Appendix to:

EFSA (European Food Safety Authority), 2019. Conclusion on the peer review of the pesticide risk assessment of the active substance pydiflumetofen. EFSA Journal 2019;17(10):5821, 92 pp. doi:10.2903/j.efsa.2019.5821

© European Food Safety Authority, 2019

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

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

| Active substance (ISO Common Name) | Pydiflumetofen |
|-----------------------------------|----------------|
| Function (e.g. fungicide)         | Fungicide      |
| Rapporteur Member State           | France         |
| Co-rapporteur Member State        | Austria        |

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

| Chemical name (IUPAC) | 3-(difluoromethyl)-N-methoxy-1-methyl-N-[(RS)-1-methyl-2-(2,4,6-trichlorophenyl)ethyl]-1\texttextsubscript{H}-pyrazole-4-carboxamide |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------|
| Chemical name (CA)    | 3-(difluoromethyl)-N-methoxy-1-methyl-N-[1-methyl-2-(2,4,6-trichlorophenyl)ethyl]-1\texttextsubscript{H}-pyrazole-4-carboxamide |
| CIPAC No              | 999                                                                                                                          |
| CAS No                | 1228284-64-7                                                                                                                  |
| EC No (EINECS or ELINCS) | Not available                                                                       |
| FAO Specification (including year of publication) | Not available                                                                       |
| Minimum purity of the active substance as manufactured | 980 g/kg                                                                 |
| Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured | Open                                                                 |
| Molecular formula     | C\textsubscript{16}H\textsubscript{16}O\textsubscript{2}N\textsubscript{3}Cl\textsubscript{3}F\textsubscript{2} |
| Molar mass            | 426.7 g/mol                                                                   |
| Structural formula    | Pydiflumetofen consists of two enantiomers as a racemate (50:50) SYN546968 3-(difluoromethyl)-N-methoxy-1-methyl-N-[\texttextsubscript{S}]-1-methyl-2-(2,4,6-trichlorophenyl)ethyl]-1\texttextsubscript{H}-pyrazole-4- |
carboxamide

SYN546969
3-(difluoromethyl)-N-methoxy-1-methyl-N-[(R)-1-methyl-2-(2,4,6-trichlorophenyl)ethyl]-1H-pyrazole-4-carboxamide
| Physical and chemical properties (Regulation (EU) N° 283/2013, Annex Part A, point 2) |  |
|-------------------------------------------------|----------------|
| Melting point (state purity)                    | 112.7 °C       |
| Boiling point (state purity)                    | NA (decomposed before boiling) |
| Temperature of decomposition (state purity)     | 283 °C         |
| Appearance (state purity)                       | White powder   |
| Vapour pressure (state temperature, state purity) | 1.84.10⁻⁷ Pa at 20 °C |
|                                               | 5.30.10⁻⁷ Pa at 25°C |
| Henry’s law constant (state temperature)        | 1.05x10⁻⁴ Pa m³ mol⁻¹ |
| Solubility in water (state temperature, state purity and pH) | 1.5 mg/L at 25°C (pH 6.5) |
| Solubility in organic solvents (state temperature, state purity) | At 25°C: acetone 220 g/l, dichloromethane >500 g/l, ethyl acetate 130 g/l, hexane 0.270 g/l, methanol 26 g/l, octanol 7.2 g/l, toluene 67 g/l |
| Surface tension (state concentration and temperature, state purity) | 71.5 mN/m at 21.5°C (90 % saturated solution) |
| Partition coefficient (state temperature, pH and purity) | log P<sub>OW</sub> = 3.8 at 25°C |
| Dissociation constant (state purity)            | There is no pKa value within the range 2.0 to 12.0 |
| UV/VIS absorption (max.) incl. ε (state purity, pH) | In acidic solution: λ<sub>max</sub> (230nm): ε = 18267 (L mol⁻¹ cm⁻¹) |
|                                               | at λ > 290 nm: 295 nm |
|                                               | or ε at 295 nm: 59.5 L mol⁻¹ cm⁻¹ |
| Flammability (state purity)                     | Not classified as a flammable substance. |
| Explosive properties (state purity)             | Not classified as an explosive substance. |
| Oxidising properties (state purity)             | Not classified as an oxidising substance. |
Summary of representative uses evaluated, for which all risk assessments needed to be completed (pydiflumetofen) (Regulation (EU) No 284/2013, Annex Part A, points 3, 4)

Tradename: A19649B
Active Substances: SYN545974 200 g/L SC formulation

| Crop and/or situation (a) | Membe State or Countr y | Product name | FG or I (b) | Pests or Group of pests controlled (c) | Preparation | Application | Application rate per treatment | PHI (days) (m) | Remarks |
|--------------------------|-------------------------|--------------|-------------|--------------------------------------|-------------|------------|-------------------------------|---------------|---------|
| Pome fruit (apple, pear) | EU A19649B F | Powdery mildew (Podosphaera leucotricha) + scab (Venturia inaequalis) scab (Venturia pyrina) | SC 200 g/L Foliar spray BBC H 56-79 | 3 | 7 | 400-150 0 | 50 65 | 0.14L/Ha LWA in 18000m² LWA/ha = 0.25 l/ha (17ml/hl) |
| Grapes (wine & table) | EU A19649B F | Grey mould (Botrytis cinerea) | SC 200 g/L Foliar spray BBC H 67-89 | 2 | 14 | 500-140 0 | 200 21 |
| Grapes (wine & table) | EU A19649B F | Powdery mildew (Uncinula necator) | SC 200 g/L Foliar spray BBC H 13-77 | 2 | 10 | 150-100 0 | 40 21 |
| Potato | EU A19649B F | Early blight (Alternaria solani) | SC 200 g/L Foliar spray BBC H 31-89 | 3 | 14 | 200-500 | 40 7 |
| Fruiting vegetables (tomato) | EU A19649B F | Early blight (Alternaria solani) | SC 200 g/L Foliar spray BBC H 51-89 | 2 | 7 | 300-100 0 | 70 1 |
| Edible cucurbit, (cucumber, | EU A19649B F | Powdery mildew (Sphaerotheca fuliginea) | SC 200 g/L Foliar spray BBC H 20-89 | 2 | 7 | 300-100 50 1 | Equivalent to 25 |
| Crop and/or situation (a) | Membe r State or Countr y | Product name | Pests or Group of pests controlled (c) | Preparation | Application | Application rate per treatment | Remarks |
|--------------------------|--------------------------|--------------|--------------------------------------|-------------|------------|--------------------------------|---------|
|                          |                          |              |                                      | Type (d-f)  | Conc. a.s. (i) | method kind (f-h) | range of growth stages & season (j) | number min-max (k) | Interval between application (min) | Water L/ha min-max | g a.s./ha min-max (l) | PHI (days) (m) | |
| courgette)               |                          |              |                                      | SC         | 200 g/L | Foliar spray | BBC H 20-89 | 2  | 7 | 300-100  0 | 50  | 1 | Equivalen t to 25 mL/hL |
| Inedible cucurbit (melon, watermelon) | EU | A19649B | F | Powdery mildew (Sphaerotheca fuliginea) and Erysiphe sp) | SC | 200 g/L | Foliar spray | BBC H 21-49 | 2  | 14 | 200-600 | 70  | 14 |
| Flowering brassica (broccoli,cauliflower), leafy brassica (kale), head brassica (cabbage) | EU | A19649B | F | Alternaria sp and Mycosphaerella sp. | SC | 200 g/L | Foliar spray | BBC H 21-49 | 2  | 14 | 200-600 | 70  | 14 |
| Head brassica (Brussels sprout), kohlrabi | NEU | A19649B | F | Alternaria sp and Mycosphaerella sp. | SC | 200 g/L | Foliar spray | BBC H 21-49 | 2  | 14 | 200-600 | 70  | 14 |
|                          |                          |              |                                      |            |           |                  |                                    |                  |                        |                |                  |               | Uses sought in Northern EU only |
Summary of additional intended uses for which MRL applications have been made, that in addition to the uses above, have also been considered in the consumer risk assessment (pydiflumetofen) Regulation (EC) N° 1107/2009 Article 8.1(g))

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

| Crop and/or situation (a) | Member State or Country | Product name | F G or I (b) | Pests or Group of pests controlled (c) | Preparatio n (d-f) | Application (g) | Application rate per treatment (h) | PHI (days) (i) | Remarks |
|---------------------------|------------------------|--------------|-------------|---------------------------------------|--------------------|----------------|----------------------------------|---------------|---------|
| Potatoes / Sweet Potatoes/ Yams | EU | NEU/SE U | Early blight (Alternaria solani) | SC | Foliar spray | BBC H 31-89 | 3 | 14 | - | 200-500 | 40 | 7 |
| Tomatoes (protected) | EU | G | Leveillula taurica, Oidium lycopersici | SC | Foliar spray | BBC H 51-89 | 2 | 7 | - | 300-1000 | 70 | 1 |
| Tomatoes (protected) | EU | G | Botrytis cinerea | SC | Foliar spray | BBC H 51-89 | 2 | 7 | - | 300-1000 | 200 | 1 |
| Peppers (protected) | EU | G | Leveillula taurica | SC | Foliar spray | BBC H 51-89 | 2 | 7 | - | 300-1000 | 70 | 3 |

MRL Application (according to Article 8.1(g) of Regulation (EC) No 1107/2009)

- 0.14l/Ha LWA in 18000m²
- LWA/ha = 0.25 l/ha (17ml/l)
| Crop and/or situation (a) | Member State or Country | Product name (b) | Pests or Group of pests controlled (c) | Preparatio n Type (d-f) | Conc .a.s. (i) | method kind (f-h) | range of growth stages & season (j) | numbe r min-max (k) | Interval between application (min) | Application rate per treatment kg a.s./hL min-max (l) | Water L/ha min-max (m) | PHI (days) (n) | Remarks |
|--------------------------|-------------------------|-----------------|--------------------------------------|------------------------|---------------|-----------------|-------------------------------------|-----------------|-----------------------------------|-----------------------------------------------|---------------------|-------------|---------|
| Peppers/ Sweet peppers/ Bell peppers (field) | EU | NEU/SE U | Leveillula taurica | SC | 200 g/L | Foliar spray | BBC H 51-89 | 2 | 7 | - | 300-1000 | 70 | 3 |
| Aubergine/Eggplants (field) | EU | NEU/SE U | Early blight (Alternaria solani) | SC | 200 g/L | Foliar spray | BBC H 51-89 | 2 | 7 | - | 300-1000 | 70 | 1 |
| Aubergine Eggplants (protected) | EU | G | Powdery mildew (Leveillula taurica, Oidium lycopersici) | SC | 200 g/L | Foliar spray | BBC H 51-89 | 2 | 7 | - | 300-1000 | 70 | 1 |
| Aubergine Eggplants (protected) | EU | G | Botrytis cinerea | SC | 200 g/L | Foliar spray | BBC H 51-89 | 2 | 7 | - | 300-1000 | 200 | 1 |
| Okra (protected) | EU | G | Leveillula taurica | SC | 200 g/L | Foliar spray | BBC H 51-89 | 2 | 7 | - | 300-1000 | 70 | 3 |
| Okra (field) | EU | NEU/SE U | Leveillula taurica | SC | 200 g/L | Foliar spray | BBC H 51-89 | 2 | 7 | - | 300-1000 | 70 | 3 |
| Cucurbit Edible peel : | EU | NEU/SE U | Powdery mildew (Sphaerotheca | SC | 200 g/L | Foliar spray | BBC H 20-89 | 2 | 7 | - | 300-1000 | 50 | 1 | Equivalent to 25 mL/hL |
| Crop and/or situation (a) | Member State or Country | Product name | FG or I (b) | Pests or Group of pests controlled (c) | Preparations 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) | Application rate per treatment kg a.s./hL min-max (l) | Water L/ha min-max (l) | PHI (days) (m) | Remarks |
|--------------------------|-------------------------|--------------|-------------|----------------------------------------|------------------------|--------------|----------------|-----------------------------------|-------------------|--------------------------------|--------------------------------------|---------------------|--------|---------|
| cucumber, courgette/ zucchini, Gherkins and others (field) | | | | | | | | | | | | | | |
| Cucurbits Edible peel (protected) | EU | | G | Sphaerotheca fuliginea | SC | 200 g/L | Foliar spray | BBC H 20-89 | 2 | 7 | - | 300-1000 | 50 | 1 |
| Cucurbits Inedible peel: melon, watermelon Pumpkin and others (field) | EU | NEU/SEU | | Powdery mildew (Sphaerotheca fuliginea and Erysiphe sp) | SC | 200 g/L | Foliar spray | BBC H 20-89 | 2 | 7 | - | 300-1000 | 50 | 1 | Equivalent to 25 mL/hL |
| Cucurbits Inedible peel (protected) | EU | | G | Sphaerotheca fuliginea | SC | 200 g/L | Foliar spray | BBC H 20-89 | 2 | 7 | - | 300-1000 | 50 | 1 |
| Kale/chinese cabbage/pe-tsai | EU | NEU/SEU | | Alternaria sp. and Mycosphaerella sp. | SC | 200 g/L | Foliar spray | BBC H 21-49 | 7 | 2 | 14 | - | 200-600 | 70 | 14 |
| Crop and/or situation (a) | Member State or Country | Product name | F or I (b) | Pests or Group of pests controlled (c) | Preparation (d-f) | Application (g) | Application rate per treatment | Remarks |
|--------------------------|-------------------------|--------------|------------|----------------------------------------|-------------------|----------------|---------------------------------|---------|
| Soya bean | import tolerance Argentina | G | Septoriaglycines Cercospora sojina, Cercospora kikuchii | SC | Foliar spray | 45 DBH | 2 | - | 100-400 | 160* | 30 |

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure).
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds.
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR).
(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(f) All abbreviations used must be explained.
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench.
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated.

(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).
(j) Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application.
(k) Indicate the minimum and maximum number of applications possible under practical conditions of use.
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha).
(m) PHI - minimum pre-harvest interval.

*160 g/ha - 60 g a.s./ha for pydiflumetofen and 100 g a.s./ha for difenoconazole.
### Further information, Efficacy

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

| Results of field trials demonstrate that A19649B, containing 200 g/l pydiflumetofen as a suspension concentrate, has a good efficacy on a broad range of crops against a broad range of diseases which are all representative across Europe. |

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

| Taking into account the results of the trials, A19649B, containing 200 g/L pydiflumetofen, is a safe product for all these representative crops, even after multiple applications. |

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

| Considering the activity of pydiflumetofen (as fungicide) and the results of crop safety trials, no negative effect is intended on succeeding crops, adjacent crops and beneficials. |

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

| Activity against target organism | Not applicable (no groundwater metabolites) |
Methods of Analysis

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

| Technical a.s. (analytical technique) | HPLC-UV (230 nm) |
|--------------------------------------|------------------|
| Impurities in technical a.s. (analytical technique) | There is no relevant impurity |
| Plant protection product (analytical technique) | HPLC-UV (230 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**

| Category | Residue Definition |
|----------|-------------------|
| Food of plant origin | Pydflumetofen |
| Food of animal origin | Pydflumetofen |
| Soil | Pydflumetofen |
| Sediment | Pydflumetofen |
| Water surface | Pydflumetofen |
| Drinking/ground | Pydflumetofen |
| Air | Pydflumetofen |
| Body fluids and tissues | Pydflumetofen and its metabolite 2,4,6-TCP (2,4,6-trichlorophenol) (free and conjugated) |

**Monitoring/Enforcement methods**

| Category | Analytical Technique and LOQ for Methods for Monitoring Purposes |
|----------|---------------------------------------------------------------|
| Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes) | HPLC/MS/MS (QuEChERS) pydflumetofen LOQ = 0.01 mg/kg Data gap: extraction efficiency |
| Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes) | HPLC-MS/MS (QuEChERS) LOQ = 0.01 mg/kg Data gap: validation data for muscle HPLC/MS/MS 2,4,6-trichlorophenol LOQ = 0.01 mg/kg |
| Soil (analytical technique and LOQ) | HPLC-MS/MS LOQ = 0.5 µg/kg |
| Water (analytical technique and LOQ) | HPLC-MS/MS LOQ = 0.05 µg/L |
| Air (analytical technique and LOQ) | HPLC-MS/MS LOQ = 30 µg/m³ |
| Body fluids and tissues (analytical technique and LOQ) | HPLC-MS/MS (QuEChERS) pydflumetofen LOQ = 0.01 mg/kg HPLC-MS/MS 2,4,6-trichlorophenol LOQ = 0.01 mg/kg |
Classification and labelling with regard to physical and chemical data (Regulation (EU) No 283/2013, Annex Part A, point 10)

| Substance          | pydiflumetofen |
|--------------------|----------------|
| Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]¹: | - |
| Peer review proposal ² for harmonised classification according to Regulation (EC) No 1272/2008: | - |

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

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

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

Rate and extent of oral absorption/systemic bioavailability

85-90% of oral dose systemically available in male and females rats (based on urinary (6-13%) and biliary (67-81%) excretion within 72 h, single oral gavage dose at 5 mg/kg bw)

Oral absorption was reduced to 50-55% at 100 mg/kg bw and 19-24% at 300 mg/kg bw

Based on > 85% oral availability at the low dose tested, no correction for the AOEL or AAOEL is required

Toxicokinetics

T_{1/2} < 2 h following iv administration of 1 mg/kg bw.

Systemic exposure (AUC(0-t)) was non-linear from 300 mg/kg bw in male rat and 100 mg/kg in female rat.

Following a single oral administration, C_{max} 0.5-2 hours (5 mg/kg bw) and 8 hours (≥100 mg/kg bw). AUC(0-t) increased sub proportionally between 5 mg/kg bw and higher doses.

|       | 5 mg/kg bw | 1000 mg/kg bw |
|-------|------------|---------------|
|       | male | female | male | female |
| C_{max} (ng equiv/g) | 562 | 715 | 11200 | 10100 |
| t_{max} (hours) | 1 | 1 | 24 | 24 |
| t_{1/2} (hours) | 46 | 43 | 22 | 20 |
| AUC(0-t) (ng equiv.h/g) | 8520 | 12800 | 449000 | 353000 |
| AUC(0-inf) (ng equiv.h/g) | 11900 | 18100 | 562000 | 401000 |

Distribution

Widely distributed, with highest concentrations of radioactivity observed in the liver and kidney

Potential for bioaccumulation

No evidence for accumulation

Rate and extent of excretion

Following a single oral gavage dose, ca. 91% was excreted within 48 h with excretion complete by 168 h; predominantly in faeces via biliary excretion. The remainder of the dose was recovered from urine, with <0.1% of dose recovered in expired air or in the carcass.

Metabolism in animals

Extensively metabolised (> 95%); in rat, unchanged parent in urine accounted for less than 3.9% of the 5 mg/kg bw oral dose.

The primary metabolic routes included demethoxylation, N-dealkylation, single and dihydroxylation, O-demethylation and oxidative and reductive dechlorination. The majority of these metabolites were also mono and di-hydroxylated and in many cases conjugated with glucuronide or glutathione.

Metabolic profile very similar in mouse, goat and hen.

In vitro metabolism

No notable difference of pydiflumetofen metabolism in a comparative in vitro study with rat and human liver
**Toxicologically relevant compounds (animals and plants)**
- Pydiflumetofen and 2,4,6-Trichlorophenol

**Toxicologically relevant compounds (environment)**
- Pydiflumetofen

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

| Toxicity | Value |
|----------|-------|
| Rat LD$_{50}$ oral | > 5000 mg/kg bw |
| Rat LD$_{50}$ dermal | > 5000 mg/kg bw |
| Rat LC$_{50}$ inhalation | > 5.11 mg/L air /4h (nose only) |
| Skin irritation | Non-irritant |
| Eye irritation | Non-irritant |
| Skin sensitisation | Non-sensitiser (LLNA) |
| Phototoxicity | Not-phototoxic (*in vitro* 3T3 NRU assay) |

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

| Target organ / critical effect | Description |
|-------------------------------|-------------|
| Body weight reduction (dog)   | Liver: increased liver weight, blood clinical chemistry parameters changes, hepatocellular hypertrophy (rat, mouse, dog) Thyroid: hypertrophy of thyroid follicular epithelium (rat) |

| Relevant oral NOAEL | 90-day, rat: 18.6 mg/kg bw per day 90-day, mouse: 17.5 mg/kg bw per day 90-day, dog: 30 mg/kg bw per day |
| Relevant dermal NOAEL | 28-day, rat: 1000 mg/kg bw per day |
| Relevant inhalation NOAEL | No data - not required |

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

| Study type | Description |
|------------|-------------|
| *In vitro* studies | Not genotoxic (*negative Ames and MLA assays, negative response for clastogenicity (CA)) |
| *In vivo* studies | Not genotoxic (*negative mouse bone marrow micronucleus and rat chromosome aberration assays*) |
| Photomutagenicity | Not required |
| Potential for genotoxicity | Pydiflumetofen is unlikely to be genotoxic |
### Long-term toxicity and carcinogenicity (Regulation (EU) N°283/2013, Annex Part A, point 5.5)

| Long-term effects (target organ/critical effect) | Rat & mouse: Lower bodyweight and increased liver weight with associated histopathology changes |
| Relevant long-term NOAEL | 2-year, rat: 9.9 mg/kg bw per day 18-month, mouse: 9.2 mg/kg bw per day |
| Carcinogenicity (target organ, tumour type) | Rat: no increased incidence of tumours over controls Mouse: liver tumours in the male mouse only. Additional work supports the tumour mode of action is not relevant to humans. Pydiflumetofen is unlikely to pose a hazard to humans. Assessment considered inconclusive regarding the potential adversity related to SDHI in human (data gap) |
| Relevant NOAEL for carcinogenicity | 2-year, rat: 102 mg/kg bw per day (highest dose tested) 18-month, mouse: 9.2 mg/kg bw per day |

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

#### Reproduction toxicity

| Reproduction target / critical effect | Parental toxicity: Liver changes (increased liver weight (>15%) and hepatocellular hypertrophy). In males only, lower bodyweight and hypertrophy of thyroid follicular epithelium. Reproductive toxicity: no adverse effect observed in rat 2-generation study Offspring’s toxicity: delayed sexual maturation in F1 (no subsequent effect on oestrus cycling, mating performance, fertility or on anogenital distance) and decrease bw in both males and females in F1 generation. |
| Relevant parental NOAEL | 36 mg/kg bw per day |
| Relevant reproductive NOAEL | 116 mg/kg bw per day (highest dose tested) |
| Relevant offspring NOAEL | 36 mg/kg bw per day |

#### Developmental toxicity

| Developmental target / critical effect | Rat: Maternal toxicity: reduced bodyweight gain and food consumption at highest dose (100 mg/kg bw per day) gestation days 6-10 only. Developmental toxicity: No treatment related effects. Rabbit: Maternal toxicity: No treatment related effects |
### Developmental toxicity: increased incidence of one skeletal variant (rib costal cartilage interrupted)

| Relevant maternal NOAEL | Rat: 30 mg/kg bw per day |
|-------------------------|--------------------------|
| Rabbit: 500 mg/kg bw per day |

| Relevant developmental NOAEL | Rat: 100 mg/kg bw per day |
|-----------------------------|--------------------------|
| Rabbit: 10 mg/kg bw per day |

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

| Acute neurotoxicity | No effects in male rats at 2000 mg/kg bw per day. In female rats, clinical signs and effect on body temperature and locomotor activity at ≥ 300 mg/kg bw. All signs of toxicity resolved by day 2. |
|---------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

| Repeated neurotoxicity | Study not required |
|------------------------|-------------------|

| Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity) | No additional studies |
|-----------------------------------------------------------------------------|---------------------|

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

| Supplementary studies on the active substance | Mechanistic study performed in the male mouse to investigate mode of action (MoA) for liver tumours. Using a WHO/IPCS MoA Framework, the key events of constitutive androstane receptor (CAR) activation and proliferation were demonstrated in the mouse and/or in vitro hepatocytes, however in vitro human hepatocytes exposed to pydiflumetofen did not elicit a proliferative response. Therefore, the MoA for liver tumours in the male mouse is considered of low relevance to humans. Pydiflumetofen is considered an inducer of hepatic microsomal UDGPT in male rats. Pydiflumetofen was not an inhibitor of rat thyroid peroxidase in vitro. No sign indicative of immunotoxicity seen in the overall data package. |
|---------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

| Endocrine disrupting properties | The Thyroid (T) modality was sufficiently investigated and no adversity was observed. The Oestrogen, Androgen and Steroidogenesis (EAS) modalities were sufficiently investigated and no adversity was observed. It is concluded that pydiflumetofen is not an ED in humans according to point 3.6.5 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605. |
|-------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

| Studies performed on metabolites or impurities | |
|-----------------------------------------------| |
| Substance Code | Description |
|----------------|-------------|
| CSAA798670 (CA4312; NOA449410; M700F001) | Rat acute oral LD$_{50}$ > 2000 mg/kg bw  
Non-genotoxic (negative Ames, MLA and CA assays \textit{in vitro})  
28/90-day, rat NOAEL: 1000 mg/kg bw per day (highest dose tested)  
Developmental toxicity in rabbit: maternal and developmental NOAELs: 250 mg/kg bw per day (highest dose tested)  
ADI: 0.25 mg/kg bw per day (rabbit developmental toxicity study, UF 1000)  
No ARfD needed. |
| SYN508272 (M700F007) | Rat acute oral LD$_{50}$ > 500 < 2000 mg/kg bw  
Non-genotoxic (Negative in Ames, MLA and \textit{in vivo} rat micronucleus assay; positive \textit{in vitro} CA)  
28-day, rat NOAEL: 37.4 mg/kg bw per day (based on lower body weight, body weight gain and food consumption)  
ADI and ARfD: 0.04 mg/kg bw per day (28-day, rat; UF 1000) |
| SYN545547 | Non-genotoxic (negative Ames, MN and MLA assays \textit{in vitro})  
Database for general toxicity considered insufficient to set toxicological reference values |
| SYN548263 | Non-genotoxic (negative Ames, MN and MLA assays \textit{in vitro})  
Database for general toxicity considered insufficient to set toxicological reference values |
| SYN547897 | Non-genotoxic (QSAR and read-across analysis)  
Database for general toxicity considered insufficient to set toxicological reference values |
| 2,4,6-TCP | Carcinogenic in mouse and rat  
Genotoxicity database inconclusive  
Data gap for a complete genotoxicity data package (including \textit{in vivo} COMET assay) |
| SYN547891 | Data gap to clarify the genotoxic potential of the metabolite |

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

Limited; new active substance, no detrimental effects on health in manufacturing personnel
Summary3 (Regulation (EU) Nº 1107/2009, Annex II, point 3.1 and 3.6)

| Parameter                                      | Value (mg/kg bw (per day)) | Study                          | Uncertainty factor |
|------------------------------------------------|-----------------------------|--------------------------------|-------------------|
| Acceptable Daily Intake (ADI)                  | 0.09                        | Mouse, 18-month study          | 100               |
| Acute Reference Dose (ARfD)                    | 0.3                         | Rat, developmental toxicity study | 100               |
| Acceptable Operator Exposure Level (AOEL)      | 0.1                         | Rabbit, developmental toxicity study | 100*              |
| Acute Acceptable Operator Exposure Level (AAOEL)| 0.3                         | Rat, developmental toxicity study | 100*              |

*No correction required for oral absorption (>80%)

CSAA798670 (CA4312; NOA449410; M700F001)

| Parameter | Value (mg/kg bw (per day)) | Study                          | Uncertainty factor |
|-----------|-----------------------------|--------------------------------|-------------------|
| ADI       | 0.25                        | Rabbit developmental toxicity study | 1000              |
| ARfD      | Not needed                  |                                |                   |

SYN508272 (M700F007)

| Parameter | Value (mg/kg bw (per day)) | Study                          | Uncertainty factor |
|-----------|-----------------------------|--------------------------------|-------------------|
| ADI       | 0.04                        | Rat, 28-day study              | 1000              |
| ARfD      | 0.04                        | Rat, 28-day study              | 1000              |

Dermal absorption (Regulation (EU) Nº 284/2013, Annex Part A, point 7.3)

Representative formulation (A19649B, SC formulation containing 200 g/L pydiflumetofen)

| Concentrate: 0.2 %*  | Spray dilution (2 g/L): 0.5% | Spray dilution (0.25 g/L): 1.5% | Spray dilution (0.05 g/L): 7.5% | Spray dilution (0.04 g/L): 9% |
|----------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| Worst case in-use spray dilution (0.033 g/L, pome fruit): 11% (pro-rata correction)* | Dermal absorption data derived from a triple pack (rat in vivo and rat/human in vitro studies) |

*used in the exposure risk assessment below

Exposure scenarios (Regulation (EU) Nº 284/2013, Annex Part A, point 7.2)

Operators

Use: High crops, tractor mounted equipment (upwards),

3 If available include also reference values for metabolites
application rate 200 g a.s./ha

| Exposure estimates | % AOEL | % AAOEL |
|--------------------|--------|---------|
| EFSA calculator    |        |         |
| Without PPE:       | 15.1   | 18      |

**Use: Low crops, tractor mounted equipment (downwards), application rate 70 g a.s./ha**

| Exposure estimates | % AOEL | % AAOEL |
|--------------------|--------|---------|
| EFSA calculator    |        |         |
| Without PPE:       | 1.5    | 4.3     |

**Workers**

**Use: grapes**, 2 applications, 200 g as/ha, measured DFR = 1.534µg/cm²/g a.s./ha

| Exposure estimates (EFSA calculator): | % AOEL |
|--------------------------------------|--------|
| No PPE (workwear, arms and legs covered) | 45.4   |

**Use: pome fruit**, 3 applications, 50 g as/ha

| Exposure estimates (EFSA calculator): | % AOEL |
|--------------------------------------|--------|
| No PPE (workwear, arms and legs covered) | 25.5   |

**Use: all low crops**, 2 applications, 70 g as/ha

| Exposure estimates (EFSA calculator): | % AOEL |
|--------------------------------------|--------|
| No PPE (workwear, arms and legs covered) | 14.2   |

**Bystanders and residents**

**Use: Grape**, tractor mounted equipment (upwards), application rate 200 g a.s./ha

| Exposure estimates (EFSA calculator): | % AAOEL |
|--------------------------------------|---------|
| **Bystander** (worst case exposure pathway) |        |
| Child                                | 4.7     |
| Adult                                | 2.6     |

| Exposure estimates (EFSA calculator): | % AOEL |
|--------------------------------------|--------|
| **Resident** (sum all exposure pathways) |        |
| Child                                | 10.6    |
| Adult                                | 5.4     |

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

#### Substance:

| Pydiflumetofen |
|----------------|
| No current harmonised classification |
| According to the ECHA RAC opinion (ECHA, 2019): | |
| Carc. 2, H351, ‘suspected of causing cancer’ |
| Repro 2, H361f, ‘suspected of damaging fertility’ |

---

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

None

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

Metabolism in plants (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.1, 6.5.1, 6.6.1 and 6.7.1)

| Primary crops | Crop groups | Crop(s) | Application(s) | DAT (days) |
|---------------|-------------|---------|----------------|------------|
| (Plant groups covered) | Fruit crops | Tomato | 2 x 200 g as/ha, BBCH 83 and 86, foliar spray 1 x 20 mg as/plant, transplanting stage, soil application | 1 and 14 days (fruits only) 103 days (fruit only) |
| OECD Guideline 501 | Cereals/grass crops | Wheat | 2 x 125 g as/ha, BBCH 32-34 and 58 | Forage: 10d after application 1 Hay: 29d after application 2 Straw and grain: 50d after application 2 |
| | Pulses/Oilseeds | Oilseed rape | 1 x 150 g as/ha, BBCH 65 | 62 days (seed and trash) |

According to the results of metabolism in primary crops, reduction of the parent molecule and demethylation of the pyrazole represent the principle metabolic transformations observed in all three crops with additional metabolism into multiple polar low residue components detected at levels at which identification was not required.

| Rotational crops | Crop groups | Crop(s) | PBI (days) | Comments |
| (metabolic pattern) | Root/tuber crops | Turnip | 30, 120, 270 | Confined studies were conducted with both labelled pydiflumetofen at max rate of 408g/ha. However, pydiflumetofen is a very highly persistent compound with DT50=8540 days (See Section 4), therefore the studies are underdosed. |
| OECD Guideline 502 | Leafy crops | Lettuce | 30, 120, 270 | |
| | Cereal (small grain) | Wheat | 30, 120, 270 | |
| | Other | - | - | |

Rotational crop and primary crop metabolism similar?

Metabolism pathway for pydiflumetofen-in primary crop and rotational crops is similar.

Besides parent compound found up to 75% of TRRs, SYN547891 was also found in wheat forage and immature lettuce only (12% TRR).

| Processed commodities | Conditions | pyrazole-5-14[14C]- pydiflumetofen |
| (standard hydrolysis study) | | SYN545547 | SYN547891 | Unidentified |
| OECD Guideline 507 | 20 min, 90°C, pH 4 | 96.15-97.47 % | 0.26-0.63% | 0.20-0.51 % | 0.78-1.09 % |
| | 60 min, 100°C, pH 5 | 95.97-96.48 % | 0.35-0.62 % | 0.37-0.51 % | 0.97-1.33 % |
| | 20 min, 120°C, pH 6 | 95.54-95.74 % | 0.64-0.78 % | 0.08-0.28 % | 1.66-1.74 % |
No hydrolysis of pydiflumetofen was observed under any of the processing conditions. Pydiflumetofen is therefore considered to be hydrolytically stable under conditions representative of pasteurisation, baking, brewing, boiling and sterilisation.

### Metabolism in livestock (Regulation (EU) No 283/2013, Annex Part A, points 6.2.2, 6.2.3, 6.2.4, 6.2.5, 6.7.1)

| OECD Guideline 503 and SANCO/11187/2013 rev. 3 (fish) | Animal | Dose (mg/kg bw/d) | Duration (days) | N rate/comment |
|---------------------------------------------|--------|-----------------|----------------|----------------|
| Animals covered | Laying hen | 3.3 - 3.6 | 14 | 792 N compared to layer hen dietary burden intake |
| | Goat/Cow | 4.6 | 7 | 43 N compared to dairy cattle dietary burden intake |

| Time needed to reach a plateau concentration in milk and eggs (days) | Eggs: 6 days (phenyl) and 7 days (pyrazole) Milk: 2 days (phenyl) and 5 days (pyrazole) |
|-----------------------------|------------------------------------------|
| Animal residue definition for monitoring (RD-Mo) OECD Guidance, series on pesticides No 31 | Pydiflumetofen |
| Animal residue definition for risk assessment (RD-RA) | All matrices: pydiflumetofen and 2,4,6-trichlorophenol (free and conjugated). The expression is pending on the submission of toxicological data on 2,4,6-TCP |
| Conversion factor (monitoring to risk assessment) | Pending on the outcome of the toxicological evaluation of 2,4,6-TCP, derivation of CF might be possible. |
| Metabolism in rat and ruminant similar (Yes/No) | Yes |
| Fat soluble residues (Yes/No) (FAO, 2009) | Yes |
Residues in succeeding crops (Regulation (EU) N° 283/2013, Annex Part A, point 6.6.2)

| Confined rotational crop study | Based on the studies conducted at the application rate of 408 g/ha no residue above 0.01 mg/kg was found in wheat grain, mature lettuce and turnip tubers and foliage at all Plant Back Intervals (PBI) tested. Nevertheless, significant residues of pydiflumetofen are expected in wheat forage and immature lettuce with a PBI of 30 days and in wheat hay and straw for all PBI. Moreover, the application rate from the study doesn’t cover the max. PEC soil (see section 4), therefore residues in succeeded crops (food and feed) cannot be excluded. |
|--------------------------------|---------------------------------------------------------------------------------------------------------------|
| (Quantitative aspect)          |                                                                                                               |
| OECD Guideline 502             |                                                                                                               |
| Field rotational crop study    | Six field trials conducted at max 600 g/ha application rate, were available in the crops representative for rotations leafy (spinach), root (carrots and radish), cereals (barley and maize). In two of the trials, other crops (kale, tomatoes, strawberries, soyabean and beans) were also investigated. At the first PBI residues pydiflumetofen were found in spinach, radish roots and tops (up to 0.04 mg/kg). In barley straw residues were found at first and second PBI up to 0.09 mg/kg, while in roots carrots (0.02 mg/kg) and in spinach (up 0.05 mg/kg) residues were found at all PBI. No residues of pydiflumetofen in barley grain, were below the LOQ at all plant-back intervals. No residues above LOQ were detected in kale, tomato, fresh beans and strawberry at PBI of 30, 120, 270 and 330 days. Since the available studies were underdosed when compared with the max PEC soil and considering also the high persistence of pydiflumetofen in the soil, the settings of MRL in rotational crops might become necessary. |
| OECD Guideline 504             |                                                                                                               |
Stability of residues (Regulation (EU) No 283/2013, Annex Part A, point 6.1)
OECD Guideline 506

| Plant products (Category) | Commodity     | T (°C)  | Stability (Month) |
|--------------------------|---------------|---------|-------------------|
| High water content       | Lettuce head  | -18°C   | 23                |
| High oil content         | Rape seed     | -18°C   | 23                |
| High protein content     | Adzuki bean   | -18°C   | 23                |
| High starch content      | Wheat grain   | -18°C   | 23                |
| High acid content        | Potato tuber  | -18°C   | 23                |
|                          | Orange fruit  | -18°C   | 23                |

The stability of pydiflumetofen residues was demonstrated in one of each commodities for all categories (high water, high oil, high protein, high starch and high acid content); thus, pydiflumetofen residues could be considered stable during storage for 23 months in all crops plant, when stored at -18°C.

| Animal | Animal commodity | T (°C)  | Stability (Month) |
|--------|------------------|---------|-------------------|
|        |                  |         | pydiflumetofen    | SYN5082  | SYN5482  | SYN5478  | SYN548  |
|        |                  |         |                   | 72       | 64       | 97       | 263      | conjuga-
|        |                  |         |                   |          |          |          |          | ted 2,4,6-
|        |                  |         |                   |          |          |          |          | TCP       |
| Bovine | Muscle           | -18°C   | 12                | -        | -        | -        | -        | 12       |
| Bovine | Liver            | -18°C   | 12                | -        | -        | 6        | -        | 12       |
| Bovine | Kidney           | -18°C   | 12                | -        | -        | 12       | 12       | 12       |
| Bovine | Milk             | -18°C   | 12                | 12       | 12       | -        | -        | 12       |
| Chicken| Egg              | -18°C   | 12                | -        | -        | -        | -        | 12       |
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) |
|------------|-------------------|--------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|-----------------------|----------------|----------------|
| **Apple**  | NEU               | <0.01, 4x0.02, 0.03, 0.05, 0.14                                                                   | According to the Student test, 5% and Mann-Whitney U-test (α=5%), residue levels in southern trials are not different from the northern ones. MRL, HR and STMR derived from the merged dataset. | 0.2                   | 0.14           | 0.02           |
|            | SEU               | <0.01, 3x0.01, 2x0.02, 2x0.04, 0.08                                                              |                                                                                                               |                       |                |                 |
| **Grape**  | NEU               | 2x0.1, 0.17, 0.21, 0.26, 0.28, 0.48, 1.19                                                        | According to the Student test, 5% and Mann-Whitney U-test (α=5%), residue levels in southern trials are not different from the northern ones. MRL, HR and STMR derived from the merged dataset. | 2                    | 1.19           | 0.265          |
|            | SEU               | 0.15, 0.19, 0.23, 0.27, 2x0.28, 0.40, 1.17                                                      |                                                                                                               |                       |                |                 |
| **Potato** | NEU               | 4x<0.01                                                                                         | Limited number of residue trials for each EU zones are acceptable since the residue levels were all below 0.01mg/kg. |                       | 0.01*          | 0.01           |
|            | SEU               | 4x<0.01                                                                                         |                                                                                                               |                       |                |                 |
| **Tomato** | NEU               | 0.01, 0.02, 0.03, 2x0.04, 2x0.05, 0.06, 0.07                                                    | According to the Student test, 5% and Mann-Whitney U-test (α=5%), residue levels in southern trials are not different from the northern ones. MRL, HR and STMR derived from the merged dataset. | 0.15                 | 0.07           | 0.04           |
|            | SEU               | 2x0.03, 3x0.04, 3x0.05                                                                           |                                                                                                               |                       |                |                 |
| **Cucumber** | NEU            | 3x0.01, 2x0.02, 0.03, 2x0.04, 0.05                                                              | According to the Mann-Whitney U-test (α=5%), residue levels in southern trials are not different from the northern ones. MRL, HR and STMR derived from the merged dataset. | 0.15                 | 0.07           | 0.03           |
|            | SEU               | 2x0.02, 0.03, 0.04, 0.05, 2x0.06, 0.07                                                           |                                                                                                               |                       |                |                 |
| **Courgette** | N+SEU      | 3x0.01, 4x0.02, 2x 0.03, 3x0.04, 2x 0.05, 2x0.06, 0.07                                           | Extrapolation from cucumbers residue dataset (see the comment above)                                           | 0.15                 | 0.07           | 0.03           |
| **Melon**  | NEU               | 3x0.02, 2x0.03, 2x0.04, 2x0.06                                                                   | According to the Student test, 5% and Mann-Whitney U-test (α=5%), residue levels in southern trials are not different from the northern ones. MRL, HR and STMR derived from the merged dataset. | 0.1                   | 0.06           | 0.03           |
| 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) |
|--------------|-------------------|--------------------------------------------------------------------------------------------------|---------------------------------------------|----------------------|----------------|-----------------|
| Watermelon   | SEU               | 0.01, 3x0.02, 2x0.03, 2x0.04                                                                   | levels in southern trials are not different from the northern ones. MRL, HR and STMR derived from the merged dataset. |                      | 0.1            | 0.06            | 0.03            |
| Broccoli     | N+SEU             | 0.01, 6x0.02, 4x0.03, 4x0.04, 2x0.06                                                           | Extrapolation from cucumbers residue dataset (see the comment above) | 0.15                 | 0.12           | 0.02            |
|              | SEU (8)           | <0.01, 0.01, 3x0.02, 2x0.03, 0.07                                                              | According to the Student test, 5% and Mann-Withney U-test (α=5%), residue levels in southern trials are not different from the northern ones. MRL, HR and STMR derived from the merged dataset. |                      | 0.15           | 0.12            | 0.02            |
|              | SEU (8)           | 3x<0.01, 0.01, 2x0.03, 0.07, 0.12                                                              |                                                                                           |                      | 0.07           | 0.04            | 0.02            |
| Cauliflower  | NEU               | 3x<0.01, 3x0.02, 0.03, 0.04                                                                  | According to the Student test, 5% and Mann-Withney U-test (α=5%), residue levels in southern trials are different from the northern ones. MRL, HR and STMR derived from each dataset. |                      | 0.07           | 0.04            | 0.02            |
|              | SEU               | 7x<0.01, 0.01                                                                                 |                                                                                           |                      | 0.07           | 0.04            | 0.02            |
| Kale         | NEU               | 0.16, 0.24, 0.72, 0.90, 1.22, 1.51, 1.87, 2.05                                               | According to the Student test, 5% and Mann-Withney U-test (α=5%), residue levels in southern trials are not different from the northern ones. MRL proposal, HR and STMR are based on NEU use. |                      | 4              | 2.05            | 1.06            |
|              | SEU               | 0.1, 0.11, 0.13, 0.18, 2x0.22, 0.26, 0.32                                                     |                                                                                           |                      | 0.6            | 0.32            | 0.2             |
| Brussels sprouts | NEU         | 0.05, 0.10, 0.12, 0.13                                                                         | No residue trials to support SEU representative gap were available (data gap). The residue dataset supports only the representative use in NEU |                      | 0.3            | 0.13            | 0.11            |
| Head cabbage | NEU               | 7x<0.01, 0.16                                                                                 | According to the Student test, 5% and Mann-Withney U-test (α=5%), residue levels in southern trials are not different from the northern ones. MRL, HR and STMR derived from the merged dataset. |                      | 0.2            | 0.16            | 0.01            |
|              | SEU               | 3x<0.01, 0.04                                                                                 |                                                                                           |                      | 0.2            | 0.16            | 0.01            |
### Crop Residue Data

| 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) | STMR (mg/kg) |
|--------------------|-------------------|-------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|-----------------------|------------|--------------|
| Kohlrabi           | NEU               | 0.02, 0.05, 2x0.08                                                                            | No residue trials to support SEU representative gap were available (data gap). The residue dataset supports only the representative use in NEU. | 0.2                  | 0.08       | 0.065        |
| **MRL application**|                   |                                                                                                 |                                                                                                                                                                      |                       |            |              |
| Apples             | NEU               | <0.01, 4x0.02, 0.03, 0.05, 0.14                                                                | According to the Student test, 5% and Mann-Whitney U-test (α=5%), residue levels in southern trials are not different from the northern ones. MRL, HR and STMR derived from the merged dataset. | 0.2                  | 0.14       | 0.02        |
|                    | SEU               | <0.01, 3x0.01, 2x0.02, 2x0.04, 0.08                                                            |                                                                                                                                                                      |                       |            |              |
| Pears              | N+SEU             | 2x<0.01, 3x0.01, 6x0.02, 0.03, 2x0.04, 0.05, 0.08, 0.14                                        | Extrapolation from apples residue dataset (see the comment above)                                                                                                        | 0.2                  | 0.14       | 0.02        |
| Quinces            | N+SEU             | 2x<0.01, 3x0.01, 6x0.02, 0.03, 2x0.04, 0.05, 0.08, 0.14                                        | Extrapolation from apples residue dataset (see the comment above)                                                                                                        | 0.2                  | 0.14       | 0.02        |
| Medlars            | N+SEU             | 2x<0.01, 3x0.01, 6x0.02, 0.03, 2x0.04, 0.05, 0.08, 0.14                                        | Extrapolation from apples residue dataset (see the comment above)                                                                                                        | 0.2                  | 0.14       | 0.02        |
| Loquats/Japanese medlars | N+SEU | 2x<0.01, 3x0.01, 6x0.02, 0.03, 2x0.04, 0.05, 0.08, 0.14                                        | Extrapolation from apples residue dataset (see the comment above)                                                                                                        | 0.2                  | 0.14       | 0.02        |
| Potato             | NEU               | 4x<0.01                                                                                         | Limited number of residue trials for each EU zone are acceptable since the residue levels were all below 0.01mg/kg.                                                                                   | 0.01*                | 0.01       | 0.01        |
|                    | SEU               | 4x<0.01                                                                                         |                                                                                                                                                                      |                       |            |              |
| Sweet potatoes     | N+SEU             | 8x<0.01                                                                                         | Extrapolation from potatoes residue dataset                                                                                                                             | 0.01*                | 0.01       | 0.01        |
| Yams               | N+SEU             | 8x<0.01                                                                                         | Extrapolation from potatoes residue dataset                                                                                                                             | 0.01*                | 0.01       | 0.01        |
| Pepper             | NEU               | 2x<0.01, 2x0.01, 2x0.02, 2x0.03                                                                | According to the Student test, 5% and                                                                                                                                 | 0.06                 | 0.03       | 0.015       |

Notes:
- NEU = Northern Europe Union
- SEU = Southern Europe Union
- MRL = Maximum Residue Level
- HR = Hazard Quotient
- STMR = Statistical Total Maximum Residue
- Student test (5%)
- Mann-Whitney U-test (α=5%)
- Extrapolation from datasets
| 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) |
|------------|-------------------|------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|-----------------------|----------------|-----------------|
| Okra       | SEU               | 2x0.03, 4x0.04, 0.09, 0.18                                                                 | Mann-Whitney U-test ($\alpha=5\%$), residue levels in southern trials are different from the northern ones. MRL, HR and STMR derived from each dataset (SEU uses is more critical). | 0.3                   | 0.18           | 0.04            |
| Okra       | N+SEU             | NEU: 2x<0.01, 2x0.01, 2x0.02, 2x0.03  
                      SEU: 2x0.03 4x0.04, 0.09, 0.18                                                                 | Extrapolation from pepper residues dataset SEU use, since it results in more critical residue situations and the population is different according to the statistical tests (see the comment on peppers). | 0.3                   | 0.18           | 0.04            |
| Pepper     | Indoor            | 0.02, 0.03, 0.05, 0.06, 0.10, 0.11, 0.14, 0.31                                                                 | The MRL proposal is based on the indoor uses since it results in a more critical residue situation               | 0.5                   | 0.31           | 0.08            |
| Okra       | Indoor            | 0.02, 0.03, 0.05, 0.06, 0.10, 0.11, 0.14, 0.31                                                                 | Extrapolation from pepper residues dataset.                                                                       | 0.5                   | 0.31           | 0.08            |
| Tomatoes   | Indoor            | Standard tomatoes: 2x0.02, 0.03, 2x0.04, 3x0.05  
                      Cherry tomatoes: 0.06, 2x0.07, 0.09, 0.11, 2x0.12, 0.16 | The dataset refers to the GAP defined with 2x70g a.s/ha application rate.                                           | 0.15                  | 0.05           | 0.04            |
|            |                   |                                                                                                                                                    | Etrapolation from standard tomatoes dataset conducted with 2x70g a.s/ha application rate. It is noted however that the residue dataset on tomatoes from outdoor use, results in more critical residue situation, and therefore that dataset will be extrapolated to aubergines use. | 0.3                   | 0.16           | 0.1             |
| Aubergine  | Indoor            | Standard tomatoes: 2x0.02, 0.03, 2x0.04, 3x0.05                                                                 |                                                                                                                 | 0.15                  | 0.05           | 0.04            |
| Tomato     | Indoor            | Standard tomato: 0.09, 0.11, 0.16, 0.20                                                                                                          | The dataset refers to the GAP defined                                                                           | 0.9                   | 0.45           | 0.22            |
| 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) (c) | HR (mg/kg) (d) | STMR (mg/kg) (d) |
|-------------------|-------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|--------------------------|----------------|------------------|
| Cherry tomato     | Indoor            | 0.16, 0.24, 0.32, 0.34, 0.35, 0.37, 0.45                                                                                                                                         | with 2x200g a.s/ha application rate. The MRL proposal, HR and STMR is derived based on residue dataset in cherry tomatoes since it results in more critical residues situation. Therefore, extrapolation of residue dataset from cherry tomatoes to aubergine is not supported for this GAP. | -                        | 0.2            | 0.14             |
| Indoor            | Standard tomato   | 0.09, 0.11, 0.16, 0.20                                                                                                                                                    | The extrapolation from standard tomatoes dataset conducted with 2x200g a.s/ha application rate is not possible since only 4 residue trials are available which is not sufficient for a major crop. | 0.15                     | 0.07           | 0.04             |
| Indoor            | NEU               | 0.01, 0.02, 0.03, 2x0.04, 2x0.05, 0.06, 0.07                                                                                                                                     | According to the Student test, 5% and Mann-Whitney U-test (α=5%), residue levels in southern trials are not different from the northern ones. MRL, HR and STMR derived from the merged dataset. | 0.15                     | 0.07           | 0.04             |
| Indoor            | SEU               | 2x0.03, 3x0.04, 3x0.05                                                                                                                                                    |                                                                                                             |                          |                |                  |
| Indoor            | N+SEU             | 0.01, 0.02, 3x0.03, 5x0.04, 5x0.05, 0.06, 0.07                                                                                                                                    | Extrapolation from tomatoes residues dataset (outdoor use)                                                | 0.15                     | 0.07           | 0.04             |
| Indoor            | Courgette         | 4x0.03, 3x0.06, 0.09                                                                                                                                                    | Although the MRLs resulting from outdoor and indoor GAPs are similar, the input values for risk assessment (HR, STMRs) are more critical for indoor use. | 0.15                     | 0.09           | 0.045            |
| Indoor            | Gerkins           | 4x0.03, 3x0.06, 0.09                                                                                                                                                    | Extrapolation from the cucumbers residue dataset (indoor use)                                             | 0.15                     | 0.09           | 0.045            |
| 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) | STMR (mg/kg) |
|------------------------------|---------------|-----------------------------------------------------------------------------------------------|---------------------------------------------|----------------------|------------|--------------|
| Other cucurbits with edible peel | Indoor        | 4x0.03, 3x0.06, 0.09                                                                          | Extrapolation from the cucumbers residue dataset (indoor use) | 0.15                 | 0.09       | 0.045        |
| Cucumber                     | NEU           | 3x0.01, 2x0.02, 0.03, 2x0.04, 0.05                                                              | According to the Mann-Whitney U-test (α=5%), residue levels in southern trials are not different from the northern ones. MRL, HR and STMR derived from the merged dataset. | 0.15                 | 0.07       | 0.03         |
|                             | SEU           | 2x0.02, 0.03, 0.04, 0.05, 2x0.06, 0.07                                                          |                                             |                      |            |              |
| Courgette                    | N-SEU         | 3x0.01, 4x0.02, 2x0.03, 3x0.04, 2x0.052x0.06, 0.07                                                | Extrapolation from the cucumbers residue dataset (outdoor use) | 0.15                 | 0.07       | 0.03         |
| Gerkins                      | N-SEU         | 3x0.01, 4x0.02, 2x0.03, 3x0.04, 2x0.052x0.06, 0.07                                                | Extrapolation from the cucumbers residue dataset (outdoor use) | 0.15                 | 0.07       | 0.03         |
| Other cucurbits with edible peel | N-SEU        | 3x0.01, 4x0.02, 2x0.03, 3x0.04, 2x0.052x0.06, 0.07                                                | Extrapolation from the cucumbers residue dataset (outdoor use) | 0.15                 | 0.07       | 0.03         |
| Melon                        | Indoor        | 3x0.02, 0.04, 0.05, 3x0.07                                                                      | The residue trials are sufficient to derive MRL and inputs values for the risk assessment (HR and STMR) | 0.15                 | 0.07       | 0.045        |
| Watermelon                   | Indoor        | 3x0.02, 0.04, 0.05, 3x0.07                                                                      | Extrapolation from melon residue dataset (indoor use) | 0.15                 | 0.07       | 0.045        |
| Pumpkin                      | Indoor        | 3x0.02, 0.04, 0.05, 3x0.07                                                                      | Extrapolation from melon residue dataset (indoor use) | 0.15                 | 0.07       | 0.045        |
| Other cucurbits with inedible peel | Indoor     | 3x0.02, 0.04, 0.05, 3x0.07                                                                      | Extrapolation from melon residue dataset (indoor use) | 0.15                 | 0.07       | 0.045        |
| Melon                        | NEU           | 3x0.02, 2x0.03, 2x0.04, 2x0.06                                                                  | According to the Student test, 5% and Mann-Whitney U-test (α=5%), residue levels in southern trials are not different from the northern ones. MRL, HR and STMR derived from the merged dataset. | 0.1                  | 0.06       | 0.03         |
|                             | SEU           | 0.01, 3x0.02, 2x0.03, 2x0.04                                                                     |                                             |                      |            |              |
| Watermelon                   | N-SEU         | 0.01, 6x0.02, 4x0.03, 4x0.04, 2x0.06                                                             | Extrapolation from the melon residue dataset (outdoor use) | 0.1                  | 0.06       | 0.03         |
| Pumpkin                      | N-SEU         | 0.01, 6x0.02, 4x0.03, 4x0.04, 2x0.06                                                             | Extrapolation from the melon residue dataset (outdoor use) | 0.1                  | 0.06       | 0.03         |
### Summary of the data on formulation equivalence OECD Guideline 509

| Crop                  | Region/Indoor (a) | Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs (b) | Recommendations/comments (OECD calculations)                                                                 | MRL proposals (mg/kg) (c) | HR (mg/kg) (c) | STMR (mg/kg) (d) |
|-----------------------|-------------------|--------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|--------------------------|----------------|-----------------|
| Other cucurbits with inedible peel | N-SEU             | 0.01, 6x0.02, 4x0.03, 4x0.04, 2x0.06                                                             | Extrapolation from the melon residue dataset (outdoor use)                                                                 | 0.1                      | 0.06           | 0.03            |
| Kale                  | NEU               | 0.16, 0.24, 0.72, 0.90, 1.22, 1.51, 1.87, 2.05                                                  | According to the Student test, 5% and Mann-Whitney U-test (α=5%), residue levels in SEU trials are different from the NEU. The MRL proposal, HR and STMR are derived from NEU residue dataset. | 4                        | 2.05           | 1.06            |
|                       | SEU               | 0.1, 0.11, 0.13, 0.18, 2x0.22, 0.26, 0.32                                                        |                                                                                                                | 0.6                      | 0.32           | 0.2             |
| Chinese cabbages      | N+SEU             | 0.16, 0.24, 0.72, 0.90, 1.22, 1.51, 1.87, 2.05                                                  | Extrapolation from kale residues dataset. Sufficient residue trials were available to cover N+SEU intended uses. However, the MRL proposal, HR and the STMR is based on NEU residue dataset since it results in more critical residue situation. | 4                        | 2.05           | 1.06            |
| Soybean               | Argentina         | 9x<0.005                                                                                         | The submitted data are sufficient to derive an import tolerance (Argentina GAP).                                 | 0.01*                    | <0.005         | <0.005          |

**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                                                                 |
|-----------------------|--------|----------------------|----------------------------------------------------------------------------------------|
| Winter oilseed rape   | Indoor | Honey: 3x<0.01       | Three residue trials were submitted to support the MRL proposal in honey. According to SANTE/1156/2016(e), at least four trials should be available instead of three. |

| **In honey:** | 0.01* | <0.01 | <0.01 |

(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 (HRMo).

*(e)*: At least four trials should be available instead of three.
(d): **STMR**: Supervised Trials Median Residue. When residue definition for monitoring and risk assessment differs, STMR according to definition for monitoring reported in brackets (STMR<sub>Mo</sub>).

(e): Technical guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residue Level in honey.
### Inputs for animal burden calculations

| Commodity         | Median dietary burden | Maximum dietary burden |
|-------------------|-----------------------|------------------------|
|                   | Input value (mg/kg)   | Comment                | Input value (mg/kg) | Comment                |
| **Risk assessment residue definition:** pydiflumetofen |
| **EU representative uses** |
| Apple pomace      | 0.07 (0.02x 3.38)     | STMRp (STMRxPF)        | 0.07 (0.02x 3.38)   | STMRp (STMRxPF)        |
| Potato culls      | 0.01                  | STMR                   | 0.01                | HR                     |
| Potato, process waste¹ | 0.01                  | STMR                   | 0.01                | STMR                   |
| Potato, dried pulp¹ | 0.01                  | STMR                   | 0.01                | STMR                   |
| Cabbage leaves    | 0.01                  | STMR                   | 0.16                | HR                     |
| Kale              | 1.06                  | STMR                   | 2.05                | HR                     |
| Cereal straw²     | 0.225                 | HR from field rotational crops | 0.225 | HR from field rotational crops |
| Soyabean¹         | ≤ 0.01*               | STMR                   | 0.01*               | HR                     |

¹ No default processing factor was used for these potato by-products since residue level in the raw product was below the LOQ.
² Since significant residue levels cannot be excluded in barley straw from field rotational crops, highest residue levels from barley straw was taken into account in the dietary burden calculation. Extrapolation was made to all cereal straw (except rice) as a worst case. Considering that the field rotational crop study is underdosed (0.4 N), residue level on straw has been upscaled.
### 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

| Highest expected intake (mg/kg bw/d) | Ruminant | Pig/Swine | Poultry | Fish |
|-------------------------------------|----------|-----------|---------|------|
| Beef cattle                         | 0.067    |           |         |      |
| Dairy cattle                        | 0.107    |           |         |      |
| Ram/Ewe                            | 0.047    |           |         |      |
| Lamb                               | 0.059    |           |         |      |

| Intake >0.004 mg/kg bw              | Yes      | Yes       | No      | Yes  |
| Feeding study submitted             | Yes      | Yes       | No      | Yes  |

| Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and N rates |
|-----------------------------|----------------|----------------|---------|---------|
| Level 0.4 mg/kg bw/d        | Level 0.4 mg/kg bw/d | Level 0.4 mg/kg bw/d | Level 0.4 mg/kg bw/d | Level 0.4 mg/kg bw/d |
| Beef: 6N Dairy: 4 N         | Lamb: 6.8 N Ewe: 8.5N | Breed: 12 N Finish: 40 N | Breed: 12 N Finish: 40 N | B or T: 168.6 N Layer: 38.4 N |

| Estimated HR at 1N (a) | MRL proposals | Estimated HR at 1N (a) | MRL proposals | Estimated HR at 1N (a) | MRL proposals | Estimated HR at 1N (a) | MRL proposals |
|-----------------------|---------------|-----------------------|---------------|-----------------------|---------------|-----------------------|---------------|
| Muscle                | 0.01          | 0.01*                 | 0.01          | 0.01                  | 0.01          | 0.01                  |                |
| Fat                   | 0.01          | 0.01*                 | 0.01          | 0.01                  | 0.01          | 0.01                  |                |
| Meat (b)              | 0.01          | 0.01                  | 0.01*         | 0.01                  | 0.01*         | 0.01                  |                |
| Liver                 |               |                       |               |                       |               |                       |                |
| Kidney                | 0.01          | 0.01*                 | 0.01*         | 0.01                  | 0.01*         | 0.01                  |                |
| Milk (a)              | 0.01          | 0.01*                 | 0.01*         | 0.01                  | 0.01*         |                     | 0.01          |
| Eggs                  | 0.01          | 0.01                  |               |                       |               |                       | 0.01          |

(a): Estimated HR calculated at 1N level (estimated mean level for milk).

(b): HR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry.

(c): The OECD guidance document on residues in livestock (series on pesticides 73) recommends three different approaches to derive MRLs for animal products; by applying a transfer factor (Tf), by intrapolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.
Conversion Factors (CF) for monitoring to risk assessment

Pending on the expression of the risk assessment residue definition for animal commodities, conversion factors might be needed.

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 studies\(^{(a)}\) | Processing Factor (PF) | Conversion Factor (CF\(_P\)) for RA\(^{(b)}\) |
|--------------------------------------------------------|-----------------------------|------------------------|-----------------------------------------------|
|                                                        | Individual values           | Median PF              |                                               |
| **Representative uses**                                 |                             |                        |                                               |
| Grape, pasteurized juice                               | 1                           | 0.02, 0.02, 0.05, 0.07 | 0.035 /                                       |
| Grape, white aged wine                                 | 1                           | 0.08, 0.11, 0.52, 0.60 | 0.32 /                                       |
| Grape, red wine                                        | 1                           | 0.10, 0.17, 0.20, 0.24 | 0.19 /                                       |
| Grape, raisin                                          | 1                           | 1.71, 2.37, 2.48, 4.75 | 2.43 /                                       |
| Grape, refined seed oil                                | 1                           | 0.71, 1.02, 1.08, 1.12 | 1.05 /                                       |
| Tomato, paste                                          | 1                           | 0.55, 0.82             | 0.69 /                                       |
| Tomato, puree                                          | 1                           | 0.26, 0.41             | 0.33 /                                       |
| Tomato, washed and peel                                | 1                           | <0.05, <0.08           | n.a.\(^{(1)}\) /                             |
| Tomato, canned                                         | 1                           | <0.05, <0.08           | n.a.\(^{(1)}\) /                             |
| Tomato, sun-dried                                      | 1                           | 9.9, 10.7              | 10 /                                          |
| Tomato, juice                                          | 1                           | <0.05, <0.08           | n.a.\(^{(1)}\) /                             |
| Apple/pear, canned                                     | 1                           | 0.03 (apple), 0.09 (pear) | 0.06 /                                      |
| Apple/pear, wet pomace                                 | 1                           | 2.99 (pear), 3.77 (apple) | 3.38 /                                      |
| Apple/pear, Juice                                      | 1                           | 0.06 (apple), 0.11 (pear) | 0.09 /                                      |
| Apple, sauce                                           | 1                           | 0.06                   | 0.06 (single value) /                        |
| Apple/pear, dried                                      | 1                           | 0.41 (apple), 0.62 (pear) | 0.52 /                                      |
| Kale, washed                                           | 1                           | 1.08, 1.18, 1.58, 1.60 | 1.38 /                                       |
| Kale, cooked                                           | 1                           | 1.2, 1.21, 1.27, 1.73  | 1.24 /                                       |
| **MRL application**                                    |                             |                        |                                               |
|                                                        |                             |                        |                                               |
\(^{(a)}\): 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

1 Results which were calculated from the LOQ value are not taken into account in the median transfer factor calculation due to high uncertainty.

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

NOTE: Consumer risk assessment performed for pydiflumetofen only. Since for animal commodities, 2,4,6-TCP is also included in the RA-RD, the consumer risk assessment for these crops is not finalised.

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

**ADI** 0.09 mg/kg bw per day  

TMDI according to EFSA PRIMo  

| Highest TMDI: 10 % ADI | (wine grapes, FR all population) |

NTMDI, according to (to be specified)  

Not provided, not required
IEDI (% ADI), according to EFSA PRIMo

|                          |                        |
|--------------------------|------------------------|
| Highest IEDI: 2% ADI (WHO Cluster diet B) | Not provided, not required |

NEDI (% ADI), according to (to be specified)

|                          |                        |
|--------------------------|------------------------|
| Highest IESTI: 46% ARfD (kale, NL diet) | Not provided, not required |

Factors included in the calculations

ARfD

|                          |                        |
|--------------------------|------------------------|
| 0.3 mg/kg bw             |                        |

IESTI (% ARfD), according to EFSA PRIMo

|                          |                        |
|--------------------------|------------------------|
| Highest IESTI: 46% ARfD (kale, NL diet) | Not provided, not required |

NESTI (% ARfD, according to (to be specified)

|                          |                        |
|--------------------------|------------------------|
| Not provided, not required |                        |

Factors included in IESTI and NESTI

Consumer risk assessment limited to the representative uses

TMDI (% ADI), according to EFSA PRIMo

|                          |                        |
|--------------------------|------------------------|
| Highest TMDI: 9% ADI (wine grapes, FR all population) | Not provided, not required |

NTMDI (% ADI), according to (to be specified)

|                          |                        |
|--------------------------|------------------------|
| Not provided, not required |                        |

IEDI (% ADI), according to EFSA PRIMo

|                          |                        |
|--------------------------|------------------------|
| Highest IEDI: 2% ADI (tomatoes, WHO Cluster diet B) | Not provided, not required |

NEDI (% ADI), according to (to be specified)

|                          |                        |
|--------------------------|------------------------|
| Not provided, not required |                        |

Factors included in the calculations

IESTI (% ARfD, according to EFSA PRIMo)

|                          |                        |
|--------------------------|------------------------|
| Highest IESTI: 46% ARfD (Kale, NL diet) | Not provided, not required |

NESTI (% ARfD, according to (to be specified)

|                          |                        |
|--------------------------|------------------------|
| Not provided, not required |                        |

Factors included in IESTI and NESTI

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

The consumer risk assessment from the consumption of drinking water is also not finalised considering the lack of appropriate information to address the effect of water treatment processes on the nature of residues of pydiflumetofen and its possible metabolites, potentially present in surface water, when surface water is abstracted for drinking water (see Section 4).

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

| Code(a)       | Commodity/Group | MRL/Import tolerance(b) (mg/kg) and Comments                      |
|---------------|-----------------|------------------------------------------------------------------|
| Plant commodities                                      |
| Representative uses                                    |
| 0130010       | Apple           | 0.2                                                              |
| 0130020       | Pear            | 0.2                                                              |
| 0151010       | Table grape     | 2                                                                |
| 0151020       | Wine grape      | 2                                                                |
| 0211000       | Potatoes        | 0.01                                                            |
| 0231010       | Tomato          | 0.15                                                             |
| 0232010       | Cucumber        | 0.15                                                             |
| 0232030       | Courgette       | 0.15                                                             |
| 0233010       | Melon           | 0.1                                                              |
| 0233030       | Watermelon      | 0.1                                                              |

The MRL proposal is based on combined residues dataset from N-SEU.
### MRL application (additional uses and import tolerance)

| Code   | Commodity         | MRL (mg/kg) | Notes                                                                 |
|--------|-------------------|-------------|----------------------------------------------------------------------|
| 0130030| Quinces           | 0.2         |                                                                       |
| 0130040| Medlar            | 0.2         |                                                                       |
| 0130050| Loquat            | 0.2         |                                                                       |
| 0130990| Others            | 0.2         |                                                                       |
| 0212020| Sweet Potatoes    | 0.01*       | Extrapolation from potato                                            |
| 0212030| Yams              | 0.01*       |                                                                       |
| 0231010| Tomato            | 0.8         | The MRL proposal is based on the most critical GAP on indoor use.     |
| 0231020| Peppers           | 0.5         | The MRL proposal is based on indoor use.                              |
| 0231040| Okra (Ladies fingers) | 0.5   | Extrapolation from pepper (indoor use)                               |
| 0231030| Aubergines        | 0.15        | Extrapolation from tomato outdoor (NEU and SEU), residue dataset since result in most critical residue situation. |
| 0232010| Cucumber          | 0.15        | The MRL proposal is based on indoor use.                              |
| 0232020| Gherkins          | 0.15        | Extrapolation of the residue dataset on cucumbers (indoor use)        |
| 0232030| Courgette         | 0.15        | Extrapolation of the residue dataset on cucumbers (indoor use)        |
| 0232990| Others            | 0.15        | Extrapolation of the residue dataset on cucumbers (indoor use)        |
| 0233010| Melon             | 0.15        | The MRL proposal is based on indoor use GAP                            |
| 0233030| Watermelon        | 0.15        | Extrapolation of the residue dataset on melon (indoor use)            |
| 0231040| Pumpkin           | 0.15        | Extrapolation of the residue dataset on melon (indoor use)            |
| 0243010| Chinese cabbages/pe-tsai | 4      | Extrapolation from kale (NEU use GAP)                                 |
| 0401070| Soy bean*         | 0.01*       | Import tolerance (Argentina GAP)                                      |

### Animal commodities

| Code   | Commodity     | MRL (mg/kg) | Notes                                                                 |
|--------|---------------|-------------|----------------------------------------------------------------------|
|        | Ruminant (c) muscle | 0.01*               |                                                                       |
|        | Ruminant (c) fat | 0.01*           |                                                                       |
|        | Ruminant (c) liver | 0.01*          |                                                                       |
|        | Ruminant (c) kidney | 0.01*       |                                                                       |
| 1020000| Milk          | 0.01*         |                                                                       |
| 1011010| Swine muscle  | 0.01*         |                                                                       |
| 1011020| Swine fat     | 0.01*         |                                                                       |

Pydiflumetofen residues in the animal commodities at 1 N rate feeding levels were <0.01*mg/kg. Therefore a default MRL of 0.01 mg/kg will be proposed.
| Commodity Code | Commodity       | MRL  |
|----------------|-----------------|------|
| 1011030        | Swine liver     | 0.01*|
| 1011040        | Swine kidney    | 0.01*|
| 1016010        | Poultry muscle  | 0.01*|
| 1016020        | Poultry fat     | 0.01*|
| 1016030        | Poultry liver   | 0.01*|
| 1016040        | Poultry kidney  | 0.01*|
| 1030000        | Eggs            | 0.01*|
| 1040000        | Honey           | 0.01*|

(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.
(c): covers all ruminants animal categories (bovine, sheep, goats, equine)
Environmental fate and behaviour

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

| Environmental Fate | Description | Mineralisation after 120 days | Non-extractable residues after 120 days | Metabolites requiring further consideration - name and/or code, % of applied (range and maximum) |
|--------------------|-------------|-------------------------------|----------------------------------------|------------------------------------------------------------------------------------------------|
| Mineralisation after 120 days | 3.2% after 120 d (14.5% after 365 d), [14C-pyrazole]-label (n=1) | 8.1% after 120 d (17.3% after 365 d), [14C-pyrazole]-label (n=1) | No metabolite ≥ 5% |
| Non-extractable residues after 120 days | 0.2-5.3% after 120 d (0.2-16.5% after 365 d), [14C-phenyl]-label (n=5) | 7.4-33.4% after 120 d (12.3-46.2% after 365 d), [14C-phenyl]-label (n=5) | |

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

| Environmental Fate | Description | Mineralisation after 120 days | Non-extractable residues after 120 days | Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum) |
|--------------------|-------------|-------------------------------|----------------------------------------|------------------------------------------------------------------------------------------------|
| Mineralisation after 120 days | 0.1% after 120 d, [14C-pyrazole]-label (n=1) | 8.3% after 120 d, [14C-pyrazole]-label (n=1) | No metabolite ≥ 5% |
| Non-extractable residues after 120 days | 0.1-0.4% after 120 d, [14C-phenyl]-label (n=4) | 7.8-32.6% after 120 d, [14C-phenyl]-label (n=4) | |

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

| Environmental Fate | Description | Mineralisation at study end | Non-extractable residues at study end |
|--------------------|-------------|-------------------------------|----------------------------------------|
| Mineralisation at study end | 0.2% after 29 d in dry soil, 0.2% after 30 d in moist soil, [14C-pyrazole]-label (n=1) | 1.4% after 29 d in dry soil, 2.6% after 30 d in moist soil, [14C-pyrazole]-label (n=1) |
| Non-extractable residues at study end | 1.5% after 31 d in dry soil, 0.4% after 30 d in moist soil, [14C-phenyl]-label (n=1) | 1.7% after 31 d in dry soil, 3.2% after 30 d in moist soil, [14C-phenyl]-label (n=1) |

---

n corresponds to the number of soils.
Rate of degradation in soil (aerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

| Parent                  | Dark aerobic conditions – Trigger endpoints | Kinetic parameters | St. \((\chi^2)\) | Method of calculation |
|-------------------------|---------------------------------------------|--------------------|-------------------|-----------------------|
| Soil type               | pH\(^b\)                                   | t. °C / % MWHC     | DT\(_{50}\) /DT\(_{90}\) \[d\] |                        |
| Gartenacker (loam)      | 6.9                                         | 20°C / pF2         | 398/1320          | -                     | 1.34 SFO |
| 18 Acres (sandy clay loam) | 5.5                                         | 20°C / pF2         | 2380/7640         | k\(_1\)=0.03734      | 0.41 DFOP |
|                         |                                             |                    |                   | k\(_2\)= 0.000264    |            |
|                         |                                             |                    |                   | g=0.06232             |            |
| Sarpy (silt loam)       | 6.2                                         | 20°C / pF2         | 567/2970          | k\(_3\)=0.04405      | 3.15 DFOP |
|                         |                                             |                    |                   | k\(_2\)= 0.000669    |            |
|                         |                                             |                    |                   | g=0.2693              |            |
| East Anglia (sandy loam)| 7.1                                         | 20°C / pF2         | 1300/4870         | k\(_1\)=0.09243      | 0.96 DFOP |
|                         |                                             |                    |                   | k\(_2\)= 0.000452    |            |
|                         |                                             |                    |                   | g=0.1005              |            |
| Capay (clay loam)       | 7.6                                         | 20°C / pF2         | 410/2540          | k\(_1\)=0.05022      | 2.54 DFOP |
|                         |                                             |                    |                   | k\(_2\)= 0.000756    |            |
|                         |                                             |                    |                   | g=0.3183              |            |
| **Maximum**             |                                             |                    | 2380              |                       | DFOP       |

\(^{a)}\) Measured in calcium chloride solution

---

| Parent                  | Dark aerobic conditions – Modelling endpoints | DT\(_{50}\) (d) | DT\(_{90}\) (d) | St. \((\chi^2)\) | Method of calculation |
|-------------------------|---------------------------------------------|----------------|----------------|-------------------|-----------------------|
| Soil type               | pH\(^b\)                                   | t. °C / % MWHC | DT\(_{50}\) /DT\(_{90}\) \[d\] |                   |                        |
| Gartenacker (loam)      | 6.9                                         | 20°C / pF2     | 398/1320         | 398               | 1.34 SFO |
| 18 Acres (sandy clay loam) | 5.5                                         | 20°C / pF2     | 1690/5600         | 1690              | 1.42 SFO |
| Sarpy (silt loam)       | 6.2                                         | 20°C / pF2     | 567/2970          | 1036\(^c\)        | 3.15 DFOP |
| East Anglia (sandy loam)| 7.1                                         | 20°C / pF2     | 1090/3620         | 1090              | 2.62 SFO |
| Capay (clay loam)       | 7.6                                         | 20°C / pF2     | 410/2540          | 917\(^c\)         | 2.54 DFOP |
| **Geometric mean** (if not pH dependent) |                                             |                | **930**          |                   | DFOP       |

\(^{a)}\) Measured in calcium chloride solution

\(^{b)}\) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

\(^{c)}\) Calculated from DFOP k\(_2\) parameter \((\ln(2)/k_2)\)
Rate of degradation field soil dissipation studies (Regulation (EU) No 283/2013, Annex Part A, point 7.1.2.1.1 and Regulation (EU) No 284/2013, Annex Part A, point 9.1.1.2.1)

| Parent                  | Aerobic conditions – Trigger endpoints |
|-------------------------|----------------------------------------|
| Soil type (indicate if bare or cropped soil was used). | Location (country or USA state). | pH<sup>a</sup> | Depth (cm) | DT<sub>50</sub> (d) actual | DT<sub>90</sub> (d) actual | St. (χ²) | Kinetic parameters | Method of calculation |
| Sandy loam (bare soil) | Germany | 5.68 | 0-20 | 8540 | >10000 | 6.5 | k<sub>1</sub>=0.05381 k<sub>2</sub>= 0.000043 g=0.2484 | DFOP |
| Clay loam (bare soil)  | Italy   | 7.40 | 0-100 | 1110 | 3680 | 11.6 | - | - | SFO |
| Silty clay loam (bare soil) | Northern France | 7.52 | 0-100 | 4030 | >10000 | 9.7 | - | - | SFO |
| Sandy loam (bare soil) | Southern France | 7.48 | 0-50 | 29 | 1820 | 13.3 | k<sub>1</sub>=0.08239 k<sub>2</sub>= 0.000842 g=0.5381 | DFOP |
| Sandy loam (bare soil) | Spain | 7.27 | 0.-30 | No reliable fit could be obtained |
| Loam (bare soil)       | UK | 6.84 | 0-30 | 2810 | 9350 | 11.2 | - | - | SFO |
| Maximum                 | | 8540 | >10000 | |

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

| Parent                  | Aerobic conditions – Modelling endpoints |
|-------------------------|----------------------------------------|
| Soil type (indicate if bare or cropped soil was used). | Location (country or USA state). | pH<sup>a</sup> | Depth (cm) | DT<sub>50</sub> (d) Norm<sup>b</sup>. | Kinetic parameters | St. (χ²) | Method of calculation |
| Sandy loam (bare soil) | Germany | 5.68 | 0-20 | 997 | - | 8.8 | SFO |
| Clay loam (bare soil)  | Italy | 7.40 | 0-100 | 1110 | - | 11.4 | SFO |
| Silty clay loam (bare soil) | Northern France | 7.52 | 0-100 | 3210 | - | 9.8 | SFO |
| Sandy loam (bare soil) | Southern France | 7.48 | 0-50 | 654<sup>c</sup> | k<sub>1</sub>=0.04618 k<sub>2</sub>= 0.00106 g=0.502 | 12.5 | DFOP |
| Sandy loam (bare soil) | Spain | 7.27 | 0.-30 | No reliable fit could be obtained |
| Loam (bare soil)       | UK | 6.84 | 0-30 | 1820 | 11.3 | SFO |
| Geometric mean (if not pH dependent) | | 1334 | |

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

<sup>b</sup> Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7, values are DegT50matrix

<sup>c</sup> Calculated from DFOP k2 parameter (ln(2)/k2)

pH dependence | No
Combined laboratory and field kinetic endpoints for modelling (when not from different populations)

Rate of degradation in soil active substance, normalised geometric mean (if not pH dependent)

| Factor | Value |
|--------|-------|
| Not relevant according to EFSA guidance since laboratory geometric DT50 > 240 days |

Soil accumulation (Regulation (EU) No 283/2013, Annex Part A, point 7.1.2.2.2 and Regulation (EU) No 284/2013, Annex Part A, point 9.1.1.2.2)

Soil accumulation and plateau concentration

| Factor | Value |
|--------|-------|
| Please refer to PECaccu reported under PECsoil calculations |

Rate of degradation in soil (anaerobic) laboratory studies active substance (Regulation (EU) No 283/2013, Annex Part A, point 7.1.2.1.3 and Regulation (EU) No 284/2013, Annex Part A, point 9.1.1.1)

| Parent | Soil type | pH<sup>a</sup> | t. °C / % MWHC | DT<sub>50</sub> / DT<sub>90</sub> (d) | DT<sub>50</sub> (d) 20 °C<sup>b</sup> | St. (χ²) | Method of calculation |
|--------|-----------|----------------|----------------|----------------|------------------|-----------|----------------------|
| Gartenacker (loam) | 7.5 | 20°C / flooded | | | | | |
| 18 Acres (sandy clay loam) | 6.1 | 20°C / flooded | | | | | No significant degradation observed |
| Sarpy (silt loam) | 6.7 | 20°C / flooded | | | | | |
| Capay (clay loam) | 6.7 | 20°C / flooded | | | | | |

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

<sup>b</sup> Normalised using a Q10 of 2.58

Rate of degradation on soil (photolysis) laboratory active substance (Regulation (EU) No 283/2013, Annex Part A, point 7.1.1.3)

| Parent | Soil type | pH<sup>a</sup> | t. °C / % MWHC | DT<sub>50</sub> / DT<sub>90</sub> (d) calculated at summer sunlight 30-50°N | St. (χ²) | Method of calculation |
|--------|-----------|----------------|----------------|---------------------------------|-----------|----------------------|
| 18 Acres (sandy clay loam) | 6.1 | 20°C / dry soil | 154/507 | 1.7 | SFO |
| | | 20°C / pF2 | 361/1198 | 1.0 | SFO |

<sup>a</sup> Measured in calcium chloride solution
### 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\(^{a)}\) | \(K_d\) (mL/g) | \(K_{doc}\) (mL/g) | \(K_F\) (mL/g) | \(K_{Foc}\) (mL/g) | \(1/n\)  |
|---------------------|------|------------------|----------------|-------------------|----------------|------------------|---------|
| Sandy clay loam     | 2.2  | 6.0              | -              | -                     | 36.10            | 1641             | 0.8794  |
| Loam                | 1.8  | 7.2              | -              | -                     | 20.97            | 1165             | 0.8733  |
| Silt loam           | 1.7  | 6.5              | -              | -                     | 30.40            | 1788             | 0.8367  |
| Clay loam           | 1.0  | 6.7              | -              | -                     | 16.68            | 1668             | 0.8983  |
| Loamy sand          | 0.6  | 5.2              | -              | -                     | 11.76            | 1960             | 0.8876  |
| Clay loam           | 1.6  | 7.6              | -              | -                     | 35.30            | 2206             | 0.8820  |

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

23.3  **1706**

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

0.876

\(^{a)}\) Measured in calcium chloride solution

### 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\(^{a)}\) | \(K_d\) (mL/g) | \(K_{doc}\) (mL/g) | \(K_F\) (mL/g) | \(K_{Foc}\) (mL/g) | \(1/n\)  |
|---------------------|------|------------------|----------------|-------------------|----------------|------------------|---------|
| SYN545547 Sand      | 0.8  | 5.3              | -              | -                 | 5.727           | 759.4            | 0.8413  |
| Sandy clay loam     | 2.2  | 5.8              | -              | -                 | 15.35           | 715.3            | 0.8955  |
| Silt loam           | 1.7  | 6.5              | -              | -                 | 12.94           | 743.8            | 0.8435  |
| Loam                | 2.7  | 7.0              | -              | -                 | 8.792           | 322.5            | 0.8686  |
| Clay                | 1.8  | 7.5              | -              | -                 | 11.45           | 637              | 0.8615  |

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

10.3  **607.9**

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

0.862

\(^{a)}\) Measured in calcium chloride solution

### NOA449410

| Soil Type           | OC % | Soil pH\(^{a)}\) | \(K_d\) (mL/g) | \(K_{doc}\) (mL/g) | \(K_F\) (mL/g) | \(K_{Foc}\) (mL/g) | \(1/n\)  |
|---------------------|------|------------------|----------------|-------------------|----------------|------------------|---------|
| NOA449410 Sand      | 0.8  | 5.3              | -              | -                 | 5.727           | 759.4            | 0.8413  |
| Sandy clay loam     | 2.2  | 5.8              | -              | -                 | 15.35           | 715.3            | 0.8955  |
| Silt loam           | 1.7  | 6.5              | -              | -                 | 12.94           | 743.8            | 0.8435  |
| Loam                | 2.7  | 7.0              | -              | -                 | 8.792           | 322.5            | 0.8686  |
| Clay                | 1.8  | 7.5              | -              | -                 | 11.45           | 637              | 0.8615  |

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

10.3  **607.9**

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

0.862

\(^{a)}\) Measured in calcium chloride solution
| soil type       | Kd [L/kg] | pH | log Kd | Tc [h] | EC50 [μM] |
|----------------|----------|----|--------|--------|-----------|
| Loam           | 2.1      | 6.1| -      | -      | 0.04      | 2.1      | 0.94|
| Sandy clay loam| 2.5      | 7.2| -      | -      | 0.07      | 2.7      | 0.85|
| Silty clay     | 0.7      | 7.6| -      | -      | 0.02      | 3.6      | 1.02|
| Sandy loam     | 3.9      | 6.8| -      | -      | 0.01      | 0.3      | 0.78|
| Loamy sand     | 0.4      | 6.8| -      | -      | 0.02      | 6.1      | 0.93|
| Geometric mean (if not pH dependent) | 0.03 | 2.1 |
| Arithmetic mean (if not pH dependent) | 0.90 |

**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)**

| Column leaching | No data, not required |

**Mobility in soil column leaching transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)**

| Column leaching | No data, not required |

**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 | No data, not required |

---

**a)** Measured in calcium chloride solution
### Hydrolytic degradation (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.1.1)

| Description                                                                 | Value                                                                 |
|----------------------------------------------------------------------------|----------------------------------------------------------------------|
| Hydrolytic degradation of the active substance and metabolites > 10 %      | Stable at pH 4, 7 and 9 at 50°C                                       |

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

| Description                                                                 | Value                                                                 |
|----------------------------------------------------------------------------|----------------------------------------------------------------------|
| Photolytic degradation of active substance and metabolites above 10 %      | pH 7 buffer:                                                         |
|                                                                             | $\text{DT}_{50}$: 89 days                                           |
|                                                                             | Estimated $\text{DT}_{50}$ at summer sunlight 30-50°N: 93 days       |
|                                                                             | No metabolite $\geq$ 5%                                             |
|                                                                             | Sterilised natural water:                                           |
|                                                                             | $\text{DT}_{50}$: 33 days                                           |
|                                                                             | Estimated $\text{DT}_{50}$ at summer sunlight 30-50°N: 35 days       |
|                                                                             | SYN548261: 7.3 % AR (21 d) (minor non transient)                      |
|                                                                             | NOA449410: 5.4 % (30 days) ($\geq$ 5% at the end of the study)        |

| Quantum yield of direct phototransformation in water at $\Sigma > 290 \text{ nm}$ | 0.0105 molecules degraded/photon |

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

| Description                                                                 | Value                                                                 |
|----------------------------------------------------------------------------|----------------------------------------------------------------------|
| 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 | System identifier (indicate fresh, estuarine or marine) | pH | pH phase | t. \(^{\circ}\)C \(^{(b)}\) | DT\(_{50}\) /DT\(_{90}\) whole sys. (suspended sediment test) | St. (\(\chi^2\)) | DT\(_{50}\) /DT\(_{90}\) Water (pelagic test) | St. (\(\chi^2\)) | Method of calculation |
|--------|------------------------------------------------------|----|----------|-----------------|-------------------------------------------------|-----------------|---------------------------------|-----------------|------------------|
|        | Fresh water, 10 µg/L, dark                          | 8.0| 7.1      | 20              | >1000/>1000                                           | -               | -                               | -               | SFO               |
|        | Fresh water, 95 µg/L, dark                          | 8.0| 7.1      | 20              | 637/>1000                                              | -               | -                               | -               | SFO               |
|        | Fresh water, 10 µg/L, light/dark                     | 8.2| 6.8      | 20              | 402/>1000                                              | 1.55            | -                               | -               | SFO               |
|        | Fresh water, 95 µg/L, light/dark                     | 8.2| 6.8      | 20              | 662/>1000                                              | 1.01            | -                               | -               | SFO               |

\(^{(a)}\) Measured in usually calcium chloride solution

\(^{(b)}\) Temperature of incubation=std temperature of 20°C

\(^{(c)}\) Normalised using a Q10 of 2.58 to the temperature of the environmental media at the point of sampling. (note temp of x should be stated).

| Metabolite SYN545547 | Max in total system 7.3 % after 60 days (light/dark incubation, low dose 10 µg a.s./L) |
|-----------------------|-------------------------------------------------------------------------------------|

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

| System identifier (indicate fresh, estuarine or marine) | pH | pH phase | Mineralisation x % after n d. (end of the study). | Non-extractable residues. max x % after n d (suspended sediment test) | Non-extractable residues. max x % after n d (end of the study) (suspended sediment test) |
|--------------------------------------------------------|----|----------|-------------------------------------------------|---------------------------------------------------------------------|------------------------------------------------------------------------------|
| Fresh water, 10 µg/L, dark                             | 8.0| 7.1      | ≤0.1% after 58 d                                | -                                                                   | -                                                                             |
| Fresh water, 95 µg/L, dark                             | 8.0| 7.1      | ≤0.1% after 58 d                                | -                                                                   | -                                                                             |
| Fresh water, 10 µg/L, light/dark                       | 8.2| 6.8      | ≤0.8 after 58 d                                 | -                                                                   | -                                                                             |
| Fresh water, 95 µg/L, light/dark                       | 8.2| 6.8      | ≤0.5 after 58 d                                 | -                                                                   | -                                                                             |
Water / sediment study (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.2)

**Water/sediment system – Aerobic conditions**

|                | Distribution (Max in water 80.5-86.4% after 0 d. Max. sed 62.1-79.0 % after 100-30 d) |
|----------------|------------------------------------------------------------------------------------------|

### Trigger endpoints

| Water / sediment system | pH | pH | t. °C | DT₅₀ / DT₉₀ whole sys. | St. (χ²) | Method of calculation | DissT₅₀ / DissT₉₀ water | St. (χ²) | Method of calculation |
|-------------------------|----|----|-------|------------------------|----------|-----------------------|------------------------|----------|-----------------------|
| Calwich Abbey           | 8.4| 7.6| 20    | 270/976                | 2.1      | HS                    | 0.74/33.1              | 9.0      | DFOPO                 |
| Swiss Lake              | 7.9| 5.1| 20    | 299/1100               | 0.9      | HS                    | 8.03/86.9              | 4.7      | HS                    |

### Modelling endpoints

| Water / sediment system | pH | pH | t. °C | DT₅₀ whole sys. | St. (χ²) | Method of calculation | DissT₅₀ water | St. (χ²) | Method of calculation |
|-------------------------|----|----|-------|-----------------|----------|-----------------------|----------------|----------|-----------------------|
| Calwich Abbey           | 8.4| 7.6| 20    | 244             | 2.8      | SFO                   | 10(b)         | 9.0      | DFOPO                 |
| Swiss Lake              | 7.9| 5.1| 20    | 252             | 2.3      | SFO                   | 26.2(b)       | 4.7      | HS                    |

|                | Geometric mean at 20°C | 248 | 16.2 |
|----------------|------------------------|-----|------|

### Metabolite SYN545547 (trigger & modelling)

- Distribution (max in water 2.3% after 45 d. Max. sed 12.3 % after 100 d). Max in total system 12.8 % after 100 days.
- kinetic formation fraction (kₙ/kₚ): from parent pydilumetofen

| Water / sediment system | pH | pH | t. °C | DT₅₀ / DT₉₀ whole sys. | St. (χ²) | Formation fraction | Method of calculation |
|-------------------------|----|----|-------|------------------------|----------|-------------------|-----------------------|
| Calwich Abbey           | 8.4| 7.6| 20    | 455/1510               | 10.4     | 0.60              | SFO                   |
| Swiss Lake              | 7.9| 5.1| 20    | 18.6/61.9              | 12.8     | 0.96              | SFO                   |

|                | Geometric mean at 20°C(b) | 92.0 | - |
|----------------|--------------------------|------|---|
| Arithmetic mean|                          | 0.78 |   |

- Measured in calcium chloride solution
- Calculated from DT90 / 3.32

---

[Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.3](http://www.efsa.europa.eu/efsajournal)

[Regulation (EU) N° 284/2013, Annex Part A, point 9.2.2](http://www.efsa.europa.eu/efsajournal)
Mineralisation and non extractable residues (from parent dosed experiments)

| Water / sediment system | pH water phase | pH sed | Mineralisation x % after n d. (end of the study) | Non-extractable residues in sed. max x % after n d | Non-extractable residues in sed. max x % after n d (end of the study) |
|-------------------------|----------------|--------|-----------------------------------------------|-----------------------------------------------|-----------------------------------------------|
|                         |                |        |                                               |                                               |                                               |
| Calwich Abbey           | 8.4            | 7.6    | ≤0.8% after 100 d                            | 10.1-10.2% after 100 d                        | 10.1-10.2% after 100 d                        |
| Swiss Lake              | 7.9            | 5.1    | ≤0.9% after 100 d                            | 14.7-16.2% after 100 d                        | 14.7-16.2% after 100 d                        |

Water/sediment system – Anaerobic conditions

| Parent                | Distribution (Max in water 82.9-86.2% after 0 d. Max. sed 43.9-51.7% after 61-100 d) | Water / sediment system | pH water phase | pH sed | t. ºC | DT₅₀ whole sys. | St. (χ²) | Method of calculation | Diss/T₅₀ water | St. (χ²) | Method of calculation |
|-----------------------|--------------------------------------------------------------------------------------|-------------------------|----------------|--------|-------|----------------|----------|----------------------|----------------|----------|----------------------|
|                       |                                                                                     | Calwich Abbey           | 7.5            | 7.6    | 20    | 152            | 1.8      | SFO                  | 33.2          | 2.6      | SFO                  |
|                       |                                                                                     | Swiss Lake              | 7.8            | 5.1    | 20    | 163            | 1.0      | SFO                  | 41.9          | 3.1      | SFO                  |
|                       |                                                                                        | Geometric mean at 20ºC  | 157            |        |       |                |          |                      | 37.3          |          |                      |

a) Measured in calcium chloride solution

Metabolite SYN545547 Distribution (max in water 10.8% after 100 d. Max. sed 26.5 % after 100 d). Max in total system 32.4 % after 100 days.

Mineralisation and non extractable residues (from parent dosed experiments)

| Water / sediment system | pH water phase | pH sed | Mineralisation x % after n d. (end of the study) | Non-extractable residues in sed. max x % after n d | Non-extractable residues in sed. max x % after n d (end of the study) |
|-------------------------|----------------|--------|-----------------------------------------------|-----------------------------------------------|-----------------------------------------------|
|                         |                |        |                                               |                                               |                                               |
| Calwich Abbey           | 7.5            | 7.6    | ≤0.3% after 100 d                            | 6.9-7.5% after 100 d                          | 6.9-7.5% after 100 d                          |
| Swiss Lake              | 7.8            | 5.1    | ≤0.2% after 100 d                            | 7.1-9.5% after 100 d                          | 7.1-9.5% after 100 d                          |

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

Direct photolysis in air Not studied - no data requested

Photochemical oxidative degradation in air DT₅₀ of 5.85 hours derived by the Atkinson model (AOP version 1.91). OH (12h) concentration assumed = 1.5x10⁶ radicals/cm³

Volatile No data, not required.

Metabolites No data, not required.

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

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

Soil: pydiflumetofen
Surface water: pydiflumetofen, SYN548261, NOA449410
Sediment: pydiflumetofen, SYN545547
Ground water: pydiflumetofen

www.efsa.europa.eu/efsajournal 48  EFSA Journal 2019;17(10):5821
Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2)

See section 5, Ecotoxicology

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

| Environment                        | Data Available       |
|------------------------------------|----------------------|
| Soil (indicate location and type of study) | No data available   |
| Surface water (indicate location and type of study) | No data available   |
| Ground water (indicate location and type of study) | No data available   |
| Air (indicate location and type of study) | No data available   |

PEC soil (Regulation (EU) N° 284/2013, Annex Part A, points 9.1.3 / 9.3.1)

Parent
Method of calculation
  
DT_{50} (d): 8540 days (kinetic parameters used:
  k_1=0.05381, k_2=0.000043, g=0.2484)
  
Kinetics: DFOP
Field or Lab: representative worst case from field studies.

Application data
  
Crop: grapes, pome fruits, cucurbits, tomatoes, potatoes, brassicas
Application schemes & Crop interception: see table below
Depth of soil layer: 5 cm for initial PECsoil, 5 or 20 cm for background concentration (plateau)
Soil bulk density: 1.5 g/cm^3

| Use (Crop, dose, interval) | Crop interception (%) | Initial PECsoil in 5 cm (mg/kg) | Background concentration after 100 years (mg/kg) | PECaccu after 100 years (mg/kg) |
|----------------------------|------------------------|----------------------------------|-------------------------------------------------|-------------------------------|
| Grapes, 2 x 200 g/ha, 14 d | 60                     | 0.1993                           | 8.062 (5 cm)                                    | 8.2613                        |
| Grapes, 2 x 40 g/ha, 10 d  | 50                     | 0.0506                           | 2.015 (5 cm)                                    | 2.0656                        |
| Pome fruits, 3 x 50 g/ha, 7 d | 60                     | 0.0744                           | 3.023 (5 cm)                                    | 3.0974                        |
| Cucurbits, 2 x 50 g/ha, 7 d | 70                     | 0.0384                           | 0.3778 (20 cm)                                  | 0.4162                        |
| Tomatoes, 2 x 70 g/ha, 7 d  | 80                     | 0.0359                           | 0.3527 (20 cm)                                  | 0.3886                        |
| Potatoes, 3 x 40 g/ha, 14 d | 60                     | 0.0570                           | 0.6049 (20 cm)                                  | 0.6619                        |
| Brassicas, 2 x 70 g/ha, 14 d | 40                     | 0.1046                           | 1.058 (20 cm)                                   | 1.1626                        |
* plateau still not reached

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

| Method of calculation and type of study (e.g. modelling, field leaching, lysimeter) | Modelling using FOCUS models, with appropriate FOCUSgw scenarios, according to FOCUS guidance. Models used: PEARL 4.4.4, PELMO 5.5.3, MACRO 5.5.4 |
| --- | --- |
| **pydiflumetofen:** | Molecular weight: 426.7 g/mol Water solubility: 1.5 mg/L at 20°C Vapour pressure: 0 Pa at 20°C (no volatilization as worst-case) Geometric mean parent DT50 field 1334 d (normalisation to pH2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7) KOC: 1706 mL/g (geometric mean) 1/n: = 0.876 (arithmetic mean) Crop uptake factor: 0 |

| Application rate | Crop: Grapes (FOCUS: Vines) Gross application rate: 200 g/ha. No. of applications: 2 Interval between applications: 14 days Crop growth stage: BBCH 67-89 Canopy interception %: 60 (1st app), 75 (2nd app) Application rate net of interception: 80 g/ha (1st app), 50 g/ha (2nd app). Time of application (determined according to AppDate SE (2015)): 1st app. at BBCH 67 |
| --- | --- |
| Crop: Grapes (FOCUS: Vines) Gross application rate: 40 g/ha. No. of applications: 2 Interval between applications: 10 days Crop growth stage: BBCH 13-77 Canopy interception %: Early: 50 (1st app), 60 (2nd app) Late: 60 (1st app), 75 (2nd app) Application rate net of interception: Early: 20 g/ha (1st app), 16 g/ha (2nd app) Late: 16 g/ha (1st app), 10 g/ha (2nd app) Time of application (determined according to AppDate SE (2015)): Early: 1st app. at BBCH 13 Late: 2nd app. at BBCH 77 |
| Crop: pome fruits (FOCUS: Apples) Gross application rate: 50 g/ha. No. of applications: 3 Interval between applications: 7 days |
Crop growth stage: BBCH 56-79
Canopy interception %:
  Early: 60 (1\textsuperscript{st}, 2\textsuperscript{nd} & 3\textsuperscript{rd} app)
  Late: 65 (1\textsuperscript{st}, 2\textsuperscript{nd} & 3\textsuperscript{rd} app)
Application rate net of interception:
  Early: 20 g/ha (1\textsuperscript{st}, 2\textsuperscript{nd} & 3\textsuperscript{rd} app)
  Late: 17.5 g/ha (1\textsuperscript{st}, 2\textsuperscript{nd} & 3\textsuperscript{rd} app)
Time of application (determined according to AppDate SE (2015)):
  Early: 1\textsuperscript{st} app. at BBCH 56
  Late: 3\textsuperscript{rd} app. at BBCH 79\textsuperscript{7}

Crop: Cucurbits (FOCUS: Tomatoes)
Gross application rate: 50 g/ha.
No. of applications: 2
Interval between applications: 7 days
Crop growth stage: BBCH 20-89
Canopy interception %:
  Early: 70 (1\textsuperscript{st} & 2\textsuperscript{nd} app)
  Late: 80 (1\textsuperscript{st} & 2\textsuperscript{nd} app)
Application rate net of interception:
  Early: 15 g/ha (1\textsuperscript{st} & 2\textsuperscript{nd} app)
  Late: 10 g/ha (1\textsuperscript{st} & 2\textsuperscript{nd} app)
Time of application (determined according to AppDate SE (2015)):
  Early: 1\textsuperscript{st} app. at BBCH 20
  Late: 2\textsuperscript{nd} app. at BBCH 89

Crop: Tomatoes (FOCUS: Tomatoes)
Gross application rate: 70 g/ha.
No. of applications: 2
Interval between applications: 7 days
Crop growth stage: BBCH 51-89
Canopy interception %: 80 (for early and late, 1\textsuperscript{st} & 2\textsuperscript{nd} app)
Application rate net of interception: 14 g/ha (for early and late, 1\textsuperscript{st} & 2\textsuperscript{nd} app)
Time of application (determined according to AppDate SE (2015)):
  Early: 1\textsuperscript{st} app. at BBCH 51
  Late: 2\textsuperscript{nd} app. at BBCH 89

Crop: Potatoes (FOCUS: Potatoes)
Gross application rate: 40 g/ha.
No. of applications: 3
Interval between applications: 14 days
Crop growth stage: BBCH 31-89
Canopy interception %:
  Early: 60 (1\textsuperscript{st} app), 85 (2\textsuperscript{nd} & 3\textsuperscript{rd} app)
  Late: 85 (1\textsuperscript{st}, 2\textsuperscript{nd} & 3\textsuperscript{rd} app)
Application rate net of interception:

\textsuperscript{7} Except when this resulted in a date beyond the date of the beginning of the pre harvest interval of 65 days. In this case the last application date was set to 65 days before harvest.
Early: 16 g/ha (1\textsuperscript{st} app), 6 g/ha (2\textsuperscript{nd} & 3\textsuperscript{rd} app)
Late: 6 g/ha (1\textsuperscript{st}, 2\textsuperscript{nd} & 3\textsuperscript{rd} app)

Time of application (determined according to AppDate SE (2015)):
   Early: 1\textsuperscript{st} app. at BBCH 30
   Late: 3\textsuperscript{rd} app. at BBCH 89\textsuperscript{8}

Crop: Brassicas (FOCUS: Cabbage)
Gross application rate: 70 g/ha.
No. of applications: 2 (2 per crop cycle, equivalent to 4 applications/year for scenarios with 2 crop cycles)
Interval between applications: 14 days
Crop growth stage: BBCH 21-49
Canopy interception %:
   Early: 25 (1\textsuperscript{st} & 2\textsuperscript{nd} app)
   Late: 70 (1\textsuperscript{st} & 2\textsuperscript{nd} app)
Application rate net of interception:
   Early: 52.5 g/ha (1\textsuperscript{st} & 2\textsuperscript{nd} app)
   Late: 21 g/ha (1\textsuperscript{st} & 2\textsuperscript{nd} app)

Time of application (determined according to AppDate SE (2015)):
   Early: 1\textsuperscript{st} app. at BBCH 19
   Late: 2\textsuperscript{nd} app. at BBCH 49

PEC(gw) - FOCUS modelling results (80\textsuperscript{th} percentile annual average concentration at 1m)
Results are the same for early and late application periods unless otherwise indicated

| Use                          | Scenario | PEC\textsubscript{gw} at 1 m soil depth [µg/L] |
|------------------------------|----------|---------------------------------------------|
|                              |          | FOCUS-PEARL 4.4.4 | FOCUS-PELMO 5.5.3 | FOCUS-MACRO 5.5.4 |
| Grapes, 2 x 200 g/ha BBCH 67-89 | Châteaudun | < 0.001            | < 0.001            | < 0.001            |
|                              | Hamburg  | < 0.001            | < 0.001            | N/A                |
|                              | Kremsmünster | < 0.001            | < 0.001            | N/A                |
|                              | Piacenza | 0.026              | 0.056              | N/A                |
|                              | Porto    | < 0.001            | 0.001              | N/A                |
|                              | Sevilla  | 0.003              | < 0.001            | N/A                |
|                              | Thiva    | < 0.001            | < 0.001            | N/A                |

| Use                          | Scenario | PEC\textsubscript{gw} at 1 m soil depth [µg/L] |
|------------------------------|----------|---------------------------------------------|
|                              |          | FOCUS-PEARL 4.4.4 | FOCUS-PELMO 5.5.3 | FOCUS-MACRO 5.5.4 |
| Grapes, 2 x 40 g/ha BBCH 13-77 | Châteaudun | < 0.001            | < 0.001            | < 0.001            |
|                              | Hamburg  | < 0.001            | < 0.001            | N/A                |
|                              | Kremsmünster | < 0.001            | < 0.001            | N/A                |
|                              | Piacenza | < 0.001            | Early: 0.002      | N/A                |
|                              |          |                          | Late: 0.001       |                     |
|                              | Porto    | < 0.001            | < 0.001            | N/A                |
|                              | Sevilla  | < 0.001            | < 0.001            | N/A                |
|                              | Thiva    | < 0.001            | < 0.001            | N/A                |

\textsuperscript{8} Except when this resulted in a date beyond the date of the beginning of the pre harvest interval of 7 days. In this case, the last application date was set to 7 days before harvest.
| Use          | Scenario                  | PEC<sub>GW</sub> at 1 m soil depth [µg/L] |
|--------------|---------------------------|-----------------------------------------|
|              |                           | FOCUS-PEARL 4.4.4 | FOCUS-PELMO 5.5.3 | FOCUS-MACRO 5.5.4 |
| Pome fruits, | Châteaudun                | < 0.001             | < 0.001             | < 0.001            |
| 3 x 50 g/ha  | Hamburg                   | < 0.001             | < 0.001             | N/A                |
| BBCH 56-79   | Jokioinen                 | < 0.001             | < 0.001             | N/A                |
|              | Kremsmünster              | < 0.001             | < 0.001             | N/A                |
|              | Okehampton                | < 0.001             | < 0.001             | N/A                |
|              | Piacenza                  | Early: 0.003        | Early: 0.017        | N/A                |
|              |                            | Late: 0.002         | Late: 0.010         | N/A                |
|              | Porto                      | < 0.001             | < 0.001             | N/A                |
|              | Sevilla                   | Early: 0.002        | < 0.001             | N/A                |
|              |                            | Late: < 0.001       |                     | N/A                |
|              | Thiva                     | < 0.001             | < 0.001             | N/A                |
| Cucurbits,   | Châteaudun                | < 0.001             | < 0.001             | < 0.001            |
| 2 x 50 g/ha, | Piacenza                  | < 0.001             | < 0.001             | N/A                |
| BBCH 51-89   | Porto                      | < 0.001             | < 0.001             | N/A                |
|              | Sevilla                   | < 0.001             | < 0.001             | N/A                |
|              | Thiva                     | < 0.001             | < 0.001             | N/A                |
| Tomatoes,    | Châteaudun                | < 0.001             | < 0.001             | < 0.001            |
| 2 x 70 g/ha, | Piacenza                  | < 0.001             | < 0.001             | N/A                |
| BBCH 51-89   | Porto                      | < 0.001             | < 0.001             | N/A                |
|              | Sevilla                   | < 0.001             | < 0.001             | N/A                |
|              | Thiva                     | < 0.001             | < 0.001             | N/A                |
| Potatoes,    | Châteaudun                | < 0.001             | < 0.001             | < 0.001            |
| 3 x 40 g/ha  | Hamburg                   | < 0.001             | < 0.001             | N/A                |
| BBCH 31-89   | Jokioinen                 | < 0.001             | < 0.001             | N/A                |
|              | Kremsmünster              | < 0.001             | < 0.001             | N/A                |
|              | Okehampton                | < 0.001             | < 0.001             | N/A                |
|              | Piacenza                  | < 0.001             | < 0.001             | N/A                |
|              | Porto                      | < 0.001             | < 0.001             | N/A                |
|              | Sevilla                   | < 0.001             | < 0.001             | N/A                |
|              | Thiva                     | < 0.001             | < 0.001             | N/A                |
| Brassicas,   | Châteaudun                | < 0.001             | < 0.001             | < 0.001            |
| 2 x 70 g/ha  | Hamburg                   | < 0.001             | < 0.001             | N/A                |
### Additional PECgw calculations

The standard 20-year FOCUS calculations resulted to be not sufficient to cover the groundwater risk assessment for a highly persistent substance such as pydiflumetofen, since even the simulations over a period of 60 or 93 years were not able to depict the plateau phase of pydiflumetofen for all representative uses and shown increasing trends.

Therefore, the additional simulations performed considering annual applications of pydiflumetofen during 60 years were used in order to assess the long-term groundwater exposure for pydiflumetofen. Although these calculations were not performed using the standard FOCUS shells of the groundwater models, it was agreed that they are necessary to illustrate that due to the persistence of pydiflumetofen, groundwater exposure from the active substance for the representative uses is likely to occur in the long-term.

The PECgw presented are the maximum from early and late season application simulations where relevant.

| Use       | Scenario                          | PECgw at 1 m soil depth [µg/L] |
|-----------|-----------------------------------|--------------------------------|
| BBCH 21-49|                                    | FOCUS-PEARL 4.4.4 | FOCUS-PELMO 5.5.3 | FOCUS-MACRO 5.5.4 |
| Jokioinen | < 0.001                           | < 0.001                        | N/A                      |
| Kremsmünster | < 0.001                           | < 0.001                        | N/A                      |
| Porto     | < 0.001 Early: 0.002 Late: < 0.001 | N/A                           |
| Sevilla   | < 0.001                           | < 0.001                        | N/A                      |
| Thiva     | < 0.001                           | < 0.001                        | N/A                      |

*Calculations do not come from using FOCUS shells of the groundwater tools*
| Use | Scenario | PEC_{GW} at 1 m soil depth [µg/L] | Following annual applications during 60 years* |
|-----|----------|---------------------------------|---------------------------------------------|
|     |          | PEARL 4.4.4                     | PELMO 5.5.3                                 |
|     |          | 0.1943                          | 0.0370                                      |
|     |          | 0.4978                          | 0.2737                                      |
|     |          | 0.6180                          | 0.0924                                      |
|     |          | 0.2397                          | 0.0973                                      |
|     |          | 0.7368                          | < 0.001                                     |
|     |          | 2.6740                          | < 0.001                                     |

* Calculations do not come from using FOCUS shells of the groundwater tools

| Use | Scenario | PEC_{GW} at 1 m soil depth [µg/L] | Following annual applications during 60 years* |
|-----|----------|---------------------------------|---------------------------------------------|
|     |          | PEARL 4.4.4                     | PELMO 5.5.3                                 |
|     |          | 0.0046                          | < 0.001                                     |
|     |          | 0.0933                          | 0.0261                                      |
|     |          | 0.0287                          | 0.0261                                      |
|     |          | < 0.001                         | < 0.001                                     |
|     |          | 0.0024                          | < 0.001                                     |

* Calculations do not come from using FOCUS shells of the groundwater tools

| Use | Scenario | PEC_{GW} at 1 m soil depth [µg/L] | Following annual applications during 60 years* |
|-----|----------|---------------------------------|---------------------------------------------|
|     |          | PEARL 4.4.4                     | PELMO 5.5.3                                 |
|     |          | 0.0036                          | < 0.001                                     |
|     |          | 0.0853                          | 0.0238                                      |
|     |          | 0.0253                          | 0.0237                                      |
|     |          | < 0.001                         | < 0.001                                     |
|     |          | 0.0019                          | < 0.001                                     |

* Calculations do not come from using FOCUS shells of the groundwater tools

| Use | Scenario | PEC_{GW} at 1 m soil depth [µg/L] | Following annual applications during 60 years* |
|-----|----------|---------------------------------|---------------------------------------------|
|     |          | PEARL 4.4.4                     | PELMO 5.5.3                                 |
|     |          | 0.0010                          | < 0.001                                     |
|     |          | 0.0435                          | 0.0114                                      |
|     |          | < 0.001                         | < 0.001                                     |
|     |          | 0.0199                          | 0.0054                                      |
|     |          | 0.0843                          | 0.0774                                      |
|     |          | 0.0712                          | 0.0227                                      |
|     |          | 0.0212                          | 0.0227                                      |
|     |          | < 0.001                         | < 0.001                                     |
|     |          | < 0.001                         | < 0.001                                     |

* Calculations do not come from using FOCUS shells of the groundwater tools

| Use | Scenario | PEC_{GW} at 1 m soil depth [µg/L] | Following annual applications during 60 years* |
|-----|----------|---------------------------------|---------------------------------------------|
|     |          | PEARL 4.4.4                     | PELMO 5.5.3                                 |
|     |          | 0.0345                          | 0.0091                                      |

* Calculations do not come from using FOCUS shells of the groundwater tools
### Peer review of the pesticide risk assessment of the active substance pydiflumetofen

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

**Parent**
- **Parameters used in FOCUSsw step 1 and 2**
  - Version control no. of FOCUS calculator: 3.2
  - Molecular weight (g/mol): 426.7
  - \(K_{OC}\) (mL/g): 1706 (geomean)
  - \(DT_{50}\) soil (d): 1334 days, geomean from field
  - \(DT_{50}\) water/sediment system (d): 248 d (geomean from sediment water studies)
  - \(DT_{50}\) water (d): 248
  - \(DT_{50}\) sediment (d): 248

**Parameters used in FOCUSsw step 3 (if performed)**
- Version control no.’s of FOCUS software: SWASH 5.3, MACRO 5.5.4, PRZM 4.3.1, TOXSWA 4.4
- Water solubility (mg/L): 1.5 (25°C)
- Vapour pressure: \(1.84 \times 10^{-7}\) Pa at 20°C
- \(DT_{50}\) soil (d): 1334 days
- \(K_{oc}\) (mL/g): 1706 (geomean)
- \(1/n\): 0.876 (arithmetic mean)
- \(DT_{50}\) water (d): 1000 (FOCUS default)
- \(DT_{50}\) sediment (d): 248 (geomean from total system)
- \(Q10=2.58\), Walker equation coefficient 0.7
- Crop uptake factor: 0

**Application rate**
- Crop and growth stage: grapes (FOCUS: Vines late), BBCH 67-89
- Number of applications: 2
- Interval (d): 14
- Application rate(s): 200 g a.s./ha
- Crop interception (Step 2): Full canopy (60%)
- Application window:
  - Step 2: June-September
  - Step 3: beginning at BBCH 67 (determined according to AppDate SE 2015)\(^9\)

- Crop and growth stage: grapes (FOCUS: Vines early for Step 1-2\(^9\), Vines early & late for Step 3), BBCH 13-77

---
\(^9\) Except when this resulted in the end of the window beyond the date of the beginning of the pre harvest interval. In this case, the end of application window was set to PHI.
| Crop and growth stage: pome fruits (FOCUS: Pome/stone fruits early for Step 1-2, Pome/stone fruits early & late for Step 3), BBCH 56-79 |
| --- |
| Number of applications: 3 |
| Interval (d): 7 |
| Application rate(s): 50 g a.s./ha |
| Crop interception (Step 2): Average crop cover (40%) |
| Application window: |
| Step 2: June-September |
| Step 3, early: beginning at BBCH 56 (determined according to AppDate SE 2015) |
| Step 3, late: ending at BBCH 79 (determined according to AppDate SE 2015) |

| Crop and growth stage: cucurbits (FOCUS: Fruiting vegetables), BBCH 20-89 |
| --- |
| Number of applications: 2 |
| Interval (d): 7 |
| Application rate(s): 50 g a.s./ha |
| Crop interception (Step 2): Minimal (25%) |
| Application window: |
| Step 2: March-May |
| Step 3, early: beginning at BBCH 20 (determined according to AppDate SE 2015) |
| Step 3, late: ending at BBCH 89 (determined according to AppDate SE 2015) |

| Crop and growth stage: tomatoes (FOCUS: Fruiting vegetables), BBCH 51-89 |
| --- |
| Number of applications: 2 |
| Interval (d): 7 |
| Application rate(s): 70 g a.s./ha |
| Crop interception (Step 2): Full canopy (70%) |
| Application window: |
| Step 2: June-September |
| Step 3, early: beginning at BBCH 51 (determined according to AppDate SE 2015) |
| Step 3, late: ending at BBCH 89 (determined according to AppDate SE 2015) |

---

10 This is not conservative for late applications. However late applications can be considered covered by calculations performed for grapes 2x200 g/ha
Crop and growth stage: potatoes (FOCUS: Potatoes), BBCH 31-89
Number of applications: 3
Interval (d): 14
Application rate(s): 40 g a.s./ha
Crop interception (Step 2): Average crop cover (50%)
Application window:
Step 2: June-September
Step 3, early: beginning at BBCH 31 (determined according to AppDate SE 2015)
Step 3, late: ending at BBCH 89 (determined according to AppDate SE 2015)

Crop and growth stage: brassicas (FOCUS: Leafy vegetables), BBCH 21-49
Number of applications: 2
Interval (d): 14
Application rate(s): 70 g a.s./ha
Crop interception (Step 2): Minimal (25%)
Application window:
Step 2: March-May
Step 3, early: beginning at BBCH 19 (determined according to AppDate SE 2015)
Step 3, late (only for D4 1st, D6 1st, R2 2nd): ending at BBCH 49 (determined according to AppDate SE 2015)

| Use               | FOCUS STEP 1 | FOCUS STEP 2 |
|-------------------|--------------|--------------|
|                   | Actual PEC<sub>SW</sub> (µg/L) | Actual PEC<sub>SED</sub> (µg/kg) | PEC<sub>SED ACCU</sub> (µg/kg) | Actual PEC<sub>SW</sub> (µg/L) | Actual PEC<sub>SED</sub> (µg/kg) | PEC<sub>SED ACCU</sub> (µg/kg) |
| Grapes, 2 x 200 g/ha | 51.4 | 748 | 1217 | 8.52 | 130 | 213 |
| Grapes, 2 x 40 g/ha** | 8.86 | 142 | 231 | 2.20 | 36.5 | 59.4 |
| Pome fruit, 3 x 50 g/ha | 29.9 | 336 | 525 | 7.36 | 107 | 167.3 |
| Cucurbits, 2 x 50 g/ha | 11.1 | 178 | 290 | 3.36 | 55.9 | 91.1 |
| Tomatoes, 2 x 70 g/ha | 15.5 | 249 | 405 | 1.72 | 27.5 | 44.9 |
| Potatoes, 3 x 40 g/ha | 13.3 | 214 | 348 | 2.12 | 34.9 | 54.7 |
| Brassicas, 2 x 70 g/ha | 15.5 | 249 | 405 | 4.70 | 78.2 | 127 |

* Calculations are reported for multiple applications only (worst-case compared to single application) and for Southern Europe only (worst-case compared to Northern Europe)
** Calculations cover early applications. Late applications can be considered covered by calculations performed for grapes 2x200 g/ha

**FOCUS Step 3**
### Application rate and timing

| Scenario | Water body | PEC<sub>SW</sub> [µg/L]<sup>*</sup> | PEC<sub>SED</sub> [µg/kg]<sup>*</sup> | Main route of entry to water body for max. PEC<sub>SW</sub> |
|----------|------------|-----------------------------------|-----------------------------------|-----------------------------------------------|
| D6       | Ditch      | 3.42                              | 11.6                              | Drift                                         |
| R1       | Pond       | 0.18                              | 1.68                              | Drift                                         |
| R1       | Stream     | 2.44                              | 0.429                             | Drift                                         |
| R2       | Stream     | 3.37                              | 1.41                              | Drift                                         |
| R3       | Stream     | 3.54                              | 4.52                              | Drift                                         |
| R4       | Stream     | 2.51                              | 1.87                              | Drift                                         |

<sup>*</sup> PEC values are the maximum of single and multiple application simulations (i.e. each value in the table is the maximum of two values)

### Application rate and timing

| Scenario | Water body | PEC<sub>SW</sub> [µg/L]<sup>*</sup> | PEC<sub>SED</sub> [µg/kg]<sup>*</sup> | Main route of entry to water body for max. PEC<sub>SW</sub> |
|----------|------------|-----------------------------------|-----------------------------------|-----------------------------------------------|
| D6       | Ditch      | 0.761                             | 2.54                              | Drainage                                      |
| R1       | Pond       | 0.036                             | 0.364                             | Drift                                         |
| R1       | Stream     | 0.502                             | 0.202                             | Drift                                         |
| R2       | Stream     | 0.673                             | 0.312                             | Drift                                         |
| R3       | Stream     | 0.708                             | 0.783                             | Drift                                         |
| R4       | Stream     | 0.502                             | 0.584                             | Drift                                         |

<sup>*</sup> PEC values are the maximum of multiple simulations of early and late application timings, single and multiple applications (i.e. each value in the table is the maximum of four values)

### Application rate and timing

| Scenario | Water body | PEC<sub>SW</sub> [µg/L]<sup>*</sup> | PEC<sub>SED</sub> [µg/kg]<sup>*</sup> | Main route of entry to water body for max. PEC<sub>SW</sub> |
|----------|------------|-----------------------------------|-----------------------------------|-----------------------------------------------|
| D3       | Ditch      | 3.89                              | 5.74                              | Drift                                         |
| D4       | Pond       | 0.501                             | 5.11                              | Drift                                         |
| D4       | Stream     | 4.12                              | 1.25                              | Drift                                         |
| D5       | Pond       | 0.514                             | 5.52                              | Drift                                         |
| D5       | Stream     | 4.45                              | 1.76                              | Drift                                         |
| R1       | Pond       | 0.450                             | 4.01                              | Drift                                         |
| R1       | Stream     | 3.16                              | 0.736                             | Drift                                         |
| R2       | Stream     | 4.23                              | 0.654                             | Drift                                         |
| R3       | Stream     | 4.45                              | 1.48                              | Drift                                         |
| R4       | Stream     | 3.08                              | 0.826                             | Drift                                         |

<sup>*</sup> PEC values are the maximum of multiple simulations of single and multiple applications (i.e. each value in the table is the maximum of two values)

### Application rate and timing

| Scenario | Water body | PEC<sub>SW</sub> [µg/L]<sup>*</sup> | PEC<sub>SED</sub> [µg/kg]<sup>*</sup> | Main route of entry to water body for max. PEC<sub>SW</sub> |
|----------|------------|-----------------------------------|-----------------------------------|-----------------------------------------------|
| D3       | Ditch      | 1.84                              | 3.30                              | Drift                                         |
| D4       | Pond       | 0.192                             | 2.37                              | Drainage                                      |
| D4       | Stream     | 1.84                              | 0.689                             | Drift                                         |
| D5       | Pond       | 0.174                             | 2.68                              | Drainage                                      |
| D5       | Stream     | 1.98                              | 0.717                             | Drift                                         |
| R1       | Pond       | 0.132                             | 1.34                              | Drift                                         |
| R1       | Stream     | 1.38                              | 0.228                             | Drift                                         |
| R2       | Stream     | 1.89                              | 0.622                             | Drift                                         |
| R3       | Stream     | 1.98                              | 0.883                             | Drift                                         |
| R4       | Stream     | 1.41                              | 0.751                             | Drift                                         |

<sup>*</sup> PEC values are the maximum of multiple simulations of single and multiple applications (i.e. each value in the table is the maximum of two values)
### Application rate and timing [g a.s./ha]

| Scenario   | Water body | PEC<sub>SW</sub> [µg/L]<sup>*</sup> | PEC<sub>SED</sub> [µg/kg]<sup>*</sup> | Main route of entry to water body for max. PEC<sub>SW</sub> |
|------------|------------|----------------------------------|----------------------------------|---------------------------------------------------------------|
| Step 3, Cucurbita 2 × 50 g a.s./ha BBCH 20-89 | D6 | Ditch | 1.34 | 2.41 | Drainage         |
|            | R2 | Stream | 0.280 | 18.9 | Drift           |
|            | R3 | Stream | 0.350 | 3.47 | Runoff          |
|            | R4 | Stream | 0.479 | 1.30 | Runoff          |

* PEC values are the maximum of multiple simulations of early and late application timings, single and multiple applications (i.e. each value in the table is the maximum of four values)

### Application rate and timing [g a.s./ha]

| Scenario   | Water body | PEC<sub>SW</sub> [µg/L]<sup>*</sup> | PEC<sub>SED</sub> [µg/kg]<sup>*</sup> | Main route of entry to water body for max. PEC<sub>SW</sub> |
|------------|------------|----------------------------------|----------------------------------|---------------------------------------------------------------|
| Step 3, Tomatoes 2 × 70 g a.s./ha BBCH 51-89 | D6 | Ditch | 1.93 | 3.12 | Drainage         |
|            | R2 | Stream | 0.392 | 25.1 | Drift           |
|            | R3 | Stream | 0.466 | 4.61 | Runoff          |
|            | R4 | Stream | 0.718 | 1.73 | Runoff          |

* PEC values are the maximum of multiple simulations of early and late application timings, single and multiple applications (i.e. each value in the table is the maximum of four values)

### Application rate and timing [g a.s./ha]

| Scenario   | Water body | PEC<sub>SW</sub> [µg/L]<sup>*</sup> | PEC<sub>SED</sub> [µg/kg]<sup>*</sup> | Main route of entry to water body for max. PEC<sub>SW</sub> |
|------------|------------|----------------------------------|----------------------------------|---------------------------------------------------------------|
| Step 3, Potatoes 3 × 40 g a.s./ha BBCH 31-89 | D3 | Ditch | 0.209 | 0.172 | Drift         |
|            | D4 | Pond | 0.282 | 3.16 | Drainage         |
|            | D4 | Stream | 0.614 | 1.19 | Drainage         |
|            | D6 | Ditch | 1.40 | 2.78 | Drainage         |
|            | R1 | Pond | 0.133 | 1.97 | Runoff          |
|            | R1 | Stream | 0.328 | 1.74 | Runoff          |
|            | R2 | Stream | 0.192 | 7.31 | Drift           |
|            | R3 | Stream | 0.372 | 4.21 | Runoff          |

* PEC values are the maximum of multiple simulations of early and late application timings, single and multiple applications (i.e. each value in the table is the maximum of four values)

### Application rate and timing [g a.s./ha]

| Scenario   | Water body | PEC<sub>SW</sub> [µg/L]<sup>*</sup> | PEC<sub>SED</sub> [µg/kg]<sup>*</sup> | Main route of entry to water body for max. PEC<sub>SW</sub> |
|------------|------------|----------------------------------|----------------------------------|---------------------------------------------------------------|
| Step 3, Brassicas 2 × 70 g a.s./ha BBCH 21-49 | D3 (1<sup>st</sup> crop) | Ditch | 0.443 | 0.382 | Drift         |
|            | D3 (2<sup>nd</sup> crop) | Ditch | 0.440 | 0.292 | Drift          |
|            | D4 (1<sup>st</sup> crop) | Pond | 0.278 | 3.18 | Drainage         |
|            | D4 (1<sup>st</sup> crop) | Stream | 0.581 | 1.18 | Drainage         |
|            | D6 (1<sup>st</sup> crop) | Ditch | 2.22 | 3.03 | Drainage         |
|            | R1 (1<sup>st</sup> crop) | Pond | 0.253 | 4.05 | Runoff          |
|            | R1 (2<sup>nd</sup> crop) | Pond | 0.199 | 3.23 | Runoff          |
|            | R1 (1<sup>st</sup> crop) | Stream | 0.407 | 15.2 | Runoff          |
|            | R2 (1<sup>st</sup> crop) | Stream | 0.375 | 3.56 | Runoff          |
|            | R2 (2<sup>nd</sup> crop) | Stream | 0.392 | 14.5 | Drift           |
|            | R3 (1<sup>st</sup> crop) | Stream | 0.412 | 12.1 | Drift           |
|            | R3 (2<sup>nd</sup> crop) | Stream | 0.411 | 7.36 | Drift           |
|            | R4 (1<sup>st</sup> crop) | Stream | 0.653 | 2.17 | Runoff          |
|            | R4 (2<sup>nd</sup> crop) | Stream | 0.640 | 2.60 | Runoff          |

* PEC values are the maximum of multiple simulations of early and late application timings, single and multiple applications (i.e. each value in the table is the maximum of four values)
FOCUS Step 4 – 10 m non-sprayed buffer zone

| Application rate and timing [g a.s./ha] | Scenario | Water body | PECsw [µg/L]* | Main route of entry to water body for max. PECsw |
|----------------------------------------|----------|------------|---------------|-----------------------------------------------|
| Step 4, 10 m NSB                       |          |            |               |                                               |
| Grapes, late                           |          |            |               |                                               |
| 2 × 200 g a.s./ha                      |          |            |               |                                               |
| BBCH 67-89                             |          |            |               |                                               |
|                                        | D6       | Ditch      | 3.38          | Drainage                                      |
|                                        | R1       | Pond       | 0.116         | Drift                                         |
|                                        | R1       | Stream     | 0.644         | Drift                                         |
|                                        | R2       | Stream     | 0.888         | Drift                                         |
|                                        | R3       | Stream     | 1.13          | Runoff                                        |
|                                        | R4       | Stream     | 1.39          | Runoff                                        |

* PEC values are the maximum of single and multiple application simulations (i.e. each value in the table is the maximum of two values)

| Application rate and timing [g a.s./ha] | Scenario | Water body | PECsw [µg/L]* | Main route of entry to water body for max. PECsw |
|----------------------------------------|----------|------------|---------------|-----------------------------------------------|
| Step 4, 10 m NSB                       |          |            |               |                                               |
| Pome fruits, early                     |          |            |               |                                               |
| 3 × 50 g a.s./ha                       |          |            |               |                                               |
| BBCH 56-69                             |          |            |               |                                               |
|                                        | D3       | Ditch      | 1.88          | Drift                                         |
|                                        | D4       | Pond       | 0.318         | Drift                                         |
|                                        | D4       | Stream     | 2.17          | Drift                                         |
|                                        | D5       | Pond       | 0.331         | Drift                                         |
|                                        | D5       | Stream     | 2.35          | Drift                                         |
|                                        | R1       | Pond       | 0.289         | Drift                                         |
|                                        | R1       | Stream     | 1.66          | Drift                                         |
|                                        | R2       | Stream     | 2.23          | Drift                                         |
|                                        | R3       | Stream     | 2.35          | Drift                                         |
|                                        | R4       | Stream     | 1.63          | Drift                                         |

* PEC values are the maximum of multiple simulations of single and multiple applications (i.e. each value in the table is the maximum of two values)

| Application rate and timing [g a.s./ha] | Scenario | Water body | PECsw [µg/L]* | Main route of entry to water body for max. PECsw |
|----------------------------------------|----------|------------|---------------|-----------------------------------------------|
| Step 4, 10 m NSB                       |          |            |               |                                               |
| Pome fruits, late                      |          |            |               |                                               |
| 3 × 50 g a.s./ha                       |          |            |               |                                               |
| BBCH 70-79                             |          |            |               |                                               |
|                                        | D3       | Ditch      | 0.553         | Drift                                         |
|                                        | D4       | Pond       | 0.174         | Drainage                                      |
|                                        | D4       | Stream     | 0.641         | Drift                                         |
|                                        | D5       | Pond       | 0.162         | Drainage                                      |
|                                        | D5       | Stream     | 0.692         | Drift                                         |
|                                        | R1       | Pond       | 0.083         | Drift                                         |
|                                        | R1       | Stream     | 0.481         | Drift                                         |
|                                        | R2       | Stream     | 0.658         | Drift                                         |
|                                        | R3       | Stream     | 0.691         | Drift                                         |
|                                        | R4       | Stream     | 0.490         | Drift                                         |

* PEC values are the maximum of multiple simulations of single and multiple applications (i.e. each value in the table is the maximum of two values)
Metabolite SYN548261

Parameters used in FOCUSsw step 1 and 2

|                        | FOCUS STEP 1’ | FOCUS STEP 2’ |
|------------------------|---------------|---------------|
|                        | Actual PEC<sub>SW</sub> (µg/L) | Actual PEC<sub>SED</sub> (µg/kg) | Actual PEC<sub>SW</sub> (µg/L) | Actual PEC<sub>SED</sub> (µg/kg) |
| Grapes, 2 x 200 g/ha   | 8.45          | 58.9          | 1.49          | 10.4          |
| Grapes, 2 x 40 g/ha    | 1.61          | 11.2          | 0.412         | 2.88          |
| Pome fruit, 3 x 50 g/ha| 3.79          | 26.4          | 1.22          | 8.52          |
| Cucurbits, 2 x 50 g/ha | 2.01          | 14.0          | 0.632         | 4.41          |
| Tomatoes, 2 x 70 g/ha  | 2.81          | 19.6          | 0.312         | 2.17          |
| Potatoes, 3 x 40 g/ha  | 2.41          | 16.8          | 0.279         | 1.95          |
| Brassicas, 2 x 70 g/ha | 2.81          | 19.6          | 0.884         | 6.17          |

*Calculations are reported for multiple applications only (worst-case compared to single application) and for Southern Europe only (worst-case compared to Northern Europe)

Application rate

Same as for parent substance

Metabolite NOA449410

Parameters used in FOCUSsw step 1 and 2

|                        | FOCUS STEP 1’ | FOCUS STEP 2’ |
|------------------------|---------------|---------------|
|                        | Actual PEC<sub>SW</sub> (µg/L) | Actual PEC<sub>SED</sub> (µg/kg) | Actual PEC<sub>SW</sub> (µg/L) | Actual PEC<sub>SED</sub> (µg/kg) |
| Grapes, 2 x 200 g/ha   | 3.44          | 0.072         | 0.605         | 0.013         |
| Grapes, 2 x 40 g/ha    | 0.653         | 0.014         | 0.168         | 0.004         |

Application rate

Same as for parent substance

Molecular weight: 291 g/mol
Soil or water metabolite: water
K<sub>oc</sub> (mL/g): 0 / 10000 (worst-case for PEC<sub>SW</sub> / PEC<sub>SED</sub>)
DT<sub>50</sub> soil (d): 1000 days (default worst-case)
DT<sub>50</sub> water/sediment system (d): 1000 d (default worst-case)
DT<sub>50</sub> water (d): 1000 d (default worst-case)
DT<sub>50</sub> sediment (d): 1000 d (default worst-case)
Maximum occurrence observed (% molar basis with respect to the parent)
Total Water and Sediment: 8.6
Soil: 0

Molecular weight: 176 g/mol
Soil or water metabolite: water
K<sub>oc</sub> (mL/g): 2.1 (geomean)
DT<sub>50</sub> soil (d): 1000 days (default worst-case)
DT<sub>50</sub> water/sediment system (d): 1000 d (default worst-case)
DT<sub>50</sub> water (d): 1000 d (default worst-case)
DT<sub>50</sub> sediment (d): 1000 d (default worst-case)
Maximum occurrence observed (% molar basis with respect to the parent)
Total Water and Sediment: 5.8
Soil: 0

Application rate

Same as for parent substance
### Use

| Use                     | FOCUS STEP 1* | FOCUS STEP 2* |
|-------------------------|---------------|---------------|
|                         | Actual PEC<sub>SW</sub> (µg/L) | Actual PEC<sub>SED</sub> (µg/kg) | Actual PEC<sub>SW</sub> (µg/L) | Actual PEC<sub>SED</sub> (µg/kg) |
| Pome fruit, 3 x 50 g/ha | 1.53          | 0.032         | 0.497         | 0.010          |
| Cucurbits, 2 x 50 g/ha  | 0.817         | 0.017         | 0.257         | 0.005          |
| Tomatoes, 2 x 70 g/ha   | 1.14          | 0.024         | 0.127         | 0.003          |
| Potatoes, 3 x 40 g/ha   | 0.981         | 0.02          | 0.161         | 0.003          |
| Brassicas, 2 x 70 g/ha  | 1.14          | 0.024         | 0.360         | 0.008          |

* Calculations are reported for multiple applications only (worst-case compared to single application) and for Southern Europe only (worst-case compared to Northern Europe)

### Metabolite SYN545547

- **Parameters used in FOCUS<sub>sw</sub> step 1 and 2**
  - Molecular weight: 396 g/mol
  - Soil or water metabolite: water
  - K<sub>oc</sub> (mL/g): 608 (geomean)
  - DT<sub>50</sub> soil (d): 1000 days (default worst-case)
  - DT<sub>50</sub> water/sediment system (d): 92 d (geomean from water/sediment studies)
  - DT<sub>50</sub> water (d): 92 d (geomean from water/sediment studies)
  - DT<sub>50</sub> sediment (d): 92 d (geomean from water/sediment studies)
  - Maximum occurrence observed (% molar basis with respect to the parent)
  - Total Water and Sediment: 33.7
  - Soil: 2.3

### Application rate

- Same as for parent substance

### Use

| Use                     | FOCUS STEP 1* | FOCUS STEP 2* |
|-------------------------|---------------|---------------|
|                         | Actual PEC<sub>SW</sub> (µg/L) | Actual PEC<sub>SED</sub> (µg/kg) | Actual PEC<sub>SW</sub> (µg/L) | Actual PEC<sub>SED</sub> (µg/kg) |
| Grapes, 2 x 200 g/ha    | 28.0          | 160           | 4.71          | 26.8           |
| Grapes, 2 x 40 g/ha     | 5.15          | 30.4          | 1.30          | 7.74           |
| Pome fruit, 3 x 50 g/ha | 13.8          | 70.9          | 3.89          | 21.5           |
| Cucurbits, 2 x 50 g/ha  | 6.44          | 38.1          | 1.99          | 11.9           |
| Tomatoes, 2 x 70 g/ha   | 9.01          | 53.3          | 0.994         | 5.78           |
| Potatoes, 3 x 40 g/ha   | 7.73          | 45.7          | 1.24          | 7.36           |
| Brassicas, 2 x 70 g/ha  | 9.01          | 53.3          | 2.79          | 16.6           |

* Calculations are reported for multiple applications only (worst-case compared to single application) and for Southern Europe only (worst-case compared to Northern Europe)

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

- **Method of calculation**
  - No data, not required
### PEC

| Maximum concentration | No data, not required |
|------------------------|------------------------|
Ecotoxicology

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

| Species                        | Test substance | Time scale | End point | Toxicity (mg/kg bw per day) |
|--------------------------------|----------------|------------|-----------|----------------------------|
| **Birds**                      |                |            |           |                            |
| Bobwhite quail *(Colinus virginianus)* | pydiflumetofen | Acute      | LD<sub>50</sub> | 3776<sup>a</sup> |
| Canary *(Serinus canaria)*     | pydiflumetofen | Acute      | LD<sub>50</sub> | 3776<sup>a</sup> |
| Bobwhite quail *(Colinus virginianus)* | pydiflumetofen | Short-term dietary | LC<sub>50</sub> | >1 258 |
| Mallard duck *(Anas platyrhynchos)* | pydiflumetofen | Short-term dietary | LC<sub>50</sub> | >2 437 |
| Bobwhite quail *(Colinus virginianus)* | pydiflumetofen | Long-term | NOEC      | 90.1 |
| Mallard duck *(Anas platyrhynchos)* | pydiflumetofen | Long-term | NOEC      | 141 |
| Bobwhite quail *(Colinus virginianus)* | A19649B       | Acute      | LD<sub>50</sub> | >2 000 (equivalent to >372 mg a.s./kg bw) |
| **Mammals**                    |                |            |           |                            |
| Rat                            | pydiflumetofen | Acute      | LD<sub>50</sub> | >5000 |
| Rat                            | A19649B        | Acute      | LD<sub>50</sub> | 2 958 (equivalent to 550 mg a.s./kg bw) |
| Rat                            | pydiflumetofen | Long-term (28 d dietary) | NOAEL | 40 |
| Mouse                          | pydiflumetofen | Long-term (28 d dietary) | NOAEL | 76 |
| Rat                            | pydiflumetofen | Long-term (90 d dietary) | NOAEL | 18.6 |
| Mouse                          | pydiflumetofen | Long-term (90 d dietary) | NOAEL | 17.5 |
| Rat                            | pydiflumetofen | Long-term (developmental) | NOAEL | 100 |
| Rabbit                         | pydiflumetofen | Long-term (developmental) | NOAEL | 10 |
| Rat                            | pydiflumetofen | Long-term (2 generations) | NOAEL | 36 |
Endocrine disrupting properties (Annex Part A, points 8.1.5)
With regard to the assessment of endocrine disruption potential according to ECHA/EFSA Guidance (2018), as reported in Section 2, pydiflumetofen is not an endocrine disruptor for humans and this conclusion also applies to mammals as non-target organisms.

For non-target organisms other than mammals, the available evidence was not considered sufficient to draw a conclusion on endocrine disrupting properties (data gap).

* Based on the LD50 >2000 with extrapolation factor of 1.888

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

**Grapes at 200 g a.s./ha x 2**

| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|--------------|----------------------------|------------|------------------------|-----|---------|
| Screening Step (Birds) | | | | | |
| All | Small omnivorous bird | Acute | 22.87 | 170 | 10 |
| All | Small omnivorous bird | Long-term | 5.77 | 16 | 5 |
| Screening Step (Mammals) | | | | | |
| All | Small herbivorous mammal | Acute | 32.74 | 150 | 10 |
| All | Small herbivorous mammal | Long-term | 10.73 | 3.36 | 5 |
| Tier 1 (Mammals) | | | | | |
| Vineyard Application crop directed BBCH ≥ 40 | Small herbivorous mammal "vole Grass + cereals 100% grass" | Long-term | 3.22 | 11.18 | 5 |
| | Small omnivorous mammal "mouse" Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods | Long-term | 0.34 | 106 | 5 |

**Risk from bioaccumulation and food chain behaviour**

| Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|---------------------------|------------|------------------------|-----|---------|
| Earthworm-eating birds    | Long-term  | 5                      | 8.1 | 5       |
| Earthworm-eating mammals  | Long-term  | 6.08                   | 2.66| 5       |
| Fish-eating birds(pydiflumetofen) | Long-term | 0.0086<sup>a</sup> | 10000 | 5 |
| Fish-eating birds(SYN545547) | Long-term | 0.023<sup>b</sup> | 390.0 | 5 |
| Fish-eating mammals (SYN545974) | Long-term | 0.0076<sup>a</sup> | 4737 | 5 |
| Fish-eating mammals (SYN545547) | Long-term | 0.021<sup>b</sup> | 171<sup>c</sup> | 5 |

<sup>a</sup> FOCUS Step 3 21 day TWA PECsw
<sup>b</sup>Maximum Step 2 PEC<sub>csw</sub>
<sup>c</sup> Default correction assuming the metabolite is 10 time more toxic
Higher tier: none

**Risk from consumption of contaminated water**

| Scenarios | Indicator or focal species | Time scale | PEC<sub>sw</sub>xDWR | TER | Trigger |
|-----------|---------------------------|------------|----------------------|-----|---------|
| Leaf scenario | Birds | acute | 21.62 | 170 | 5 |

**Puddle scenario, Screening step**

1) Application rate (g a.s./ha)/relevant endpoint <3000 (koc≥500 L/kg), TER calculation not needed
### Grapes at 40 g a.s./ha x 2

| Growth stage | Indicator or focal species                  | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|--------------|--------------------------------------------|------------|------------------------|-----|---------|
| Screening Step (Birds) | All Small omnivorous bird                  | Acute      | 4.96                   | 762 | 10      |
|                | All Small omnivorous bird                  | Long-term  | 1.24                   | 72.8| 5       |
| Screening Step (Mammals) | All Small herbivorous mammal               | Acute      | 7.09                   | 705 | 10      |
|                | All Small herbivorous mammal               | Long-term  | 2.30                   | 15.66| 5      |

### Risk from bioaccumulation and food chain behaviour

| Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|---------------------------|------------|------------------------|-----|---------|
| Earthworm-eating birds    |            |                        |     |         |
| Earthworm-eating mammals  |            |                        |     |         |
| Fish-eating birds         |            |                        |     |         |
| Fish-eating mammals       |            |                        |     |         |
| Higher tier : none         |            |                        |     |         |

### Risk from consumption of contaminated water

| Scenarios  | Indicator or focal species | Time scale | PEC<sub>dw</sub>xDWR | TER | Trigger |
|------------|----------------------------|------------|-----------------------|-----|---------|
| Leaf scenario | Birds                     | acute      | 21.62                 | 170 | 5       |
| Puddle scenario | Screening step |            |                      |     |         |

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

### Pome fruits at 50 g a.s./ha x 3

| Growth stage | Indicator or focal species                  | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|--------------|--------------------------------------------|------------|------------------------|-----|---------|
| Screening Step (Birds) | All Small insectivorous bird               | Acute      | 3.74                   | 1000| 10      |
|                | All Small insectivorous bird               | Long-term  | 0.96                   | 94  | 5       |
| Screening Step (Mammals) | All Small herbivorous mammal              | Acute      | 10.91                  | 460 | 10      |
|                | All Small herbivorous mammal              | Long-term  | 3.83                   | 9.4 | 5       |

### Risk from bioaccumulation and food chain behaviour

| Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|---------------------------|------------|------------------------|-----|---------|
| Earthworm-eating birds    |            |                        |     |         |
| Earthworm-eating mammals  |            |                        |     |         |
| Fish-eating birds(pydiflumetofen) |          |                        |     |         |
| Fish-eating birds(SYN545547) |          |                        |     |         |
| Fish-eating mammals (pydiflumetofen) |        |                        |     |         |
| Fish-eating mammals (SYN545547) |         |                        |     |         |
| Higher tier : none         |            |                        |     |         |

### Risk from consumption of contaminated water

| Scenarios  | Indicator or focal species | Time scale | PEC<sub>dw</sub>xDWR | TER | Trigger |
|------------|----------------------------|------------|-----------------------|-----|---------|
| Leaf scenario | Birds                     | acute      | 21.62                 | 170 | 5       |
**Puddle scenario, Screening step**

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

---

**Tomatoes at 70 g a.s./ha x 2**

| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|--------------|--------------------------|------------|------------------------|-----|---------|
| Screening Step (Birds) | All Small omnivorous bird | Acute | 15.56 | 240 | 10 |
| | All Small omnivorous bird | Long-term | 3.85 | 23 | 5 |
| Screening Step (Mammals) | All Small herbivorous mammal | Acute | 13.37 | 370 | 10 |
| | All Small herbivorous mammal | Long-term | 4.29 | 8.4 | 5 |

**Risk from bioaccumulation and food chain behaviour**

| Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|----------------------------|------------|------------------------|-----|---------|
| Earthworm-eating birds | Covered by use on Grapes at 200 g a.s./ha x 2 | | | |
| Earthworm-eating mammals | Covered by use on Pome fruits at 50 g a.s./ha x 3 | | | |
| Fish-eating birds | Covered by use on Grapes at 200 g a.s./ha x 2 | | | |
| Fish-eating mammals | Covered by use on Grapes at 200 g a.s./ha x 2 | | | |

**Higher tier: none**

---

**Risk from consumption of contaminated water**

| Scenarios | Indicator or focal species | Time scale | PEC<sub>dw</sub>xDWR | TER | Trigger |
|-----------|---------------------------|------------|----------------------|-----|---------|
| Leaf scenario Birds acute | 21.62 | 170 | 5 |

**Puddle scenario, Screening step**

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

---

**Cucurbits at 50 g a.s./ha x 2**

| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|--------------|--------------------------|------------|------------------------|-----|---------|
| Screening Step (Birds) | Small omnivorous bird | Acute | 11.12 | 340 | 10 |
| | Small omnivorous bird | Long-term | 2.75 | 33 | 5 |
| Screening Step (Mammals) | All Small herbivorous mammal | Acute | 9.55 | 520 | 10 |
| | All Small herbivorous mammal | Long-term | 3.07 | 11.7 | 5 |

**Risk from bioaccumulation and food chain behaviour**

| Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|---------------------------|------------|------------------------|-----|---------|
| Earthworm-eating birds | Covered by use on Grapes at 200 g a.s./ha x 2 | | | |
| Earthworm-eating mammals | Covered by use on Pome fruits at 50 g a.s./ha x 3 | | | |
| Fish-eating birds | Covered by use on Grapes at 200 g a.s./ha x 2 | | | |
| Fish-eating mammals | Covered by use on Grapes at 200 g a.s./ha x 2 | | | |
| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|--------------|---------------------------|------------|------------------------|-----|---------|
|              |                           |            |                        |     |         |
| Higher tier  | none                      |            |                        |     |         |
|              |                           |            |                        |     |         |

**Risk from consumption of contaminated water**

**Scenarios** | Indicator or focal species | Time scale | PEC<sub>dw</sub>xDWR | TER | Trigger |
|---------------|---------------------------|------------|-----------------------|-----|---------|
| Leaf scenario | Birds                     | acute      | 21.62                 | 170 | 5       |

**Puddle scenario, Screening step**

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

**Potatoes at 40 g a.s./ha x 3**

| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|--------------|---------------------------|------------|------------------------|-----|---------|
|              |                           |            |                        |     |         |
| Screening Step (Birds) |                       |            |                        |     |         |
| All          | Small omnivorous bird     | Acute      | 8.26                   | 460 | 10      |
|              | Small omnivorous bird     | Long-term  | 2.06                   | 44  | 5       |

| Screening Step (Mammals) |                       |            |                        |     |         |
| All          | Small herbivorous mammal | Acute      | 6.16                   | 810 | 10      |
|              | Small herbivorous mammal | Long-term  | 1.54                   | 23.4| 5       |

**Risk from bioaccumulation and food chain behaviour**

| Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|----------------------------|------------|------------------------|-----|---------|
| Earthworm-eating birds    |            | Covered by use on Grapes at 200 g a.s./ha x 2 |     |         |
| Earthworm-eating mammals  |            | Covered by use on Pome fruits at 50 g a.s./ha x 3 |     |         |
| Fish-eating birds         |            | Covered by use on Grapes at 200 g a.s./ha x 2 |     |         |
| Fish-eating mammals       |            | Covered by use on Grapes at 200 g a.s./ha x 2 |     |         |
| Higher tier : none        |            |                        |     |         |

**Risk from consumption of contaminated water**

**Scenarios** | Indicator or focal species | Time scale | PEC<sub>dw</sub>xDWR | TER | Trigger |
|---------------|---------------------------|------------|-----------------------|-----|---------|
| Leaf scenario | Birds                     | acute      | 21.62                 | 170 | 5       |

**Puddle scenario, Screening step**

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

**Brassicas at 70 g a.s./ha x 2**

| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|--------------|---------------------------|------------|------------------------|-----|---------|
|              |                           |            |                        |     |         |

| Screening Step (Birds) |                       |            |                        |     |         |
| All          | Small omnivorous bird     | Acute      | 13.34                  | 280 | 10      |
|              | Small omnivorous bird     | Long-term  | 3.37                   | 27  | 5       |

| Screening Step (Mammals) |                       |            |                        |     |         |
| All          | Small herbivorous mammal | Acute      | 11.46                  | 440 | 10      |
|              | Small herbivorous mammal | Long-term  | 3.76                   | 9.57| 5       |
| Growth stage | Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
|--------------|---------------------------|------------|-----------------------|-----|---------|
| Risk from bioaccumulation and food chain behaviour | | | | |
| Indicator or focal species | Time scale | DDD (mg/kg bw per day) | TER | Trigger |
| Earthworm-eating birds | Covered by use on Grapes at 200 g a.s./ha x 2 | | | |
| Earthworm-eating mammals | Covered by use on Pome fruits at 50 g a.s./ha x 3 | | | |
| Fish-eating birds | Covered by use on Grapes at 200 g a.s./ha x 2 | | | |
| Fish-eating mammals | Covered by use on Grapes at 200 g a.s./ha x 2 | | | |
| Higher tier: none | | | | |
| Risk from consumption of contaminated water | | | | |
| Scenarios | Indicator or focal species | Time scale | PEC_{dw} x DWR | TER | Trigger |
| Leaf scenario | Birds | acute | 21.62 | 170 | 5 |
| Puddle scenario, Screening step | | | | |
| 1) Application rate (g a.s./ha)/relevant endpoint <3000 (koc ≥ 500 L/kg), TER calculation not needed |

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

| Group | Test substance | Time-scale (Test type) | End point | Toxicity<sup>1</sup> |
|-------|----------------|------------------------|-----------|---------------------|
| Laboratory tests | | | | |
| Group              | Test substance | Time-scale (Test type) | End point          | Toxicity¹ |
|--------------------|----------------|-----------------------|--------------------|-----------|
| **Fish**           |                |                       |                    |           |
| *Oncorhynchus mykiss* (Rainbow trout) | pydiflumetofen | Acute 96 hr (flow-through) | Mortality, LC₅₀ | 0.18 mg a.s./L (mm) |
| *Pimephales promelas* (Fathead minnow) | pydiflumetofen | Acute 96 hr (flow-through) | Mortality, LC₅₀ | 0.35 mg a.s./L (mm) |
| *Cyprinus carpio* (Common carp) | pydiflumetofen | Acute 96 hr (flow-through) | Mortality, LC₅₀ | 0.33 mg a.s./L (mm) |
| *Cyprinodon variegatus* (Sheepshead minnow) | pydiflumetofen | Acute 96 hr (flow-through) | Mortality, LC₅₀ | 0.66 mg a.s./L (mm) |
| *Lepomis macrochirus* (Bluegill sunfish) | pydiflumetofen | Acute 96 hr (flow-through) | Mortality, LC₅₀ | 0.48 mg a.s./L (mm) |
| *Oncorhynchus mykiss* (Rainbow trout) | A19649B | Acute 96 hr (static) | Mortality, LC₅₀ | 1.23 (mm) (equivalent to 0.23 mg a.s./L) |
| *Cyprinus carpio* (Common carp) | A19649B | Acute 96 hr (static) | Mortality, LC₅₀ | 1.16 (mm) (equivalent to 0.21 mg a.s./L) |
| *Oncorhynchus mykiss* (Rainbow trout) | SYN545547 | 96 hr (static) | Mortality, LC₅₀ | 1.4 (mm) |
| *Oncorhynchus mykiss* (Rainbow trout) | SYN548261 | 96 hr (static) | Mortality, LC₅₀ | >100 (nom) |
| *Oncorhynchus mykiss* (Rainbow trout) | NOA449410 | 96 hr (static) | Mortality, LC₅₀ | >100 (nom) |
| *Pimephales promelas* (Fathead minnow) | pydiflumetofen | Early Life Stage (ELS) (flow-through) | 32 d NOEC | 0.025 (mm) |
| *Cyprinodon variegatus* (Sheepshead minnow) | pydiflumetofen | Early Life Stage (ELS) (flow-through) | 34 d NOEC | 0.17 (mm) |

¹ Toxicity values are given in mg a.s./L (mm) unless otherwise specified.
| Group                                      | Test substance | Time-scale (Test type) | End point               | Toxicity¹ |
|--------------------------------------------|----------------|------------------------|-------------------------|-----------|
| **Aquatic invertebrates**                  |                |                        |                         |           |
| *Daphnia magna* (Water flea)              | pydiflumetofen | 48 h (static)          | Mortality, EC<sub>50</sub> | 0.42 mg a.s./L (mm) |
| *Americamysis bahia* (Mysid shrimp)        | pydiflumetofen | 48 h (static)          | Mortality, EC<sub>50</sub> | 0.16 mg a.s./L (mm) |
| *Asellus aquaticus* (Water louse)          | pydiflumetofen | 48 h (static)          | Mortality, EC<sub>50</sub> | 4.21 mg a.s./L (mm) |
| *Chaoborus crystallinus* (Phantom midge)   | pydiflumetofen | 48 h (static)          | Mortality, EC<sub>50</sub> | 2.49 mg a.s./L (mm) |
| *Chironomus riparius* (Non-biting midge / Harlequin fly) | pydiflumetofen | 48 h (static)          | Mortality, EC<sub>50</sub> | 0.69 mg a.s./L (nom) |
| *Cloeon dipterum* (Mayfly)                 | pydiflumetofen | 48 h (static)          | Mortality, EC<sub>50</sub> | >5.01 mg a.s./L (mm) |
| *Crangonx pseudogracilis* (Freshwater amphipod) | pydiflumetofen | 48 h (static)          | Mortality, EC<sub>50</sub> | 1.23 mg a.s./L (mm) |
| *Crassostrea virginica* (Eastern oyster)   | pydiflumetofen | 48 h (flow-through)    | Mortality, EC<sub>50</sub> | 0.31 mg a.s./L (mm) |
| *Cyclops agilis speratus* (Copepod)        | pydiflumetofen | 48 h (static)          | Mortality, EC<sub>50</sub> | 4.17 mg a.s./L (mm) |
| *Hyalella Azteca* (Freshwater amphipod)     | pydiflumetofen | 48 h (static)          | Mortality, EC<sub>50</sub> | 0.12 mg a.s./L (mm) |
| *Lumbriculus variegatus* (Blackworm)       | pydiflumetofen | 48 h (static)          | Mortality, EC<sub>50</sub> | 4.65 mg a.s./L (mm) |
| *Lymnaea stagnalis* (Great pond snail)     | pydiflumetofen | 48 h (static)          | Mortality, EC<sub>50</sub> | >7.30 mg a.s./L (mm) |
| *Daphnia magna* (Water flea)              | A19649B        | 48 h (static)          | Mortality, EC<sub>50</sub> | 2.1 mg prep./L (0.39 mg a.s./L (nom)) |
| *Daphnia magna* (Water flea)              | SYN545547      | 48 h (static)          | Mortality, EC<sub>50</sub> | 7.3 mg a.s/L (nom) |
| *Daphnia magna* (Water flea)              | SYN548261      | 48 h (static)          | Mortality, EC<sub>50</sub> | >100 mg a.s/L (nom) |
| *Daphnia magna* (Water flea)              | NOA449410      | 48 h (static)          | Mortality, EC<sub>50</sub> | >100 mg a.s/L (nom) |
| *Daphnia magna* (Water flea)              | pydiflumetofen | 21 d (semi-static)     | Reproduction NOEC        | 0.042 mg a.s./L (mm) |
|                                             |                |                        |                         | 0.085 mg a.s./L (mm) |
| *Americamysis bahia* (Mysid shrimp)        | pydiflumetofen | 28 d (flow-through)    | NOEC                    | 0.076 mg a.s./L (mm) |
| **Sediment-dwelling organisms**            |                |                        |                         |           |
| *Leptocheirus plumulosus* (Amphipod)       | pydiflumetofen | 10 d (spiked sediment) | LC<sub>50</sub>         | >92 mg a.s./kg dry sediment (mm) |
| Group                        | Test substance | Time-scale (Test type) | End point | Toxicity¹          |
|------------------------------|----------------|------------------------|-----------|--------------------|
| *Chironomus dilutus*         | pydiflumetofen | 59 d (spiked sediment) | NOEC      | 15 mg a.s./kg dry sediment (mm) |
| (Dipteran midge)             |                |                        |           |                    |
| *Hyalella azteca*            | pydiflumetofen | 42 d (spiked sediment) | NOEC      | 36 mg a.s./kg dry sediment (mm) |
| (Amphipod)                   |                |                        |           |                    |
| *Chironomus riparius*        | SYN545547      | 28 d (static)          | NOEC      | 7.2 mg a.s./kg dry sediment (mm) |

¹ Toxicity values are given in mg a.s./kg dry sediment (mm)
| Group                          | Test substance | Time-scale (Test type) | End point | Toxicity$^1$                               |
|-------------------------------|----------------|------------------------|-----------|-------------------------------------------|
| **Algae**                     |                |                        |           |                                           |
| *Pseudokirchneriella*         | pydiflumetofen | 72 h (static)          | Growth rate: E$_{C_{50}}$ (EC$_{10}$) >5.9 mg a.s./L (mm)  |
| *subcapitata* (Green alga)    |                |                        | Biomass: E$_{b_{C_{50}}}$ (EC$_{10}$) 2.3 mg a.s./L (mm)    |
|                               |                |                        | Yield: E$_{y_{C_{50}}}$ (EC$_{10}$) 4.3 mg a.s./L (mm)      |
| *Anabaena flos-aquae*         | pydiflumetofen | 72 h (static)          | Growth rate: E$_{C_{50}}$ (EC$_{10}$) 3.6 mg a.s./L (mm)    |
| (Blue-green alga)             |                |                        | Biomass: E$_{b_{C_{50}}}$ (EC$_{10}$) 2.8 mg a.s./L (mm)    |
|                               |                |                        | Yield: E$_{y_{C_{50}}}$ (EC$_{10}$) 3.5 mg a.s./L (mm)      |
| *Navicula pelliculosa*        | pydiflumetofen | 72 h (static)          | Growth rate: E$_{C_{50}}$ (EC$_{10}$) 1.6 mg a.s./L (mm)    |
| (Diatom)                      |                |                        | Biomass: E$_{b_{C_{50}}}$ (EC$_{10}$) 0.97 mg a.s./L (mm)   |
|                               |                |                        | Yield: E$_{y_{C_{50}}}$ (EC$_{10}$) 1.5 mg a.s./L (mm)      |
| *Skeletonema costatum*        | pydiflumetofen | 72 h (static)          | Growth rate: E$_{C_{50}}$ (EC$_{10}$) 2.7 mg a.s./L (mm)    |
| (Diatom)                      |                |                        | Biomass: E$_{b_{C_{50}}}$ (EC$_{10}$) 2.5 mg a.s./L (mm)    |
|                               |                |                        | Yield: E$_{y_{C_{50}}}$ (EC$_{10}$) 2.5 mg a.s./L (mm)      |
| *Pseudokirchneriella*         | A19649B        | 72 h (static)          | Growth rate: E$_{C_{50}}$ (EC$_{10}$) >57 mg prep./L (mm)   |
| *subcapitata* (Green alga)    |                |                        | Biomass: E$_{b_{C_{50}}}$ (EC$_{10}$) 10 mg prep./L (mm)    |
|                               |                |                        | Yield: E$_{y_{C_{50}}}$ (EC$_{10}$) 17.6 mg prep./L (mm)    |

$^1$ Toxicity values are expressed as mg a.s./L (mm) or mg prep./L (mm).
| Group | Test substance | Time-scale (Test type) | End point | Toxicity¹ |
|-------|----------------|------------------------|-----------|-----------|
| *Pseudokirchneriella subcapitata* (Green alga) | SYN545547 | 72 h (static) | Growth rate: $E_{c_{50}}$ (EC₁₀) | 4.1 mg a.s./L (mm) |
| | | | Biomass: $E_{b_{50}}$ (EC₁₀) | 3.0 mg a.s./L (mm) |
| | | | Yield: $E_{y_{50}}$ (EC₁₀) | 2.9 mg a.s./L (mm) |
| | SYN548261 | 72 h (static) | Growth rate: $E_{c_{50}}$ (EC₁₀) | >100 mg a.s./L (mm) |
| | | | Biomass: $E_{b_{50}}$ (EC₁₀) | |
| | | | Yield: $E_{y_{50}}$ (EC₁₀) | |
| | NOA449410 | 72 h (static) | Growth rate: $E_{c_{50}}$ (EC₁₀) | 36.31 mg a.s./L (mm) |
| | | | Fronds number, EC₅₀ (NOEC) | 20.60 mg a.s./L (mm) |
| | | | Frond dry weight, $E_{c_{50}}$ (NOEC) | 26.42 mg a.s./L (mm) |
| | | | | 19.43 mg a.s./L (mm) |
| Higher plant | *Lemna gibba* (Duckweed) | 7 d EC₅₀ / NOEC (Semi-Static) | Fronds number, EC₅₀ (NOEC) | >6.3 mg a.s./L (mm) |
| | | | Frond dry weight, $E_{c_{50}}$ (NOEC) | >6.3 mg a.s./L (mm) |

Further testing on aquatic organisms

A SSD is proposed for the acute toxicity for invertebrates with 9 species (excluding taxa with toxicity value “greater than”) with an HC₅ = 92 µg a.s./L and an AF = 4 leading to an SSD RAC = 23 µg a.s./L. A SSD is proposed for the acute toxicity fish with 5 species (excluding taxa with toxicity value “greater than”) with an HC₅ = 154.74 µg a.s./L and an AF =9 leading to an SSD RAC = 17.19 µg a.s./L. The chronic NOEC of pelagic invertebrates are summarised as NOEC Geomean = 0.056 mg a.s./L leading to a Geomean RAC = 5.6 µg a.s./L.

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

With regard to the assessment of endocrine disruption potential according to ECHA/EFSA Guidance (2018), as reported in Section 2, pydiflumetofen is not an endocrine disruptor for humans and this conclusion also applies to mammals as non-target organisms.

For non-target organisms other than mammals, the available evidence was not considered sufficient to draw a conclusion on endocrine disrupting properties (data gap).

¹ (nom) nominal concentration; (mm) mean measured concentration; prep.: preparation; a.s.: active substance
*EC₁₀ “dry weight” cover the EC₁₀ “live, normal larvae at hatch”
### Bioconcentration in fish (Annex Part A, point 8.2.2.3)

| Parameter                                                                 | Value                          |
|---------------------------------------------------------------------------|--------------------------------|
| **Active substance**                                                      |                                |
| logP<sub>O/W</sub>                                                        | 3.8 at 25°C (pH )              |
| Steady-state bioconcentration factor (BCF)                                 | 31.1*                          |
| (total wet weight/normalised to 5% lipid content)                          |                                |
| Uptake/depuration kinetics BCF                                            | 189                            |
| (total wet weight/normalised to 5% lipid content)                          |                                |
| Annex VI Trigger for the bioconcentration factor                          |                                |
| Clearance time (days) (CT<sub>50</sub>)                                   | 0.41                           |
| (CT<sub>90</sub>)                                                          | Not determined                 |
| Level and nature of residues (%) in organisms after the 14 day depuration phase | 7 day : 95 % (whole body) 14 day : not determined |

* based on total <sup>14</sup>C
### Toxicity/exposure ratios for the most sensitive aquatic organisms (Regulation (EU) N° 284/2013, Annex Part A, point 10.2)

Only the South STEP 2 PEC\textsubscript{sw} are worst-case value and cover the STEP 2 PEC\textsubscript{sw} North.

**FOCUS\textsubscript{sw} step 1-3 - RACs for Pydiflumetofen – Grapes at 200 g a.s./ha x 2 applications**

| Scenario | PEC\textsubscript{sw} (µg L) | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Algae | Higher plant | PEC sediment (µg/kg) | Sed. dweller prolonged |
|----------|-----------------|------------|--------------|----------------------|--------------------------------|-------|-------------|---------------------|-----------------------|
|          | Odyssey         | Oncorhynchus mykiss | Pimephales promelas | Hyalella azteca | Navicula pelliculosa | Lemma gibba | Chironomus dilutus |
|          |                 | LC\textsubscript{50} | SSD | EC\textsubscript{10} | EC\textsubscript{50} | HC\textsubscript{5} | NOEC | Geomean | EC\textsubscript{50} | EC\textsubscript{50} | NOEC |
|          |                 | 180 µg/L | 154.74 µg/L | 130 µg/L | 120 µg/L | 92 µg/L | 42 µg/L | 56 µg/L | 1600 µg/L | >6300 µg/L | 15000 µg/L |
|          | RAC             | 1.8 µg/L | 17.19 µg/L | 13 µg/L | 1.2 µg/L | 23 µg/L | 4.2 µg/L | 5.6 µg/L | 160 µg/L | >6300 µg/L | 1500 µg/L |
| FOCUS Step 1 |                 | 51.4 | No | No | No | No | No | Yes | Yes | 1394 | No |
| FOCUS Step 2 | North Europe | 8.54 | No | Yes | Yes | No | 10.8 | No | No | 242 | Yes |
| FOCUS Step 3 | South Europe | 3.83 | No | No | No | No | Yes | Yes | Yes |
| R1 / pond | 0.180 | Yes | Yes | Yes | Yes | Yes |
| R1 / stream | 2.44 | No | Yes | Yes | Yes | Yes |
| R2 / stream | 3.37 | No | No | Yes | Yes | Yes |
| R3 / stream | 3.54 | No | No | Yes | Yes | Yes |
| R4 / stream | 2.51 | No | No | Yes | Yes | Yes |
FOCUS<sub>sw</sub> step 1-2 - RACs for Metabolite SYN545547 – Grapes at 200 g a.s./ha x 2 applications as worst case

| Scenario | PEC<sub>sw</sub> (µg L) | fish acute | Aquatic invertebrates | Algae | PEC sediment (µg/kg) | Sed. dweller prolonged |
|----------|-----------------|------------|---------------------|-------|---------------------|------------------------|
|          |                 | Oncorhynchus mykiss | Hyalella azteca | Navicula pelliculosa | Chironomus riparius |
|          |                 | LC<sub>50</sub> | EC<sub>50</sub> | EC<sub>50</sub> | NOEC |
| RAC      | 14 µg/L, 73 µg/L | 400 µg/L | 7200 µg/kg |

FOCUS Step 1

| 28 | No | Yes | Yes | 160 | Yes |

FOCUS Step 2

| North Europe | 4.72 | Yes |
| South Europe |      |     |

FOCUS<sub>sw</sub> step 1 - RACs for Metabolite SYN548261 – Grapes at 200 g a.s./ha x 2 applications as worst case

| Scenario | PEC<sub>sw</sub> (µg L) | fish acute | Aquatic invertebrates | Algae |
|----------|-----------------|------------|---------------------|-------|
|          |                 | Oncorhynchus mykiss | Daphnia magna | Pseudokirchneriella subcapitata |
|          |                 | LC<sub>50</sub> | EC<sub>50</sub> | EC<sub>50</sub> |
| RAC      | >100 000 µg/L | >100 000 µg/L | >100 000 µg/L |

FOCUS Step 1

| 8.45 | Yes | Yes | Yes |
FOCUS<sub>sw</sub> step 1 - RACs for Metabolite NOA449410 – Grapes at 200 g a.s./ha x 2 applications as worst case

| Scenario | PEC<sub>sw</sub> (µg L) | fish acute | Aquatic invertebrates | Algae |
|----------|-------------------------|------------|----------------------|-------|
|          |                         | Oncorhynchus mykiss | Daphnia magna | Pseudokirchneriella subcapitata |
|          |                         | LC<sub>50</sub> | EC<sub>50</sub> | EC<sub>50</sub> |
|          |                         | >100 000 µg/L | >100 000 µg/L | 36 310 µg/L |
| RAC      |                         | >1000 µg/L   | >1000 µg/L   | 3631 µg/L   |
| FOCUS Step 1 | 3.44 | Yes | Yes | Yes |
### FOCUSsw step 1-3 - RACs for Pydiflumetofen – Pome fruits at 50 g a.s./ha x 3 applications

| Scenario | PECsw (µg L) | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Algae | Higher plant | PEC sediment (µg/kg) | Sed. dweller prolonged |
|----------|--------------|------------|--------------|-----------------------|-------------------------------|-------|---------------|----------------------|------------------------|
| Oncorhynchus mykiss | SSD | Onthurus mykiss | SSD | Hyalella azteca | NOEC | Overall | Navicula pelliculosa | Overall | Chironomus dilutus |
| LC50 | 180 µg/L | 154.74 µg/L | 130 µg/L | 120 µg/L | 42 µg/L | 56 µg/L | 1600 µg/L | >6300 µg/L | 15000 µg/L |
| HC5 | 17.19 µg/L | 13 µg/L | 1.2 µg/L | 23 µg/L | 4.2 µg/L | 5.3 µg/L | 160 µg/L | >630 µg/L |
| EC10 | 1.8 µg/L | 1.2 µg/L | 23 µg/L | 4.2 µg/L | 5.3 µg/L | 160 µg/L | >630 µg/L |
| EC50 | 56 µg/L | 42 µg/L | 42 µg/L | 4.2 µg/L | 5.3 µg/L | 160 µg/L | >630 µg/L |
| NOEC | 1600 µg/L | >6300 µg/L | 15000 µg/L |

**FOCUS Step 1**

| 23.1 | No | No | No | No | No | No | No | Yes | Yes | 560 | Yes |
|-------|----|----|----|----|----|----|----|-----|-----|-----|-----|

**FOCUS Step 2**

| North Europe | South Europe | 3.72 | No | Yes | Yes | No | Yes | No | Yes | 560 | Yes |
|---------------|--------------|------|----|-----|-----|----|-----|----|-----|-----|-----|

**FOCUS Step 3**

| D3 | 1.84 | No | Yes | Yes | No | Yes | Yes |
| D4 | 0.207 | Yes | Yes | Yes | Yes | Yes |
| D4 | 1.84 | No | Yes | No | Yes | Yes |
| D5 | 0.211 | Yes | Yes | Yes | Yes | Yes |
| D5 | 1.98 | No | Yes | No | Yes | Yes |
| R1 | 0.145 | Yes | Yes | Yes | Yes | Yes |
| R1 | 1.41 | Yes | Yes | No | Yes | Yes |
| R2 | 1.89 | No | Yes | No | Yes | Yes |
| R2 | 1.98 | No | Yes | No | Yes | Yes |
| R4 | 1.41 | Yes | Yes | No | Yes | Yes |
### FOCUS$_{sw}$ step 1-3 - RACs for Pydiflumetofen – Tomatoes at 70 g a.s./ha x 2 applications

| Scenario | PEC$_{sw}$ (µg L)$^{-1}$ | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Algae | Higher plant | PEC sediment (µg/kg) | Sed. dweller prolonged |
|----------|--------------------------|------------|--------------|----------------------|---------------------------------|-------|--------------|----------------------|------------------------|
|         |                          | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged |       |              |                      |                        |
| Oncorhynchus mykiss | SSD | LC$_{50}$ | SSD | H$_{C_{5}}$ | EC$_{10}$ | EC$_{50}$ | H$_{C_{5}}$ | NOEC | Geomean | EC$_{50}$ | EC$_{50}$ | NOEC |
|         |                            | 180 µg/L | 154.74 µg/L | 130 µg/L | 120 µg/L | 92 µg/L | 42 µg/L | 56 µg/L | 1600 µg/L | >6300 µg/L | 15000 µg/L |
| RAC | 1.8 µg/L | 17.19 µg/L | 13 µg/L | 1.2 µg/L | 23 µg/L | 4.2 µg/L | 5.6 µg/L | 160 µg/L | >6300 µg/L | 1500 µg/L |

**FOCUS Step 1**

|  | 15.5 | No | Yes | 7.7 | 7.7 | No | No | No | Yes | Yes | 464 | Yes |
|---|------|----|-----|-----|-----|----|----|----|-----|-----|-----|----|

**FOCUS Step 2**

|  | North Europe | South Europe | 1.72 | Yes | Yes | No | Yes | Yes | Yes |
|---|--------------|--------------|------|-----|-----|----|-----|-----|-----|

**FOCUS Step 3**

|  | D6 | 2.17 | No |  | No |
|---|----|------|----|---|----|
| R2 | 0.392 | Yes |  | Yes |
| R3 | 0.468 | Yes |  | Yes |
| R4 | 0.719 | Yes |  | Yes |
### FOCUS Sw step 1-3 - RACs for Pydiflometofen – Cucurbits at 50 g a.s./ha x 2 applications

| Scenario | PEC$_{sw}$ (µg L) | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Algae | Higher plant | PEC sediment (µg/kg) | Sed. dweller prolonged |
|----------|------------------|------------|--------------|------------------------|----------------------------------|-------|--------------|----------------------|------------------------|
|          |      | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Algae | Higher plant | PEC sediment (µg/kg) | Sed. dweller prolonged |
|          |      | Oncorhynchus mykiss | SSD | Pimephales promelas | Hyalella azteca | SSD | Daphnia magna | Overall | Navicula pelliculosa | Lemma gibba | Chironomus dilutus |
|          |      | LC$_{50}$ | HC$_{5}$ | EC$_{10}$ | EC$_{50}$ | HC$_{5}$ | NOEC | Geomean | EC$_{50}$ | EC$_{50}$ | NOEC |
|          |      | 180 µg/L | 154.74 µg/L | 130 µg/L | 120 µg/L | 92 µg/L | 42 µg/L | 56 µg/L | 1600 µg/L | >6300 µg/L | 15000 µg/L |
|          |      | 1.8 µg/L | 17.19 µg/L | 13 µg/L | 1.2 µg/L | 23 µg/L | 4.2 µg/L | 5.6 µg/L | 160 µg/L | >630 µg/L | 1500 µg/L |

**FOCUS Step 1**

|          | 11.1 | No | Yes | No | No | Yes | No | No | Yes | Yes | 332 | Yes |

**FOCUS Step 2**

|          | No | Yes | No | No | Yes | Yes | Yes |

**FOCUS Step 3**

|          | 1.51 | Yes | Yes |
|          | 0.28 | Yes | Yes |
|          | 0.353 | Yes | Yes |
|          | 0.481 | Yes | Yes |
## FOCUS<sub>SW</sub> step 1-2 - RACs for Pydiflumetofen – Potatoes at 40 g a.s./ha x 3 applications

| Scenario | PEC<sub>sw</sub> (µg L) | fish acute | fish chronic | Aquatic invertebrates | Aquatic invertebrates prolonged | Algae | Higher plant | PEC sediment (µg/kg) | Sed. dweller prolonged |
|----------|-----------------|-------------|--------------|-----------------------|-------------------------------|-------|--------------|---------------------|------------------------|
|          |     |             |              |          |                 |       |              |                     |                        |
| Oncorhynchus mykiss | SSD | Pimephales promelas | Hyalella azteca | SSD | Overall | Navicula pelliculosa | Lemma gibba | Chironomus dilutus |
| LC<sub>50</sub> | HC<sub>s</sub> | EC<sub>10</sub> | EC<sub>50</sub> | HC<sub>s</sub> | NOEC | Geomean | EC<sub>50</sub> | EC<sub>50</sub> | NOEC |
| 180 µg/L | 154.74 µg/L | 130 µg/L | 120 µg/L | 92 µg/L | 42 µg/L | 56 µg/L | 1600 µg/L | >6300 µg/L | 15000 µg/L |
| RAC | 1.8 µg/L | 17.19 µg/L | 13 µg/L | 1.2 µg/L | 23 µg/L | 4.2 µg/L | 5.6 µg/L | 160 µg/L | >630 µg/L | 1500 µg/L |

### FOCUS Step 1

| Scenario | Value | Decision | Value | Decision | Value | Decision | Value | Decision | Value | Decision |
|----------|-------|----------|-------|----------|-------|----------|-------|----------|-------|----------|
| FOCUS Step 1 | 13.3 | No | Yes | No | No | Yes | No | No | Yes | Yes |
| FOCUS Step 2 | 1.4 | Yes | Yes | No | Yes | Yes | Yes | Yes | Yes | Yes |
| North Europe | | | | | | | | | | |
| South Europe | | | | | | | | | | |
| FOCUS Step 3 | | | | | | | | | | |
| D3 | 0.209 | Yes | Yes | | | | | | | |
| D4 | 0.316 | Yes | Yes | | | | | | | |
| D4 | 0.67 | Yes | Yes | | | | | | | |
| D6 | 1.57 | No | Yes | | | | | | | |
| D6 | 1.72 | No | Yes | | | | | | | |
| R1 | 0.135 | Yes | Yes | | | | | | | |
| R1 | 0.331 | Yes | Yes | | | | | | | |
| R2 | 0.192 | Yes | Yes | | | | | | | |
| R3 | 0.375 | Yes | Yes | | | | | | | |
| D3 | 0.209 | Yes | Yes | | | | | | | |
### FOCUSsw step 1-3 - RACs for Pydiflumetofen – Brassicas at 70 g a.s/ha x 2 applications

| Scenario | PECsw (µg L) | fish acute | fish chronic | Aquatic invertebrate s | Aquatic invertebrate s-prolonged | Aquatic invertebrate s-prolonged | Algae | Higher plant | PEC sediment (µg/kg) | Sed. dweller prolonged |
|----------|--------------|------------|--------------|------------------------|----------------------------------|----------------------------------|-------|--------------|----------------------|------------------------|
| Oncorhynchus mykiss | SSD | Pimephales promelas | Hyalella azteca | SSD | Daphnia magna | Overall | Navicula pelliculosa | Lemma gibba | Chironomus dilutus |
| LC₅₀ | HC₅ | EC₁₀ | EC₅₀ | HC₅ | NOEC | Geomean | EC₅₀ | EC₅₀ | NOEC |
| 180 µg/L | 154.74 µg/L | 130 µg/L | 120 µg/L | 92 µg/L | 42 µg/L | 56 µg/L | 1600 µg/L | >6300 µg/L | 15000 µg/L |
| 1.8 µg/L | 17.19 µg/L | 13 µg/L | 1.2 µg/L | 23 µg/L | 4.2 µg/L | 5.6 µg/L | 160 µg/L | >630 µg/L | 1500 µg/L |
| **FOCUS Step 1** | | | | | | | | | |
| 15.5 | No | Yes | No | No | No | No | No | Yes | 464 | Yes |
| **FOCUS Step 2** | | | | | | | | | |
| North Europe | | | | | | | | | |
| South Europe | 4.7 | No | Yes | Yes | No | Yes | No | No | No |
| **FOCUS Step 3** | | | | | | | | | |
Peer review of the pesticide risk assessment of the active substance pydiflumetofen

| Season   | Crop | Concentration | LC50 | EC50 | EC10 | LC90 |
|----------|------|---------------|------|------|------|------|
| D3 (1st crop) | 0.443 | Yes | Yes | Yes | Yes |
| D3 (2nd crop) | 0.44 | Yes | Yes | Yes | Yes |
| D4 (1st crop) | 0.312 | Yes | Yes | Yes | Yes |
| D4 (2nd crop) | 0.633 | Yes | Yes | Yes | Yes |
| D6 (1st crop) | 2.37 | No | No | Yes | Yes |
| R1 (1st crop) | 0.256 | Yes | Yes | Yes | Yes |
| R1 (2nd crop) | 0.2 | Yes | Yes | Yes | Yes |
| R2 (1st crop) | 0.392 | Yes | Yes | Yes | Yes |
| R2 (2nd crop) | 0.392 | Yes | Yes | Yes | Yes |
| R3 (1st crop) | 0.414 | Yes | Yes | Yes | Yes |
| R3 (2nd crop) | 0.411 | Yes | Yes | Yes | Yes |
| R4 (1st crop) | 0.655 | Yes | Yes | Yes | Yes |
| R4 (2nd crop) | 0.642 | Yes | Yes | Yes | Yes |

*1st and 2nd crop correspond to the both annual period of sewing during a year (see details in Section 4)
### Effects on bees (Regulation (EU) No 283/2013, Annex Part A, point 8.3.1 and Regulation (EU) No 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 melifera   | pydiflumetofen | Acute                       | Oral toxicity (LD50) | >116 µg/bee               |
| Apis melifera   | pydiflumetofen | Acute                       | Contact toxicity (LD50) | >100 µg/bee               |
| Apis melifera   | A19649B        | Acute                       | Oral toxicity (LD50) | >1 132 µg A19649B/bee (equivalent to >211 µg a.s./bee) |
| Apis melifera   | A19649B        | Acute                       | Contact toxicity (LD50) | >1 000 µg A19649B/bee (equivalent to >186 µg a.s./bee) |
| Apis melifera   | A19649B        | Chronic                     | 10 d-LDD50         | >138 µg/bee/day           |
| Apis melifera   | A19649B        | Chronic Larvae 8-days       | 8 d-NOED           | 55 µg a.s./larva          |
|                 |                |                              |                    | 13.75 µg a.s./larva/day   |
| Apis melifera   | pydiflumetofen | Bee brood development       | 8 d-NOED           | <0.014 µg a.s./larva      |
|                 |                |                              |                    | <0.0035 µg a.s./larva/day |
|                 |                |                              |                    | <0.014 µg a.s./larva      |
|                 |                |                              |                    | <0.0035 µg a.s./larva/day |
| Apis melifera   | A19649B        | Bee brood development       | 8 d-NOED           | 0.08 µg a.s./larva        |
|                 |                |                              |                    | 0.02 µg a.s./larva/day    |
|                 |                |                              |                    | 0.1 µg a.s./larva         |
|                 |                |                              |                    | 0.026 µg a.s./larva/day   |
|                 |                |                              |                    | 0.872 µg a.s./larva/day   |
|                 |                |                              |                    | 0.218 µg a.s./larva/day   |
|                 |                |                              |                    | 0.097 µg a.s./larva       |
|                 |                |                              |                    | 0.024 µg a.s./larva/day   |
|                 |                |                              |                    | 0.165 µg a.s./larva       |
|                 |                |                              |                    | 0.041 µg a.s./larva/day   |

Potential for accumulative toxicity: no

Semi-field test (Cage and tunnel test)

Three studies were performed to assess the effects of A19649B on the bee brood and larvae. No adverse effect have been demonstrated for application rate of 200 g a.s./ha.

### Risk assessment for – Grapes at 200 g a.s./ha x 2 applications

| Species         | Test substance | Risk quotient | HQ | Trigger |
|-----------------|----------------|---------------|----|---------|
| Apis mellifera  | pydiflumetofen | HQcontact     | <2 | 50      |
In addition, semi-field studies have been conducted to support the larval component of the bee risk assessment for the registration of pydiflumetofen globally (*Gonsior, 2017; Kleinhenz, 2017; Schnurr, 2018*). The objective of these studies was to determine potential effects on honeybees from exposure to flowering *Phacelia tanacetifolia* treated once at the start of flowering during daily bee flight with A19649B under semi-field conditions. Test item treatment groups included 75, 125 and 200 g a.s./ha.

Honeybee colonies were placed in the tunnels at the start of flowering. The mortality, foraging activity, behaviour of the bees, development of the bee brood assessed in individually marked cells and condition of the colonies were examined prior to and post application. The colonies were monitored at a remote location for two further brood cycles following the initial detailed brood assessments (first brood cycle). The influence of pydiflumetofen was evaluated by comparing the assessment data of the three test item groups (75, 125 and 200 g a.s./ha) to the reference item group and the control group, and by comparing the pre-application data to the post-application data.

Samples of forager bees (for preparation of pollen and nectar), leaves, flowers and samples of soil were collected during the exposure phase. Samples of pollen and nectar (in-hive products), pollen (from pollen trap) and dead bees (from dead bee traps and from the hive bottoms) were collected during the monitoring phase of the study. Samples of pollen and nectar (prepared from forager bees), leaves, flowers, samples of in-hive products and pollen from pollen trap were analysed for residues of pydiflumetofen.

There were no detectable residues of pydiflumetofen in any of the samples taken in the control group throughout the study period or in the samples from the test item treatment groups (75, 125 and 200 g a.s./ha) taken prior to application. During the exposure phase in the tunnels, residues of pydiflumetofen were found in leaves, flowers and in pollen and nectar samples from forager bees after application at 0DAA in all treatment groups and decreased within 6 days after application.

In both trials, during the post-application period, no effect on honeybee mortality was observed in the test item treatment groups compared to the control. No test item related effects were observed regarding foraging activity. Slight, but not test item related behavioural changes were observed during the post-application period. The brood and compensation indices and termination rates for eggs, young larvae and old larvae were not statistically different from the control on any assessment date. The overall honeybee colony development in the test item treatment groups, measured as mean number of cells covered with the different types of brood (eggs, larvae and pupae) or food (nectar, pollen) per colony were not significantly different when compared to the control (except *Gonsior, 2017* mean amount of nectar, 75 g a.s./ha, DAA9).

Overall, there was no test item related effect on honeybee mortality, foraging activity, behaviour and brood development in both studies.
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*       | A19649B        | Mortality, LR₅₀       | >408 g/ha      |
|                           |                | Reproduction, ER₅₀    | >408 g/ha      |
| *Aphidius rhopalosiphi*   | A19649B        | Mortality, LR₅₀       | >408 g/ha      |
|                           |                | Reproduction, ER₅₀    | >408 g/ha      |

First tier risk assessment for – Grapes at 200 g a.s./ha x 2 applications (cover other representative uses)

| Test substance | Species                  | Effect (LR₅₀ g/ha) | HQ in-field | HQ off-field¹ | Trigger |
|----------------|--------------------------|--------------------|-------------|---------------|---------|
| A19649B        | *Typhlodromus pyri*      | >408               | <0.83       | <0.33         | 2       |
| A19649B        | *Aphidius rhopalosiphi*  | >408               | <0.83       | <0.33         | 2       |

¹ 1 meter

Extended laboratory tests, aged residue tests

| Species                 | Life stage | Test substance, substrate | Time scale | Dose (g/ha)¹² | End point                      | % effect³ | ER₅₀       |
|-------------------------|------------|----------------------------|------------|----------------|--------------------------------|-----------|------------|
| *Aphidius rhopalosiphi* | Adult      | A19649B Barley seedling   | 14 d       | 800 g a.s./ha  | Mortality reproduction         | 6.7-4.5   | >800 g a.s./ha |
| *Typhlodromus pyri*     | Adult      | A19649B Leaf discs        | 14 d       | 800 g a.s./ha  | Mortality reproduction         | 8 0.8     | >800 g a.s./ha |

¹ indicate whether initial or aged residues
² for preparations indicate whether dose is expressed in units of a.s. or preparation
³ indicate if positive percentages relate to adverse effects or not
Effects on non-target soil meso- and macro fauna; effects on soil nitrogen transformation (Regulation (EU) N° 283/2013, Annex Part A, points 8.4, 8.5, and Regulation (EU) N° 284/2013 Annex Part A, points 10.4, 10.5)

| Test organism | Test substance | Application method of test a.s./OM\(^1\) | Time scale | End point | Toxicity |
|---------------|----------------|-----------------------------------------|------------|-----------|----------|
| Earthworms    |                |                                         |            |           |          |
| *Eisenia fetida* | A19649B | Mixed to water to hydrate soil/5% | Acute      | Mortality | 14d EC\(_{50}\) >1000 mg a.s./kg d.w.soil |
|               |                |                                         |            |           |          |
| *Eisenia fetida* | A19649B | Mixed to water to hydrate soil/5% Corrected (factor 2 due to log Pow>2 and/or 10% peat) | Chronic    | Reproduction | 56d NOEC = 85.5 mg A19649B/kg soil (15.9 mg a.s./kg soil) 56d EC\(_{10}\) = 16.5 mg a.s./kg soil 56d EC\(_{20}\) = 25.11 mg a.s./kg soil |
| Other soil macroorganisms | | | | | |
| *Folsomia candida* | A19649B | Mixed to water to hydrate soil/5% | Chronic    | Mortality, reproduction, behaviour | 28d NOEC = 1 000 mg A19649B/kg soil (equivalent to 186.0 mg a.s./kg soil) |
| *Hypoaspis aculeifer* | A19649B | Mixed to water to hydrate soil/5% | Chronic    | Mortality, growth, reproduction, behaviour | 14d NOEC = 1 000 mg A19649B/kg soil (equivalent to 186.0 mg a.s./kg soil) |

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

Nitrogen transformation pydiflumetofen +13.4 % effect at day 7 at 2.71 mg a.s./kg d.w.soil (mg a.s/ha)
Nitrogen transformation | pydiflumetofen | +17 % effect at day 7 at 13.5 mg a.s./kg d.w.soil (mg a.s/ha)

Toxicity/exposure ratios for soil organisms

Grapes at 200 g a.s./ha x 2 applications

| Test organism       | Test substance | Time scale | Soil PEC<sup>1</sup> | TER  | Trigger |
|---------------------|----------------|------------|----------------------|------|---------|
| Earthworms          |                |            |                      |      |         |
| *Eisenia fetida*    | A19649B        | Chronic    | 8.2613               | **1.9** | 5       |
| Other soil macroorganisms
| *Folsomia candida*  | A19649B        | Chronic    | 8.2613               | 22.5 | 5       |
| *Hypoaspis aculeifer* | A19649B      | Chronic    | 8.2613               | 22.5 | 5       |

<sup>1</sup>PEC<sub>soil acc</sub> from the active substance

Pome fruit at 50 g a.s./ha x 3 applications

| Test organism       | Test substance | Time scale | Soil PEC<sup>1</sup> | TER  | Trigger |
|---------------------|----------------|------------|----------------------|------|---------|
| Earthworms          |                |            |                      |      |         |
| *Eisenia fetida*    | A19649B        | Chronic    | 3.0974               | **5.1** | 5       |
| Other soil macroorganisms
| *Folsomia candida*  | A19649B        | Chronic    | 3.0974               | 60.1 | 5       |
| *Hypoaspis aculeifer* | A19649B      | Chronic    | 3.0974               | 60.1 | 5       |

<sup>1</sup>PEC<sub>soil acc</sub> from the active substance

Effects on terrestrial non target higher plants (Regulation (EU) Nº 283/2013, Annex Part A, point 8.6 and Regulation (EU) Nº 284/2013 Annex Part A, point 10.6)

Screening data

Not required for herbicides or plant growth regulators as ER<sub>50</sub> tests should be provided

Laboratory dose response tests

| Species                     | Test substance | ER<sub>50</sub> (g a.s./ha)<sup>2</sup> vegetative vigour | ER<sub>50</sub> (g a.s./ha)<sup>2</sup> emergence | Exposure<sup>1</sup> (g a.s./ha)<sup>2</sup> (maximum requested application rate) | TER  | Trigger |
|-----------------------------|----------------|----------------------------------------------------------|-------------------------------------------------|---------------------------------------------------------------------------------|------|---------|
| Monocotyledonae:            |                |                                                         |                                                 |                                                                                 |      |         |
|  *Zea mays*, *Allium cepa*,*Lolium perenne*, *Triticum aestivum* | A19649B (pydiflumetofen 200 SC) | >200                                                     | >200                                            | 200 (maximum requested application rate)                                       | >12.47 | 5       |
| Dicotyledonae:              |                |                                                         |                                                 |                                                                                 |      |         |
|  *Brassica oleracea*,      |                |                                                         |                                                 |                                                                                 |      |         |
### Effects on biological methods for sewage treatment (Regulation (EU) No 283/2013, Annex Part A, point 8.8)

| Test type/organism | end point |
|--------------------|-----------|
| Activated sludge   | 3 h NOEC = 1000 mg a.s./L |

### Monitoring data (Regulation (EU) No 283/2013, Annex Part A, point 8.9 and Regulation (EU) No 284/2013, Annex Part A, point 10.8)

- Available monitoring data concerning adverse effect of the a.s.
  - None
- Available monitoring data concerning effect of the PPP.
  - None

### Definition of the residue for monitoring (Regulation (EU) No 283/2013, Annex Part A, point 7.4.2)

#### Ecotoxically relevant compounds

| Compartment      | pydiflumetofen |
|------------------|----------------|
| soil             | pydiflumetofen |
| water            | pydiflumetofen, SYN548261, NOA449410 |
| sediment         | pydiflumetofen |
| groundwater      | pydiflumetofen |
Classification and labelling with regard to ecotoxicological data (Regulation (EU) No 283/2013, Annex Part A, Section 10)

Substance

Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended][11]:

Peer review proposal[12] for harmonised classification according to Regulation (EC) No 1272/2008:

| Pydiflumetofen       |
|----------------------|
| ECHA RAC Opinion (ECHA, 2019): |
| H400: Very toxic to aquatic life |
| H410: Very toxic to aquatic life with long lasting effects |
| –                     |

[11] 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.

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