub>sed</sub>** denote the toxic unit water and sediment, respectively.

† Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles
Peer review of the pesticide risk assessment of the active substance spiroxamine

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

www.efsa.europa.eu/efsajournal

| Water body | PEC<sub>sw, max</sub> [µg/L] | PEC<sub>sed, max</sub> [µg/kg] | TWA<sub>sw, 21 d</sub> [µg/L] | PEC<sub>sw, max</sub> [µg/L] | PEC<sub>sed, max</sub> [µg/kg] | TWA<sub>sw, 21 d</sub> [µg/kg] |
|------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| FOCUS STEP 4, Spring cereals, 5 m buffer zone |
| D1 (Lanna) ditch | 0.647 | 1.623 | 0.170 | 0.593 | 2.234 | 0.220 |
| stream | 0.763 | 0.462 | 0.031 | 0.639 | 0.614 | 0.050 |
| D3 (Vredepeel) ditch | 0.640 | 0.417 | 0.029 | 0.537 | 0.659 | 0.054 |
| pond | 0.070 | 0.193 | 0.017 | 0.061 | 0.286 | 0.024 |
| stream | 0.744 | 0.150 | 0.010 | 0.624 | 0.217 | 0.016 |
| D4 (Skousbo) pond | 0.070 | 0.268 | 0.025 | 0.065 | 0.370 | 0.031 |
| stream | 0.730 | 0.034 | 0.002 | 0.629 | 0.061 | 0.004 |
| D5 (La Jaillière) pond | 0.070 | 0.300 | 0.029 | 0.071 | 0.455 | 0.037 |
| stream | 0.734 | 0.103 | 0.007 | 0.623 | 0.186 | 0.014 |
| R4 (Roujan) stream | 0.908 | 6.419 | 0.130 | 0.911 | 6.595 | 0.135 |
| FOCUS STEP 4, Winter cereals, 5 m buffer zone |
| D1 (Lanna) ditch | 0.647 | 1.623 | 0.170 | 0.593 | 2.234 | 0.220 |
| stream | 0.763 | 0.462 | 0.031 | 0.639 | 0.614 | 0.050 |
| D2 (Brimstone) ditch | 0.648 | 1.569 | 0.125 | 0.548 | 2.074 | 0.183 |
| stream | 0.777 | 1.864 | 0.144 | 0.650 | 1.568 | 0.126 |
| D3 (Vredepeel) ditch | 0.640 | 0.433 | 0.030 | 0.536 | 0.602 | 0.050 |
| D4 (Skousbo) pond | 0.070 | 0.236 | 0.022 | 0.062 | 0.336 | 0.026 |
| stream | 0.734 | 0.103 | 0.007 | 0.623 | 0.186 | 0.014 |
| D5 (La Jaillière) pond | 0.070 | 0.300 | 0.029 | 0.071 | 0.455 | 0.037 |
| stream | 0.694 | 0.022 | 0.001 | 0.633 | 0.058 | 0.004 |
| D6 (Thiva) ditch | 0.631 | 0.184 | 0.012 | 0.538 | 0.726 | 0.055 |
| R1 Wetterbach) pond | 0.070 | 0.449 | 0.027 | 0.102 | 1.036 | 0.054 |
| stream | 0.568 | 3.386 | 0.033 | 1.258 | 8.887 | 0.098 |
| R3 (Bologna) stream | 0.798 | 3.025 | 0.023 | 1.228 | 6.482 | 0.064 |
| R4 (Roujan) stream | 0.698 | 3.907 | 0.097 | 1.726 | 9.502 | 0.247 |
| Water body   | 1 x 375 g as/ha* | 2 x 375 g as/ha* |
|-------------|-----------------|-----------------|
|             | PECsw, max [µg/L] | PECsed, max [µg/kg] | TWÅw, 21 d [µg/L] | PECsw, max [µg/L] | PECsed, max [µg/kg] | TWÅw, 21 d [µg/kg] |
| D1 (Lanna)  | ditch 0.177 | 0.316 | 0.023 | 0.155 | 0.630 | 0.057 |
|             | stream 0.197 | 0.017 | 0.001 | 0.168 | 0.170 | 0.013 |
| D3 (Vredepeel) | ditch 0.176 | 0.113 | 0.008 | 0.142 | 0.182 | 0.014 |
|             | stream 0.184 | 0.008 | 0.001 | 0.164 | 0.059 | 0.004 |
| D4 (Skousbo) | pond 0.034 | 0.156 | 0.014 | 0.029 | 0.139 | 0.011 |
|             | stream 0.183 | 0.004 | < 0.001 | 0.166 | 0.017 | 0.001 |
| D5 (La Jaillière) | pond 0.034 | 0.135 | 0.012 | 0.030 | 0.180 | 0.014 |
|             | stream 0.183 | 0.004 | < 0.001 | 0.166 | 0.017 | 0.001 |
| R4 (Roujan) | stream 0.197 | 2.047 | 0.028 | 0.217 | 0.658 | 0.032 |

FOCUS STEP 4, Winter cereals, 20 m buffer zone

| Water body   | 1 x 375 g as/ha* | 2 x 375 g as/ha* |
|-------------|-----------------|-----------------|
|             | PECsw, max [µg/L] | PECsed, max [µg/kg] | TWÅw, 21 d [µg/L] | PECsw, max [µg/L] | PECsed, max [µg/kg] | TWÅw, 21 d [µg/kg] |
| D1 (Lanna)  | ditch 0.178 | 0.453 | 0.044 | 0.155 | 0.630 | 0.057 |
|             | stream 0.210 | 0.128 | 0.008 | 0.168 | 0.170 | 0.013 |
| D2 (Brimstone) | ditch 0.178 | 0.447 | 0.035 | 0.144 | 0.592 | 0.048 |
|             | stream 0.214 | 0.531 | 0.041 | 0.171 | 0.430 | 0.033 |
| D3 (Vredepeel) | ditch 0.175 | 0.087 | 0.006 | 0.141 | 0.167 | 0.013 |
|             | pond 0.034 | 0.113 | 0.010 | 0.029 | 0.164 | 0.012 |
|             | stream 0.205 | 0.044 | 0.003 | 0.164 | 0.051 | 0.004 |
| D5 (La Jaillière) | pond 0.034 | 0.141 | 0.013 | 0.033 | 0.222 | 0.017 |
|             | stream 0.221 | 0.063 | 0.004 | 0.167 | 0.016 | 0.001 |
| D6 (Thiva)  | ditch 0.177 | 0.344 | 0.027 | 0.142 | 0.198 | 0.015 |
|             | pond 0.034 | 0.292 | 0.015 | 0.032 | 0.281 | 0.017 |
| R1 Weiherbach | pond 0.034 | 2.145 | 0.010 | 0.299 | 0.678 | 0.023 |
|             | stream 0.256 | 112.253 | 0.043 | 0.294 | 0.544 | 0.016 |
| R4 (Roujan) | stream 0.289 | 1.122 | 0.013 | 0.412 | 1.095 | 0.059 |

#RMS values used soil DT50 45 days, note application dates for winter cereals used by RMS may not have been completely correct

~Applicant values used soil DT50 30.3. days

| Time after max. peak [days] | PECsw [µg/L] | TWÅsw [µg/L] | PECsed [µg/kg] | TWÅsed [µg/kg] | PECsw [µg/L] | TWÅsw [µg/L] | PECsed [µg/kg] | TWÅsed [µg/kg] |
|------------------------------|--------------|--------------|-----------------|-----------------|--------------|--------------|-----------------|-----------------|

**spring cereals**

**FOCUS STEP 4 5 m buffer**

| Water body   | PECsw [µg/L] | TWÅsw [µg/L] | PECsed [µg/kg] | TWÅsed [µg/kg] |
|--------------|--------------|--------------|-----------------|-----------------|
| D1 (Lanna), ditch single application | 0.647 | - | 1.623 | - | 0.763 | - | 0.462 | - |
| D1 (Lanna), stream single application | 0.524 | 0.582 | 1.620 | 1.623 | 0.211 | 0.561 | 0.449 | 0.460 |
| 2 | 0.427 | 0.527 | 1.612 | 1.622 | 0.008 | 0.316 | 0.431 | 0.454 |
| 4 | 0.290 | 0.440 | 1.582 | 1.619 | 0.001 | 0.159 | 0.399 | 0.439 |
| 7 | 0.175 | 0.349 | 1.514 | 1.610 | < 0.001 | 0.091 | 0.359 | 0.418 |
| 14 | 0.073 | 0.231 | 1.348 | 1.570 | < 0.001 | 0.046 | 0.292 | 0.375 |
| 21 | 0.033 | 0.170 | 1.215 | 1.514 | < 0.001 | 0.031 | 0.249 | 0.342 |
| 28 | 0.020 | 0.134 | 1.112 | 1.455 | < 0.001 | 0.023 | 0.219 | 0.316 |
| 42 | 0.011 | 0.094 | 0.967 | 1.346 | < 0.001 | 0.016 | 0.180 | 0.278 |
| 50 | 0.008 | 0.081 | 0.907 | 1.291 | < 0.001 | 0.013 | 0.165 | 0.261 |
| 100 | 0.002 | 0.043 | 0.694 | 1.059 | < 0.001 | 0.007 | 0.118 | 0.200 |

† Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

www.efsa.europa.eu/efsajournal 29 EFSA Journal 2020;19(2):6385
| spring cereals | FOCUS STEP 4 5 m buffer | D3 (Vredepeel), single application | Ditch | D4 (Skousbo), single application | D5 (La Jailliere) pond, single application | R4 (Roujan), stream multiple application |
|----------------|-------------------------|-----------------------------------|-------|----------------------------------|------------------------------------------|----------------------------------------|
| Initial        | 0                       | 0.640 -                           | 0.417 | -                                | 0.070 -                                  | 0.193 -                                 |
| Short-term     | 1                       | 0.250 0.460 0.406 0.415           | 0.058 | 0.064 0.193 0.193               |                                          |                                        |
|                | 2                       | 0.025 0.285 0.390 0.411           | 0.047 | 0.058 0.192 0.193               |                                          |                                        |
|                | 4                       | 0.001 0.146 0.362 0.399           | 0.032 | 0.048 0.188 0.193               |                                          |                                        |
| Long-term      | 7                       | 0.001 0.084 0.328 0.381           | 0.018 | 0.038 0.180 0.191               |                                          |                                        |
|                | 14                      | < 0.001 0.042 0.269 0.344         | 0.005 | 0.024 0.160 0.186               |                                          |                                        |
|                | 21                      | < 0.001 0.029 0.231 0.315         | 0.002 | 0.017 0.143 0.180               |                                          |                                        |
|                | 28                      | < 0.001 0.022 0.204 0.292         | 0.001 | 0.013 0.130 0.172               |                                          |                                        |
|                | 42                      | < 0.001 0.014 0.169 0.258         | < 0.001| 0.009 0.111 0.159               |                                          |                                        |
|                | 50                      | < 0.001 0.012 0.155 0.243         | < 0.001| 0.008 0.103 0.152               |                                          |                                        |
|                | 100                     | < 0.001 0.006 0.111 0.187         | < 0.001| 0.004 0.077 0.122               |                                          |                                        |
| spring cereals | FOCUS STEP 4 5 m buffer | D4 (Skousbo), stream single application | D5 (La Jailliere) pond, single application | | |
| Initial        | 0                       | 0.744 -                           | 0.150 | -                                | 0.070 -                                  | 0.268 -                                 |
| Short-term     | 1                       | < 0.001 0.198 0.145 0.148         | 0.063 | 0.066 0.268 0.268               |                                          |                                        |
|                | 2                       | < 0.001 0.099 0.140 0.146         | 0.056 | 0.063 0.266 0.268               |                                          |                                        |
|                | 4                       | < 0.001 0.050 0.131 0.141         | 0.045 | 0.057 0.262 0.267               |                                          |                                        |
| Long-term      | 7                       | < 0.001 0.028 0.119 0.135         | 0.030 | 0.048 0.253 0.266               |                                          |                                        |
|                | 14                      | < 0.001 0.014 0.099 0.122         | 0.011 | 0.034 0.229 0.261               |                                          |                                        |
|                | 21                      | < 0.001 0.010 0.085 0.113         | 0.005 | 0.025 0.207 0.253               |                                          |                                        |
|                | 28                      | < 0.001 0.007 0.075 0.105         | 0.003 | 0.020 0.189 0.245               |                                          |                                        |
|                | 42                      | < 0.001 0.005 0.062 0.093         | < 0.001| 0.014 0.161 0.228               |                                          |                                        |
|                | 50                      | < 0.001 0.004 0.057 0.087         | < 0.001| 0.012 0.150 0.219               |                                          |                                        |
|                | 100                     | < 0.001 0.002 0.040 0.067         | < 0.001| 0.006 0.108 0.177               |                                          |                                        |
| spring cereals | FOCUS STEP 4 5 m buffer | D5 (La Jailliere), stream single application | R4 (Roujan), stream single application | | |
| Initial        | 0                       | 0.730 -                           | 0.034 | -                                | 0.911 -                                  | 6.595 -                                 |
| Short-term     | 1                       | < 0.001 0.046 0.033 0.033         | 0.891 | 0.855 6.583 6.590               |                                          |                                        |
|                | 2                       | < 0.001 0.023 0.032 0.033         | 0.267 | 0.735 6.572 6.585               |                                          |                                        |
|                | 4                       | < 0.001 0.012 0.031 0.032         | 0.002 | 0.381 6.551 6.574               |                                          |                                        |
| Long-term      | 7                       | < 0.001 0.007 0.029 0.031         | 0.681 | 0.280 6.519 6.559               |                                          |                                        |
|                | 14                      | < 0.001 0.003 0.025 0.029         | 0.001 | 0.202 6.499 6.527               |                                          |                                        |
|                | 21                      | < 0.001 0.002 0.022 0.027         | < 0.001| 0.135 6.433 6.509               |                                          |                                        |
|                | 28                      | < 0.001 0.002 0.019 0.025         | < 0.001| 0.105 6.372 6.488               |                                          |                                        |

† Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles
| Term | Winter Cereals | Winter Cereals | Winter Cereals | Winter Cereals |
|------|---------------|---------------|---------------|---------------|
|      | FOCUS STEP 4  | D4 (Skousbo)  | D5 (La Jailliere), pond | **FOCUS STEP 4**  |
|      | 5 m buffer    | stream,      | multiple application | **5 m buffer**    |
|      |               | single       |               |               |
| Initial | 0              | 0.734        | 0.071         | 0.455         |
|        | Short-term    |              |               |               |
| 1      | < 0.001       | 0.137        | 0.064         | 0.454         |
| 2      | < 0.001       | 0.069        | 0.058         | 0.452         |
| 4      | < 0.001       | 0.034        | 0.047         | 0.445         |
|        | Long-term     |              |               |               |
| 7      | < 0.001       | 0.020        | 0.035         | 0.430         |
| 14     | < 0.001       | 0.010        | 0.015         | 0.390         |
| 21     | < 0.001       | 0.007        | 0.007         | 0.354         |
| 28     | < 0.001       | 0.005        | 0.004         | 0.324         |
| 42     | < 0.001       | 0.003        | 0.002         | 0.278         |
| 50     | < 0.001       | 0.003        | 0.001         | 0.259         |
| 100    | < 0.001       | 0.001        | < 0.001       | 0.190         |
|        | Time after max. peak [days] | PECsw [µg/L] | TWA_{sw} [µg/L] | PEC_{sed} [µg/kg] | TWA_{sed} [µg/kg] |
| Initial | 0              | 0.647        | 1.623         | 0.763         | 0.462         |
|        | Short-term    |              |               |               |               |
| 1      | 0.524         | 0.582        | 1.620         | 0.211         | 0.561         |
| 2      | 0.427         | 0.527        | 1.612         | 0.008         | 0.316         |
| 4      | 0.290         | 0.440        | 1.582         | 0.001         | 0.159         |
|        | Long-term     |              |               |               |               |
| 7      | 0.175         | 0.349        | 1.514         | < 0.001       |
| 14     | 0.073         | 0.231        | 1.348         | < 0.001       |
| 21     | 0.033         | 0.170        | 1.215         | < 0.001       |
| 28     | 0.020         | 0.134        | 1.112         | < 0.001       |
| 42     | 0.011         | 0.094        | 0.967         | < 0.001       |
| 50     | 0.008         | 0.081        | 0.907         | < 0.001       |
| 100    | 0.004         | 0.043        | 0.701         | < 0.001       |
|        | Winter Cereals | FOCUS STEP 4  | D2 (Brimstone), ditch | **FOCUS STEP 4**  |
|        | 5 m buffer    | 5 m buffer   | single application | **5 m buffer**    |
| Initial | 0              | 0.648        | 1.569         | 0.777         | 1.864         |
|        | Short-term    |              |               |               |               |
| 1      | 0.530         | 0.586        | 1.494         | 0.636         | 1.768         |
| 2      | 0.437         | 0.533        | 1.428         | 0.524         | 1.681         |
| 4      | 0.304         | 0.449        | 1.314         | 0.365         |

‡ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles
Peer review of the pesticide risk assessment of the active substance spiroxamine

| Long-term | 7  | 0.003 | 0.359 | 1.175 | 1.433 | < 0.001 | 0.428 | 1.357 | 1.692 |
|-----------|----|-------|-------|-------|-------|---------|-------|-------|-------|
|           | 14 | 0.006 | 0.182 | 0.995 | 1.304 | < 0.001 | 0.214 | 1.101 | 1.526 |
|           | 21 | 0.016 | 0.125 | 0.909 | 1.205 | 0.011   | 0.144 | 0.992 | 1.392 |
|           | 28 | 0.014 | 0.098 | 0.842 | 1.134 | 0.013   | 0.111 | 0.918 | 1.296 |
|           | 42 | 0.008 | 0.069 | 0.740 | 1.031 | 0.008   | 0.078 | 0.810 | 1.165 |
|           | 50 | 0.007 | 0.059 | 0.696 | 0.986 | 0.007   | 0.067 | 0.762 | 1.109 |
|           | 100| 0.002 | 0.031 | 0.526 | 0.801 | 0.003   | 0.035 | 0.578 | 0.893 |

Winter cereals

FOCUS STEP 4

| Time after max. peak [days] | PEC<sub>sw</sub> [µg/L] | TWA<sub>sw</sub> [µg/L] | PEC<sub>sed</sub> [µg/kg] | TWA<sub>sed</sub> [µg/kg] |
|-----------------------------|------------------------|------------------------|------------------------|------------------------|
| Initial                     | 0.640                  | -                      | 0.433                  | -                      |
| Short-term                  |                        |                        |                        |                        |
| 1                           | 0.264                  | 0.473                  | 0.422                  | 0.431                  |
| 2                           | 0.027                  | 0.296                  | 0.406                  | 0.427                  |
| 4                           | 0.001                  | 0.151                  | 0.377                  | 0.415                  |
| Long-term                   |                        |                        |                        |                        |
| 7                           | < 0.001                | 0.087                  | 0.340                  | 0.396                  |
| 14                          | < 0.001                | 0.044                  | 0.279                  | 0.357                  |
| 21                          | < 0.001                | 0.030                  | 0.239                  | 0.327                  |
| 28                          | < 0.001                | 0.022                  | 0.210                  | 0.303                  |
| 42                          | < 0.001                | 0.015                  | 0.174                  | 0.267                  |
| 50                          | < 0.001                | 0.013                  | 0.160                  | 0.251                  |
| 100                         | < 0.001                | 0.006                  | 0.114                  | 0.193                  |

Winter cereals

FOCUS STEP 4

| Time after max. peak [days] | PEC<sub>sw</sub> [µg/L] | TWA<sub>sw</sub> [µg/L] | PEC<sub>sed</sub> [µg/kg] | TWA<sub>sed</sub> [µg/kg] |
|-----------------------------|------------------------|------------------------|------------------------|------------------------|
| Initial                     | 0.694                  | -                      | 0.022                  | -                      |
| Short-term                  |                        |                        |                        |                        |
| 1                           | < 0.001                | 0.030                  | 0.021                  | 0.021                  |
| 2                           | < 0.001                | 0.015                  | 0.021                  | 0.021                  |
| 4                           | < 0.001                | 0.007                  | 0.020                  | 0.021                  |

 Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles
Peer review of the pesticide risk assessment of the active substance spiroxamine

Long-term  | 7  | < 0.001 | 0.004 | 0.018 | 0.020 | < 0.001 | 0.035 | 0.148 | 0.167
| 14 | < 0.001 | 0.002 | 0.016 | 0.019 | < 0.001 | 0.018 | 0.124 | 0.152
| 21 | < 0.001 | 0.001 | 0.014 | 0.017 | < 0.001 | 0.012 | 0.108 | 0.140
| 28 | < 0.001 | 0.001 | 0.013 | 0.016 | < 0.001 | 0.009 | 0.097 | 0.131
| 42 | < 0.001 | < 0.001 | 0.011 | 0.015 | < 0.001 | 0.006 | 0.082 | 0.117
| 50 | < 0.001 | < 0.001 | 0.010 | 0.014 | < 0.001 | 0.005 | 0.076 | 0.111
| 100 | < 0.001 | < 0.001 | 0.007 | 0.011 | < 0.001 | 0.003 | 0.055 | 0.088

winter cereals | FOCUS STEP 4 5 m buffer | R1 (Weiherbach), pond multiple application | R1 (Weiherbach), stream multiple application
Initial  | 0  | 0.102 | - | 1.036 | - | 1.258 | - | 8.887 | -
Short-term | 1  | 0.090 | 0.096 | 1.034 | 1.035 | < 0.001 | 0.667 | 8.828 | 8.868
| 2  | 0.077 | 0.091 | 1.031 | 1.035 | < 0.001 | 0.334 | 8.770 | 8.842
| 4  | 0.056 | 0.080 | 1.019 | 1.034 | 0.004 | 0.167 | 8.663 | 8.787
Long-term  | 7  | 0.035 | 0.066 | 0.993 | 1.030 | < 0.001 | 0.163 | 8.525 | 8.710
| 14 | 0.014 | 0.063 | 0.925 | 1.015 | 0.038 | 0.125 | 8.263 | 8.556
| 21 | 0.007 | 0.054 | 0.872 | 0.992 | < 0.001 | 0.098 | 8.057 | 8.428
| 28 | 0.026 | 0.052 | 0.826 | 0.985 | < 0.001 | 0.078 | 8.024 | 8.345
| 42 | 0.004 | 0.044 | 0.776 | 0.980 | < 0.001 | 0.062 | 8.009 | 8.201
| 50 | 0.003 | 0.040 | 0.742 | 0.966 | < 0.001 | 0.054 | 7.818 | 8.157
| 100 | 0.005 | 0.025 | 0.697 | 0.865 | < 0.001 | 0.031 | 7.746 | 7.935

winter cereals | FOCUS STEP 4 5 m buffer | R3 (Bologna), stream multiple application | R4 (Roujan), stream multiple application
Initial  | 0  | 1.228 | - | 6.482 | - | 1.726 | - | 9.502 | -
Short-term | 1  | 0.233 | 1.040 | 6.409 | 6.464 | 1.632 | 1.567 | 9.320 | 9.446
| 2  | 0.004 | 0.549 | 6.333 | 6.433 | 0.490 | 1.366 | 9.148 | 9.372
| 4  | 0.003 | 0.276 | 6.199 | 6.364 | 0.003 | 0.707 | 8.851 | 9.248
Long-term  | 7  | 0.002 | 0.159 | 6.034 | 6.268 | 1.226 | 0.543 | 8.496 | 9.071
| 14 | 0.001 | 0.096 | 5.753 | 6.160 | 0.002 | 0.370 | 7.919 | 8.906
| 21 | < 0.001 | 0.064 | 5.557 | 6.112 | 0.001 | 0.247 | 7.541 | 8.635
| 28 | < 0.001 | 0.066 | 6.035 | 6.058 | < 0.001 | 0.189 | 7.264 | 8.392
| 42 | < 0.001 | 0.056 | 6.088 | 6.000 | < 0.001 | 0.126 | 6.854 | 8.007
| 50 | < 0.001 | 0.052 | 5.859 | 5.997 | < 0.001 | 0.106 | 6.663 | 7.832
| 100 | < 0.001 | 0.028 | 5.224 | 5.735 | < 0.001 | 0.054 | 6.380 | 7.097

 Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles
Appendix III.6: Chapter 6 (effects on non-target species)

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

| Group                     | Test substance | Time-scale (Test type) | Endpoint                           | Toxicity¹ (mg/L) |
|---------------------------|----------------|------------------------|------------------------------------|------------------|
| Laboratory tests ‡        |                |                        |                                    |                  |
| Fish                      | Danio rerio    | 230 d (flow-through)   | FLC, Mortality F1-ELS, NOEC/EC₁₀   | 0.002 nom        |
|                           | Danio rerio    | 160 d (with sediment, static conditions – pulsed exposure) 2 pulses, 14 d interval) | FLC, biomarker vitellogenin NOEC | 0.0158 mm*       |
|                           | Oncorhynchus mykiss | 93 d (flow-through) | ELS, EC₀                         | 0.014 based on nom NOEC values |

¹ indicate whether based on nominal (nom) or mean measured concentrations (mm). In the case of preparations indicate whether endpoints are presented as units of preparation or as mean measured initial (mm).
² nominal = measured initial concentration
* Endpoints given are based on mean measured initial concentration. Due to study design, actual exposure might be much lower. The endpoints of the study are not acceptable to be used on the risk assessment. They are listed as additional information only.

Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

FOCUS Step 2

1) Spiroxamine EC 500:
European use pattern: Vines, grapes, 1-3 x 300 g as/ha, BBCH 13-85, Specific countries use pattern: Grapes, early, 1-2 x 200 g as/ha, BBCH 13-19, and Grapes late, BBCH 79-85, 2-3 x 300-400 g as/ha. Maximum PECₜₐₘₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚportion

FOCUS Step 2

2) Prothioconazole & Spiroxamine EC 460:
Cereals, 2 x 200 g Prothioconazole/ha and 375 g Spiroxamine/ha, BBCH 30-69
Maximum PECₜₐₘₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚₚportion

1 indicate whether Northern or Southern
2 include critical groups which fail at Step 1.
3 indicate whether maximum or twa values have been used.

† Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

www.efsa.europa.eu/efsajournal 34 EFSA Journal 2020;19(2):6385
If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.

Refined aquatic risk assessment using higher tier FOCUS modelling.

FOCUS Step 3

1) Spiroxamine EC 500:
   European use pattern: Vines, grapes, 1-3 x 300 g as/ha, BBCH 13-85; Specific countries use pattern:
   Grapes, early, 1-2 x 200 g as/ha, BBCH 13-19, and Grapes late, BBCH 79-85, 2-3 x 300-400 g as/ha.

   Maximum PECsw values used

   | Scenario1,2,3 | PECsw,max4µg as/L | Fish prolonged | Annex VI trigger5 |
   |---------------|-------------------|----------------|-------------------|
   |               | Danio rerio       | Ec10 = 2.0 µg as/L |

   European use pattern

   |             |                  |                |                  |
   | D6 /ditch   | 5.09             | 0.4            | 10               |
   | R1 /pond    | 0.182            | 11             | 10               |
   | R1 /stream  | 3.671            | 0.5            | 10               |
   | R2 /stream  | 5.018            | 0.4            | 10               |
   | R3 /stream  | 5.275            | 0.4            | 10               |
   | R4 /stream  | 3.684            | 0.5            | 10               |

   Specific countries use pattern

   |             |                  |                |                  |
   | D6 /ditch   | 6.834            | 0.3            | 10               |
   | R1 /pond    | 0.243            | 8.2            | 10               |
   | R1 /stream  | 4.875            | 0.4            | 10               |
   | R2 /stream  | 6.72             | 0.3            | 10               |
   | R3 /stream  | 7.066            | 0.3            | 10               |
   | R4 /stream  | 5.011            | 0.4            | 10               |

2) Prothioconazole & Spiroxamine EC 460:
   Cereals, 2 x 200 g Prothioconazole/ha and 375 g Spiroxamine/ha, BBCH 30-69

   | Scenario1,2,3 | PECsw,max4µg as/L | Fish prolonged | Annex VI trigger5 |
   |---------------|-------------------|----------------|-------------------|
   |               | Danio rerio       | Ec10 = 2.0 µg as/L |

   |             |                  |                |                  |
   | D1 /ditch   | 2.392            | 0.8            | 10               |
   | D1 /stream  | 2.092            | 1.0            | 10               |
   | D2 /ditch   | 2.395            | 0.8            | 10               |
   | D2 /stream  | 2.131            | 0.9            | 10               |
   | D3 /ditch   | 2.355            | 0.8            | 10               |

† Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles
Peer review of the pesticide risk assessment of the active substance spiroxamine

† Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

www.efsa.europa.eu/efsajournal 36  EFSA Journal 2020;19(2):6385

| Scenario | Water body type | Test organism | Toxicity endpoint (mg/L) | Buffer zone distance | PEC_{sw}^4 max (µg/L) | TER | Annex VI trigger^5 |
|----------|----------------|---------------|--------------------------|----------------------|----------------------|-----|---------------------|
| European use pattern |
| D4 /pond | 0.081 | 24.6 | 10 |
| D4 /stream | 2.045 | 1.0 | 10 |
| D5 /pond | 0.081 | 24.6 | 10 |
| D5 /stream | 2.206 | 0.9 | 10 |
| D6 /ditch | 2.382 | 0.8 | 10 |
| R1 /pond | 0.115 | 17.4 | 10 |
| R1 /stream | 1.554 | 1.3 | 10 |
| R3 /stream | 2.187* | 0.9 | 10 |
| R4 /stream | 1.557* | 1.3 | 10 |

1 drainage (D1 - D6) and run-off (R1 - R4)
2 ditch/stream/pond
3 include critical groups which fail at Step 2.
4 indicate whether PEC_{sw}, or PEC_{sed} and whether maximum or twa values used
5 If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a Trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.
* Due to only minor effects of recalculation of DT_{50} on the PEC values in single applications, PEC values for multiple application were not recalculation and therefore still based on the notifier’s DT_{50}

FOCUS Step 4

1) Spiroxamine EC 500:
European use pattern: Vines, grapes, 1-3 x 300 g as/ha, BBCH 13-85,
Specific countries use pattern: Grapes, early, 1-2 x 200 g as/ha, BBCH 13-19, and Grapes late, BBCH 79-85, 2-3 x 300-400 g as/ha.
Maximum PEC_{sw} values used (related to the EC_{10} of 2.0 µg as/L)

| Scenario | Water body type | Test organism | Toxicity endpoint (mg/L) | Buffer zone distance | PEC_{sw}^4 max (µg/L) | TER | Annex VI trigger^5 |
|----------|----------------|---------------|--------------------------|----------------------|----------------------|-----|---------------------|
| European use pattern |
| D6 | ditch | Fish | Chronic | 0.002 | 20 m | 0.390 | 5.1 | 10 |
| R1 | pond | Fish | Chronic | 0.002 | 20 m | 0.058 | 34.5 | 10 |
| R1 | stream | Fish | Chronic | 0.002 | 20 m | 0.339 | 5.9 | 10 |
| R2 | stream | Fish | Chronic | 0.002 | 20 m | 0.463 | 4.3 | 10 |
| R3 | stream | Fish | Chronic | 0.002 | 20 m | 0.487 | 4.1 | 10 |
| R4 | stream | Fish | Chronic | 0.002 | 20 m | 0.340 | 5.9 | 10 |

| Scenario | Water body type | Test organism | Toxicity endpoint (mg/L) | Buffer zone distance | PEC_{sw}^4 max (µg/L) | TER | Annex VI trigger^5 |
|----------|----------------|---------------|--------------------------|----------------------|----------------------|-----|---------------------|
| Specific countries use pattern |
| D6 | ditch | Fish | Chronic | 0.002 | 20 m | 0.523 | 3.8 | 10 |
| R1 | pond | Fish | Chronic | 0.002 | 20 m | 0.078 | 26 | 10 |
| R1 | stream | Fish | Chronic | 0.002 | 20 m | 0.450 | 4.4 | 10 |

^ Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles
Peer review of the pesticide risk assessment of the active substance spiroxamine

‡ Endpoints identified by the EU-Commission as relevant for Member States when applying the Uniform Principles.

www.efsa.europa.eu/efsajournal

EFSA Journal 2020;19(2):6385

| Scenario | Water body type | Test organism | Time scale | Toxicity endpoint (mg/L) | Buffer zone distance (m) | PEC_{sw} max (µg/L) | TER | Annex VI trigger |
|----------|----------------|---------------|------------|--------------------------|--------------------------|------------------|-----|------------------|

### Spring cereals

| Scenario | Water body type | Test organism | Time scale | Toxicity endpoint (mg/L) | Buffer zone distance (m) | PEC_{sw} max (µg/L) | TER | Annex VI trigger |
|----------|----------------|---------------|------------|--------------------------|--------------------------|------------------|-----|------------------|
| D1       | ditch          | Fish          | Chronic    | 0.002                    | 20 m                     | 0.177            | 11.3| 10               |
| D1       | stream         | Fish          | Chronic    | 0.002                    | 20 m                     | 0.197            | 10.2| 10               |
| D3       | ditch          | Fish          | Chronic    | 0.002                    | 20 m                     | 0.176            | 11.4| 10               |
| D4       | pond           | Fish          | Chronic    | 0.002                    | 20 m                     | 0.034            | 58.8| 10               |
| D4       | stream         | Fish          | Chronic    | 0.002                    | 20 m                     | 0.184            | 10.9| 10               |
| D5       | pond           | Fish          | Chronic    | 0.002                    | 20 m                     | 0.034            | 58.8| 10               |
| D5       | stream         | Fish          | Chronic    | 0.002                    | 20 m                     | 0.183            | 10.9| 10               |
| R4       | stream         | Fish          | Chronic    | 0.002                    | 20 m                     | 0.217            | 9.2 | 10               |

### Winter cereals

| Scenario | Water body type | Test organism | Time scale | Toxicity endpoint (mg/L) | Buffer zone distance (m) | PEC_{sw} max (µg/L) | TER | Annex VI trigger |
|----------|----------------|---------------|------------|--------------------------|--------------------------|------------------|-----|------------------|
| D1       | ditch          | Fish          | Chronic    | 0.002                    | 20 m                     | 0.178            | 11.2| 10               |
| D1       | stream         | Fish          | Chronic    | 0.002                    | 20 m                     | 0.21             | 9.5 | 10               |
| D2       | ditch          | Fish          | Chronic    | 0.002                    | 20 m                     | 0.178            | 11.2| 10               |
| D2       | stream         | Fish          | Chronic    | 0.002                    | 20 m                     | 0.214            | 9.3 | 10               |
| D3       | ditch          | Fish          | Chronic    | 0.002                    | 20 m                     | 0.175            | 11.4| 10               |
| D4       | pond           | Fish          | Chronic    | 0.002                    | 20 m                     | 0.034            | 58.8| 10               |
| D4       | stream         | Fish          | Chronic    | 0.002                    | 20 m                     | 0.205            | 9.7 | 10               |
| D5       | pond           | Fish          | Chronic    | 0.002                    | 20 m                     | 0.034            | 58.8| 10               |
| D5       | stream         | Fish          | Chronic    | 0.002                    | 20 m                     | 0.221            | 9.0 | 10               |
| D6       | ditch          | Fish          | Chronic    | 0.002                    | 20 m                     | 0.177            | 11.3| 10               |
| R1       | pond           | Fish          | Chronic    | 0.002                    | 20 m                     | 0.034            | 58.8| 10               |
| R1       | stream         | Fish          | Chronic    | 0.002                    | 20 m                     | 0.299*           | 6.7 | 10               |
| R3       | stream         | Fish          | Chronic    | 0.002                    | 20 m                     | 0.294*           | 6.8 | 10               |
| R4       | stream         | Fish          | Chronic    | 0.002                    | 20 m                     | 0.412*           | 4.9 | 10               |

1 drainage (D1-D6) and run-off (R1-R4)
2 ditch/stream/pond
3 include critical groups which fail at Step 3.
4 indicate whether PEC_{sw}, or PEC_{sed} and whether maximum or twa values used
5 If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a Trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.

† Endpoint identified by the EU-Commission as relevant for Member States when applying the Uniform Principles.
* Due to only minor effects of recalculation of DT_{50} on the PEC values in single applications, PEC values for multiple application were not recalculation and therefore still based on the notifier’s DT_{50}

### Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

| Active substance | RMS/peer review proposal |
|------------------|--------------------------|
| Spiroxamine: Acute Category 1, Chronic Category 1 | environment, GSH 09 |

| Preparation | RMS/peer review proposal |
|-------------|--------------------------|
| Spiroxamine EC 500: Acute Category 1, Chronic Category 1 Label: environment, GSH 09 |  |
| Prothioconazole & Spiroxamine EC 460: Acute Category 1, Chronic Category 1 Label: environment, GSH 09 |  |