Appendix to:
EFSA (European Food Safety Authority), 2022. Conclusion on the peer review of the pesticide risk assessment of the active substance Oxamyl. EFSA Journal 2022;20(5):7296, 93 pp. doi:10.2903/j.efsa.2022.7296
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Appendix B - List of end points for the active substance and the representative formulation

Identity, Physical and Chemical Properties, Details of Uses, Further Information (Regulation (EU) No 283/2013, Annex Part A, points 1.3 and 3.2)

| Active substance (ISO Common Name) | Oxamyl |
|-----------------------------------|--------|
| Function (e.g. fungicide)         | Nematicide |

Rapporteur Member State
Italy

Co-rapporteur Member State
France
### Identity (Regulation (EU) No 283/2013, Annex Part A, point 1)

| Chemical name (IUPAC) | Methyl (EZ)-2-(dimethylamino)-N-{[(methylcarbamoyl)oxy]-2-oxothioacetimidate |
|-----------------------|--------------------------------------------------------------------------|
| Chemical name (CA)    | Methyl 2-(dimethylamino)-N-[[methylamino]carbonyl][oxy]-2-oxoethanimidothioate |
| CIPAC No              | 342                                                                      |
| CAS No                | 23135-22-0                                                               |
| EC No (EINECS or ELINCS) | 245-445-3                                                           |
| FAO Specification (including year of publication) | Oxamyl is not isolated as a technical material (TC), its manufacture involves dilution of the product from synthesis with a solvent, to nominal concentrations of 42% % (w/w) oxamyl in the TK. 42% TK containing 407 g/kg FAO specification 342 (April 2008) |
| Minimum purity of the active substance as manufactured | 936 g/kg based on theoretically calculated dry weight (based on latest 5 batch data). TC is not isolated during the manufacturing process. Theoretical dry weight calculations are based on the removal of diluents from the 42% oxamyl TK. Oxamyl is manufactured as technical concentrate (TK) by the applicant. The minimum and maximum content of the active substance in the TK 42% based on the renewal batches is 41.8% and 42.9% (equal to 392.1 to 402.0 g/kg pure oxamyl). FAO specifications are in place and still valid (2008). |
| Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured | Open |
| Location of the (proposed) reference specification (for significant impurities) | RAR June/2021. Vol. 4, Table 7 |
| Molecular formula     | C₇H₁₃O₃N₃S                                                           |
| Molecular mass        | 219.3 g/mol                                                              |
| Structural formula    | ![Structural formula](image)                                            |
### Physical-chemical properties (Regulation (EU) N° 283/2013, Annex Part A, point 2)

| Property                                      | Value and Details                                                                 |
|-----------------------------------------------|-----------------------------------------------------------------------------------|
| **Melting point** (state purity)              | Heated block method: 98.5-100°C (99.9% purity)                                     |
|                                              | Differential scanning calorimetry method: 99.2°C (98.0% purity)                   |
| **Boiling point** (state purity)              | No boiling point was observed for oxamyl, as it was observed to decompose at 165°C (98.0% purity) |
| **Temperature of decomposition** (state purity) | >165°C (98.0% purity)                                                            |
| **Appearance** (state purity)                | **Oxamyl 42TK (active substance as manufactured)**: Translucent liquid of light green color (Munsell 10Y 9/2) (420 g a.s./kg) |
|                                              | **Oxamyl PAI (Pure Active Ingredient)**: White, crystalline solid which corresponds to the Munsell colour N 9.5 (100.0% purity) |
| **Vapour pressure** (state temperature, state purity) | 1.80 × 10^{-5} Pa at 20°C (98.0% purity)                                         |
| **Henry’s law constant** (state temperature)  | pH 5: 2.7 × 10^{-8} Pa m³/mol (98.0% purity)                                       |
| **Solubility in water** (state temperature, state purity and pH) | 148.1 g/L at 20 ± 0.5°C (pH 5) (98.3% purity)                                   |
| **Solubility in organic solvents** (state temperature, state purity) | In acetone: >250 g/kg at 20°C |
|                                              | In dichloromethane: >250 g/kg at 20°C                                             |
|                                              | In ethyl acetate: 4.13 × 10^4 mg/L at 20°C                                       |
|                                              | In n-heptane: 10.5 mg/L at 20°C                                                   |
|                                              | In methanol: >250 g/kg at 20°C                                                   |
|                                              | In o-xylene: 3.14 × 10^3 mg/L at 20°C                                            |
|                                              | (100.0% purity)                                                                  |
| **Surface tension** (state concentration and temperature, state purity) | 73.1 ± 0.3 dynes/cm at 20.4 ± 0.1°C (100.0% purity)                             |
| **Partition coefficient** (state temperature, pH and purity) | log $P_{OW}$ = 0.43 at 23°C (double distilled water) (99.1% purity) |
|                                              | metabolites (calculation KOWWIN): IN-A2213, log $P_{OW}$ = -0.71  |
|                                              | IN-D2708, log $P_{OW}$ = -1.72                                                   |
|                                              | IN-N0079, log $P_{OW}$ = -1.95                                                   |
|                                              | IN-T2921, log $P_{OW}$ = -1.77                                                   |
| **Dissociation constant** (state purity)      | Oxamyl does not dissociate between pH 2.4 to pH 11.6 at 20 ± 0.5°C (98.0% purity) |
| **UV/VIS absorption (max.) incl. ε** (state purity, pH) | ε at 290 nm: 61.6 L/mol/cm at pH 2 |
|                                              | 80.1 L/mol/cm at pH 7                                                           |
|                                              | 1150 L/mol/cm at pH 10                                                          |
|                                              | (100.0% purity)                                                                  |
| **Flammability** (state purity)               | **Oxamyl 42TK (active substance as manufactured)**: The flash point was 57.4°C (135.26°F). (420 g a.s./kg) |
|                                              | The auto-ignition temperature was determined to be 303°C (± 5°C). (420 g a.s./kg) |
|                                              | **Oxamyl PAI (Pure Active Ingredient)**: No self-ignition (auto-flammability) (98.0% purity) |
| **Explosive properties** (state purity)       | Not explosive (420 g a.s./kg)                                                    |
| **Oxidising properties** (state purity)       | Not an oxidizer (99.1% purity)                                                   |
### Summary of representative uses evaluated, for which all risk assessments needed to be completed (Oxamyl)

(Regulation (EU) N° 284/2013, Annex Part A, points 3, 4)

| 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 | PHI (days) (m) | Remarks |
|---------------------------|--------------------------|--------------|--------------|--------------------------------------|-------------|------------|--------------------------------|---------------|---------|
| **Potato**                | Central zone             | Oxamyl 10GR  | F            | Nematodes                            | GR 100 g/Kg| In-furrow application/ Application to be made only with tractor mounted equipment at soil incorporation at 5-10 cm | At planting (BBCH 00) 1 Not applicable | PHI 1.0, 90 |         |
| **Tobacco**               | Southern zone            | Oxamyl 10GR  | F            | Nematodes                            | GR 100 g/Kg| In-furrow application/ Application to be made only with tractor mounted equipment at soil incorporation at 5-10 cm | At trans-planting (BBCH 00) 1 Not applicable | PHI 3.0 |         |
| **Tobacco**               | Southern zone            | Oxamyl 10GR  | F            | Nematodes                            | GR 100 g/Kg| Evenly soil incorporated to a depth of 5-10 cm/ Application to be made | Pre-planting (BBCH 00) 1 Not applicable | PHI 4.25-5.50 | Not applicable |
### Crop and/or situation (a)
- **Member State or Country:**
- **Product name:**
- **F G or I (b):**
  - F: For field use
  - G: For greenhouse use
  - I: For indoor use
- **Pests or Group of pests controlled (c):**
  - e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
  - e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
- **Preparation:**
  - Type (d-f)
  - Conc. a.s. (i)
  - method kind (f-h)
  - range of growth stages & season (j)
  - number min-max (k)
  - interval between application (min) (l)
  - Application rate per treatment kg a.s./ha min-max (l)
  - PHI (days) (m)
  - Water L/ha min-max
  - Remarks

### Application Rate and Use Conditions

#### Tomato
- **Intercultural Oxamyl 10SL G Nematodes SL 100 g/L Drip irrigation (a.1) Immediately after transplant (a.2) Starting with BBCH 11 (10-14 days after transplant application). Up to 42 days after transplant.**
  - PHI: 1-4 days
  - Interval: 10 days
  - Application rate: Not applicable
  - Water: Not applicable
  - Remarks: Apply up to 2 kg a.s/ha immediately after transplant. Followed by up to 3 appl of 1 kg a.s/ha each starting with BBCH 11 (10-14 days after transplant application), up to 42 days after transplanting. The use is only in high technology or permanent closed greenhouses.

#### Solarization
- **Soil bed preparation in greenhouse s designated for the growing of: Tomato, Cucurbits (edible and inedible peel), Pepper, Aubergine, and plants nurseries of the above mentioned crops**
  - **Intercultural Oxamyl 10SL G Nematodes SL 100 g/L Drip irrigation with transparent plastic foil covering soil Before transplant on bare soil (June-September)**
  - PHI: 1 days
  - Interval: Not applicable
  - Application rate: Not applicable
  - Water: Not applicable
  - Remarks: Plant Back Interval (PBI) = 30 days. Application to bare soil covered with plastic foil to control soil nematodes before transplant. The use is only in high technology or permanent closed greenhouses.

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(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)
(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., benthiavalcarb-isopropyl).
| (e) | CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide |
|-----|--------------------------------------------------------------------------------------------------|
| (f) | All abbreviations used must be explained |
| (g) | Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench |
| (h) | Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant-type of equipment used must be indicated |
| (j) | Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application |
| (k) | Indicate the minimum and maximum number of applications possible under practical conditions of use |
| (l) | The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha |
| (m) | PHI - minimum pre-harvest interval |
Further information, Efficacy

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

General:
Oxamyl is used to control a wide range of important plant parasitic nematodes in a range of crops. Nematode pests that are controlled include *Meloidogyne sp.* (rootknot nematodes), *Globodera* and *Heterodera sp.* (cyst nematodes), *Trichodoras* and *Paratrichodoras sp.* (stubby root nematodes), *Radopholus similis* (burrowing nematode), *Belonolaimus longicaudatus* (sting nematode), *Hipelalaimus galeatus* (lance nematode), *Ditylenchus sp.* (stem and bulb nematodes), and *Pratylenchus penetrans* (root lesion nematode).

Oxamyl 10GR:
On potato, Oxamyl 10GR is intended to be applied once at planting (BBCH 00). The maximum intended application rate is 1.0 kg a.s./ha.
On tobacco, Oxamyl 10GR is intended to be applied once at transplanting (BBCH 00) with a maximum application rate of 3.0 kg a.s./ha. Also, on tobacco, one application at pre-planting stage (BBCH 00) of the product evenly soil incorporated to a depth of 5–10 cm at maximum application rate of 5.5 kg a.s./ha. Application is made in open field.

Oxamyl 10SL:
On tomato, Oxamyl 10SL is applied via drip irrigation and recommended to be used up to 2 kg a.s./ha immediately after transplant; followed by up to 3 applications of 1 kg a.s./ha each starting with BBCH 11 (10–14 days after transplant application), up to 42 days after transplanting at planting (BBCH 00).

Considering the solarisation use, Oxamyl 10SL is applied via drip irrigation with transparent plastic foil covering soil and before transplant on bare soil (approximately between June and September) at maximum application rate of 5.5 kg a.s./ha. The recommended Plant Back Interval is 30 days, and the application to bare soil covered with plastic foil to control soil nematodes before transplant. Application of oxamyl 10SL is sought for permanent closed greenhouses.

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

No crop damage due to the use of Oxamyl 10GR in re-cropping has been observed.

No crop damage due to the use of Oxamyl 10SL in re-cropping has been observed.
Observations on other undesirable or unintended side-effects (Regulation (EU) N° 284/2013, Annex Part A, point 6.5)

Oxamyl containing products used in agriculture via broadcast or in-furrow application and soil incorporation prior to or at (trans)planting or sowing, and via drip irrigation in fruiting vegetables and various field crops have been proven to be safe to the target crops at the established product label rates.

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

| Activity against target organism | IN-A2213 | IN-D2708 |
|----------------------------------|----------|----------|
| no                               | no       |

It is generally recognized that carbamate insecticides lose their biological activity upon cleavage of the carbamate moiety. Therefore, the metabolites of oxamyl identified above are not expected to be toxicologically active by this mechanism, since the carbamate ester moiety has been either hydrolysed or metabolically degraded in each case. This conclusion is supported by the lack of insecticidal activity that has been observed with IN-A2213 and IN D2708.
Methods of Analysis

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

Technical a.s. (analytical technique)

The method involves dissolution by ultrasonication of oxamyl in a solution of 5% methanol and 95% water adjusted to pH 3.0 with H₃PO₄. Analysis is conducted by reversed-phase liquid chromatography (HPLC) or ultra-high pressure liquid chromatography (UPLC), with quantitation by ultraviolet absorbance at 240 nm.

Impurities in technical a.s. (analytical technique)

The method involves dissolution by ultrasonication of oxamyl in a sample diluent of pH 3.0 water adjusted with H₃PO₄. Analysis is conducted by reverse-phase liquid chromatography (HPLC) or ultra-high pressure liquid chromatography (UPLC) with quantitation by ultraviolet absorbance at 205 nm.

Plant protection product (analytical technique)

Oxamyl 10GR/Oxamyl 10SL method involves dissolution by ultrasonication in a solution of 5% methanol and 95% water adjusted to pH 3.0 with H₃PO₄. Analysis by reversed-phase liquid chromatography (HPLC) or ultra-high pressure liquid chromatography (UPLC), with quantitation by ultraviolet absorbance at 240 nm.

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

Residue definitions for monitoring purposes

| Food of plant origin | Oxamyl parent |
|----------------------|---------------|
| Food of animal origin| Residue definition currently not proposed and not required based on the representative uses |
| Soil                 | Oxamyl parent |
| Water surface        | Oxamyl parent |
| Drinking/ground      | Oxamyl parent |
| Air                  | Oxamyl parent |
| Body fluids and tissues | Oxamyl parent |
### Monitoring/Enforcement methods

| Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes) | Matrices: Dry, watery, oily, acidic and difficult to analyse crops |
|-----------------------------------------------------------------------------------------|---------------------------------------------------------------|
|                                                                                         | Separation/Quantitation: QuECHERS MRM and HPLC/MS/MS         |
|                                                                                         | LOQ: 0.01 mg/kg                                               |
|                                                                                         | Matrix effects were not studied in the original method and in the ILV (data gap). Efficiency of the extraction procedure used was not verified for all matrix groups (data gap). |
| Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes) | Matrices: Meat (bovine), fat (bovine), liver (bovine), milk, eggs |
|                                                                                         | Separation/Quantitation: QuECHERS MRM HPLC/MS/MS            |
|                                                                                         | LOQ: 0.01 mg/kg                                               |
|                                                                                         | The absence of matrix effects and the extraction efficiency was not verified for the monitoring method (data gap) and its ILV study |
| Soil (analytical technique and LOQ)                                                      | Separation/Quantitation: HPLC-MS/MS                          |
|                                                                                         | LOQ: 0.001 mg/kg                                              |
| Water (analytical technique and LOQ)                                                    | Separation/Quantitation: HPLC-MS/MS                          |
|                                                                                         | LOQ: 0.0001 mg/L                                              |
| Air (analytical technique and LOQ)                                                      | Separation/Quantitation: HPLC-MS/MS                          |
|                                                                                         | LOQ: 0.25 µg/m³                                               |
| Body fluids and tissues (analytical technique and LOQ)                                  | (blood) Separation/Quantitation: HPLC-MS/MS                  |
|                                                                                         | LOQ: 0.05 mg/L                                                |
|                                                                                         | Absence of matrix effects was not verified (data gap).       |

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

| Substance | Oxamyl Technical 42% TK (Pure Active Ingredient [PAI] is never isolated nor shipped and thus is not relevant for CLP classification). PAI already has a harmonized classification according to regulation 1278/2008. |
|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended] | - |

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

-
Impact on Human and Animal Health

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

| Rate and extent of oral absorption/systemic bioavailability | >90% after single dose of [14C]oxamyl (1 mg/kg bw) to rats (based on urine excretion and residues in tissues and carcass) |
|------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|
| Toxicokinetics                                             | Not available                                                                                                                  |
| Distribution                                               | Widely distributed                                                                                                             |
|                                                           | Highest concentration in whole blood (0.1 µg eq/g), in heart, liver, kidney, lungs, spleen, and the gastrointestinal tract (0.04 to 0.09 µg eq/g). Concentrations in all other tissues were approximately 0.01 to 0.03 µg eq/g. No significant gender differences. |
| Potential for bioaccumulation                              | No evidence for bioaccumulation. Tissue residues were low (0.003 to 0.09 mg/kg).                                               |
| Rate and extent of excretion                               | After single doses of [1-14C]oxamyl (1 mg/kg bw) to rats, the majority of the dose (>90%) was eliminated in the urine within 168 hours of dosing. Faeces and expired air were minor elimination routes. |
| Metabolism in animals                                       | Extensive (very minor amount of the parent present in the urine). Major metabolic pathway included hydrolysis (into IN-A2213) or enzymatic conversion into IN-N0079 (N,N-dimethyl-carbonocyanidamide), IN-D2708 (N,N'-dimethyloxamic acid) and IN-KP532 (N-methyloxamic acid), and conjugation (into IN-A2213 glucuronide, major urinary metabolite). Minor unidentified metabolites were considered to be conjugates of demethylated compounds (e.g., IN-L2953) or IN-D2708. |

In vitro metabolism

A comparative in vitro metabolism study performed using cryopreserved hepatocytes from mouse, rat, rabbit, dog, and human indicated IN-A2213 as a major metabolite in hepatocyte incubations of all five species. No unique metabolites were identified in human hepatocyte suspensions compared with hepatocytes from the mouse, rat, rabbit or dog. In vitro and in vivo metabolic profiles of oxamyl are in good agreement.

Toxicologically relevant compounds (animals and plants)

Oxamyl.
For the metabolites IN-A2213, IN-D2708, IN-QKT34 and IN-N0079, the reference values of the parent compound can be applied.

Toxicologically relevant compounds (environment)

Oxamyl.
For the metabolites IN-A2213, IN D2708, as well as IN-N0079 and IN-L2953 (oxamyl metabolites found in soil, water, and/or sediment), the reference values of the parent compound can be applied.

Acute toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.2)
### Peer review of the pesticide risk assessment of the active substance oxamyl

**Rat LD₅₀ oral**  
2.5 mg/kg bw (female rat)  
Cat. 1 H300

**Rat LD₅₀ dermal**  
5027 mg/kg bw (male rat)  
>5000 mg/kg bw (female rat)  
Cat. 4 H312

**Rat LC₅₀ inhalation**  
LC₅₀ 56 mg/m³  
(equivalent to 0.056 mg/L, rat, nose only)  
Cat. 2 H330

**Skin irritation**  
Non-irritant (rabbit)  
-

**Eye irritation**  
Non-irritant (rabbit)  
-

**Skin sensitisation**  
Not sensitiser (42% TK; Buehler test with 3 applications)  
QSAR analysis (Derek Nexus and OECD QSAR toolbox): negative predictions  
-

**Phototoxicity**  
Not phototoxic  
-

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

**Target organ/critical effect**  
Rat: ↓ body weight gain, urine blood, ↓ absolute organ weight  
Dog: ↓ plasma and brain cholinesterase activity among males and clinical signs among females  
Rabbit: ↓ plasma, erythrocyte and brain cholinesterase activity

**Relevant oral NOAEL**  
Rat (13-week):  
3.9 mg/kg/bw per day (males)  
4.3 mg/kg/bw per day (females)  
-

Dog (12-month, 2 studies):  
LOAEL: 1.46 mg/kg bw per day (based on tremors and cholinesterase inhibition)  
NOAEL: 0.93 mg/kg bw per day (based on clinical signs) rounded to 1 mg/kg bw per day

**Relevant dermal NOAEL**  
Rabbit, 21 day:  
50 mg/kg bw per day (based on decreases in plasma and erythrocyte cholinesterase activity)  
-

**Relevant inhalation NOAEL**  
No data - not required  
-

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

**In vitro studies**  
Reverse mutation assay (Ames test): negative  
Mammalian cell gene mutation (Chinese hamster ovary cells): negative  
Chromosome aberration assay (human peripheral blood lymphocytes): negative

**In vivo studies**  
Micronucleus assay (mouse): negative

**Photomutagenicity**  
Not required

**Potential for genotoxicity**  
No genotoxic potential
### Long term toxicity and carcinogenicity (Regulation (EU) N°283/2013, Annex Part A, point 5.5)

| Long-term effects (target organ/critical effect) | Relevant long-term NOAEL | Carcinogenicity (target organ, tumour type) | Relevant NOAEL for carcinogenicity |
|-------------------------------------------------|--------------------------|------------------------------------------|----------------------------------|
| Rats: ovary atrophy in females, lower body weight and body weight gain, clinical signs and plasma cholinesterase inhibition in males; Mice: decreased body weight | 2-year, rat: 1.97 mg/kg bw per day (male, based on lower body weight (gain)); 1.32 mg/kg bw per day, (female, based on atrophy in ovaries); 2-year, mouse: 4.2 mg/kg bw per day (males, based on decreased body weight) | No evidence of carcinogenic potential (rat and mouse) | Rats: 6.99/11.1 mg/kg bw per day (M/F) (highest dose tested); Mice: 13.5/16.8 mg/kg bw per day (M/F) |

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

#### Reproduction toxicity

| Reproduction target/critical effect | Relevant parental NOAEL | Relevant reproductive NOAEL | Relevant offspring NOAEL |
|------------------------------------|-------------------------|----------------------------|-------------------------|
| Multigeneration rat study:         | Rat: 1.43 mg/kg bw per day | Rat: 4.22 mg/kg bw per day | Rat: 1.43 mg/kg bw per day |
| - Parental toxicity: reduced body weight (gain), food consumption & efficiency | - | - | - |
| - Reproductive toxicity: reduced pup survival and reduced litter size | - | - | - |
| - Offspring toxicity: reduced pup body weight | - | - | - |

#### Developmental toxicity

| Developmental target/critical effect | Relevant maternal NOAEL | Relevant developmental NOAEL |
|--------------------------------------|-------------------------|-----------------------------|
| Maternal toxicity: decreased food consumption and body weight gain (rat and rabbit), tremors (rat). Developmental toxicity: decreased foetal body weight (rat), increased foetal resorption (rabbit). | Rat: 0.5 mg/kg bw per day; Rabbit: 1 mg/kg bw per day | Rat: 0.5 mg/kg bw per day; Rabbit: 1 mg/kg bw per day |

| Relevant maternal NOAEL | Relevant developmental NOAEL |
|-------------------------|-----------------------------|
| Rat: 0.5 mg/kg bw per day; Rabbit: 1 mg/kg bw per day | - |
### Neurotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.7)

**Acute neurotoxicity**

| NOAEL: 0.1 mg/kg bw (rat gavage); based on clinical signs and significant reductions in brain, plasma and erythrocyte cholinesterase activity on day 1, decreases in body weight, perturbations in Functional Observation Battery (FOB) and in motor activity parameters | STOT SE3, H336 |

**Repeated neurotoxicity**

| 90-day rat NOAEL (male): 1.69 mg/kg bw per day; based on clinical signs indicative of cholinesterase inhibition, significant reductions in body weight, food consumption and food efficiency, perturbations in FOB and motor activity parameters and significant reductions in plasma, erythrocyte and brain cholinesterase activity | - |

| 90-day rat NOAEL (female): 0.67 mg/kg bw per day; based on increased incidences of exophthalmos | - |

**Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity)**

| Acute inhalation neurotoxicity (rat): NOAEL <0.0049 mg/L equivalent to 1.64 mg/kg bw, based on erythrocyte and brain AChE inhibition (rapid and reversible) No delayed neurotoxicity. Comparative cholinesterase study: Pups seem more sensitive than adults on the basis of brain ChE inhibition (plasma and erythrocyte ChE inhibition being the same) | - |

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

**Supplementary studies on the active substance**

| See studies below |

**Endocrine disrupting properties**

| No potential for endocrine activity |

**Pubertal development and thyroid function in intact juvenile/peripubertal male rats (oral administration):**

| Concentration range: 0.25 and 0.5 mg/kg bw per day Result: no potential to disrupt hypothalamic-pituitary-thyroid axis. |

**Pubertal development and thyroid function in intact juvenile/peripubertal female rats (oral administration):**

| Concentration range: 0.25 and 0.5 mg/ bw per day Result: no potential to disrupt the hypothalamic-pituitary-thyroid axis. |

**In vitro aromatase inhibition:**

| With human recombinant microsomes Concentration range: $1.0 \times 10^{-10}$ M to $1.0 \times 10^{-3}$ M Result: no inhibition of aromatase |

**Estrogen receptor transcriptional assay:**

| With human cell line [HeLa-9903] Concentration range: $1 \times 10^{-6.8}$ M to $1 \times 10^{-3.3}$ M Result: not considered an agonist of human oestrogen receptor alpha (hERα) in HeLa-9903 |
**In vitro estrogen receptor binding assay:**
Using rat uterine cytosol (ER-RUC)
Concentration range: $1.0 \times 10^{-10}$ to $1.0 \times 10^{-3}$ M
Result: no inhibition in the oestrogen receptor binding assay

**3-day Uterotrophic assay:**
Concentration range: 0, 01, 0.25, or 0.5 mg/ bw per day
Result: no induction of oestrogenic effects when administered up to 0.5 mg/kg bw per day for 3 consecutive days.

**10-Day Hershberger bioassay:**
With young adult castrated Crl:CD(SD) rats
Concentration range: 0, 01, 0.25, or 0.5 mg/kg bw per d
Result: no induction of androgenic or antiandrogenic activity in the Hershberger Bioassay when administered up to 0.5 mg/kg bw per day for 10 consecutive days.

**In vitro Steroidogenesis assay:**
With human cell line, H295R
Concentration range: 100, 10, 1, 0.1, 0.01, 0.001, and 0.0001 μM
Result: no induction or inhibition of steroid biosynthesis.

**In vitro androgen receptor binding assay:**
With rat prostate cytosol
Concentration range: $1.0 \times 10^{-10}$ to $1.0 \times 10^{-3}$ M
No competitive binding to the androgen receptor when tested up to a maximum concentration of $1.0 \times 10^{-3}$ M.
Result: No inhibition of the androgen receptor binding.
Studies performed on metabolites or impurities

| Metabolite | Description |
|------------|-------------|
| **IN-A2213** | Major rat metabolite of oxamyl (14.5% in urine) | Rat oral LD$_{50}$ = 11000 mg/kg bw | Rat 10-day oral study (with males): no NOAEL, LOAEL 1000 mg/kg bw per day based on clinical signs, body weight loss and histopathological changes (spleen, thymus, bone marrow) | Ames study (*S.typhimurium and E.coli*): negative | *In vitro* mammalian gene mutation (HPRT): negative | *In vitro* mammalian cell micronucleus test: negative | Unlikely to be genotoxic |
| **IN-L2953** | Major rat metabolite of oxamyl (23.9% in urine) | Rat oral LD$_{50}$ = 6675 mg/kg bw (males) | Rat 10-day oral study (males): NOAEL, LOAEL 90 mg/kg bw per day based on ↓ bw/bw gain; effects in liver (↓ abs. weight, partially reversed loss of cytoplasmic vacuolation of centrilobular hepatocytes), in kidney (↓ abs. weight), in spleen (↓ rel. weight, reversible atrophy), in thymus (↓ rel. weight, reversible atrophy), in testes (↑ rel. weight, ↓ abs. weight), in bone marrow (reversible atrophy). | Rat 90-day oral study, followed by one-generation study: | - NOAEL parental = 4.0 mg/kg bw per day based on reduced body weight and altered clinical chemistry/haematological parameters | - NOAEL fertility = 34.3 mg/kg bw per day (top dose) | - NOAEL developmental = 11.4 mg/kg bw per day based on decreased body weight in F1 pups during lactation | *Ames* study (*S.typhimurium*): negative |
| **IN-N0079** | Major rat metabolite of oxamyl (64.3% in urine) | Rat oral LD$_{50}$ = 450 mg/kg bw (males) | Rat 10-day oral study (males): NOAEL, LOAEL 90 mg/kg bw per day based on ↓ bw/bw gain; effects in liver (↓ abs. weight, partially reversed loss of cytoplasmic vacuolation of centrilobular hepatocytes), in kidney (↓ abs. weight), in spleen (↓ rel. weight, reversible atrophy), in thymus (↓ rel. weight, reversible atrophy), in testes (↑ rel. weight, ↓ abs. weight), in bone marrow (reversible atrophy). | Rat 90-day oral study, followed by one-generation study: | - NOAEL parental = 4.0 mg/kg bw per day based on reduced body weight and altered clinical chemistry/haematological parameters | - NOAEL fertility = 34.3 mg/kg bw per day (top dose) | - NOAEL developmental = 11.4 mg/kg bw per day based on decreased body weight in F1 pups during lactation | *Ames* study (*S.typhimurium*): negative |
| **IN-D2708** | Major rat metabolite of oxamyl (18% in urine) | Rat oral LD$_{50}$ = 3540 mg/kg bw (males) | Ames study (*S.typhimurium and E.coli*): inconclusive | *In vitro* mammalian gene mutation (CHO/HPRT): negative | *In vitro* mammalian cell micronucleus test: negative |
| **IN-T2921** | Ames study (*S.typhimurium and E.coli*): negative | *In vitro* mammalian cell micronucleus test: negative |
| **INA2213; IND2708; IN-N0079; IN-L2953 and IN-T2921** | All tested metabolites were negative up to a concentration of 1000 µM or 5000 µM. These concentrations are over 1000-fold higher than the IC$_{50}$ of oxamyl. |
| **Metabolite thiocyanate** | QSAR analysis: negative in Ames test; negative in mamm. mutag *in vitro*; negative in chromos. aberr. *in vitro*; negative in *in vivo* MN | No data on general toxicity. |

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

no incidents or accidents during the manufacturing process. No data relating to exposure of the general public to oxamyl or epidemiological studies.
Summary (Regulation (EU) N°1107/2009, Annex II, point 3.1 and 3.6)

|                                | Value (mg/kg bw (per day)) | Study                           | Uncertainty factor |
|--------------------------------|----------------------------|---------------------------------|--------------------|
| Acceptable Daily Intake (ADI)  | 0.0001                     | Rat acute neurotoxicity study   | 1000               |
| Acute Reference Dose (ARfD)    | 0.0001                     | Rat acute neurotoxicity study   | 1000               |
| Acceptable Operator Exposure Level (AOEL) | 0.0001              | Rat acute neurotoxicity study   | 1000               |
| Acute Acceptable Operator Exposure Level (AAOEL) | 0.0001          | Rat acute neurotoxicity study   | 1000               |

The reference values from the first peer review (European Commission, 2011b) were all set to 0.001 mg/kg bw (per day) (ADI, ARfD and AOEL).

Metabolites IN-A2213, IN-2708, IN-QKT34, IN-N0079

|                                | Value (mg/kg bw (per day)) | Study                           | Uncertainty factor |
|--------------------------------|----------------------------|---------------------------------|--------------------|
| Acceptable Daily Intake (ADI)  | 0.0001                     | Rat acute neurotoxicity study   with oxamyl | 1000               |
| Acute Reference Dose (ARfD)    | 0.0001                     | Rat acute neurotoxicity study   with oxamyl | 1000               |

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

Oxamyl 10GR  
A default value of 10% is proposed for the concentrate. (no value for dilution is considered since the product is applied undiluted).

Oxamyl 10SL  
Based on an in vitro study with human skin samples, according to the EFSA guidance 2017, the dermal absorption value for the concentrate is 5.4% (no value for dilution is considered since the product is introduced directly to the soil by drip irrigation).

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

Oxamyl 10GR Operators

Use: Potato (pre-plant soil incorporated to a depth of 10 cm)  
Application method: tractor mounted equipment

Tier 1: EFSA Model (2014)  
With use of PPE (including gloves and RPE for both mixing/loading and application (M/L and A)), and considering the default treated area of 50 ha/day, the estimates for long term and acute exposure are 3733% of the AOEL and 12406% of the AAOEL respectively.

Tier 2: Field study (Brouwer, 2000)  
Use of the highest individual operator exposure values (from subject 8), including:
- use of gloves during M/L and A (reDUCTION factor 0.05)  
- use of RPE (FP2, P2 & similar) during M/L and A (reDUCTION factor 0.1 for inhalation exposure, 0.2 for headband exposure)

Total combined dermal exposure = 5.5865 µg/kg a.s.  
Total inhalation exposure is 0.2356 µg/kg a.s.
Peer review of the pesticide risk assessment of the active substance oxamyl

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

| Substance: | Oxamyl |
|-----------|--------|
| Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]²: | Acute Tox 2; H300: Fatal if swallowed.  
Acute Tox 4; H312: Harmful in contact with skin  
Acute Tox 2; H330: Fatal if inhaled. |
| According to the Peer review, the criteria for classification may be met for: | Acute Tox 1; H300: Fatal if swallowed.  
Acute Tox 4; H312: Harmful in contact with skin  
Acute Tox 2; H330: Fatal if inhaled. |

² Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.
Residues in or on treated products food and feed
Metabolism in plants (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.1, 6.5.1, 6.6.1 and 6.7.1)

| Primary crops | Crop groups | Crop(s) | Application(s) | DAT (days) |
|---------------|-------------|---------|----------------|------------|
| Fruit crops   | Apple - supportive | 0.1 kg a.s./hL (painting of fruit) | 47 |
| Orange - supportive | 0.1 kg a.s./hL (painting of fruit) | 42 |
| Tomato - supportive | 0.1 kg a.s./hL; surface treatment | 7, 11, 14, 21 |
| Tomato | 4 foliar applications: 1x 2 kg a.s./ha at transplant and 3x1 kg. a.s./ha, 14 days apart | 7, 14, 21 |
| Tomato | 4 soil applications: 1x 2 kg a.s./ha at transplant and 3x1 kg. a.s./ha, 14 days apart | |
| Root crops   | Potato | 1 x 8.0 kg a.s./ha; soil treatment | 127 |
| Potato - supportive | 1 x 3.36 kg a.s./ha; In-furrow soil treatment | 84 |
| Potato - supportive | 1 x 0.56 kg a.s./ha and 4x1.12 kg a.s./ha; foliar treatment | 13 |
| Leafy crops | Tobacco - supportive | 1 x 10 mg a.s./plant; foliar treatment | 7, 15 |
| Tobacco - supportive | 1x 6 mg a.s/kg; soil treatment | 21 |
| Tobacco - supportive | 1 x 6.7 kg a.s./ha; soil treatment | 30 (harvest) |
| Pulses/Oilseeds | Peanut-supportive | 1 x 2.24 kg a.s./ha; foliar treatment | 28 (harvest) |
| Peanut-supportive | 1 x 1.68 kg a.s./ha; pre-planting (in furrow) + 2 x 1.12 kg a.s./ha; foliar treatment | 40, 70 |
| Bean and cotton seedlings-supportive | 15 and 20 µL of a 10% aqueous solution; stem injection | 1,3, 7, 15 (bean) |

Rotational crops
(metabolic pattern)
OECD Guideline 502

| Crop groups | Crop(s) | PBI (days) | Comments |
|-------------|---------|------------|----------|
| Root/tuber crops | Beets roots and leaves | 30, 120, 363 | Bare soil application of 1-14C Oxamyl at different
### Rotational crop and primary crop metabolism similar?

The proposed metabolic pathway of oxamyl in rotational crops is consistent with the pathway observed in primary crops following oxamyl application at planting or post-emergence.

### Processed commodities (standard hydrolysis study)

**OECD Guideline 507**

| Conditions | Oxamyl (% AR) | IN-A2213 (% AR) |
|------------|---------------|-----------------|
| 20 min, 90°C, pH 4 | 100 | 0 |
| 60 min, 100°C, pH 5 | 57.80 | 41.42 |
| 20 min, 120°C, pH 6 | 0 | 100 |

AR: Applied radioactivity

With increasing temperatures, oxamyl was found to be increasingly labile with a rapid degradation to IN-A2213 (oxamyl oxime).

### Plant residue definition for monitoring (RD-Mo)

**OECD Guidance, series on pesticides No 31**

| Plant residue definition for risk assessment (RD-RA) |
|-----------------------------------------------------|
| Primary crops: Oxamyl – Provisional\(^{(1)}\) – Limited to the representative uses |
| Rotational crops: Oxamyl – Provisional\(^{(1)}\) |

Conversion factor (monitoring to risk assessment)

\(^{(1)}\): Data gap: Residue datasets on tomatoes and potatoes compliant with the respective GAPs for the determination of the residues of the compounds (IN-D2708, IN-A2213, IN-QKT34 (IN-A2213 glucoside conjugate) and IN-N0079) that are relevant for these crops.

Data gap: Rotational crops field trials covering the NEU and SEU zones for the determination of the residues of oxamyl and of the metabolites IN-D2708, IN-A2213, IN-QKT34 (IN-A2213 glucoside conjugate) and IN-N0079 in the edible parts of the representative rotational crops at the shortest PBI of 30 days.

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| Leafy crops | Cereal (small grain) | Other | dose rates of application covering the maximum seasonal rates of application for the representative uses (1.5-3.2N rate). |
|-------------|----------------------|-------|------------------------------------------------------------------|
| cabbage, lettuce | Barley | sorghum | 30, 120, 363 | 30, 120, 363 | 30, 120 |
Metabolism in livestock (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.2, 6.2.3, 6.2.4, 6.2.5 6.7.1)

| OECD Guideline 503 and SANCO/11187/2013 rev. 3 (fish) | Animal | Dose (mg/kg bw/d) | Duration (days) | N rate/comment |
|------------------------------------------------------|--------|-------------------|-----------------|---------------|
| Animals covered                                      | Laying hen 2.4 mg/kg bw/d | 3 | Open(2) |
|                                                      | Goat/Cow 1.6 mg/kg bw/d | 5 | Open(2) |
|                                                      | Pig - | - | - |
|                                                      | Fish - | - | Open(2) |

Time needed to reach a plateau concentration in milk and eggs (days)
Animal residue definition for monitoring (RD-Mo)
OECD Guidance, series on pesticides No 31
Animal residue definition for risk assessment (RD-RA)
Conversion factor (monitoring to risk assessment)
Metabolism in rat and ruminant similar (Yes/No)
Fat soluble residues (Yes/No)
(FAO, 2009)

(2): Pending the outcome of the requested field residue trials on potatoes and rotational crops to conclude whether the residue levels of oxamyl and the relevant metabolites may lead to a significant livestock dietary intake (>0.004 mg/kg bw per day) that trigger the setting of residue definitions for products of animal origin - see also footnote (1).

Oxamyl: No – based on the log Pow<3
Thiocyanate: open
Residues in succeeding crops (Regulation (EU) N° 283/2013, Annex Part A, point 6.6.2)

Confined rotational crop study (Quantitative aspect) OECD Guideline 502

- In the confined rotational crops metabolism studies following soil treatments at 9 and 18 kg oxamyl/ha, respectively, oxamyl, IN-A2213, and IN-D2708 were identified at concentrations >0.01 mg/kg (oxamyl equivalents) in barley forage, straw, chaff and grain, sorghum fodder/seed, beet root and leaves, cabbage and lettuce commodities planted 30 and 120 days after treatment.

- In additional confined rotational crops metabolism studies following bare soil treatment at 8 kg a.s./ha, at 30 d PBI, oxamyl was recovered in barley forage, hay and straw but not in grain. The structure of the following identified metabolites IN-D2708, IN-A2213, IN-QKT34 and IN-N0079 was fully elucidated. Metabolites IN-KP532, IN-T2921 and IN-L2953 were tentatively identified in barley crop parts. These components have been previously identified in primary crops metabolism studies, and all were present in the soil at planting.

Field rotational crop study OECD Guideline 504

- In four northern EU residue trials, oxamyl residues were determined in rotational crops planted in a field that had previously contained potatoes treated with Oxamyl 10GR applied at planting at 5.0–5.5 kg a.s./ha. Oxamyl residues in succeeding crops (lettuce, carrot roots and tops, and cereal grain, hay, and straw) planted 80 and 120 days after Oxamyl 10GR application and harvested at maturity were <0.007 mg/kg.

- In two southern EU residue trials, oxamyl residues were determined in rotational crops planted in protected plots that had previously contained melons treated with Oxamyl 10SL applied at 6.0 kg a.s./ha/season. Oxamyl residues in succeeding crops (lettuce and radish roots and radish tops) planted ca. 30, 60, 90, and 120 days after Oxamyl 10SL application and harvested at maturity were <0.007 mg/kg.

Data gap: rotational crops field trials covering the NEU and SEU zones are required to analyse the residues of oxamyl and the metabolites IN-D2708, IN-A2213, IN-QKT34 (IN-A2213 glucoside conjugate) and IN-N0079 in the edible parts of the representative rotational crops at the shortest PBI of 30 days.

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

| Plant products | Category | Commodity | T (°C) | Stability period Value | Compounds covered | Comment/Source |
|----------------|----------|-----------|--------|------------------------|-------------------|----------------|
|                |          |           |        |                        |                   |                |

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| (available studies) | Leaf lettuce | -18 | 24 Months | Oxamyl | - |
|---------------------|--------------|-----|-----------|--------|---|
| Tomato fruit        |              | 24  | Months    | Oxamyl  | - |
| High water content  | Potato tuber | -18 | 24 Months | Oxamyl  | - |
| High starch content | Sugarbeet    | 24  | Months    | Oxamyl  | - |
| High acid content   | Orange fruit | -20 | 12 Months | Oxamyl  | - |
| Others              | Tobacco      | -20 | 6 Months  | Oxamyl  | - |
|                     | leaves, dried|     |           |        |   |

| Animal products (available studies) | Animal | Commodity | T (°C) | Stability period | Compounds covered | Comment/ Source |
|------------------------------------|--------|-----------|--------|------------------|-------------------|-----------------|
|                                    |        |           | Value  | Unit             |                   |                 |
| Not submitted.                     |        |           |        |                  |                   |                 |

The need to provide and assess livestock feeding studies supported by acceptable storage stability data is pending the finalisation of the livestock dietary burden calculation and a reassessment of the livestock metabolism studies – see footnotes (1) and (2).
Summary of residues data from the supervised residue trials (Regulation (EU) N° 283/2013, Annex Part A, point 6.3) OECD Guideline 509, OECD Guidance, series on pesticides No 66 and OECD MRL calculator
| Crop | Region/Indoor (a) | Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs (b) | Recommendations/comments (OECD calculations) | MRL proposals (mg/kg) | HR (mg/kg) (c) | STMR (mg/kg) (d) |
|------|------------------|-------------------------------------------------------------------------------------------------|---------------------------------------------|----------------------|----------------|------------------|
|      |                  |                                                                                  |                                             |                      |                |                  |

**Representative uses**
### Crop Residue Levels and Recommendations

| Crop     | Region/Indoor | Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs (a) | Recommendations/comments (OECD calculations) | MRL proposals (mg/kg) | HR (mg/kg) (c) | STMR (mg/kg) (d) |
|----------|---------------|------------------------------------------------------------------------------------------------|-----------------------------------------------|----------------------|----------------|------------------|
| Potato   | NEU           | -                                                                                               | No GAP compliant residue trials available.    | 0.01* (provisional)  | 0.01 (provisional) | 0.01 (provisional) |

**Data gap:**
A complete residue dataset on potatoes, compliant with the representative use and analysing the residues of the compounds (IN-D2708, IN-A2213, IN-QKT34 (IN-A2213 glucoside conjugate) and IN-N0079) relevant for this crop is required. These trials should be supported by acceptable storage stability data.

**Data gap:**
Sufficient GAP-compliant residue trials on potatoes should be provided to confirm the residues of oxamyl to be below the LOQ as observed from the metabolism data.
### Crop Region/Indoor Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs (b) Recommendations/comments (OECD calculations) MRL proposals (mg/kg) HR (mg/kg) (c) STMR (mg/kg) (d)

| Crop         | Region/Indoor | Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs | Recommendations/comments (OECD calculations) | MRL proposals (mg/kg) | HR (mg/kg) (c) | STMR (mg/kg) (d) |
|--------------|---------------|-------------------------------------------------------------------------------------------------|-----------------------------------------------|----------------------|----------------|------------------|
| Tomato       | Indoor        | Oxamyl residues: 9x<0.01 (tomatoes); 8x<0.01 (cherry tomatoes)                                  | Data gap:                                    | 0.01* (provisional) | 0.01           | 0.01             |
|             |               |                                                                                                 | A complete residue dataset on tomatoes, compliant with the representative use and analysing for the predominant compounds of the residues in tomato fruits, i.e. IN-D2708, IN-A2213, IN-QKT34 (IN-A2213 glucoside conjugate) and IN-N0079 should be provided. These trials should be supported by acceptable storage stability data. |
| Tobacco      | SEU           | Oxamyl residues: 3x<0.01                                                                         |                                               | 0.01*                | 0.01           | 0.01             |
| Solarization | Indoor        | Oxamyl residues: Cherry tomatoes: 2x<0.01 Courgettes: 2x<0.01                                    | Data gap:                                    | 0.01* (provisional) | 0.01           | 0.01             |
|             |               |                                                                                                 | In accordance with the current recommendations, at least 2 additional GAP compliant residue trials on tomatoes and cucumbers and analysing for oxamyl residues should be provided to confirm that no quantifiable residues are expected in fruiting vegetables when oxamyl is applied in accordance with the representative use on solarization. Possible extrapolation to the whole group of fruiting vegetables, except sweet corn. |

**Summary of the data on formulation equivalence OECD Guideline 509**
## Summary of data on residues in pollen and bee products (Regulation (EU) No 283/2013, Annex Part A, point 6.10.1)

| Product(s) | Region | Residue data (mg/kg) | Recommendations/comments |
|------------|--------|----------------------|-------------------------|
| Data not triggered for the representative uses on tomatoes, potatoes and tobacco as these crops have low or no melliferous capacity (low attractivity for pollen collection and not relevant at all for nectar collection). However, and pending upon the magnitude of residues of the relevant metabolites in rotational crops (see data gap under footnote (1)), the residues in pollen and bee products might need to be addressed. |

(a): **NEU** or **SEU** for northern or southern outdoor trials in EU member states (N+SEU if both zones), **Indoor** for glasshouse/protected crops, **Country** if non-EU location.  
(b): Residue levels in trials conducted according to GAP reported in ascending order (e.g. 3x <0.01, 0.01, 6x 0.02, 0.04, 0.08, 3x 0.10, 2x 0.15, 0.17). When residue definition for monitoring and risk assessment differs, use **Mo/RA** to differentiate data expressed according to the residue definition for Monitoring and Risk Assessment.  
(c): **HR**: Highest residue. When residue definition for monitoring and risk assessment differs, HR according to residue definition for monitoring reported in brackets (**HR_{Mo}**).  
(d): **STMR**: Supervised Trials Median Residue. When residue definition for monitoring and risk assessment differs, STMR according to definition for monitoring reported in brackets (**STMR_{Mo}**).
## Inputs for animal burden calculations

| Feed commodity          | Median dietary burden | Maximum dietary burden |
|-------------------------|-----------------------|------------------------|
|                         | (mg/kg)               | (mg/kg)                |
|                         | Comment               | Comment                |
| **Representative uses** |                       |                        |
| Potato tubers           | Open$^{(2)}$          | Open$^{(2)}$           |
| Rotational crops feed items | Open$^{(2)}$          | Open$^{(2)}$           |
Residues from livestock feeding studies (Regulation (EU) No 283/2013, Annex Part A, points 6.4.1, 6.4.2, 6.4.3 and 6.4.4)

OECD Guideline 505 and OECD Guidance, series on pesticides No 73

| MRL calculations                  | Ruminant | Pig/Swine | Poultry | Fish                  |
|-----------------------------------|----------|-----------|---------|-----------------------|
| **Highest expected intake (mg/kg bw/d)** | Beef cattle 0.0012 | Ram/Ewe 0.0016 | Breeding 0.0010 | Broiler 0.0005, Carp |
| (mg/kg DM for fish)               | Dairy cattle 0.0015 | Lamb 0.0011 | Finishing 0.0008 | Layer 0.0005, Trout |
| Intake >0.004 mg/kg bw            | Open(2) | Open(2) | Open(2) | Open(2) |
| Feeding study submitted           | Open(2) | | | |

Intake >0.004 mg/kg bw
Open(2)

Fish intake >0.1 mg/kg DM
Processing factors (Regulation (EU) N° 283/2013, Annex Part A, points 6.5.2 and 6.5.3)

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

| Crop (RAC)/Edible part or Crop (RAC)/Processed product | Number of tests(a) | Processing Factor (PF) | Conversion Factor (CF<sub>P</sub>) for RA(b) |
|--------------------------------------------------------|--------------------|-----------------------|------------------------------------------|
|                                                        |                    | Individual values | Median PF |                                |
|                                                        |                    | 3                    | <0.1, 0.08, 0.15 | 0.08 |
|                                                        |                    | 3                    | 3 x <0.1 | <0.1 |
|                                                        |                    | 3                    | 3 x <0.1 | <0.1 |

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

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

Consumer risk assessment limited to the representative uses

The consumer dietary risk assessment could not be concluded since the risk assessment residue definition for primary and rotational crops could not be finalised in view of the identified data gaps.

ADI

TMDI (% ADI), according to EFSA PRIMo rev. 3.1

Highest TMDI: 90% of the ADI (GEMS/Food G06)

TMDI (% ADI), according to EFSA PRIMo rev. 2A

Highest TMDI: 83.5% of the ADI (WHO Cluster diet B)

IEDI (% ADI), according to EFSA PRIMo

Highest IEDI: Not conducted since TMDI <100% of the ADI

Factors included in the calculations

Risk assessment input value for oxamyl: STMR: 0.01 mg/kg for all crops.

ARfD

IESTI (% ARfD, according to EFSA PRIMo rev. 3.1

Highest IESTI:

Potato: 1538% ARfD (children)
Watermelons: 1223% ARfD (children)
Cucumbers: 656% ARfD (children)
Tomato: 581.5% ARfD (children)
Watermelons: 406% (adults)
Potatoes: 298% (adults)
Tomatoes: 159% (adults)

IESTI (% ARfD, according to EFSA PRIMo rev. 2A

Highest IESTI:

1538% of the ARfD (potatoes; UK infant)
1516% of the ARfD (melons; BE children)
630% of the ARfD (peppers; DE children)
581.5% of the ARfD (tomatoes; BE children)

Factors included in IESTI and NESTI

Risk assessment input value for oxamyl: HR: 0.01 mg/kg for all crops.

Additional contribution to the consumer intakes through drinking water resulting from groundwater metabolite(s) expected to be present above 0.75 µg/L

Metabolite(s)

IN-D2708 and IN-A2213 are expected to be present in groundwater above 0.75 µg/L, at levels of 7.527 µg/L and 0.98 µg/L, respectively (see Section 4)

ADI (mg/kg bw per day)

ADI of 0.0001 mg/kg bw per day as derived for Oxamyl is applicable to both metabolites (see section 2).

Groundwater intake (% ADI)

Assessment according consumption figures reported in WHO guideline (WHO, 2009)

IN-D2708:
A global exposure of the consumers to IN-A2213 and IN-D2708 residues through dietary intake and drinking water in compliance with the Guidance document (EC, 2003) could not be carried out in view of the identified data gaps.

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

| Code<sup>(a)</sup> | Commodity/Group | MRL/Import tolerance<sup>(b)</sup> (mg/kg) and Comments |
|-------------------|-----------------|-----------------------------------------------------|
| **Plant commodities** | | |
| 0211000 | Potato | 0.01* | Provisional |
| 0231010 | Tomato | 0.01* | Provisional |
| 0230000 | Fruiting vegetables, except sweet corn - Solarization | 0.01* | Provisional |
| | Tobacco | 0.01* | |
| **Animal commodities** | | |
| No MRL proposals - see footnotes<sup>(1)</sup> and<sup>(2)</sup> |

(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005

(b): MRLs proposed at the LOQ, should be annotated by an asterisk (*) after the figure.
### Section 4: Environmental fate and behaviour

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

| Mineralisation after 100 days | 17.9 – 35.2% AR at Day 90 (n=9, duration 123 – 179 days); 25.6 – 52.1% AR at Day 123 (n=9, duration 123 – 179 days) |
| Non-extractable residues after 100 days | 15.3–19.3% AR at Day 90 (n=9, duration 123–179 days); 15.4–20.7% AR at Day 123 (n=9, duration 123–179 days). |
| Metabolites requiring further consideration - name and/or code, % of applied (range and maximum) | **IN-A2213** : maximum 5 – 51.0 % after 2 – 60 d, [14C-oxamyl]-label (n= 10 incubations; 9 soils tested – 7 soils incubated at 20 °C, 1 soil incubated at 10 °C and 20 °C, 1 soil incubated at 25 °C) |
|  | **IN-D2708** : maximum 20.3 – 78 % after 7 – 90 d, [14C-oxamyl]-label (n= 10 incubations; 9 soils tested – 7 soils incubated at 20 °C, 1 soil incubated at 10 °C and 20 °C, 1 soil incubated at 25 °C) |

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

| Mineralisation after 100 days | 12 – 21 % after 71 d, [14C-oxamyl]-label (n= 2 soils tested – 11 days aerobic incubation followed by 60 days anaerobic incubation at 25 °C) |
| Non-extractable residues after 100 days | 18.4 – 25 % after 71 d, [14C-oxamyl]-label (n= 2 soils tested – 11 days aerobic incubation followed by 60 days anaerobic incubation at 25 °C) |
| Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum) | **IN-D2708 (DMOA)** : 20 – 23.1 % at 45 and 32 d, [14C-oxamyl]-label (n= 2 soils tested – 11 days aerobic incubation followed by 60 days anaerobic incubation at 25 °C) |
|  | **IN-A2213 (Oxime)** : 13 – 69.5 % at 11 and 20 d, [14C-oxamyl]-label (n= 2 soils tested – 11 days aerobic incubation followed by 60 days anaerobic incubation at 25 °C) |
Route of degradation (photolysis) on soil (Regulation (EU) No 283/2013, Annex Part A, point 7.1.1.3)

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

| Metabolite | % after d, [14C-oxamyl]-label | n=1 irradiated samples |
|------------|-------------------------------|-----------------------|
| IN-D2708   | maximum 45.4 % after 15 d     | 14C-oxamyl-label      |
| IN-N0079   | maximum 8.7 % after 5 d       | 14C-oxamyl-label      |

Mineralisation at study end

| Metabolite | % after 15d, [14C-oxamyl]-label | n=1 irradiated samples |
|------------|---------------------------------|-----------------------|
| IN-D2708   | 17.5 %                          | 14C-oxamyl-label      |
| IN-N0079   | 4.1 %                           | 14C-oxamyl-label      |

Rate of degradation in soil (aerobic) laboratory studies active substance (Regulation (EU) No 283/2013, Annex Part A, point 7.1.2.1.1 and Regulation (EU) No 284/2013, Annex Part A, point 9.1.1.1)

Normalized modeling endpoints for oxamyl

| Oxamyl | Dark aerobic conditions |
|--------|-------------------------|
| Soil type | pH | t.°C/|% MWHC | DT50 (d) | St. | Method of calculation |
| Silt loam (Commerce) | 7.0 | 20°C/33.3 | 1.8 | 20°C pF2/10kPa<sup>2</sup> | SFO |
| Silt loam (Gross-Umstadt) | 7.8 | 20°C/50 | 3.3 | 6.2 | SFO |
| Silty clay loam (Drummer#6) | 4.8 | 20°C/49.4 | 83.2 | 2.2 | SFO |
| Sandy loam caly (Madera) | 7.7 | 25°C/15.4 | 11.4 | 5.5 | SFO |
| Loam (Nijmegen) | 7 | 20°C/33.3 | 5 | 6.6 | SFO |
| Silt loam (Goch) | 6 | 20°C/pF 2 | 0.6 | 0.7 | SFO |
| Sandy loam (LRA-D) | 5.6 | 20°C/pF 2 | 19.4 | 3.3 | FOMC DegT50/3.32 |
| Loamy sand (Speyer 582) | 6.4 | 20°C/pF 2 | 19.4 | 3.3 | FOMC DegT50/3.32 |
| Silty clay loam (Tama) | 7 | 20°C/pF 2 | 14.3 | 5.7 | SFO |
| Sandy loam (Ottersun, NL)<sup>d</sup> | 6.5 | 20°C/pF 2 | 14.3 | 5.7 | SFO |
| Silty loam (Spalding, UK)<sup>d</sup> | 7.4 | 20°C/pF 2 | 6.9 | 8.2 | DFOP |
| Geometric mean (if not pH dependent) | 6.7<sup>c</sup> | | | | |
| pH dependence | No clear pH dependence<sup>e</sup> | |

a) Measured in water
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
c) Geometric mean calculated combining the two DegT50 values from the field studies with lab studies, following the EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2014;12(5):3662, 37 pp., doi:10.2903/j.efsa.2014.3662.
d) Field dissipation studies
e) No clear pH dependency of the soil degradation can be established, and then potential pH dependency of the soil degradation of oxamyl in acidic soils should be investigated (data gap).

Non-normalized persistence endpoints for oxamyl

| Oxamyl | Dark aerobic conditions |
|--------|-------------------------|
| Soil type | pH | t.°C | DT50/DT90 (d) | St. |
| Silt loam (Commerce) | 7.0 | 20°C/33.3 | | |
| Silt loam (Gross-Umstadt) | 7.8 | 20°C/50 | | |
| Silty clay loam (Drummer#6) | 4.8 | 20°C/49.4 | | |
| Sandy loam caly (Madera) | 7.7 | 25°C/15.4 | | |
| Loam (Nijmegen) | 7 | 20°C/33.3 | | |
| Silt loam (Goch) | 6 | 20°C/pF 2 | | |
| Sandy loam (LRA-D) | 5.6 | 20°C/pF 2 | | |
| Loamy sand (Speyer 582) | 6.4 | 20°C/pF 2 | | |
| Silty clay loam (Tama) | 7 | 20°C/pF 2 | | |
| Sandy loam (Ottersun, NL)<sup>d</sup> | 6.5 | 20°C/pF 2 | | |
| Silty loam (Spalding, UK)<sup>d</sup> | 7.4 | 20°C/pF 2 | | |
### Rate of degradation in soil (aerobic) laboratory studies transformation products (Regulation (EU) No 283/2013, Annex Part A, point 7.1.2.1.2 and Regulation (EU) No 284/2013, Annex Part A, point 9.1.1.1)

| Soil type                      | pH | t.°C | DT50 (d) | DT90 (d) | Method of calculation |
|--------------------------------|----|------|----------|----------|-----------------------|
| Commerce                       | 7  | 20°C | 2.8/9.3  | 7.8      | SFO-SFO               |
| Silt loam (Commerce)           | 7  | 10°C | 15.8/52.3| 4.4      | SFO-SFO               |
| Silt loam (Gross-Unstadt)      | 7.8| 20°C | 4.0/13.3 | 4.4      | SFO-SFO               |
| Silty clay loam (Drummer#6)    | 4.8| 20°C | 115.3/370.5| 2.2   | SFO-SFO               |
| Sandy loam caly (Madera)       | 7.7| 25°C | 11.1/36.8| 5.5      | SFO-SFO               |
| Loam (Nijmegen)                | 7  | 20°C | 7.8/25.8 | 6.6      | SFO-SFO               |
| Silt loam (Goch)               | 6  | 20°C | 0.6/2.0  | 0.7      | SFO-SFO               |
| Sandy loam (LRA-D)             | 5.6| 20°C | 9.7/79.5 | 2.8      | DFOP-SFO              |
| Loamy sand (Speyer 582)        | 6.4| 20°C | 7.2/24.0 | 5.2      | SFO-SFO               |
| Silty clay loam (Tama)         | 7  | 20°C | 7.8/48.5 | 3.3      | FOMC-SFO              |
| Sandy loam (Ottersun, NL)      | 6.5| 20°C | 9.5/31.4 | 7.2      | SFO-SFO               |
| Silty loam (Spalding, UK)      | 7.4| 20°C | 0.7/30.6 | 8.9      | DFOP-SFO              |
| Worst-case                     |    |      |          | 111.5    | SFO-SFO               |

a) Measured in water  
b) Based on the longest DT50 from Drummer#6 soil  
c) Field dissipation studies

d) Field dissipation studies

### Normalized modeling endpoints for IN-A2213

| Soil type                      | pH | t°C/| f. f | DT50 (d) | DT90 (d) | Method of calculation |
|--------------------------------|----|-----|------|----------|----------|-----------------------|
| Derived from laboratory or field studies dosed with oxamyl |
| Commerce                       | 7  | 20°C/33.3 | 0.98 | 3.6      | 6.3      | SFO-SFO               |
| Gross-Umstadt                  | 7.8| 20°C/50  | 0.98 | 1.3      | 11.8     | SFO-SFO               |
| Madera (25°C)                  | 7.7| 25°C/75  | 1.0  | 6.7      | 14.7     | SFO-SFO               |
| Nijmegen                       | 7  | 20°C/33.3 | 1    | 1.1      | 23.2     | SFO-SFO               |
| Speyer 582                     | 6.4| 20°C/pF 2 | 0.75 | 1.4      | 16.3     | SFO-SFO               |
| Tama 583                       | 7  | 20°C/pF 2 | 0.86 | 1.8      | 17       | FOMC-SFO              |
| Sandy loam (Ottersun, NL)      | 6.5| 20°C/pF 2 | 0.77 | 0.8      | 16.9     | SFO-SFO               |
| Silty loam (Spalding, UK)      | 7.4| 20°C/pF 2 | -    | 8.8      | 13       | SFO                   |
| Geometric mean (if not pH dependent) |    |    |      | 2.2      |          |                      |
| Maximum                        |    |    |      |          |          |                      |
| pH dependence                  |    |    |      |          | No       |                      |

a) Measured in water  
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7  
c) Geometric mean calculated combining the two DegT50 values from the field studies with lab studies, following the EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2014;12(5):3662, 37 pp., doi:10.2903/j.efsa.2014.3662.

d) Field dissipation studies

### Non-normalized persistence endpoints for IN-A2213

| Soil type                      | pH | t.°C | DT50/DT90 (d) | St. | Method of calculation |
|--------------------------------|----|------|---------------|-----|-----------------------|
| Derived from the studies dosed with oxamyl |
| Silt loam (Commerce)           | 7  | 20°C | 5.8/19.1      | 6.3 | SFO-SFO               |
| Silt loam (Commerce)           | 7  | 10°C | 22.1/73.3     | 7.5 | SFO-SFO               |
### Normalized modeling endpoints for IN-D2708

| Soil type | pH | t.°C/% MWHC | f. f. | DT\(_{50}\) (d) | St. | Method of calculation |
|-----------|----|-------------|------|----------------|-----|---------------------|
| Derived from the laboratory studies dose with oxamyl | | | | | | |
| Tama 583 | 7 | 20°C/pF 2 | 1 | 6.8 | 15.7 | FOMC-SFO |
| Commerce | 7 | 20°C/33.3 | - | 2.2 | 18.1 | SFO-SFO |
| Gross-Umstadt | 7.8 | 20°C/50 | - | 2.6 | 17.9 | SFO-SFO |
| Madera | 7.7 | 25°C/75 | 1.0 | 4.9 | 25.9 | SFO-SFO |
| Nijmegen | 7 | 20°C/33.3 | 0.73 | 5.7 | 9 | SFO-SFO |
| LRA-D 588 | 5.6 | 20°C/pF2 | 0.51 | 53.6 | 3.9 | FOMC-DFOP-SFO |
| Speyer 582 | 6.4 | 20°C/pF2 | 1 | 77 | 5.5 | SFO-SFO |
| Derived from the field studies dose with IN-D2708 | | | | | | |
| Commerce | 7 | 20°C/33.3 | - | 4.8 | 17.7 | SFO |
| Gross-Umstadt | 7.8 | 20°C/50 | - | 8.5 | 15.1 | SFO |
| Drummer | 4.8 | 20°C/49.4 | - | 10.6 | 14.7 | SFO |
| Derived from the field studies dose with oxamyl | | | | | | |
| Sandy loam (Ottersun, NL)\(^{c}\) | 6.5 | 20°C/pF 2 | 1 | 2.9 | 11.5 | SFO-SFO |
| Silty loam (Spalding, UK)\(^{c}\) | 7.4 | 20°C/pF 2 | - | 4.7 | 14.4 | SFO |
| Geometric mean (if not pH dependent) | | | | | | 8.4\(^{d}\) |
| Maximum | | | | | | 1 |

a) Measured in water
b) Normalized using a Q10 of 2.58 and Walker equation coefficient of 0.7
c) Geometric mean calculated for Commerce and Gross

### Non-normalized persistence endpoints for IN-D2708

| Soil type | pH\(^{e}\) | t.°C | DT\(_{50}\)/DT\(_{90}\) | St. | Method of calculation |
|-----------|----|------|----------------|-----|---------------------|
| Derived from the laboratory studies dose with oxamyl | | | | | | |
| Commerce | 7 | 20°C | 3.5/11.8 | 18.1 | SFO-SFO |
| Gross-Umstadt | 7.8 | 20°C | 3.1/10.4 | 17.9 | SFO-SFO |
| Madera | 7.7 | 25°C | 4.8/15.9 | 25.9 | SFO-SFO |
| Nijmegen | 7 | 20°C | 8.8/29.4 | 9 | SFO-SFO |
| Tama 583 | 7 | 20°C | 6.8/22.4 | 15.7 | FOMC-SFO |
| LRA-D 588 | 5.6 | 20°C | 53.6/178.1 | 3.9 | FOMC-DFOP-SFO |

a) Measured in water
b) Normalized using a Q10 of 2.58 and Walker equation coefficient of 0.7
c) Geometric mean calculated combining the two DegT50 values from the field studies with lab studies, following the EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2014;12(5):3662, 37 pp., doi:10.2903/j.efsa.2014.3662.
### Rate of degradation field soil dissipation studies (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.1)

| Soil type                              | Location                        | pH \(^a\) | Depth (cm) | DT\(_{50}\) (d) actual | DT\(_{90}\) (d) actual | St. (\(\chi^2\)) | DT\(_{50}\) (d) Norm\(^b\)) | St. (\(\chi^2\)) | Method of calculation |
|----------------------------------------|---------------------------------|------------|------------|-------------------------|-----------------------|-------------------|-----------------------------|-------------------|-----------------------|
| Ottersum (bare soil; incorporated)     | Netherlands                     | 6.6        | 0-90       | 9.5                     | 31.4                  | 7.2               | 5.0                         | 5.7               | SFO                   |
| Spalding (bare soil; incorporated)     | United Kingdom                  | 7.27       | 0-90       | 0.7                     | 30.6                  | 8.9               | 6.9                         | 8.2               | DFOP slow phase        |
| Greenhouse (bare soil and planted with cucumbers, chemigation) | Spain                           | 7.79       | 0-90       | 3.3                     | 10-12                 | \(r^2 = 0.98\)   | -                           | -                 | SFO                   |
| Greenhouse (bare soil and planted with cucumbers, chemigation) | Italy                           | 7.4        | 0-90       | 5.3                     | 18                    | \(r^2 = 0.97\)   | -                           | -                 | SFO                   |

**Geometric mean (if not pH dependent):** 6.0\(^c\)

| pH dependence | Not possible to determine |
|---------------|---------------------------|

\(^a\) Measured in calcium chloride solution

\(^b\) FOCUS evaluation. Values are normalised using a Q\(_{10}\) of 2.58 and Walker equation coefficient of 0.7, values are DegT_{Staurs}.

\(^c\) Based on the field trials from the Netherlands and the UK. Dissipation in greenhouses in Spain and Italy was not kinetically evaluated based on the recent FOCUS kinetics guidance.
### IN-A2213

| Soil type                                      | Location                  | pH \(^{a}\) | Depth (cm) | DT\(_{50}\) (d) actual | DT\(_{50}\) (d) Norm\(^{b}\) | St. \(\chi^2\) | St. \(\chi^2\) | f. f. \(k_{d}/k_{dp}\) | Method of calculation |
|-----------------------------------------------|---------------------------|-------------|------------|------------------------|-----------------------------|----------------|----------------|-----------------------|----------------------|
| Ottersum (bare soil; incorporated)            | Netherlands               | 6.6 (0-15 cm) | 0 - 90     | 1.4                    | 4.6                         | 16.8           | 0.8            | 16.9                  | 0.77 SFO-SFO          |
| Spalding (bare soil; incorporated)            | United Kingdom            | 7.27 (0 - 15 cm) | 0 - 90     | 17.5                   | 58.0                        | 14.4           | 8.8            | 13.0                  | SFO                  |
| Greenhouse (bare soil and planted with cucumbers, chemigation) | Italy                    | 7.4 (0 - 10 cm) | 0 - 90     | 5.7                    | -                           | -              | -              | -                     | SFO                  |

**Soil type**

- Aerobic conditions precursor from which the f.f. was derived was oxamyl

**Location**

- Ottersum (bare soil; incorporated)
- Spalding (bare soil; incorporated)
- Greenhouse (bare soil and planted with cucumbers, chemigation)
- Greenhouse (bare soil and planted with cucumbers, chemigation)

**pH dependence**

- Not possible to determine

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

- 4.8 \(^{c}\)

**Single value**

- 0.77

**IN-D2708**

| Soil type                                      | Location                  | pH \(^{a}\) | Depth (cm) | DT\(_{50}\) (d) actual | DT\(_{50}\) (d) Norm\(^{b}\) | St. \(\chi^2\) | St. \(\chi^2\) | f. f. \(k_{d}/k_{dp}\) | Method of calculation |
|-----------------------------------------------|---------------------------|-------------|------------|------------------------|-----------------------------|----------------|----------------|-----------------------|----------------------|
| Ottersum (bare soil; incorporated)            | Netherlands               | 6.6 (0-15 cm) | 0 - 90     | 5.0                    | 16.6                        | 13.3           | 2.9            | 11.5                  | 1.0 (fixed) SFO-SFO       |
| Spalding (bare soil; incorporated)            | United Kingdom            | 7.27 (0 - 15 cm) | 0 - 90     | 9.1                    | 30.1                        | 14.7           | 4.7            | 14.4                  | SFO                  |
| Greenhouse (bare soil and planted with cucumbers, chemigation) | Spain                    | 7.79 (0 - 10 cm) | 0 - 90     | 0.52                   | -                           | -              | -              | -                     | SFO                  |
| Greenhouse (bare soil and planted with cucumbers, chemigation) | Italy                    | 7.4 (0 - 10 cm) | 0 - 90     | 3.2                    | -                           | -              | -              | -                     | SFO                  |

**Soil type**

- Aerobic conditions precursor from which the f.f. was derived was IN-A2213

**Location**

- Ottersum (bare soil; incorporated)
- Spalding (bare soil; incorporated)
- Greenhouse (bare soil and planted with cucumbers, chemigation)
- Greenhouse (bare soil and planted with cucumbers, chemigation)

**pH dependence**

- Not possible to determine

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

- 4.8 \(^{c}\)

**Single value**

- 1.0

**Combined laboratory and field kinetic endpoints for modelling (when not from different populations)**

Modeling is based on the combined laboratory and field kinetic endpoints as they are considered not significantly different
Soil accumulation (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.2)

Oxamyl is not expected to be accumulated based on its short half-life in the aerobic laboratory and field dissipation studies. Plateau concentration of 4.000 mg/kg reached after 1 year (worst case result calculated for tobacco use at 1 × 3 kg a.s./ha based on the spreadsheet).

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

| Parent | Dark anaerobic conditions |
|--------|--------------------------|
| Soil type | pH$^{a1}$ | t.$^\circ$C/% MWHC | DT$_{50}$/DT$_{90}$ (d) | DT$_{50}$ (d) 20$^\circ$C$^{b}$ | $\chi^2$ (%) | Method of calculation |
| Madera | 7.7 | 25$^\circ$C/50-50% | 5.8/19.2 | n.a. | 10.8 | SFO |
| Geometric mean (if not pH dependent) | | | | | | |

a) Measured in water  
b) Normalised using a Q$_{10}$ of 2.58

| IN-A2213 | Dark anaerobic conditions |
|----------|--------------------------|
| Soil type | pH$^{a1}$ | t.$^\circ$C/% MWHC | DT$_{50}$/DT$_{90}$ (d) | DT$_{50}$ (d) 20$^\circ$C$^{b}$ | $\chi^2$ (%) | Method of calculation |
| Madera | 7.7 | 25$^\circ$C/50-50% | 27.7/91.9 | n.a. | 5.6 | SFO |
| Geometric mean (if not pH dependent) | | | | | | |

a) Measured in water  
b) Normalised using a Q$_{10}$ of 2.58

| IN-D2708 | Dark anaerobic conditions |
|----------|--------------------------|
| Soil type | pH$^{a1}$ | t.$^\circ$C/% MWHC | DT$_{50}$/DT$_{90}$ (d) | DT$_{50}$ (d) 20$^\circ$C$^{b}$ | $\chi^2$ (%) | Method of calculation |
| Madera | 7.7 | 25$^\circ$C/50-50% | * | | | |
| Geometric mean (if not pH dependent) | | | | | | |

a) Measured in water  
b) Normalised using a Q$_{10}$ of 2.58  
*The kinetic analysis with decline phase data for metabolite IN-D2708 was not considered acceptable

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

| Parent | Dark anaerobic conditions |
|--------|--------------------------|
| Soil type | pH$^{a1}$ | t.$^\circ$C/% MWHC | DT$_{50}$/DT$_{90}$ (d) calculated at 40$^\circ$N | f. f. k$_{f}$ /k$_{dp}$ | DT$_{50}$ (d) 20$^\circ$C pF2/10kPa | St. ($\chi^2$) | Method of calculation |
| Tama | 6.7 | 21$^\circ$C/75% FC | 4.6/15.2 | - | 3.8 | 4.5 | SFO |
| IN-N0079 | | | | | | | |
| Soil type | pH$^{a1}$ | t.$^\circ$C/% MWHC | DT$_{50}$/DT$_{90}$ (d) calculated at 40$^\circ$N | f. f. k$_{f}$ /k$_{dp}$ | DT$_{50}$ (d) 20$^\circ$C pF2/10kPa$^{b}$ | St. ($\chi^2$) | Method of calculation |
| Tama | 6.7 | 21$^\circ$C/75% FC | 2/6.5 | 0.35 | 1.6 | 18.0 | SFO-SFO |

a) Measured in water
Soil adsorption active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

| Soil Type                        | OC % | Soil pH<sup>a</sup> | K<sub>d</sub> (mL/g) | K<sub>doc</sub> (mL/g) | K<sub>F</sub> (mL/g) | K<sub>Foc</sub> (mL/g) | l/n       |
|----------------------------------|------|---------------------|----------------------|-----------------------|---------------------|------------------------|----------|
| Silt clay loam (Drummer, 20°C)   | 2.6  | 4.8                 | 0.44                 | 17                    | 0.41                | 16                     | 0.99     |

Geometric mean (if not pH dependent): -

Arithmetic mean (if not pH dependent):

Default low K<sub>Foc</sub>: 10<sup>b</sup> 1.0<sup>b</sup>

Default high K<sub>Foc</sub>: 10000<sup>b</sup> 1.0<sup>b</sup>

pH dependence: No

<sup>a</sup> Measured in water

<sup>b</sup> The default K<sub>Foc</sub> of 10 L/kg and 10000 L/kg with 1/n of 1.0 are used for exposure modeling as agreed during the Pesticides Peer Review Experts’ Meeting TC 61 in September 2021. As only one soil at 20°C is available for deriving adsorption endpoints, reliable batch adsorption experiments at 20°C on at least three additional soils should be provided (data gap).

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

| Soil Type                    | OC % | Soil pH<sup>a</sup> | K<sub>d</sub> (mL/g) | K<sub>doc</sub> (mL/g) | K<sub>F</sub> (mL/g) | K<sub>Foc</sub> (mL/g) | l/n       |
|------------------------------|------|---------------------|----------------------|-----------------------|---------------------|------------------------|----------|
| Silt loam (Mattapex)         | 2.5  | 6.9                 | 0.107                | 4.31                  | 0.119               | 4.8                    | 0.89     |
| Loam (Nijmegen)              | 1.4  | 7.0                 | 0.067                | 4.78                  | 0.052               | 3.7                    | 1.06     |
| Loam (Commerce)              | 0.5  | 5.8                 | 0.051                | 10.91                 | 0.048               | 10.3                   | 1.24     |
| Silt loam (Gross Umstadt)    | 1.1  | 7.5                 | 0.108                | 9.80                  | 0.113               | 10.2                   | 0.87     |
| Silt loam (Drummer)          | 3.7  | 5.8                 | 0.200                | 5.48                  | 0.203               | 5.6                    | 1.07     |

Geometric mean (if not pH dependent): 0.09 6.37

Arithmetic mean (if not pH dependent): 1.03

pH dependence: No

<sup>a</sup> Measured in water

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

| Soil Type                    | OC % | Soil pH<sup>a</sup> | K<sub>d</sub> (mL/g) | K<sub>doc</sub> (mL/g) | K<sub>F</sub> (mL/g) | K<sub>Foc</sub> (mL/g) | l/n       |
|------------------------------|------|---------------------|----------------------|-----------------------|---------------------|------------------------|----------|
| Silt loam (Mattapex)         | 2.5  | 6.9                 | 0.09                 | 3.56                  | 0.17                | 7.0                    | 0.592    |
| Loam (Nijmegen)              | 1.4  | 7.0                 | 0.03                 | 1.94                  | 0.08                | 5.5                    | 0.727    |
| Loam (Commerce)              | 0.5  | 5.8                 | 0.05                 | 9.73                  | 0.05                | 11.1                   | 0.728    |
| Silt loam (Gross Umstadt)    | 1.1  | 7.5                 | 0.07                 | 6.79                  | 0.15                | 13.9                   | 0.532    |
| Silt loam (Drummer)          | 3.7  | 5.8                 | 0.31                 | 8.57                  | 0.39                | 10.7                   | 0.762    |

Geometric mean (if not pH dependent): 0.13 9.13

Arithmetic mean (if not pH dependent): 0.67

pH dependence: No

<sup>a</sup> Measured in water

Mobility in soil column leaching active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

| Soil Type                    | OC % | Soil pH<sup>a</sup> | K<sub>d</sub> (mL/g) | K<sub>doc</sub> (mL/g) | K<sub>F</sub> (mL/g) | K<sub>Foc</sub> (mL/g) | l/n       |
|------------------------------|------|---------------------|----------------------|-----------------------|---------------------|------------------------|----------|
| Silt loam (Mattapex)         | 2.5  | 6.9                 | 0.09                 | 3.56                  | 0.17                | 7.0                    | 0.592    |
| Loam (Nijmegen)              | 1.4  | 7.0                 | 0.03                 | 1.94                  | 0.08                | 5.5                    | 0.727    |
| Loam (Commerce)              | 0.5  | 5.8                 | 0.05                 | 9.73                  | 0.05                | 11.1                   | 0.728    |
| Silt loam (Gross Umstadt)    | 1.1  | 7.5                 | 0.07                 | 6.79                  | 0.15                | 13.9                   | 0.532    |
| Silt loam (Drummer)          | 3.7  | 5.8                 | 0.31                 | 8.57                  | 0.39                | 10.7                   | 0.762    |

Geometric mean (if not pH dependent): 0.13 9.13

Arithmetic mean (if not pH dependent): 0.67

pH dependence: No

<sup>a</sup> Measured in water

Column leaching: It was not necessary to conduct such a study since reliable absorption coefficient values have been obtained.
Mobility in soil column leaching transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Column leaching

It was not necessary to conduct such a study since reliable absorption coefficient values have been obtained.

Lysimeter/field leaching studies (Regulation (EU) N° 283/2013, Annex Part A, points 7.1.4.2/7.1.4.3 and Regulation (EU) N° 284/2013, Annex Part A, points 9.1.2.2/9.1.2.3)

Lysimeter/field leaching studies

Neither lysimeter nor field leaching studies were conducted for oxamyl. Data from the adsorption/desorption studies, the aerobic soil degradation studies, and field dissipation studies can be used to adequately define the leaching potential of oxamyl and its metabolites in soil.

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

| pH | Reaction Conditions | DT\textsubscript{50} at 20°C | DT\textsubscript{50} at 20°C (1\textsuperscript{st} order, r\textsuperscript{2}=0.9965) | DT\textsubscript{90} at 20°C (1\textsuperscript{st} order, r\textsuperscript{2}=0.9926) |
|----|-------------------|-----------------|-----------------|-----------------|
| pH 4: | Stable at 20°C | 21.1 | 62.7 % AR at day 29.67 | 66.6 % AR at day 0.34 |
| pH 7: | | 21.1 | 62.7 % AR at day 29.67 | 66.6 % AR at day 0.34 |
| pH 9: | | 0.2 | 67.6 % AR at day 10 (n = 2) | 66.6 % AR at day 0.34 |

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

Photolytic degradation of active substance and metabolites above 10 %

Quantum yield of direct phototransformation in water at Σ >290 nm

Not calculated as oxamyl does not have any significant absorbance at wavelengths >290 nm

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

Readily biodegradable (yes/no)

no

Aerobic mineralisation in surface water (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.1)

| Parent | pH\textsubscript{water} | pH\textsubscript{sed} | t°C | DT\textsubscript{50}/DT\textsubscript{90} | St. (χ\textsuperscript{2}) | DT\textsubscript{50}/DT\textsubscript{90} | St. (χ\textsuperscript{2}) | Method of calculation |
|--------|-----------------|-----------------|-----|-----------------|-----------------|-----------------|-----------------|-----------------|
| Fresh water Chula Pond | 7.2 | na | 20 | 6.68 | 22.2 | 14.2 | 47.5 | 6.04 | SFO |

a) Temperature of incubation= std temperature of 20°C
b) DT\textsubscript{50}/DT\textsubscript{90} was normalized to 12°C with a Q10 of 2.58, in accordance with ECHA R11 PBT guidance (See notices from the European Commission in the Official Journal of the European Union 2013/C 95/01).
### IN-A2213

| System identifier | pH water phase | pH sed | t.°C<sup>a</sup> | DT₅₀/DT₉₀ whole sys. (suspended sediment test) | Normalised to x°C<sup>c</sup> | St. DT₅₀ (χ²) | DT₅₀/DT₉₀ Water (pelagic test) | Normalised to x°C<sup>c</sup> | St. DT₅₀ (χ²) | Method of calculation |
|------------------|---------------|--------|-----------------|---------------------------------------------|-----------------------------|-------------|---------------------------------|-----------------------------|-------------|----------------------|
| Fresh water Chula Pond | 7.2 | na | 20 | na | na | - | Not evaluated | Not evaluated | - | - |

<sup>a</sup> Temperature of incubation = std temperature of 20°C

#### Mineralisation and non-extractable residues (for parent dosed experiments)

| System identifier (indicate fresh, estuarine or marine) | pH water phase | pH sed | Mineralisation (end of the study) | Non-extractable residues. max x % after n d (suspended sediment test) | Non-extractable residues. max x % after n d (end of the study) (suspended sediment test) |
|---------------------------------------------------------|---------------|--------|---------------------------------|-------------------------------------------------|---------------------------------------------------------------------|
| Fresh water Chula Pond | 7.2 | na | 5.2% after 60 d. | na– no extractions performed | na– no extractions performed |

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

| Parent | Modelling endpoints | Distribution (Max. sed 1.2 %AR after 61 d in Red Oak Stream) |
|--------|---------------------|-------------------------------------------------------------|
| Water/sediment system | pH water phase | pH sed | t.°C | DT₅₀ whole sys. | St. DT₅₀ (χ²) | DT₅₀ | St. DT₅₀ (χ²) | DT₅₀/DT₉₀ | St. DT₅₀ (χ²) | Method of calculation<sup>a</sup> |
| Red Oak Stream | 7.3 | 6.7 | 20 | 0.69/2.28 | 8.4 | 0.69/2.28 | 8.4 | na | - | SFO, SFO |
| Town Park Pond | 7.5 | 6.1 | 20 | 0.82/8.31 | 5.9 | 0.82/8.31 | 5.1 | na | - | HS, HS |
| Worst case DT₅₀ at 20°C | 0.82/8.31 | - | 0.82/8.31 | - | na |

<sup>a</sup> The kinetic models are indicated for the whole system, water, and sediment phase respectively.

| Parent | Persistence endpoints | Distribution (Max. sed 1.2 %AR after 61 d in Red Oak Stream) |
|--------|-----------------------|-------------------------------------------------------------|
| Water/sediment system | pH water phase | pH sed | t.°C | DT₅₀ / DT₉₀ whole sys. | St. DT₅₀ / DT₉₀ (χ²) | DT₅₀ / DT₉₀ water | St. DT₅₀ / DT₉₀ (χ²) | DT₅₀ / DT₉₀ sed | St. DT₅₀ / DT₉₀ (χ²) | Method of calculation<sup>a</sup> |
| Red Oak Stream | 7.3 | 6.7 | 20 | 0.82/8.31 | 5.9 | 0.82/8.31 | 5.1 | na | - | HS, HS |
| Town Park Pond | 7.5 | 6.1 | 20 | 0.69/2.28 | 8.4 | 0.69/2.28 | 8.4 | na | - | SFO, SFO |
| Worst case at 20°C | 0.82/8.31 | - | 0.82/8.31 | - | na |

<sup>a</sup> The kinetic models are indicated for the whole system, water, and sediment phase respectively.
## IN-A2213

### Modelling endpoints.
- Distribution (max in water 48.8 %AR after 2 d, max in sed 4.4 %AR after 2 d; both in Red Oak Stream), leading to max in total system of 53.2 %AR after 2 days.
- Kinetic formation fraction in total system: from oxamyl of 0.83 (Red Oak Stream) and 0.35 (Red Oak Stream) respectively.

### Water/sediment system

| System          | pH water phase | pH sed | t°C | DT$_{50}$ whole sys. | St. ($\chi^2$) | DT$_{50}$ water | St. ($\chi^2$) | DT$_{50}$ sed | St. ($\chi^2$) | Method of calculation$^a$ |
|-----------------|----------------|--------|-----|----------------------|----------------|----------------|----------------|----------------|----------------|---------------------------|
| Red Oak Stream  | 7.3            | 6.7    | 20  | 13.95                | 5.90           | 14.16          | 6.07           | 11.62         | 7.94           | all SFO, decline fits    |
| Town Park Pond  | 7.5            | 6.1    | 20  | 6.65                 | 8.51           | 6.50           | 9.51           | 7.29           | 5.00           | all SFO, decline fits    |

**Geometric mean DT$_{50}$ at 20°C**

| System          | DT$_{50}$ at 20°C |
|-----------------|-------------------|
|                 | 9.6               |

$^a$The kinetic pathway fit or decline fit models are indicated for the whole system, water, and sediment phase respectively.

## IN-A2213

### Persistence endpoints.

### Water/sediment system

| System          | pH water phase | pH sed | t°C | DT$_{50}$ / DT$_{90}$ whole sys. | St. ($\chi^2$) | DT$_{50}$ / DT$_{90}$ water | St. ($\chi^2$) | DT$_{50}$ / DT$_{90}$ sed | St. ($\chi^2$) | Method of calculation$^a$ |
|-----------------|----------------|--------|-----|----------------------------------|----------------|-----------------------------|----------------|----------------------------|----------------|---------------------------|
| Red Oak Stream  | 7.3            | 6.7    | 20  | 8.24/27.38                      | 6.30           | 14.16/47.05                 | 6.07           | 11.62/38.61                | 7.94           | HS-SFO, SFO, SFO decline fits |
| Town Park Pond  | 7.5            | 6.1    | 20  | 5.67/18.84                      | 10.5           | 6.50/21.58                  | 9.51           | 5.15/28.10                 | 8.00           | SFO-SFO, SFO, HS, decline fits |

**Worst case at 20°C**

| System          | DT$_{50}$ / DT$_{90}$ whole sys. | St. ($\chi^2$) | DT$_{50}$ / DT$_{90}$ water | St. ($\chi^2$) | DT$_{50}$ / DT$_{90}$ sed | St. ($\chi^2$) | Method of calculation$^a$ |
|-----------------|----------------------------------|----------------|-----------------------------|----------------|----------------------------|----------------|---------------------------|
|                 | 8.24/27.38                       | -              | 14.16/47.05                 | -              | 11.62/38.61                | -              | -                         |

$^a$The kinetic pathway fit or decline fit models were indicated for the whole system, water, and sediment phase respectively.

## IN-D2708

### Modelling endpoints.
- Distribution (max in water 66.8 %AR after 30 d, max in sed 12.1 %AR after 61 d; Red Oak Stream/Town Park Pond, respectively). Max in total system of 77.2 %AR after 30 days (Red Oak Stream).
- Kinetic formation fraction in total system: from IN-A2213 of 1.00 in both systems and from IN-T2921 of 1.00 in both systems

### Water/sediment system

| System          | pH water phase | pH sed | t°C | DT$_{50}$ whole sys. | St. ($\chi^2$) | DT$_{50}$ water | St. ($\chi^2$) | DT$_{50}$ sed | St. ($\chi^2$) | Method of calculation$^b$ |
|-----------------|----------------|--------|-----|----------------------|----------------|----------------|----------------|----------------|----------------|---------------------------|
| Red Oak Stream  | 7.3            | 6.7    | 20  | na                   | na             | na             | -              | na             | -              | SFO-SFO                  |
| Town Park Pond  | 7.5            | 6.1    | 20  | 185.73               | 11.95          | na             | -              | na             | -              | SFO-SFO                  |

**Single value DT$_{50}$ at 20°C**

| System          | DT$_{50}$ at 20°C |
|-----------------|-------------------|
|                 | 185.73            |

$^a$The default DegT$_{90}$ of 1000 days for IN-D2708 is used for modelling as DegT$_{90}$ from single water/sediment system was derived.

$^b$The kinetic pathway fit or decline fit models are indicated for the whole system, water, and sediment phase respectively.

## IN-D2708

### Persistence endpoints.

### Water/sediment system

| System          | pH water phase | pH sed | t°C | DT$_{50}$ / DT$_{90}$ whole sys. | St. ($\chi^2$) | DT$_{50}$ / DT$_{90}$ water | St. ($\chi^2$) | DT$_{50}$ / DT$_{90}$ sed | St. ($\chi^2$) | Method of calculation$^a$ |
|-----------------|----------------|--------|-----|----------------------------------|----------------|-----------------------------|----------------|----------------------------|----------------|---------------------------|
| Red Oak Stream  | 7.3            | 6.7    | 20  | na                               | na             | na                          | -              | na                        | -              | -                         |
| Town Park Pond  | 7.5            | 6.1    | 20  | 185.73/617                      | 11.95          | na                          | -              | na                        | -              | SFO-SFO                  |

**Single value DT$_{50}$ at 20°C**

| System          | DT$_{50}$ at 20°C |
|-----------------|-------------------|
|                 | 185.73/617        |

$^a$The kinetic pathway fit or decline fit models were indicated for the whole system, water, and sediment phase respectively.
### Modelling endpoints.

**IN-N0079**

Distribution (max in water 52.9 %AR after 2 d, max in sed 3.7 %AR after 7 d; both in Town Park Pond). Max in total system of 54.2 %AR after 2 days (Town Park Pond). Kinetic formation fraction in total system: from oxamyl of 0.17 (Red Oak Stream) and 0.65 (Town Park Pond); arithmetic mean is 0.41.

| Water/sediment system | pH water phase | pH sed | t°C | DT$_{50}$ whole sys. (χ²) | DT$_{50}$ water (χ²) | DT$_{50}$ sed (χ²) | Method of calculation | Worst-case DT$_{50}$ at 20°C |
|-----------------------|---------------|--------|-----|---------------------------|---------------------|-------------------|----------------------|--------------------------|
| Red Oak Stream        | 7.3           | 6.7    | 20  | 4.69/15.58                | 1.36                | 4.26              | 0.71                 | 17.79/59.08              |
| Town Park Pond        | 7.5           | 6.1    | 20  | 8.80/18.99                | 8.07                | 16.8              | 11.38/16.66          |

Worst-case DT$_{50}$ at 20°C: 6.42/8.07/17.79

a) The kinetic pathway fit or decline fit models are indicated for the whole system, water, and sediment phase respectively.

### Persistence endpoints.

**IN-N0079**

| Water/sediment system | pH water phase | pH sed | t°C | DT$_{50}$ / DT$_{90}$ whole sys. (χ²) | DT$_{50}$ / DT$_{90}$ water (χ²) | DT$_{50}$ / DT$_{90}$ sed (χ²) | Method of calculation | Worst case at 20°C |
|-----------------------|---------------|--------|-----|-------------------------------------|----------------------------------|-------------------------------|----------------------|-------------------|
| Red Oak Stream        | 7.3           | 6.7    | 20  | 4.69/15.58                          | 1.36                            | 4.26                          | 0.71                 | 17.79/59.08       |
| Town Park Pond        | 7.5           | 6.1    | 20  | 8.80/18.99                          | 8.07                            | 16.8                          | 11.38/16.66         |

Worst case at 20°C: 8.53/28.34/17.79

a) The kinetic pathway fit or decline fit models are indicated for the whole system, water, and sediment phase respectively.

### Modelling endpoints.

**IN-T2921**

Distribution (max in water 11.4 %AR after 14 d, max in sed 0.4 %AR after 14 d; Town Park Pond). Max in total system of 11.8 %AR after 14 days. Kinetic formation fraction (k$_{f}$/k$_{dp}$) in total system: from IN-N0079 of 1.00 (Red Oak Stream) and of 0.64 (Town Park Pond).

| Water/sediment system | pH water phase | pH sed | t°C | DT$_{50}$ / DT$_{90}$ whole sys. (χ²) | DT$_{50}$ / DT$_{90}$ water (χ²) | DT$_{50}$ / DT$_{90}$ sed (χ²) | Method of calculation | Single value DT$_{50}$ at 20°C |
|-----------------------|---------------|--------|-----|-------------------------------------|----------------------------------|-------------------------------|----------------------|-----------------|
| Red Oak Stream        | 7.3           | 6.7    | 20  | 27.31/90.71                         | 19.67                            | na                           | -                    | 19.67           |
| Town Park Pond        | 7.5           | 6.1    | 20  | na/na                               | na/na                            | -                            | SFO-SFO              |

Single value DT$_{50}$ at 20°C: 27.31

a) The default DegT$_{50}$ of 1000 days for IN-T2921 is used for modelling as DegT$_{50}$ from single water/sediment system was derived.

### Persistence endpoints.

**IN-T2921**

| Water/sediment system | pH water phase | pH sed | t°C | DT$_{50}$ / DT$_{90}$ whole sys. (χ²) | DT$_{50}$ / DT$_{90}$ water (χ²) | DT$_{50}$ / DT$_{90}$ sed (χ²) | Method of calculation | Single value DT$_{50}$ at 20°C |
|-----------------------|---------------|--------|-----|-------------------------------------|----------------------------------|-------------------------------|----------------------|-----------------|
| Red Oak Stream        | 7.3           | 6.7    | 20  | 27.31/90.71                         | 19.67                            | na                           | -                    | 19.67           |
| Town Park Pond        | 7.5           | 6.1    | 20  | na/na                               | na/na                            | -                            | SFO-SFO              |

Single value DT$_{50}$ at 20°C: 27.31

a) The kinetic pathway fit or decline fit models are indicated for the whole system, water, and sediment phase respectively.
Mineralisation and non extractable residues (from parent dosed experiments)

| Water/sediment system | pH water phase | pH sed | Mineralisation (end of the study) | Non-extractable residues in sed. max % after 100 d | Non-extractable residues in sed. max % end of the study (after 100 d) |
|-----------------------|--------------|-------|---------------------------------|----------------------------------------|------------------------------------------|
| Red Oak Stream        | 7.3          | 6.7   | 60.9                            | 18                                     | 18                                       |
| Town Park Pond        | 7.5          | 6.1   | 27.9                            | 9                                      | 9                                        |

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

| Fate and behaviour in air | Description |
|---------------------------|-------------|
| Direct photolysis in air  | Not studied - no data requested |
| Photochemical oxidative degradation in air | DT$_{50}$ of 5.68 hours derived by the Atkinson model (version 1.83). OH (12) concentration assumed = 1.5 x 10$^6$ |
| Volatilisation            | Study not needed based on low measured vapour pressure |
| Metabolites               | Oxamyl does not produce any volatile metabolites |

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

| Residues requiring further assessment | Description |
|--------------------------------------|-------------|
| Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure | Soil: Oxamyl, IN-A2213 and IN-D2708 Ground water: Oxamyl, IN-A2213, and IN D2708 Surface water: Oxamyl, IN-A2213, IN-D2708, IN-N0079, IN-T2921 Sediment: Oxamyl, IN-A2213, IN-D2708, IN-N0079, IN-T2921 Air: Oxamyl |

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

| Definition of the residue for monitoring | Description |
|-----------------------------------------|-------------|
| Parent oxamyl                           |             |

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

| Monitoring data, if available | Description |
|------------------------------|-------------|
| Soil (indicate location and type of study) | - |
| Surface water (indicate location and type of study) | - |
| Ground water (indicate location and type of study) | England and Wales groundwater monitoring (Environmental Agency, 2005–2011). |
| Air (indicate location and type of study) | - |
PEC\textsubscript{soil} (Regulation (EU) N° 284/2013, Annex Part A, points 9.1.3/9.3.1)

| Parent | Method of calculation |
|--------|------------------------|
|        | DT\textsubscript{50} (d): 111.5 days |
|        | Kinetics: SFO \*         |
|        | Worst case from lab studies for standard calculations |

| Application data | |
|------------------|------------------|
| Crop:            | potatoes at 1 $\times$ 1000 g a.s./ha (in-furrow) |
|                  | tobacco at 1 $\times$ 3000 g a.s./ha (in-furrow) |
|                  | tobacco at 1 $\times$ 5500 g a.s./ha (broadcast with immediate soil incorporation) |
| Greenhouse uses *| Depth of soil layer = evaluation depth: |
|                  | 5 cm for in-furrow application to tobacco |
|                  | 5 cm and 10 cm for in-furrow application to potatoes and broadcast application to tobacco |
|                  | Soil bulk density: 1.5 g/cm$^3$ |
|                  | % plant interception: no interception |

\* Oxamyl and the soil metabolites IN-A2213 and IN-D2708 are not persistent substances, thus no PEC\textsubscript{soil} calculations are necessary for indoor uses according to the EFSA Guidance Document on clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from protected crops [greenhouses and crops grown under cover] to relevant environmental compartments (EFSA Journal 2014;12[3]:3615, 43 pp., doi:10.2903/j.efsa.2014.3615): “For permanent structures a risk assessment is only necessary for persistent substances (DegT\textsubscript{90} >1 year from Uniform principles (Regulation (EU no. 546/2011))”.
### PEC_{\text{EC}_{10}} (mg/kg)

| Soil depth | Initial | Short term | Long term | Plateau concentration | PEC (accumulation) |
|------------|---------|------------|-----------|-----------------------|-------------------|
|            |         | 24h        | 2d        | 4d                    |                   |
| 5 cm       | 1.3333  | 1.3251     | 1.3169    | 1.3006                | 0.1538            |
|            | 0.6667  | 0.6625     | 0.6584    | 0.6503                | 0.0769            |
| 10 cm      | 0.6667  | 0.6625     | 0.6584    | 0.6503                | 0.7436            |

| Potatoes (in-furrow) | Tobacco (in-furrow) | Tobacco (broadcast) |
|-----------------------|---------------------|---------------------|
| Potatoes 1 x 1000 g a.s./ha | Tobacco 1 x 3000 g a.s./ha | Tobacco 1 x 5500 g a.s./ha |
| Single application Actual | Single application Time weighted average | Single application Actual |
| PEC_{\text{EC}_{10}} (mg/kg) |          |          |
| 0.7296 |          |          |
IN-A2213

Molecular weight relative to the parent: 0.740 (=162.2/219.3)

DT\textsubscript{50} (d): 17.5 days

Kinetics: SFO

Worst case from lab studies.

Application data

Application rate assumed:
- Potatoes 1 x 384.6 g/ha (in-furrow)
- Tobacco 1 x 1153.8 g/ha (in-furrow)
- Tobacco 1 x 2115.3 g/ha (broadcast)

(assumed IN-A2213 is formed at a maximum of 52.0 % of the applied dose)

| PEC\textsubscript{50} (mg/kg) | Potatoes (in-furrow) | Tobacco (in-furrow) | Tobacco (broadcast) |
|-----------------------------|----------------------|---------------------|---------------------|
|                             | Single application   | Single application  | Single application  |
|                             | Actual               | Time weighted       | Actual              | Time weighted   |
| Soil depth                  |                      |                     |                     |
| Initial                     | 5 cm                 |                     |                     |
| 24h                         | 0.4929               | 0.5028              | 1.4787              | 1.5084          | 2.7109          | 2.7653          |
| 2d                          | 0.4738               | 0.4930              | 1.4213              | 1.4791          | 2.6056          | 2.7116          |
| 4d                          | 0.4377               | 0.4742              | 1.3130              | 1.4227          | 2.4072          | 2.6084          |
| Short term                  |                      |                     |                     |
| 7d                          | 0.3886               | 0.4479              | 1.1659              | 1.3436          | 2.1375          | 2.4632          |
| 14d                         | 0.2945               | 0.3936              | 0.8836              | 1.1809          | 1.6199          | 2.1650          |
| 21d                         | 0.2232               | 0.3482              | 0.6696              | 1.0445          | 1.2277          | 1.9149          |
| 28d                         | 0.1692               | 0.3099              | 0.5075              | 0.9296          | 0.9304          | 1.7042          |
| 50d                         | 0.0708               | 0.2232              | 0.2123              | 0.6696          | 0.3893          | 1.2276          |
| 100d                        | 0.0098               | 0.1270              | 0.0293              | 0.3810          | 0.0537          | 0.6985          |
| Long term                   |                      |                     |                     |
| 7d                          | 0.1943               | 0.2239              | 0.5830              | 0.6718          | 1.0687          | 1.2316          |
| 14d                         | 0.1473               | 0.1968              | 0.4418              | 0.5905          | 0.8100          | 1.0825          |
| 21d                         | 0.1116               | 0.1741              | 0.3348              | 0.5222          | 0.6138          | 0.9575          |
| 28d                         | 0.0846               | 0.1549              | 0.2537              | 0.4648          | 0.4652          | 0.8521          |
| 50d                         | 0.0354               | 0.1116              | 0.1062              | 0.3348          | 0.1946          | 0.6138          |
| 100d                        | 0.0049               | 0.0635              | 0.0147              | 0.1905          | 0.0269          | 0.3493          |
| Soil depth                  |                      |                     |                     |
| Initial                     | 0.2564               | 0.7692              | 1.4102              |
| 24h                         | 0.2464               | 0.2514              | 0.7393              | 0.7542          | 1.3555          | 1.3827          |
| 2d                          | 0.2369               | 0.2465              | 0.7106              | 0.7395          | 1.3028          | 1.3558          |
| 4d                          | 0.2188               | 0.2371              | 0.6565              | 0.7114          | 1.2036          | 1.3042          |
| Short term                  |                      |                     |                     |
| 7d                          | 0.1943               | 0.2239              | 0.5830              | 0.6718          | 1.0687          | 1.2316          |
| 14d                         | 0.1473               | 0.1968              | 0.4418              | 0.5905          | 0.8100          | 1.0825          |
| 21d                         | 0.1116               | 0.1741              | 0.3348              | 0.5222          | 0.6138          | 0.9575          |
| 28d                         | 0.0846               | 0.1549              | 0.2537              | 0.4648          | 0.4652          | 0.8521          |
| 50d                         | 0.0354               | 0.1116              | 0.1062              | 0.3348          | 0.1946          | 0.6138          |
| 100d                        | 0.0049               | 0.0635              | 0.0147              | 0.1905          | 0.0269          | 0.3493          |
| Long term                   |                      |                     |                     |
| 7d                          | 0.1943               | 0.2239              | 0.5830              | 0.6718          | 1.0687          | 1.2316          |
| 14d                         | 0.1473               | 0.1968              | 0.4418              | 0.5905          | 0.8100          | 1.0825          |
| 21d                         | 0.1116               | 0.1741              | 0.3348              | 0.5222          | 0.6138          | 0.9575          |
| 28d                         | 0.0846               | 0.1549              | 0.2537              | 0.4648          | 0.4652          | 0.8521          |
| 50d                         | 0.0354               | 0.1116              | 0.1062              | 0.3348          | 0.1946          | 0.6138          |
| 100d                        | 0.0049               | 0.0635              | 0.0147              | 0.1905          | 0.0269          | 0.3493          |

Plateau concentration: Not accumulated
**IN-D2708**

Molecular weight relative to the parent: 0.534 (=117.1/219.3)

DT$_{50}$ (d): 77 days

Kinetics: SFO

Worst case from lab studies.

### Application data

Application rate assumed:
- Potatoes 420.2 g/ha (in-furrow)
- Tobacco 1260.7 g/ha (in-furrow)
- Tobacco 2311.3 g/ha (broadcast)

(assumed IN-D2708 is formed at a maximum of 78.7 % of the applied dose)

### PEC$_{50}$ (mg/kg)

| Soil depth | Potatoes (in-furrow) | Tobacco (in-furrow) | Tobacco (broadcast) |
|------------|----------------------|---------------------|---------------------|
|            | Single application | Single application | Single application | Single application | Single application |
|            | Actual   | Time weighted | Actual   | Time weighted | Actual   | Time weighted |
| Initial   | 0.5603   | 1.6809      | 3.0817   |              |              |              |
| Short term|          |             |          |              |              |              |
| 24h       | 0.5553   | 0.5578      | 1.6659   | 1.6734       | 3.0541     | 3.0679       |
| 2d        | 0.5503   | 0.5553      | 1.6510   | 1.6659       | 3.0267     | 3.0542       |
| 4d        | 0.5405   | 0.5503      | 1.6215   | 1.6510       | 2.9727     | 3.0269       |
| Long term|          |             |          |              |              |              |
| 7d        | 0.5261   | 0.5430      | 1.5783   | 1.6291       | 2.8935     | 2.9866       |
| 14d       | 0.4940   | 0.5264      | 1.4819   | 1.5793       | 2.7168     | 2.8954       |
| 21d       | 0.4638   | 0.5105      | 1.3914   | 1.5316       | 2.5509     | 2.8080       |
| 28d       | 0.4355   | 0.4953      | 1.3064   | 1.4858       | 2.3951     | 2.7240       |
| 50d       | 0.3572   | 0.4512      | 1.0717   | 1.3536       | 1.9648     | 2.4815       |
| 100d      | 0.2278   | 0.3694      | 0.6833   | 1.1083       | 1.2527     | 2.0318       |
| Plateau concentration | 0.0218 | - | 0.0653 | - | 0.1198 | - |

### Soil depth 10 cm

| Initial   | 0.2802   | 0.8405   | 1.5409   |
| Short term|          |          |          |
| 24h       | 0.2776   | 0.2789   | 0.8329   | 0.8367     | 1.5271     | 1.5339       |
| 2d        | 0.2752   | 0.2777   | 0.8255   | 0.8330     | 1.5134     | 1.5271       |
| 4d        | 0.2702   | 0.2752   | 0.8107   | 0.8255     | 1.4864     | 1.5135       |
| Long term|          |          |          |
| 7d        | 0.2630   | 0.2715   | 0.7891   | 0.8145     | 1.4468     | 1.4933       |
| 14d       | 0.2470   | 0.2632   | 0.7410   | 0.7897     | 1.3584     | 1.4477       |
| 21d       | 0.2319   | 0.2553   | 0.6957   | 0.7658     | 1.2755     | 1.4040       |
| 28d       | 0.2177   | 0.2476   | 0.6532   | 0.7429     | 1.1976     | 1.3620       |
| 50d       | 0.1786   | 0.2256   | 0.5359   | 0.6768     | 0.9824     | 1.2408       |
| 100d      | 0.1139   | 0.1847   | 0.3416   | 0.5541     | 0.6263     | 1.0159       |
| Plateau concentration | 0.0109 | - | 0.0327 | - | 0.0599 | - |
PEC ground water (Regulation (EU) N° 284/2013, Annex Part A, point 9.2.4.1)

Method of calculation and type of study (modelling)

| For FOCUSgw modelling, values used: |
|--------------------------------------|
| Models used: FOCUS PEARL 4.4.4, FOCUS PELMO 5.5.3 and FOCUS MACRO 5.5.4 |

Crop:
Field uses:
Potatoes at 1 × 1000 g a.s./ha (in-furrow)
Tobacco at 1 × 3000 g a.s./ha (in-furrow)
Tobacco at 1 × 5500 g a.s./ha (broadcast)

Greenhouse uses:
Tomatoes at 2000 + 1000 + 1000 + 1000 g a.s./ha
Solarisation at 5500 g a.s./ha

Crop uptake factor: 0 for oxamyl and for all metabolites

Water solubility (mg/L): 148100 at pH 4 and 20°C for oxamyl and metabolites

Vapour pressure: 1.8 × 10^-5 Pa at 20°C for oxamyl and metabolites

Half-lives (normalised to pH2, 20°C with Q10 of 2.58 and Walker equation coefficient 0.7):
Oxamyl DT50 lab 6.7 d (geometric mean)
IN-A2213 DT50 lab 2.2 d (geometric mean)
IN-D2708 DT50 lab 8.4 d (geometric mean)

KFOC and 1/n:
Oxamyl 10 ml/g and 10,000 ml/g (default values) and 1 (default value)
IN-A2213 6.37 mL/g (geometric mean) and 1.03 (arithmetic mean)
IN-D2708 9.13 mL/g (geometric mean) and 0.67 (arithmetic mean)

Formation fraction of metabolites:
IN-A2213 1.0 (from oxamyl)
IN-D2708 1.0 (from IN-A2213)

Application rate

Potatoes: 1 × 1000 g a.s./ha (in-furrow, at planting), 0% interception, soil incorporation into 10 cm, applications on 15-Apr (C), 01-May (H), 15-May (J), 01-May (K), 15-Apr (N), 01-Apr (P), 28-Feb (O), 15-Jan (S), 15-Feb (T)

Tobacco: 1 × 3000 g a.s./ha (in-furrow, pre-planting), 0% interception, 5 cm soil incorporation depth, applications on 20-May (P) and 01-May (T)
1 × 5500 g a.s./ha (broadcast, at planting), 0% interception, immediate soil incorporation into 10 cm (mixing with 10 cm soil), applications on 20-May (P) and 01-May (T)

Tomatoes 2000 + 1000 + 1000 + 1000 g a.s./ha, 10-days interval, at planting, 0% interception, application to soil surface, first applications on 10-May (C,P), 15-Mar (O), 15-Apr (S), 10-Apr (T).

Solarisation 5500 g a.s./ha – FOCUSgw crop tomatoes, 0% interception, application to soil surface, for all scenarios applications on 01-Jul and 01-Aug.

PECgw - FOCUS modelling results (80th percentile annual average concentration at 1 m)
Potatoes (in-furrow) at the rate of 1000 g a.s/ha
### FOCUS PEARL 4.4.4

Once every three years

| Scenario       | Oxamyl | IN-A2213 | IN-D2708 |
|----------------|--------|----------|----------|
| **K_{foc} of 10 mL/g** |        |          |          |
| Châteaudun     | 0.024  | 0.010    | 0.030    |
| Hamburg        | 0.117  | 0.048    | 0.228    |
| Jokioinen      | 0.109  | 0.047    | 0.057    |
| Kremsmünster   | 0.070  | 0.027    | 0.180    |
| Okehampton     | 0.080  | 0.034    | 0.211    |
| Piacenza       | 0.054  | 0.023    | 0.121    |
| Porto          | 0.124  | 0.059    | 0.043    |
| Sevilla        | 0.004  | 0.002    | 0.003    |
| Thiva          | <0.001 | <0.001   | <0.001   |

| **K_{foc} of 10,000 mL/g** |
|----------------------------|
| Châteaudun | <0.001 | <0.001   | <0.001   |
| Hamburg    | <0.001 | 0.001    | 0.017    |
| Jokioinen  | <0.001 | 0.008    | 0.002    |
| Kremsmünster | <0.001 | <0.001   | 0.011    |
| Okehampton | <0.001 | 0.001    | 0.024    |
| Piacenza   | <0.001 | 0.002    | 0.010    |
| Porto      | <0.001 | 0.003    | <0.001   |
| Sevilla    | <0.001 | <0.001   | <0.001   |
| Thiva      | <0.001 | <0.001   | <0.001   |

### FOCUS PELMO 5.5.3

Once every three years

| Scenario       | Oxamyl | IN-A2213 | IN-D2708 |
|----------------|--------|----------|----------|
| **K_{foc} of 10 mL/g** |        |          |          |
| Châteaudun     | 0.013  | 0.005    | 0.006    |
| Hamburg        | 0.064  | 0.027    | 0.039    |
| Jokioinen      | 0.213  | 0.100    | 0.128    |
| Kremsmünster   | 0.084  | 0.033    | 0.193    |
| Okehampton     | 0.130  | 0.054    | 0.291    |
| Piacenza       | 0.186  | 0.083    | 0.203    |
| Porto          | 0.359  | 0.191    | 0.087    |
| Sevilla        | 0.067  | 0.034    | 0.001    |
| Thiva          | 0.008  | 0.003    | <0.001   |

| **K_{foc} of 10,000 mL/g** |
|----------------------------|
| Châteaudun | <0.001 | <0.001   | <0.001   |
| Hamburg    | <0.001 | 0.001    | 0.002    |
| Jokioinen  | <0.001 | 0.031    | 0.013    |
| Kremsmünster | <0.001 | 0.002    | 0.012    |
| Okehampton | <0.001 | 0.006    | 0.035    |
| Piacenza   | <0.001 | 0.015    | 0.022    |
| Porto      | <0.001 | 0.029    | 0.002    |
| Sevilla    | <0.001 | 0.010    | <0.001   |
| Thiva      | <0.001 | 0.001    | <0.001   |

### FOCUS MACRO 5.5.3

Once every three years

| Scenario       | Oxamyl | IN-A2213 | IN-D2708 |
|----------------|--------|----------|----------|
| **K_{foc} of 10 mL/g** |        |          |          |
| Châteaudun     | 0.013  | 0.005    | <0.001   |

| **K_{foc} of 10,000 mL/g** |
|----------------------------|
| Châteaudun | <0.001 | <0.001   | <0.001   |
Tobacco (in-furrow) at the rate of 3000 g a.s./ha

| Scenario       | Oxamyl (µg/L) | IN-A2213 | IN-D2708 |
|----------------|---------------|----------|----------|
| **FOCUS PEARL 4.4.4** |               |          |          |
| K_{foc} of 10 mL/g |               |          |          |
| Piacenza       | 0.059         | 0.023    | 0.239    |
| Thiva          | <0.001        | <0.001   | <0.001   |
| K_{foc} of 10,000 mL/g |           |          |          |
| Piacenza       | <0.001        | <0.001   | 0.013    |
| Thiva          | <0.001        | <0.001   | <0.001   |

| **FOCUS PELMO 5.5.3** |       |          |          |
| K_{foc} of 10 mL/g |     |          |          |
| Piacenza       | 0.203         | 0.087    | 0.630    |
| Thiva          | <0.001        | <0.001   | <0.001   |
| K_{foc} of 10,000 mL/g |       |          |          |
| Piacenza       | <0.001        | 0.009    | 0.088    |
| Thiva          | <0.001        | <0.001   | <0.001   |

Tobacco (broadcast) at the rate of 1 \times 5500 g a.s./ha

| Scenario       | Oxamyl (µg/L) | IN-A2213 | IN-D2708 |
|----------------|---------------|----------|----------|
| **FOCUS PEARL 4.4.4** |               |          |          |
| K_{foc} of 10 mL/g |               |          |          |
| Piacenza       | 0.128         | 0.050    | 0.722    |
| Thiva          | <0.001        | <0.001   | <0.001   |
| K_{foc} of 10,000 mL/g |           |          |          |
| Piacenza       | <0.001        | <0.001   | 0.081    |
| Thiva          | <0.001        | <0.001   | <0.001   |

| **FOCUS PELMO 5.5.3** |       |          |          |
| K_{foc} of 10 mL/g |     |          |          |
| Piacenza       | 0.403         | 0.171    | 1.686    |
| Thiva          | <0.001        | <0.001   | <0.001   |
| K_{foc} of 10,000 mL/g |       |          |          |
| Piacenza       | <0.001        | 0.020    | 0.377    |
| Thiva          | <0.001        | <0.001   | <0.001   |

The 80th percentile annual average PEC_{gw} concentration for oxamyl and its soil metabolites following applications to tomatoes at 2000 + 1000 + 1000 + 1000 g a.s./ha, Tier 1
### 80th percentile annual average PEC_{gw} (μg/L)

| Scenario | Oxamyl | IN-A2213 | IN-D2708 |
|----------|--------|----------|----------|
| **FOCUS PEARL 4.4.4** |        |          |          |
| Châteaudun | 0.998  | 0.386    | 5.046    |
| Piacenza   | 0.282  | 0.110    | 1.197    |
| Porto      | 0.208  | 0.101    | 0.236    |
| Sevilla    | 0.003  | 0.001    | <0.001   |
| Thiva      | 0.004  | 0.001    | 0.002    |
| **K_{foc} of 10,000 mL/g** |        |          |          |
| Châteaudun | <0.001 | 0.001    | 0.789    |
| Piacenza   | <0.001 | <0.001   | 0.133    |
| Porto      | <0.001 | 0.009    | 0.014    |
| Sevilla    | <0.001 | <0.001   | <0.001   |
| Thiva      | <0.001 | <0.001   | <0.001   |
| **FOCUS PELMO 5.5.3** |        |          |          |
| Châteaudun | 0.496  | 0.200    | 1.912    |
| Piacenza   | 0.859  | 0.412    | 2.411    |
| Porto      | 1.814  | 0.980    | 0.805    |
| Sevilla    | 0.022  | 0.010    | 0.001    |
| Thiva      | 0.004  | 0.002    | <0.001   |
| **K_{foc} of 10,000 mL/g** |        |          |          |
| Châteaudun | <0.001 | 0.002    | 0.212    |
| Piacenza   | <0.001 | 0.062    | 0.299    |
| Porto      | <0.001 | 0.156    | 0.083    |
| Sevilla    | <0.001 | <0.001   | <0.001   |
| Thiva      | <0.001 | <0.001   | <0.001   |
| **FOCUS MACRO 5.5.4** |        |          |          |
| Châteaudun | 0.221  | 0.087    | 0.033    |
| **K_{foc} of 10000 mL/g** |        |          |          |
| Châteaudun | <0.001 | <0.001   | 0.033    |
The 80th percentile annual average PEC_{gw} concentration for oxamyl and its soil metabolites following application with solarisation at 1 x 5500 g a.s./ha, application on 1 July, Tier 1 (with tomatoes as open field scenario)

| Scenario | 80th percentile annual average PEC_{gw} (µg/L) | Oxamyl | IN-A2213 | IN-D2708 |
|----------|-----------------------------------------------|--------|----------|----------|
|          | **FOCUS PEARL 4.4.4**                          |        |          |          |
|          | \[K_{foc}\] of 10 mL/g                         |        |          |          |
| Châteaudun | 1.002                                         | 0.394  | 4.381    |          |
| Piacenza  | 0.243                                         | 0.095  | 0.581    |          |
| Porto     | 0.109                                         | 0.047  | 0.176    |          |
| Sevilla   | 0.008                                         | 0.004  | 0.001    |          |
| Thiva     | 0.050                                         | 0.019  | 0.170    |          |
|          | **FOCUS PELMO 5.5.3**                          |        |          |          |
|          | \[K_{foc}\] of 10 mL/g                         |        |          |          |
| Châteaudun | <0.001                                        | <0.001 | 0.702    |          |
| Piacenza  | <0.001                                        | 0.001  | 0.180    |          |
| Porto     | <0.001                                        | 0.002  | 0.034    |          |
| Sevilla   | <0.001                                        | <0.001 | <0.001   |          |
| Thiva     | <0.001                                        | <0.001 | 0.002    |          |
|          | **FOCUS MACRO 5.5.4**                          |        |          |          |
|          | \[K_{foc}\] of 10 mL/g                         |        |          |          |
| Châteaudun | 0.934                                         | 0.376  | 4.244    |          |
| Piacenza  | 0.946                                         | 0.396  | 3.276    |          |
| Porto     | 0.119                                         | 0.052  | 0.195    |          |
| Sevilla   | 0.004                                         | 0.002  | <0.001   |          |
| Thiva     | 0.069                                         | 0.026  | 0.121    |          |
|          | \[K_{foc}\] of 10,000 mL/g                     |        |          |          |
| Châteaudun | <0.001                                        | 0.001  | 0.391    |          |
| Piacenza  | <0.001                                        | 0.006  | 0.309    |          |
| Porto     | <0.001                                        | 0.003  | 0.050    |          |
| Sevilla   | <0.001                                        | <0.001 | <0.001   |          |
| Thiva     | <0.001                                        | <0.001 | <0.001   |          |
|          | **K_{foc}** of 10 mL/g                         |        |          |          |
| Châteaudun | 0.380                                         | 0.153  | 0.057    |          |
|          | \[K_{foc}\] of 10,000 mL/g                     |        |          |          |
| Châteaudun | <0.001                                        | 0.001  | 0.057    |          |
Peer review of the pesticide risk assessment of the active substance oxamyl

The 80th percentile annual average PECgw concentration for oxamyl and its soil metabolites following application with solarisation at 1 × 5500 g a.s./ha, application on 1 August, Tier 1 with tomatoes as the open field scenarios

| Scenario | 80th percentile annual average PECgw (μg/L) |
|----------|------------------------------------------|
|          | Oxamyl | IN-A2213 | IN-D2708 |
| FOCUS PEARL 4.4.4 |
| Kfoc of 10 mL/g |
| Châteaudun | 0.724 | 0.298 | 1.364 |
| Piacenza   | 1.747 | 0.719 | 7.527 |
| Porto      | 0.925 | 0.415 | 2.457 |
| Sevilla    | 0.050 | 0.021 | 0.026 |
| Thiva      | 0.202 | 0.078 | 0.391 |
| Kfoc of 10,000 mL/g |
| Châteaudun | <0.001 | 0.003 | 0.145 |
| Piacenza   | <0.001 | 0.036 | 3.530 |
| Porto      | <0.001 | 0.039 | 1.969 |
| Sevilla    | <0.001 | 0.001 | 0.006 |
| Thiva      | <0.001 | 0.001 | 0.001 |
| FOCUS PELMO 5.5.3 |
| Kfoc of 10 mL/g |
| Châteaudun | 0.500 | 0.208 | 0.759 |
| Piacenza   | 1.573 | 0.687 | 6.310 |
| Porto      | 0.953 | 0.442 | 2.608 |
| Sevilla    | 0.063 | 0.026 | 0.022 |
| Thiva      | 0.189 | 0.076 | 0.100 |
| Kfoc of 10,000 mL/g |
| Châteaudun | <0.001 | 0.003 | 0.087 |
| Piacenza   | <0.001 | 0.093 | 3.785 |
| Porto      | <0.001 | 0.095 | 2.522 |
| Sevilla    | <0.001 | 0.001 | 0.001 |
| Thiva      | <0.001 | 0.001 | 0.001 |
| FOCUS MACRO 5.5.4 |
| Kfoc of 10 mL/g |
| Châteaudun | 0.469 | 0.200 | 0.013 |
| Kfoc of 10000 mL/g |
| Châteaudun | <0.001 | 0.005 | 0.013 |
PEC surface water and PEC sediment (Regulation (EU) N° 284/2013, Annex Part A, points 9.2.5/9.3.1)

| Parent                  | Parameters used in FOCUS_sw step 1 and 2 |
|-------------------------|------------------------------------------|
|                         | Version control no. of FOCUS calculator: Steps 1-2 in FOCUS 3.2 |
|                         | Molecular weight (g/mol): 219.3          |
|                         | $K_{foc}$ (mL/g): 10 and 10000 L/kg (default) |
|                         | DT$_{soil}$ (d): 6.7 d (geometric mean, lab and field) |
|                         | DT$_{water/sediment}$ (d): 2.5 d (worst case from sediment water studies) |
|                         | DT$_{water}$ (d): 2.5 d                 |
|                         | DT$_{sediment}$ (d): 1000 d             |

| Parameters used in FOCUSsw step 3 |
|-------------------------------------|
| Version control no. of FOCUS software: FOCUS SWASH 5.3, FOCUS MACRO 5.5.4, FOCUS PRZM 4.3.1, FOCUS TOXSWA 5.5.3 and SWAN 5.0.1 |
| Water solubility (mg/L): 148100 at 20°C and pH 5 |
| Vapour pressure: $1.8 \times 10^{-5}$ Pa at 20°C |
| $K_{Foc}$ (mL/g): 10 and 10000 L/kg (default) |
| $1/n$: 1.0 (default) |
| $Q_{10}$: 2.58; Walker equation coefficient 0.7 |
| Crop uptake factor: 0.0 |

| Application rate |
|------------------|
| Crop and growth stage: |
| potatoes at $1 \times 1000$ g a.s./ha (in-furrow, at planting) |
| tobacco at $1 \times 3000$ g a.s./ha (in-furrow, pre-planting) |
| tobacco at $1 \times 5500$ g a.s./ha (broadcast, at planting) |
| Greenhouse uses: |
| Tomatoes $2000 + 1000 + 1000 + 1000$ g a.s./ha, 10-days interval (at planting) |
| Solarisation $5500$ g a.s./ha (no crop, application in July-August) |

Steps 1&2
Crop interception: 0% interception for all applications.
Dust drift for Oxamyl 10GR: as a conservative worst case, spray drift values for the open field uses
Spray drift for Oxamyl 10SL: zero drift
Region/period: Southern Europe and March-May represents the worst case for all proposed oxamyl uses

Step 3a
Dust drift for Oxamyl 10GR: worst case estimates for spinning disks provided in EFSA (2004)$^4$.
Conservative values for “application method”, CAM, and DEPI.

Step 4b
Broadcast application to tobacco: various NSZ

Summary of Step 1 and 2 calculations for oxamyl and its metabolites

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$^4$ EFSA (2004) Opinion of the Scientific Panel on Plant health, Plant protection products and their Residues on a request from EFSA on the appropriateness of using the current FOCUS surface water scenarios for estimating exposure risk assessment in aquatic ecotoxicology in the context of Council Directive 91/414/EEC. EFSA Journal 2004; 145. 31pp.
| Compound | Step 1 | Step 2 Southern Europe Mar-May |
|----------|--------|-------------------------------|
|          | PEC<sub>sw</sub> (µg/L) | PEC<sub>sed</sub> (µg/kg) | PEC<sub>sw</sub> (µg/L) | PEC<sub>sed</sub> (µg/kg) |
| **Potatoes 1 x 1000 g a.s./ha**<sup>a)</sup> |
| Oxamyl<sup>b)</sup> | 338.144 | 32.895 | 90.022 | 8.996 |
| Oxamyl<sup>c)</sup> | 32.453 | 2325.581 | 9.197 | 667.689 |
| IN-A2213 | 285.923 | 17.939 | 53.883 | 3.364 |
| IN-D2708 | 277.941 | 25.352 | 75.406 | 6.878 |
| IN-N0079 | 115.056 | 11.227 | 25.453 | 2.486 |
| IN-T2921<sup>d)</sup> | 20.344 | - | 4.827 | - |
| **Tobacco 1 x 3000 g a.s./ha**<sup>a)</sup> |
| Oxamyl<sup>b)</sup> | 1014.432 | 98.684 | 270.066 | 26.986 |
| Oxamyl<sup>c)</sup> | 97.357 | 6976.744 | 27.590 | 2003.067 |
| IN-A2213 | 857.770 | 53.818 | 161.648 | 10.093 |
| IN-D2708 | 833.823 | 76.063 | 226.218 | 20.635 |
| IN-N0079 | 345.167 | 33.682 | 76.359 | 7.457 |
| IN-T2921<sup>d)</sup> | 61.033 | - | 14.482 | - |
| **Tobacco 1 x 5500 g a.s./ha**<sup>a)</sup> |
| Oxamyl<sup>b)</sup> | 1859.792 | 180.921 | 495.121 | 49.475 |
| Oxamyl<sup>c)</sup> | 178.489 | 12790.698 | 50.582 | 3672.290 |
| IN-A2213 | 1572.579 | 98.667 | 296.354 | 18.504 |
| IN-D2708 | 1528.676 | 139.449 | 414.734 | 37.831 |
| IN-N0079 | 632.806 | 61.751 | 139.991 | 13.671 |
| IN-T2921<sup>d)</sup> | 111.894 | - | 26.551 | - |
| **Tomatoes in greenhouse 1 x 5000 (for 2000+1000+1000+1000) g a.s./ha**<sup>a)</sup> |
| Oxamyl<sup>b)</sup> | 1690.720 | 164.474 | 450.110 | 44.977 |
| Oxamyl<sup>c)</sup> | 162.262 | 11627.907 | 45.983 | 3338.445 |
| IN-A2213 | 1429.617 | 89.697 | 269.413 | 16.822 |
| IN-D2708 | 1389.705 | 126.771 | 377.031 | 34.392 |
| IN-N0079 | 575.278 | 56.137 | 127.264 | 12.429 |
| IN-T2921<sup>d)</sup> | 101.722 | - | 24.137 | - |
| **Solarisation in green house 1 x 5500 g a.s./ha** |
| Oxamyl<sup>b)</sup> | 1859.792 | 180.921 | 495.121 | 49.475 |
| Oxamyl<sup>c)</sup> | 178.489 | 12790.698 | 50.582 | 3672.290 |
| IN-A2213 | 1572.579 | 98.667 | 296.354 | 18.504 |
| IN-D2708 | 1524.741 | 139.449 | 414.734 | 37.831 |
| IN-N0079 | 632.806 | 61.751 | 139.991 | 13.671 |
| IN-T2921<sup>d)</sup> | 111.894 | - | 26.551 | - |

<sup>a)</sup> As a worst case, spray drift values were considered in calculations. They are expected to be higher than dust drift resulting from application of granules in the field.

<sup>b)</sup> Steps 1-2 calculations for oxamyl with default K<sub>foc</sub> of 10 ml/g.

<sup>c)</sup> Steps 1-2 calculations for oxamyl with default K<sub>foc</sub> of 10000 ml/g.

<sup>d)</sup> The results represent PEC of IN-T2921 after formation in the water body. The PEC<sub>sw</sub> were calculated from the maximum PEC<sub>sw</sub> of oxamyl in the respective scenario. IN-T2921 metabolite is only relevant in the water phase.

Summary of maximum Step 3a PEC<sub>sw</sub> and PEC<sub>sed</sub> values for oxamyl following application to potatoes at 1 x 1000 g a.s./ha

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### Application parameterisation:

Application mode “granular”, dust drift as defined in EFSA (2004) for spinning disks, CAM 6 and DEPI 10.

**Summary of maximum Step 3a PEC\textsubscript{sw} and PEC\textsubscript{sed} values for oxamyl following application to tobacco at 1 × 3000 g a.s./ha**

| Scenarios | Maximum PEC\textsubscript{sw} (µg/L) | 7 days TWA PEC\textsubscript{sw} (µg/L) | 14 days TWA PEC\textsubscript{sw} (µg/L) | Maximum PEC\textsubscript{sw} caused by | Maximum PEC\textsubscript{sed} (µg/kg ds) |
|-----------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|
| K\textsubscript{foc} of 10 mL/g | R3, stream | 15.38 | 1.372 | 0.7843 | Drift | 0.7599 |
| K\textsubscript{foc} of 10,000 mL/g | R3, stream | 15.26 | 1.338 | 0.7668 | Drift | 5.114 |

**Summary of maximum Step 3a PEC\textsubscript{sw} and PEC\textsubscript{sed} values for oxamyl following application to tobacco at 1 × 5500 g a.s./ha**

| Scenarios | Maximum PEC\textsubscript{sw} (µg/L) | 7 days TWA PEC\textsubscript{sw} (µg/L) | 14 days TWA PEC\textsubscript{sw} (µg/L) | Maximum PEC\textsubscript{sw} caused by | Maximum PEC\textsubscript{sed} (µg/kg ds) |
|-----------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|
| K\textsubscript{foc} of 10 mL/g | R3, stream | 28.19 | 2.516 | 1.438 | Drift | 1.393 |
| K\textsubscript{foc} of 10,000 mL/g | R3, stream | 27.97 | 1.406 | 0.706 | Drift | 7.269 |

Application parameterisation: application mode “granular”, dust drift as defined in EFSA (2004) for spinning disks, CAM 6 and DEPI 10.
Summary of maximum Step 4b PEC\textsubscript{sw} and PEC\textsubscript{sed} values for oxamyl following application to tobacco at 1 × 5500 g a.s./ha

| Scenarios | Maximum PEC\textsubscript{sw} (µg/L) | 7 days TWA PEC\textsubscript{sw} (µg/L) | 14 days TWA PEC\textsubscript{sw} (µg/L) | Maximum PEC\textsubscript{sw} caused by | Maximum PEC\textsubscript{sed} (µg/kg ds) |
|-----------|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|
| R3, stream, 10 m NSZ | 5.459 | 0.487 | 0.279 | Drift | 0.270 |
| R3, stream, 20 m NSZ | 2.838 | 0.253 | 0.145 | Drift | 0.140 |
| R3, stream, 25 m NSZ | 2.291 | 0.204 | 0.117 | Drift | 0.113 |

K\textsubscript{foc} of 10 L/kg

| Scenarios | Maximum PEC\textsubscript{sw} (µg/L) | 7 days TWA PEC\textsubscript{sw} (µg/L) | 14 days TWA PEC\textsubscript{sw} (µg/L) | Maximum PEC\textsubscript{sw} caused by | Maximum PEC\textsubscript{sed} (µg/kg ds) |
|-----------|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|
| R3, stream, 10 m NSZ | 5.417 | 0.475 | 0.272 | Drift | 1.408 |
| R3, stream, 20 m NSZ | 2.816 | 0.247 | 0.142 | Drift | 0.876 |
| R3, stream, 25 m NSZ | 2.273 | 0.199 | 0.114 | Drift | 0.839 |

Step4b calculations are based on the result of Step 3a.

Summary of maximum Step 3a PEC\textsubscript{sw} and PEC\textsubscript{sed} values for oxamyl following greenhouse applications to tomatoes at 2000 + 1000 + 1000 + 1000 g a.s./ha

| Scenarios | Maximum PEC\textsubscript{sw} (µg/L) | 7 days TWA PEC\textsubscript{sw} (µg/L) | 14 days TWA PEC\textsubscript{sw} (µg/L) | Maximum PEC\textsubscript{sw} caused by | Maximum PEC\textsubscript{sed} (µg/kg ds) |
|-----------|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|
| D6, ditch | 11.36 | 3.375 | 2.138 | Drainage | 1.022 |

K\textsubscript{foc} of 10 mL/g

| Scenarios | Maximum PEC\textsubscript{sw} (µg/L) | 7 days TWA PEC\textsubscript{sw} (µg/L) | 14 days TWA PEC\textsubscript{sw} (µg/L) | Maximum PEC\textsubscript{sw} caused by | Maximum PEC\textsubscript{sed} (µg/kg ds) |
|-----------|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|
| D6, ditch | <0.001 | <0.001 | <0.001 | Drainage | <0.001 |

Application parameterisation: application mode “granular”, no drift, CAM 1, and DEPI 4.

Summary of maximum Step 3a PEC\textsubscript{sw} and PEC\textsubscript{sed} values for oxamyl following greenhouse application at 1 × 5500 g a.s./ha in combination with solarisation

| Scenarios | Maximum PEC\textsubscript{sw} (µg/L) | 7 days TWA PEC\textsubscript{sw} (µg/L) | 14 days TWA PEC\textsubscript{sw} (µg/L) | Maximum PEC\textsubscript{sw} caused by | Maximum PEC\textsubscript{sed} (µg/kg ds) |
|-----------|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|
| D6, ditch | 0.010 | 0.009 | 0.008 | Drainage | 0.003 |

K\textsubscript{foc} of 10 mL/g

| Scenarios | Maximum PEC\textsubscript{sw} (µg/L) | 7 days TWA PEC\textsubscript{sw} (µg/L) | 14 days TWA PEC\textsubscript{sw} (µg/L) | Maximum PEC\textsubscript{sw} caused by | Maximum PEC\textsubscript{sed} (µg/kg ds) |
|-----------|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|
| D6, ditch | <0.001 | <0.001 | <0.001 | Drainage | <0.001 |

Application window starts on 1 July

| Scenarios | Maximum PEC\textsubscript{sw} (µg/L) | 7 days TWA PEC\textsubscript{sw} (µg/L) | 14 days TWA PEC\textsubscript{sw} (µg/L) | Maximum PEC\textsubscript{sw} caused by | Maximum PEC\textsubscript{sed} (µg/kg ds) |
|-----------|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|
| D6, ditch | 0.012 | 0.012 | 0.012 | Drainage | 0.006 |

K\textsubscript{foc} of 10 mL/g

| Scenarios | Maximum PEC\textsubscript{sw} (µg/L) | 7 days TWA PEC\textsubscript{sw} (µg/L) | 14 days TWA PEC\textsubscript{sw} (µg/L) | Maximum PEC\textsubscript{sw} caused by | Maximum PEC\textsubscript{sed} (µg/kg ds) |
|-----------|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|
| D6, ditch | <0.001 | <0.001 | <0.001 | Drainage | <0.001 |

Application window starts on 1 August
### Metabolite IN-A2213

| Parameters used in FOCUSsw step 1 and 2 |
|----------------------------------------|
| Molecular weight (g/mol): 162.2      |
| Soil or water metabolite: soil and water |
| $K_{foc}$ (mL/g): 6.37 (geometric mean) |
| $DT_{50}$ soil (d): 2.2 (geometric mean lab, SFO) |
| $DT_{50}$ water/sediment system (d): 9.6 |
| $DT_{50}$ water (d): 9.6 |
| $DT_{50}$ sediment (d): 9.6 |
| Maximum occurrence observed (% AR)    |
| Total Water and Sediment: 63.2 (worst case from aqueous hydrolysis studies) |
| Soil: 52.0                           |

### Metabolite IN-D2708

| Parameters used in FOCUSsw step 1 and 2 |
|----------------------------------------|
| Molecular weight (g/mol): 117.1        |
| Soil or water metabolite: soil and water |
| $K_{foc}$ (mL/g): 9.13 (geometric mean) |
| $DT_{50}$ soil (d): 8.4 (geometric mean lab, SFO) |
| $DT_{50}$ water/sediment system (d): 1000 |
| $DT_{50}$ water (d): 1000 |
| $DT_{50}$ sediment (d): 1000 |
| Maximum occurrence observed (% AR)    |
| Total Water and Sediment: 77.2        |
| Soil: 78.7                            |

### Metabolite IN-N0079

| Parameters used in FOCUSsw step 1 and 2 |
|----------------------------------------|
| Molecular weight (g/mol): 98.1         |
| Soil or water metabolite: soil and water |
| $K_{foc}$ (mL/g): 10 (default value)   |
| $DT_{50}$ soil (d): 1.0 (conservative worst case) |
| $DT_{50}$ water/sediment system (d): 6.4 |
| $DT_{50}$ water (d): 5.86 |
| $DT_{50}$ sediment (d): 14.23 |
| Maximum occurrence observed (% AR)    |
| Total Water and Sediment: 54.2        |
| Aqueous photolysis: 67.6 (used in PEC$_{sw}$ calculation) |
| Soil: 8.7                             |

### Metabolite IN-T2921

| Parameters used in spreadsheet calculations |
|---------------------------------------------|
| Molecular weight (g/mol): 116.1             |
| Soil or water metabolite: water             |
| $DT_{50}$ water/sediment system (d): 1000   |
| $DT_{50}$ water (d): 1000                   |
| $DT_{50}$ sediment (d): 1000                |
| Maximum occurrence observed (% AR)         |
| Total Water and Sediment: 11.4              |
| Soil: -                                    |

Application rate: Same as for parent

See Step1&2 PEC$_{sw}$/PEC$_{sed}$ values of metabolites for all uses in the PEC$_{sw}$ section for parent oxamyl.

**Estimation of concentrations from other routes of exposure (Regulation (EU) No 284/2013, Annex Part A, point 9.4)**

| Method of calculation |
|-----------------------|
| FOCUS Step 3 for Oxamyl 10GR proposed uses |
| PEC | Maximum concentration | Results are reported for the parent compound above. |
Effects on birds and other terrestrial vertebrates (Regulation (EU) N° 283/2013, Annex Part A, point 8.1 and Regulation (EU) N° 284/2013, Annex Part A, point 10.1)

| Species                  | Test substance | Time scale       | End point | Toxicity (mg/kg bw/day) |
|--------------------------|----------------|------------------|-----------|-------------------------|
| **Birds**                |                |                  |           |                         |
| Mallard duck             | Oxamyl         | Acute            | LD$_{50}$ | 3.16                    |
| Northern bobwhite quail  | Oxamyl         | Acute            | LD$_{50}$ | 9.5                     |
| Geometric mean           | Oxamyl         | Acute            | LD$_{50}$ | 5.86                    |
| Northern bobwhite quail  | Oxamyl 10GR    | Acute            | LD$_{50}$ | 12.5                    |
| Northern bobwhite quail  | Oxamyl 10SL    | Acute            | LD$_{50}$ | 11.0                    |
| Mallard duck             | Oxamyl         | Short-term       | LC$_{50}$ | 96.6                    |
|                         |                |                  |           | (766 mg a.s./kg feed)   |
| Northern bobwhite quail  | Oxamyl         | Short-term       | LC$_{50}$ | 85                      |
|                         |                |                  |           | (340 mg a.s./kg feed)   |
| Mallard duck             | Oxamyl         | Long-term (Subchronic and reproductive) | NOEC | 1.5 |
|                         |                |                  |           | (10 mg a.s./kg feed)    |
| Northern bobwhite quail  | Oxamyl         | Long-term (Subchronic and reproductive) | NOEC | 4.36 |
|                         |                |                  |           | (50 mg a.s./kg feed)    |

During the Pesticide Peer Review TC 63, it was pointed out that, according to EFSA, 2009, the geomean acute endpoint may be used when toxicity data for more than one species are present and if the most sensitive endpoint is less than 10 times lower than the geomean. The resulting endpoint of 5.86 mg a.s./kg bw was by less than a factor of 10 higher than the lowest endpoint derived for the mallard duck, and for this reason, it was considered justified to use the geomean for risk assessment purposes.

| Mammals                  |                |                  |           |                         |
|--------------------------|----------------|------------------|-----------|-------------------------|
| Rat                      | Oxamyl         | Acute            | Lowest lethal dose LD$_{50}$ | 2.5 |
| Rat                      | Oxamyl 10GR    | Acute            | Lowest lethal dose LD$_{50}$ | 3.5 |
| Rat                      | IN-A2213       | Acute            | Acute lethal dose (ALD)       | 11000 |
| Rat                      | IN-D2708       | Acute            | LD$_{50}$ | 3540                    |
| Rat                      | IN-L2953       | Acute            | LD$_{50}$ | 6675                    |
| Rat                      | IN-N0079       | Acute            | ALD       | 450                     |
| Rat                      | Oxamyl         | Long-term        | NOAEL     | 1.43                    |
|                         |                |                  |           | (25 mg a.s./kg feed)    |
| Rabbit                   | Oxamyl         | Long-term (developmental) | NOAEL | 1.0                      |

In the Pesticide Peer Review TC 63, the experts agreed on the selection of the NOAEL resorption of 1 mg/kg bw/day from the rabbit developmental toxicity study, as the ecotoxicologically relevant endpoint for wild mammals. The use of the LD$_{50}$/10 was dismissed, since its use is not specifically envisaged by EFSA (2009). It was further reported that a data gap was set for a DNT (developmental neurotoxicity study) in the mammalian toxicology peer-review meeting. Therefore, the agreed endpoint may need to be reconsidered in future, in case a more adverse, ecotoxicologically relevant endpoint will be available.

Endocrine disrupting properties (Annex Part A, points 8.1.5)
Oxamyl is not classified R2 or C2 for mammals, thus it does not qualify to be suspected to have endocrine properties. No endocrine effects were documented on the amphibian thyroid in this study.

Additional higher tier studies (Annex Part A, points 10.1.1.2):
Not required

Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3):
Oxamyl is a carbamate insecticide with a reversible cholinesterase inhibition mode of action. Acute single-dose exposures in oral toxicity tests to birds, mammals, and other terrestrial vertebrate wildlife elicit rapid onset of toxic responses with steep dose-response slopes and low LD$_{50}$ values. Short-term dietary exposures to birds and mammals elicit moderate toxic responses with low dose-response slopes and moderate LC$_{50}$ values. Long-term dietary exposures to birds and mammals elicit reproductive NOECs at doses that are toxic to parents. Birds and mammals are able to metabolize oxamyl after dietary exposures, thus reducing any toxic effects. Similar responses are anticipated for reptiles and amphibians.

Toxicity/exposure ratios for terrestrial vertebrates (Regulation (EU) No 284/2013, Part A, Annex point 10.1)

Risk Assessment for birds exposed to Oxamyl 10GR

Exposure scenario: 1 - Animals ingesting granules as source of food
Oxamyl 10GR granules are pieces of irregularly shaped, angular blue clay. A granule has no nutritional value, and therefore is unlikely to be actively selected as a food source by birds. The granules do not look like food and would not be ingested by birds as a source of food. No risk assessment is required.

Exposure scenario: 2 - Birds ingesting granules with/as grit; focal species: small birds (25 g), LD$_{50}$=0.079 mg a.s./small bird,

Tier 1 bird TER$_a$ values after accidental ingestion of granules with soil (in the main field, cultivated headlands and uncultivated headlands)

| a) Main field area | Exposure Scenario | Potato | Tobacco in-furrow | Tobacco broadcast |
|--------------------|-------------------|--------|-------------------|-------------------|
| Application rate (kg a.s./ha) | 1 | 3 | 5.5 |
| Soil surface granule density (G$_{density}$) [granules/m$^2$] | 2.8 | 8.5 | 51.1 |
| Acute risk | 0.003 | 0.010 | 0.058 |
| Toxicity endpoint (mg a.s./kg bw) | 5.86 |
| Toxicity endpoint (mg a.s./small bird) | 0.1465 |
| TER$_a$ (= small bird LD$_{50}$/ DGrItD$_{acute}$) | 46 | 15 | 2.5 |
| Trigger | 10 | 10 | 10 |
| Long-term risk | 0.002 | 0.006 | 0.034 |
| Toxicity endpoint (mg a.s./kg bw) | 0.586 |
| Toxicity endpoint (mg a.s./small bird) | 0.01465 |
| TER$_t$ (= small bird NOEC / DGrItD$_{repro}$) | 7.8 | 2.57 | 0.43 |
| Trigger | 5 | 5 | 5 |

b) Cultivated headlands area
| Exposure Scenario | Potato | Tobacco in-furrow | Tobacco broadcast |
|-------------------|--------|-------------------|-------------------|
| Application rate (kg a.s./ha) | 1 | 3 | 5.5 |
| Soil surface granule density (G<sub>density</sub>) [granules/m<sup>2</sup>] | 3.3 | 9.8 | 72.3 |

### Acute risk

| Daily grit dose (DGritD<sub>acute</sub>) = 651 × (G<sub>density</sub>/(15200 + G<sub>density</sub>)) × 0.0264 | 0.004 | 0.011 | 0.081 |
| Toxicty endpoint (mg a.s./kg bw) | 5.86 |
| Toxicty endpoint (mg a.s./small bird) | 0.1465 |
| TER<sub>a</sub> (= small bird LD<sub>50</sub>/DGritD<sub>acute</sub>) | 39 | 13 | 1.8 |
| Trigger | 10 | 10 | 10 |

### Long-term risk

| Daily grit dose (DGritD<sub>repro</sub>) = 386 × (G<sub>density</sub>/(15200 + G<sub>density</sub>)) × 0.0264 | 0.002 | 0.007 | 0.048 |
| Toxicty endpoint (mg a.s./kg bw) | 0.586 |
| Toxicty endpoint (mg a.s./small bird) | 0.01465 |
| TER<sub>lt</sub> (= small bird NOEC/DGritD<sub>repro</sub>) | 6.6 | 2.23 | 0.30 |
| Trigger | 5 | 5 | 5 |

**c) Uncultivated healdands area**

| Exposure Scenario | Potato | Tobacco in-furrow | Tobacco broadcast |
|-------------------|--------|-------------------|-------------------|
| Application rate (kg a.s./ha) | 1 | 3 | 5.5 |
| Soil surface granule density (G<sub>density</sub>) [granules/m<sup>2</sup>] | 16 | 48 | 74.3 |

### Acute risk

| Daily grit dose (DGritD<sub>acute</sub>) = 651 × (G<sub>density</sub>/(15200 + G<sub>density</sub>)) × 0.0264 | 0.018 | 0.054 | 0.084 |
| Toxicty endpoint (mg a.s./kg bw) | 5.86 |
| Toxicty endpoint (mg a.s./small bird) | 0.1465 |
| TER<sub>a</sub> (= small bird LD<sub>50</sub>/DGritD<sub>acute</sub>) | 8 | 3 | 1.8 |
| Trigger | 10 | 10 | 10 |

### Long-term risk

| Daily grit dose (DGritD<sub>repro</sub>) = 386 × (G<sub>density</sub>/(15200 + G<sub>density</sub>)) × 0.0264 | 0.011 | 0.032 | 0.050 |
| Toxicty endpoint (mg a.s./kg bw) | 0.586 |
| Toxicty endpoint (mg a.s./small bird) | 0.01465 |
| TER<sub>lt</sub> (= small bird NOEC/DGritD<sub>repro</sub>) | 1.4 | 0.46 | 0.30 |
| Trigger | 5 | 5 | 5 |

**Refined Tier 1 TER<sub>a</sub> and TER<sub>lt</sub> values after accidental ingestion of granules with grit**

Refinement: A maximum of 7-13 granules/m<sup>2</sup> and 4-4.4 granules/m<sup>2</sup> could remain on the surface to pass the acute and chronic grit intake risk assessment for in-furrow and broadcast applications to tobacco. The label provides clear stewardship guidelines for mitigating and documenting risk to wildlife and birds. Users are
required to cover all granules with soil so they are completely buried and to remove spills. In addition, a position paper including a weight of evidence assessment concluded that low (virtually zero) number of Oxamyl 10GR granules are available on the soil surface of a correctly treated field and that the color of the granules is very unattractive to birds searching for grit (based on literature studies), which further reduces the risk of uptake of granules as grit.

All proposed refinements (maximum number of granules exposed to soil surface to get acceptable risk, mitigation measures, avoidance) were not considered sufficient to address the acute and chronic risk to small birds ingesting granules as grit. For main field area and cultivated headlands, a high risk to small birds is identified for tobacco broadcast and in-furrow applications. When considering the uncultivated headlands, a high risk to small birds is identified for all intended uses.

**Exposure scenario: 3 - Birds ingesting granules when seeking seeds as food**

Oxamyl 10GR granules are pieces of irregularly shaped, angular blue clay. They do not resemble seeds and would not be ingested by birds as a source of food. No risk assessment is required.

**Tier TERₐ values after accidental ingestion of granules with soil**

| Exposure scenario | Potato | Tobacco in-furrow | Tobacco broadcast |
|-------------------|--------|-------------------|-------------------|
| Application rate (kg a.s./ha) | 1      | 3                 | 5.5               |
| – Shortcut (5cm depth incorporation) |        | 0.0566            |                   |
| Exposure Daily dry soil dose - acute (mg a.s./kg bw/d) | 0.0566 | 0.1698            | 0.3113            |
| Toxicity endpoint (mg a.s./kg bw) |          | 5.86              |                   |
| TERₐ₁ | 104    | 35                | 19                |
| Trigger | 10     | 10                | 10                |

**Tier 1 bird TERₐ₁ values after accidental ingestion of granules with soil**

| Exposure scenario | Potato | Tobacco in-furrow | Tobacco broadcast |
|-------------------|--------|-------------------|-------------------|
| Application rate (kg a.s./ha) | 1      | 3                 | 5.5               |
| Shortcut – x twa |        | 0.025 x 0.53     |                   |
| Exposure Daily dry soil dose - chronic (mg a.s./kg bw/d) | 0.013  | 0.040             | 0.073             |
| Toxicity endpoint (mg a.s./kg bw/d) |          | 0.586             |                   |
| TERₐ₁₂ | 44     | 15                | 8                 |
| Trigger | 5      | 5                 | 5                 |

An acceptable acute and chronic risk to birds ingesting granules when eating soil contaminated food can be concluded for all intended uses.

A position paper including a refinement of PD value in tobacco fields based on literature evidence was submitted. An arbitrary value cannot be accepted without a field study. The chronic risk for earthworms eating birds cannot be addressed for tobacco uses.
Exposure scenario: 5 - Animals consuming other food items with residues from granular applications

| Herbivores: Acute and chronic risk assessment |
|---------------------------------------------|
| The applicant submitted a proposal for a risk assessment considering residues studies conducted with the 10GR formulation in rye grass, clover and emerged weeds (DuPont-46124); sugar beet seedlings and emerged weeds (DuPont-46123) and carrot seedlings and emerged weeds (DuPont-46122). The applicant proposed to use the geometric mean residue concentration from all the 14 trials (equal to 0.057 mg as/kg), as the refined RUD value for weeds. The proposal by the applicant to use residue studies to address the risk through weed seedlings was discussed in the Pesticide Peer Review TC 63. Overall, it was agreed not to consider the studies for further refinement for the weeds’ seedlings scenario for birds. |

**The risk for herbivorous birds cannot be addressed** in absence of any reliable RUD value for weeds (data gap and issue not finalised for the field representative uses). |

Residues in soil arthropods |
|----------------------------|
| The exposure through soil arthropods was discussed in the Pesticide Peer Review TC 63. This was driven by the available evidence of detectable residues in soil arthropods. However, it was acknowledged that this was not a standard scenario considered by EFSA, 2009. It was pointed out that residue in earthworms was higher than that in ground dwelling arthropods (DuPont-40221). In conclusion, it was agreed that the risk to birds from consumption of ground dwelling arthropod is covered by the vermivore scenario. |
Vermivores: 

Acute risk assessment

The worst case exposure value is 1.544 mg/kg worms after a 2 kg a.s./ha application, which is equivalent to an RUD of 0.772 mg a.s./kg worm after 1 kg a.s./ha/ha application. However, the poor GAP representativeness of the study from which the RUD is derived (i.e., in terms of application depth and formulation type) was deemed particularly relevant during the Pesticide Peer Review TC 63. Overall, the experts agreed that the study should not be used to refine the RUD values for the representative granular formulation in tobacco and potatoes.

In Pesticide Peer Review TC 63 it was agreed to dismiss the use of RUD values in earthworms from the study DuPont-40221 and to reject the refinement based on PD value of 0.1.

Therefore, the acute risk assessment to birds ingesting contaminated earthworms cannot be addressed data gap and issue not finalised for the field representative uses).

Chronic risk assessment

Tier 1 bird TERlt for exposure to residues in earthworms

| Parameter                  | Potatoes (1 × 1 kg a.s./ha) (5 cm) | Potatoes (1 × 1 kg a.s./ha) (10 cm) | Tobacco (1 × 3 kg a.s./ha) (5 cm) | Tobacco (1 × 3 kg a.s./ha) (10 cm) | Tobacco (1 × 5.5 kg a.s./ha) (5 cm) | Tobacco (1 × 5.5 kg a.s./ha) (10 cm) |
|----------------------------|------------------------------------|------------------------------------|----------------------------------|-----------------------------------|------------------------------------|------------------------------------|
| PECsoil (mg a.s./kg)*       | 1.333                              | 0.667                              | 4.000                            | 2.000                             | 7.333                              | 3.667                              |
| BAF                        | 0.03                               | 0.03                               | 0.03                             | 0.03                              | 0.03                               | 0.03                               |
| PECworm (mg a.s./kg bw)     | 0.04                               | 0.02                               | 0.12                             | 0.06                              | 0.22                               | 0.11                               |
| Daily dose for birds       | 0.044                              | 0.022                              | 0.132                            | 0.066                             | 0.242                              | 0.121                              |
| (PECworm × 1.1)            |                                    |                                    |                                  |                                   |                                    |                                    |
| NOEL for birds (mg a.s./kg bw/d) | 0.586                              | 0.586                              | 0.586                            | 0.586                             | 0.586                              | 0.586                              |
| TERlt                      | 13.3                               | 26.6                               | **4.4**                          | **8.9**                           | **2.4**                            | **4.8**                            |

* Maximum instantaneous PECs as calculated in Vol 3 B8 for each scenario

A position paper including a refinement of PD value in tobacco fields based on literature evidence was submitted. An arbitrary value cannot be accepted without a field study. The chronic risk for earthworm-eating birds cannot be addressed for tobacco uses.
**Exposure scenario: 6 - Exposure via Drinking Water**

**Acute drinking water risk assessment**

Drinking water risk assessment - ratio of effective application rate to bird acute toxicity endpoints for birds exposed to Oxamyl 10GR in tobacco or potatoes

| Scenario           | Species   | LD50 (dietary) (mg a.s./kg bw/day) | Rate applied (g a.s./ha) | MAF_in | AR_eff | HQ | Trigger value |
|--------------------|-----------|------------------------------------|--------------------------|--------|--------|----|----------------|
| Tobacco, 5.5 kg a.s/ha | Bird     | 5.86                               | 5500                     | 1      | 5500   | 938 | 50             |
| Tobacco, 3.0 kg a.s/ha | Bird     | 5.86                               | 3000                     | 1      | 3000   | 512 | 50             |
| Potato, 1.0 kg a.s/ha | Bird     | 5.86                               | 1000                     | 1      | 1000   | 170 | 50             |

a Multiple application factor
b Effective application rate
c Hazard quotient (ratio of effective application rate to relevant endpoint)
d Trigger defined assuming Koc <500 L/kg

**Tier 1 bird acute drinking water TER, for Oxamyl 10GR – puddle scenario**

| Crop                | Focal species | LD50 (mg/kg bw/day) | DWR* in L/kg bw/d | PEC-puddle (mg a.s./L) | DDD | TER   | Trigger |
|---------------------|---------------|---------------------|-------------------|------------------------|-----|-------|--------|
| Tobacco, 5.5 kg a.s/ha | Granivorous bird | 5.86               | 0.46              | 15.7                   | 7.22 | 0.81  | 10      |
| Tobacco, 3.0 kg a.s/ha | Granivorous bird | 5.86               | 0.46              | 8.5                    | 3.91 | 1.49  | 10      |
| Potato, 1.0 kg a.s/ha    | Granivorous bird | 5.86               | 0.46              | 2.8                    | 1.29 | 4.54  | 10      |

* Drinking water rates as published by DEFRA (Department for Environment, Food and Rural Affairs), 2007. Improved estimates of daily food and water requirements for use in risk assessments – DEFRA Project Code PS2308.
### Refine bird acute drinking water TER<sub>a</sub> for Oxamyl 10GR – puddle scenario

| Scenario           | Species                  | LD<sub>50</sub> (mg/kg bw/day) | DWR<sup>a</sup> in L/kg bw/d | FOCUS Step 3a PEC<sub>puddle</sub> (mg a.s./L) | DDD | TER | Trigger |
|--------------------|--------------------------|-------------------------------|-------------------------------|-----------------------------------------------|-----|-----|---------|
| Tobacco, 5.5 kg a.s/ha | Granivorous bird        | 5.86                          | 0.46                          | 0.028                                         | 0.0128 | 457 | 10      |
| Tobacco, 3.0 kg a.s/ha | Granivorous bird        | 5.86                          | 0.46                          | 0.015                                         | 0.0069 | 849 | 10      |
| Potato, 1.0 kg a.s/ha  | Granivorous bird        | 5.86                          | 0.46                          | 0.055                                         | 0.0253 | 231 | 10      |

<sup>a</sup> Drinking water rates as published by DEFRA (Department for Environment, Food and Rural Affairs), 2007. Improved estimates of daily food and water requirements for use in risk assessments – DEFRA Project Code PS2308.

### Chronic drinking water risk assessment

#### Tier 1 bird chronic drinking water TER<sub>a</sub> for Oxamyl 10GR – puddle scenario

| Crop                | Focal species         | LD<sub>50</sub>/10 (mg/kg bw/day) | DWR<sup>a</sup> in L/kg bw/d | PEC<sub>puddle</sub> (mg a.s./L) | DDD | TER | Trigger |
|---------------------|-----------------------|-----------------------------------|-------------------------------|---------------------------------|-----|-----|---------|
| Tobacco, 5.5 kg a.s/ha | Granivorous bird      | 0.586                             | 0.46                          | 15.7                            | 7.22 | 0.081 | 10      |
| Tobacco, 3.0 kg a.s/ha | Granivorous bird      | 0.586                             | 0.46                          | 8.5                             | 3.91 | 0.149 | 10      |
| Potato, 1.0 kg a.s/ha  | Granivorous bird      | 0.586                             | 0.46                          | 2.8                             | 1.29 | 0.454 | 10      |

<sup>a</sup> Drinking water rates as published by DEFRA (Department for Environment, Food and Rural Affairs), 2007. Improved estimates of daily food and water requirements for use in risk assessments – DEFRA Project Code PS2308.

### Refinement: run off concentrations directly from relevant FOCUS Step 3 scenarios

#### Refine bird chronic drinking water TER<sub>a</sub> for Oxamyl 10GR – puddle scenario

| Scenario           | Species                  | LD<sub>50</sub>/10 (mg/kg bw/day) | DWR<sup>a</sup> in L/kg bw/d | FOCUS Step 3a PEC<sub>puddle</sub> (mg a.s./L) | DDD | TER | Trigger |
|--------------------|--------------------------|-----------------------------------|-------------------------------|-----------------------------------------------|-----|-----|---------|
| Tobacco, 5.5 kg a.s/ha | Granivorous bird        | 0.586                             | 0.46                          | 0.028                                         | 0.0128 | 45.7 | 10      |
| Tobacco, 3.0 kg a.s/ha  | Granivorous bird        | 0.586                             | 0.46                          | 0.015                                         | 0.0069 | 84.9 | 10      |
| Potato, 1.0 kg a.s/ha   | Granivorous bird        | 0.586                             | 0.46                          | 0.055                                         | 0.0253 | 23.1 | 10      |

<sup>a</sup> Drinking water rates as published by DEFRA (Department for Environment, Food and Rural Affairs), 2007. Improved estimates of daily food and water requirements for use in risk assessments – DEFRA Project Code PS2308.
Risk Assessment for mammals exposed to Oxamyl 10GR

Exposure scenario: Mammals ingesting granules as source of food

Oxamyl 10GR granules are pieces of irregularly shaped, angular blue clay. They do not look like food and would not be ingested by mammals as a source of food.

Exposure scenario: Mammals ingesting granules when eating soil-contaminated food

Acute risk assessment

Tier 1 mammal TER values after ingesting granules with soil contaminated food

| Exposure scenario | Potato | Tobacco in-furrow | Tobacco broadcast |
|-------------------|--------|-------------------|-------------------|
| Application rate (kg a.s./ha) | 1      | 3                 | 5.5               |
| Shortcut value (5cm) | 0.0194 |                   |                   |
| Exposure Daily dry soil dose - acute (mg a.s./kg bw/d) | 0.0194 | 0.0582 | 0.1067 |
| Toxicity endpoint (mg a.s./kg bw) | 129    | 43                | 23                |
| Trigger            | 10     | 10                | 10                |

Chronic risk assessment

| Exposure scenario | Potato | Tobacco in-furrow | Tobacco broadcast |
|-------------------|--------|-------------------|-------------------|
| Application rate (kg a.s./ha) | 1      | 3                 | 5.5               |
| – Shortcut value | 0.005 x 0.53 |                   |                   |
| Exposure Daily dry soil dose – chronic (mg a.s./kg bw/d) | 0.003 | 0.008 | 0.015 |
| Toxicity endpoint (mg a.s./kg bw) | 1      |                   |                   |
| TER_χ           | 377    | 126               | 69                |
| Trigger         | 5      | 5                 | 5                 |

An acceptable acute and chronic risk to mammals ingesting granules when eating soil contaminated food can be concluded for all intended uses.

Exposure scenario: Mammals consuming other food items with residue from granular applications

Acute and chronic risk assessments – herbivores

The applicant submitted a proposal for a risk assessment considering residues studies conducted with the 10GR formulation in rye grass, clover and emerged weeds (DuPont-46124); sugar beet seedlings and emerged weeds (DuPont-46123) and carrot seedlings and emerged weeds (DuPont-46122). The applicant proposed to use the geometric mean residue concentration from all the 14 trials (equal to 0.057 mg as/kg), as the refined RUD value for weeds. The proposal by the applicant to use residue studies to address the risk through weed seedlings was discussed in the Pesticide Peer Review TC 63. Overall, it was agreed not to consider the studies for further refinement for the weeds’ seedlings scenario for mammals.

The risk for herbivorous mammals cannot be addressed in absence of any reliable RUD value for weeds (data gap and an issue not finalised for the field representative uses).

Residues in soil arthropods
The exposure through soil arthropods was discussed in the Pesticide Peer Review TC 63. This was driven by the available evidence of detectable residues in soil arthropods. However, it was acknowledged that this was not a standard scenario considered by EFSA, 2009. It was pointed out that residue in earthworms was higher than that in ground dwelling arthropods (DuPont-40221). In conclusion, it was agreed that the risk to birds from consumption of ground dwelling arthropod is covered by the vermivore scenario.

**Vermivore assessment**

The poor GAP representativeness of the study from which the RUD is derived (i.e., in terms of application depth and formulation type) was deemed particularly relevant during the Pesticide Peer Review TC 63. Overall, the experts agreed that the study should not be used to refine the RUD values for the representative granular formulation in tobacco and potatoes.

In Pesticide Peer Review TC 63 it was agreed to dismiss the use of RUD values in earthworms from the study DuPont-40221 and to reject the refinement based on PT value of 0.25.

Therefore, the acute risk assessment to mammals ingesting contaminated earthworms cannot be addressed (data gap and an issue not finalised for the field representative uses).

**Tier 1 TER<sub>lt</sub> for earthworms-eating mammals**

| Parameter                        | Potatoes (1 × 1 kg a.s./ha) in furrow (5 cm) | Potatoes (1 × 1 kg a.s./ha) (10 cm) | Tobacco (1 × 3 kg a.s./ha) (5 cm) | Tobacco (1 × 3 kg a.s./ha) in furrow (10 cm) | Tobacco (1 × 5.5 kg a.s./ha) soil incorporation broadcast (5 cm) | Tobacco (1 × 5.5 kg a.s./ha) (10 cm) |
|---------------------------------|---------------------------------------------|-----------------------------------|----------------------------------|-----------------------------------------------|----------------------------------------------------------------|----------------------------------|
| PEC<sub>soil</sub> (mg a.s./kg)* | 1.333                                       | 0.667                             | 4.000                            | 2.000                                         | 7.333                                                            | 3.667                            |
| BAF                             | 0.03                                        | 0.03                              | 0.03                             | 0.03                                          | 0.03                                                            | 0.03                             |
| PEC<sub>worm</sub> (mg a.s./kg bw/d) | 0.04                                        | 0.02                              | 0.12                             | 0.06                                          | 0.22                                                            | 0.11                             |
| Daily dose for mammals (PEC<sub>worm</sub> x 1.28) | 0.0512                                      | 0.0256                            | 0.1536                           | 0.0768                                         | 0.2816                                                          | 0.1408                           |
| NOEL for mammals (mg a.s./kg bw/d) | 1                                           | 1                                 | 1                                | 1                                             | 1                                                               | 1                                |
| TER<sub>lt</sub>                 | **19.5**                                    | **39.1**                          | **6.5**                          | **13.0**                                       | **3.6**                                                         | **7.1**                          |

* Maximum instantaneous PECs as calculated in Vol 3 B8 for each scenario

For the chronic risk in tobacco fields, the applicant proposed a refinement of PT without any field study. An arbitrary refined PT value is not justified. The chronic risk for earthworms-eating mammals cannot be addressed for tobacco broadcast application (data gap and issue not finalised for the representative field uses).
## Exposure scenario: Drinking water risk assessment -

**Mammal tier 1 acute drinking water TER\textsubscript{a} for Oxamyl 10GR – puddle scenario**

| Scenario       | Species                  | LD\textsubscript{50} (mg/kg bw/day) | DWR\textsuperscript{a} in L/kg bw/d | PEC\textsubscript{puddle} (mg a.s./L) | DDD   | TER   | Trigger |
|----------------|--------------------------|-------------------------------------|-------------------------------------|-------------------------------------|-------|-------|---------|
| Tobacco, 5.5 kg a.s/ha | Granivorous mammal       | 2.5                                 | 0.24                                | 15.7                                | 3.76  | 0.66  |         |
| Tobacco, 3.0 kg a.s/ha | Granivorous mammal       | 2.5                                 | 0.24                                | 8.5                                 | 2.04  | 1.22  |         |
| Potato, 1.0 kg a.s/ha  | Granivorous mammal       | 2.5                                 | 0.24                                | 2.8                                 | 0.67  |       | 3.73    |

\* EFSA 2009.

## Refinement: Using run off concentrations directly from relevant FOCUS Step 3 scenarios. Refined mammal tier 1 acute drinking water TER\textsubscript{a} for Oxamyl 10GR – puddle scenario

| Scenario       | Species                  | LD\textsubscript{50} (mg/kg bw/day) | DWR\textsuperscript{a} in L/kg bw/d | FOCUS Step 3a PEC\textsubscript{puddle} (mg a.s./L) | DDD   | TER   | Trigger |
|----------------|--------------------------|-------------------------------------|-------------------------------------|-----------------------------------------------------|-------|-------|---------|
| Tobacco, 5.5 kg a.s/ha | Granivorous mammal       | 2.5                                 | 0.24                                | 0.028                                               | 0.00672 | 372   | 10      |
| Tobacco, 3.0 kg a.s/ha | Granivorous mammal       | 2.5                                 | 0.24                                | 0.015                                               | 0.0036 | 694   | 10      |
| Potato, 1.0 kg a.s/ha  | Granivorous mammal       | 2.5                                 | 0.24                                | 0.055                                               | 0.0132 | 189   | 10      |

\* EFSA 2009.

## Refinement: Using run off concentrations directly from relevant FOCUS Step 3 scenarios. Refined mammal tier 1 chronic drinking water TER\textsubscript{a} for Oxamyl 10GR – puddle scenario

| Scenario       | Species                  | NOEC (mg/kg bw/day) | DWR\textsuperscript{a} in L/kg bw/d | FOCUS Step 3a PEC\textsubscript{puddle} (mg a.s./L) | DDD   | TER\textsubscript{lt} | Trigger |
|----------------|--------------------------|---------------------|-------------------------------------|-----------------------------------------------------|-------|-----------------------|---------|
| Tobacco, 5.5 kg a.s/ha | Granivorous mammal       | 1                   | 0.24                                | 0.028                                               | 0.00672 | 148     | 5       |
| Tobacco, 3.0 kg a.s/ha | Granivorous mammal       | 1                   | 0.24                                | 0.015                                               | 0.0036 | 277      | 5       |
| Potato, 1.0 kg a.s/ha  | Granivorous mammal       | 1                   | 0.24                                | 0.055                                               | 0.0132 | 75       | 5       |

\* EFSA 2009.

### Oxamyl 10SL

Oxamyl 10SL will be used within enclosed spaces (permanent greenhouse); therefore, birds and mammals are considered to be not exposed to residues of the formulated product, the active substance oxamyl, or its metabolites.
Toxicity data for all aquatic tested species (Regulation (EU) N° 283/2013, Annex Part A, points 8.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.2)*

* This section does not yet reflect the new EFSA Guidance Document on aquatic organisms which has been noted in the meeting of the Standing Committee on Plants, Animals, Food and Feed on 11 July 2014.

| Group                          | Test substance | Time-scale (Test type) | End point | Toxicity$^a$       |
|--------------------------------|----------------|------------------------|-----------|--------------------|
| **Fish**                      |                |                        |           |                    |
| *Oncorhynchus mykiss*          |                |                        |           |                    |
| Rainbow trout                  | Oxamyl         | Acute 96 h (static)    | Mortality, LC$_{50}$ | 3.13 (mg a.s./L)$_{\text{nom}}$ |
| *Lepomis macrochirus*          |                |                        |           |                    |
| Bluegill sunfish               | Oxamyl         | Acute 96 h (semi-static)| Mortality, LC$_{50}$ | 6.12 (mg a.s./L)$_{\text{nom}}$ |
| *Oncorhynchus mykiss*          |                |                        |           |                    |
| Rainbow trout                  | Oxamyl 10GR    | Acute 96 h (static)    | Mortality, LC$_{50}$ | 3.6 (mg a.s./L)$_{\text{nom}}$ |
| *Lepomis macrochirus*          |                |                        |           |                    |
| Bluegill sunfish               | Oxamyl 10GR    | Acute 96 h (semi-static)| Mortality, LC$_{50}$ | 4.7 (mg a.s./L)$_{\text{nom}}$ |
| *Oncorhynchus mykiss*          |                |                        |           |                    |
| Rainbow trout                  | Oxamyl 10SL    | Acute 96 h (static)    | Mortality, LC$_{50}$ | 27 (mg prep./L)$_{\text{nom}}$ |
| *Lepomis macrochirus*          |                |                        |           |                    |
| Bluegill sunfish               | Oxamyl 10SL    | Acute 96 h (static)    | Mortality, LC$_{50}$ | 51 (mg prep./L)$_{\text{nom}}$ |
| *Cyprinodon variegatus*        |                | early life stage 29 d (flow-through)| NOEC EC$_{10}$ | 0.356 (mg a.s./L)$_{\text{mm}}$ |
| Sheephead minnow               | Oxamyl         |                        |           | Supportive information |
| *Oncorhynchus mykiss*          |                |                        |           |                    |
| Rainbow trout                  | IN-A2213       | 96 h (static)          | LC$_{50}$ | >132 (mg met/L)$_{\text{mm}}$ |
| *Oncorhynchus mykiss*          |                |                        |           |                    |
| Rainbow trout                  | IN-D2708       | 96 h (static)          | LC$_{50}$ | 93.8 (mg met/L)$_{\text{mm}}$ |
| *Oncorhynchus mykiss*          |                |                        |           |                    |
| Rainbow trout                  | IN-N0079       | 96 h (static)          | LC$_{50}$ | 22.4 (mg met/L)$_{\text{mm}}$ |
| *Oncorhynchus mykiss*          |                |                        |           |                    |
| Rainbow trout                  | IN-T2921       | 96 h (static)          | LC$_{50}$ | >127 (mg met/L)$_{\text{mm}}$ |
| **Aquatic invertebrates**      |                |                        |           |                    |
| *Daphnia magna*                |                |                        |           |                    |
|                                | Oxamyl         | 48 h (semi-static)     | EC$_{50}$ | 0.319 (mg a.s./L)$_{\text{mm}}$ |
| *Daphnia magna*                |                |                        |           |                    |
|                                | Oxamyl 10GR    | 48 h (semi-static)     | EC$_{50}$ | 0.33 (mg a.s./L)$_{\text{nom}}$ |
| *Daphnia magna*                |                |                        |           |                    |
|                                | Oxamyl 10SL    | 48 h (static)          | EC$_{50}$ | 3.0 (mg prep./L)$_{\text{nom}}$ |
| *Chimarra atterima*            |                |                        |           |                    |
|                                | Oxamyl         | 48 h (static)          | EC$_{50}$ | 0.096 (mg a.s./L)$_{\text{mm}}$ |
| *Centroptilum triangulifer*    |                |                        |           |                    |
|                                | Oxamyl         | 48 h (static)          | EC$_{50}$ | 0.067 (mg a.s./L)$_{\text{mm}}$ |
| *Hyalella azteca*              |                |                        |           |                    |
|                                | Oxamyl         | 48 h (static)          | EC$_{50}$ | 0.320 (mg a.s./L)$_{\text{mm}}$ |
| *Daphnia pulex*                |                |                        |           |                    |
|                                | Oxamyl         | 48 h (static)          | EC$_{50}$ | 0.08 (mg a.s./L)$_{\text{mm}}$ |
| *Ceriodaphnia dubia*           |                |                        |           |                    |
|                                | Oxamyl         | 48 h (static)          | EC$_{50}$ | 0.094 (mg a.s./L)$_{\text{mm}}$ |

$^a$ (nom) nominal concentration; (mm) mean measured concentration; prep.: preparation; a.s.: active substance
### Aquatic invertebrates (continued)

| Group                    | Test substance | Time-scale (Test type) | End point | Toxicity<sup>a</sup> |
|--------------------------|----------------|------------------------|-----------|-----------------------|
| *Americamysis bahia*     | Oxamyl         | 48 h (flow-through)    | EC<sub>50</sub> | 0.0465 (mg a.s./L)<sub>mm</sub> |
| *Crassostrea virginica*  | Oxamyl         | 96 h (flow-through)    | EC<sub>50</sub> | 27.5 (mg a.s./L)<sub>mm</sub> |
| *Daphnia magna*          | Oxamyl         | 21 d (flow-through)    | NOEC      | 0.0268 (mg a.s./L)<sub>mm</sub> |
| *Americamysis bahia*     | Oxamyl         | 28 d (flow-through)    | NOEC      | 0.0189 (mg a.s./L)<sub>mm</sub> |
| *Daphnia magna*          | IN-A2213       | 48 h (static)          | EC<sub>50</sub> | >125 (mg met/L)<sub>mm</sub> |
| *Daphnia magna*          | IN-D2708       | 48 h (static)          | EC<sub>50</sub> | >134 (mg met/L)<sub>mm</sub> |
| *Daphnia magna*          | IN-D2708       | 21 d (semi-static)     | NOEC      | 66.1 (mg met/L)<sub>mm</sub> |
| *Daphnia magna*          | IN-N0079       | 48 h (static)          | EC<sub>50</sub> | >128 (mg met/L)<sub>mm</sub> |
| *Daphnia magna*          | IN-T2921       | 48 h (static)          | EC<sub>50</sub> | >123 (mg met/L)<sub>mm</sub> |

### Sediment-dwelling organisms

| *Chironomus tentans*     | Oxamyl         | 48 h (static)          | EC<sub>50</sub> | 0.350 (mg a.s./L)<sub>mm</sub> |

### Algae

| *Raphidocelis subcapitata* | Oxamyl         | 96-h (static)         | EC<sub>50</sub> | 2.0 (mg a.s./L)<sub>mm</sub> |
| *Pseudokirchneriella subcapitata* | Oxamyl 10GR | 96-h (static)         | EC<sub>50</sub> | 2.1 (mg a.s./L)<sub>mm</sub> |
| *Pseudokirchneriella subcapitata* | IN-A2213 | 72 h (static)         | EC<sub>50</sub> | >122 (mg met/L)<sub>mm</sub> |
| *Raphidocelis subcapitata* | IN-D2708       | 96-h (static)         | EC<sub>50</sub> | 16 (mg met/L)<sub>mm</sub>  |
| *Pseudokirchneriella subcapitata* | IN-N0079 | 96-h (static)         | EC<sub>50</sub> | >9.3 (mg met/L)<sub>mm</sub> |
| *Pseudokirchneriella subcapitata* | IN-T2921 | 72 h (static)         | EC<sub>50</sub> | >113 (mg met/L)<sub>mm</sub> |

### Higher plant

| *Lemna gibba* | Oxamyl | 7-d (semi-static) | EC<sub>50</sub> frond count | 3.57 (mg a.s./L)<sub>mm</sub> |
| *Lemna gibba* | Oxamyl | 7-d (semi-static) | EC<sub>50</sub> dry weight  | 3.16 (mg a.s./L)<sub>mm</sub> |
| *Lemna gibba* | Oxamyl | 7-d (semi-static) | EC<sub>50</sub> dry weight  | >7.17 (mg a.s./L)<sub>mm</sub> |
| *Lemna gibba* | Oxamyl | 7-d (semi-static) | EC<sub>50</sub> dry weight  | 2.20 (mg a.s./L)<sub>mm</sub> |
| *Lemna gibba* | Oxamyl | 7-d (semi-static) | EC<sub>50</sub> dry weight  | 1.67 (mg a.s./L)<sub>mm</sub> |
| *Lemna gibba* | Oxamyl | 7-d (semi-static) | EC<sub>50</sub> dry weight  | 3.30 (mg a.s./L)<sub>mm</sub> |
| *Lemna gibba* | Oxamyl | 7-d (semi-static) | NOEC overall               | 0.640 (mg a.s./L)<sub>mm</sub> |

<sup>a</sup> (nom) nominal concentration; (mm) mean measured concentration; prep.: preparation; a.s.: active substance

Further testing on aquatic organisms

Additional testing with aquatic invertebrates was conducted, please refer to endpoints listed in table above.
Potential endocrine disrupting properties (Annex Part A, point 8.2.3)

Two studies with vertebrates are available, i.e., “Fort, D.J. (2015), 21-D amphibian metamorphosis assay (AMA) with south African clawed frog, Xenopus laevis” and “Hicks, S.L. (2012); Oxamyl technical (DPX-D1410): Short term reproduction assay with the fathead minnow, Pimephales promelas, determined under flow-through conditions”.

The NOEC for X. laevis exposed to oxamyl in a 21 day amphibian metamorphosis assay (AMA) was 130.1 μg a.s./L based on time-weighted mean measured concentrations and AMA apical endpoints. The prevalence and severity of follicular cell hypertrophy were slightly increased in frogs of the 120 dose group as compared to controls, but the magnitude of the increased prevalence and severity was insufficient to conclude that this necessarily represented a treatment effect. Since the incidence of follicular cell hypertrophy (mild) observed at the highest tested dose is lower or comparable to those detected in several control groups, this alteration might be considered a typical response and cannot be attributed to an endocrine mode of action.

The results of the 21d short term reproduction assay with fish provided a NOEC based on the endocrine-relevant endpoints (i.e., reproductive parameters, VTG, GSI, gonad histopathology) of 0.989 mg a.s./L. The overall study NOEC based on the most sensitive endpoint, female wet weight, was 0.305 mg a.s./L.

There is no indication of endocrine activity in fish from this test.

For the conclusions on the updated ED assessment for non-target organisms please refer to birds and mammals section above.

Bioconcentration in fish (Annex Part A, point 8.2.2.3)

The triggers for this study are log P < 3 and potential exposure that may lead to bioconcentration where the DT90 is ≤24 hours via hydrolysis. The log P for oxamyl is -0.44. The logPow of metabolites was calculated using the KOWWIN program (Log Octanol-Water Partition Coefficient Program). The calculated Log Pow values for IN-A2213 is -0.7064; IN-D2708 is -1.7218; and IN-N0079 is -1.9541. The calculated BCF values for IN-A2213 is 0.009; IN-D2708 is 0.0009; and IN-N0079 is 0.0005.
Oxamyl 10GR:
FOCUS<sub>sw</sub> step 2-3 – Risk assessment for oxamyl

|                     | Fish acute | Fish chronic | Aquatic invertebrates acute | Refined Aquatic invertebrates acute | Aquatic invertebrates prolonged | Algae | Higher plant |
|---------------------|------------|--------------|------------------------------|-------------------------------------|----------------------------------|-------|--------------|
| Rainbow trout       | LC<sub>50</sub> | EC<sub>50</sub> | SSD                          | SS<sub>D</sub>                     | P. subcapitata                   | Algae | Higher plant |
| Sheepshead minnow   | 3130 µg/L  | 217.9 µg/L   | Americamysis bahia           | 46.5 µg/L                          | 32.6 µg/L                       | 18.9 µg/L | 2000         |
| Americamysis bahia  | 32.6 µg/L  | 18.9 µg/L    | NOEC                         | 2000                               | 3300 µg/L                        |       |              |

| Assessment factor | 100 | 10 | 100 | 5 | 10 | 10 | 10 |
|-------------------|-----|----|-----|---|----|----|----|

| RAC                | 31.30 µg/L | 21.79 µg/L | 0.465 µg/L | 6.52 µg/L | 1.89 µg/L | 200 µg/L | 330 µg/L |

| Scenario          | PEC global max (µg L) | PEC / RAC |
|-------------------|-----------------------|-----------|
| FOCUS Step 2      |                       |           |
| South Europe      |                       |           |
| Tobacco (5.5 kg/ha) | 495.121 | 15.82 | 22.7 | 1064 | - | 262 | 2.48 | 1.50 |

| FOCUS Step 3a (potatoes, 1 kg/ha) |
|-----------------------------------|
| D3/ditch                          | 4.9120 | 0.16 | 0.23 | 0.75 | 2.60 | 0.02 | 0.01 |
| D4/pond                           | 0.1561 | 0.00 | 0.01 | 0.02 | 0.08 | 0.00 | 0.00 |
| D4/stream                         | 4.3700 | 0.14 | 0.20 | 0.67 | 2.31 | 0.02 | 0.01 |
| D6/ditch                          | 4.8590 | 0.16 | 0.22 | 0.75 | 2.57 | 0.02 | 0.01 |
| D6/ditch                          | 4.9440 | 0.16 | 0.23 | 0.76 | 2.62 | 0.02 | 0.01 |
| R1/pond                           | 0.1497 | 0.00 | 0.01 | 0.02 | 0.08 | 0.00 | 0.00 |
| R1/stream                         | 4.3720 | 0.14 | 0.20 | 0.67 | 2.31 | 0.02 | 0.01 |
| R2/stream                         | 4.7970 | 0.15 | 0.22 | 0.74 | 2.54 | 0.02 | 0.01 |
| R3/stream                         | 54.680 | 1.75 | 2.51 | 8.39 | 28.93 | 0.27 | 0.17 |
### FOCUS Step 3a (tobacco, 5.5 kg/ha)

| Scenario | R3/stream |  |  |  |  |  |
|----------|-----------|---|---|---|---|---|
|          | 28.19     | 0.90 | 1.29 | 4.32 | 14.92 | 0.14 | 0.09 |

### FOCUS Step 4b (tobacco, 5.5 kg/ha), 10 m NSZ

| Scenario | R3/stream |  |  |  |  |  |
|----------|-----------|---|---|---|---|---|
|          | 5.459     | 0.25 | 0.84 |  |  |  |

### FOCUS Step 4b (tobacco, 5.5 kg/ha), 25 m NSZ

| Scenario | R3/stream |  |  |  |  |  |
|----------|-----------|---|---|---|---|---|
|          | 2.291     |  |  |  |  |  |

### FOCUS Step 3a (tobacco, 3 kg/ha)

| Scenario | R3/stream |  |  |  |  |  |
|----------|-----------|---|---|---|---|---|
|          | 15.38     | 0.49 | 0.71 | 2.36 | 8.14 | 0.08 | 0.05 |

### Oxamyl 10SL:

#### FOCUSsw Step 2 and Step 3– PEC/RAC ratios for oxamyl

| Fish acute | Fish chronic | Aquatic invertebrates acute | Refined Aquatic invertebrates acute | Aquatic invertebrates prolonged | Algae | Higher plant |
|------------|--------------|------------------------------|-------------------------------------|---------------------------------|-------|--------------|
| **Rainbow trout** | **Sheepshead minnow** | **Americamysis bahia** | **SSD** | **Americamysis bahia** | **P. subcapitata** | **Lemna gibba** |
| LC₅₀ | EC₁₀ | EC₅₀ | HC₅ | NOEC | EC₅₀ | EC₅₀ |
| 3130 µg/L | 217.9 µg/L | 46.5 µg/L | 32.6 µg/L | 18.9 µg/L | 2000 | 3300 µg/L |

| Assessment factor | 100 | 10 | 100 | 5 | 10 | 10 |

| RAC | 31.30 µg/L | 21.79 µg/L | 0.465 µg/L | 6.52 µg/L | 1.89 µg/L | 200 µg/L |

| Scenario | PEC global max (µg/L) | PEC > RAC |
|----------|-----------------------|-----------|

PEC > RAC
### FOCUS Step 2

| Activity          | LOEC100  | NOEC100 | LOEC95 | NOEC95 | LOEC50 | NOEC50 | LOEC20 | NOEC20 |
|-------------------|----------|---------|--------|--------|--------|--------|--------|--------|
| Tomato, Solarization, South Europe | 450.110  | 14.38   | 20.65  | 968    | -      | 238    | 2.25   | 1.36   |
| Tomato, Solarization, South Europe | 495.121  | 15.82   | 22.72  | 1065   | -      | 262    | 2.48   | 1.50   |

### FOCUS Step 3a

| Activity          | LOEC100  | NOEC100 | LOEC95 | NOEC95 | LOEC50 | NOEC50 | LOEC20 | NOEC20 |
|-------------------|----------|---------|--------|--------|--------|--------|--------|--------|
| Tomato, D6/ditch  | 11.36    | 0.36    | 0.52   | 24.43  | 1.74   | 6.01   | 0.006  | 0.03   |
| Solarisation, D6/ditch | 0.012   | 0.0004  | 0.0005 | 0.02   | -      | 0.006  | 0.00006 | 0.0004 |
Effects on bees (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.1 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.1)*

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

| Species            | Test substance | Time scale/type of endpoint | End point | toxicity          |
|--------------------|----------------|-----------------------------|-----------|------------------|
| *Apis mellifera*   | Oxamyl         | 48-hr Oral                  | LD$_{50}$ | 0.38 µg a.s./bee  |
| *Apis mellifera*   | Oxamyl         | 48-hr Contact               | LD$_{50}$ | 0.47 µg a.s./bee  |
| *Apis mellifera*   | Oxamyl 10SL    | 48-hr Oral                  | LD$_{50}$ | 0.26 µg a.s./bee  |
| *Apis mellifera*   | Oxamyl 10SL    | 48-hr Contact               | LD$_{50}$ | 0.23 µg a.s./bee  |
| *Apis mellifera*   | Oxamyl         | 10-d adult oral             | LDD$_{50}$ NOED | 0.14 µg a.s./bee/d 0.07 µg a.s./bee |
| *Apis mellifera*   | Oxamyl         | 7d larvae                   | LD$_{50}$ NOED | 0.81 µg a.s./larva/d 0.18 µg a.s./larva/d |
| *Apis mellifera*   | Oxamyl         | 22-day larvae               | NOED      | 0.616 µg a.s./larva per developmental period |
| *Bombus terrestris*| Oxamyl         | 48-hr Oral                  | LD$_{50}$ | 0.36 µg a.s./bee  |
| *Bombus terrestris*| Oxamyl         | 48-hr Contact               | LD$_{50}$ | 39.3 µg a.s./bee  |
| *Bombus terrestris*| Oxamyl 10SL    | 6 drip irrigation x 1 kg a.s./ha at 14 day intervals | NOED | Supportive information |

Toxicity endpoint values for honeybees (*Apis mellifera*) and bumblebees (*Bombus terrestris*) exposed to oxamyl metabolites

| Metabolite | Species/life stage | Test/duration | Measurement endpoint | Endpoint value | Reference       |
|------------|--------------------|---------------|----------------------|----------------|-----------------|
| IN-A2213   | Honeybees, adult   | Oral 48 h     | LD$_{50}$            | >181.32 µg a.s./bee | DuPont-46916   |
| IN-A2213   | Bumblebees, adult  | Oral 48 h     | LD$_{50}$            | >103.2 µg a.s./bee | Study ID 180556 |
| IN-D2708   | Honeybees, adult   | Oral 48 h     | LD$_{50}$            | >141.84 µg a.s./bee | DuPont-46917   |
| IN-D2708   | Bumblebees, adult  | Oral 48 h     | LD$_{50}$            | >105.8 µg a.s./bee | Study ID 180557 |
| IN-N0079   | Honeybees, adult   | Oral 96 h     | LD$_{50}$            | 88.02 µg a.s./bee | DuPont-46918   |
| IN-N0079   | Bumblebees, adult  | Oral 48 h     | LD$_{50}$            | >109.9 µg a.s./bee | Study ID 180558 |
Potential for accumulative toxicity: No

Semi-field test (Cage and tunnel test)

*Bombus terrestris* (Oxamyl 10GR). Tunnel test with at 1.0 or 3.5 kg a.s./ha in potatoes with brood observations – mortality, flight intensity, condition of colonies, behaviour. Oxamyl 10GR was applied once during planting of *Solanum tuberosum*. In the *Solanum tuberosum* pollen samples taken from the forager bumblebees, a maximum value of 0.008 mg oxamyl/kg was found; and in the flower samples, a maximum value of 0.019 mg oxamyl/kg could be found in the treatment group of 3.5 kg oxamyl a.s./ha. Biological results are judged not valid. Residues could be used for risk refinement.

*Apis mellifera* extended colony feeding study to evaluate effects on the brood of Honey Bees. No adverse effects up to 600 μg a.s./kg. Results can be used for bee brood refinement.

Field tests: None

Risk Assessment for applications of Oxamyl 10GR to Potatoes at 1 x 1000 g/Ha

**Acute Contact Exposure**

| scenario          | BBCH | Honeybee | Bumble bee |
|-------------------|------|----------|------------|
|                   |      | HQ       | trigger    | HQ     | trigger |
| treated crop      | < 10 | N/A      | N/A        | N/A    | N/A     |
| weeds             | < 10 | N/A      | N/A        | N/A    | N/A     |
| field margin      | < 10 | **204.3**| 14         | **2.4**| 2.3     |

**Acute Oral Exposure – Bare Soil, pollen attractive crop and Potatoes.**

| category            | scenario | BBCH | Honeybee | Bumble bee |
|---------------------|----------|------|----------|------------|
| acute               | treated crop | < 10 | 0.03 | 0.2 | **0.08** | 0.036 |
| acute               | weeds     | < 10 | **0.92** | 0.2 | 1.28 | 0.036 |
| acute               | field margin | < 10 | **0.93** | 0.2 | **1.73** | 0.036 |
| acute               | adjacent crop | < 10 | **0.90** | 0.2 | **1.40** | 0.036 |
| acute               | next crop | < 10 | **1.84** | 0.2 | **2.50** | 0.036 |
| chronic             | treated crop | < 10 | **0.09** | 0.03 | - | - |
| chronic             | weeds     | < 10 | **1.93** | 0.03 | - | - |
| chronic             | field margin | < 10 | **1.99** | 0.03 | - | - |
| chronic             | adjacent crop | < 10 | **1.86** | 0.03 | - | - |
| chronic             | next crop | < 10 | **3.86** | 0.03 | - | - |
| larva               | treated crop | < 10 | 0.00 | 0.2 | - | - |
| larva               | weeds     | < 10 | **0.32** | 0.2 | - | - |
| larva               | field margin | < 10 | **0.34** | 0.2 | - | - |
| larva               | adjacent crop | < 10 | **0.32** | 0.2 | - | - |
| larva               | next crop | < 10 | **0.65** | 0.2 | - | - |
| acute               | treated crop | < 10 | 0.03 | 0.2 | **0.08** | 0.036 |
| acute               | weeds     | < 10 | **2.92** | 0.2 | **5.42** | 0.036 |
| acute               | field margin | < 10 | **0.93** | 0.2 | **1.73** | 0.036 |
| acute               | adjacent crop | < 10 | **0.90** | 0.2 | **1.40** | 0.036 |
| acute               | next crop | < 10 | **1.84** | 0.2 | **2.50** | 0.036 |
| chronic             | treated crop | < 10 | **0.09** | 0.03 | - | - |
| chronic             | weeds     | < 10 | **6.21** | 0.03 | - | - |
| chronic             | field margin | < 10 | **1.99** | 0.03 | - | - |
| chronic             | adjacent crop | < 10 | **1.86** | 0.03 | - | - |
| chronic             | next crop | < 10 | **3.86** | 0.03 | - | - |
| larva               | treated crop | < 10 | 0.00 | 0.2 | - | - |
| larva               | weeds     | < 10 | **1.07** | 0.2 | - | - |
### Risk Assessment for applications of Oxamyl 10GR to Tobacco at 1 x 3000 g/ha

**Acute Contact Exposure** (listed as fruiting/leafy vegetable as there was no tobacco category)

| Scenario       | BBCH | Honeybee | Bumble Bee |
|----------------|------|----------|------------|
|                |      |HQ trigger|HQ trigger  |
| treated crop   | < 10 |N/A       |N/A         |
| weeds          | < 10 |N/A       |N/A         |
| field margin   | < 10 |612.8     |7.3         |

**Acute Oral Exposure** (bare soil, crop attractive for pollen as there was no tobacco category)

| Category  | Scenario       | BBCH | Honeybee | Bumble Bee |
|-----------|----------------|------|----------|------------|
|           |                |      |ETR trigger|ETR trigger|
| acute     | treated crop   | < 10 |0.09      |0.25       |
|           | weeds          | < 10 |2.76      |3.83       |
|           | field margin   | < 10 |2.80      |5.20       |
|           | adjacent crop  | < 10 |2.70      |4.20       |
|           | next crop      | < 10 |5.53      |7.50       |
| chronic   | treated crop   | < 10 |0.26      |-          |
|           | weeds          | < 10 |5.79      |-          |
|           | field margin   | < 10 |5.97      |-          |
|           | adjacent crop  | < 10 |5.59      |-          |
|           | next crop      | < 10 |11.57     |-          |
| larva     | treated crop   | < 10 |0.01      |-          |
|           | weeds          | < 10 |0.97      |-          |
|           | field margin   | < 10 |1.03      |-          |
|           | adjacent crop  | < 10 |0.96      |-          |
|           | next crop      | < 10 |1.95      |-          |

### Risk Assessment for applications of Oxamyl 10GR to Tobacco at 1 x 5500 g/ha

**Acute Contact Exposure** (listed as fruiting/leafy vegetable as there was no tobacco category)

| Scenario       | BBCH | Honeybee | Bumble Bee |
|----------------|------|----------|------------|
|                |      |HQ trigger|HQ trigger  |
| treated crop   | < 10 |N/A       |N/A         |
| weeds          | < 10 |N/A       |N/A         |
| field margin   | < 10 |1123.4    |13.4        |

**Acute Oral Exposure** (bare soil, crop attractive for pollen as there was no tobacco category)

| Category  | Scenario       | BBCH | Honeybee | Bumble Bee |
|-----------|----------------|------|----------|------------|
|           |                |      |ETR trigger|ETR trigger|
| acute     | treated crop   | < 10 |0.17      |0.46       |
|           | weeds          | < 10 |5.07      |7.03       |
|           | field margin   | < 10 |5.14      |9.53       |
Risk assessment for toxicity of Oxamyl 10SL

 TERpollen = Oral LD50/Exposure = Oral LD50/Generic residue value x food ingestion = 0.36 µg a.s./bee/(0.000413 mg a.s./kg x 30.3 mg/bee/day) = 0.36 µg/0.0125 µg = 28.8 (Trigger of 10 is met)

The resulting TERpollen value is above the proposed trigger value of 10. Tomato plants do not produce nectar, only pollen. So only the TERpollen value is relevant for bumblebees in greenhouses. This shows safe use of Oxamyl 10SL to bumblebees for drip-irrigated tomatoes in permanent greenhouses.

Since no clear recommendation is given to perform risk assessment in a fully closed greenhouses following drip irrigation methods of application, RMS agrees with applicant approach and considers the risk assessment provided adequate to conclude on an acceptable risk for managed bumblebees. RMS stresses that managed bumblebees are usually put into a greenhouse only for the scope to pollinate crop during the flowering period, with a limited range of time of few weeks. Those colonies are not expected to survive during year like a wild bumblebees colonies.

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

### Laboratory tests with standard sensitive species

| Species              | Test substance                          | End point                          | Toxicity                        |
|----------------------|-----------------------------------------|------------------------------------|---------------------------------|
| Typhlodromus pyri    | Oxamyl 10SL, Glass plate dose response (14 d) | 7 d LR₅₀, 7 d LR₃₀, 30% effect on reproduction | 1.8 g oxamyl/ha, 1.0 g oxamyl/ha, >0.8 g a.s/ha, Supportive information |
| Aphidius rhopalosiphi| Oxamyl 10SL, sprayed 2D exposure, glass plate | LR₅₀                             | 1.11 ml product/ha (0.11 g a.s./ha)² |

### Extended Laboratory tests

| Additional species     | Tier 2 laboratory (Oxamyl 10SL, sprayed 2-D exposure, barley plants) | LR₅₀ | 0.103 L product/ha (10.51 g a.s./ha) |
|-----------------------|------------------------------------------------------------------------|------|-------------------------------------|
| Aphidius rhopalosiphi | Effect on reproduction                                                  |      | No effect on dose levels assessed for reproduction |
| Species               | Test substance                                                                 | End point                                      | Toxicity                                                                 |
|----------------------|--------------------------------------------------------------------------------|------------------------------------------------|--------------------------------------------------------------------------|
| *Typhlodromus pyri*  | Tier 2 laboratory (Oxamyl 10SL, sprayed 2-D exposure, bean leaves)            | LR50                                           | 24.8 ml product/ha (2.53 g a.s./ha)                                      |
|                      |                                                                                | Effect of reproduction                          | 31 ml product/ha (3.16 g a.s./ha)                                        |
| *Aleochara bilineata*| Laboratory Tier 2 Oxamyl 10L (0, 1.5, 2, 2.5, 3 mg a.s./kg dry soil) (LUFA 2.1 soil) | 7-d Mortality:                                  | 2.50, 3.75, 1.25, 0.0%                                                  |
|                      |                                                                                | Reduction in reproduction (versus control):     | 9.0, 10.4, 21.9, 29.3%                                                  |
| *Poecilus cupreus*   | Laboratory Tier 2 Oxamyl 10L (3.3 and 33 mg a.s./kg dry soil)                  | 14-d Corrected mortality:                      | 6.7, 10%                                                               |
|                      |                                                                                | Reduction in food consumption (versus control): | -7.4, -6.7%                                                          |
| *Pardosa spp.*       | Laboratory Tier 2 Oxamyl 10L (2, 4, 6 mg a.s./kg dry soil)                      | 21-d Corrected mortality:                      | 8.8%, 35.3%, 35.3%                                                     |
|                      |                                                                                | Mean feeding rate (flies/spider/day):           | 3.7, 3.4, 3.4, 3.0 (Control), 4.4 (toxic standard)                      |
|                      |                                                                                | % reduction in feeding rate (versus control)    | -23.3, -13.3, -13.3,                                                    |
| *Pardosa spp.*       | Laboratory Tier 2 Oxamyl 10L (7,15,23 mg a.s./kg dry soil)                     | 14-d Corrected mortality:                      | 52, 100, 100%                                                        |
|                      |                                                                                | Reduction in mean feeding rate (flies/spider/day): | 4.3, 30.4, 52.2%          |
| *Aphidius rhopalosiphi*| Tier 2 laboratory (Oxamyl 10GR mixed with LUFA 2.2 soil applied to maize leaves) | LR50                                           | >2.0 g a.s./ha (>26.49 g Oxamyl 10GR dust/ha)                           |
|                      |                                                                                | ER50                                           | 1.42 g a.s./ha (18.81 g Oxamyl 10GR dust/ha)                            |
| *Aleochara bilineata*| Oxamyl 10GR (3.85 mg oxamyl/kg dry soil) Tier 2 (LUFA 2.1 soil)                | 7 d mortality:                                  | 0%                                                                      |
|                      |                                                                                | 0 d aged soil                                  | 2.5%                                                                   |
|                      |                                                                                | 7 d aged soil                                  | 0%                                                                      |
|                      |                                                                                | 14 d aged soil                                 | 0%                                                                      |
|                      |                                                                                | 28 d aged soil                                 | 0%                                                                      |
|                      |                                                                                | Reduction in reproduction:                     | 40.4%                                                                 |
|                      |                                                                                | 0 d aged soil                                  | 31.8%                                                                  |
|                      |                                                                                | 7 d aged soil                                  | 24.6%                                                                  |
|                      |                                                                                | 14 d aged soil                                 | 13.4%                                                                  |
|                      |                                                                                | 28 d aged soil                                 | >3.85 mg a.s./kg dws (55 kg prod./ha)                                   |
|                      |                                                                                | LR50/ER50 for reproduction (EC50)               |                                                                         |
| *Aleochara bilineata*| Tier 2 laboratory (oxamyl 10GR, mixed into LUFA 2.1 soil)                      | ER50                                           | 48.08 mg product/kg (5.00 mg a.s./kg soil)                               |
### Peer review of the pesticide risk assessment of the active substance oxamyl

#### Species, Test substance, End point, Toxicity

| Species          | Test substance          | End point                                      | Toxicity          |
|------------------|-------------------------|------------------------------------------------|-------------------|
| Poecilus cupreus | Oxamyl 10GR (3.85 mg oxamyl/kg dry soil) Tier 2 (LUFA 2.1 soil) | 14-d corrected mortality Reduction in Feeding rate (relative to controls) LR50/ER50 for feeding rate | 0% -41.4% >3.85 mg a.s./kg dws (55 kg prod./ha) |
| Poecilus cupreus | Tier 2 laboratory (Oxamyl 10GR mixed into natural soil) | LR50 ER50 | >10 mg a.s./kg >10 mg a.s./kg |
| Pardosa spp.     | Oxamyl 10GR (3.85 mg oxamyl/kg dry soil) Tier 2 (LUFA 2.1 soil) | 21 d mortality 21 d Reduction in feeding rate LR50/ER50 for food consumption (EC50) | 17% 4.3% >3.85 mg a.s./kg dws (55 kg prod./ha) |
| Pardosa spp.     | Tier 2 extended laboratory (Oxamyl 10GR mixed into natural soil) | LR50 ER50 | >10 mg a.s./kg >10 mg a.s./kg |

#### First tier risk assessment for non-target arthropods exposed to Oxamyl 10GR

| Test substance | Species              | Effect (LR₅₀ g/ha) | HQ in-field | HQ off-field | Trigger |
|----------------|----------------------|--------------------|-------------|-------------|---------|
| Oxamyl 10GR    | Typhlodromus pyri    | 1.8 Supportive information | 3056        | 46          | 2       |
| Aphidius rhopalosiphi |                 | 0.11               | 50000       | 745         | 2       |

* 1.49% (drift value for granule broadcast application, 1.5 m distance according to EFSA 2004

#### In-field risk assessment for soil dwelling arthropods for the use of Oxamyl 10GR in potato and tobacco

| Use pattern | Application method | Soil depth (cm) | Maximum PEC₅₀ (mg a.s./kg soil) | EC₅₀ (mg a.s./kg soil) | Acceptable risk? |
|-------------|--------------------|-----------------|---------------------------------|-----------------------|------------------|
| Potato      | in-furrow          | 5               | 1.333* 1.487**                  | 5.00                  | Yes              |
| Tobacco     | in-furrow          | 5               | 4.000* 4.461**                  | 5.00                  | Yes              |
| Tobacco     | broadcast          | 5               | 7.333* 8.179**                  | 5.00                  | No               |

* Maximum initial PEC; ** Maximum peak PEC.

An aged residue study was performed with A. bilineata for Oxamyl 10GR. Considering, the toxicity studies and risk assessment, a low in-field risk was concluded for the field uses of oxamyl on potato and tobacco applied in-furrow. In contrast, a high in-field risk was identified for the broadcast application on tobacco since the...
concentration tested in the extended laboratory and aged-residue studies on the most sensitive species, *A. bilineata*, did not cover the predicted environmental concentration in soil.

**Off-field risk assessment for Tobacco at 1 × 55 kg Oxamyl 10GR/ha, broadcast, based on extended lab test or aged residue tests**

**Soil dwelling arthropods**

| Species                          | ER$_{50}$ (g/ha) | Off-field rate$^1$ |
|----------------------------------|------------------|-------------------|
| *Poecilus cupreus*, *Aleochara bilineata*, and *Pardosa* spp | >55000           | 409.8             |

$^1$1.49% (drift value for granule broadcast application, 1.5 m distance according to EFSA 2004. Exposure in soil. Vegetative distribution factor of 10.

**Foliar dwelling arthropods**

| Use pattern | Drift factor | Off-field PER (g Oxamyl 10GR/ha) | Aphidius ER$_{50}$ (g Oxamyl 10GR/ha) | Acceptable risk? |
|-------------|--------------|----------------------------------|--------------------------------------|-----------------|
| Tobacco at 1 x 55 kg Oxamyl 10GR/ha, broadcast | 0.0149       | 409.8                            | 18.81                  | No              |
| Tobacco at 1 x 30 kg Oxamyl 10 GR/ha, in furrow | 0.0149       | 223.5                            | 18.81                  | No              |
| Potato at 1 x 10 kg Oxamyl 10 GR/ha, in furrow | 0.0149       | 74.5                             | 18.81                  | No              |

refinement of dust deposition value in off-field area cannot be accepted. A high risk is identified. The risk to foliage dwelling organisms off-field remains to be addressed.

**Risk assessment for solarization in glasshouse at 1 x 55 kg Oxamyl 10SL/ha with drip irrigation.**

Although oxamyl is very toxic to standard sensitive species in the laboratory, exposure to foliage dwelling arthropods is expected to negligible because Oxamyl 10SL is applied to the bare glasshouse soils by direct incorporation into soil and concurrent coverage by plastic foil. Extended studies on three ground-dwelling species (*Poecilus cupreus*, *Aleochara bilineata*, and *Pardosa* spp) exposed to soil residues of oxamyl after application of Oxamyl 10SL on LUFA 2.1 soil were submitted. Feeding rates of carabid beetles and spiders were not significantly affected after exposure to formulation at PECsoil equivalent to 3.85 mg a.s./kg dry soil (5.5 kg a.s./ha, 10-cm soil depth). Reproduction of staphilinid beetles *Aleochara bilineata* was not significantly affected (<30% effect) after exposure to formulation at 3.00 mg a.s./kg dry soil after soil was allowed to age for 14 days. Even if the study did not consider the relevant application rate, taking into account the decline of oxamyl (DT$_{50}$ = 11 days, worst case at 20°C) acceptable effects on reproduction can also be expected for *Aleochara bilineata* after few weeks.

**Risk assessment for tomato in glasshouse at 20 + 10 +10+10 kg Oxamyl 10SL/ha with drip irrigation based on extended lab test or aged residue tests.**

Although oxamyl is very toxic to standard sensitive species in the laboratory, exposure to foliage dwelling arthropods is expected to negligible because Oxamyl 10SL is applied to the bare glasshouse soils by direct incorporation into soil.
Effects on non-target soil meso- and macro fauna; effects on soil nitrogen transformation (Regulation (EU) N° 283/2013, Annex Part A, points 8.4, 8.5, and Regulation (EU) N° 284/2013 Annex Part A, points 10.4, 10.5)

| Test organism      | Test substance | Time scale       | End point | Toxicity                           |
|--------------------|----------------|------------------|-----------|------------------------------------|
| **Earthworms**     |                |                  |           |                                    |
| *Eisenia fetida*   | Oxamyl 10GR    | Sub-lethal, 56 d, 10% OM | NOEC      | \( \geq 6.4 \text{ mg a.s./kg dry wt soil} \) |
| *Eisenia fetida*   | Oxamyl 10GR    | Sub-lethal, 56 d, 10% OM | NOEC      | \(< 7 \text{ mg a.s./kg dry wt soil}\) |
| *Eisenia fetida*   | Oxamyl 10SL    | Sub-lethal, 56 d, 10% OM | NOEC \( \text{EC}_{10} \) | 3.2 \text{ mg a.s./kg dry wt soil} |
| *Eisenia fetida*   | IN-A2213       | Sub-lethal, 56 d, 10% OM | NOEC \( \text{EC}_{10} \) | 25 \text{ mg met/kg dry wt soil} |
| *Eisenia fetida*   | IN-D2708       | Sub-lethal, 56 d, 10% OM | NOEC      | 100 \text{ mg met/kg dry wt soil} |
| *Eisenia fetida*   | IN-N0079       | Sub-lethal, 56 d, 10% OM | NOEC \( \text{EC}_{10} \) | 50 \text{ mg met/kg dry wt soil} |
| *Hypoaspis aculeifer* | Oxamyl         | Sub-lethal, 14 d, 5% OM | NOEC \( \text{EC}_{10} \) | 16 \text{ mg a.s/kg dry wt soil} |
| *Hypoaspis aculeifer* | IN-A2213      | Sub-lethal, 14 d, 5% OM | NOEC \( \text{EC}_{10} \) | 100 \text{ mg met/kg dry wt soil} |
| *Hypoaspis aculeifer* | IN-D2708      | Sub-lethal, 14 d, 5% OM | NOEC \( \text{EC}_{10} \) | 100 \text{ mg met/kg dry wt soil} |
| *Hypoaspis aculeifer* | IN-N0079      | Sub-lethal, 14 d, 5% OM | NOEC \( \text{EC}_{10} \) | 25 \text{ mg met/kg dry wt soil} |

| **Other soil macro-organisms** | | | | |
| *Folsomia candida* | Oxamyl | Sub-lethal, 28 d, 5% OM | NOEC \( \text{EC}_{10} \) | 0.25 \text{ mg a.s/kg dry wt soil} |
| *Folsomia candida* | IN-A2213 | Sub-lethal, 28 d, 5% OM | NOEC \( \text{EC}_{10} \) | \(< 100 \text{ mg met/kg dry wt soil} \) |
| *Folsomia candida* | IN-D2708 | Sub-lethal, 28 d, 5% OM | NOEC \( \text{EC}_{10} \) | \(< 100 \text{ mg met/kg dry wt soil} \) |
| *Folsomia candida* | IN-N0079 | Sub-lethal, 28 d, 5% OM | NOEC \( \text{EC}_{10} \) | 12.5 \text{ mg met/kg dry wt soil} |
| *Hypoaspis aculeifer* | Oxamyl | Sub-lethal, 14 d, 5% OM | NOEC \( \text{EC}_{10} \) | 16 \text{ mg a.s/kg dry wt soil} |
| *Hypoaspis aculeifer* | IN-A2213 | Sub-lethal, 14 d, 5% OM | NOEC \( \text{EC}_{10} \) | 100 \text{ mg met/kg dry wt soil} |
| *Hypoaspis aculeifer* | IN-D2708 | Sub-lethal, 14 d, 5% OM | NOEC \( \text{EC}_{10} \) | 100 \text{ mg met/kg dry wt soil} |
| *Hypoaspis aculeifer* | IN-N0079 | Sub-lethal, 14 d, 5% OM | NOEC \( \text{EC}_{10} \) | 25 \text{ mg met/kg dry wt soil} |

\(^1\) Indicate distance assumed to calculate the drift rate and if 3D or 2D.
Higher tier testing

Three earthworm field studies in Germany (DuPont-9157), United Kingdom (DuPont-14076), and The Netherlands (DuPont-14075) were performed. The three field studies are not deemed completely reliable, mainly considering that no clear effects on abundance or biomass (>50% compared to the control) were observed in the reference item group. Moreover, different uncertainties have been identified in the studies. A population modelling study was performed to evaluate potential effects of oxamyl on Collembola following applications to potato and tobacco. The suitability of the population model was further discussed in the Pesticide Peer Review TC 63. Overall, the majority of the experts were of the opinion that, whilst the model appears to be reasonable, they would not accept the modelling as presented (even as supporting information). This was owing to the uncertainties raised. A new collembolan field study in Germany (DuPont-45959) was submitted. The field study was discussed in the Pesticide Peer Review TC 63. Overall, the experts agreed that the study should not be completely rejected and should be considered as reliable with restrictions. However, the study covers only the intended uses on potatoes (1.0 kg a.s./ha) in Central Zone and cannot be considered to address the risk for collembolan from the intended uses on tobacco in Southern Zone. The majority of the experts considered that a low risk for collembolans can be concluded for the representative use to potatoes in the Central zone. The risk assessment for tobacco in the Southern zone remains unresolved.

| Nitrogen transformation (nitrate formation rate) | Oxamyl 10SL | Oxamyl 10GR (tested as GF-4078) | Oxamyl 10GR | IN-A2213 | IN-D2708 | IN-N0079 | IN-T2921 |
|-----------------------------------------------|-------------|--------------------------------|-------------|----------|----------|----------|----------|
| Oxamyl | 28-day laboratory | <25% effect at doses of 12.0 and 60.0 mg a.s./kg d.w.soil | 28-day laboratory | <25% effect at day 28 1.5 and 15 kg a.s./ha and 23 mg a.s./Kg soil dw (0.6%, +15.3%, +7.2%) | 42-day laboratory | 25% effect at doses of 72.6 and 363 mg/kg soil d.w | 56-day laboratory | <25% effect at day 56 at 4.9 mg a.s./kg d.w.soil (+3.54%) | 28-day laboratory | <25% effects at doses of 1.59 and 15.9 mg/kg soil d.w | 56-day laboratory | <25% effect at day 56 at 3.0 and 15 mg a.s./kg d.w.soil (+6%, +15%) | 28-day laboratory | <25% effect at doses of 3.67 and 36.7 mg/kg soil d.w |

The LogP values of the metabolites were calculated using the KOWWIN program. For all of them, LogP values <2 were calculated, hence correction of the endpoints are not needed.

Toxicity/exposure ratios for soil organisms

Oxamyl 10GR applied on potato at 1000 g a.s./ha (using maximum initial PECₐ)
### Test organisms

| Test organism     | Test substance | Time scale | Soil depth (cm) | Soil PEC<sub>1</sub> (initial) | TER | Trigger |
|-------------------|----------------|------------|-----------------|-------------------------------|-----|---------|
| **Earthworms**    |                |            |                 |                               |     |         |
| *Eisenia fetida*  | 10GR           | Chronic    | 5               | 1.333                         | ≥4.8| 5       |
|                   |                |            | 10              | 0.667                         | ≥9.6| 5       |
| *Eisenia fetida*  | IN-A2213       | Chronic    | 5               | 0.513                         | 51.9| 5       |
|                   |                |            | 10              | 0.256                         | 104 | 5       |
| *Eisenia fetida*  | IN-D2708       | Chronic    | 5               | 0.560                         | 179 | 5       |
|                   |                |            | 10              | 0.280                         | 357 | 5       |
| **Other soil macro-organisms** |      |            |                 |                               |     |         |
| *Folsomia candida* | a.s.           | Chronic    | 5               | 1.333                         | 0.19| 5       |
|                   |                |            | 10              | 0.667                         | 0.37| 5       |
| *Hypoaspis aculeifer* | a.s.        | Chronic    | 5               | 1.333                         | 12  | 5       |
|                   |                |            | 10              | 0.667                         | 24  | 5       |
| *Folsomia candida* | IN-A2213       | Chronic    | 5               | 0.513                         | 195 | 5       |
|                   |                |            | 10              | 0.256                         | 391 | 5       |
| *Hypoaspis aculeifer* | IN-A2213  | Chronic    | 5               | 0.513                         | 195 | 5       |
|                   |                |            | 10              | 0.256                         | 391 | 5       |
| *Folsomia candida* | IN-D2708       | Chronic    | 5               | 0.560                         | 179 | 5       |
|                   |                |            | 10              | 0.280                         | 357 | 5       |
| *Hypoaspis aculeifer* | IN-D2708 | Chronic    | 5               | 0.560                         | 179 | 5       |
|                   |                |            | 10              | 0.280                         | 357 | 5       |

**Oxamyl 10GR applied on potato at 1000 g a.s./ha (using maximum peak PEC<sub>s</sub>).**

| Test substance component | Duration of test (days) | NOEC (mg a.s./kg soil) | Soil depth (cm) | Maximum peak PEC<sub>s</sub> (mg a.s./kg soil) | TER<sub>lt</sub> |
|--------------------------|-------------------------|------------------------|-----------------|-----------------------------------------------|-----------------|
| **Earthworms**           |                         |                        |                 |                                               |                 |
| Oxamyl 10GR              | 56                      | ≥6.4                   | 5               | 1.487                                         | ≥4.3            |
|                          |                         |                        | 10              | 0.744                                         | ≥8.6            |
| IN-D2708                | 56                      | 100                    | 5               | 0.582                                         | 172             |
|                          |                         |                        | 10              | 0.291                                         | 344             |

**Oxamyl 10GR applied on tobacco at 3000 g a.s./ha (using maximum initial PEC<sub>s</sub>).**
| Test organism         | Test substance | Time scale | Soil depth (cm) | Soil PEC (initial) | TER | Trigger |
|-----------------------|----------------|------------|-----------------|--------------------|-----|---------|
| **Earthworms**        |                |            |                 |                    |     |         |
| *Eisenia fetida*      | 10GR           | Chronic    | 5               | 4.000              | ≥1.6| 5       |
|                       |                |            | 10              | 2.000              | ≥3.2| 5       |
| *Eisenia fetida*      | IN-A2213       | Chronic    | 5               | 1.538              | 17  | 5       |
|                       |                |            | 10              | 0.769              | 34.6| 5       |
| *Eisenia fetida*      | IN-D2708       | Chronic    | 5               | 1.681              | 59  | 5       |
|                       |                |            | 10              | 0.841              | 119 | 5       |
| **Other soil macroorganisms** |       |            |                 |                    |     |         |
| *Folsomia candida*    | a.s.           | Chronic    | 5               | 4.000              | 0.06| 5       |
|                       |                |            | 10              | 2.000              | 0.13| 5       |
| *Hypoaspis aculeifer*| a.s.           | Chronic    | 5               | 4.000              | 4.0 | 5       |
|                       |                |            | 10              | 2.000              | 8   | 5       |
| *Folsomia candida*    | IN-A2213       | Chronic    | 5               | 1.538              | 65  | 5       |
|                       |                |            | 10              | 0.769              | 130 | 5       |
| *Hypoaspis aculeifer*| IN-A2213       | Chronic    | 5               | 1.538              | 65  | 5       |
|                       |                |            | 10              | 0.769              | 130 | 5       |
| *Folsomia candida*    | IN-D2708       | Chronic    | 5               | 1.681              | 59  | 5       |
|                       |                |            | 10              | 0.841              | 119 | 5       |
| *Hypoaspis aculeifer*| IN-D2708       | Chronic    | 5               | 1.681              | 59  | 5       |
|                       |                |            | 10              | 0.841              | 119 | 5       |

**Oxamyl 10GR applied on tobacco at 3000 g a.s./ha (using maximum peak PEC<sub>s</sub>)**

| Test substance component | Duration of test (days) | NOEC (mg a.s./kg soil) | Soil depth (cm) | Maximum peak PEC<sub>s</sub> (mg a.s./kg soil) | TER<sub>s</sub> |
|--------------------------|-------------------------|------------------------|-----------------|-----------------------------------------------|-----------------|
| **Earthworms**           |                         |                        |                 |                                               |                 |
| Oxamyl 10GR              | 56                      | ≥6.4                   | 5               | 4.461                                         | ≥1.4            |
|                          |                         |                        | 10              | 2.231                                         | ≥2.9            |
| IN-D2708                 | 56                      | 100                    | 5               | 1.746                                         | 57              |
|                          |                         |                        | 10              | 0.873                                         | 114             |
### Test Substance Component

| Test Substance Component | Species          | Duration of Test (days) | NOEC (mg a.s./kg soil) | Soil depth (cm) | Maximum Peak PECs (mg a.s./kg soil) | TER<sub>lt</sub> |
|--------------------------|------------------|-------------------------|------------------------|----------------|-------------------------------------|-----------------|
| **Oxamyl**               | **Folsomia candida** | 28                      | 0.25                   | 5              | 4.461                               | 0.06            |
|                          | **Hypoaspis aculeifer** | 14                      | 16                     | 5              | 4.461                               | 3.59            |
| **IN-D2708**             | **Folsomia candida** | 28                      | 100                    | 5              | 1.746                               | 57              |
|                          | **Hypoaspis aculeifer** | 14                      | 100                    | 10             | 0.873                               | 115             |

### Other Soil Macroorganisms

Oxamyl 10GR applied on tobacco at 5500 g a.s./ha (using maximum initial PEC<sub>i</sub>)

| Test Organism | Test Substance | Time Scale | Soil Depth (cm) | SOIL PEC | TER | Trigger |
|---------------|---------------|------------|----------------|----------|-----|---------|
| **Earthworms** |               |            |                |          |     |         |
| Eisenia fetida | 10GR         | Chronic    | 5              | 7.333    | ≥0.87 | 5       |
|                |              |            | 10             | 3.667    | ≥1.7  | 5       |
| Eisenia fetida | IN-A2213     | Chronic    | 5              | 2.820    | 9.4   | 5       |
|                |              |            | 10             | 1.410    | 18.9  | 5       |
| Eisenia fetida | IN-D2708     | Chronic    | 5              | 3.082    | 32.4  | 5       |
|                |              |            | 10             | 1.541    | 65    | 5       |

### Other Soil Macroorganisms

Oxamyl 10GR applied on tobacco at 5500 g a.s./ha (using maximum peak PEC<sub>s</sub>)

| Test Substance Component | Duration of Test (days) | NOEC (mg a.s./kg soil) | Soil Depth (cm) | Maximum Peak PEC<sub>s</sub> (mg a.s./kg soil) | TER<sub>lt</sub> |
|--------------------------|-------------------------|------------------------|----------------|-----------------------------------------------|-----------------|
| **Earthworms**           |                         |                        |                |                                               |                 |
| Oxamyl 10GR              | 56                      | ≥6.4                   | 5              | 8.179                                          | ≥0.8            |
| IN-D2708                 | 56                      | 100                    | 5              | 3.202                                          | 31              |
Effects on terrestrial non target higher plants (Regulation (EU) N° 283/2013, Annex Part A, point 8.6 and Regulation (EU) N° 284/2013 Annex Part A, point 10.6)

Screening data
Not available. ER50 tests have been provided.

Laboratory dose response tests

Risk for Oxamyl 10GR applied broadcast on tobacco at 5500 g a.s./ha.

| Species                  | Test substance | ER50 (kg a.s./ha) | ER50 (kg a.s./ha) | Exposure (kg a.s./ha<sup>+</sup>) | TER | Trigger |
|--------------------------|----------------|-------------------|-------------------|-----------------------------------|-----|---------|
| Zea mays                 | Oxamyl 10GR    | >5.5              | >5.5              | 0.08195                           | >67 | 5       |
| Avena sativa             | >5.5           | >5.5              |                   | 0.08195                           | >67 | 5       |
| Allium cepa              | >5.5           | >5.5              |                   | 0.08195                           | >67 | 5       |
| Lolium perenne           | >5.5           | >5.5              |                   | 0.08195                           | >67 | 5       |
| Cucumis sativus          | >5.5           | >5.5              |                   | 0.08195                           | >67 | 5       |
| Brassica napus           | >5.5           | >5.5              |                   | 0.08195                           | >67 | 5       |
| Pisum sativum            | >5.5           | >5.5              |                   | 0.08195                           | >67 | 5       |
| Glycine max              | >5.5           | >5.5              |                   | 0.08195                           | >67 | 5       |
| Beta vulgaris            | >5.5           | >5.5              |                   | 0.08195                           | >67 | 5       |
| Lycopersicon esculentum  | >5.5           | >5.5              |                   | 0.08195                           | >67 | 5       |

<sup>+</sup> Drift estimates are based on EFSA (2004) drift values for granular application with spinning disk, worst-case value.

Risk for Oxamyl 10SL

The exposure of non-target plants to Oxamyl 10SL can be considered negligible as the product is intended to be applied in closed glasshouses.
Effects on biological methods for sewage treatment (Regulation (EU) N° 283/2013, Annex Part A, point 8.8)

| Test type/organism | Respiration rate |
|--------------------|-----------------|
| Activated sludge   | EC50 >100mg/L.  |

As the PECsw at step 1 is 1.69 mg/L for applications of Oxamyl 10SL to tomatoes, and 1.85 mg/L for applications of oxamyl 10SL for use in solarization, there should be no effects of oxamyl 10SL applications on activated sludge activity.

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

- Available monitoring data concerning adverse effect of the a.s.
  - No monitoring data is available for this active substance
- Available monitoring data concerning effect of the PPP.
  - No monitoring data is available for Oxamyl 10SL and Oxamyl 10GR

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

Ecotoxicologically relevant compounds

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

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

| Substance       | Oxamyl 42%TK |
|-----------------|--------------|
| Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]5: | H411: Toxic to aquatic life with long lasting effects Aquatic Chronic 2 |
| According to the Peer review, the criteria for classification may be met for: | Oxamyl is already classified according to regulation 1272/2008 |

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