Annex to: Conclusion on the peer review of the pesticide risk assessment of the active substance fludioxonil. doi:10.2903/j.efsa.2024.9047

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

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

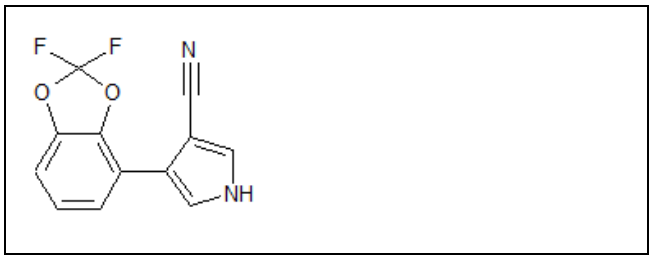
Active substance (ISO Common Name)	Fludioxonil
Function (*e.g.* fungicide)	Fungicide

Rapporteur Member State	FR (France)
Co-rapporteur Member State	ES (Spain)

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

Chemical name (IUPAC)	4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1*H*-pyrrole-3-carbonitrile
Chemical name (CA)	4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1*H*-pyrrole-3-carbonitrile
Producer's development code number	CGA173506
CIPAC No	522
CAS No	131341-86-1
EC No (EINECS or ELINCS)	Not available
FAO Specification (including year of publication)	None
Minimum purity of the active substance as manufactured	950 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	1-[2-cyano-1-(2,2-difluoro-2*H*-1,3-benzodioxol-4-yl)ethyl]-4-(2,2-difluoro-2*H*-1,3-benzodioxol-4-yl)-1*H*-pyrrole-3-carbonitrile (SYN549129) max 3 g/kg Open for other impurities.
Location of the (proposed) reference specification (for significant impurities)	RAR Volume 4 (2023-12)
Molecular formula	$C_{12}H_6F_2N_2O_2$
Molar mass	248.2 g/mol

Structural formula



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

Melting point (state purity)	199.8 °C (99.8%)
Boiling point (state purity)	Decomposition occurs before boiling point (99.8%)
Temperature of decomposition (state purity)	306 °C (99.8%)
Appearance (state purity)	Faintly yellow odourless powder (99.9% pure) Light olive green odourless powder (96.8% technical)
Vapour pressure (state temperature, state purity)	3.9×10^{-9} hPa at 25 °C (99.8%)
Henry's law constant (state temperature)	5.4×10^{-5} Pa.m^3.mol^{-1} at 25 °C
Solubility in water (state temperature, state purity and pH)	1.8 mg/L at 25 °C (99.8%) The solubility has not been carried out at different pH as the molecule does not dissociate within the range pH 2 to pH 12.
Solubility in organic solvents (state temperature, state purity)	At 25 °C (96.8%) Acetone 190 g/L Dichloromethane 7.3 g/L Ethyl Acetate 86 g/L Hexane 10 mg/L Methanol 42 g/L Octanol 20 g/L Toluene 2.7 g/L
Surface tension (state concentration and temperature, state purity)	71.2 mN/m at 20 °C (90 % saturated solution) (99.8%) 47.7 - 48.5 mN/m at 20 °C (100 % saturated solution) (96.8%)
Partition coefficient (state temperature, pH and purity)	log P_{OW} = 4.12 at 25 °C (99.8%) Effect of pH was not investigated since there is no dissociation in water in the environmentally relevant pH range.
Dissociation constant (state purity)	$pK_{a1} < 0$ (basic) (99.8%) $pK_{a2} \simeq 14.1$ (acidic) (99.8%)
UV/VIS absorption (max.) incl. ε (state purity, pH)	At 99.9%, Solution / Wavelength λ_{max} (nm) / Extinction coeff. ε (L.mol^{-1}.cm^{-1}) neutral 266 12384 acidic 265 12327 basic 271 11790 at λ > 290 nm: 3204 L.mol^{-1}.cm^{-1} Absorption measured up to 750 nm Data gap: spectral data for the relevant impurity SYN549129
Flammability (state purity)	Not a flammable solid (97.7%)
Self-heating (state purity)	Not a self-heating substance (97.7%)
Explosive properties (state purity)	Not explosive (97.7%)
Oxidising properties (state purity)	Not oxidising (97.7%)

Summary of representative uses evaluated, for which all risk assessments needed to be completed (*fludioxonil*)
(Regulation (EU) N° 284/2013, Annex Part A, points 3, 4)

Crop and/or situation (a)	Member State	Product Name	F G I (b)	Pests or group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	Method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s/hL min-max (l)	Water L/ha min-max	kg a.s/ha min-max (l)		
Grapes, wine	EU S	A8240D	F	*Botrytis cinerea*	WG	500 g/kg	Foliar	BBCH 67 BBCH 85-89	1-2	21	0.0417-0.0625	800-1200	0.5 kg a.s/ha 1.0 kg a.s./ha/ season	21	
Grapes, table	EU S	A8240D	F	*Botrytis cinerea*	WG	500 g/kg	Foliar	BBCH 67-69 BBCH 85-89	1-2	21	0.0417-0.0625	800-1200	0.5 kg a.s/ha 1.0 kg a.s./ha/ season	7	
Pome fruit (apple and pear)	EU	A8240D	F	*Storage diseases (Gloeosporium spp., Penicillium spp., Botrytis spp, Monilia spp.)*	WG	500 g/kg	Foliar	BBCH 74-89	1-2	7	0.015-0.075	300-1500	0.225 kg a.s/ha 0.450 kg a.s./ha/ season	3	
Strawberry	EU	A8240D	F/G	*Botrytis cinerea*	WG	500 g/kg	Foliar	BBCH 61-89	1-2	10	0.0125-0.0833	300-2000	0.25 kg a.s/ha 0.5 kg a.s./ha/ season	3	
Wheat	EU	A8207M	F	*Fusarium spp. Monographella nivalis, Tilletia caries, Tilletia foetida, Leptosphaeria nodorum*	FS	25 g/L	Seed treatment	BBCH 00	1	Not applicable	Not applicable	Slurry volume 0-1.5 L/100 kg seeds	0.0125	-	0.2 L product/ 100 kg seeds Seeding rate: maximum 250 kg seeds/ha TGW: 45-55 g/1000 seeds 5 g a.s./100 kg seeds 2.75 max µg a.s./seed
Oat	EU	A8207M	F	*Fusarium spp. Pyrenophora avenae*	FS	25 g/L	Seed treatment	BBCH 00	1	Not applicable	Not applicable	Slurry volume 0-1.5 L/100 kg seeds	0.0085	-	0.2 L product/ 100 kg seeds Seeding rate: maximum 170 kg seeds/ha TGW: 30-45 g/1000 seeds 5 g a.s./100 kg seeds 2.25 max µg a.s./seed

TGW – thousand grain weight

(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)
(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.

(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	fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).** (j) Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application (k) Indicate the minimum and maximum number of applications possible under practical conditions of use (l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha (m) PHI - minimum pre-harvest interval

Further information, Efficacy

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

No new data have been provided (not required for renewal of approval of active substances). Fludioxonil containing products A8207M (Celest) and A8240D (Geoxe) have been tested in field development trials and has demonstrated efficacious activity. Fludioxonil containing products A8207M (Celest) and A8240D (Geoxe) are registered in many EU countries based on detailed national assessments of the efficacy package in compliance with Regulation (EC) No 545/2011 and according to the Uniform Principles (Regulation (EC) No 546/2011). More detailed consideration will be fully assessed in the context of any subsequent applications for product authorisation.

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

Same as above.

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

Same as above.

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

	CGA192155	CGA339833
Activity against target organism	no	no

Open for some other 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
Impurities in technical a.s. (analytical technique)	HPLC-UV
Plant protection product (analytical technique)	HPLC-UV Data gap: method for relevant impurity (SYN549129)

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

Residue definitions for monitoring purposes

Food of plant origin		Fludioxonil
Food of animal origin		Sum of fludioxonil and its metabolites, which can be oxidised to metabolite CGA 192155 (2,2-difluoro-*2H*-1,3-benzodioxole-4-carboxylic acid), expressed as fludioxonil
Soil		Fludioxonil
Sediment		Fludioxonil
Water	surface	Fludioxonil
	drinking/ground	Fludioxonil
Air		Fludioxonil
Body fluids and tissues		Sum of fludioxonil and its metabolites, which can be oxidised to metabolite CGA 192155 (2,2-difluoro-*2H*-1,3-benzodioxole-4-carboxylic acid), expressed as fludioxonil

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Multi-residue method QuEChERS: fludioxonil HPLC-MS/MS, 0.01 mg/kg **Data gap:** Extraction efficiency
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	GRM025.03A: After oxidation to CGA 192155 HPLC-MS/MS, 0.01 mg/kg (expressed as fludioxonil)
Soil (analytical technique and LOQ)	GRM025.06A: fludioxonil HPLC-MS/MS, 0.01 mg/kg
Water (analytical technique and LOQ)	GRM025.01A: fludioxonil HPLC-MS/MS, 0.05 µg/L
Air (analytical technique and LOQ)	REM 133.03: fludioxonil HPLC-UV, 2 µg/m^3

Body fluids and tissues (analytical technique and LOQ)	GRM025.03A: After oxidation to CGA 192155 HPLC-MS/MS, 0.01 mg/kg (expressed as fludioxonil)

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

Substance	Fludioxonil
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended][1]:	none
According to the Peer review, the criteria for classification according to Regulation (EC) No 1272/2008 may be met for:	none

[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.

Impact on Human and Animal Health

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

Rate and extent of oral absorption/systemic bioavailability	56 % in male 76% in females (based on oral bioavailability vs Iv administration) Value considered for the AOEL: 56% (worst case value).
Toxicokinetics	Cmax: 0.027-0.0.65 and 3.2-4.5 ppm in animals dosed at 0.5 and 100 mg/kg bw respectively Tmax: 0.25 hours and 4-8 hours ppm in animals dosed at 0.5 and 100 mg/kg respectively
Distribution	Uniformly distributed (highest residues found in liver , kidney and lungs)
Potential for bioaccumulation	No evidence for accumulation
Rate and extent of excretion	15 % in the urine and about 70 % in the faeces within 24 hours. The excretion was mainly via the bile.
Metabolism in animals	Extensive metabolism: no parent compound in urine, approx. 10% parent in faeces. Phase I: major metabolic pathway is oxidation at position 2 of the pyrrole ring; minor pathways are oxidation at position 5 of the pyrrole ring and hydroxylation of the phenyl ring. Phase II: predominantly glucuronidation, in bile approx. 56% of glucuronide conjugate of metabolite SYN 518577. After repeated exposure: blue coloured metabolite in urine resulting from autoxidative dimerization.
In vitro metabolism	No qualitative difference between human and rat microsomes. Extensively metabolised in rat liver incubates, slightly lesser in in human liver incubates.
Toxicologically relevant compounds (animals and plants)	Fludioxonil and its metabolites, which can be oxidised to metabolite CGA192155 (2,2-difluoro-*2H*-1,3-benzodioxole-4-carboxylic acid) CGA227731.
Toxicologically relevant compounds (environment)	Fludioxonil; open for metabolites.

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

Rat LD_{50} oral	> 5000 mg/kg bw	Not classified Not classified
Rat LD_{50} dermal	> 2000 mg/kg bw	Not classified
Rat LC_{50} inhalation	>2.636 mg/L air /4h (*nose only*) Highest technically achievable concentration	Not classified
Skin irritation	Non-irritant	Not classified
Eye irritation	Non-irritant	Not classified

Skin sensitisation	Non-sensitising (M&K)	Not classified
Phototoxicity	Not phototoxic	

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

Target organ / critical effect	Liver; rat, mice, dog (increased weight, hepatocyte hypertrophy, bile duct proliferation) Kidney; rat, mice (increased weight, nephropathy) General signs (whole body), dog (body weight changes) Blood chemical examination (Blood serum (Lipid)), dog (increased cholesterol).	Not classified Not classified
Relevant oral NOAEL	28-day, rat: 10 mg/kg bw per day (gavage) 90-day, rat: 64 mg/kg bw per day 90-day, mouse : 445 mg/kg bw per day 90-day, dog: 58.5 mg/kg bw per day 1-year, dog: 33 mg/kg bw per day	
Relevant dermal NOAEL	28-day, rat: Systemic effects: 200 mg/kg bw/day local effect: 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)

In vitro studies	3 Bacterial reverse mutation assays – negative *In vitro* mammalian cell gene mutation test – negative *In vitro* mammalian cytogenetic test in Chinese hamster ovary – positive (+/- S9) *In vitro* mammalian cell DNA repair test - positive	
In vivo studies	Chromosome aberration test in Chinese hamster bone marrow – negative Micronucleus test in mouse bone marrow – negative Micronucleus test in rat hepatocytes (1991)– equivocal, study repeated Micronucleus test in rat hepatocytes (1999)– negative Aneuploidy test in rat bone marrow – negative UDS and replicative DNA synthesis test in rat hepatocytes – negative Dominant lethal test in mice - negative	
Photomutagenicity	Not required: negative response from the phototoxicity test	
Potential for genotoxicity	Fludioxonil is unlikely to be genotoxic	Not classified

		Not classified

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: Liver (increased weight, hepatocyte hypertrophy, bile duct proliferation) Kidney (increased weight, renal tubular casts)	Not classified Not classified
Relevant long-term NOAEL	2-year, rat: 37 mg/kg bw per day 18-month, mouse: 112 mg/kg bw per day	
Carcinogenicity (target organ, tumour type)	Rat: no treatment-related tumours Mouse: no treatment-related tumours	Not classified
Relevant NOAEL for carcinogenicity	2-year, rat: 113 mg/kg bw per day; 18-month, mouse: 851 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: reduced bodyweight and body weight gain in an existing 2-generation-study; in a new 2-generation reproductive toxicity study increased liver weight; increased kidney weight (M) with nephropathy and inclusions; decreased adrenals weights, decreased thyroid weight. Reproductive toxicity: no adverse effect observed in an existing 2-generation-study; in a new 2-generation toxicity study : delayed preputial separation, decreased number of estrus cycles, increased estrus cycle length, decreased number of implantations, decreased number of born live animals, decreased ano-genital distance. Offspring's toxicity: reduced growth during lactation in an existing 2-generation-study; in a new 2-generation reproductive toxicity study delayed balano-preputial separation	Repr. 2 H361f
Relevant parental NOAEL	Existing 2-gen: 18.9 mg/kg bw per day/new 2-gen. 175 mg/kg bw/day	
Relevant reproductive NOAEL	Existing 2-gen 188 mg/kg bw per day/new 2-gen. 58 mg/kg bw/day	
Relevant offspring NOAEL	Existing 2-gen 18.9 mg/kg bw per day/new 2-gen 58 mg/kg bw/day	

Developmental toxicity

Developmental target / critical effect	Rat:	Not classified

	Maternal toxicity: decreased body weight gain and food consumption Developmental toxicity: increased fetal and litter incidences of ureteral and/or pelvic dilatations Rabbit: Maternal toxicity: decreased body weight gain and food consumption Developmental toxicity : no adverse effects	
Relevant maternal NOAEL	Rat: 100 mg/kg bw per day Rabbit: 100 mg/kg bw per day	
Relevant developmental NOAEL	Rat: 10 mg/kg bw per day Rabbit: 300 mg/kg bw per day	

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

Acute neurotoxicity	Rat: Acute neurotoxicity study in rats: reduced locomotor activity. Reduced mean body weight gain and food consumption. NOAEL $_{\text{neurotoxicity}}$ < 500 mg/kg bw NOAEL $_{\text{general toxicity}}$ = 500 mg/kg bw	Not classified
Repeated neurotoxicity	90-day neurotoxicity study in rats: no indications of neurotoxicity. Reduced body weight gain NOAEL $_{\text{neurotoxicity}}$ = 493 mg/kg bw/day NOAEL $_{\text{general toxicity}}$ = 207 mg/kg bw/day	
Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity)	Study not required	

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

Supplementary studies on the active substance	28 day immunotoxicity study in the mouse. No evidence of immunosuppression or general toxicity NOAEL $_{\text{immunotoxicity}}$ = 1230 mg/kg bw/day NOAEL $_{\text{general toxicity}}$ = 1230 mg/kg bw/day
Endocrine disrupting properties	The **T-modality** has been considered sufficiently investigated and a pattern of T-mediated adversity was not identified (scenario 1a of the ECHA/EFSA ED Guidance 2018). Fludioxonil is an endocrine disruptor for the **EAS- modalities** according to the ED scientific criteria laid down in Regulation (EC) 2018/605 (**scenario 1b** of the ECHA/EFSA ED Guidance 2018). **NOAEL/LOAEL (endocrine adversity)** = 58/175 mg/kg bw per day respectively based on delayed sexual maturation in males in the 2-generation toxicity study in rats.
Studies performed on metabolites or impurities	
Metabolites, Group 1	Group accepted: **SYN518576, SYN518577, SYN518578 and their glucuronide and sulfate conjugates** Toxicological profile (genotoxicity and general toxicity) covered by parent (fludioxonil)

	Group not yet accepted **CGA173506 lactic acid (SYN551031)** Ames test: negative *In vitro* micronucleus test: positive *In vivo* micronucleus test: negative Proof of bone marrow exposure **→Unlikely to be genotoxic.** **→ For general toxicity conclusion cannot be drawn based on the data provided.**
Metabolites, Group 2	**CGA339833:** Acute Oral: LD_{50}>2000 mg/kg bw 90 day feeding: NOAEL = 800 ppm (58 mg/kg bw/day in males) Ames test: negative Gene mutation in mammalian cells: positive (- S9 24h) In vitro cytogenetic test in Chinese hamster cells: positive (-S9: 18h) In vivo micronucleus test in rat bone marrow: negative Proof of bone marrow exposure in rat. Comet assay negative **→ Unlikely to be genotoxic** **→ ADI: 0.29 mg/kg bw/day** based on NOAEL of 800 ppm (58 mg/kg bw/day) in the 90-day study UF = 200 extra factor of 2 for extrapolation from subacute to subchronic or from subchronic to chronic exposure The metabolite showed a different toxicological profile (i.e. qualitatively than parent, additional target organs identified). **CGA308103:** Acute Oral: LD_{50} >1000 mg/kg bw, <2000 mg/kg bw Ames test: negative *In vitro* micronucleus test: negative **→ Unlikely to be genotoxic** **→ For general toxicity read-across to CGA339833, agreed ADI of CGA339833 can apply** Group accepted: CGA308103 and CGA339833 are the lead compounds and their toxicological profile cover CGA344624, CGA344623 and SYN518581.
Metabolites, Group 3	**CGA265378:** Acute Oral: LD_{50}>2000 mg/kg bw Ames test: negative Gene mutation in mammalian cells: negative *In vitro* chromosome aberrations : positive *In vivo* micronucleus test: negative Proof of bone marrow exposure (qualitative method) Group accepted:

	CGA265378 is the lead compound and its toxicological profile would cover SYN518579 and SYN518579 tautomer **→Unlikely to be genotoxic** **→ For general toxicity conclusion cannot be drawn based on the data provided (data gap for the lead compound).**
Metabolites, Group 4	**CGA335892** Genotoxicity and general toxicity: inconclusive based on QSAR prediction. Glucoronide conjugate: covered by CGA335892.
Metabolites, No group	**CGA192155:** Acute Oral: LD_{50}>2000 mg/kg bw Ames test: negative Gene mutation in mammalian cells: negative In vitro cytogenetic test in Chinese hamster cells: positive (-S9) In vivo micronucleus test in mouse bone marrow: negative Proof of bone marrow exposure **→Non genotoxic** 28 day feeding; NOEL = 5000 ppm (382/389 mg/kg bw/day) 90 day feeding: NOAEL = 1000 ppm (57.5/66.2 mg/kg bw/day); toxicological profile is qualitatively similar to the parent and it is considered not more toxic than the parent. **→ The reference values of the parent can apply**
	CGA227731 Ames test: positive In vitro micronucleus test: negative *In vivo* comet assay: positive **→Genotoxic** **→For general toxicity: setting of reference values not possible due to the genotoxic potential.** **CGA308565:** Acute Oral: LD_{50}>2000 mg/kg bw Ames test: negative *In vitro* micronucleus test: positive *In vivo* micronucleus test: negative Proof of bone marrow exposure **→ Unlikely to be genotoxic** **→ For general toxicity conclusion cannot be drawn based on the data provided** **SYN518580** Genotoxicity and general toxicity: inconclusive based on QSAR prediction.
Relevant impurity	**SYN549129** Relevant (teratogenicity concern based on QSAR prediction, maximum content of 3 g/kg).

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

No adverse effects on health in manufacturing personnel A review of the exposure incidences of fludioxonil formulations reported between 2004 and 2014 has been conducted. After occupational, accidental, intentional and uncertain exposure only health effects of transient nature were observed, with almost all causing no or mild symptoms (92%). All other incidents were assigned to moderate severity grade. No epidemiological studies are available.

Summary[2] (Regulation (EU) N°1107/2009, Annex II, point 3.1 and 3.6)

Fludioxonil

	Value (mg/kg bw (per day))	Study	Uncertainty factor
Acceptable Daily Intake (ADI) [(a)]	**0.37**	2-year rat study	100
Acute Reference Dose (ARfD) [(a)]	**1**	Rat and rabbit, developmental study (maternal NOAEL)	100
Acceptable Operator Exposure Level (AOEL)	**0.2**	1-year dog study, supported by short- and long-term rat studies	178*
Acute Acceptable Operator Exposure Level (AAOEL)	**0.56**	Rat and rabbit, developmental study (maternal NOAEL)	178*

* Including correction for limited oral absorption/bioavailability (56 %).

[(a)] Applicable to metabolites CGA192155 and SYN518576, SYN518577, SYN518578 and their glucuronide and sulfate conjugates.

During the previous peer review the same ADI was set; ARfD and AAOEL were not set and a different AOEL was set (EFSA, 2007)

Summary[3] (Regulation (EU) N°1107/2009, Annex II, point 3.1 and 3.6)

CGA339833

	Value (mg/kg bw (per day))	Study	Uncertainty factor
Acceptable Daily Intake (ADI) [(a)]	**0.29**	90-day study	200

[(a)] Applicable to CGA308103, CGA344624, CGA344623 and SYN518581.

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

Representative formulation 'A8207M' Fludioxonil FS 25g/L	Concentrate: 0.4 % *In vitro human study performed on formulation*

[2] If available include also reference values for metabolites
[3] If available include also reference values for metabolites

Representative formulation 'A8240D' Fludioxonil WG 500 g/L	Concentrate: 0.1 % Concentrate (250 g/L) 0.07% Dilution 1: 0.83 g/L 5% Dilution 2: 0.42 g/L 5% Dilution 3 : 0.125 g/L 8% *In vitro human study performed on formulation*

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

Operators	**A8207M FS 25 g/L** Use: cereals, seed treatment, application rate 5 g a.s./100 kg seed Exposure estimates: % of AOEL **Generic SeedTropex geometric mean values** *Seed treatment* With PPE (gloves) – 70kg (scenario 1): 11 With PPE (gloves)– 60kg (scenario 1): 13 *Loading and Sowing* Without PPE – 70 kg: 1.3 Without PPE – 60 kg: 1.6 *Without PPE means:* *SeedTropex: Operator wearing one layer of work clothing*

A8240D WG 500 g/kg

Use: grapes, tractor mounted airblast application, application rate 0.5 kg a.s./ha

EFSA model (AOEM):

Without PPE AOEL:	8.9
Without PPE AAOEL:	12

Use: pome fruit, tractor mounted airblast application, application rate 0.225 kg a.s./ha

EFSA model (AOEM):

Without PPE AOEL:	6.6
Without PPE AAOEL:	8.6

Use: strawberries outdoors, tractor mounted boom sprayer, application rate 0.250 kg a.s./ha

EFSA model (AOEM):

Without PPE AOEL:	2
Without PPE AAOEL:	4.5

Use: strawberries indoor, hand-held application indoors, application rate 0.250 kg a.s./ha

EFSA model (AOEM) outdoor by default upward:

Hand-held sprayer/Manual-knapsack

Without PPE AOEL:	3.6/1.8
Without PPE AAOEL:	4.1/1.7

EFSA model (AOEM) outdoor by default downward:

Hand-held sprayer/Manual-knapsack

Without PPE AOEL:	7.5/7.5
Without PPE AAOEL:	17/16

Dutch Greenhouse model:

Without PPE AOEL:	30

German IVA model:

Without PPE AOEL:	2.4

Without PPE means:
EFSA Guidance: Operator wearing long sleeved shirt, long trousers ("permeable") but no gloves
Southern Greenhouse Model (ECPA): Operator wearing one layer of work clothing
Dutch Greenhouse Model: Operator wearing normal work clothes
German Greenhouse Study (IVA): Operator wearing no clothes

Workers	**A8207M FS 25 g/L** Exposure of operator directly involved in seed treatment as well as exposure of operator loading and sowing treated seeds represent the worst-case covering worker exposure. % of AOEL **Generic Seed-TROPEX** 0.04 **fork lift truck drivers**
	A8240D WG 500 g/kg Use: grapes Exposure estimates (model): % of AOEL **EFSA model (AOEM):** Without PPE (work wear): 82 Use: pome fruit Exposure estimates (model): % of AOEL **EFSA model (AOEM):** With PPE (work wear gloves): 30 Use: strawberry Exposure estimates (model): % of AOEL **EFSA model (AOEM):** Outdoors Without PPE (work wear): 22 Indoors Without PPE (work wear): 22
Bystanders and residents	**A8207M FS 25 g/L** Based on proposed assumptions, bystander and resident exposures to dust from treated seed during sowing activities, in relation to the amount of active substance that might be present in this dust, are far below the AOEL.

	A8240D WG 500 g/kg Use: grapes, tractor mounted airblast application, application rate 0.5 kg a.s./ha Buffer = 5 m **EFSA model (AOEM):** Bystander child spray drift (%AAOEL): 1.8 Bystander adult spray drift (%AAOEL): 1 Resident child all pathways (%AOEL): 3.4 Resident adult all pathways (%AOEL): 2.5 Use: pome fruit, tractor mounted airblast application, application rate 0.225 kg a.s./ha Buffer = 5 m **EFSA model (AOEM):** Bystander child spray drift (%AAOEL): 3.4 Bystander adult spray drift (%AAOEL): 1.9 Resident child all pathways (%AOEL): 6.2 Resident adult all pathways (%AOEL): 3.1 Use: strawberries outdoors, tractor mounted boom sprayer, application rate 0.250 kg a.s./ha Buffer = 2-3 m **EFSA model (AOEM):** Bystander child entry into the crop (%AAOEL): 1.1 Bystander adult entry into the crop (%AAOEL): 0.6 Resident child all pathways (%AOEL): 3.7 Resident adult all pathways (%AOEL): 1.7

Assessment of Negligible Exposure for ornamentals[4]: Refer to Volume 1, section 2.6.14.2

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

Substance :	Fludioxonil
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended][5] :	No current harmonised classification. RAC opinion June 2017[6]: No classification for human health
According to the peer review[7], criteria for harmonised classification according to Regulation (EC) No 1272/2008[8] may be met for:	Repr 2 H361f

[4] An assessment of negligible exposure for these uses has not been included in this Conclusion since not part of the representative uses. A negligible exposure assessment for the representative uses is not available.

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

[6] ECHA (European Chemicals Agency), 2017. Committee for Risk Assessment (RAC) Opinion proposing harmonised classification and labelling at EU level of fludioxonil (ISO); 4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile. CLH-O-0000001412-86-162/F. Adopted 9 June 2017. Available at www.echa.europa.eu
ATP14 (Commission Delegated Regulation (EU) 2020/217 of 4 October 2019)

[7] The RMS is invited to consider submitting a CLH dossier to ECHA in order to propose a modification of the existing Annex VI entry of the CLP Regulation for fludioxonil. This dossier could be targeted to one or more hazard classes only as based on new data which become available since the harmonised classification was agreed. EFSA recommends the RMS to send an updated CLH dossier to ECHA in order to propose a revision of the current Annex VI entry of the CLP Regulation.

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

Residues in or on treated products food and feed

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

Primary crops (Plant groups covered) OECD Guideline 501	**Crop groups**	**Crop(s)**	**Application(s)**	**DAT** (days)
	Fruit crops	Grapes	3x500g a.s./ha (Foliar)	0, 14, 35
		Tomato	3x 750 g a.s./ha(Foliar)	0, 40
		Peach	3x280 g a.s./ha(Foliar) 3x2800 g a.s./ha 2100+6300 g a.s./ha	28 28 30, 114
	Root crops	Potato	2.5 g a.s./100kg seeds	0, 40, 71, 95
	Leafy crops	Lettuce	3x200 g a.s./ha (Foliar) 3x600g a.s./ha	0, 6, 13
		Spring onion (whole plant)	557+683 g a.s./ha (Foliar) 2793+3376 g a.s./ha	0, 7, 14, 28
	Cereals/grass crops	Rice	6.5 g a.s./100 kg seeds	0, 38, 76 and 152
		Wheat	3.9-7.4 g a.s./100kg seeds Injection in stem (supportive)	48, 83, 106 21, 40, 69
	Pulses/Oilseeds	Cotton	2.5 g a.s./100kg seeds 5 g a.s./100kg seeds	186
		Soybean	5 g a.s./100kg seeds	28, 38, 133
	Miscellaneous	-	-	-
	Pyrrole-^{14}C labelling for all crops except for peaches and Spring onions (phenyl-^{14}C labelling form). Seed treatment: a low residue situation is expected. Foliar application: no major difference observed between metabolic pathways in fruits and fruiting vegetables, leafy vegetables or root and tubers vegetables.			

Rotational crops (metabolic pattern) OECD Guideline 502	**Crop groups**	**Crop(s)**	**PBI** (days)	**Comments**
	Root/tuber crops	Sugar beet Turnip, radish	320 30, 90, 210	4 different studies have been submitted, with different applications rates
	Leafy crops	Lettuce Mustard	90 30, 90, 210	
	Cereal (small grain)	Winter wheat Spring wheat Maize	140 30, 90, 210 345	
	Other			
Rotational crop and primary crop metabolism similar?	Yes, but fludioxonil is extensively degraded.			

Processed commodities (standard hydrolysis study) **OECD Guideline 507**	**Conditions**	**[4-^{14}C]-pyrrole-labelled fludioxonil**
	20 min, 90°C, pH 4	No degradation of the parent fludioxonil was observed
	60 min, 100°C, pH 5	
	20 min, 120°C, pH 6	
Residue pattern in processed commodities similar to residue pattern in raw commodities?	No degradation of parent compound was observed	

Plant residue definition for monitoring (RD-Mo) **OECD Guidance, series on pesticides No 31**	Primary crops: Fludioxonil - all categories of crops following foliar and seed treatment Rotational crops: Fludioxonil (by default)
Plant residue definition for risk assessment (RD-RA)	Primary crops: Sum of fludioxonil and its metabolites which can be oxidised to metabolite 2,2-difluoro-*2H*-1,3-benzodioxole-4-carboxylic acid (CGA192155), expressed as fludioxonil – provisional **(see data gap (1))** **Data gap (1)**: complete datasets of residue trials compliant with the representative uses and analysing respectively fludioxonil alone, and fludioxonil and all its metabolites that can be oxidised to metabolite 2,2-difluoro-*2H*-1,3-benzodioxole-4-carboxylic acid (CGA192155), expressed as fludioxonil. Rotational crops: Fludioxonil (by default) – Provisional (See **Data gap (2) below)**
Conversion factor (monitoring to risk assessment)	Open (see data gap (1))

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

OECD Guideline 503 and **SANCO/11187/2013 rev. 3** (fish)	**Animal**	**Dose** (mg/kg bw/d)	**Duration** (days)	**N rate/comment**
Animals covered	Laying hen	6.3	8	1260N
	Goat/Cow	3.5	4	875N
	Pig	No study	-	-
	Fish	No study	-	-
	Studies conducted with the pyrrole-^{14}C labelled fludioxonil only			

Time needed to reach a plateau concentration in milk and eggs (days)	Eggs: day 4 (2 animals out of 5; unclear for others) Milk: not reached during metabolism study; identified at day 3 or 10 depending on the dose in the feeding study
Animal residue definition for monitoring (RD-Mo) **OECD Guidance, series on pesticides No 31**	Sum of fludioxonil and its metabolites oxidised to metabolite 2,2-difluoro-*2H*-1,3-benzodioxole-4-carboxylic acid (CGA192155), expressed as fludioxonil
Animal residue definition for risk assessment (RD-RA)	Sum of fludioxonil and its metabolites oxidised to metabolite 2,2-difluoro-*2H*-1,3-benzodioxole-4-carboxylic acid (CGA192155), expressed as fludioxonil
Conversion factor (monitoring to risk assessment)	Not necessary

Metabolism in rat and ruminant similar (Yes/No)	Yes
Fat soluble residues (Yes/No) **(FAO, 2009)**	Yes (Log Po/w > 4; preferential concentration in fat and egg yolk rather than in muscle and egg white, respectively)

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

Confined rotational crop study (Quantitative aspect) **OECD Guideline 502**	For field strawberries, a PECplateau of parent compound was determined at 0.137 mg fludioxonil/kg soil, which is equivalent to 411 g a.s./ha. For seed treatment, the sowing of treated seeds on a soil in which the plateau has been reached is deemed equivalent to an application on bare soil at a rate of 81.5 g a.s./ha. Individual metabolites of fludioxonil are unlikely to be present at levels above 0.01 mg/kg in commodities for human consumption produced by rotational crops planted following treatment with fludioxonil in accordance with the representative uses. For feed items, no individual compound is expected at levels above 0.05 mg/kg. No further data are required.
Field rotational crop study **OECD Guideline 504**	Uptake of the parent fludioxonil was studied in rotational lettuce, turnips and wheat in three US states (California, Florida, and New York). Fludioxonil was applied onto bare soil four times, with seven-day intervals, at a rate of 282 g a.s./ha per application (total application rate 1128 g a.s./ha). Planting or sowing was carried out 30, 90, 150 and 210 DAT. These results confirm that levels of fludioxonil above 0.01 mg/kg are not expected in rotational crops. However, no metabolites were analysed in this study. These studies can only be considered as supportive since these are not European residue trials. **Data gap (2)**: sufficient rotational crops field trials covering the Northern and Southern zones of Europe to determine the magnitude of CGA227731 residues in cereal forage, grain and straw at the different standard plant back intervals (PBIs), covering the maximum PECsoil for fludioxonil and supported by validated methods and acceptable storage stability data are required.

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

Plant products (Category)	Commodity	T (°C)	Stability (Months)			
			Fludioxonil			
High water content	Tomato	-18	24			
	Apples	-18	24			
	Fresh peas	-18	24			
	Maize forage	-18	24			
	Sweet corn ears	-18	24			
High oil content	Rapeseed	-18	No stability			
	Corn oil	-18	25			
High protein content	-	-	-			
High starch content	Cereal grain	-18	24			
	Maize grain	-18	24			
	Potato tubers	-18	24			
High acid content	Grapes	-18	28.5			
No group	Cereal straw	-18	24			
	Corn meal	-18	27			
	Sorghum hay	-18	24			
	Sorghum flour	-18	27			
	Potato flakes	-18	27			
Data gap: an additional storage stability study on a crop representative of the high acid content commodities is required to comply with the current OECD recommendations (OECD TGL 506).						

Animal	Animal commodity	T (°C)	Stability (Month/Year)			
			Fludioxonil *			
Beef	Muscle	-20	4			
	Liver	-20	19			
	Kidney	-20	19			
Cattle	Milk	-20	3			
Poultry	Egg	-20	19			
* Samples spiked with fludioxonil, analysed with a method which convert fludioxonil and its oxidizable metabolites into CGA 192155						

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

The residues data given below is only considering Fludioxonil. See above for data gap (1) regarding complete datasets of residue trials compliant with the representative uses and analysing respectively fludioxonil alone, and fludioxonil and all its metabolites that can be oxidised to metabolite 2,2-difluoro-*2H*-1,3-benzodioxole-4-carboxylic acid (CGA192155), expressed as fludioxonil

Crop	**Region/ Indoor** (a)	**Residue levels** (mg/kg) **observed in the supervised residue trials relevant to the supported GAPs** (b)	**Recommendations/comments** (OECD calculations)	**MRL** proposals (mg/kg)	**HR** (mg/kg) (c)	**STMR** (mg/kg) (d)
Representative uses						
Pome fruits (apples and pears)	NEU (8)	Apple: 2x0.18, 2x0.23, 2x0.25, 0.43, 0.54	Only GAP compliant residue trials with two applications were considered.	0.9	0.54	0.24
	SEU (8)	Apple: 0.05, 0.08, 0.11, 0.17, 0.19, 0.25, 0.37, 0.41		0.8	0.41	0.18
	NEU+SEU (16)	Apple: 0.05, 0.08, 0.11, 0.17, 2x0.18, 0.19, 2x0.23, 3x0.25, 0.37, 0.43, 0.54	NEU and SEU datasets were not identified as different by a Mann and Whitney test and therefore pooled.	0.9	0.54	0.24
Table grapes (PHI:7 days)	SEU (8)	0.16, 0.22, 0.27, 0.30, 0.34, 0.82, 1.80, 1.93	For table grapes results from grapes without stem are considered	4	1.93	0.32
Wine grapes (PHI:21 days)	SEU (8)	0.15, 0.20, 0.26, 0.27, 0.38, 0.49, 1.95, 2.65		5	2.65	0.32
Strawberries	NEU		Presented residue trials were not GAP-compliant with three instead of two applications. See the data gap (1) for complete datasets of residue trials compliant with the representative uses and analysing respectively fludioxonil alone, and fludioxonil and all its metabolites that can be oxidised to metabolite 2,2-difluoro-*2H*-1,3-benzodioxole-4-carboxylic acid (CGA192155), expressed as fludioxonil.			
	SEU					
	Indoor					

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)
Wheat grain ➔ Oats grain	NEU (21)	Wheat: 13x <0.02, 8x <0.04		**0.07**	0.04	0.02
	SEU (9)	Wheat: 9x <0.02		0.02*	0.02	0.02
Wheat straw ➔ Oats straw	NEU (21)	Wheat: 4x <0.02, 10x <0.04, 7x <0.05		-	0.05	0.04
	SEU (9)	Wheat: 2x <0.02, <0.04, 6x <0.05		-	0.05	0.05

Summary of the data on formulation equivalence OECD Guideline 509

Crop	Region	Residue data (mg/kg)	Recommendations/comments			
Not necessary						

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			

Not available

Data gap: additional residue trials on a crop representative of a worst-case scenario with respect to potential residues in honey and conducted at an appropriate dose rate of application should be provided; the residue situation in the rotational crops should also be considered in the overall assessment to determine the residues of fludioxonil in pollen and bee products

(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 **Mo**nitoring and **R**isk **A**ssessment.
(c): **HR**: Highest residue. When residue definition for monitoring and risk assessment differs, HR according to residue definition for monitoring reported in brackets (HR_{Mo}).
(d): **STMR:** Supervised Trials Median Residue. When residue definition for monitoring and risk assessment differs, STMR according to definition for monitoring reported in brackets ($STMR_{Mo}$).

Inputs for animal burden calculations – Provisional (see data gaps (1) and (2))

Feed commodity	Median dietary burden		Maximum dietary burden	
	(mg/kg)	Comment	(mg/kg)	Comment
Representative uses				
Oat, Triticale, Wheat straw	0.05	STMR	0.05	HR
Oat, Triticale, Wheat grain	0.02	STMR		
Apple pomace, wet	0.32	STMR-P (PF 1.4)		
Distiller's grain dried	0.07	STMR-P (default PF = 3.3)		
Wheat gluten, meal	0.04	STMR-P (default PF = 1.8)		
Wheat, milled by-pdts	0.14	STMR-P (default PF = 7)		

Residues from livestock feeding studies (Regulation (EU) N° 283/2013, Annex Part A, points 6.4.1, 6.4.2, 6.4.3 and 6.4.4) - Provisional (see data gaps (1) and (2) OECD Guideline 505 and OECD Guidance, series on pesticides No 73

MRL calculations	**Ruminant**				**Pig/Swine**		**Poultry**		**Fish**	
Highest expected intake (mg/kg bw/d) (mg/kg DM for fish)	Beef cattle	0.004	Ram/Ewe	0.004	Breeding	0.002	Broiler	0.003	Carp	0.011
	Dairy cattle	0.004	Lamb	0.005	Finishing	0.003	Layer	0.004	Trout	0.010
							Turkey	0.003	Fish intake >0.1 mg/kg DM	
Intake >0.004 mg/kg bw	Yes		Yes		No		No		No	
Feeding study submitted	Yes (cows)		No (extrapolated from cows)		No (not necessary)		No (not necessary)		No (not necessary)	
Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and **N rates**	Level 0.8/ 0.02 (milk)	Beef: 120 N Dairy: 3.3 N	Level 0.8/ 0.02 (milk)	Lamb: 126 N Ewe: 162 N	Level	N rate Breed/Finish	Level	B or T: N Layer: N	Level	N rate Carp/Trout
	Estimated HR[(a)] at 1N	**MRL** proposals	Estimated HR[(a)] at 1N	**MRL** proposals	Estimated HR[(a)] at 1N	**MRL** proposals	Estimated HR[(a)] at 1N	**MRL** proposals	Estimated HR[(a)] at 1N	**MRL** proposals
Muscle	0.01	0.01*	0.01	0.01*					-	-
Fat	0.01	0.01*	0.01	0.01*					-	-
Meat[(b)]	0.01		0.01							
Liver	0.01	0.01*	0.01	0.01*						
Kidney	0.01	0.01*	0.01	0.01*						
Milk[(a)]	0.01	0.01*	0.01	0.01*						
Eggs										
Method of calculation[(c)]		Tf		Tf						

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

STMR calculations	**Ruminant**				**Pig/Swine**		**Poultry**		**Fish**	
Median expected intake (mg/kg bw/d)	Beef cattle	0.0044	Ram/Ewe	0.0037	Breeding	0.002	Broiler	0.003	Carp	0.011
	Dairy cattle	0.0039	Lamb	0.0049	Finishing	0.003	Layer	0.004	Trout	0.010

STMR calculations (mg/kg DM for fish)	**Ruminant**				**Pig/Swine**		**Poultry**		**Fish**	
							Turkey	0.003		
Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and **N rates**	Level 0.8/ 0.02 (milk)	Beef: 120N Dairy: 145 N	Level 0.8/ 0.02 (milk)	Lamb: 126 N Ewe: 162 N	Level	N rate Breed/Finish	Level	B or T: N Layer: N	Level	N rate Carp/Trout
	Mean level in feeding level	Estimated **STMR**[(b)] at 1N	Mean level in feeding level	Estimated **STMR**[(b)] at 1N	Mean level in feeding level	Estimated **STMR**[(b)] at 1N	Mean level in feeding level	Estimated **STMR**[(b)] at 1N	Mean level in feeding level	Estimated **STMR**[(b)] at 1N
Muscle	0.01	0.01	0.01	0.01						
Fat	0.01	0.01	0.01	0.01						
Meat[(a)]	0.01	0.01	0.01	0.01						
Liver	0.07	0.01	0.07	0.01						
Kidney	0.08	0.01	0.08	0.01						
Milk	0.01	0.01	0.01	0.01						
Eggs										
Method of calculation[(c)]		Tf		Tf						

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

Conversion Factors (CF) for monitoring to risk assessment

Plant products
Open (see data gap (1)

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				
Grapes				
Must	14	0.10, 0.42, 0.32, 0.02, 1.12, 0.27, 1.25, 0.40, 0.28, 0.53, 0.76, 0.28, 0.98, 1.11, 1.86, 0.98, 1.02, 1.14, 0.68, 0.50, 1.52, 1.85, 1.03	0.76	-
Juice	12	0.68, 0.95, 0.74, 0.80, 0.86, 0.79, 0.93, 0.67, 0.83, 0.73, 1.05, 1.02	0.82	-
Pasteurised juice	2	0.05, 0.07, 0.13, 0.09	0.08	-
Young wine	12	0.21, 0.04, 0.04, 0.08, 0.18, 0.76, 0.06, 0.33, 0.11, 0.17, 0.21, 0.98	0.18	-
Red wine	2	0.03, 0.09, 0.22, 0.07, 0.10, 0.21, 0.16	0.10	-
White wine	2	0.01, 0.03, 0.03, 0.03, 0.04, 0.04, 0.11, 0.21, 0.24, 0.19, 0.16, 0.19, 0.41	0.11	-
Raisins	14	Sun-dried: 0.56, 0.84, 0.63, 0.67, 1.04, 1.18 Industrial (sulfur gas + oven): 1.69, 1.25, 1.10, 1.13, 1.21, 1.07 Oven: 0.93, 2.19, 0.60, 0.55	0.84 1.12 0.58	-
Wet pomace	2	1.88, 1.36, 5.02, 6.52, 3.93, 8.24, 1.85, 2.83, 5.23, 3.64, 7.09, 6.76	4.48	-
Dry pomace	2	4.69, 5.03, 11.87, 10.73, 11.20, 13.41, 3.98, 6.97, 11.40, 9.18, 20.97, 21.79	10.97	-
Grape seed oil	2	8.28, 10.38, 18.66, 18.18	14.28	-
Apple				
Washed fruit	1	0.84	-	-
Washing water	1	0.48	-	-
Wet pomace	1	0.93, 1.36, 1.52	1.36	-

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	
Dry pomace	2	3.05, 4.84, 5.32	4.84	-
Pasteurised juice	2	0.02, 0.03, 0.08	0.03	-
Waste	1	1.48	-	-
Sauce	2	0.02, 0.03,0.12	0.03	-
Strawberry				
Washed berries	3	0.86, 0.45, 0.33	0.45	-
Preserved strawberries	3	0.79, 0.55, 0.37	0.55	-
Jam	3	0.50, 0.22, 0.21	0.22	-
Juice	1	0.11	-	-

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

Consumer risk assessment (Regulation (EU) N° 283/2013, Annex Part A, point 6.9) – Provisional (see data gaps (1) and (2))

Representative uses only.

ADI	0.37 mg/kg bw per day
TMDI according to EFSA PRIMo rev.3.1	Highest TMDI: 6% ADI (NL toddler)
TMDI according to EFSA PRIMo rev.2A	Highest TMDI: 5.3% ADI (DE child)
NTMDI, according to (to be specified)	Not conducted as TMDI does not lead to an exposure above 100 % ADI
IEDI (% ADI), according to EFSA PRIMo rev.3.1	Not conducted as TMDI does not lead to an exposure above 100 % ADI
NEDI (% ADI), according to (to be specified)	Not conducted as TMDI does not lead to an exposure above 100 % ADI
Factors included in the calculations	Open (see data gap (1))
ARfD	1 mg/kg bw
IESTI (% ARfD), according to EFSA PRIMo rev.3.1	Highest IESTI: 27% ARfD (Tables grapes) Second highest IESTI: 7% ARfD (Pears)
IESTI (% ARfD), according to EFSA PRIMo rev.2A	Highest IESTI: 24% ARfD (Tables grapes)
NESTI (% ARfD), according to (to be specified)	Not conducted
Factors included in IESTI and NESTI	Open (see data gap (1))

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

Metabolite(s)	CGA339833

ADI (mg/kg bw per day)	0.29
Intake of groundwater metabolites (% ADI) **WHO Guideline (WHO, 2017)**	Adult (60 kg bw, 2 L): 0.05 % ADI Child (10 kg bw, 1 L): 0.14 % ADI Infant (5 kg bw, 0.75 L): 0.21 % ADI

Metabolite(s)	CGA192155
ADI (mg/kg bw per day)	0.37
Intake of groundwater metabolites (% ADI) **WHO Guideline (WHO, 2009~~09~~17)**	Adult (60 kg bw, 2 L): 0.003% ADI Child (10 kg bw, 1 L): 0.01 % ADI Infant (5 kg bw, 0.75 L): 0.01 % ADI

Metabolite(s)	Unidentified metabolites MF2 and D9
ADI (mg/kg bw per day)	open
Intake of groundwater metabolites (% ADI) WHO Guideline (WHO, 2009)	Adult (60 kg bw, 2 L): open Child (10 kg bw, 1 L): open Infant (5 kg bw, 0.75 L): open

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			
130010	Apples	0.9	Provisional (see data gaps (1) and (2)
130020	Pears	0.9	
151010	Table grapes	4	
151020	Wine grapes	5	
152000	Strawberry	open	
500050	Oats	0.07	
500090	Wheat	0.07	
MRL application			
152000	Strawberry	open	Provisional (see data gaps (1) and (2)
Animal commodities			
1011000	Swine	0.01*	Provisional (see data gaps (1) and (2)
1012000	Bovine	0.01*	
1013000	Sheep	0.01*	
1014000	Goat	0.01*	
1020000	Milk	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.

Environmental fate and behaviour

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

Mineralisation after 100 days	*28.36* % after *364* d, [^{14}C-*pyrole*]-label (n[9]=*12*) *44.93* % after *363* d, [^{14}C-*phenyl*]-label (n=*4*)
Non-extractable residues after 100 days	*28.60* % after *362* d, [^{14}C- *pyrole*]-label (n=*12*) *26.50* % after *363* d, [^{14}C- *phenyl*]-label (n=*4*)
Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)	No major metabolite observed Minor non-transient metabolites *unknown metabolite:* **Data gap** MF2 - 7.7% AR at 61 d (n=1) Sterile conditions: *90.1* % as fludioxonil after *90* d (n= *1*)

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

Mineralisation after 100 days	*2.9* % after *62* d of anaerobic conditions, [^{14}C-*pyrole*]-label (n= *2*) *1.0* % after *362* d of anaerobic conditions, [^{14}C-*phenyl*]-label (n= *1*)
Non-extractable residues after 100 days	*11.9* % after *62* d of anaerobic conditions, [^{14}C-*pyrole*]-label (n= *2*) *8.3* % after *272* d of anaerobic conditions, [^{14}C-*phenyl*]-label (n= *1*)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	*No major nor minor non-transient metabolites observed.*

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

Mineralisation at study end	*9.1* % after *44* eq. sunlight d, [^{14}C-*pyrole*]-label (n= *2*) *7.8* % after *44* eq. sunlight d, [^{14}C-*phenyl*]-label (n= *3*)
Non-extractable residues at study end	*20.3* % after *32* eq. sunlight d, [^{14}C-*pyrole*]-label (n= *2*) *29.1* % after *32* eq. sunlight d, [^{14}C-*phenyl*]-label (n= *3*)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	*Met CGA265378 – 11* % after 10 days (repeat test) / 10.1 % after 19 eq. sunlight d (n= *4*) [^{14}C-*pyrole*] & [^{14}C-*phenyl*] labels *Met CGA192155- 26.95* % at 32 eq. sunlight (n= *3*) [^{14}C-*pyrole*] & [^{14}C-*phenyl*] labels *Met CGA339833- 13.35* % at 19 eq. sunlight (n= *4*) [^{14}C-*pyrole*] & [^{14}C-*phenyl*] labels *Met SYN545245- 29.4* % at 19 eq. sunlight (n= *1*) [^{14}C-*phenyl*] labels Other unidentified compounds: *Met D9 – 7.3* % (n= 1) at 19 eq. sunlight d [^{14}C-*pyrole*] label

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

Parent	Dark aerobic conditions						
Soil type	**pH[a)]**	**t. °C / % MWHC**	**DT_{50} /DT_{90} (d)** **Persistence endpoint**	**DT_{50} (d)** **20 °C** **pF2/10kPa[b)]** **Normalized endpoint**		**St. (χ^2)**	**Method of calculation**
Sandy loam Abildt (1991)	5.4	20 °C - 30% FC, 2.0 ppm 20 °C - 60% FC, 0.2 ppm 20 °C - 60% FC, 2.0 ppm	457 / 1950 466 / 2200 404 / 1650	202.8 315.4 293.7	265.8 c)	2.83/5.94 1.16/6.36 1.39/4.77	HS / SFO DFOP / SFO HS / SFO
Sand Ellgehausen (1992a)	6.6	20° C - 40% MWHC	1280 / 5580	513.8		5.04	HS[d)] / SFO
Sandy loam Ellgehausen (1992a)	7.0	20° C - 40% MWHC	332 / 1550	191.0	156.6 c)	0.95/6.32	DFOP / SFO
Sandy loam Ellgehausen (1992b)	7.0	20° C - 40% MWHC	148 / 492	101.3		1.63	SFO / SFO
Sandy loam Minet (1994a)	7.0	20° C - 40% MWHC	274 / 1040	198.6		4.12	DFOP / SFO
Loamy sand Minet (1994b)	7.2	20° C - 40% MWHC	327 / 1270	243.7		1.88/3.68	DFOP / SFO
Silt loam Minet (1994b)	7.3	20° C - 40% MWHC	331 / 1340	216.7		1.78/3.86	DFOP / SFO

[9] n corresponds to the number of soils.

Silt loam Minet (1994c)	7.0	20° C - 40% MWHC, 0.2 ppm 20° C - 40% MWHC, 0.4 ppm 20° C - 40% MWHC, 0.8 ppm	137 / 742 214/1510 179 / 843	143.1 197.9 166.8	167.8[c)]	1.59/6.45 2.94/4.9 1.39/4.56	DFOP / SFO DFOP/ SFO DFOP / SFO
Silt loam Reischmann (1994)	7.0	20° C - 50% MWHC	268/1150	181.5		2.81	HS / SFO
Loam Piskorski (2015)	7.6*	20°C – pF2	183 / 909	183		0.95	SFO / SFO
Sandy clay loam Piskorski (2015)	6.3*	20°C – pF2	318 / 1060	318		0.87	SFO / SFO
Sandy loam Piskorski (2015)	7.7*	20°C – pF2	188 / 625	188		2.11	SFO / SFO
Geometric mean (if not pH dependent)				**234.13**			
pH dependence, *Yes or No*				**no**			

[a)] Measured in KCl except when marked with * (measured in water)
[b)] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
[c)] geomean value
[d)] HS kinetics parameters: k_1 0.01, k_2 0.000375, tb 22.08

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

CGA265378	**Dark aerobic conditions - Metabolite dosed study**							
Soil type	pH[a)]	t. °C / % MWHC	DT_{50} (d)	DT_{90} (d)	f. f. k_f / k_{dp}	DT_{50} (d) 20 °C pF2/10kPa	St. (χ^2)	Method of calculation
Loamy sand (18 Acres)	6.36	20 °C – pF2	0.042 α: 0.67 β: 0.08	0.703	-	0.21*	5.52	FOMC
Loam (Gartenacker)	7.53	20 °C – pF2	0.025 α: 0.7522 β: 0.3645	0.309	-	0.09*	4.25	FOMC
Sandy loam (East Anglia)	7.63	20 °C – pF2	0.017 α: 0.7755 β: 0.2645	0.204	-	0.06*	2.5	FOMC
Geometric mean (if not pH dependent)						**0.11**		
Arithmetic mean					-			
pH dependence, *Yes or No*						No		

[a] Measured in water
* normalized DT90/3.32

CGA339833	**Dark aerobic conditions - Metabolite dosed study**						
Soil type	pH[a)]	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	DT_{50} (d) 20 °C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
Silt loam (Gartenacker)	7.18	20° C - 40% MWHC	8.66 / 28.8	-	6.46	9.39	SFO
Loamy sand (Pappelacker)	7.43	20° C - 40% MWHC	15.5 / 51.4	-	10.10	4.42	SFO
Sandy loam (Weide)	7.36	20° C - 40% MWHC	11.4 / 37.8	-	7.49	5.68	SFO
Geometric mean (if not pH dependent)					**7.88**		
Arithmetic mean				-			
pH dependence, *Yes or No*					No		

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

CGA192155	**Dark aerobic conditions - Metabolite dosed study**						
Soil type	pH[a)]	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	DT_{50} (d) 20 °C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
Silt loam (Gartenacker)	7.18	20° C - 40% MWHC	15.4 / 51.3	-	15.4	13.6	SFO
Loamy sand (Pappelacker)	7.43	20° C - 40% MWHC	23.7 / 78.8	-	23.7	5.45	SFO
Sandy loam (Weide)	7.36	20° C - 40% MWHC	16.0 / 53.0	-	16.0	10.5	SFO
Geometric mean (if not pH dependent)					**18.0**		
Arithmetic mean				-			
pH dependence, *Yes or No*					No		

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

SYN545245	Dark aerobic conditions - Metabolite dosed study						
Soil type	pH[a)]	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	DT_{50} (d) 20 °C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
Silt loam (Gartenacker)	6.36	20 °C – pF2	0.06 / 0.21	-	0.07	3.12	SFO
Loamy sand (Pappelacker)	7.53	20 °C – pF2	0.67 / 2.22	-	0.75	5.27	SFO
Sandy loam (Weide)	7.63	20 °C – pF2	0.61 / 2.01	-	0.68	2.98	SFO
Geometric mean (if not pH dependent)					**0.33**		
Arithmetic mean				-			
pH dependence, *Yes or No*					No		

[a] Measured in [medium to be stated, usually calcium chloride solution or water]
[b] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

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

Parent	Aerobic conditions						
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	pH[a)]	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	DT_{50} (d) Norm[b)].	Method of calculation
Silty clay loam	Codogdan (FR)	7.95	0-20	8.91	186	-	HS
Silt loam	Padua (IT)	8.1*	0-20	10.3	34.1	-	SFO
Sandy loam	Euskirchen-Weisesheim (DE)	6.3	0-20	20.3	203	228	HS / SFO
Sand	Winzerhausen (DE)	7.0	0-20	8.77	268	-	HS
Sandy silty loam	Achern-Gamshurst (DE)	6.2	0-20	4.04	337	-	DFOP
Loam	Meissner-Vockerode (DE)	6.4	0-20	24.6	321	-	HS
Silt loam	Goch-Nierswalde (DE)	5.9	0-20	4.06	191	112	DFOP / SFO
Silty loam	Obernburg (DE)	6.9	0-20	7.69	132	74.7	HS / SFO
Sandy loam	Vouvry, Plot 4 (CH)	7.39	0-30	104	332	-	SFO
Sandy loam	Vouvry, Plot 6 (CH)	7.39	0-30	105	350	-	SFO
Sandy loam	Vouvry, Plot 7 (CH)	7.39	0-30	21.5	71.6	-	SFO
Sandy loam	Vouvry, Plot 9 (CH)	7.39	0-30	11.7	214	-	DFOP
Sandy loam (Covered)	Klus (CH)	7.3	0-30	197.2	790	-	HS
Sandy loam (Non covered)	Klus (CH)	7.3	0-30	16.44	269.9	-	DFOP
pH dependence, *Yes or No*		no					

[a] Measured in water when *, other matrix unknown
[b] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7, values are DegT50matrix

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)	Only 3 normalised field data are acceptable, therefore the recommended endpoint is the geomean pool field and lab studies 199.7 d (geomean pool field and lab studies, n=12)	
Rate of degradation in soil transformation products, normalised geometric mean (if not pH dependent)	-	-
Kinetic formation fraction (f. f. k_f / k_{dp}) of transformation products, arithmetic mean	-	

* Only relevant after implementation of the published EFSA guidance describing how to amalgamate laboratory and field endpoints.

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

Soil accumulation and plateau concentration	Plateau concentration calculated (see PECsoil below)

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

Parent	Dark anaerobic conditions					
Soil type	pH[a)]	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C[b)]	St. (χ^2)	Method of calculation
Sandy silt loam, Goole *Kirkpatrick, 1991*	7.9	25 / pF2	- stable	-	-	

Sandy loam, Stein *Minet, 1994a*	7.0	20 / 40 % MWHC	- stable	-	-	
Sand loam, California *Adam, 1998*	7.5	25 / -	- stable	-	-	
Geometric mean (if not pH dependent)						

[a] Measured in [medium to be stated, usually calcium chloride solution or water]
[b] Normalised using a Q10 of 2.58

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

Parent	Soil photolysis				
Soil type	pH[a]	t. °C / soil moisture	DT_{50} / DT_{90} (d) (corrected to natural sunlight at 30-50°N)	χ^2	Method of calculation
Milton, Sandy loam	7.0 (KCl)	25°C / 75% FC	18.8 / 185		DFOP
Somersham, Sandy loam	6.5 (KCl)	20°C / 75% FC	17.3 / 120		DFOP
Madison, Loamy sand	5.4 (water)	25°C / 75% FC	4.6* / 59.1*		DFOP
Gartenacker, Loam	7.56 (water)	20°C / 75% FC	25.8 / 85.3		DFOP

* geomean n=3 results corrected to natural sunlight at 30, 40 and 50° N (respective DT_{50} / DT_{90} : 4.7/59; 4.45/57.6; 4.77/60.6 d)

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

Parent							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Sandy Loam	1.9	6.2			63	3317	0.86
Silt loam	2	6.3			57.7	2884	0.77
Loam	2.1	7.1			54.4	2589	0.86
Loam	2.1	7.7			51.6	2455	0.76
Geometric mean, n=4						2792.6	
Arithmetic mean, n=4							0.81
pH dependence, *Yes or No*			No				

[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)

CGA265378 – Data gap							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
-							
pH dependence, *Yes or No*			-				

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

CGA339833 – Data gap for information on two more soils							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Loam (Niagara)	2.38	6.7			0.055	2.3	1.344
pH dependence, *Yes or No*			-				

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

CGA192155							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Sand (Lakeland)	0.58	5.3			0.25	43.87	0.779
Loam (Collamer)	2.15	6.5			0.27	12.37	0.810
Loam (Niagara)	2.38	6.7			0.29	12.00	0.809
Geometric mean value						**18.67**	
Arithmetic value							**0.799**
pH dependence, *Yes or No*			No				

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

SYN545245 – Data gap							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
-							
pH dependence, *Yes or No*			-				

[a] Measured in calcium chloride

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	Elution (mm): 200 mm Time period (d): 2 d
	Leachate: 0.02-0.1 % total residues/radioactivity in leachate.

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	Elution (mm): 200 mm – 508 mm Time period (d): 2-45 d after 321-32 days of ageing, n= 2.
	Leachate: 0.02-3.6 % total residues/radioactivity in leachate. Radioactivity in leachates not identified.

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	Not required

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

Hydrolytic degradation of the active substance and metabolites > 10 %	pH 5: stable No relevant metabolite
	pH 7: stable No relevant metabolite
	pH 9: stable No relevant metabolite

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

Photolytic degradation of active substance and metabolites above 10 %	DT_{50} : 0.8 experimental days Natural light, 30°N; DT_{50} 0.33 days 40°N; DT_{50} 0.29 days 50°N; DT_{50} 0.43 days No major metabolites were observed
Quantum yield of direct phototransformation in water at Σ > 290 nm	2.6 x 10^{-3} mol · Einstein $^{-1}$

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

Readily biodegradable (yes/no)	No

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

Parent										
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed [a)]	t. °C[b)]	DT_{50} /DT_{90} whole sys. (suspended sediment test)		St. (χ^2)	DT_{50} /DT_{90} Water (pelagic test)		St. (χ^2)	Method of calculation
				At study temp	Normalised to x °C[c)]		At study temp	Normalised to x °C[c)]		
Fresh water (Tuckahoe Lake) Phenyl/Pyrrole 10□g/L	7.0 – 8.5	NA	20	NA	NA	NA	28/92	NA	6.94	SFO
Fresh Water (Tuckahoe Lake) Phenyl/Pyrrole 95□g/L	7.0 – 8.5	NA	20	NA	NA	NA	35/116	NA	7.19	SFO

[a] Measured in [medium to be stated, usually calcium chloride solution or water]
[b] Temperature of incubation=temperature that the environmental media was collected or 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).

Mineralisation and non extractable residues (for parent dosed experiments)

System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed	Mineralisation x % after n d. (end of the study).	Non-extractable residues. max x % after n d (suspended sediment test)	Non-extractable residues. max x % after n d (end of the study) (suspended sediment test)
Fresh water (Tuckahoe Lake) Phenyl/Pyrrole 10□g/L	7.0 – 8.5	NA	1.7 – 2.0% after 60 d	NA	NA
Fresh Water (Tuckahoe Lake) Phenyl/Pyrrole 95□g/L	7.0 – 8.5	NA	1.5 – 3.3% after 60 d	NA	NA

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

Parent	Distribution Dark water/sediment system (max in water 7.4 after 177 d) Irradiated water/sediment system (max in water 0.1 after 100 d. Max. sed 53.5 % after 7 d)										
Water / sediment system	pH water phase	pH sed [a)]	t. °C	DT_{50} /DT_{90} whole sys.		St. (χ^2)	DT_{50} /DT_{90} water	St. (χ^2)	DT_{50} /DT_{90} sed	St. (χ^2)	Method of calculation
				persistence	modelling						
Dark conditions											
River (Rhine)[d]	8.4	7.2	20	442[b]		-	9.97[c]	-	576[b]		SFO

Pond (Tugbach)[d]	8.4	6.9	20	677[b]		-	2.52[c]	-	797[b]		SFO
Geometric mean at 20°C[b)]				**547**							
Irradiated water/sediment system											
River (Rhine)[ef]	7.4-7.5	7.2	20	52.6[g]	34.6	-	7.5[g]	-	64.7[b]		DFOP / SFO
Pond (Fröschweiher)[ef]	7.3-8.0	7.2	20	48.2[g]	30.2	-	3.7[h]	-	55.5[b]		DFOP / SFO
Geometric mean at 20°C[b)]				**50.4**	**32.3**						

[a] Measured in [medium to be stated, usually calcium chloride solution or water]
[b] SFO model
[c] FOMC model
[d] Original degradation rates determined by Gonazalez-Valero (1992) re-evaluated by Pietsch (2015).
[e] Original degradation rates determined by Adam (2004) re-evaluated by Pietsch (2015).
[f] Irradiated system
[g] DFOP model (ln2 / k_{slow})
[h] HS model (ln2 / k_{slow})

Metabolite CGA192155	Max in irradiated total system: 17.3 % AR after 100 days; max in irradiated water: 11.9 % AR after 100 days; max in irradiated sediment: 5.5 % AR after 100 days * kinetic formation fraction (k_f/k_{dp}): Not calculated									
Irradiated water / sediment system	pH water phase	pH sed [a)]	t. °C	DT_{50} /DT_{90} whole sys.	St. (χ^2)	DT_{50} /DT_{90} water	St. (χ^2)	DT_{50} /DT_{90} sed	St. (χ^2)	Method of calculation
River (Rhine)	7.4-7.5	7.2	20	1000[a]		1000[a]		1000[a]		SFO/ DFOP
Pond (Fröschweiher)	7.3-8.0	7.2	20	1000[a]		1000[a]		1000[a]		
Geometric mean at 20°C				1000		1000		1000		

[a]Default value; no decline or insufficient number of data points
*The maximum occurrence of CGA339833 was 3.8% AR in the total water sediment system

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)
River (Rhine)	8.4	7.2	1.6 after 177 days	-	16.8 after 177 days
Pond (Tugbach)	8.4	6.9	1.9 after 177 days	-	14.4 after 177 days
River (Rhine)[a]	7.4-7.5	7.2	6.4 after 100 days	36.5 after 100 days	36.5 after 100 days
Pond (Fröschweiher)[a]	7.3-8.0	7.2	10.4 after 100 days	42.6 after 100 days	42.6 after 100 days

[a] irradiated test system

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

Direct photolysis in air	Not relevant
Photochemical oxidative degradation in air	DT_{50}: 3.6 hours derived by the Atkinson model concentration assumed = $1.5x10^6$ OH radicals/cm^3, 12 h day
Volatilisation	from plant surfaces (BBA guideline): 7 % after 24 hours
	from soil surfaces (BBA guideline): 1.6 % AR after 24 h (indirect method) 0.04 % AR after 24 h (direct method) < 2.6 ng/cm^2/h
Metabolites	No potentially volatile metabolites

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: fludioxonil, unidentified MF2 and soil photolysis metabolites CGA192155, CGA265378, CGA339833, SYN545245 and unidentified D9 (only fludioxonil and unidentified MF2 for seed treatments) Surface water: fludioxonil, CGA192155, CGA265378, CGA339833, SYN545245, unidentified MF2 and unidentified D9 (only fludioxonil, unidentified MF2 and CGA192155for seed treatments) Sediment: fludioxonil and CGA192155 (also fludioxonil and CGA192155 for seed treatments)

Groundwater:	fludioxonil, CGA192155, CGA265378, CGA339833, SYN545245, unidentified MF2 and unidentified D9 (only fludioxonil and unidentified MF2 for seed treatments)
Air:	fludioxonil

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

Soil (indicate location and type of study)	Not required
Surface water (indicate location and type of study)	Not required
Ground water (indicate location and type of study)	Not required
Air (indicate location and type of study)	Not required

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

Parent Method of calculation	DT_{50} (d): k_1= 0.01, k_2= 0.000375, tb= 22.08 Kinetics: HS Field or Lab: Maximum non-normalised laboratory (dark conditions, photolysis not taken into account for seed treatment)
Application data (A8207M)	Crop: wheat (and oats with exposure envelope approach) Depth of soil layer: 20 cm (ultimate application on 5cm) Soil bulk density: 1.5g/cm^3 % plant interception: 0% (Pre-emergence) Number of applications: 1 Interval (d): - Application rate(s): 12.5 g a.s./ha

A8207M – wheat

PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.017			
Short term				
24h	0.017	0.017		
2d	0.017	0.017		
4d	0.017	0.017		
Long term				
7d	0.017	0.017		
28d	0.016	0.016		
50d	0.016	0.016		
100d	0.015	0.016		
Plateau concentration	0.040 mg/kg after 22 yr			

Method of calculation MF2	Molecular weight: 248.2 g/mol (parent value) Maximum % = 7.7 %

PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.001			

Parent Method of calculation	Rate constants (d): k_1= 0.0576, k_2= 0.0027146, tb= 2.87733 Kinetics: HS Field or Lab: Maximum non-normalised field (to include photolysis for spray applications)
Application data (A8240D)	**Crop: vines** Depth of soil layer: 5cm Soil bulk density: 1.5g/cm^3 % plant interception: 60% / 75% Number of applications: 2 Interval (d): 21 Application rate(s): 500 g a.s./ha
	Crop: pome/stone fruits Depth of soil layer: 5cm Soil bulk density: 1.5g/cm^3 % plant interception: 65% Number of applications: 2 Interval (d): 7 Application rate(s): 225 g a.s./ha
	Crop: strawberries Depth of soil layer: 20 cm (ultimate application on 5cm) Soil bulk density: 1.5g/cm^3 % plant interception: 60% Number of applications: 2 Interval (d): 10 Application rate(s): 250 g a.s./ha

A8240D – Vines, Pome/stone, Strawberries

	Vines, Multiple applications		Pome/stone, Multiple applications		Strawberries, Multiple applications	
PEC$_{(s)}$ (mg/kg)	Actual	Time weighted average	Actual	Time weighted average	Actual	Time weighted average
Initial	0.382		0.193		0.244	
Plateau concentration	0.606 mg/kg after 6 yrs		0.300 mg/kg after 6 yrs		0.381 mg/kg after 6 yrs	

Method of calculation Metabolite CGA265378	Molecular weight: 278.2 g/mol DT_{50} (d): 0.21 days Kinetics: FOMC (DT_{90} / 3.32) Field or Lab: representative worst case from lab studies. maximum % = 10.1 %
Metabolite CGA339833	Molecular weight: 312.2 g/mol DT_{50} (d): 15.5 days Kinetics: SFO Field or Lab: representative worst case from lab studies. maximum % = 13.35%
Metabolite CGA192155	Molecular weight: 202.1 g/mol DT_{50} (d): 23.7 days Kinetics: SFO Field or Lab: representative worst case from lab studies. maximum % = 26.95%
Metabolite SYN545245	Molecular weight: 255.2 g/mol DT_{50} (d): 0.67 days Kinetics: SFO Field or Lab: representative worst case from lab studies. maximum % = 29.40 %
MF2	Molecular weight: 248.2 g/mol (parent value) DT_{50} (d): 1000 days Kinetics: SFO

	Field or Lab: default value. maximum % = 7.7 %
D9	Molecular weight: 248.2 g/mol (parent value) DT_{50} (d): 1000 days Kinetics: SFO Field or Lab: default value. maximum % = 7.0 %
Application data	Crop: Grapes (worst representative case) Application rate assumed: 500 g/ha Parent MW = 248.2 g/mol

$PEC_{(s)}$ (mg/kg)	CGA265378	CGA339833	CGA192155	SYN545245	MF2*	D9*
Initial	0.030	0.046	0.068	0.081	0.036	0.030
Plateau concentration	-	-	-	-	-	-

* in view of laboratory studies, no PECaccumulation needed for these metabolites

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) **A8207M**	For FOCUS gw modelling, values used – Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. *Model(s) used*: (FOCUS-PEARL (v 4.4.4), FOCUS-PELMO (v 5.5.3) and FOCUS-MACRO (v5.5.4)) ***Crop*: Spring and Winter Cereals** **Parameters for the active substance** *Crop uptake factor*: 0 *Water solubility* (mg/L) at 25°C: 1.8 *Vapour pressure* (Pa) at 20°C: 0 (worst case assumption) Geometric mean parent DT_{50} (d) 234.1* (geometric mean, normalised to pF2 at 20ºC with Q10 of 2.58, n= 9) K_{FOC}/ K_{FOM} (mL/g) 2792 / 1619 (geometric mean, n= 4) *1/n* 0.81 (arithmetic mean, n= 4) **Parameters for MF2** *Crop uptake factor*: 0 *Water solubility* (mg/L) at 25°C: 1.8 (parent value) *Vapour pressure* (Pa) at 20°C: 0 (worst case assumption) $DT_{50\ lab}$ (d) 1000 (default value) K_{FOC}/ K_{FOM} (mL/g) 0 (default value) *1/n* 1.0 (default value) *Max occurrence : 8.4 %* [a] *Formation fraction* - (metabolite applied calculations, corrected rate of 1.05 g/ha)
Application rate	Gross application rate: 12.5 g/ha. Crop growth stage: Spring and Winter Cereals (Wheat) BBCH 00 (seed treatment) Canopy interception %: 0% Application rate net of interception: 12.5 g/ha. No. of applications: 1 Time of application (relative application dates): 10 days pre-emergence

* The geomean DT_{50} of 199.7 d (field and lab study, n=12) is the recommended EU endpoint.
[a] recommended max occurrence is 7.7%

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

Use	Scenario	FOCUS-PEARL 4.4.4		FOCUS-PELMO 5.5.3		FOCUS-MACRO 5.5.4	
		Parent	MF2	Parent	MF2	Parent	MF2
Spring cereals, 1 x 12.5 g a.s./ha, BBCH 00	Châteaudun	< 0.001	0.761	< 0.001	0.648	< 0.001	0.614
	Hamburg	< 0.001	0.736	< 0.001	0.554		
	Jokioinen	< 0.001	0.802	< 0.001	0.670		
	Kremsmünster	< 0.001	0.384	< 0.001	0.446		
	Okehampton	< 0.001	0.338	< 0.001	0.306		
	Porto	< 0.001	0.303	< 0.001	0.232		
Winter cereals, 1 x 12.5 g a.s./ha, BBCH 00	Chateaudun	< 0.001	1.010	< 0.001	0.970	< 0.001	1.070
	Hamburg	< 0.001	0.650	< 0.001	0.537		
	Jokioinen	< 0.001	0.906	< 0.001	0.751		
	Kremsmunster	< 0.001	0.329	< 0.001	0.393		
	Okehampton	< 0.001	0.314	< 0.001	0.315		
	Piacenza	< 0.001	0.575	< 0.001	0.521		
	Porto	< 0.001	0.289	< 0.001	0.305		
	Sevilla	< 0.001	1.410	< 0.001	0.744		
	Thiva	< 0.001	1.800	< 0.001	0.916		

Method of calculation and type of study (e.g. modelling, field leaching, lysimeter) (for product **A8240D**)	Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. Model(s) used: (FOCUS-PEARL (v 4.4.4), FOCUS-PELMO (v 5.5.3) and FOCUS-MACRO (v5.5.4)) **Crop: Grapes, pome fruit (apples) and strawberries** **fludioxonil** *Crop uptake factor*: 0 *Water solubility* (mg/L): 1.8 at 25°C

Vapour pressure: 0 Pa (worst case assumption) at 20°C
Geometric mean parent DT_{50}: 234.1 d (geometric mean, normalised to pF2 at 20ºC with Q10 of 2.58, n= 9)
K_{FOC}/ K_{FOM} (mL/g): 2792 / 1619 (geometric mean, n=4)
1/n = 0.81 (arithmetic mean, n=4)

Metabolites: **CGA265378**
Molar mass: 278.2 g/mol
Crop uptake factor: 0
Water solubility (mg/L): 120 at 25°C
Vapour pressure: 0 Pa (worst case assumption) at 20°C
Geometric mean $DT_{50\ (lab)}$ 0.11d (geometric mean, normalised to pF2 at 20ºC with Q10 of 2.58, n=3).
Max occurrence: 10.1% [a]
K_{FOC}/ K_{FOM}: 0 (default value)
1/n = 1.00 (default value).

Metabolites: CGA339833
Molar mass: 312.2 g/mol
Crop uptake factor: 0
Water solubility (mg/L): 31000 at 25°C
Vapour pressure: 0 Pa (worst case assumption) at 20°C
Geometric mean $DT_{50\ (lab)}$ 7.88 d (geometric mean, normalised to pF2 at 20ºC with Q10 of 2.58, n=3).
Max occurrence: 13.35% [a]
K_{FOC}/ K_{FOM}: 2.3 / 1.3 mL/g (single acceptable value)
1/n = 1.344 (value corresponding to min Kfoc*)*

Metabolites: CGA192155
Molar mass: 202.1 g/mol
Crop uptake factor: 0
Water solubility (mg/L): 4900 at 25°C
Vapour pressure: 0 Pa (worst case assumption) at 20°C
Geometric mean DT_{50} (d): 18.0d (geometric mean, laboratory, normalised to pF2 at 20ºC with Q10 of 2.58, n=3).
Formation from parent
Max occurrence: 26.95 % [a]
K_{FOC}/ K_{FOM}: 18.7 / 10.8 mL/g (geometric mean, n=3)
1/n = 0.80 (arithmetic mean, n=3)

Metabolites: SYN545245
Molar mass: 255.2 g/mol
Crop uptake factor: 0
Water solubility (mg/L): 1.8 at 25°C (parent value)
Vapour pressure: 0 Pa (worst case assumption) at 20°C
Geometric mean DT_{50}: 0.33d (geometric mean, laboratory, normalised to pF2 at 20ºC with Q10 of 2.58, n=3).
Max occurrence: 29.40 % [a]
K_{FOC}/ K_{FOM}0 (default value)
1/n = 1 (default value)

Metabolites: MF2
Molar mass: 248.2 g/mol (parent value)
Crop uptake factor: 0
Water solubility (mg/L): 1.8 at 25°C (parent value)
Vapour pressure: 0 Pa (worst case assumption) at 20°C
Geometric mean DT_{50}: 1000 d (default value)
Max occurrence: 8.4 % [a, b]
K_{FOC}/ K_{FOM}: 0 (default value)
1/n = 1 (default value)

Metabolites: D9
Molar mass: 248.2 g/mol (parent value)
Crop uptake factor: 0
Water solubility (mg/L): 1.8 at 25°C (parent value)
Vapour pressure: 0 Pa (worst case assumption) at 20°C
Geometric mean DT_{50}: 1000 d (default value)

	Max occurrence: 6.9 % [a, c] K_{FOC}/ K_{FOM}: 0 (default value) *1/n* = 1 (default value)
Application rate: (for product A8240D)	Gross application rate of fludioxonil: Grapes = 2 x 500 g/ha (interval 21 d) pome fruit (apples) = 2 x 225 g/ha (interval 7 d) strawberries = 2 x 250 g/ha (interval 10 d) Gross application rate of CGA265378: [a] Grapes = 61.6 g/ha, pome fruit (apples) = 27.7 g/ha, strawberries = 30.8 g/ha Gross application rate of CGA339833: [a] Grapes = 84.0 g/ha, pome fruit (apples) = 37.8 g/ha, strawberries = 42.0 g/ha Gross application rate of CGA192155: [a] Grapes = 109.7 g/ha, pome fruit (apples) = 9.4 g/ha, strawberries = 54.9 g/ha Gross application rate of SYN545245: [a] Grapes = 151.1 g/ha, pome fruit (apples) = 68.0 g/ha, strawberries = 75.6 g/ha Canopy interception (%): Grapes = 60 / 75 % (BBCH 67-69 / 85-89 [d]) pome fruit (apples) = 65 / 65 (BBCH 74-89) strawberries = 60 / 60 (BBCH 61-89) Time of application (absolute or relative application dates): relative

[a] max occurrence (%), used to calculate the application rate for metabolites, along with a molar correction factor
[b] max occurrence for MF2 is 7.7%
[c] max occurrence for D9 is 7.0%
[d] the first application is intended to take place at flowering (BBCH 67-69), while the second application takes place at fruit ripening (BBCH 85-89)

Table 0-1: Application dates used in the modelling

Crop	Scenario	Application dates (absolute)	
		1st Application	2nd Application
Vine Use No.1 BBCH 67 as 1st and BBCH 85 as 2nd appl (AppDate v2.0b)	Châteaudun	22-Aug (234)	17-Oct (290)
	Hamburg	1-Aug (213)	1-Oct (274)
	Kremsmünster	1-Aug (213)	1-Oct (274)
	Piacenza	22-Aug (234)	17-Oct (290)
	Porto	14-Aug (226)	20-Sep (263)
	Sevilla	24-Jul (205)	2-Nov (306)
	Thiva	26-Jul (207)	2-Oct (275)
Apple Use No.2 BBCH 74 as 1st appl., 7 day interval (AppDate v2.0b)	Châteaudun	27-Jul (208)	3-Aug (215)
	Hamburg	6-Jul (187)	13-Jul (194)
	Jokioinen	31-Jul (212)	7-Aug (219)
	Kremsmünster	6-Jul (187)	13-Jul (194)
	Okehampton	28-Jul (209)	4-Aug (216)
	Piacenza	11-Aug (223)	18-Aug (230)
	Porto	26-Aug (238)	2-Sep (245)
	Sevilla	3-Aug (215)	10-Aug (222)
	Thiva	21-Aug (233)	28-Aug (240)
Strawberry Use No.3 BBCH 61 as 1st appl., 10 day interval (AppDate v2.0b)	Hamburg	2-May (122)	12-May (132)
	Jokioinen	27-Jun (178)	7-Jul (188)
	Kremsmünster	2-May (122)	12-May (132)
	Sevilla	3-May (123)	13-May (133)

Numbers in brackets are the corresponding 'Julian Day' numbers
Application dates in grey boxes are not considered as representative of the intended use. The recommended application date for calculation is 21 days after the first application date (intended GAP).
For CGA339833, PECgw after applications on vines were performed considering the same 1st application date and a 2nd application date 21 days after the first one.

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

	Scenario	Parent (µg/L)	Metabolites (µg/L)					
			CGA265378	CGA339833	CGA192155	SYN545245	MF2	D9
FOCUS PEARL 4.4.4 Vines	Chateaudun	< 0.001	< 0.001	0.665	0.077	< 0.001	11.4	9.38
	Hamburg	< 0.001	< 0.001	3.213	0.225	< 0.001	9.85	8.09
	Kremsmunster	< 0.001	< 0.001	1.222	0.089	< 0.001	6.5	5.34
	Piacenza	< 0.001	< 0.001	1.246	0.262	< 0.001	13.8	11.3
	Porto	< 0.001	< 0.001	0.729	0.144	< 0.001	5.1	4.19
	Sevilla	< 0.001	< 0.001	0.555	0.047	< 0.001	11.1	9.08
	Thiva	< 0.001	< 0.001	0.622	0.015	< 0.001	26.6	21.8
FOCUS PELMO 5.5.3 Vines	Chateaudun	< 0.001	< 0.001	0.334	0.050	< 0.001	12.5	10.3
	Hamburg	< 0.001	< 0.001	1.113	0.210	< 0.001	12.3	10.1
	Kremsmunster	< 0.001	< 0.001	0.598	0.096	< 0.001	7.77	6.38
	Piacenza	< 0.001	< 0.001	0.632	0.392	< 0.001	7.72	6.34
	Porto	< 0.001	< 0.001	0.474	0.223	< 0.001	5.8	4.77
	Sevilla	< 0.001	< 0.001	0.010	0.033	< 0.001	24.7	20.3
	Thiva	< 0.001	< 0.001	0.005	0.014	< 0.001	28.8	23.6
FOCUS MACRO 5.5.4 - Vines	Chateaudun	< 0.001	< 0.001	-	0.026	< 0.001	15.1	12.4

	Scenario	Parent (µg/L)	Metabolites (µg/L)					
			CGA265378	CGA339833	CGA192155	SYN545245	MF2	D9
FOCUS PEARL 4.4.4 Pome/stone fruits	Chateaudun	< 0.001	< 0.001	0.304	0.016	< 0.001	7.07	5.81
	Hamburg	< 0.001	< 0.001	2.652	0.060	< 0.001	13	10.7
	Jokioinen	< 0.001	< 0.001	3.391	0.015	< 0.001	13.5	11.1
	Kremsmunster	< 0.001	< 0.001	0.486	0.021	< 0.001	5.08	4.18
	Okehampton	< 0.001	< 0.001	1.109	0.038	< 0.001	4.68	3.84
	Piacenza	< 0.001	< 0.001	0.382	0.074	< 0.001	7.46	6.13
	Porto	< 0.001	< 0.001	0.792	0.044	< 0.001	2.76	2.27
	Sevilla	< 0.001	< 0.001	0.149	0.012	< 0.001	9.25	7.60
	Thiva	< 0.001	< 0.001	0.049	0.008	< 0.001	14.8	12.1
FOCUS PELMO 5.5.3 Apple	Chateaudun	< 0.001	< 0.001	0.114	0.006	< 0.001	7.17	5.89
	Hamburg	< 0.001	< 0.001	1.857	0.029	< 0.001	7.53	6.18
	Jokioinen	< 0.001	< 0.001	4.016	0.016	< 0.001	9.29	7.63
	Kremsmunster	< 0.001	< 0.001	0.969	0.022	< 0.001	6.02	4.95
	Okehampton	< 0.001	< 0.001	0.307	0.041	< 0.001	4.54	3.73
	Piacenza	< 0.001	< 0.001	0.853	0.106	< 0.001	3.63	2.98
	Porto	< 0.001	< 0.001	0.568	0.052	< 0.001	2.48	2.03
	Sevilla	< 0.001	< 0.001	0.068	< 0.001	< 0.001	21.6	17.8
	Thiva	< 0.001	< 0.001	0.131	0.001	< 0.001	14.8	12.2
FOCUS MACRO 5.5.4 - Apple	Chateaudun	< 0.001	< 0.001	-	< 0.001	< 0.001	20.2	16.6

	Scenario	Parent (µg/L)	Metabolites (µg/L)					
			CGA265378	CGA339833	CGA192155	SYN545245	MF2	D9
FOCUS PEARL 4.4.4	Hamburg	< 0.001	< 0.001	1.984	0.019	< 0.001	11.1	9.10
	Jokioinen	< 0.001	< 0.001	3.356	0.004	< 0.001	10.2	8.42
	Kremsmunster	< 0.001	< 0.001	0.528	0.013	< 0.001	5.9	4.84
	Sevilla	< 0.001	< 0.001	0.012	< 0.001	< 0.001	17.9	14.7
FOCUS PELMO 5.5.3	Hamburg	< 0.001	< 0.001	0.306	0.013	< 0.001	7.86	6.46
	Jokioinen	< 0.001	< 0.001	1.592	0.003	< 0.001	9.21	7.57
	Kremsmunster	< 0.001	< 0.001	0.196	0.013	< 0.001	6.66	5.47
	Sevilla	< 0.001	< 0.001	0.001	< 0.001	< 0.001	6.72	5.52

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

Parent Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: Step 1-2 (v 3.2) Molecular weight (g/mol): 248.2 K_{OC}/K_{OM} (mL/g): 2792 *(geomean, n=4)* DT_{50} soil (d): *234.1 days (geomean normalized lab, n=9)** DT_{50} water/sediment/system (d): *547 d (geomean dark sediment water studies n=2)*
Parameters used in FOCUSsw step 3 (if performed)	Version control no.'s of FOCUS software: SWASH (v 5.3; with FOCUS-MACRO (v 5.5.4), FOCUS-PRZM (v 4.3.1) and FOCUS-TOXSWA (v 4.4.3)). ECPA tool SWAN (v 4.0.1). Water solubility (mg/L): 1.8 Vapour pressure: *0.* Pa at 20°C (worst case) 1/n: 0.81 DT_{50} water (d): 1000 DT_{50} sediment (d): 547 Crop uptake factor: 0
Application rate **A8207M**	Crop and growth stage: spring and winter cereals BBCH 00 Number of applications: *1 (seed treatment)* Interval (d): - Application rate(s): *12.5* g a.s./ha Application window: *Oct-Feb* Crop interception (%): *0 % (no interception)*
Application rate **A8240D**	Crop and growth stage: vines, late applications BBCH 67-69 / 85-89 Number of applications: *2* Interval (d): *21* Application rate(s): *500* g a.s./ha Application window: *Oct-Feb (STEP 1-2), see below for STEP 3-4* Crop interception (%): *full canopy*
	Crop and growth stage: pome fruit, late applications BBCH 74-89 Number of applications: *2* Interval (d): *7* Application rate(s): *225* g a.s./ha Application window: *Oct-Feb (STEP 1-2), see below for STEP 3-4* Crop interception (%): *full canopy*
	Crop and growth stage: fruiting vegetables (strawberries), BBCH 61-89 Number of applications: *2* Interval (d): *10* Application rate(s): *250* g a.s./ha Application window: *Oct-Feb (STEP 1-2), see below for STEP 3-4* Crop interception (%): *full canopy*
	Crop and growth stage: Protected strawberries Number of applications: *1* Interval (d): - Application rate(s): *500* g a.s./ha Application window: *Oct-Feb* Crop interception (%): *full canopy*

* the recommended DT_{50} value is 199.7 d, geomean normalized lab and field studies, n=12

Application windows for STEP 3-4 modelling

Crop	Scenario	Start of Window	End of Window
Vine (late application) BBCH 67	D6	22-Jul (203)	11-Sep (254)
	R1	29-Jul (210)	18-Sep (261)
	R2 [a]	20-Jul (201)	9-Sep (252)
	R3	22-Aug (234)	12-Oct (285)

Crop	Scenario	Start of Window	End of Window
	R4 [a]	10-Jul (191)	30-Aug (242)
Vine (late application) Harvest - PHI	D6	30-Aug (242)	20-Oct (293)
	R1	19-Aug (231)	9-Oct (282)
	R2	20-Jul (201)	9-Sep (252)
	R3	21-Aug (233)	11-Oct (284)
	R4	10-Jul (191)	30-Aug (242)
Pome/stone fruit (late application)	D3	26-Aug (238)	2-Oct (275)
	D4	29-Aug (241)	5-Oct (278)
	D5	18-Aug (230)	24-Sep (267)
	R1	26-Aug (238)	2-Oct (275)
	R2 [a]	20-Aug (233)	27-Sep (270)
	R3	3-Aug (215)	9-Sep (252)
	R4	3-Aug (215)	9-Sep (252)
Vegetables, fruiting	D6	1-Jun (152)	11-Jul (192)
	R2	18-Jun (169)	28-Jul (209)
	R3	2-Jul (183)	11-Aug (223)
	R4 [a]	2-Jun (153)	12-Jul (193)

[a] Window chosen to end at harvest – pre-harvest interval.
Numbers in brackets are the corresponding 'Julian Day' numbers

FOCUS Step 1-2 Global Maximum PECsw and PECsed for fludioxonil

Crop	Scenario	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)
		Actual	TWA	
Cereals	STEP 1	0.882		24.6
	STEP 2 North EU (Oct-Feb)	0.436	0.430	12.2
	STEP 2 South EU (Oct-Feb)	0.349	0.344	9.74
Vines, late applications	STEP 1	97.3		2130
	STEP 2 North EU (Oct-Feb)	20.3 (13.4)	18.3 (9.15)	515 (273)
	STEP 2 South EU (Oct-Feb)	17.6 (13.4)	15.6 (8.00)	439 (234)
Pome/stone fruits, late applications	STEP 1	55.3		1020
	STEP 2 North EU (Oct-Feb)	11.7 (11.8)	8.82 (5.26)	258 (146)
	STEP 2 South EU (Oct-Feb)	11.7 (11.8)	7.93 (4.81)	228 (131)
Strawberries	STEP 1	39.9		1010
	STEP 2 North EU (Oct-Feb)	6.32 (3.28)	5.93 (3.06)	167 (86.4)
	STEP 2 South EU (Oct-Feb)	5.28 (2.76)	4.92 (2.55)	139 (71.9)

Single applications are presented in brackets

FOCUS Step 3 Global Maximum PECsw and PECsed for fludioxonil

Application	Scenario	PECsw (µg/L)	PECsed (µg/kg)	Entry Route	PECsw (µg/L)	PECsed (µg/kg)	Entry Route
		Single application			Multiple application		
Vine (late application) BBCH 67	D6 d	**8.54**	24.2	drift	**7.86**	34.5	drift
	R1 p	0.312	3.47	drift	0.428	6.02	drift
	R1 s	**6.09**	0.723	drift	**5.52**	1.42	drift
	R2 s	**8.39**	3.87	drift	**7.40**	6.77	drift
	R3 s	**8.83**	9.17	drift	**7.79**	18.0	drift
	R4 s	**6.26**	2.48	drift	**5.52**	5.38	drift
Vine (late application) Harvest - PHI	D6 d	**8.54**	24.3	drift	**7.84**	34.7	drift
	R1 p	0.309	3.54	drift	0.410	6.09	drift
	R1 s	**6.26**	1.19	drift	**5.52**	1.53	drift
	R2 s	**8.39**	3.87	drift	**7.40**	6.77	drift
	R3 s	**8.83**	9.17	drift	**7.79**	18.0	drift
	R4 s	**6.26**	2.48	drift	**5.52**	5.38	drift

Application	Scenario	PEC_{SW} (µg/L)	PEC_{SED} (µg/kg)	Entry Route	PEC_{SW} (µg/L)	PEC_{SED} (µg/kg)	Entry Route
		Single application			Multiple application		
Pome/stone fruit (late application) BBCH 74	D3 d	**8.23**	9.71	drift	**6.55**	15.8	drift
	D4p	0.367	4.30	drift	0.525	7.05	drift
	D4s	**7.94**	0.712	drift	**6.37**	0.977	drift
	D5p	0.367	4.71	drift	0.557	7.70	drift
	D5s	**8.91**	2.53	drift	**7.13**	3.55	drift
	R1p	0.37	4.11	drift	0.558	6.70	drift
	R1s	**6.31**	1.12	drift	**5.06**	1.64	drift
	R2s	**8.46**	3.67	drift	**6.78**	6.19	drift
	R3s	**8.90**	2.89	drift	**7.13**	5.54	drift
	R4s	**6.31**	1.82	drift	**5.06**	3.92	drift

Application	Scenario	PEC_{SW} (µg/L)	PEC_{SED} (µg/kg)	Entry Route	PEC_{SW} (µg/L)	PEC_{SED} (µg/kg)	Entry Route
		Single application			Multiple application		
Vegetables, fruiting	D3 d	1.56	0.708	drift	1.37	0.972	drift
	R2s	1.40	67.6	drift	1.21	109	drift
	R3s	1.47	22.6	drift	1.27	43.6	drift
	R4s	1.04	9.50	drift	1.49	19.6	run-off

FOCUS Step 4 Global Maximum PEC_{sw} for fludioxonil

Application	Nozzle reduction	**PECsw (µg/L)**	**STEP 4 –Single application**				**STEP 4 –Multiple applications**						
		Vegetative strip (m)	None				None						10
		No spray buffer (m)	0	5	10	15	0	5	10	15	20	30	10
Vines, late applications BBCH 67	None	D6 d		5.160	1.870	1.200		4.730	1.690				–
		R1 p		0.360				0.496					
		R1 s		4.430	1.600			4.010	1.440				
		R2 s		6.110	2.210	0.506		5.380	1.930	1.040			
		R3 s		6.430	2.330	0.075		5.660	2.030	1.450			
		R4 s		4.560	1.650			4.010	2.180	2.180	2.180	2.180	1.440
	50%	D6 d	4.04	2.580	0.932		3.84	2.360	0.845				–
		R1 p	0.146	0.185			0.176	0.253					
		R1 s	2.88	2.220	0.801		2.61	2.000	0.962				
		R2 s	3.97	3.050	1.110		3.50	2.690	0.964				
		R3 s	4.17	3.210	1.160		3.68	2.830	1.450				
		R4 s	2.96	2.280	0.980		2.61	2.180	2.180	2.180	2.180	2.180	0.973

	75%	D6 d	2.02	1.290			1.92	1.180					
		R1 p	0.074	0.097			0.090	0.133					
		R1 s	1.44	1.110			1.31	1.000					
		R2 s	1.99	1.530			1.75	1.340					
		R3 s	2.09	1.600			1.84	1.450					
		R4 s	1.48	1.140			1.31	2.180	2.180	2.180	2.180	2.180	0.973
	90%	D6 d	0.808	0.514			0.769	0.617					
		R1 p	0.031	0.044			0.038	0.061					
		R1 s	0.576	0.497			0.523	0.962					
		R2 s	0.794	0.609			0.701	0.536					
		R3 s	0.835	0.641			0.737	1.450					
		R4 s	0.592	0.980			0.523	2.180	2.180	2.180	2.180	2.180	0.973

Application	Nozzle reduction	**PECsw (µg/L)**	**STEP 4 –Single application**				**STEP 4 –Multiple applications**						
		Vegetative strip (m)	None				None						10
		No spray buffer (m)	0	5	10	15	0	5	10	15	20	30	10
Vines, late applications Harvest - PHI	None	D6 d		5.160	1.870	1.010		4.720	2.040	2.040	2.040	2.040	-
		R1 p		0.358				0.476					
		R1 s		4.560	1.650			4.010	1.440				
		R2 s		6.110	2.210	1.200		5.380	1.930	1.040			
		R3 s		6.430	2.330	1.260		5.660	2.030	1.450			
		R4 s		4.560	1.650			4.010	2.180	2.180	2.180	2.180	1.440
	50%	D6 d	4.04	2.580	0.932		3.83	2.360	2.040	2.040	2.040	2.040	
		R1 p	0.145	0.182			0.171	0.241					
		R1 s	2.96	2.280			2.61	2.000	0.900				
		R2 s	3.97	3.050	1.110		3.50	2.690	0.964				
		R3 s	4.17	3.210	1.160		3.68	2.830	1.450				
		R4 s	2.96	2.280			2.61	2.180	2.180	2.180	2.180	2.180	0.973
	75%	D6 d	2.02	1.290			1.91	2.040	2.040	2.040	2.040	2.040	
		R1 p	0.073	0.095			0.086	0.124					
		R1 s	1.48	1.140			1.31	1.000					
		R2 s	1.99	1.530			1.75	1.340					
		R3 s	2.09	1.600			1.84	1.450					
		R4 s	1.48	1.140			1.31	2.180	2.180	2.180	2.180	2.180	0.973
	90%	D6 d	0.808	0.781			0.766	2.040	2.040	2.040	2.040	2.040	
		R1 p	0.030	0.042			0.036	0.056					
		R1 s	0.592	0.454			0.523	0.900					
		R2 s	0.794	0.609			0.701	0.536					
		R3 s	0.835	0.641			0.737	1.450					
		R4 s	0.592	0.980			0.523	2.180	2.180	2.180	2.180	2.180	0.973

Application	Nozzle reduction	**PECsw (µg/L)**	**STEP 4 –Single application**				**STEP 4 –Multiple applications**			
		Vegetative strip (m)	None				None			
		No spray buffer (m)	0	5	10	15	0	5	10	15
Pome/stone fruits, late applications	None	D3 d		5.550	2.480	1.250		4.550	2.190	1.070
		D4 p		0.420				0.600		
		D4 s		6.200	2.770	1.400		5.060	2.430	1.190
		D5 p		0.420				0.636		
		D5 s		6.950	3.100	1.570		5.680	2.720	1.330
		R1 p		0.423				0.636		
		R1 s		4.930	2.200	1.110		4.020	1.930	0.944
		R2 s		6.610	2.950	1.490		5.390	2.590	1.270
		R3 s		6.950	3.100	1.570		5.670	2.720	1.330
		R4 s		4.930	2.200	1.110		4.020	1.930	1.220
	50%	D3 d	3.89	2.770	1.240		3.11	2.280	1.090	
		D4 p	0.174	0.210			0.217	0.298		
		D4 s	3.76	3.100	1.380		3.01	2.530	1.210	
		D5 p	0.174	0.210			0.229	0.318		
		D5 s	4.21	3.470	1.550		3.38	2.840	1.360	
		R1 p	0.175	0.213			0.229	0.321		

		R1 s	2.99	2.460	1.100		2.39	2.010	0.964	
		R2 s	4.00	3.300	1.470		3.21	2.690	1.290	
		R3 s	4.21	3.470	1.550		3.37	2.830	1.360	
		R4 s	2.99	2.460	1.100		2.39	2.010	1.220	
	75%	D3 d	1.95	1.390			1.56	1.140		
		D4 p	0.087	0.105			0.108	0.148		
		D4 s	1.88	1.550			1.51	1.260		
		D5 p	0.087	0.105			0.115	0.159		
		D5 s	2.11	1.740			1.69	1.420		
		R1 p	0.088	0.108			0.115	0.164		
		R1 s	1.49	1.230			1.20	1.000		
		R2 s	2.00	1.650			1.60	1.350		
		R3 s	2.11	1.730			1.69	1.420		
		R4 s	1.49	1.230			1.20	1.220		
	90%	D3 d	0.778	0.553			0.622	0.454		
		D4 p	0.035	0.042			0.043	0.059		
		D4 s	0.752	0.618			0.603	0.505		
		D5 p	0.035	0.042			0.046	0.063		
		D5 s	0.843	0.693			0.676	0.566		
		R1 p	0.036	0.045			0.047	0.070		
		R1 s	0.598	0.491			0.479	0.500		
		R2 s	0.801	0.659			0.641	0.538		
		R3 s	0.842	0.693			0.675	0.565		
		R4 s	0.598	0.491			0.479	1.220		

Metabolites

CGA192155 Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: Molecular weight (g/mol): 202.1 Water solubility (mg/L): 4900 at 25ºC K_{OC}/K_{OM} (mL/g): 18.67 (geomean, n=3) DT_{50} soil (d): 18.0 d (geometric mean, laboratory, n=3) DT_{50} water/sediment system (d): 1000 (default value) Maximum occurrence observed Total Water and Sediment: 17.3% AR (irradiated system) Soil: 26.95 % (laboratory, soil photolysis)
Application rate A8207M	See parent
Application rate A8240D	See parent

Crop	Scenario	PEC_{SW} (µg/L)	PEC_{SED} (µg/kg)
Cereals	STEP 1	0.573	0.107
	STEP 2 North EU (Oct-Feb)	0.283	0.053
	STEP 2 South EU (Oct-Feb)	0.226	0.042
Vines, late applications	STEP 1	121	22.5
	STEP 2 North EU (Oct-Feb)	20.9 (12.5)	3.89 (2.33)
	STEP 2 South EU (Oct-Feb)	17.4 (10.4)	3.23 (1.93)
Pome/stone fruits, late applications	STEP 1	56.1	10.4
	STEP 2 North EU (Oct-Feb)	10.3 (5.82)	1.92 (1.08)
	STEP 2 South EU (Oct-Feb)	8.73 (4.98)	1.63 (0.93)
Strawberries	STEP 1	59.2	11.0
	STEP 2 North EU (Oct-Feb)	7.76 (4.31)	1.45 (0.80)
	STEP 2 South EU (Oct-Feb)	6.32 (3.51)	1.18 (0.66)

Single applications are presented in brackets

MF2 Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: Step 1-2 (v 3.2) Molecular weight (g/mol): 248.2 (parent value) Water solubility (mg/L): 1.8 (25°C, Parent Value) K_{OC}/K_{OM} (mL/g): 0 (Default value for conservative PECsw) DT_{50} soil (d): 1000 (default value) DT_{50} water/sediment system (d): 1000 (default value) Maximum occurrence observed Total Water and Sediment: 0% AR Soil: 8.4% AR
Application rate A8207M	See parent
Application rate A8240D	See parent

Crop	Scenario	PEC_{SW} (µg/L)	PEC_{SED} (µg/kg)
Cereals	STEP 1	0.350	<0.001
	STEP 2 North EU (Oct-Feb)	0.175	<0.001
	STEP 2 South EU (Oct-Feb)	0.140	<0.001
Vines, late applications	STEP 1	28.0	<0.001
	STEP 2 North EU (Oct-Feb)	5.54 (2.79)	< 0.001 (<0.001)
	STEP 2 South EU (Oct-Feb)	4.44 (2.23)	< 0.001 (<0.001)
Pome/stone fruits, late applications	STEP 1	12.6	<0.001
	STEP 2 North EU (Oct-Feb)	2.19 (1.10)	< 0.001 (<0.001)
	STEP 2 South EU (Oct-Feb)	1.75 (0.88)	< 0.001 (<0.001)
Strawberries	STEP 1	14.0	<0.001
	STEP 2 North EU (Oct-Feb)	2.09 (1.05)	< 0.001 (<0.001)
	STEP 2 South EU (Oct-Feb)	1.67 (0.84)	< 0.001 (<0.001)

Single applications are presented in brackets

CGA265378
Parameters used in FOCUSsw step 1 and 2

Version control no. of FOCUS calculator: Step 1-2 (v 3.2) Molecular weight (g/mol): 278.2 Water solubility (mg/L): 120 (25°C) K_{OC}/K_{OM} (mL/g): 0 (Default value for conservative PECsw) DT_{50} soil (d): 0.11 d (geometric mean, laboratory, n=3) DT_{50} water/sediment system (d): 1000 (default value) Maximum occurrence observed Total Water and Sediment: 0% AR Soil: 10.1 % AR (soil photolysis study)
See parent

Application rate A8240D

Crop	Scenario	PEC_{SW} (µg/L)	PEC_{SED} (µg/kg)
Vines, late applications	STEP 1	41.1	<0.001
	STEP 2 North EU (Oct-Feb)	< 0.001 (< 0.001)	< 0.001 (< 0.001)
	STEP 2 South EU (Oct-Feb)	< 0.001 (< 0.001)	< 0.001 (< 0.001)
Pome/stone fruits, late applications	STEP 1	18.5	<0.001
	STEP 2 North EU (Oct-Feb)	< 0.001 (< 0.001)	< 0.001 (< 0.001)
	STEP 2 South EU (Oct-Feb)	< 0.001 (< 0.001)	< 0.001 (< 0.001)
Strawberries	STEP 1	20.5	<0.001
	STEP 2 North EU (Oct-Feb)	< 0.001 (< 0.001)	< 0.001 (< 0.001)
	STEP 2 South EU (Oct-Feb)	< 0.001 (< 0.001)	< 0.001 (< 0.001)

Single applications are presented in brackets

CGA339833
Parameters used in FOCUSsw step 1 and 2

Version control no. of FOCUS calculator: Step 1-2 (v 3.2) Molecular weight (g/mol): 312.2 Water solubility (mg/L): 31000 at 25ºC K_{OC}/K_{OM} (mL/g): 2.3 (n=1) DT_{50} soil (d): 7.88 d (geometric mean, laboratory, n=3) DT_{50} water/sediment system (d): 1000 (default value) Maximum occurrence observed Total Water and Sediment: 3.8 % (irradiated system) Soil: 13.4 % AR (soil photolysis study)
See parent

Application rate A8240D

Crop	Scenario	PEC_{SW} (µg/L)	PEC_{SED} (µg/kg)
Vines, late applications	STEP 1	73.0	1.68
	STEP 2 North EU (Oct-Feb)	8.71 (6.13)	0.200 (0.141)
	STEP 2 South EU (Oct-Feb)	7.19 (5.03)	0.165 (0.116)
Pome/stone fruits, late applications	STEP 1	33.4	0.767
	STEP 2 North EU (Oct-Feb)	4.47 (2.72)	0.103 (0.063)
	STEP 2 South EU (Oct-Feb)	3.75 (2.29)	0.086 (0.053)
Strawberries	STEP 1	36.1	0.829
	STEP 2 North EU (Oct-Feb)	3.44 (2.17)	0.079 (0.050)
	STEP 2 South EU (Oct-Feb)	2.79 (1.76)	0.064 (0.040)

Single applications are presented in brackets

SYN545245
Parameters used in FOCUSsw step 1 and 2

Version control no. of FOCUS calculator: Step 1-2 (v 3.2) Molecular weight (g/mol): 255.2 Water solubility (mg/L): 1.8 at 25ºC (Parent value) K_{OC}/K_{OM} (mL/g): 0 (Default value for conservative PECsw) DT_{50} soil (d): 0.33 d (geometric mean, laboratory, n=3) DT_{50} water/sediment system (d): 1000 (default value) Maximum occurrence observed Total Water and Sediment: 0 % Soil: 29.4 % AR (soil photolysis study)
See parent

Application rate A8240D

Crop	Scenario	PEC_{SW} (µg/L)	PEC_{SED} (µg/kg)
Vines, late applications	STEP 1	101	< 0.001
	STEP 2 North EU (Oct-Feb)	0.002 (0.002)	< 0.001 (<0.001)
	STEP 2 South EU (Oct-Feb)	0.002 (0.002)	< 0.001 (<0.001)
Pome/stone fruits, late applications	STEP 1	45.3	< 0.001
	STEP 2 North EU (Oct-Feb)	0.001 (0.001)	< 0.001 (<0.001)
	STEP 2 South EU (Oct-Feb)	0.001 (0.001)	< 0.001 (<0.001)
Strawberries	STEP 1	50.4	< 0.001
	STEP 2 North EU (Oct-Feb)	0.001 (0.001)	< 0.001 (<0.001)
	STEP 2 South EU (Oct-Feb)	0.001 (0.001)	< 0.001 (<0.001)

Single applications are presented in brackets

D9
Parameters used in FOCUSsw step 1 and 2

Version control no. of FOCUS calculator: Step 1-2 (v 3.2) Molecular weight (g/mol): 248.2 (parent value) Water solubility (mg/L): 1.8 at 25ºC (Parent value) K_{OC}/K_{OM} (mL/g): 0 (Default value for conservative PECsw) DT_{50} soil (d): 1000 d (default value) DT_{50} water/sediment system (d): 1000 (default value) Maximum occurrence observed Total Water and Sediment: 0 % Soil: 6.9 % AR (soil photolysis study)
See parent

Application rate A8240D

Crop	Scenario	PEC_{SW} (µg/L)	PEC_{SED} (µg/kg)
Vines, late applications	STEP 1	23.0	<0.001
	STEP 2 North EU (Oct-Feb)	4.55 (2.29)	< 0.001 (<0.001)
	STEP 2 South EU (Oct-Feb)	3.64 (1.83)	< 0.001 (<0.001)
Pome/stone fruits, late applications	STEP 1	10.4	<0.001
	STEP 2 North EU (Oct-Feb)	1.80 (0.90)	< 0.001 (<0.001)
	STEP 2 South EU (Oct-Feb)	1.44 (0.72)	< 0.001 (<0.001)
Strawberries	STEP 1	11.5	<0.001
	STEP 2 North EU (Oct-Feb)	1.74 (0.86)	< 0.001 (<0.001)
	STEP 2 South EU (Oct-Feb)	1.37 (0.69)	< 0.001 (<0.001)

Single applications are presented in brackets

Overall maximum PECsed accumulation for all uses for fludioxonil

The Scientific Opinion on the effect assessment for pesticides on sediment organisms in edge-of-field surface water (EFSA Journal 2015;13(7):4176) recommends calculating the accumulation of active substances in sediment with the following formula:

$$PEC_{sed,accu} = PEC_{sed,FOCUS} + PEC_{sed,max,FOCUS}\frac{X}{1-X}$$

$$X = \exp\left(-\frac{365\ln(2)\,f}{DegT50}\right) \qquad f = \exp\left(\frac{-E}{R}\left[\frac{1}{T_{arr,scen}+273.15}-\frac{1}{T_0+273.15}\right]\right)$$

With

PECsed,accu: predicted sediment concentration including accumulation (µg/kg)
PECsed,FOCUS: predicted concentration in sediment according to FOCUS (µg/kg)
PECsed,max,FOCUS: maximum concentration in sediment according to FOCUS (µg/kg)
f: temperature correction factor (–)
DegT50 water/sediment system: degradation in water/sediment at reference temperature (days)
Tarr,scen: Arrhenius-weighted average concentration of the scenario (°C)
T_0: Reference temperature during the degradation study (20 °C)
E: Arrhenius activation energy, (kJ/mol)
R: Gas constant (kJ/mol/K)

Crop	Scenario	Waterbody	Max PECsed	PEC,sed,accu
Cereals seed treatment – STEP 2	North	-	12.2	78.3
Vine (late application) BBCH 67 – STEP 3	D6	ditch	34.5	107
Vine (late application) Harvest – PHI – STEP 3	D6	ditch	34.7	108
Pome/stone fruit BBCH 74– STEP 3	D3	ditch	15.8	78.9
Fruiting vegetables BBCH 61 – STEP 3	R2	stream	109	414

Overall maximum initial PEC_{SW} of CGA192155 following application of A8240D to protected strawberries – GEM soil-less scenarios

Input parameters related to application for PEC_{sw} calculation in GEM

Crop	Strawberries
Application rate (g as/ha)	250
Number of applications/interval (d)	2 / 10
Application method	Foliar spray application
Model used for calculation	Greenhouse Emission Model v3.3.2
Cultivation –Assessment type	Soilless – surface water
Nutrient emission reference period	2015-2017 (without - filter water reused) 2015-2017 (filter water reused)
Manage appication with regard to discharge + minimal interval between application and discharge (d)	No – 0 d (without - filter water reused) Yes – 3 d (filter water reused)

Application selected within GEM for PEC_{sw} of fludioxonil

Crop / emission scenario	Month of application simulated	Date of first simulated application	Date of second simulated application
Strawberries (2015-2017; filter water not reused)	November	1/11	10/11
	March	1/3	11/3
	August	1/8	11/8
Strawberries (2015-2017; filter water not reused)	November	1/11	10/11
	March	4/3	14/3
	August	2/8	12/8

Input parameters related to **fludioxonil and CGA192155** for $PEC_{sw/sed}$ calculations

Parameter	Substance	Remarks
fludioxonil		
Molecular weight (g/mol)	248.2	-
Water solubility at 25ºC (g/L)	1.80	
Vapour pressure at 25ºC (Pa)	3.9×10^{-7}	
Octanol-water partitioning coefficient (-)	Log Pow = 4.12	
K_{FOC} (mL/g)	80341	Geometric mean (n = 5)
K_{FOM} (mL/g)	46601	Calculated $K_{FOM} = K_{FOC} / 1.724$
1/n (-)	1.00	Arithmetic mean (n =5)
DT_{50} water (d)	1000	FOCUS default
DT_{50} sediment (d)	547	Geometric mean whole system (n = 2)
DT_{50} in recirculation water (d)	30.4	Geometric mean (n = 2; Aerobic mineralization OECD 309)
DT_{50} in disinfection tank (d)	30.4	Geometric mean (n = 2; Aerobic mineralization OECD 309)
DT_{50} in substrate (d)	134	(Geometric mean, field, normalised to pF2 and 20°C, n = 6); no specific DT_{50} in substrate available
DT_{50} in greenhouse air (d)	0.15	The photochemical oxidative degradation of fludioxonil in air was rapid, with a DT_{50} value of 3.6 h
CGA192155		
Molecular weight (g/mol)	202.1	-
Water solubility at 25ºC (g/L)	4900	
Vapour pressure at 25ºC (Pa)	0	
Octanol-water partitioning coefficient (-)	Log P_{ow} = 0.81 at pH 5.0	
K_{FOC} (mL/g)	20.2	Geometric mean (n = 5)
K_{FOM} (mL/g)	11.7	Calculated $K_{FOM} = K_{FOC} / 1.724$
1/n (-)	0.80	Arithmetic mean (n =5)
DT_{50} water (d)	1000	FOCUS default
DT_{50} sediment (d)	1000	Geometric mean whole system (n = 2)
Formation fraction from fludioxonil	0.173 (all compartments)	Max observed = 17.3% *
DT_{50} in recirculation water (d)	30.4	Geometric mean (n = 2; Aerobic mineralization OECD 309)
DT_{50} in disinfection tank (d)	30.4	Geometric mean (n = 2; Aerobic mineralization OECD 309)
DT_{50} in substrate (d)	18.0	(Geometric mean, field, normalised to pF2 and 20°C, n = 6); no specific DT_{50} in substrate available
DT_{50} in greenhouse air (d)	1.0	Conservative value
Default values for both compounds		
DT_{50} on the greenhouse floor (d)	100	Default value in GEM
Canopy process option	Lumped	Default value in GEM
DT_{50} on crop canopy (d)	10	Default value in GEM

* Although the formation fraction is always higher than the maximum observed percentage, as the value was used in all compartments (surface water/recirculation water/disinfection tank) it is considered conservative as the level of formation observed in irradiated water/sediment is unlikely to be replicated in the other two compartments

50^{th} centile PEC_{sw} for fludioxonil and CGA192155 following application to strawberries in a greenhouse in a soil-less system

Substance		with filter rinsing water	without filter rinsing water

	Application period	Date of maximum (in water)	50th centile PEC_{sw} (µg/L)	Date of maximum (in water)	50th centile PEC_{sw} (µg/L)
50th centile PEC_{sw}					
fludioxonil	November	08-Nov-2006	3.13	15-Dec-2004	0.821
	March	12-Apr-2005	16.4	03-Apr-2004	5.20
	August	16-Aug-2001	2.08	27-Aug-2003	0.387
CGA192155	November	26-Feb-2004	1.27	20-Jan-2001	0.578
	March	28-Mar-2000	1.43	03-Apr-2004	0.984
	August	16-Aug-2001	0.127	26-Aug-2001	0.080
	with 90% end of pipe mitigation			**with 70% end of pipe mitigation**	
fludioxonil	November	08-Nov-2006	0.313	15-Dec-2004	0.246
	March	12-Apr-2005	1.64	03-Apr-2004	1.56
	August	16-Aug-2001	0.208	27-Aug-2003	0.116
CGA192155	November	26-Feb-2004	0.127	26-Aug-2001	0.024
	March	28-Mar-2000	0.143	03-Apr-2004	0.293
	August	16-Aug-2001	0.013	20-Jan-2001	0.172

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

Method of calculation	Not expected
PEC	
Maximum concentration	Not expected

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				
Colinus virginianus	Fludioxonil	Acute	LD_{50}	> 2000
Colinus virginianus	Fludioxonil	Short-term	LD_{50}	> 833
Anas platyrhynchos	Fludioxonil	Short-term	LD_{50}	> 1191
Serinus canaria	Fludioxonil	Short-term	LD_{50}	183.8
Geometric mean (3 species, short-term)	Fludioxonil	Short-term	Geomean LD_{50}	**567**
Colinus virginianus	Fludioxonil	Long-term	NOAEL	65[1]
Colinus virginianus	Fludioxonil	Long-term	NOAEL	432[1]
Colinus virginianus	Fludioxonil	Long-term	NOAEL	384[1]
Anas platyrhynchos	Fludioxonil	Long-term	NOAEL	**134[1]**
Mammals				
Rat	Fludioxonil	Acute	LD_{50}	**> 5000**
Rat	A8240B[2]	Acute	LD_{50}	> 2000
Rat	A8207M	Acute	LD_{50}	> 5000
Rat	Fludioxonil	Long-term	NOAEL [2-generation study]	**58**

Endocrine disrupting properties (Annex Part A, points 8.1.5)

The pattern of EAS-mediated adversity identified in mammalian studies was considered relevant at the level of population and thus also adverse for wild mammals.

For non-mammalian species, the following data were available:

1. Amphibian Metamorphosis Assay according to OECD TG 231;
2. Fish Short-Term Reproduction Assay according to OECD TG 229
3. Fish Sexual development Test according to OECD TG 234
4. Fish Full life cycle toxicity test according to USEPA 850.1500.

While the AMA is relevant for the investigation of the ED properties of fludioxonil through the T-modality, the other studies are relevant for the EAS-modalities.

Overall, the experts agreed that the effects observed in the AMA are more likely attributable to systemic toxicity and therefore concluded that the study did not show a pattern showing interference with the HPT axis.

The available fish studies, as reported above, showed all a consistent pattern of effects, change in female gonad histopathology, reduced secondary sex characteristics in males, reduced fecundity.

When considering all the mammalian and non-mammalian data together, the experts agreed that there was a clear pattern of adversity and endocrine activity across species and taxa suggesting an anti-androgenic MoA.

Additional higher tier studies (Annex Part A, points 10.1.1.2): - Residue data in pome fruits: Southern and Northern Europe: RUD_m = 1.34 mg fludioxonil/kg - Residue decline in treated cereal seeds: Geomean DT_{50} = = 6.93 days - PT woodmouse in cereal = 0.716
Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3): *No relevant data are available from open literature.*

Values in **bold** are used for TER calculation

[1] highest dose tested

[2] formulation variant equivalent to A8240D

Toxicity/exposure ratios for terrestrial vertebrates (Regulation (EU) N° 284/2013, Part A, Annex point 10.1)

A8240D: Grapes at 500 g a.s./ha [2 applications]

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Screening Step (Birds)					
All	Small omnivorous birds	Acute	57.2	**9.9**	10
All	Small omnivorous birds	Long-term	14.4	9.3	5
Tier 1 (Birds)					
BBCH ≥ 20	Small insectivorous birds	Acute	15.42	37.0	10
BBCH ≥ 40	Small granivorous bird	Acute	4.44	127.7	10
BBCH ≥ 40	Small omnivorous bird	Acute	4.32	131.3	10
Ripening	Frugivorous bird	Acute	17.34	32.7	10
Higher tier (birds): Not required.					
Screening Step (Mammals)					
All	Small herbivorous mammal	Acute	75.02	> 66.5	10
All	Small herbivorous mammal	Long-term	22.99	**2.52**	5
Tier 1 (Mammals)					
BBCH>20	Small insectivorous mammal	Long-term	0.60	96.67	5
BBCH >40	Large herbivorous mammal	Long-term	1.05	55.24	5
Crop directed BBCH >40	Small herbivorous mammal	Long-term	6.90	8.41	5
Crop directed BBCH >40	Small omnivorous mammal	Long-term	0.73	79.45	5

Risk from bioaccumulation and food chain behaviour

Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Earthworm-eating birds	Long-term	0.231	580	5
Earthworm-eating mammals	Long-term	0.282	205.7	5
Fish-eating birds	Long-term	0.0739	1800	5
Fish-eating mammals	Long-term	0.0660	879	5
Higher tier: Not required.				

Risk from consumption of contaminated water

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Puddle scenario, Screening step Application rate (g a.s./ha)/relevant endpoint <3000 (Koc≥500 L/kg), TER calculation not needed.					

A8240D: Orchards (Pome) at 225 g a.s./ha [2 applications]

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Screening Step (Birds)					
All	Small insectivorous birds	Acute	14.7	38.6	10
All	Small insectivorous birds	Long-term	3.47	39	5
Tier 1 (Birds)					
Higher tier (birds): Not required.					
Screening Step (Mammals)					
All	Small herbivorous mammal	Acute	43	> 120	10
All	Small herbivorous mammal	Long-term	13.8	**4.20**	5
Tier 1 (Mammals)					
Crop directed BBCH >40	Small herbivorous mammal	Long-term	4.14	14.01	5
Crop directed BBCH >40	Large herbivorous mammal	Long-term	0.82	70.73	5
Crop directed BBCH >40	Small omnivorous mammal	Long-term	0.44	131.82	5
Fruit stage	Small frugivorous mammal	Long-term	4.33	13.39	5

Risk from bioaccumulation and food chain behaviour

Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Earthworm-eating birds	Long-term	0.089	1506	5
Earthworm-eating mammals	Long-term	0.109	532.1	5
Fish-eating birds	Long-term	0.0466	2900	5
Fish-eating mammals	Long-term	0.0416	1394	5
Higher tier: Not required.				

Risk from consumption of contaminated water

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

A8240D: Strawberry at 250 g a.s./ha [2 applications]

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Screening Step (Birds)					
All	Small omnivorous bird	Acute	51.6	11	10

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
All	Small omnivorous bird	Long-term	12.9	10	5
Tier 1 (Birds)					
Higher tier (birds): Not required.					
Screening Step (Mammals)					
All	Small herbivorous mammal	Acute	38.5	> 130	10
All	Small herbivorous mammal	Long-term	9.60	6.04	5
Tier 1 (Mammals)					
BBCH>20	Small insectivorous mammal	Long-term	0.38	152.63	5
BBCH >40	Small herbivorous mammal	Long-term	5.74	10.10	5
BBCH >40	Large herbivorous mammal	Long-term	1.13	51.33	5
BBCH >40	Small omnivorous mammal	Long-term	0.62	93.55	5

Risk from bioaccumulation and food chain behaviour

Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Earthworm-eating birds	Long-term	0.056	2393	5
Earthworm-eating mammals	Long-term	0.068	852.9	5
Fish-eating birds	Long-term	0.0187	7166	5
Fish-eating mammals	Long-term	0.0167	3473	5
Higher tier : Not required.				

Risk from consumption of contaminated water

Puddle scenario, Screening step

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

A8207M: Treated cereals seed at 12.5 g a.s./ha (50 mg a.s.//kg seed) (worst-case scenario)

	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Screening Step (Birds)					
Not relevant for seed treatment.					
Tier 1 (Birds)					
BBCH 00	Small granivorous bird	Acute	15	37.8	10
BBCH 00	Small granivorous bird	Long-term	15	8.93	5
Higher tier (birds): Not required.					
Screening Step (Mammals)					
Not relevant for seed treatment.					

	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Tier 1 (Mammals)					
BBCH 00	Small omnivorous mammal	Acute	12	> 420	10
BBCH 00	Small omnivorous mammal	Long-term	5.04*	11.51	5
Higher tier (Mammals): PT = 0.716					
BBCH 00	Small omnivorous mammal	Long-term	3.609	5.37	5

Risk from bioaccumulation and food chain behaviour

Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Earthworm-eating birds	Long-term	0.0034	39412	5
Earthworm-eating mammals	Long-term	0.0041	14146	5
Fish-eating birds	Long-term	0.00221	61000	5
Fish-eating mammals	Long-term	0.00200	29000	5
Higher tier: Not required.				

Risk from consumption of contaminated water

Puddle scenario, Screening step

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

* Based on a DT50 of 6.93. See experts' consultation 5.2 of the Pesticides Peer Review Experts' Meeting PREV 03 (EFSA, 2024)

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[1]
Laboratory tests				
Fish				
Oncorhynchus mykiss	Fludioxonil	Acute 96 hr (flow-through)	Mortality, LC_{50}	0.23 mg a.s./L (mm)
Oncorhynchus mykiss	Fludioxonil	Acute 96 hr (flow-through)	Mortality, LC_{50}	0.47 mg a.s./L (mm)
Oncorhynchus mykiss (formerly *Salmo gairdneri*)	Fludioxonil	Acute 96 hr (static)	Mortality, LC_{50}	0.50 mg a.s./L (mm)
Geometric mean (*Oncorhynchus mykis*, acute)	Fludioxonil	Acute	Geomean LC_{50}	0.38 mg a.s./L
Lepomis macrochirus	Fludioxonil	Acute 96 hr (flow-through)	Mortality, LC_{50}	0.74 mg a.s./L (mm)
Cyprinodon variegatus	Fludioxonil	Acute 96 hr (flow-through)	Mortality, LC_{50}	1.2 mg a.s./L (mm)
Cyprinodon variegatus	Fludioxonil	Acute 96 hr (flow-through)	Mortality, LC_{50}	0.54 mg a.s./L (mm)
Geometric mean (*Cyprinodon variegatus*, acute)	Fludioxonil	Acute	Geomean LC_{50}	0.80 mg a.s./L
Pimephales promelas	Fludioxonil	Acute 96 hr (semi-static)	Mortality, LC_{50}	0.70 mg a.s./L (mm)
Geometric mean (4 species, acute)	Fludioxonil	Acute	Geomean LC_{50}	**0.63** mg a.s./L
Rana limnocharis	Fludioxonil	Acute 48 hr (static)	Mortality, LC_{50}	2.32 mg a.s./L (nom)
Oncorhynchus mykiss	Fludioxonil	Chronic (flow-through)	Growth, NOEC	0.040 mg a.s./L (mm)
Pimephales promelas	Fludioxonil	Chronic (flow-through)	ELS, NOEC ELS, EC_{10}	0.039 mg a.s./L (mm) 0.0344 mg a.s./L (mm)
Pimephales promelas	Fludioxonil	Chronic (flow-through)	ELS, NOEC	0.019 mg a.s./L (mm)
Cyprinodon variegatus	Fludioxonil	Chronic (flow-through)	ELS, NOEC	0.1 mg a.s./L (nom)
Cyprinodon variegatus	Fludioxonil	Chronic (flow-through)	ELS, NOEC	0.038 mg a.s./L (mm)
Pimephales promelas	Fludioxonil	Chronic (flow-through)	Full LC, NOEC	**0.018** mg a.s./L (twmm)
Oncorhynchus mykiss	CGA192155	Acute 96 hr (static)	Mortality, LC_{50}	> **100** mg met../L (nom)
Oncorhynchus mykiss	CGA339833	Acute 96 hr (static)	Mortality, LC_{50}	> **100** mg met/L (nom)
Oncorhynchus mykiss	CGA265378	Acute 96 hr	Mortality, LC_{50}	**0.038** mg met./L [4]

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Oncorhynchus mykiss	SYN545245	Acute 96 hr	Mortality, LC_{50}	**0.038** mg met./L [4]
Oncorhynchus mykiss	D9	Acute 96 hr	Mortality, LC_{50}	**0.038** mg met./L [4]
Oncorhynchus mykiss	MF2	Acute 96 hr	Mortality, LC_{50}	**0.038** mg met./L [4]
Aquatic invertebrates				
Daphnia magna	Fludioxonil	48 h (flow-through)	Mortality, EC_{50}	0.40 mg a.s./L (mm)
Daphnia magna	Fludioxonil	48 h (flow-through)	Mortality, EC_{50}	0.90 mg a.s./L (mm)
Geometric mean *(Daphnia magna, acute)*	Fludioxonil	Acute	Geomean EC_{50}	0.60 mg a.s./L
Americamysis bahia	Fludioxonil	96 h (flow-through)	Mortality, EC_{50}	0.27 mg a.s./L (mm)
Geometric mean *(2 species, acute)*	Fludioxonil	Acute	Geomean EC_{50}	**0.402** mg a.s./L
Daphnia magna	A8207M	48 h (static)	Mortality, EC_{50}	24.6 mg prep./L (ini meas) **(**0.615 mg a.s./L) (ini meas)
Crassostrea virginica	Fludioxonil	96 h (shell growth)	Mortality, EC_{50}	0.37 mg a.s./L (mm)
Daphnia magna	Fludioxonil	21 d (semi-static)	Full LC, NOEC	0.035 mg a.s./L (mm)
Daphnia magna	Fludioxonil	21 d (flow-through)	Full LC, NOEC	0.019 mg a.s./L (mm) [6]
Americamysis bahia	Fludioxonil	28 d (flow-through)	Full LC, NOEC	0.018 mg a.s./L (mm)
Americamysis bahia	Fludioxonil	28 d (flow-through)	Full LC, NOEC	**0.024** mg a.s./L (twm)
Daphnia magna	CGA192155	48 h (static)	Mortality, EC_{50}	> **100** mg met./L (nom)
Daphnia magna	CGA265378	48 h (static)	Mortality, EC_{50}	**0.040** mg met./L [3]
Daphnia magna	CGA339833	48 h (static)	Mortality, EC_{50}	> **100** mg met./L (nom)
Daphnia magna	CGA344623	48 h (static)	Mortality, EC_{50}	> **100** mg met/L (nom)
Americamysis bahia	D9	48 h (static)	Mortality, EC_{50}	**0.027** mg met./L [3]
Americamysis bahia	MF2	48 h (static)	Mortality, EC_{50}	**0.027** mg met./L [3]
Daphnia magna	SYN545245	48 h (static)	Mortality, EC_{50}	> **100** mg met./L (nom)
Sediment-dwelling organisms				
Hyalella azteca (spiked sediment study)	Fludioxonil	10 d (semi-static)	Mortality, EC_{50}	> 84 mg a.s./kg dry sediment (mm)
Leptocheirus plumulosa (spiked sediment study)	Fludioxonil	48 h (static)	Mortality, EC_{50}	> 90 mg a.s./kg dry sediment (mm)

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Chironomus dilutus (spiked sediment study)	Fludioxonil	48 h (semi-static)	Mortality, EC_{50}	**100** mg a.s./kg dry sediment $_{(mm)}$
Chironomus riparius (spiked sediment study)	Fludioxonil	28 d (static)	Emergence and development, NOEC	**40** mg a.s./kg dry sediment$_{(nom)}$
Chironomus dilutus (spiked sediment study)	CGA192155	48 h (semi-static)	Mortality, EC_{50}	10 mg a.s /kg dw [3]
Chironomus riparius (spiked sediment study)	CGA192155	28 d (static)	Emergence and development, NOEC	4 mg a.s./kg dw [3]
Algae				
Pseudokirchneriella subcapitata	Fludioxonil	96 h (static)	Growth rate: E_rC_{50} Growth rate: E_rC_{10}	0.259 mg a.s./L $_{(mm)}$ 0.077 mg a.s./L $_{(mm)}$
Pseudokirchneriella subcapitata	Fludioxonil	72 h (static)	Growth rate: E_rC_{50} Growth rate: E_rC_{50} Growth rate: E_rC_{10} Yield: E_yC_{50} Yield: E_yC_{10}	> 0.442 mg a.s./L $_{(mm)}$ > 0.442 mg a.s./L $_{(mm)}$ (96 h) 0.255 mg a.s./L $_{(mm)}$ 0.244 mg a.s./L $_{(mm)}$ 0.012 mg a.s./L $_{(mm)}$
Geometric mean (*Pseudokirchneriella subcapitata)*	Fludioxonil	96 h	Geomean E_rC_{50}	**0.34**-mg a.s./L
Navicula pelliculosa	Fludioxonil	72 h (static)	Growth rate: E_rC_{50} NOErC Yield: E_yC_{50} Biomass: E_bC_{50}	> 1.2 mg a.s./L $_{(mm)}$ 0.63 mg a.s./L $_{(mm)}$ 0.86 mg a.s./L $_{(mm)}$ 0.88 mg a.s./L $_{(mm)}$
Desmodesmus subspicatus	A8240B[2]	72 h (static)	Growth rate: E_rC_{50} Growth rate: E_rC_{10} Biomass: E_bC_{50} NOE_bC	**0.544** mg prep./L$_{(nom)}$ (0.278 mg a.s./L$_{(nom)}$) 0.183 mg prep./L$_{(nom)}$ 0.25 mg prep./L$_{(nom)}$ 0.11 mg prep./L$_{(nom)}$
Pseudokirchneriella subcapitata	A8207M	72 h (static)	Growth rate: E_rC_{50}	**5.45** mg prep./L$_{(nom}$ (0.133 mg a.s./L$_{(nom)}$)
Pseudokirchneriella subcapitata	CGA192155	72 h (static)	Growth rate: E_rC_{50} NOErC	> **100** mg met./L $_{(nom)}$ 100 mg met./L $_{(nom)}$
Pseudokirchneriella subcapitata	CGA339833	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50} Growth rate: E_rC_{10}	95.8 mg met./L $_{(nom)}$ >**100** mg met./L $_{(nom)}$ 36.59 mg met./L $_{(nom)}$
Pseudokirchneriella subcapitata	SYN545245	72 h (static)	Biomass: E_bC_{50} Yield: E_yC_{50} Growth rate: E_rC_{50} NOEC	30 mg met./L $_{(nom)}$ 41 mg met./L $_{(nom)}$ **44** mg met./L $_{(nom)}$ 25 mg met./L $_{(nom)}$

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Pseudokirchneriella subcapitata	CGA265378	96 h	Growth rate: E_rC_{50}	**0.034** mg met./L [5]
Pseudokirchneriella subcapitata	D9	96 h	Growth rate: E_rC_{50}	**0.034** mg met./L [5]
Pseudokirchneriella subcapitata	MF2	96 h	Growth rate: E_rC_{50}	**0.034** mg met./L [5]
Higher plant				
Further testing on aquatic organisms Mesocosm (*Giddings*, 2013) NOEC fish = 0.0328 mg a.s./L				
Potential endocrine disrupting properties (Annex Part A, point 8.2.3) The pattern of EAS-mediated adversity identified in mammalian studies was considered relevant at the level of population and thus also adverse for wild mammals. For non-mammalian species, the following data were available: 1. Amphibian Metamorphosis Assay according to OECD TG 231; 2. Fish Short-Term Reproduction Assay according to OECD TG 229 3. Fish Sexual development Test according to OECD TG 234 4. Fish Full life cycle toxicity test according to USEPA 850.1500. While the AMA is relevant for the investigation of the ED properties of fludioxonil through the T-modality, the other studies are relevant for the EAS-modalities. Overall, the experts agreed that the effects observed in the AMA are more likely attributable to systemic toxicity and therefore concluded that the study did not show a pattern showing interference with the HPT axis. The available fish studies, as reported above, showed all a consistent pattern of effects, change in female gonad histopathology, reduced secondary sex characteristics in males, reduced fecundity. When considering all the mammalian and non-mammalian data together, the experts agreed that there was a clear pattern of adversity and endocrine activity across species and taxa suggesting an anti-androgenic MoA.				

Values in **bold** are used for TER calculation

[1] ($_{nom}$) nominal concentration; ($_{mm}$) mean measured concentration; ($_{twmm}$) time-weighted mean measured concentrations; ($_{ini\ meas}$) initial measured concentration; prep.: preparation; a.s.: active substance

[2] formulation variant equivalent to A8240D

[3] the metabolite is assumed 10 times more toxic than the active substance

[4] The metabolites are assumed as 10 times more toxic of parental geometric mean for *Oncorhynchus mykiss* where LC_{50} = 0.38 mg fludioxonil/L

[5] The metabolites are assumed as 10 times more toxic of parental geometric mean for *Pseudokirchneriella subcapitata* where E_rC50 = 0.34 mg fludioxonil/L

[6] Study not suitable for the risk assessment due to the following shortcomings: 1/ Number of neonates in solvent control 35% lower than in the control, and some dead neonates also present in the solvent control. Scale of difference suggests data may be unreliable. 2/ Solvent used in unequal concentrations in test concentrations. 3/ Test concentrations produced by diluting suspensions of fludioxonil prepared above limit of functional solubility. Insufficient number of analytical samples did not cover 72h renewal interval. Undissolved test material visible on day 21. As fludioxonil is not easy to get into solution, the analytical results are unreliable.

Bioconcentration in fish (Annex Part A, point 8.2.2.3)

	Active substance	Metabolite1	Metabolite2	Metabolite3
$logP_{O/W}$	4			

Steady-state bioconcentration factor (BCF) (total wet weight/normalised to 5% lipid content)	366 (whole fish)*			
Uptake/depuration kinetics BCF (total wet weight/normalised to 5% lipid content)	-			
Annex VI Trigger for the bioconcentration factor	-			
Clearance time (days) (CT_{50})	0.6			
(CT_{90})	1.8			
Level and nature of residues (%) in organisms after the 14 day depuration phase	-			
Higher tier study				
-				

* based on ^{14}C-fludioxonil

Toxicity/exposure ratios for the most sensitive aquatic organisms (Regulation (EU) N° 284/2013, Annex Part A, point 10.2)

A8240D: Grapes at 500 g a.s./ha [1 applications]

FOCUS$_{sw}$ step 1-3 – PEC/RAC ratio for fludioxonil – Grapes at 500 g a.s./ha [1 application]

Scenario	PEC$_{sw}$ global max(µg/L)	fish acute	fish chronic	Aquatic invertebrates acute	Aquatic invertebrates prolonged	Algae	PEC$_{sed}$ (µg/kg)	Sed. dweller acute	Sed. dweller prolonged
		Geometric mean 4 species	*Pimephales promelas*	Geometric mean 2 species	*Americamysis bahia*	Geometric mean *Pseudokirchneriella subcapitata*		*Chironomus dilutus*	*Chironomus riparius*
		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}		LC_{50}	NOEC
		630 µg/L	18 µg/L	402 µg/L	24 µg/L	430 µg/L		100000 µg/kg	40000 µg/kg
RAC		6.3	1.8	4.02	2.4	34		1000	4000
FOCUS Step 1									
	97.3	**15.4**	**54.06**	**24.23**	**40.54**	**2.86**	2130	**2.13**	0.53
FOCUS Step 2									
North Europe	13.4	**2.13**	**7.44**	**3.33**	**5.58**	0.39	273	0.27	-
South Europe	13.4	**2.13**	**7.44**	**3.33**	**5.58**	0.39	234	0.23	-
FOCUS Step 3 (window starting at BBCH 67)*									
D6 / ditch	8.54	**1.36**	**4.74**	**2.12**	**3.56**	-	-	-	-
R1 / pond	0.312	0.05	0.17	0.08	0.13	-	-	-	-
R1 / stream	6.09	0.97	**3.38**	**1.51**	**2.54**	-	-	-	-
R2 / stream	8.39	**1.33**	**4.66**	**2.09**	**3.50**	-	-	-	-
R3 / stream	8.83	**1.40**	**4.91**	**2.20**	**3.68**	-	-	-	-
R4 / stream	6.26	0.99	**3.48**	**1.56**	**2.61**	-	-	-	-
FOCUS Step 3 (window ending at harvest - PHI)*									
D6 / ditch	8.54	**1.36**	**4.74**	**2.12**	**3.56**	-	-	-	-

							-	-	-
R1 / pond	0.309	0.05	0.17	0.08	0.13	-	-	-	-
R1 / stream	6.26	0.99	**3.48**	**1.56**	**2.61**	-	-	-	-
R2 / stream	8.39	**1.33**	**4.66**	**2.09**	**3.50**	-	-	-	-
R3 / stream	8.83	**1.40**	**4.91**	**2.20**	**3.68**	-	-	-	-
R4 / stream	6.26	0.99	**3.48**	**1.56**	**2.61**	-	-	-	-

*[Only scenarios where the trigger is not met at FOCUSsw step 1-2 should be included in step 3.]

FOCUS$_{sw}$ step 4 - PEC/RAC ratio for fludioxonil – Grapes at 500 g a.s./ha [1 application]

Organisms *Fish, geomean acute*
RAC: 6.3 µg/L

Mitigation options	[x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction)	[x] % drift reduction from use of drift reducing nozzles	PECsw (µg/L)	PEC/RAC ratio
FOCUS Step 4 (window starting at BBCH 67)*				
D6 / ditch	5	-	5.16	0.82
D6 / ditch	-	50	4.04	0.64
R2 / stream	5	-	6.11	0.97
R2 / stream	-	50	3.97	0.63
R3 / stream	10	-	2.33	0.37
R3 / stream	-	50	4.17	0.66
FOCUS Step 4 (window ending at harvest - PHI)*				
D6 / ditch	5	-	5.16	0.82
D6 / ditch	-	50	4.04	0.64
R2 / stream	5	-	6.11	0.97
R2 / stream	-	50	3.97	0.63
R3 / stream	10	-	2.33	0.37
R3 / stream	-	50	4.17	0.66

Organisms
Pimephales promelas, chronic
RAC: 1.8 µg/L

Mitigation options	[x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction)	[x] % drift reduction from use of drift reducing nozzles	PECsw (µg/L)	PEC/RAC ratio

FOCUS Step 4 (window starting at BBCH 67)*				
D6 / ditch	15	-	1.2	0.67
D6 / ditch	10	50	0.932	0.52
D6 / ditch	5	75	1.29	0.72
D6 / ditch	-	90	0.808	0.45
R1 / stream	10	-	1.6	0.89
R1 / stream	10	50	0.801	0.45
R1 / stream	-	75	1.44	0.80
R2 / stream	15	-	0.506	0.28
R2 / stream	10	50	1.11	0.62
R2 / stream	5	75	1.53	0.85
R2 / stream	-	90	0.794	0.44
R3 / stream	15	-	0.075	0.04
R3 / stream	10	50	1.16	0.64
R3 / stream	5	75	1.6	0.89
R3 / stream	-	90	0.835	0.46
R4 / stream	10	-	1.65	0.92
R4 / stream	10	50	0.98	0.54
R4 / stream	-	75	1.48	0.82
FOCUS Step 4 (window ending at harvest - PHI)*				
D6 / ditch	15	-	1.01	0.56
D6 / ditch	10	50	0.932	0.52
D6 / ditch	5	75	1.29	0.72
D6 / ditch	-	90	0.808	0.45
R1 / stream	10	-	1.65	0.92
R1 / stream	10	50	0.824	0.46
R1 / stream	-	75	1.48	0.82
R2 / stream	15	-	1.2	0.67
R2 / stream	10	50	1.11	0.62
R2 / stream	5	75	1.53	0.85
R2 / stream	-	90	0.794	0.44
R3 / stream	15	-	1.26	0.70
R3 / stream	10	50	1.16	0.64
R3 / stream	5	75	1.6	0.89
R3 / stream	-	90	0.835	0.46
R4 / stream	10	-	1.65	0.92
R4 / stream	10	50	0.98	0.54

R4 / stream	-	75	1.48	0.82
Organisms: *Aquatic invertebrate, geomean acute*				
RAC: 4.02 µg/L				
Mitigation options	**[x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction)**	**[x] % drift reduction from use of drift reducing nozzles**	**PECsw (µg/L)**	**PEC/RAC ratio**
FOCUS Step 4 (window starting at BBCH 67)*				
D6 / ditch	10	-	1.87	0.47
D6 / ditch	-	50	4.04	1.00
R1 / stream	10	-	1.6	0.40
R1 / stream	-	50	2.88	0.72
R2 / stream	10	-	2.21	0.55
R2 / stream	-	50	3.97	0.99
R3 / stream	10	-	2.33	0.58
R3 / stream	5	50	3.21	0.80
R3 / stream	-	75	2.09	0.52
R4 / stream	10	-	1.65	0.41
R4 / stream	-	50	2.96	0.74
FOCUS Step 4 (window ending at harvest - PHI)*				
D6 / ditch	10	-	1.87	0.47
D6 / ditch	-	50	4.04	1.00
R1 / stream	10	-	1.65	0.41
R1 / stream	-	50	2.96	0.74
R2 / stream	10	-	2.21	0.55
R2 / stream	-	50	3.97	0.99
R3 / stream	10	-	2.33	0.58
R3 / stream	5	50	3.21	0.80
R3 / stream	-	75	2.09	0.52
R4 / stream	10	-	1.65	0.41
R4 / stream	-	50	2.96	0.74
Organisms: *Americamysis bahia, chronic*				
RAC: 2.4 µg/L				

Mitigation options	[x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction)	[x] % drift reduction from use of drift reducing nozzles	PECsw (µg/L)	PEC/RAC ratio
FOCUS Step 4 (window starting at BBCH 67)*				
D6 / ditch	10	-	1.87	0.78
D6 / ditch	10	50	0.932	0.39
D6 / ditch	-	75	2.02	0.84
R1 / stream	10	-	1.6	0.67
R1 / stream	5	50	2.22	0.93
R1 / stream	-	75	1.44	0.60
R2 / stream	10	-	2.21	0.92
R2 / stream	10	50	1.11	0.46
R2 / stream	-	75	1.99	0.83
R3 / stream	10	-	2.33	0.97
R3 / stream	10	50	1.16	0.48
R3 / stream	-	75	2.09	0.87
R4 / stream	10	-	1.65	0.69
R4 / stream	5	50	2.28	0.95
R4 / stream	-	75	1.48	0.62
FOCUS Step 4 (window ending at harvest - PHI)*				
D6 / ditch	10	-	1.87	0.78
D6 / ditch	10	50	0.932	0.39
D6 / ditch	-	75	2.02	0.84
R1 / stream	10	-	1.65	0.69
R1 / stream	5	50	2.28	0.95
R1 / stream	-	75	1.48	0.62
R2 / stream	10	-	2.21	0.92
R2 / stream	10	50	1.11	0.46
R2 / stream	-	75	1.99	0.83
R3 / stream	10	-	2.33	0.97
R3 / stream	10	50	1.16	0.48
R3 / stream	-	75	2.09	0.87
R4 / stream	10	-	1.65	0.69
R4 / stream	5	50	2.28	0.95
R4 / stream	-	75	1.48	0.62

*[Only scenarios where the trigger is not met at FOCUSsw step 3 should be included in step 4].

A8240D: Grapes at 500 g a.s./ha [2 applications]

FOCUS$_{sw}$ step 1-3 – PEC/RAC ratio for fludioxonil – Grapes at 500 g a.s./ha [2 applications]

Scenario	PEC$_{sw}$ global max(µg/L)	fish acute	fish chronic	Aquatic invertebrates acute	Aquatic invertebrates prolonged	Algae	PEC$_{sed}$ (µg/kg)	Sed. dweller acute	Sed. dweller prolonged
		Geometric mean 4 species	*Pimephales promelas*	Geometric mean 2 species	*Americamysis bahia*	Geometric mean *Pseudokirchneriella subcapitata*		*Chironomus dilutus*	*Chironomus riparius*
		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}		LC_{50}	NOEC
		630 µg/L	18 µg/L	402 µg/L	24 µg/L	430 µg/L		100000 µg/kg	40000 µg/kg
RAC		6.3	1.8	4.02	2.4	34		1000	4000
FOCUS Step 1									
	97.3	**15.4**	**54.06**	**24.2**	**40.54**	**2.86**	2130	**2.13**	0.53
FOCUS Step 2									
North Europe	20.3	**3.22**	**11.28**	**5.05**	**8.46**	0.60	515	0.52	-
South Europe	17.6	**2.79**	**9.78**	**4.38**	**7.33**	0.52	439	0.44	-
FOCUS Step 3 (window starting at BBCH 67)*									
D6 / ditch	7.86	**1.25**	**4.37**	**1.96**	**3.28**	-	-	-	-
R1 / pond	0.428	0.07	0.24	0.11	0.18	-	-	-	-
R1 / stream	5.52	0.88	**3.07**	**1.37**	**2.30**	-	-	-	-
R2 / stream	7.4	**1.17**	**4.11**	**1.84**	**3.08**	-	-	-	-
R3 / stream	7.79	**1.24**	**4.33**	**1.94**	**3.25**	-	-	-	-
R4 / stream	5.52	0.88	**3.07**	**1.37**	**2.30**	-	-	-	-
FOCUS Step 3 (window ending at harvest - PHI)*									
D6 / ditch	7.84	**1.24**	**4.36**	**1.95**	**3.27**	-	- 108**	- 0.108	- 0.027

R1 / pond	0.41	0.07	0.23	0.10	0.17	-	-	-	-
R1 / stream	5.52	0.88	**3.07**	**1.37**	**2.30**	-	-	-	-
R2 / stream	7.4	**1.17**	**4.11**	**1.84**	**3.08**	-	-	-	-
R3 / stream	7.79	**1.24**	**4.33**	**1.94**	**3.25**	-	-	-	-
R4 / stream	5.52	0.88	**3.07**	**1.37**	**2.30**	-	-	-	-

*[Only scenarios where the trigger is not met at FOCUSsw step 1-2 should be included in step 3.]
** Sediment accumulation PEC (presented only for the worst case maximum PEC sediment).

FOCUS$_{sw}$ step 4 - PEC/RAC ratio for fludioxonil – Grapes at 500 g a.s./ha [2 applications]

Organisms *Fish, geomean acute* **RAC:** 6.3 µg/L					
Mitigation options	**[x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction)**	**[x] m vegetated buffer strip (corresponding to ≤ 90 % run-off reduction)**	**[x] % drift reduction from use of drift reducing nozzles**	**PECsw (µg/L)**	**PEC/RAC ratio**
FOCUS Step 4 (window starting at BBCH 67)*					
D6 / ditch	5	-	-	4.73	0.75
D6 / ditch	-	-	50	3.84	0.61
R2 / stream	5	-	-	5.38	0.85
R2 / stream	-	-	50	3.50	0.56
R3 / stream	5	-	-	5.66	0.90
R3 / stream	-	-	50	3.68	0.58
FOCUS Step 4 (window ending at harvest - PHI)*					
D6 / ditch	5	-	-	4.72	0.75
D6 / ditch	-	-	50	3.83	0.61
R2 / stream	5	-	-	5.38	0.85
R2 / stream	-	-	50	3.50	0.56
R3 / stream	5	-	-	5.66	0.90
R3 / stream	-	-	50	3.68	0.58
Organisms *Pimephales promelas, chronic* **RAC:** 1.8 µg/L					

Mitigation options	[x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction)	[x] m vegetated buffer strip (corresponding to ≤ 90 % run-off reduction)	[x] % drift reduction from use of drift reducing nozzles	PECsw (µg/L)	PEC/RAC ratio
FOCUS Step 4 (window starting at BBCH 67)*					
D6 / ditch	10	-	-	1.69	0.94
D6 / ditch	10	-	50	0.845	0.47
D6 / ditch	5	-	75	1.18	0.66
D6 / ditch	-	-	90	0.769	0.43
R1 / stream	10	-	-	1.44	0.80
R1 / stream	10	-	50	0.962	0.53
R1 / stream	-	-	75	1.31	0.73
R2 / stream	15	-	-	1.04	0.58
R2 / stream	10	-	50	0.964	0.54
R2 / stream	-	-	75	1.75	0.97
R3 / stream	15	-	-	1.45	0.81
R3 / stream	10	-	50	1.45	0.81
R3 / stream	5	-	75	1.45	0.81
R3 / stream	-	-	90	0.737	0.41
R4 / stream	10	10	-	1.44	0.80
FOCUS Step 4 (window ending at harvest - PHI)*					
D6 / ditch	30	-	-	2.04	**1.13**
R1 / stream	10	-	-	1.44	0.80
R1 / stream	10	-	50	0.90	0.50
R1 / stream	-	-	75	1.31	0.73
R2 / stream	15	-	-	1.04	0.58
R2 / stream	10	-	50	0.964	0.54
R2 / stream	-	-	75	1.75	0.97
R3 / stream	15	-	-	1.45	0.81
R3 / stream	10	-	50	1.45	0.81
R3 / stream	5	-	75	1.45	0.81
R3 / stream	-	-	90	0.737	0.41
R4 / stream	10	10	-	1.44	0.80
Organisms: *Aquatic invertebrate, geomean acute*					

RAC: 4.02 µg/L

Mitigation options	[x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction)	[x] % drift reduction from use of drift reducing nozzles	PECsw (µg/L)	PEC/RAC ratio
FOCUS Step 4 (window starting at BBCH 67)*				
D6 / ditch	10	-	1.69	0.42
D6 / ditch	-	50	3.84	0.96
R1 / stream	5	-	4.01	1.00
R1 / stream	-	50	2.61	0.65
R2 / stream	10	-	1.93	0.48
R2 / stream	-	50	3.50	0.87
R3 / stream	10	-	2.03	0.50
R3 / stream	-	50	3.68	0.97
R4 / stream	5	-	4.01	1.00
R4 / stream	-	50	2.61	0.65
FOCUS Step 4 (window ending at harvest - PHI)*				
D6 / ditch	10	-	2.04	0.51
D6 / ditch	-	50	3.83	0.95
R1 / stream	5	-	4.01	1.00
R1 / stream	-	50	2.61	0.65
R2 / stream	10	-	1.93	0.48
R2 / stream	-	50	3.50	0.87
R3 / stream	10	-	2.03	0.50
R3 / stream	-	50	3.68	0.92
R4 / stream	5	-	4.01	1.00
R4 / stream	-	50	2.61	0.65

Organisms:
Americamysis bahia, chronic

RAC: 2.4 µg/L

Mitigation options	[x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction)	[x] % drift reduction from use of drift reducing nozzles	PECsw (µg/L)	PEC/RAC ratio
FOCUS Step 4 (window starting at BBCH 67)*				
D6 / ditch	10	-	1.69	0.70
D6 / ditch	5	50	2.36	0.98
D6 / ditch	-	75	1.92	0.80
R1 / stream	10	-	1.44	0.60

R1 / stream	5	50	2.00	0.83
R1 / stream	-	75	1.31	0.55
R2 / stream	10	-	1.93	0.80
R2 / stream	10	50	0.964	0.40
R2 / stream	-	75	1.75	0.73
R3 / stream	10	-	2.03	0.85
R3 / stream	10	50	1.45	0.60
R3 / stream	-	75	1.84	0.77
R4 / stream	10	-	2.18	0.91
R4 / stream	5	50	2.18	0.91
R4 / stream	-	75	1.31	0.55
FOCUS Step 4 (window ending at harvest - PHI)*				
D6 / ditch	10	-	2.04	0.85
D6 / ditch	5	50	2.36	0.98
D6 / ditch	-	75	1.91	0.80
R1 / stream	10	-	1.44	0.60
R1 / stream	5	50	2.00	0.83
R1 / stream	-	75	1.31	0.55
R2 / stream	10	-	1.93	0.80
R2 / stream	10	50	0.964	0.40
R2 / stream	-	75	1.75	0.73
R3 / stream	10	-	2.03	0.85
R3 / stream	10	50	1.45	0.60
R3 / stream	-	75	1.84	0.77
R4 / stream	10	-	2.18	0.91
R4 / stream	5	50	2.18	0.91
R4 / stream	-	75	1.31	0.55

*[Only scenarios where the trigger is not met at FOCUSsw step 3 should be included in step 4].

FOCUS$_{sw}$ step 1 – PEC/RAC ratio for fludioxonil metabolites– Grapes at 500 g a.s./ha [2 applications]

Test organism	Metabolite	Tier 1-RAC (µg/L)	Max PEC$_{sw}$ (µg/L)	PEC/RAC
Oncorhynchus mykiss	CGA192155	>1 000	121	< 0.12
	CGA339833	>1 000	73	< 0.07
	CGA265378	0.38[a]	< 0.001[b]	< 0.003
	SYN545245	0.38[a]	0.002[b]	0.01
	D9	0.38[a]	4.55[b]	**11.97**
	MF2	0.38[a]	5.54[b]	**14.58**
Daphnia magna	CGA192155	>1000	121	< 0.12
	CGA265378	0.40	< 0.001[b]	< 0.003
	CGA339833	>1000	73	< 0.07
	SYN545245	>1000	101	< 0.10
Mysidopsis bahia	D9	0.27[a]	4.55[b]	**16.85**
	MF2	0.27[a]	5.54[b]	**20.52**
Chironomus dilutus	CGA192155	100 µg/kg [a]	20.9[b]	0.209
Chironomus riparius	CGA192155	400 µg/kg [a]	121	0.303
Pseudokirchneriella subcapitata	CGA192155	>10 000	121	< 0.01
	CGA339833	>10 000	73	< 0.01
	SYN545245	4 400	101	0.02
	CGA265378	3.4[a]	< 0.001[b]	< 0.0003
	D9	3.4[a]	4.55[b]	**1.34**
	MF2	3.4[a]	5.54[b]	**1.63**

Values in **bold** are above the trigger value of 1 and hence further consideration is needed
[a] Toxicity of metabolites are assumed to be 10 times more toxic than fludioxonil
[b] FOCUS Step 2 PEC values

A8240D: Orchards (Pome) at 225 g a.s./ha [1 applications]

FOCUS$_{sw}$ step 1-3 - PEC/RAC ratio for fludioxonil – Orchards (Pome) at 225 g a.s./ha [1 applications]

Scenario	PEC$_{sw}$ global max (µg/L)	fish acute	fish chronic	Aquatic invertebrates acute	Aquatic invertebrates prolonged	Algae	PEC$_{sed}$ (µg/kg)	Sed. dweller acute	Sed. dweller prolonged
		Geometric mean 4 species	*Pimephales promelas*	Geometric mean 2 species	*Americamysis bahia*	Geometric mean *Pseudokirchneriella subcapitata*		*Chironomus dilutus*	*Chironomus riparius*
		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}		LC_{50}	NOEC
		630 µg/L	18 µg/L	402 µg/L	24 µg/L	430 µg/L		100000 µg/kg	40000 µg/kg
RAC		6.3	1.8	4.02	2.4	34		1000	4000
FOCUS Step 1									
	55.3	0.88	**30.72**	**13.76**	**23.04**	**1.63**	1020	**1.02**	0.255
FOCUS Step 2									
North Europe	11.8	0.19	**6.56**	**2.94**	**4.92**	0.35	146	0.15	-
South Europe	11.8	0.19	**6.56**	**2.94**	**4.92**	0.35	131	0.13	-
FOCUS Step 3*									
D3 / ditch	8.23	**1.31**	**4.57**	**2.05**	**3.43**	-	-	-	-
D4 / pond	0.367	0.06	0.20	0.09	0.15	-	-	-	-
D4 / stream	7.94	**1.26**	**4.41**	**1.98**	**3.31**	-	-	-	-
D5 / pond	0.367	0.06	0.20	0.09	0.15	-	-	-	-
D5 / stream	8.91	**1.41**	**4.95**	**2.22**	**3.71**	-	-	-	-
R1 / pond	0.37	0.06	0.21	0.09	0.15	-	-	-	-
R1 / stream	6.31	**1.00**	**3.51**	**1.57**	**2.63**	-	-	-	-
R2 / stream	8.46	**1.34**	**4.70**	**2.10**	**3.53**	-	-	-	-
R3 / stream	8.9	**1.41**	**4.94**	**2.21**	**3.71**	-	-	-	-
R4 / stream	6.31	**1.00**	**3.51**	**1.57**	**2.63**	-	-	-	-

*[Only scenarios where the trigger is not met at FOCUSsw step 1-2 should be included in step 3.]

FOCUS$_{sw}$ step 4 - PEC/RAC ratio for fludioxonil – Orchards (Pome) at 225 g a.s./ha [1 application]

Organisms *Fish, geomean acute*
RAC: 6.3 µg/L

Mitigation options	[x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction)	[x] % drift reduction from use of drift reducing nozzles	PECsw (µg/L)	PEC/RAC ratio
FOCUS Step 4*				
D3 / ditch	5	-	5.55	0.88
D3 / ditch	-	50	3.89	0.62
D4 / ditch	5	-	6.20	0.98
D4 / ditch	-	50	3.76	0.60
D5 / stream	10	-	3.1	0.49
D5 / stream	-	50	4.21	0.67
R2 / stream	10	-	2.95	0.47
R2 / stream	-	50	4.00	0.63
R3 / stream	10	-	6.95	0.49
R3 / stream	-	50	4.21	0.67

Organisms
Pimephales promelas, chronic
RAC: 1.8 µg/L

Mitigation options	[x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction)	[x] % drift reduction from use of drift reducing nozzles	PECsw (µg/L)	PEC/RAC ratio
FOCUS Step 4*				
D3 / ditch	15	-	1.25	0.69
D3 / ditch	10	50	1.24	0.69
D3 / ditch	5	75	1.39	0.77
D3 / ditch	-	90	0.778	0.43
D4 / ditch	15	-	1.40	0.78
D4 / ditch	10	50	1.38	0.77
D4 / ditch	5	75	1.55	0.86
D4 / ditch	-	90	0.752	0.42
D5 / stream	15	-	1.57	0.87
D5 / stream	10	50	1.55	0.86
D5 / stream	5	75	1.74	0.97
D5 / stream	-	90	0.843	0.47
R1 / stream	15	-	1.11	0.62
R1 / stream	10	50	1.10	0.61
R1 / stream	-	75	1.49	0.83
R2 / stream	15	-	1.49	0.83
R2 / stream	10	50	1.47	0.82
R2 / stream	5	75	1.65	0.92
R2 / stream	-	90	0.801	0.45

R3 / stream	15	-	1.57	0.87
R3 / stream	10	50	1.55	0.86
R3 / stream	5	75	1.73	0.96
R3 / stream	-	90	0.842	0.47
R4 / stream	15	-	1.11	0.62
R4 / stream	10	50	1.10	0.61
R4 / stream	-	75	1.49	0.83

Organisms:
Aquatic invertebrate, geomean acute
RAC: 4.02 µg/L

Mitigation options	[x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction)	[x] % drift reduction from use of drift reducing nozzles	PECsw (µg/L)	PEC/RAC ratio
FOCUS Step 4*				
D3 / ditch	10	-	2.48	0.62
D3 / ditch	-	50	3.89	0.97
D4 / ditch	10	-	2.77	0.69
D4 / ditch	-	50	3.76	0.94
D5 / stream	10	-	3.10	0.77
D5 / stream	5	50	3.47	0.86
D5 / stream	-	75	2.11	0.52
R1 / stream	10	-	2.20	0.55
R1 / stream	-	50	2.99	0.74
R2 / stream	10	-	2.95	0.73
R2 / stream	-	50	4.00	1.00
R3 / stream	10	-	3.10	0.77
R3 / stream	5	50	3.47	0.86
R3 / stream	-	75	2.11	0.52
R4 / stream	10	-	2.20	0.55
R4 / stream	-	50	2.99	0.74

Organisms:
Americamysis bahia, chronic
RAC: 2.4 µg/L

Mitigation options	[x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction)	[x] % drift reduction from use of drift reducing nozzles	PECsw (µg/L)	PEC/RAC ratio
FOCUS Step 4*				
D3 / ditch	15	-	1.25	0.52
D3 / ditch	10	50	1.24	0.52
D3 / ditch	-	75	1.95	0.81

D4 / ditch	15	-	1.40	0.58
D4 / ditch	10	50	1.38	0.58
D4 / ditch	-	75	1.88	0.78
D5 / stream	15	-	1.57	0.65
D5 / stream	10	50	1.55	0.65
D5 / stream	-	75	2.11	0.88
R1 / stream	10	-	2.20	0.92
R1 / stream	10	50	1.10	0.46
R1 / stream	-	75	1.49	0.62
R2 / stream	15	-	1.49	0.62
R2 / stream	10	50	1.47	0.61
R2 / stream	-	75	2.00	0.83
R3 / stream	15	-	1.57	0.65
R3 / stream	10	50	1.55	0.65
R3 / stream	-	75	2.11	0.88
R4 / stream	10	-	2.20	0.92
R4 / stream	10	50	1.10	0.46
R4 / stream	-	75	1.49	0.62

*[Only scenarios where the trigger is not met at FOCUSsw step 3 should be included in step 4].

A8240D: Orchards (Pome) at 225 g a.s./ha [2 applications]

FOCUS$_{sw}$ step 1-3 - PEC/RAC ratio for fludioxonil – Orchards (Pome) at 225 g a.s./ha [2 applications]

Scenario	**PEC$_{sw}$ global max (µg/L)**	**fish acute**	**fish chronic**	**Aquatic invertebrates acute**	**Aquatic invertebrates prolonged**	**Algae**	**PEC$_{sed}$ (µg/kg)**	**Sed. dweller acute**	**Sed. dweller prolonged**
		Geometric mean 4 species	*Pimephales promelas*	Geometric mean 2 species	*Americamysis bahia*	Geometric mean *Pseudokirchneriella subcapitata*		*Chironomus dilutus*	*Chironomus riparius*
		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}		LC_{50}	NOEC
		630 µg/L	18 µg/L	402 µg/L	24 µg/L	430 µg/L		100000 µg/kg	40000 µg/kg
RAC		6.3	1.8	4.02	2.4	34		1000	4000
FOCUS Step 1									
	14.55	0.23	**30.72**	**3.62**	**23.04**	**1.63**	1020	**1.02**	0.255
FOCUS Step 2									

North Europe	11.7	0.19	**6.50**	**2.91**	**4.88**	0.34	258	0.258	-
South Europe	11.7	0.19	**6.50**	**2.91**	**4.88**	0.34	258	0.258	-

FOCUS Step 3*									
D3 / ditch	6.55	**1.04**	**3.64**	**1.63**	**2.73**	-	- 78.9**	-	-
D4 / pond	0.525	0.08	0.29	0.13	0.22	-	-	-	-
D4 / stream	6.37	**1.01**	**3.54**	**1.58**	**2.65**	-	-	-	-
D5 / pond	0.557	0.09	0.31	0.14	0.23	-	-	-	-
D5 / stream	7.13	**1.13**	**3.96**	**1.77**	**2.97**	-	-	-	-
R1 / pond	0.558	0.09	0.31	0.14	0.23	-	-	-	-
R1 / stream	5.06	0.80	**2.81**	**1.26**	**2.11**	-	-	-	-
R2 / stream	6.78	**1.08**	**3.77**	**1.69**	**2.83**	-	-	-	-
R3 / stream	7.13	**1.13**	**3.96**	**1.77**	**2.97**	-	-	-	-
R4 / stream	5.06	0.80	**2.81**	**1.26**	**2.11**	-	-	-	-

*[Only scenarios where the trigger is not met at FOCUSsw step 1-2 should be included in step 3.]
** Sediment accumulation PEC (presented only for the worst case maximum PEC sediment).

FOCUS$_{sw}$ step 4 - PEC/RAC ratio for fludioxonil – Orchards (Pome) at 225 g a.s./ha [2 applications]

Organisms *Fish, geomean acute*
RAC: 6.3 µg/L

Mitigation options	[x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction)	[x] % drift reduction from use of drift reducing nozzles	PECsw (µg/L)	PEC/RAC ratio
FOCUS Step 4*				
D3 / ditch	5	-	4.55	0.72
D3 / ditch	-	50	3.11	0.49
D4 / ditch	5	-	5.06	0.80
D4 / ditch	-	50	3.01	0.48
D5 / stream	5	-	5.68	0.90
D5 / stream	-	50	3.38	0.54
R2 / stream	5	-	5.39	0.86
R2 / stream	-	50	3.21	0.51
R3 / stream	5	-	5.67	0.90

R3 / stream	-	50	3.37	0.53

Organisms
Pimephales promelas, chronic
RAC: 1.8 µg/L

Mitigation options	[x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction)	[x] % drift reduction from use of drift reducing nozzles	PECsw (µg/L)	PEC/RAC ratio
FOCUS Step 4*				
D3 / ditch	15	-	1.07	0.59
D3 / ditch	10	50	1.09	0.61
D3 / ditch	-	75	1.56	0.87
D4 / ditch	15	-	1.19	0.66
D4 / ditch	10	50	1.21	0.67
D4 / ditch	-	75	1.51	0.84
D5 / stream	15	-	1.33	0.74
D5 / stream	10	50	1.36	0.76
D5 / stream	-	75	1.69	0.94
R1 / stream	15	-	0.944	0.52
R1 / stream	10	50	0.964	0.54
R1 / stream	-	75	1.20	0.67
R2 / stream	15	-	1.27	0.71
R2 / stream	10	50	1.29	0.72
R2 / stream	-	75	1.35	0.89
R3 / stream	15	-	1.33	0.74
R3 / stream	10	50	1.36	0.76
R3 / stream	-	75	1.69	0.94
R4 / stream	15	-	1.22	0.68
R4 / stream	10	50	1.22	0.68
R4 / stream	-	75	1.20	0.67

Organisms:
Aquatic invertebrate, geomean acute
RAC: 4.02 µg/L

Mitigation options	[x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction)	[x] % drift reduction from use of drift reducing nozzles	PECsw (µg/L)	PEC/RAC ratio
FOCUS Step 4*				
D3 / ditch	10	-	2.19	0.54
D3 / ditch	-	50	3.11	0.77
D4 / ditch	10	-	2.43	0.60
D4 / ditch	-	50	3.01	0.75

D5 / stream	10	-	2.72	0.68
D5 / stream	-	50	3.38	0.84
R1 / stream	5	-	4.02	1.00
R1 / stream	-	50	2.39	0.59
R2 / stream	10	-	5.39	0.64
R2 / stream	-	50	3.21	0.80
R3 / stream	10	-	2.72	0.68
R3 / stream	-	50	3.37	0.84
R4 / stream	5	-	4.02	1.00
R4 / stream	-	50	2.39	0.59

Organisms:
Americamysis bahia, chronic
RAC: 2.4 µg/L

Mitigation options	[x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction)	[x] % drift reduction from use of drift reducing nozzles	PECsw (µg/L)	PEC/RAC ratio
FOCUS Step 4*				
D3 / ditch	10	-	2.19	0.91
D3 / ditch	5	50	2.28	0.95
D3 / ditch	-	75	1.56	0.65
D4 / ditch	15	-	1.19	0.50
D4 / ditch	10	50	1.21	0.50
D4 / ditch	-	75	1.51	0.63
D5 / stream	15	-	1.33	0.55
D5 / stream	10	50	1.36	0.57
D5 / stream	-	75	1.69	0.70
R1 / stream	10	-	1.93	0.80
R1 / stream	-	50	2.39	1.00
R2 / stream	15	-	1.27	0.53
R2 / stream	10	50	1.29	0.54
R2 / stream	-	75	1.60	0.67
R3 / stream	15	-	1.33	0.55
R3 / stream	10	50	1.36	0.57
R3 / stream	-	75	1.69	0.70
R4 / stream	10	-	1.93	0.80
R4 / stream	-	50	2.39	1.00

*[Only scenarios where the trigger is not met at FOCUSsw step 3 should be included in step 4].

FOCUS$_{sw}$ step 1-2 – PEC/RAC ratio for fludioxonil metabolites – Orchards (Pome) at 225 g a.s./ha [2 applications]

Test organism	Metabolite	Tier 1-RAC (µg/L)	Max PEC$_{SW}$ (µg/L)	PEC/RAC
Oncorhynchus mykiss	CGA192155	>1 000	56.1	< 0.06
	CGA339833	>1 000	33.4	< 0.03
	SYN545245	0.38[a]	0.001[b]	0.003
	CGA265378	0.38[a]	< 0.001[b]	< 0.003
	D9	0.38[a]	1.80[b]	**4.74**
	MF2	0.38[a]	2.19[b]	**5.76**
Daphnia magna	CGA192155	>1000	56.1	< 0.06
	CGA265378	0.40	< 0.001[b]	< 0.003
	CGA339833	>1000	33.4	< 0.03
	SYN545245	>1000	45.3	< 0.05
Mysidopsis bahia	D9	0.27[a]	1.80[b]	**6.67**
	MF2	0.27[a]	2.19[b]	**8.11**
Chironomus dilutus	CGA192155	100 µg/kg [a]	56.1	0.561
Chironomus riparius	CGA192155	400 µg/kg [a]	56.1	0.140
Pseudokirchneriella subcapitata	CGA192155	>10 000	56.1	< 0.01
	CGA339833	>10 000	33.4	< 0.003
	SYN545245	4 400	45.3	0.01
	CGA265378	3.4[a]	< 0.001[b]	< 0.0003
	D9	3.4[a]	1.80[b]	0.53
	MF2	3.4[a]	2.19[b]	0.64

Values in **bold** are above the trigger value of 1 and hence further consideration is needed
[a] Toxicity of metabolites are assumed to be 10 times more toxic than fludioxonil
[b] FOCUS Step 2 PEC values

A8240D: Strawberry at 250 g a.s./ha [Outdoor-1 application]

FOCUS$_{sw}$ step 1-3 - PEC/RAC ratio for fludioxonil – Strawberry at 250 g a.s./ha [1 application] **

Scenario	PEC_{sw} global max (µg/L)	fish acute	fish chronic	Aquatic invertebrates acute	Aquatic invertebrates prolonged	Algae	PEC_{sed} (µg/kg)	Sed. dweller acute	Sed. dweller prolonged
		Geometric mean 4 species	*Pimephales promelas*	Geometric mean 2 species	*Americamysis bahia*	Geometric mean *Pseudokirchneriella subcapitata*		*Chironomus dilutus*	*Chironomus riparius*
		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}		LC_{50}	NOEC
		630 µg/L	18 µg/L	402 µg/L	24 µg/L	430 µg/L		100000 µg/kg	40000 µg/kg
RAC		6.3	1.8	4.02	2.4	34		1000	4000
FOCUS Step 1									
	39.9	0.63	**22.17**	**9.93**	**16.63**	1.17	1010	**1.010**	0.253
FOCUS Step 2									
North Europe	3.28	-	**1.82**	0.82	**1.37**	0.10 -	86.4	0.086	-
South Europe	2.76	-	**1.53**	0.69	**1.15**	0.08 -	71.9	0.072	-
FOCUS Step 3*									
D6 / ditch	1.56	-	0.87	-	-	-	-	-	-
R2 / stream	1.4	-	0.78	-	-	-	-	-	-
R3 / stream	1.47	-	0.82	-	-	-	-	-	-
R4 / stream	1.04	-	0.58	-	-	-	-	-	-

*[Only scenarios where the trigger is not met at FOCUSsw step 1-2 should be included in step 3.]
** The outdoor use risk assessment covers the open type of protected structures.

A8240D: Strawberry at 250 g a.s./ha [Outdoor-2 applications]

$FOCUS_{sw}$ step 1-3 - PEC/RAC ratio for fludioxonil – Strawberry at 250 g a.s./ha [2 applications] ***

Scenario	PEC_{sw} global max (µg/L)	fish acute	fish chronic	Aquatic invertebrates acute	Aquatic invertebrates prolonged	Algae	PEC_{sed} (µg/kg)	Sed. dweller acute	Sed. dweller prolonged
		Geometric mean 4 species	*Pimephales promelas*	Geometric mean 2 species	*Americamysis bahia*	Geometric mean *Pseudokirchneriella subcapitata*		*Chironomus dilutus*	*Chironomus riparius*
		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}		LC_{50}	NOEC
		630 µg/L	18 µg/L	402 µg/L	24 µg/L	430 µg/L		100000 µg/kg	40000 µg/kg

RAC		6.3	1.8	4.02	2.4	34		1000	4000
FOCUS Step 1									
	39.9	0.63	**22.17**	**9.93**	**16.63**	1.17	1010	**1.010**	0.253
FOCUS Step 2									
North Europe	6.32	-	**3.51**	**1.57**	**2.63**	0.19 –	167	0.167	-
South Europe	5.28	-	**2.93**	**1.31**	**2.20**	0.16 –	139	0.139	-
FOCUS Step 3*									
D6 / ditch	1.37	-	0.76	0.34	0.57	-	-	-	-
R2 / stream	1.21	-	0.67	0.30	0.50	-	414**	- 0.414	- 0.414
R3 / stream	1.27	-	0.71	0.32	0.53	-	-	-	-
R4 / stream	1.49	-	0.83	0.37	0.62	-	-	-	-

*[Only scenarios where the trigger is not met at FOCUSsw step 1-2 should be included in step 3.]
** Sediment accumulation PEC (presented only for the worst case maximum PEC sediment).
*** The outdoor use risk assessment covers the open type of protected structures.

FOCUS$_{sw}$ step 1-2 – PEC/RAC ratio for fludioxonil metabolites – Strawberry at 250 g a.s./ha [Outdoor-2 applications]*

Test organism	Metabolite	Tier 1-RAC (µg/L)	Max PEC$_{sw}$ (µg/L)	PEC/RAC
Oncorhynchus mykiss	CGA192155	>1 000	59.2	< 0.06
	CGA339833	>1 000	36.1	< 0.04
	SYN545245	0.38[a]	0.001[b]	0.003
	CGA265378	0.38[a]	< 0.001[b]	< 0.003
	D9	0.38[a]	1.74[b]	**4.58**
	MF2	0.38[a]	2.09[b]	**5.50**
Daphnia magna	CGA192155	>1000	59.2	< 0.06
	CGA265378	0.40	< 0.001[b]	< 0.003
	CGA339833	>1000	36.1	< 0.04
	SYN545245	>1000	50.4	< 0.05
Mysidopsis bahia	D9	0.27[a]	1.74[b]	**6.44**
	MF2	0.27[a]	2.09[b]	**7.74**
Chironomus dilutus	CGA192155	100 µg/kg [a]	59.2	0.592
Chironomus riparius	CGA192155	400 µg/kg [a]	59.2	0.148
Pseudokirchneriella subcapitata	CGA192155	>10 000	59.2	< 0.01
	CGA339833	>10 000	36.1	< 0.004
	SYN545245	4 400	< 0.001[b]	< 0.0003
	CGA265378	3.4[a]	50.4	0.01
	D9	3.4[a]	1.74[b]	0.51
	MF2	3.4[a]	2.09[b]	0.61

Values in **bold** are above the trigger value of 1 and hence further consideration is needed
* The outdoor use risk assessment covers the open type of protected structures
[a] Toxicity of metabolites are assumed to be 10 times more toxic than fludioxonil
[b] FOCUS Step 2 PEC values

Tier 1 risk assessment for fludioxonil based on NL glasshouse emissions strawberry (2 × 250 g a.s./ha)

Group			Fish - acute	Fish - chronic	Invertebrate - acute	Invertebrate - chronic	Algae
Tier 1 RAC (µg/L)			3.8	1.8	2.7	2.4	43
Protected uses (NL Glasshouse emissions)		PEC_{sw} (µg/L)	PEC/RAC (pelagic species)				
Fludioxonil	Soil-less system with filter	16.4	**4.3**	**9.1**	**6.1**	**6.8**	0.38
	Soil-less system without filter	5.20	**1.4**	**2.9**	**1.9**	**2.2**	0.12

Tier 2 risk assessment for fludioxonil based on NL glasshouse emissions strawberry (2 × 250 g a.s./ha)

Group			Fish - acute	Fish - chronic	Invertebrate - acute	Invertebrate - chronic	Algae
Tier 1 RAC (µg/L)			3.8	1.8	2.7	2.4	43
Protected uses (NL Glasshouse emissions)		PECsw (µg/L)	PEC/RAC (pelagic species)				
Fludioxonil	Soil-less system with filter with 90% end of pipe mitigation	1.64	0.43	0.91	0.61	0.68	0.038
	Soil-less system without filter with 70% end of pipe mitigation	1.56	0.41	0.87	0.58	0.65	0.036

A8207M: Cereals at 225 g a.s./ha [2 applications]

$FOCUS_{sw}$ step 1 - PEC/RAC ratio for fludioxonil – Treated cereals seed at 12.5 g a.s./ha (worst-case scenario)

Scenario	PEC_{sw} global max (µg/L)	fish acute	fish chronic	Aquatic invertebrates acute	Aquatic invertebrates prolonged	Algae	PEC_{sed} (µg/kg)	Sed. dweller acute	Sed. dweller prolonged
		Geometric mean 4 species	*Pimephales promelas*	Geometric mean 2 species	*Americamysis bahia*	Geometric mean *Pseudokirchneriella subcapitata*		*Chironomus dilutus*	*Chironomus riparius*
		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}		LC_{50}	NOEC

		630 µg/L	18 µg/L	402 µg/L	24 µg/L	340 µg/L		100000 µg/kg	40000 µg/kg
RAC		6.3	1.8	4.02	2.4	34		1000	4000
FOCUS Step 1									
	0.882	0.140	0.490	0.0219	0.368	0.026	78.3*	0.	0.020

* STEP 2 PEC sediment accumulation

FOCUS$_{sw}$ step 1-2 – PEC/RAC ratio for metabolite CGA192155 –Treated cereals seed at 12.5 g a.s./ha (worst-case scenario)

Group	Tier 1 RAC (µg/L)	FOCUS Step 1 PEC$_{SW}$ (µg/L)	PEC/RAC ratio
Fish – acute	>1 000	0.573	<0.00057
Invertebrate – acute	>1 000		<0.00057
Algae	>10 000		<0.000057
Sediment dweller - acute	100 µg/kg [a]	0.107 µg/kg	0.00107
Sediment dweller - chronic	4 00 µg/kg [a]		0.00027

[a] The toxicity of CGA192155 to sediment dwelling organisms is assumed to be 10 times more toxic than fludioxonil.

FOCUS$_{sw}$ step 1-2 – PEC/RAC ratio for metabolite MF2 –Treated cereals seed at 12.5 g a.s./ha (worst-case scenario)

Group	Tier 1 RAC (µg/L)	FOCUS Step 1 PEC$_{SW}$ (µg/L)	PEC/RAC ratio
Fish – acute	0.63	0.350	<0.55
Invertebrate – acute	0.4		<0.87
Algae	3.44		<0.1
Sediment dweller - acute	100 µg/kg [a]	<0.001	<0.00001

[a] The toxicity of MF2 to aquatic and sediment organisms is assumed to be 10 times more toxic than fludioxonil

Effects on bees (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.1 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.1)

Species	Test substance	Time scale/type of endpoint	End point	toxicity
Apis mellifera	Fludioxonil	Acute	Oral toxicity (48 h LD_{50})	> 100 µg a.s./bee
Apis mellifera	A8240B[1]	Acute	Oral toxicity (48 h LD_{50})	> 101 µg prep./bee (>50 µg a.s./bee)
Apis mellifera	Fludioxonil	Acute	Contact toxicity (48 h LD_{50})	> 100 µg a.s./bee
Apis mellifera	A8240B[1]	Acute	Contact toxicity (48 h LD_{50})	> 100 µg prep./bee (>50 µg a.s./bee)
Apis mellifera	A8207M	Acute	Oral toxicity (48 h LD_{50})	572 µg prep./bee (13.78 µg a.s./bee)
Apis mellifera	A8207M	Acute	Contact toxicity (48 h LD_{50})	> 1000 µg prep./bee (>24 µg a.s./bee)
Apis mellifera	A8240D	Chronic, adult	10 d-NOED	44.06 µg/consumed a.s/bee/day
Apis mellifera	A8240D	Chronic, adult	10 d LDD_{50}	> 166 µg a.s./consumed a.s/bee/day
Apis mellifera	A8240D	Chronic, larval	8 d-NOED	28.9 µg a.s./larva
Apis mellifera	A8207M	Chronic, adult	10 d-LDD_{50}	7.08 µg/consumed a.s/bee/day
Apis mellifera	A8207M	Chronic, larval	8 d-NOED	8.26 µg a.s./larva

[1] formulation variant equivalent to A8240D

Potential for accumulative toxicity: *Not studied.*
Semi-field test (Cage and tunnel test): *Not available.*
Field tests: *Not available.*

A8240D: Risk assessment for grapes at 500 g a.s./ha [2 applications] (SANCO, 2002)

Species	Test substance	Risk quotient	HQ/ETR	Trigger
Apis mellifera	Fludioxonil	HQ_{oral}	< 5.0	50
Apis mellifera	A8240B[1]	HQ_{oral}	< 9.9	50
Apis mellifera	Fludioxonil	$HQ_{contact}$	< 5.0	50
Apis mellifera	A8240B[1]	$HQ_{contact}$	< 10	50

[1] formulation variant equivalent to A8240D

A8240D: Risk assessment for grapes at 500 g a.s./ha [2 applications] (EFSA, 2013)

Species	Test substance	Scenario	Risk quotient	HQ/ETR	Trigger
Screening level assessment					
Apis mellifera	Fludioxonil	Not relevant	$HQ_{contact}$	5.0	42
Apis mellifera	Fludioxonil	Not relevant	$ETR_{acute\ adult\ oral}$	0.05	0.2
Apis mellifera	A8240D	Not relevant	$ETR_{chronic\ adult}$	**<0.032**	0.03
Apis mellifera	A8240D	Not relevant	ETR_{larvae}	0.11	0.2
1st tier oral assessment					
Apis mellifera	A8240D	Treated crop, BBCH 40-69	$ETR_{chronic\ adult}$	0.018	0.03
		Treated crop BBCH ≥ 70	$ETR_{chronic\ adult}$	0.000	0.03
		Weeds, BBCH 40-69	$ETR_{chronic\ adult}$	0.002	0.03
		Weeds BBCH ≥ 70	$ETR_{chronic\ adult}$	0.002	0.03
		Field margin, BBCH 40-69	$ETR_{chronic\ adult}$	0.000	0.03
		Field margin BBCH ≥ 70	$ETR_{chronic\ adult}$	0.000	0.03
		Adjacent crop, BBCH 40-69	$ETR_{chronic\ adult}$	0.000	0.03
		Adjacent crop BBCH ≥ 70	$ETR_{chronic\ adult}$	0.000	0.03
		Next crop, BBCH 40-69	$ETR_{chronic\ adult}$	0.001	0.03
		Next crop BBCH ≥ 70	$ETR_{chronic\ adult}$	0.001	0.03

A8240D: Risk assessment for orchards (Pome) at 225 g a.s./ha [2 applications] (SANCO, 2002)

Species	Test substance	Risk quotient	HQ/ETR	Trigger
Apis mellifera	Fludioxonil	HQ_{oral}	< 2.3	50
Apis mellifera	A8240B[1]	HQ_{oral}	< 4.5	50
Apis mellifera	Fludioxonil	$HQ_{contact}$	< 2.3	50
Apis mellifera	A8240B[1]	$HQ_{contact}$	< 4.5	50

[1] formulation variant equivalent to A8240D

A8240D: Risk assessment for orchards (Pome) at 225 g a.s./ha [2 applications] (EFSA, 2013)

Species	Test substance	Scenario	Risk quotient	HQ/ETR	Trigger
Screening level assessment					
Apis mellifera	Fludioxonil	Not relevant	$HQ_{contact}$	2.3	42
Apis mellifera	Fludioxonil	Not relevant	$ETR_{acute\ adult\ oral}$	0.02	0.2
Apis mellifera	A8240D	Not relevant	$ETR_{chronic\ adult}$	<0.014	0.03
Apis mellifera	A8240D	Not relevant	ETR_{larvae}	0.05	0.2

A8240D: Risk assessment for strawberry at 250 g a.s./ha [2 applications] (SANCO, 2002)

Species	Test substance	Risk quotient	HQ/ETR	Trigger
Apis mellifera	Fludioxonil	HQ_{oral}	< 2.5	50
Apis mellifera	A8240B[1]	HQ_{oral}	< 5	50
Apis mellifera	Fludioxonil	$HQ_{contact}$	< 2.5	50
Apis mellifera	A8240B[1]	$HQ_{contact}$	< 5	50

[1] formulation variant equivalent to A8240D

A8240D: Risk assessment for strawberry at 250 g a.s./ha [2 applications] (EFSA, 2013)

Species	Test substance	Scenario	Risk quotient	HQ/ETR	Trigger
Screening level assessment					
Apis mellifera	Fludioxonil	Not relevant	$HQ_{contact}$	2.5	42
Apis mellifera	Fludioxonil	Not relevant	$ETR_{acute\ adult\ oral}$	0.02	0.2
Apis mellifera	A8240D	Not relevant	$ETR_{chronic\ adult}$	<0.011	0.03
Apis mellifera	A8240D	Not relevant	ETR_{larvae}	0.04	0.2

A8207M: Risk assessment for treated cereal seeds at 12.5 g a.s./ha (worst-case scenario) (SANCO, 2002)

Species	Test substance	Risk quotient	HQ/ETR	Trigger
Apis mellifera	Fludioxonil	HQ_{oral}	< 0.125	50
Apis mellifera	A8207M	HQ_{oral}	0.90	50
Apis mellifera	Fludioxonil	$HQ_{contact}$	< 0.125	50
Apis mellifera	A8207M	$HQ_{contact}$	< 0.515	50

A8207M: Risk assessment for treated cereal seeds at 12.5 g a.s./ha (worst-case scenario)) (EFSA, 2013)

Species	Test substance	Scenario	Single application rate	Risk quotient	HQ/ETR	Trigger
Screening level assessment						
Apis mellifera	Fludioxonil[1]	Not relevant	12.5 g a.s./ha	$HQ_{contact}$	<0.0	42
Apis mellifera	Fludioxonil[1]	Not relevant	0.0125 kg/ha	$ETR_{acute\ adult\ oral}$	<0.00	0.2
			0.00275 mg/seed		0.00	
Apis mellifera	A8207M	Not relevant	0.0125 kg/ha	$ETR_{chronic\ adult}$	0.004	0.03
			0.00275 mg/seed		0.000	
Apis mellifera	A8207M	Not relevant	0.0125 kg/ha	ETR_{larvae}	0.00	0.2
			0.00275 mg/seed		0.00	

[1] the endpoint obtained with the formulation have been used in the risk assessment as the formulation seems to be more acutely toxic than the active substance.

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)

Extended laboratory tests, aged residue tests

Species	Life stage	Test substance, substrate	Time scale	Dose (g/ha)[1]	End point	% effect[2]	ER_{50}
Typhlodromus pyri	protonymphs	A8240D	7-d	125 250 500 1000 2000	Mortality	42 23 25 18 20	> 2000 g prep./ha (> 1000g a.s./ha)
Typhlodromus pyri	protonymphs	A8240D	7-d	125 250 500 1000 2000	Reproduction	4 12 29 3 40	> 2000 g prep./ha (> 1000g a.s./ha)
Aphidius rhopalosiphi	adult	A8240D	48 h	125 250 500 1000 2000	Mortality	0 0 0 0 6.7	> 2000 g prep./ha (> 1000g a.s./ha)
Aphidius rhopalosiphi	adult	A8240D	48 h	125 250 500 1000 2000	Reproduction	N/A N/A 13.3 1.5 12.4	> 2000 g prep./ha (> 1000g a.s./ha)
Chrysoperla carnea	larvae	A8240D	6 weeks	125 250 500 1000 2000	Mortality	20 5.0 12.5 12.5 15.0	> 2000 g prep./ha (> 1000g a.s./ha)
Chrysoperla carnea	larvae	A8240D	6 weeks	125 250 500 1000 2000	Reproduction	N/A N/A 3.1 2.8 2.7	> 2000 g prep./ha (> 1000g a.s./ha)
Typhlodromus pyri	protonymphs	A8207M	7-d	125 250 500 1000 2000	Mortality	17 17 8 17 10	> 2102 g prep./ha (> 50 g a.s./ha)
Typhlodromus pyri	protonymphs	A8207M	7-d	125 250 500 1000 2000	Reproduction	15.1 6.5 -18.1 -24.2 -6.5	> 2102 g prep./ha (> 50 g a.s./ha)

Species	Life stage	Test substance, substrate	Time scale	Dose (g/ha)[1]	End point	% effect[2]	ER_{50}
Aphidius rhopalosiphi	adult	A8207M	48 h	125 250 500 1000 2000	Mortality	2.5 0.0 7.5 15 20	> 2102 g prep./ha (> 50 g a.s./ha)
Aphidius rhopalosiphi	adult	A8207M	48 h	125 250 500 1000 2000	Reproduction	N/A N/A -8.2 -3.2 -13.9	> 2102 g prep./ha (> 50 g a.s./ha)
Aleochara bilineata	adult	A8207M	70-d	(mg/kg soil) 5 10 20 37.5 75 150	Mortality	 2.5 2.5 3.8 2.5 1.3 3.8	> 150 mg prep./kg soil (3.615 mg a.s./kg soil) NOEC = 5 mg prep./kg soil (0.13 mg a.s./kg soil)
Aleochara bilineata	adult	A8207M	70-d	(mg/kg soil) 5 10 20 37.5 75 150	Reproduction	 6.4 9.7 11.6 14.2 18.8 11.7	> 150 mg prep./kg soil (3.615 mg a.s./kg soil) NOEC = 5 mg prep./kg soil (0.13 mg a.s./kg soil)

[1] dose is expressed in units of preparation
[2] positive percentages relate to adverse effects
N/A : Not applicable - no assessment of reproductive capacity was made.

A8240D: Risk assessment for grapes at 500 g a.s./ha [2 applications] based on extended lab test or aged residue tests

Species	ER_{50} (g a.s./ha)	In-field rate	Off-field rate[1]
Typhlodromus pyri	> 1000	425	30.75
Aphidius rhopalosiphi	> 1000	425	307.5
Chrysoperla carnea	> 1000	425	30.75

[1] Off-field rate estimated with the drift rate at 3 m and considering 3D tests for *A. rhopalosiphi*-or 2D tests for *T. pyri* and *C. carnea*.

A8240D: Risk assessment for orchards (Pome) at 225 g a.s./ha [2 applications] based on extended lab test or aged residue tests

Species	ER_{50} (g a.s./ha)	In-field rate	Off-field rate[1]
Typhlodromus pyri	> 1000	191.25	23.2
Aphidius rhopalosiphi	> 1000	191.25	232
Chrysoperla carnea	> 1000	191.25	23.2

[1] Off-field rate estimated with the drift rate at 3 m and considering 3D tests for *A. rhopalosiphi*-or 2D tests for *T. pyri* and *C. carnea*.

A8240D: Risk assessment for strawberry at 250 g a.s./ha [2 applications] based on extended lab test or aged residue tests

Species	ER_{50} (g a.s./ha)	In-field rate	Off-field rate[1]
Typhlodromus pyri	> 1000	425	5.05
Aphidius rhopalosiphi	> 1000	425	50.5
Chrysoperla carnea	> 1000	425	5.05

[1] Off-field rate estimated with the drift rate at 1 m and considering 3D tests for *A. rhopalosiphi*-or 2D tests for *T. pyri* and *C. carnea*.

A8207M: Risk assessment for treated cereal seeds at 12.5 g a.s./ha (worst-case scenario)

Test item	Species	NOEC	$PEC_{in\text{-}field\ soil}$	Acceptable effects
A8207M	*Aleochara bilineata*	5.0 (mg product/kg dry soil)	0.701 (mg product/kg dry soil)	Yes
Fludioxonil	*Aleochara bilineata*	0.1205 (mg a.s/.kg dry soil)[1]	0.040 (mg a.s./kg dry soil)[2]	Yes

[1] Data of the formulation expressed as fludioxonil.
[2] Peak accumulation PEC_S

Semi-field tests
No studies are available.
Field studies
No studies are available.
Additional specific test
No studies are available.

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 foetida	Fludioxonil	Mixed with soil/ 10 % OM	Chronic	Reproduction	EC_{10} > 20 mg a.s./kg soil EC_{20}> 20 mg a.s./kg soil NOEC = 20 mg a.s./kg soil (**$NOEC_{corr}$ = 10 mg a.s./kg soil**)
Eisenia foetida	A8240D	Mixed with soil/ 5 % OM	Chronic	Reproduction	EC_{10} = 104 mg/kg soil EC_{20} = 132 mg/kg soil NOEC = 100 mg prep./kg soil (**$NOEC_{corr}$ = 50 mg prep../kg soil**)
Eisenia foetida	A8207M	Mixed with soil/ 10 % OM	Chronic	Reproduction	NOEC = 2688 mg prep./kg soil (**$NOEC_{corr}$ = 1344 mg prep./kg soil**)
Eisenia foetida	CGA192155	Mixed with soil/ 10 % OM	Chronic	Reproduction	**EC_{10} = 14.3 mg met./kg soil** EC_{20} = 20.7 mg met./kg soil NOEC = 26 mg met./kg soil
Eisenia foetida	CGA265378	Mixed with soil/ 5 % OM	Chronic	Reproduction	EC_{10} = 104 mg met./kg soil EC_{20} = 130 mg met./kg soil NOEC = 95.3 mg met./kg soil (**$NOEC_{corr}$ = 47.65 mg met./kg soil**)
Eisenia foetida	CGA339833	Mixed with soil/ 10 % OM	Chronic	Reproduction	**EC_{10} = 28.5 mg met./kg soil** EC_{20} = 57.9 mg met./kg soil NOEC = 31.25 mg met./kg soil
Eisenia foetida	SYN545245	Mixed with soil/ 5 % OM	Chronic	Reproduction	EC_{10} = 60.6 mg met./kg soil EC_{20} = 90.6 mg met./kg soil **NOEC = 55.6 mg met./kg soil**
Eisenia foetida	MF2	N/A	Chronic	Reproduction	**NOEC = 1 mg met./kg soil** [2]
Eisenia foetida	D9	N/A	Chronic	Reproduction	**NOEC = 1 mg met./kg soil** [2]
Other soil macroorganisms					
Folsomia candida	Fludioxonil (represented by A8240D)	Mixed with soil/ 5 % OM	Chronic	Reproduction	NOEC = 500 mg a.s./kg soil (**$NOEC_{corr}$ = 250 mg a.s./kg soil**)
Folsomia candida	MF2	N/A	Chronic	Reproduction	**NOEC = 25 mg met./kg soil** [2]
Folsomia candida	D9	N/A	Chronic	Reproduction	**NOEC = 25 mg met./kg soil** [2]

Test organism	Test substance	Application method of test a.s./ OM[1]	Time scale	End point	Toxicity
Folsomia candida	A8240D	Mixed with soil/ 5 % OM	Chronic	Reproduction	EC_{10} > 1000 mg prep./kg soil EC_{20} > 1000 mg prep./kg soil NOEC = 1000 mg prep./kg soil (**$NOEC_{corr}$ = 500 mg prep./kg soil**)
Folsomia candida	Fludioxonil (represented by A8207M)	Mixed with soil/ 10 % OM	Chronic	Reproduction	EC_{10} = 2.43 mg a.s./kg soil **($EC_{10\ corr}$ = 1.22 mg a.s./kg soil)** NOEC = 12.5 mg a.s./kg soil
Folsomia candida	MF2	N/A	Chronic	Reproduction	**NOEC = 0.122 mg met./kg soil** [3]
Folsomia candida	A8207M	Mixed with soil/ 10 % OM	Chronic	Reproduction	NOEC = 525 mg prep./kg soil EC_{10} = 102.5 mg prep./kg soil (**$EC_{10\ corr}$ = 51.25 mg prep./kg soil**)
Folsomia candida	CGA192155	Mixed with soil/ 5 % OM	Chronic	Reproduction	**NOEC = 53 mg met./kg soil**
Folsomia candida	CGA265378	Mixed with soil/ 5 % OM	Chronic	Reproduction	NOEC = 29 mg met./kg soil (**$NOEC_{corr}$ = 14.5 mg met./kg soil**)
Folsomia candida	CGA339833	Mixed with soil/ 5 % OM	Chronic	Reproduction	EC_{10} > 1000 mg met./kg soil EC_{20} > 1000 mg met./kg soil **NOEC = 1000 mg met./kg soil**
Folsomia candida	SYN545245	Mixed with soil/ 5 % OM	Chronic	Reproduction	EC_{10} > 100 mg met./kg soil EC_{20} > 100 mg met./kg soil **NOEC = 100 mg met./kg soil**
Hypoaspis aculeifer	Fludioxonil (represented by A8240D)	Mixed with soil/ 5 % OM	Chronic	Reproduction	NOEC = 500 mg s.a./kg soil (**$NOEC_{corr}$ = 250 mg s.a./kg soil**)
Hypoaspis aculeifer	MF2	N/A	Chronic	Reproduction	**NOEC = 25 mg met./kg soil** [2]
Hypoaspis aculeifer	D9	N/A	Chronic	Reproduction	**NOEC = 25 mg met./kg soil** [2]
Hypoaspis aculeifer	A8240D	Mixed with soil/ 5 % OM	Chronic	Reproduction	EC_{10} > 1000 mg prep./kg soil EC_{20} > 1000 mg prep./kg soil **NOEC = 1000 mg prep./kg soil** ($NOEC_{corr}$ = 500 mg prep./kg soil)
Hypoaspis aculeifer	Fludioxonil (represented by A8207M)	Mixed with soil/ 5 % OM	Chronic	Reproduction	NOEC = 24.1 mg a.s./kg soil (**$NOEC_{corr}$ = 12.05 mg a.s./kg soil**)
Hypoaspis aculeifer	MF2	N/A	Chronic	Reproduction	**NOEC = 1.205 mg met./kg soil** [3]

Test organism	Test substance	Application method of test a.s./ OM[1]	Time scale	End point	Toxicity
Hypoaspis aculeifer	A8207M	Mixed with soil/ 5 % OM	Chronic	Reproduction	EC_{10} > 1000 mg prep./kg soil EC_{20} > 1000 mg prep./kg soil **NOEC = 1000 mg prep./kg soil** ($NOEC_{corr}$ = 500 mg prep./kg soil)
Hypoaspis aculeifer	CGA192155	Mixed with soil/ 5 % OM	Chronic	Reproduction	EC_{10} > 1000 mg met./kg soil EC_{20} > 1000 mg met./kg soil **NOEC = 1000 mg met./kg soil**
Hypoaspis aculeifer	CGA265378	Mixed with soil/ 5 % OM	Chronic	Reproduction	EC_{10} > 1000 mg met./kg soil EC_{20} > 1000 mg met./kg soil **NOEC = 1000 mg met./kg soil**
Hypoaspis aculeifer	CGA339833	Mixed with soil/ 5 % OM	Chronic	Reproduction	**NOEC = 500 mg met./kg soil**
Hypoaspis aculeifer	SYN545245	Mixed with soil/ 5 % OM	Chronic	Reproduction	EC_{10} > 1000 mg met./kg soil EC_{20} > 1000 mg met./kg soil **NOEC = 1000 mg met./kg soil**

Values in **bold** are used in the risk assessment
[1] To indicate whether the test substance was oversprayed/to indicate the organic content of the test soil (e.g. 5 % or 10 %).
[2] Toxicity endpoint is derived from the endpoint of the active substance (represented by A8240D) including a safety factor of 10.
[3] Toxicity endpoint is derived from the endpoint of the active substance (represented by A8207M) including a safety factor of 10.
N/A: Not applicable.

Higher tier testing (e.g. modelling or field studies)
No data available.

Nitrogen transformation	Fludioxonil	< 25 % effect at day 28	1.33 mg a.s./kg soil
Nitrogen transformation	A8240D	< 25 % effect at day 28	10 mg prep./kg soil
Nitrogen transformation	A8207M	< 25 % effect at day 28	7.01 mg prep./kg soil
Nitrogen transformation	CGA192155	< 25 % effect at day 28	0.353 mg met./kg soil
Nitrogen transformation	CGA265378	< 25 % effect at day 28	0.37 mg met./kg soil
Nitrogen transformation	CGA339833	< 25 % effect at day 28	20 mg met./kg soil
Nitrogen transformation	SYN545245	< 25 % effect at day 28	2.07 mg met./kg soil

Toxicity/exposure ratios for soil organisms

A8240D: Risk assessment for grapes at 500 g a.s./ha [2 applications]

Test organism	Test substance	Time scale	Soil PEC	TER	Trigger
Earthworms					
Eisenia fetida	A8240D	Chronic	0.533[1]	94	5
Eisenia fetida	Fludioxonil	Chronic	0.606[2]	17	5
Eisenia fetida	CGA192155	Chronic	0.068	210	5

Test organism	Test substance	Time scale	Soil PEC	TER	Trigger
Eisenia fetida	CGA265378	Chronic	0.030	1588	5
Eisenia fetida	CGA339833	Chronic	0.046	620	5
Eisenia fetida	SYN545245	Chronic	0.081	686	5
Eisenia fetida	MF2	Chronic	0.036	28	5
Eisenia fetida	D9	Chronic	0.030	33	5
Other soil macroorganisms					
Hypoaspis aculeifer	A8240D	Chronic	0.533[1]	938	5
Hypoaspis aculeifer	Fludioxonil	Chronic	0.606[2]	413	5
Hypoaspis aculeifer	CGA192155	Chronic	0.068	14706	5
Hypoaspis aculeifer	CGA265378	Chronic	0.030	16667	5
Hypoaspis aculeifer	CGA339833	Chronic	0.046	10870	5
Hypoaspis aculeifer	SYN545245	Chronic	0.081	12346	5
Hypoaspis aculeifer	MF2	Chronic	0.036	694	5
Hypoaspis aculeifer	D9	Chronic	0.030	833	5
Folsomia candida	A8240D	Chronic	0.533[1]	938	5
Folsomia candida	Fludioxonil	Chronic	0.606[2]	413	5
Folsomia candida	CGA192155	Chronic	0.068	779	5
Folsomia candida	CGA265378	Chronic	0.030	483	5
Folsomia candida	CGA339833	Chronic	0.046	21739	5
Folsomia candida	SYN545245	Chronic	0.081	1235	5
Folsomia candida	MF2	Chronic	0.036	694	5
Folsomia candida	D9	Chronic	0.030	833	5

[1] Initial PECs
[2] Peak accumulation PECs

A8240D: Risk assessment for orchards (Pome) at 225 g a.s./ha [2 applications]

Test organism	Test substance	Time scale	Soil PEC	TER	Trigger
Earthworms					
Eisenia fetida	A8240D	Chronic	0.533[1]	94	5
Eisenia fetida	Fludioxonil	Chronic	0.300[2]	33	5
Eisenia fetida	CGA192155	Chronic	0.042	340	5
Eisenia fetida	CGA265378	Chronic	0.012	7942	5
Eisenia fetida	CGA339833	Chronic	0.031	919	5
Eisenia fetida	SYN545245	Chronic	0.032	1738	5
Eisenia fetida	MF2	Chronic	0.018	56	5
Eisenia fetida	D9	Chronic	0.014	71	

Test organism	Test substance	Time scale	Soil PEC	TER	Trigger
Other soil macroorganisms					
Hypoaspis aculeifer	A8240D	Chronic	0.533[1]	938	5
Hypoaspis aculeifer	Fludioxonil	Chronic	0.300[2]	833	5
Hypoaspis aculeifer	CGA192155	Chronic	0.042	23810	5
Hypoaspis aculeifer	CGA265378	Chronic	0.012	41667	5
Hypoaspis aculeifer	CGA339833	Chronic	0.031	16129	5
Hypoaspis aculeifer	SYN545245	Chronic	0.032	31250	5
Hypoaspis aculeifer	MF2	Chronic	0.018	1389	5
Hypoaspis aculeifer	D9	Chronic	0.014	1786	5
Folsomia candida	A8240D	Chronic	0.533[1]	938	5
Folsomia candida	Fludioxonil	Chronic	0.300[2]	833	5
Folsomia candida	CGA192155	Chronic	0.042	1262	5
Folsomia candida	CGA265378	Chronic	0.012	1208	5
Folsomia candida	CGA339833	Chronic	0.031	32258	5
Folsomia candida	SYN545245	Chronic	0.032	3125	5
Folsomia candida	MF2	Chronic	0.018	1389	5
Folsomia candida	D9	Chronic	0.014	1786	5

[1] Initial PECs
[2] Peak accumulation PECs

A8240D: Risk assessment for strawberry at 250 g a.s./ha [2 applications]

Test organism	Test substance	Time scale	Soil PEC	TER	Trigger
Earthworms					
Eisenia fetida	A8240D	Chronic	0.533[1]	94	5
Eisenia fetida	Fludioxonil	Chronic	0.381[2]	26	5
Eisenia fetida	CGA192155	Chronic	0.051	280	5
Eisenia fetida	CGA265378	Chronic	0.015	6353	5
Eisenia fetida	CGA339833	Chronic	0.037	770	5
Eisenia fetida	SYN545245	Chronic	0.040	1390	5
Eisenia fetida	MF2	Chronic	0.022	45	5
Eisenia fetida	D9	Chronic	0.018	56	5
Other soil macroorganisms					
Hypoaspis aculeifer	A8240D	Chronic	0.533[1]	938	5
Hypoaspis aculeifer	Fludioxonil	Chronic	0.381[2]	656	5
Hypoaspis aculeifer	CGA192155	Chronic	0.051	19608	5
Hypoaspis aculeifer	CGA265378	Chronic	0.015	33333	5
Hypoaspis aculeifer	CGA339833	Chronic	0.037	13514	5

Test organism	Test substance	Time scale	Soil PEC	TER	Trigger
Hypoaspis aculeifer	SYN545245	Chronic	0.040	25000	5
Hypoaspis aculeifer	MF2	Chronic	0.022	1136	5
Hypoaspis aculeifer	D9	Chronic	0.018	1389	5
Folsomia candida	A8240D	Chronic	0.533[1]	938	5
Folsomia candida	Fludioxonil	Chronic	0.381[2]	656	5
Folsomia candida	CGA192155	Chronic	0.051	1039	5
Folsomia candida	CGA265378	Chronic	0.015	967	5
Folsomia candida	CGA339833	Chronic	0.037	27027	5
Folsomia candida	SYN545245	Chronic	0.040	2500	5
Folsomia candida	MF2	Chronic	0.022	1136	5
Folsomia candida	D9	Chronic	0.018	1389	5

[1] Initial PECs
[2] Peak accumulation PECs

A8207M: Risk assessment for treated cereal seeds at 12.5 g a.s./ha (worst-case scenario)

Test organism	Test substance	Time scale	Soil PEC	TER	Trigger
Earthworms					
Eisenia fetida	A8207M	Chronic	0.701[1]	1917	5
Eisenia fetida	Fludioxonil	Chronic	0.040[2]	250	5
Eisenia fetida	MF2	Chronic	0.001	1000	5
Other soil macroorganisms					
Hypoaspis aculeifer	A8207M	Chronic	0.701[1]	713	5
Hypoaspis aculeifer	Fludioxonil	Chronic	0.040[2]	301	5
Hypoaspis aculeifer	MF2	Chronic	0.001	1205	5
Folsomia candida	A8207M	Chronic	0.701[1]	73	5
Folsomia candida	Fludioxonil	Chronic	0.040[2]	30.5	5
Folsomia candida	MF2	Chronic	0.001	122	5

[1] Initial PECs
[2] Peak accumulation PEC_S

Effects on terrestrial non target higher plants (Regulation (EU) N° 283/2013, Annex Part A, point 8.6 and Regulation (EU) N° 284/2013 Annex Part A, point 10.6)

Screening data

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

Laboratory dose response tests

Species	Test substance	ER_{50} (g/ha) vegetative vigour	ER_{50} (g/ha) emergence	Exposure[1] (g/ha)
Allium cepa, Avena sativa, Glycine max, Beta vulgaris, Brassica napa, Cucumis sativa	A8240D	> 1000 g prep./ha	> 1000 g prep./ha	-Grapes: 80.2 g prep./ha (3 m distance, late application (8.02%)) -Orchards: 70.8 g prep./ha (3 m distance, late application (15.73%)) -Strawberry: 13 g prep./ha (1m distance, (2.77%))
Glycine max, Lactuca sativa, Allium cepa, Avena sativa, Lolium perenne, Brassica oleracea, Zea mays, Cucumis sativa, Daucus carota, Lycopersicon esculentum	Fludioxonil	-	> 1121 g a.s./ha	-Grapes: 40.1 g a.s./ha (3 m distance, late application (8.02%)) -Orchards: 35.4 g a.s./ha (3 m distance, late application (15.73%)) -Strawberry: 13 g a.s./ha (1m distance, (2.77%))
Glycine max, Lactuca sativa, Allium cepa, Avena sativa, Lolium perenne, Brassica	Fludioxonil	> 1121 g a.s./ha	-	

Species	Test substance	ER_{50} (g/ha) vegetative vigour	ER_{50} (g/ha) emergence	Exposure[1] (g/ha)
oleracea, Zea mays, Cucumis sativa, Daucus carota, Lycopersicon esculentum				

[1] exposure has been estimated with Ganzelmeier drift data

Effects on biological methods for sewage treatment (Regulation (EU) N° 283/2013, Annex Part A, point 8.8)

Test type/organism	end point
Activated sludge	EC_{50} > 100 mg a.s./L
Activated sludge	EC_{50} > 1000 mg a.s./L

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

Available monitoring data concerning adverse effect of the a.s. : *No data available.*
Available monitoring data concerning effect of the PPP: *No data available.*

Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2) Ecotoxicologically relevant compounds[1]

Compartment	
soil	Fludioxonil
water	Fludioxonil
sediment	Fludioxonil
groundwater	Fludioxonil

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

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

Substance	Fludioxonil
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][10]:	-
According to the peer review criteria for harmonised classification according to Regulation (EC) No 1272/2008 may be met for:	Aquatic acute 1, H400: Very toxic to aquatic life (Acute M = 1) Aquatic chronic 1, H410: Very toxic to aquatic life with long lasting effects (Chronic M = 1)

[10] 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.