Appendix to:

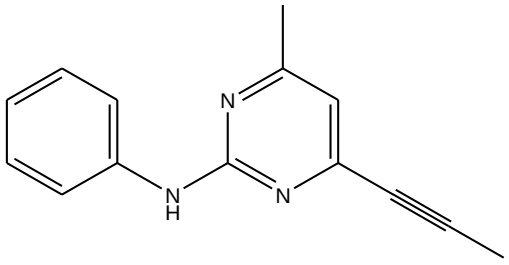
EFSA (European Food Safety Authority), 2017. Conclusion on the peer review of the pesticide risk assessment of the active substance mepanipyrim. EFSA Journal 2017;15(6):4852, 80 pp. doi:10.2903/j.efsa.2017.4852

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)	Mepanipyrim
Function (*e.g.* fungicide)	Fungicide

Rapporteur Member State	Belgium
Co-rapporteur Member State	Greece

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

Chemical name (IUPAC)	*N*-(4-methyl-6-prop-1-ynylpyrimidin-2-yl)aniline
Chemical name (CA)	4-methyl-*N*-phenyl-6-(1-propynyl)-2-pyrimidinamine
CIPAC No	611
CAS No	110235-47-7
EC No (EINECS or ELINCS)	600-951-7
FAO Specification (including year of publication)	No FAO specifications exist for mepanipyrim
Minimum purity of the active substance as manufactured	970 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	Toluene (max. 5 g/kg). Open for two impurities.
Molecular formula	$C_{14}H_{13}N_3$
Molar mass	223.3 g/mol
Structural formula	

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

Melting point (state purity)	132.8 °C (99.7%)
Boiling point (state purity)	Boiling point not determined because of decomposition
Temperature of decomposition (state purity)	Decomposition at 288°C (99.99%)
Appearance (state purity)	Pure grade (99.7%): powder; off-white/pale yellow; odourless Technical grade (97.7%): powder; cream coloured; odourless
Vapour pressure (state temperature, state purity)	2.32×10^{-5} Pa at 25°C (99.7%)
Henry's law constant (state temperature)	1.67×10^{-3} Pa m^3 mol^{-1} (20 to 25°C)
Solubility in water (state temperature, state purity and pH)	Distilled water: 3.10×10^{-3} g/L at 20°C (99.7%) 4.6×10^{-3} g/L at 20°C (pH 4) (99.7%) 2.08×10^{-3} g/L at 20°C (pH 7) (99.7%) 1.94×10^{-3} g/L at 20°C (pH 9) (99.7%)
Solubility in organic solvents (state temperature, state purity)	acetone: 139 g/L at 20°C (99.7%) methanol: 15.4 g/L at 20°C (99.7%) ethyl acetate: 102 g/L at 20°C (99.7%) toluene: 55.4 g/L at 20°C (99.7%) dichloromethane: 277 g/L at 20°C (99.7%) hexane: 2.06 g/L at 20°C (99.7%) acetonitrile: 38.5 g/L at 20°C (98.7%)
Surface tension (state concentration and temperature, state purity)	72.0 mN/m at 24°C (90 % saturated solution) (99.7%)
Partition coefficient (state temperature, pH and purity)	log P_{OW} = 3.28 at 20°C (pH range: 6.5 – 6.8) (99.7%) log Pow = 3.18 (pH 4) (99.8%) log Pow = 3.20 (pH 7) (99.8%) log Pow = 3.19 (pH 9) (99.8%)
Dissociation constant (state purity)	pKa = 2.7 at 18°C (99.5%) Dissociation product is the protonated aniline nitrogen product

UV/VIS absorption (max.) incl. ε (state purity, pH)	(99.7%) Acidic solution: λ_{max} (nm) / ε (L mol^{-1} cm^{-1}) 358 / 5.02×10^3 278 / 2.83×10^4 Neutral solution : λ_{max} (nm) / ε (L mol^{-1} cm^{-1}) 344 / 3.17×10^3 287 / 2.94×10^4 Basic solution : λ_{max} (nm) / ε (L mol^{-1} cm^{-1}) 344 / 3.22×10^3 287 / 2.98×10^4
Flammability (state purity)	Not flammable
Explosive properties (state purity)	Not explosive
Oxidising properties (state purity)	Not oxidising

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

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					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) a) max. rate per appl. b) max. total rate per crop/season		
Table and wine grapes	CY, ES, FR, GR, IT, PT (S-EU zone)	Frupica	F	grey mould *Botryotinia fuckeliana* (BOTRCI)	WP	500 g/kg	foliar spray applications, upward spraying tractor-mounted broadcast air-assisted sprayers hand-held knapsack sprayers, including motorized knapsack mist-blowers	BBCH 77-89 summer-autumn (01-Jun/15-Nov)	1	n.a.	0.05 – 0.6	100-1000	a) 0.5-0.6 b) 0.5-0.6	21	None
Strawberries	CY, ES, FR, GR, IT, PT (S-EU zone)	Frupica	F	grey mould *Botryotinia fuckeliana* (BOTRCI)	WP	500 g/kg	foliar spray applications, downward spraying tractor-mounted ground boom sprayers hand-held knapsack sprayers	BBCH 60-89 spring-summer (15-Apr/15-Aug)	1-2	7 days	0.015 – 0.2	200-2000	a) 0.3-0.4 b) 0.6-0.8	1	None

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					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) a) max. rate per appl. b) max. total rate per crop/season		
Strawberries	CY, ES, FR, IT, PT (S-EU zone)	Frupica	G	grey mould *Botryotinia fuckeliana* (BOTRCI)	WP	500 g/kg	foliar spray applications, downward/up-ward spraying hand-held knapsack sprayers	BBCH 60-89 spring-summer (01-Mar/01-Oct)	1-2	7 days	0.015 – 0.2	200-2000	a) 0.3-0.4 b) 0.6-0.8	1	None
Tomatoes	CY, ES, GR, IT (S-EU zone)	Frupica	F	grey mould *Botryotinia fuckeliana* (BOTRCI)	WP	500 g/kg	foliar spray applications, downward spraying tractor-mounted ground boom sprayers hand-held knapsack sprayers	BBCH 61-89 summer (01-Jun/15-Sep)	1-2	7 days	0.05 – 0.2	200-800	a) 0.4 b) 0.8	1	None
Tomatoes	CY, ES, GR, IT (S-EU zone)	Frupica	G	grey mould *Botryotinia fuckeliana* (BOTRCI)	WP	500 g/kg	foliar spray applications, upward spraying hand-held knapsack sprayers	BBCH 61-89 at any season (15-Feb/31-Dec)	1-2	7 days	0.04 – 0.2	200-1000	a) 0.4 b) 0.8	1	None

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and sucking insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide
(f) All abbreviations used must be explained
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(j) Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of applications possible under practical conditions of use

(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	(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

Summary of additional intended uses for which MRL applications have been made, that in addition to the uses above, have also been considered in the consumer risk assessment (*name of active substance or the respective variant*)
Regulation (EC) N° 1107/2009 Article 8.1(g))

Not applicable

Further information, Efficacy

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

Mepanipyrim containing products are used in agriculture as a fungicide in strawberry, grapes and tomato and are applied by foliar sprays.
The original authorizations of Frupica have been granted on the basis of a detailed biological dossier (1997).
It has been concluded that the formulation Frupica gave control of *Botryotinia fuckeliana* (BOTRCI) which was equivalent to the reference standards.
More detailed assessment will be performed for products authorization applications.

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

The original authorizations of Frupica have been granted on the basis of a detailed biological dossier (1997). It has been concluded that the formulation Frupica had no detrimental adverse effects, nor adverse effects on the quality or on the transformation processes (wine-making) of the following crops: strawberry, grapevine, tomato.
More detailed assessment will be performed for products authorization applications.

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

The original authorizations of Frupica have been granted on the basis of a detailed biological dossier (1997). It has been concluded that the formulation Frupica had no detrimental adverse effects on beneficial arthropods (*Typhlodromus*, *Amblyseius*).
More detailed assessment will be performed for products authorization applications.

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

	Met1	*Met2*	*Met3*	*Met4*	*Met5*	*Met6*
Activity against target organism	*no*	*no*	*no*	*no*	*no*	*no*

Assessment not triggered since there are no relevant metabolisms in groundwater for mepanipyrim.

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 GC-HSS for determination of toluene in the technical material (LOQ = 0.03 % w/w)
Plant protection product (analytical technique)	HPLC-UV for the determination of mepanipyrim in the plant protection product Toluene: GC headspace

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		Mepanipyrim (fruit crops only)
Food of animal origin		Not necessary
Soil		Mepanipyrim
Sediment		Mepanipyrim
Water	surface	Mepanipyrim
	drinking/ground	Mepanipyrim
Air		Mepanipyrim
Body fluids and tissues		Mepanipyrim

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	QuECHERS citrate multi-residue method (LC-MS/MS) LOQ = 0.01 mg/kg (high water, acidic, dry) (GC) LOQ = 0.01 mg/kg (oily)
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	No method submitted: not necessary
Soil (analytical technique and LOQ)	GC-MS (LOQ = 0.01 mg/kg , mepanipyrim) LC-MS/MS (LOQ = 0.01 mg/kg) (mepanipyrim)
Water (analytical technique and LOQ)	Surface water: GC-MS (DB-5) (LOQ = 0.1 µg/L for mepanipyrim) Confirmatory technique: GC-MS (using another stationary phase (DB-1701)) Drinking water: LC-MS/MS (LOQ = 0.05 µg/L for mepanipyrim) Independently validated.

Air (analytical technique and LOQ)	GC-MS (LOQ = 0.75 µg/m^3 for mepanipyrim) Confirmatory technique not required since sufficient confirmatory methods are available for soil and water
Body fluids and tissues (analytical technique and LOQ)	Data gap

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

Substance	Mepanipyrim
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
Peer review proposal [2] for harmonised classification according to Regulation (EC) No 1272/2008:	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.

[2] It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

Impact on Human and Animal Health

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

Rate and extent of oral absorption/systemic bioavailability	Rapidly and extensively absorbed in rat (approximately 80% of the administered dose at 5 mg/kg, via faeces (55%) and urine (25%)). In bile duct cannulated rats 48 - 72 % of the dose in bile.
Toxicokinetics	T_{max} = 6 h C_{max}= 6.63 µg/mL AUC=256.4 µg × h / mL $T_{1/2}$ (6 h - 24 h) = 9.95 hours; $T_{1/2}$ (48 h - 168 h) = 89.5 hours
Distribution	Widely distributed (mainly in fat, liver, skin, kidney, adrenals, thyroid at 24 h, mainly in liver until 168 h)
Potential for bioaccumulation	No evidence for bioaccumulation
Rate and extent of excretion	Rapid, representing >90% of the dose within 48 h (18-28% in urine and 65-73% in faeces, in major part via bile (21-78% in Study 4)). Complete at 168 h. Distribution and excretion are similar between 5 mg/kg and 500 mg/kg. Excretion through urine slightly delayed at high dose in relation to the low dose. Patterns of distribution and excretion are similar for unique and repeated doses.
Metabolism in animals	Investigated in bile, urine, faeces extracts and plasma. Extensive in rats by hydroxylation of the phenyl ring and on the lateral chains of the pyrimidine ring. Further conjugation reactions lead to numerous sulphate, glucuronide and cysteine-glycine conjugates. Metabolite identification was considered sufficient. No sex-differences. Unchanged parent is a major compound in faeces (20-35%) after high dose administration
In vitro metabolism	Not performed – *In vitro* metabolism study is missing
Toxicologically relevant compounds (animals and plants)	Mepanipyrim
Toxicologically relevant compounds (environment)	Mepanipyrim

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

Rat, mouse LD_{50} oral	> 5000 mg/kg bw	
Rat LD_{50} dermal	> 2000 mg/kg bw	

Rat LC_{50} inhalation	> 0.59 mg/L air /4h (*nose only*)	
Skin irritation	Non-irritant	
Eye irritation	Non-irritant	
Skin sensitisation	Non-sensitising (*Magnusson-Kligman*)	
Phototoxicity	Phototoxic *in vitro* – No phototoxicity data *in vivo* available	

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

Target organ / critical effect	Rat: hematology (↓MCHC, ↑neutrophils and ↓lymphocytes in ♂), and clinical chemistry findings (↑T. cholesterol, ↓triglyceride and ↓non-esterified fatty acid) Mouse: liver (hypertrophy) Dog: liver (hypertrophy), prostate (atrophy)	
Relevant oral NOAEL	90-day rat: 6.95 mg/kg bw per day 90-day, dog: 7.5 mg/kg bw per day 13-week, mouse: 19 mg/kg bw-per day 52-week dog: 2.5 mg/kg bw per day	
Relevant dermal NOAEL	28-day, rabbit: 300 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	Ames reverse gene mutation assay: negative Gene mutation test: negative DNA damage and repair: negative *In-vitro* chromosome aberration assay: -Main test : positive w/o S9 mix; negative with S9 -Confirmatory test: negative w/o S9 mix Unscheduled DNA synthesis assay: negative	
In vivo studies	Micronucleus test, mouse bone marrow: negative Chromosome aberration, rat bone marrow: negative	
Photomutagenicity	Open considering the phototoxic potential	
Potential for genotoxicity	Mepanipyrim is unlikely to be genotoxic	

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

Long-term effects (target organ/critical effect)	Rat: -Target organs: liver (main), kidneys, parathyroid, pancreas. -Critical effect: pancreas atrophy Mouse: -Target organ: Liver (hypertrophy) -Critical effects: ↓MCV, ↑Plt, ↑liver weight, ↑hyperplastic foci, ↑hepatocyte swelling.	
Relevant long-term NOAEL	Rat (2-year): <2.45 mg/kg bw per day Mouse (18-month): 56.0 mg/kg b.w per day	
Carcinogenicity (target organ, tumour type)	Rat: benign liver tumours (adenomas, cystadenoma) and uterine adenocarcinoma (in the limits of HCV) Mouse: liver adenomas and carcinomas	Cat. 2 H351
Relevant NOAEL for carcinogenicity	Rat (2-year): 7.3 mg/kg bw per day; Mouse (18-month): 56.0 mg/kg bw per day	

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

Reproduction toxicity

Reproduction target / critical effect	Parental toxicity: liver; increased incidence of hepatocytic fatty vacuolation. Reproductive toxicity: ↓implantation sites, ↓litter size (study 1), fertility index decrease in rat (study 2). Offspring's toxicity: Liver, increased incidence of hepatocytic fatty vacuolation.	
Relevant parental NOAEL	<2.45 mg/kg bw per day	
Relevant reproductive NOAEL	46 mg/kg bw per day	
Relevant offspring NOAEL	<2.45 mg/kg bw per day	

Developmental toxicity

Developmental target / critical effect	Rat: Maternal toxicity: ↓ body weight Developmental toxicity: ↑ hind-limb intramuscular haemorrhage Rabbit: Maternal toxicity: few faeces in under-tray Developmental toxicity: ↑resorptions, ↑post-implantation loss	
Relevant maternal NOAEL	Rat: 150 mg/kg bw per day Rabbit: 10 mg/kg bw per day	
Relevant developmental NOAEL	Rat: 150 mg/kg bw per day Rabbit: 10 mg/kg bw per day	

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

Acute neurotoxicity	Neurotoxicity NOAEL: 80 mg/kg Neurotoxicity LOAEL: 400 mg/kg, based on lower rearing / activity counts Systemic NOAEL: 2000 mg/kg	
Repeated neurotoxicity	Repeated neurotoxicity studies and additional studies were not submitted as not considered necessary	
Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity)	Developmental neurotoxicity studies were not submitted as not considered necessary	

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

Supplementary studies on the active substance

MoA studies regarding carcinogenicity

Six investigative toxicology studies were conducted on Mepanipyrim to elucidate the mode of action (MoA) of liver tumour formation in rats and mice.

The potential of Mepanipyrim to induce hepatic microsomal metabolising enzymes and hepatocellular proliferation was investigated. The hepatic PCNA (proliferating cell nuclear antigen) index was raised and there was immuno-histochemical evidence of induction of cytochrome P450 isoforms (♂ only), and proliferation of SER following single doses (5000 mg/kg bw) and repeated doses for seven days (2000 mg/kg bw) when administered to rats by gavage. Similar effects were seen in ♂ mice given single (5000 mg/kg bw) or seven daily (3000 mg/kg bw) oral doses by gavage.

Two short-term tests carried out to investigate the initiating and promoting activity in relation to the inciduction of liver cell tumours in rodents. An increase of liver weight and an increase of γ-GTP$^+$ foci in rodents receiving diet containing Mepanipyrim at the highest doses (5000 ppm in ♀ rats and 7000 ppm in ♂ mice). A weak increase of P-450 content was recorded in mice after dietary administration of Mepanipyrim at 350 and 7000 ppm for 13 weeks.

Two studies examined the effect of Mepanipyrim on hepatic enzyme parameters after dietary administration to Fischer 344 rats and on $B_6C_3F_1$ mice for 4 weeks. These studies indicated that Mepanipyrim was not acting as a typical phenobarbital-type enzyme inducer, since it also showed some characteristics of a peroxisome proliferator. These effects were only observed at the high dose (highest tumourigenic dose level in the 2-year study). There was very limited hepatic enzyme induction at a dose level lower than the NOAEL for tumours.

MoA studies regarding effects on lipid metabolism

In publications of the open literature, notifier suggested that Mepanipyrim inhibits intracellular transport process of VLDL from the Golgi to the cell surface. Since the trans-Golgi apparatus regulates important general post-translational modifications of proteins, thereby directing its final destination, the finding is considered toxicologically relevant. A final MoA for the induction of fatty vacuolation in rat hepatocytes was not demonstrated. There was also no evidence that the effect would be of no concern for human health. Therefore, it should remain of potential toxicological relevance, and animal-derived NOAEL's are considered adequate for further risk assessment.

Endocrine disrupting properties	Prostate atrophy in the dogs (90d, 1 yr), uterine carcinoma in rats (2years), and decrease of the fertility index on the two generation study in rats, were noted. A clear mechanism for the vague effects on prostate and uterus was absent, and the toxicological profile of mepanipyrim is indicative for RMS and co-RMS to consider the a.s. not an overt endocrine perturbator. On the other hand, uterus was a target organ in the 2-year rat carcinogenicity study, including limited increase of uterus adenocarcinoma at 2000 ppm (1 case) and at 4000 ppm (2 cases). As several effects are observed in the available studies, as sensitive endpoints like sexual maturation and sperm parameters have not been investigated, and the mechanistic information in the RAR is not sufficient, further clarification of the ED potential is needed using mechanistic data.
Studies performed on metabolites or impurities	Impurity I3 Acute, oral, rat: LD_{50} = 836 mg/kg bw M11 • Acute, oral, rat: LD50>5000 mg/kg b.w. • Ames-test: positive in TA98 (+S9) • Clastogenicity: positive in-vitro (CHL) ±S9; (equivocal ↑polyploid cells) • UDS in-vivo (rat liver): negative • Micronucleus in-vivo (mouse BM): negative • Comet-assay in-vivo (hepatocytes): negative M31 (identified in plant residues) Acute, oral, rat: LD_{50} >5000 mg/kg bw Ames-test: negative Genotoxicity covered by M11 due to structural similarity QSAR data and repeated dose toxicity study are missing M33 (identified in plant residues) No studies available Genotoxicity covered by M11 due to structural similarity QSAR data and repeated dose toxicity study will be covered by M31 M36 (identified in plant residues) Acute, oral, rat: LD_{50} >5000 mg/kg bw Ames-test: negative Genotoxicity covered by M11 due to structural similarity QSAR data and repeated dose toxicity study will be covered by M31

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

Based on information from the manufacturing plants, as well as a review of published literature, it is concluded that there have been no reported incidents of mepanipyrim poisoning in humans.

Summary[1] (Regulation (EU) N°1107/2009, Annex II, point 3.1 and 3.6)	Value (mg/kg bw (per day))	Study	Uncertainty factor
Acceptable Daily Intake (ADI)	0.012(1)	LOAEL from the 2yr rat-study, and the 2G-study	200 (4)
Acute Reference Dose (ARfD)	0.10 (2)	rabbit, developmental	100
Acceptable Operator Exposure Level (AOEL)	0.012 (3)	LOAEL from the 2yr rat-study and the 2G-study	200 (4)
Acute Acceptable Operator Exposure Level (AAOEL)	0.10	rabbit, developmental	100

[1] Previously set ADI was 0.024 mg/kg bw per day
[2] Previously set ARfD was 0.30 mg/kg bw
[3] Previously set AOEL was 0.07 mg/kg bw per day (European Commission, 2004)
[4] An additional UF of 2 was used (further than the standard UF of 100) due to the use of LOAEL instead of the NOAEL

* No correction for limited oral absorption/bioavailability (100 %).

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

Representative formulation (50% WP formulation in water-soluble bags)	Concentrate: 0.4% Dilutions: 6% for low volume applications and 13% for high volume applications

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

Operators

German model (70 kg bw default)	**Level of PPE**	**% AOEL**
strawberry or tomato; Tractor-mounted trailed boom sprayer outdoor • 20 ha/day • Low spray volume[1]	No gloves	127%
	No gloves, coverall and sturdy footwear	**40%**
	Gloves, coverall and sturdy footwear	**18%**
strawberry or tomato; Tractor-mounted trailed boom sprayer outdoor • 20 ha/day • High spray volume[2]	No gloves	263%
	No gloves, coverall and sturdy footwear	**74%**
	Gloves, coverall and sturdy footwear	**28%**
strawberry or tomato; Hand-held knapsack outdoors • 1 ha/day • Low spray volume[1]	No PPE	134%
	No additional PPE, coverall and sturdy footwear	**67%**
	PPE (gloves), coverall and sturdy footwear	**37%**
Vines; Tractor-mounted broadcast air-assisted sprayer outdoors • 8 ha/day • Low spray volume[1]	No PPE	410%
	No additional PPE, coverall and sturdy footwear	**98%**
	PPE (gloves), coverall and sturdy footwear	**73%**
Vines; Tractor-mounted broadcast air-assisted sprayer outdoors • 8 ha/day • High spray volume[2]	No PPE	870%
	No additional PPE, coverall and sturdy footwear	193%
	PPE (gloves), coverall and sturdy footwear	141%
Vines; Hand-held knapsack application outdoors • 1 ha/day • Low spray volume[1]	No PPE	202%
	No additional PPE, coverall and sturdy footwear	**100%**
	PPE (gloves), coverall and sturdy footwear	**55%**

[1]:Low spray volume, DA=6%; [2]:high spray volume, DA=13%

UK POEM model (60 kg b.w. default)	**Level of PPE**	**% AOEL**
strawberry or tomato; Tractor-mounted trailed boom sprayer outdoor • 50 ha/day[3], 6 h/day[3] • 200 L/ha	No gloves	709%
	Gloves during application	124%
strawberry or tomato; Tractor-mounted trailed boom sprayer outdoor • 50 ha/day[3], 6 h/day[3] • 1000 L/ha10 •	No PPE	303%
	Gloves during application	50%
strawberry or tomato; Hand-held knapsack outdoors • 1 ha/day[4], 6 h/day[4] • 2008 L/ha •	No PPE	1733%
	Gloves during application	858%
Vines; Tractor-mounted broadcast air-assisted sprayer outdoors • 15 ha/day[3], 6 h/day[3] • 100 L/ha8	No PPE	3813%
	Gloves during application	2463%
Vines; Tractor-mounted broadcast air-assisted sprayer outdoors • 15 ha/day[5], 6 h/day[5] • 1000 L/ha11	No PPE	1338%
	Gloves during application	948%
Vines; Hand-held knapsack application outdoors • 1 ha/day[4], 6 h/day[4] • 1008 L/ha	No PPE	3763%
	Gloves and impermeable coverall during application	875%

[3] UK POEM default values for field crops tractor-mounted boom sprayer
[4] UK POEM default value for field crops hand-held knapsack sprayer
[5] Lower spray concentration using worst case 13% dermal absorption

Dutch Model[1]		
Hand-held knapsack application indoors to fruit and fruiting vegetable crops (strawberry or tomato) *Application rate: 0.4 kg a.s./ha (using WP-SB)[2] with realistic low volume application*		
• 70 kg operator[4] • Low spray volume[5]	No PPE	**618%**
	Additional PPE including Gloves	**105%**

[1] No PPE (defined as operator wearing long sleeved shirt, long trousers ("permeable") but no gloves)

[2] Water-Soluble Bags (WP-SB) cannot be considered during mixing and loading in the Dutch glasshouse model, therefore the actual exposures will be lower than estimated

[3] Dutch model default value for indoor application

[4] Dutch model default body weight

[5] 6% dermal absorption applied

Workers **German model of worker re-entry**

Re-entry Scenario		% AOEL
Vine crops (grapes) – harvesting, 13% DA	No PPE	576%
	With PPE	115%
Vine crops (grapes) – crop-inspection, 13% DA	No PPE	650%
	With PPE	130%
Tomato crops – harvesting, 13% DA	No PPE	117%
	With PPE	6%
Strawberry crops – harvesting, 13% DA	No PPE	468%
	With PPE	23%

Bystanders and residents

BYSTANDERS AND RESIDENTS

BfR model for estimation of bystander and resident exposure to mepanipyrim

Crop scenario	Bystander or resident, adults or children		% AOEL (10m-drift)	%AOEL (3m-drift)
Tractor-mounted broadcast air-assisted sprayer application outdoors to vine crops (low volume)	Bystander	adults	6.32%	40.27%
		children	5.15%	31.64%
	Resident	adults	2.75%	5.23%
		children	5.83%	14.37%
Tractor-mounted broadcast air-assisted sprayer application outdoors to vine crops (high volume)	Bystander	adults	13.49%	87.05%
		children	10.75%	68.14%
	Resident	adults	3.28%	8.64%
		children	6.53%	18.89%
Hand-held knapsack sprayer application outdoors to vine crops (low volume)	Bystander	adults	6.50%	40.45%
		children	5.54%	32.03%
	Resident	adults	2.75%	5.23%
		children	5.83%	14.37%
Tractor-mounted trailed boom sprayer application outdoors to low field crops (strawberry or tomato, low volume)	Bystander	adults	0.98%	
		children	0.78%	
	Resident	adults	2.42%	
		children	4.69%	
Tractor-mounted trailed boom sprayer application outdoors to low field crops (strawberry or tomato, high volume)	Bystander	adults	2.11%	
		children	1.67%	
	Resident	adults	2.56%	
		children	4.87%	
Hand-held knapsack sprayer application outdoors to low field crops (strawberry or tomato, low volume)	Bystander	adults	1.20%	
		children	1.25%	
	Resident	adults	2.42%	
		children	4.69%	

The UK CRD model was also used giving in overall higher values

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

Substance :	Mepanipyrim
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][4] :	Carc. Cat. 2; H351
Peer review proposal [5] for harmonised classification according to Regulation (EC) No 1272/2008:	Carc. Cat. 2; H351

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

[5] 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	Foliar, 3x500 g a.s./ha	30-32 DALA
		Tomatoes	Foliar, 3x500 g a.s./ha	26 & 62 DALA
		Apples	Foliar, 3x500 g a.s./ha	15 & 31 DALA
	Root crops	-	-	-
	Leafy crops	-	-	-
	Cereals/grass crops	-	-	-
	Pulses/Oilseeds	-	-	-
	Miscellaneous	-	-	-
	Investigation conducted using radiolabelled [^{14}C-Aniline]-mepanipyrim or [^{14}C-Pyrimidine]-mepanipyrim; Major residue component in fruits at final harvest: mepanipyrim (39-44%TRR grapes; 23-38%TRR tomatoes; 56-70%TRR apples); Significant proportions of metabolite M-31 in grapes (20-30%TRR).			
Rotational crops (metabolic pattern) **OECD Guideline 502**	**Crop groups**	**Crop(s)**	**PBI** (days)	**Comments**
	Root/tuber crops	Carrot	30,120,365	0.8 kg a.s./ha on bare soil (1N considering representative use on tomatoes)
	Leafy crops	Lettuce	30,120,365	
	Cereal (small grain)	Wheat	30,120,365	
	Other	-		
Rotational crop and primary crop metabolism similar?	Yes; Major residue component in rotational crops (and soil): mepanipyrim; Acidic metabolite (B-11) observed in wheat hay and straw (max. 13%TRR/0.083 mg/kg)			
Processed commodities (standard hydrolysis study) **OECD Guideline 507**	**Conditions**	**Mepanipyrim (% applied radioactivity)**		
	20 min, 90°C, pH 4	102.0 +/- 2.5		
	60 min, 100°C, pH 5	105.3 +/- 4.7		
	20 min, 120°C, pH 6	99.7 +/- 1.2		
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes; Mepanipyrim is hydrolytically stable under processing conditions representative of pasteurisation, boiling and sterilisation. For metabolite M31, stability under standard hydrolysis conditions representative of processing have to be demonstrated. For the time being the residue definition for processed commodities remains open			
Plant residue definition for monitoring (RD-Mo) **OECD Guidance, series on pesticides No 31**	Mepanipyrim (fruit crops only)			
Plant residue definition for risk assessment (RD-RA)	Mepanipyrim and M-31 (free and conjugated) *(provisional: the way the residue definition will be expressed is pending the toxicity profile of M-31)*			
Conversion factor (monitoring to risk assessment)	-Table and wine grapes: 1.6 -Strawberries: 1.1 -Tomato: none			

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	-	-	-
	Goat/Cow	-	-	-
	Pig	-	-	-
	Fish	mg/kg DM	-	-
	No data available, no data required.			

Time needed to reach a plateau concentration in milk and eggs (days)	Not applicable
Animal residue definition for monitoring (RD-Mo) **OECD Guidance, series on pesticides No 31**	Not applicable
Animal residue definition for risk assessment (RD-RA)	Not applicable
Conversion factor (monitoring to risk assessment)	Not applicable
Metabolism in rat and ruminant similar (Yes/No)	Not applicable
Fat soluble residues (Yes/No) **(FAO, 2009)**	Not applicable

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**	Confined rotational crop study conducted on carrot, lettuce and wheat (0.8 kg a.s./ha on bare soil): Mepanipyrim residues >0.01 mg/kg in wheat straw (30 DAT) and carrot (root and foliage – 30 & 120 DAT).
Field rotational crop study **OECD Guideline 504**	Limited field rotational crop study conducted on cabbage, parsnip/turnip and spinach (representative use tomatoes, i.e. 2x 400 g a.s./ha): Minimal uptake of residues mepanipyrim observed (mepanipyrim <0.01 mg/kg in rotational crops)

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)	
			mepanipyrim	M31
High water content	Tomatoes,	-20	≥ 18	≥ 18
	Spinach,	-18	≥ 9	-
	Cabbage head	-18	≥ 9	-
High oil content	-	-	-	-
High protein content	-	-	-	-
High starch content	Parsnip root	-18	≥ 9	
High acid content	Grapes	-20	≥ 16	≥ 16
	Strawberries		≥ 19	≥ 18
Processed products	Tomato juice/puree, canned tomatoes	-20	≥ 18	≥ 18
	Strawberry jam	-20	≥ 18	≥ 18
	Grape juice, raisins	-20	≥ 18	≥ 18
	Wine	-20	≥ 15	≥ 15
Other	-	-	-	-

Overall, residues of mepanipyrim are stable in tomatoes (high water content), strawberries and grapes (high acid content) and their processed products for at least 18 months when stored frozen. Frozen storage stability of mepanipyrim for at least 9 months was demonstrated in a high starch commodity (parsnip root).

Animal	Animal commodity	T (°C)	Stability (Month/Year)			
-	Muscle		-	-	-	-
-	Liver		-	-	-	-
-	Kidney		-	-	-	-
-	Milk		-	-	-	-
-	Egg		-	-	-	-

No data available, no data required.

Summary of residues data from the supervised residue trials (Regulation (EU) N° 283/2013, Annex Part A, point 6.3) OECD Guideline 509, OECD Guidance, series on pesticides No 66 and OECD MRL calculator

Crop (cGAP)	**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)
RD Monitoring (Mo): mepanipyrim **RD Risk Assessment (RA) *(provisional)*: mepanipyrim and M31 (free and conjugated),-expressed as mepanipyrim, combined or separately (pending the outcome on toxicological profile of M31)**						
Grapes (1 x 0.6 kg a.s./ha, PHI 21 days)	NEU	Mo: 0.15, 0.16, 0.31, 0.40, 0.46, 0.53, 0.87, 0.92(f) ,1.05, 1.16; RA: 0.15, 0.16, 0.31, 0.40, 0.46, 0.53, 0.87, 0.92(f) ,1.05, 1.16	NEU (n=10) and SEU (n=17) datasets were merged because statistically similar (Mann-Whitney U-test; α=0.05); The MRL of 2 mg/kg is derived from merged datasets.	2	Mo: 1.16 RA: 1.16	Mo: 0.50 RA: 0.50
	SEU	Mo: 0.06(e), 0.07, 0.10, 0.15, 0.18, 0.19, 0.21, 0.28, 0.54, 0.71, 0.85, 1.04, 1.11, 0.05, 0.18, 0.41, 0.67 RA: 0.09(e), 0.07, 0.11, 0.26, 0.19, 0.19, 0.23, 0.43, 0.55, 0.73, 0.86, 1.09, 1.25(e) ,0.07, 0.18, 0.49, 0.73		2	Mo: 1.11 RA:1.25	Mo: 0.21 RA: 0.26
	NEU+SEU (merged datasets)	Mo: 0.05, 0.06(e), 0.07, 0.10, 0.15, 0.15, 0.16, 0.18, 0.18, 0.19, 0.21, 0.28, 0.31, 0.40, 0.41, 0.46, 0.53, 0.54, 0.67, 0.71, 0.85, 0.87, 0.92(f), 1.04, 1.05, 1.11, 1.16 RA: 0.07, 0.07, 0.09(e), 0.11, 0.15, 0.16, 0.18, 0.19, 0.19, 0.23, 0.26, 0.31, 0.40, 0.43, 0.48, 0.49, 0.53, 0.55, 0.73, 0.73, 0.86, 0.87, 0.92(f), 1.05, 1.09, 1.16, 1.25(e)		**2**	Mo: 0.16 **RA: 1.25**	Mo: 0.40 **RA: 0.43**
Strawberries (1 x 0.8 kg a.s./ha; PHI 1 day; outdoor/ indoor)	NEU	Mo: 0.11, 0.13, 0.27(e), 0.33(e), 0.36, 0.47, 0.54(f), 0.59 RA: 0.17, 0.17, 0.27(e), 0.35(e), 0.39, 0.50, 0.57(f), 0.65	Outdoor datasets (NEU and SEU – merged, because statistically similar according to Mann-Whitney U-test (α=0.05)). The MRL proposal of 3 mg/kg derived from the indoor dataset (n=8).	1.5	Mo: 0.59 RA: 0.65	Mo: 0,35 RA: 0.37

Crop (cGAP)	**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)
	SEU	Mo: 2 x 0.19, 0.25, 0.51, 0.65, 0.74, 0.86[f] RA: 2 x 0.19, 0.30, 0.62, 0.67, 0.96[e], 0.94[f]		*2 (n=7)*	Mo: 0.86 RA: 0.96	Mo: 0.51 RA: 0.62
	NEU+SEU (merged datasets)	Mo: 0.11, 0.13, 2 x 0.19, 0.25, 0.27[e], 0.33[e], 0.36, 0.47, 0.51, 0.54[f], 0.59, 0.65, 0.74, 0.86[f] RA: 0.17, 0.17, 0.19, 0.19, 0.27[e], 0.30, 0.35[e], 0.39, 0.50, 0.57[f], 0.62, 0.65, 0.67, 0.94[f], 0.96[e]		1.5	Mo: 0.86 RA: 0.96	Mo: 0.36 RA: 0.39
	Indoor	Mo: 0.26[e], 0.27[e], 0.31, 0.39, 0.42[e], 0.95, 1.18, 1.57 RA: 0.28[e], 0.30[e], 0.40[e], 0.41, 0.46[e], 0.97, 1.24, 1.63		**3**	Mo: 1.57 **RA:1.63**	Mo: 0.41 **RA: 0.44**
Tomatoes (1 x 0.8 kg a.s./ha; PHI 1 day; outdoor/ indoor)	SEU	Mo: 0.19[e], 0.21, 0.23[e], 0.25[e], 0.26, 0.37, 0.42, 0.43, 0.49 RA: 0.19[e], 0.21, 0.23[e], 0.25[e], 0.26, 0.37, 0.42, 0.43, 0.49	Outdoor (SEU) dataset and indoor dataset were not merged, even though statistically similar (Mann-Whitney U-test; α=0.05), because of presumed significantly different crop cultivation between outdoor and indoor situation. No full dataset of independent indoor trials is available (n=7); one additional GAP compliant residue trial is required (data gap)	1	Mo: 0.49 RA: 0.49	Mo: 0.26 RA: 0.26
	Indoor	Mo: 0.19, 0.22, 0.29, 0.30 (cherry), 0.32, 0.51[f], 0.86 (cherry) RA: 0.19, 0.22, 0.29, 0.30 (cherry), 0.32, 0.51[f], 0.86 (cherry)		**1.5**	Mo: 0.86 **RA: 0.86**	Mo: 0.30 **RA: 0.30**
Summary of the data on formulation equivalence OECD Guideline 509						

Crop (cGAP)	**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)
Crop	**Region**	**Residue data** (mg/kg)	**Recommendations/comments**			
-	-	*No data provided; no data required*	-	-	-	-
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**			
-	-	*No data provided; no data required*	-	-	-	-

(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 ($STMR_{Mo}$).
(e) Result at higher PHI since it was higher than at shorter PHI
(f) Averaged value from dependent trials

Inputs for animal burden calculations

Feed commodity	Median dietary burden		Maximum dietary burden	
	(mg/kg)	Comment	(mg/kg)	Comment
not applicable	-	-	-	-

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)

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		Ram/Ewe		Breeding		Broiler		Carp	n.a.
	Dairy cattle		Lamb		Finishing		Layer		Trout	n.a.
							Turkey		Fish intake >0.1 mg/kg DM	
Intake >0.004 mg/kg bw	No		No		No		No		No	
Feeding study submitted	No		No		No		No		No	
Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and **N rates**	Level	Beef: N Dairy: N	Level	Lamb: N Ewe: 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										
Fat										
Meat[(b)]										
Liver										
Kidney										
Milk[(a)]										
Eggs										
Method of calculation[(c)]	*Not required*		*Not required*		*Not required*		*Not required*		*Not required*	

[(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) (mg/kg DM for fish)	Beef cattle		Ram/Ewe		Breeding		Broiler		Carp	
	Dairy cattle		Lamb		Finishing		Layer		Trout	
							Turkey			
Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and **N rates**	Level	Beef: N Dairy: N	Level	Lamb : N Ewe: 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										
Fat										
Meat[(a)]										
Liver										
Kidney										
Milk										
Eggs										
Method of calculation[(c)]	*Not required*		*Not required*		*Not required*		*Not required*		*Not required*	

[(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

Median Conversion Factors (CF) calculated at the different PHIs in the supervised residues trials[a] OECD Guidance, series on pesticides No 66								
PHI (days)	1	3	5	7	20-22	28-36	57-63	**Comments**
Grapes	n.r.	n.r.	n.r.	n.r.	1.05 (n=28)	1.08 (n=19)	**1.61** (n=9	Supported GAP (BBCH 77 – BBCH 89; PHI 21 days) allows for treatment around 60 days pre-harvest; n.r.: not relevant
Strawberries	**1.06** (n=25)	**1.09** (n=25)	1.10 (n=3)	1.17 (n=3)	-	-	-	
Tomatoes	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	not applicable, as M31 residues < LOQ (<0.01 mg/kg)
-Table and wine grapes: 1.6 -Strawberries: 1.1 -Tomato: none								

(a): CF calculated at the supported PHI are underlined

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	
Strawberries / canned	8	0.15, 0.25, 0.35, 0.50, 0.70, 0.88, 1.00, 1.07	0.60	-
Strawberries / jam	8	0.16, 0.21, 0.32, 0.45, 0.48, 0.50, 0.54, 0.59	0.47	-
Tomatoes / juice	8	0.03, 0.04, 0.08, 0.15, 0.15, 0.21, 0.45, 0.60	0.15	-
Tomatoes / puree	11	0.28, 0.42, 0.52, 0.55, 0.56, 0.62, 0.73, 0.76, 0.90, 1.22, 1.25	0.62	-
Tomatoes/ paste	3	0.71, 0.92, 1.33	0.92	-
Tomatoes / ketchup	4	0.42, 0.62, 0.80, 1.25	0.71	-
Tomatoes / canned	8	0.03, 0.04, 2x 0.05, 0.06, 0.06, 0.08, 0.10	0.05	-
Grapes / raisins	31	0.49 – 4.20; 0.65, 0.81, 1.71, 2.50	1.83	-
Grapes / juice	31	0.03 – 0.23; 0.05, 0.06, 0.20, 0.21	0.08	-
Grapes / must	34	0.09 – 3.00	0.50	-
Grapes / red wine	34	0.01 – 0.5	0.05	-
Grapes / white wine	38	0.01 – 0.3	0.10	-

[a]: Studies with residues in the RAC at or close to the LOQ should be disregarded (unless concentration)

[b]: Conversion factors for processed commodities cannot be derived for the time being since the residue definition for risk assessment in processed commodities is pending the hydrolysis studies on M31.

[c]: M31 residue levels were <LOQ in RAC and ≤LOQ in processed commodities

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

Consumer risk assessment limited to the representative uses (provisional)

ADI	0.012 mg/kg bw per day
TMDI according to EFSA PRIMo (rev.2)	76% ADI (WHO Cluster diet B)
NTMDI, according to (to be specified)	Not applicable
IEDI (% ADI), according to EFSA PRIMo (rev.2)	Highest IEDI: 16% ADI (FR, all population)
NEDI (% ADI), according to (to be specified)	Not applicable
Factors included in the calculations	MRL (TMDI calculations); STMR (IEDI calculations)
ARfD	0.1 mg/kg bw
IESTI (% ARfD), according to EFSA PRIMo	Highest IESTI: 82% ARfD (table grapes)
NESTI (% ARfD), according to (to be specified)	Not applicable
Factors included in IESTI and NESTI	HR

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)	Not applicable
ADI (mg/kg bw per day)	Not applicable
Intake of groundwater metabolites (% ADI)	Not applicable

WHO Guideline (WHO, 2009)

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			
0151010/ 0151020	Table grapes/ Wine grapes	2	-
0152000	Strawberries	3	NEU, SEU and indoor uses
0231010	Tomatoes	1.5	SEU and indoor uses. (dataset incomplete, an additional GAP compliant trial is required)
Animal commodities			
-	Not required		

(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	2.4-14.2 % AR after 120 d, [^{14}C- pyrimidine]-mepanipyrim (n[6]= 4) 5.4 % AR after 120 d, [^{14}C- phenyl]-mepanipyrim (n= 1)
Non-extractable residues after 100 days	18.6-67.7 % AR after 120 d, [^{14}C- pyrimidine]-mepanipyrim (n= 4) 26.0 % AR after 120 d, [^{14}C- phenyl]-mepanipyrim (n= 1)
Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)	No chromatographically resolved metabolites exceeded 5% AR Sterile conditions: No data available

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

Mineralisation after 100 days	0.7 % after 90 d, [^{14}C-phenyl]-mepanipyrim (n= 1) 0.8 % after 90 d, [^{14}C-pyrimidine]-mepanipyrim (n= 1)
Non-extractable residues after 100 days	22.4-27.8 % after 90 d, [^{14}C-phenyl]-mepanipyrim (n= 1) 23.7-26.8 % after 90 d, [^{14}C-pyrimidine]-mepanipyrim (n= 1)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	No chromatographically resolved metabolites exceeded 5% AR Sterile conditions: No data available

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

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	No chromatographically resolved metabolites exceeded 5% AR Sterile conditions: No data available
Mineralisation at study end	1.8 % after 14 d, [^{14}C-pyrimidine]-CO_2 (n= 1) 3.5 % after 14 d, [^{14}C-phenyl]-CO_2 (n= 1)
Non-extractable residues at study end	7.2-7.4 % after 14 d, [^{14}C-pyrimidine]-mepanipyrim (n= 1) 8.4-8.7 % after 14 d, [^{14}C-phenyl]-residues (n= 1)

[6] n corresponds to the number of soils.

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

Parent Mepanipyrim	Dark aerobic conditions								
				Persistence endpoints			Modelling endpoints		
Soil type	*X*[7]	pH[a)]	t. °C / % water content at pF2	DT_{50} /DT_{90} (d)	St. (χ^2)	Method of calculation	DT_{50} (d) 20 °C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
Loam (study No. 35TM028)		6.4 (NA)	20°C /19.6	155.0/744.5	4.7	HS	253.92[d)]	4.7	HS[c)] k1: 0.0132, k2: 0.0027
Sandy loam (study No. OVJ0024)		4.3 ($CaCl_2$)	20°C /22.0	152.6/506.9	1.7	SFO	152.6	1.7	SFO
Clay loam (study No. OVJ0024)		7.1 ($CaCl_2$)	20°C /40.0	38.8/128.9	2.4	SFO	38.8	2.4	SFO
Sandy clay (study No. OVJ0024)		6.1 ($CaCl_2$)	20°C / 44.9	155.8/>1000	1.9	FOMC	123.4	4.5	SFO
Geometric mean (if not pH dependent)							116.7		
pH dependence								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
c) DT_{50} from slow phase of HS and DFOP models are used for modelling
d) $DT_{50} = \ln 2/k_2$

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)

No chromatographically resolved metabolites exceeding 5% AR were identified.

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).	*X*[8]	pH[a)]	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St. (χ^2)	Method of calculation	DT_{50} (d) Norm[b)].	St. (χ^2)	Method of calculation
Loamy sand (Study No. 35TM033) (bare soil)	Netherlands		6.2	20	42.9	142	8.97	SFO	35.7	12.9	SFO

[7] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate. Column and this footnote may be removed if not used.

[8] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate. Column and this footnote may be removed if not used.

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).	X^{8}	pH[a)]	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St. (χ^2)	Method of calculation	DT_{50} (d) Norm[b)].	St. (χ^2)	Method of calculation
Silt loam (Study No. 35TM033) (bare soil)	France		6.9	20	11.9	127	8.74	DFOP (modified)	59.7	10.8	HS k1: 0.060704, k2: 0.01161
Clay loam (Study No. 35TM033) (bare soil)	Spain		8.3	20	82.1	273	15.3	SFO	-	-	-
Clay (Study No. 35TM033) (bare soil)	Italy		7.7	20	11.8	158	11.5	HS (modified)	127	11.5	HS k1: 0.05545, k2: 0.005462
Geometric mean (if not pH dependent)											
pH dependence						No					

[a)] Measured in 1M KCl
[b)] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7, values are $DegT_{50}$matrix

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)	Mepanipyrim 90.6 (d)**	
Rate of degradation in soil transformation products, normalised geometric mean (if not pH dependent)	Met I No chromatographically resolved metabolites exceeded 5% AR	Met II /
Kinetic formation fraction (f. f. k_f / k_{dp}) of transformation products, arithmetic mean	Met I from No chromatographically resolved metabolites exceeded 5% AR	Met 2 from /

* Only relevant after implementation of the published EFSA guidance describing how to amalgamate laboratory and field endpoints.
** Derived by pooling laboratory and field data to be used for future simulations.

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	Not applicable: DT_{90} was < 1 year in each test soil, ranging from 71 to 275 days, based on FOCUS kinetics. No studies on soil accumulation were submitted.

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	*X* [9]	pH[a)]	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C[b)]	St. (χ^2)	Method of calculation
UK sandy loam soil (study No. OVJ0025)		5.8 ($CaCl_2$)	20°C/pF2	337/1121		0.8	SFO
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

[9] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate. Column and this footnote may be removed if not used.

Rate of degradation in soil (anaerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.4 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Met 1	Dark anaerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was *xxx.*							
Soil type	*X*[10]	pH[a)]	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	DT_{50} (d) 20°C[b)]	St. (χ^2)	Method of calculation
No chromatographically resolved metabolites exceeded 5% AR								
Geometric mean (if not pH dependent)								
Arithmetic mean								

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	*X*[10]	pH[a)]	t. °C / % MWHC	DT_{50} / DT_{90} (d) calculated at 40°N	St. (χ^2)	Method of calculation
Clay loam soil (Study report No. 35TM029)		7.2 (NA[b)])	20°C/ 45%	138.6/ 460.5	NA	NA
Clay loam soil (Study report No. OVJ0079)		7.0 ($CaCl_2$)	20°C/ NA[b)]	479[c)]/1592[c)]	NA	NA

a) Measured in [medium to be stated, usually calcium chloride solution or water]
b) NA = not available
c) to be treated with caution since these values far exceed the incubation period

[10] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate. Column and this footnote may be removed if not used.

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_{oc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Acidic UK sand soil (Study report No. 35TM004)	0.9	5.2 (H_2O)	-	874.4	7.870	874	0.829
Loamy sand soil (Study report No. 35TM004)	2.4	5.8 (H_2O)	-	635.0	15.241	635	0.766
Alkaline loam soil (Study report No. 35TM004)	1.6	7.9 (H_2O)	-	395.3	6.324	395	0.805
California sandy loam soil (Study report No. 35TM004)	0.6	8.3 (H_2O)	-	5859.3	35.156	5859	0.910
Loamy sand soil (Study No. 35TM0031)	9.1	4.1	-	1756	159.8	1756	0.837
Geometric mean (if not pH dependent)*						1177	0.828
Arithmetic mean (if not pH dependent)					44.88	1903.8	0.829
pH dependence			No				

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

* Only relevant after implementation of the published EFSA guidance.

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

Metabolite 1							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
No chromatographically resolved metabolites exceeded 5% AR							
Geometric mean (if not pH dependent)*							
Arithmetic mean (if not pH dependent)							
pH dependence, *Yes or No*							

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

* Only relevant after implementation of the published EFSA guidance.

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): 300 mm Time period (d): 2 d
	Leachate: 0.009% - 0.134% total residues/radioactivity in leachate (3 soils) (Study report No. 6177-535/17) Leachate: < 0.1% total residues/radioactivity in leachate (3 soils tested, but in two of the three soils investigated radioactivity was not present in the leachate from the soil columns) (Study report No. 6750) 88-94 % total residues/radioactivity retained in top 6 cm after 2 days (Study report No. 6750)

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): x mm Time period (d*):* x d
	No chromatographically resolved metabolites exceeded 5% AR

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	Acceptable predicted environmental concentrations in groundwater (<0.001 µg/L) were calculated (vol. 3 CP B8) therefore no field leaching data are provided or are considered necessary.

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: <9% after 30 days No degradation of metabolite > 10%
	pH 7: <9% after 30 days No degradation of metabolite > 10%
	pH 9: 31.80% after 30 days at 70 °C

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 %	Artifical light equivalent to natural Florida summer sunlight, 50°N; DT_{50} 10.5 days (30 days irradiation) None of the 6 minor metabolites accounted for >3% of applied radioactivity at any time point (Study report No. 6765)
	Artificial sunlight, DT_{50} = 846.15 hours equivalent to 63.41 days with natural sunlight at latitude 30°N No photodegradates representing more than 10 % of the applied radioactivity were detected. (Study report No. 35TM030)
Quantum yield of direct phototransformation in water at Σ > 290 nm	5.87 x 10^{-6} mol · Einstein $^{-1}$

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

Readily biodegradable (yes/no)	There is a study indicating that the substance is **not readily biodegradable** (Study report No. 35TM027)

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]		
No study available (data requirement)										

[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).

Metabolite X	Max in total system x % after n days									
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]		
No chromatographically resolved metabolites exceeded 5% AR										

[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)
No data available					

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 (max in water 1-4% after 100 days)								
Water / sediment system	pH water phase	pH sed [a]	t. °C	Type data	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
Millstream Pond (Study report No. 535/26-1015)	6.88 ± 0.05	7.7 (H_2O)	20	triggers	12.2/40.4	3.9	2.6/8.7	7.1	17.0/56.5	2.5	SFO, level P-I
				modelling	NR [c]	NR [c]	1000	NA [d]	12.2	NA [d]	SFO, level P-II, 1st default
Iron Hatch (Study report No. 535/26-1015)	7.40 ± 0.05	8.0 (H_2O)	20	triggers	21.5/71.4	4.9	9.9/33.0	6.4	29.6/98.3	6.4	SFO, level P-I
				modelling	NR [c]	NR [c]	1000	NA [d]	21.5	NA [d]	SFO, level P-II, 1st default
Geometric mean at 20°C [b]				**Step 1** **Level P-I** **Total System** **$DegT_{50}$ modelling** **= 16.2 d (geomean), SFO**		**Step 2** **Level P-I** **DT_{50} modelling** **= 16.2 d for both compartments (geomean $DegT_{50}$ total system), SFO**		**Steps 3 and 4** **DT_{50} water modelling** **= 1000 days** **DT_{50} sediment modelling = 16.2 d (geomean $DegT_{50}$ total system), SFO**			

[a] Measured in [medium to be stated, usually calcium chloride solution or water]
[b] Normalised using a Q10 of 2.58
[c] NR = not relevant
[d] NA = not applicable

Metabolite X	Distribution (e.g. max in water x after n d. Max. sed x % after n d). Max in total system x % after n days, kinetic formation fraction (k_f/k_{dp}): where possible indicate a value for each experiment, clarifying whether fraction was derived for whole system or sediment and or water compartments. The identity of the precursor should also be included (e.g. from parent). Arithmetic mean of kinetic formation fractions to be stated. When calculating arithmetic means, the compartments: whole system, water, sediment should not be mixed.

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
No chromatographically resolved metabolites exceeded 5% AR										
Geometric mean at 20°C[b]										

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

Mineralisation and non-extractable residues (from parent dosed experiments)					
Water / sediment system	pH water phase	pH sed	Mineralisation x % after 100 d. (end of the study)	Non-extractable residues in sed. max x % after x d	Non-extractable residues in sed. max x % after 100 d (end of the study)
Millstream Pond (Study report No. 535/26-1015)	6.88 ± 0.05	7.7 (H_2O)	5.55	84.28 (100 d)	84.28
Iron Hatch (Study report No. 535/26-1015)	7.40 ± 0.05	8.0 (H_2O)	14.61	67.52 (100 d)	67.52

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

Direct photolysis in air	Not studied
Photochemical oxidative degradation in air	DT_{50} of 0.5 hours derived by the Atkinson model (SANCO/1412/2001/01-Final). The OH radicals concentration and day length values were 1.5 x 10^6 cm^{-3} (Flack, 1997, CA 2.8/01)
Volatilisation	/
	from soil surfaces (BBA guideline): /
Metabolites	No metabolite of concern

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	Soil: mepanipyrim

ecotoxicology) and or requiring consideration for groundwater exposure	Surface water: mepanipyrim Sediment: mepanipyrim Ground water: mepanipyrim Air: mepanipyrim

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)	/
Surface water (indicate location and type of study)	/
Ground water (indicate location and type of study)	/
Air (indicate location and type of study)	Mepanipyrim was detected in all samples but at very low levels (0.18 to 0.44 ng/m^3) Atmospheric samples, Strasbourg, France, Environmental Pollution 158 (2010) 576-584

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

Parent Method of calculation	DT_{50} (d): 82.1 days Kinetics: SFO Field or Lab: representative worst case trigger value from field studies (Graham, 2016a, Vol. 3 A.S – B.8)
Application data	Crops: grapevines, strawberries, tomatoes Depth of soil layer: 5cm Soil bulk density: 1.5g/cm^3 % plant interception: 70% for grapevines (flowering), 60% for strawberries (BBCH 60-89), 80% for tomatoes (BBCH 61-89) Number of applications: 1 for grapevines, 1-2 for strawberries and tomatoes Interval (d): NA for grapevines, 7 days for strawberries and tomatoes Application rate(s): 600 g a.s./ha for grapevines, 400 g a.s./ha for strawberries and tomatoes (corrected application rates: 180 g a.s./ha for grapevines, 160 g a.s./ha for strawberries, 80 g a.s./ha for tomatoes)

		Grapevines 1 x 600g a.i/ha		Strawberries 1 x 400g a.i/ha		Strawberries 2 x 400g a.i/ha		Tomatoes 1 x 400g a.i/ha		Tomatoes 2 x 400g a.i/ha	
$PEC_{(s)}$ (mg/kg)		Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
Initial		0.240		0.213		0.414		0.107		0.207	
Short term	24h	0.238	0.239	0.212	0.212	0.411	0.413	0.106	0.106	0.205	0.206
	2d	0.236	0.238	0.210	0.212	0.407	0.411	0.105	0.106	0.204	0.205
	4d	0.232	0.236	0.206	0.210	0.401	0.408	0.103	0.105	0.200	0.204
Long term	7d	0.226	0.233	0.201	0.207	0.391	0.402	0.101	0.104	0.195	0.201
	28d	0.189	0.214	0.168	0.190	0.327	0.369	0.084	0.095	0.164	0.185
	50d	0.157	0.196	0.140	0.174	0.272	0.338	0.070	0.087	0.136	0.169
	100d	0.103	0.162	0.092	0.144	0.178	0.280	0.046	0.072	0.089	0.140
Plateau concentration		Maximum peak concentration: 0.252 Baseline concentration: 0.0112 mg/kg After 1 year				Maximum peak concentration: 0.434 Baseline concentration: 0.021 mg/kg After 1 year				Maximum peak concentration: 0.217 Baseline concentration: 0.011 mg/kg After 1 year	

Metabolite I Method of calculation	Molecular weight relative to the parent: DT_{50} (d): x days Kinetics: SFO Field or Lab: representative worst case from field studies.
Application data	Application rate assumed: x g/ha (assumed Met I is formed at a maximum of x % of the applied dose) or formation fraction (if sequential modelling is employed)

$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		**No major metabolites**			
Short term	24h				
	2d				
	4d				
Long term	7d				
	28d				
	50d				
	100d				
Plateau concentration		x mg/kg after n yr			

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)	For FOCUS gw modelling, values used – Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. Model(s) used: FOCUS PEARL (version 4.4.4), FOCUS PELMO (version 4.4.3), FOCUS MACRO (version 5.5.3) Crops: grapevines, strawberries, tomatoes Crop uptake factor: / Water solubility (mg/L): 3.1 at pH 7 and 20°C Vapour pressure: 2.32 x 10-5 Pa at 25°C Geometric mean parent DT50 field 59.2 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7 for PELMO and PEARL and 0.49 for MACRO 5.5.3)*. KOC: parent, geometric mean 1177 mL/g, arithmetic mean 1/n= 0.83. Metabolites: no major metabolite For field and lysimeter studies Location: Europe (Netherlands, France, Spain, Italy) Study type (e.g. lysimeter, field): field Soil properties: <u>Netherlands</u> pH = 6.3, OC= 1.4, MWHC = / <u>France</u> pH = 7.5, OC= 1.1, MWHC = / <u>Spain</u> pH = 9.1, OC= 0.8, MWHC = / <u>Italy</u> pH = 8.7, OC= 1.2, MWHC = / Dates of application : grapevines: summer, autumn strawberries: spring/summer, summer tomatoes: early summer, late summer Crop : Interception estimated: grapevines (0.60, 0.75), strawberries (0.60, 0.60), tomatoes (0.80, 0.50) Number of applications: 1 year, 1 application per year for grapevines, 1-2 applications per year for strawberries and tomatoes Duration: one season Daily weather data (air temperature range and rainfall) throughout the field phase were collected from regional weather stations located within a distance of 5 – 20 km from the trial sites. Average annual leachate volume (mm): unknown

Application rate	Gross application rate: 600 g/ha for grapevines, 400 g/ha for strawberries and tomatoes Crop growth stage: 77 (summer)/89 (autumn) for grapevines, 60 (spring/summer)/89 (summer) for strawberries, 61 (early summer)/89 (late summer) for tomatoes Canopy interception %: grapevines: 0.60/0.75, strawberries: 0.60/0.60, tomatoes: 0.80/0.50 Application rate net of interception: grapevines: 240/150 g/ha, strawberries: 160/160 g/ha, tomatoes: 80/200 g/ha No. of applications: 1 for grapevines, 1-2 for strawberries and tomatoes Time of application (absolute or relative application dates): please refer to table B.2.4.1-3 in Vol. 3 CP B.8

* Geometric mean DT50 of 90.6 d derived by pooling laboratory and field data should be used for future simulations.

Crop	Scenario	Application timing	Predicted 80th percentile average annual concentrations (µg/L)		
			PEARL	PELMO	MACRO
Grapevines	Châteaudun	Summer	< 0.001	< 0.001	< 0.001
		Autumn	< 0.001	< 0.001	< 0.001
	Hamburg	Summer	< 0.001	< 0.001	NA
		Autumn	< 0.001	< 0.001	NA
	Kremsmünster	Summer	< 0.001	< 0.001	NA
		Autumn	< 0.001	< 0.001	NA
	Piacenza	Summer	< 0.001	< 0.001	NA
		Autumn	< 0.001	< 0.001	NA
	Porto	Summer	< 0.001	< 0.001	NA
		Autumn	< 0.001	< 0.001	NA
	Sevilla	Summer	< 0.001	< 0.001	NA
		Autumn	< 0.001	< 0.001	NA
	Thiva	Summer	< 0.001	< 0.001	NA
		Autumn	< 0.001	< 0.001	NA
Strawberries	Hamburg	Spring/summer	< 0.001	< 0.001	< 0.001
		Summer	< 0.001	< 0.001	< 0.001
	Jokioinen	Spring/summer	< 0.001	< 0.001	NA
		Summer	< 0.001	< 0.001	NA
	Kremsmünster	Spring/summer	< 0.001	< 0.001	NA
		Summer	< 0.001	< 0.001	NA
	Sevilla	Spring/summer	< 0.001	< 0.001	NA
		Summer	< 0.001	< 0.001	NA
Tomatoes	Châteaudun	Early summer	< 0.001	< 0.001	< 0.001
		Late summer	< 0.001	< 0.001	< 0.001
	Piacenza	Early summer	< 0.001	< 0.001	NA
		Late summer	< 0.001	< 0.001	NA
	Porto	Early summer	< 0.001	< 0.001	NA
		Late summer	< 0.001	< 0.001	NA
	Sevilla	Early summer	< 0.001	< 0.001	NA
		Late summer	< 0.001	< 0.001	NA
	Thiva	Early summer	< 0.001	< 0.001	NA
		Late summer	< 0.001	< 0.001	NA

$PEC_{(gw)}$ From lysimeter / field studies

Parent	1st year	2nd year	3rd year
Annual average (µg/L)	/	/	/

Metabolite X	1st year	2nd year	3rd year
Annual average (µg/L)	**No major metabolites**		

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: Molecular weight (g/mol): 223.3 K_{OC}/K_{OM} (mL/g): 1177/682.6 (geomean, n = 5) DT_{50} soil (d): 59.2 days (field, in accordance with FOCUS SFO)* DT_{50} water/sediment system @ 20°C (d): 16.2 d (highest DT_{50} (total system) of 2 water/sediment systems) DT_{50} water @ 20°C (d): 1000 (worst-case default value according to FOCUS recommendation) DT_{50} sediment @ 20°C (d): 16.2 (highest DT_{50} (total system) of 2 water/sediment systems) Crop interception (%): vines 60%, strawberries 40%, tomatoes 70% (the agreed % was max. 70 % for all crops)
Parameters used in FOCUSsw step 3 (if performed)	Version control no.'s of FOCUS software: FOCUS PRZM, MACRO and TOXSWA Water solubility @ 20°C (mg/L): 3.1 Vapour pressure: 1.21 x 10^{-5} Pa at 20°C Kom/Koc (mL/g): 682.6/1177 (geomean, n = 5) 1/n: (Freundlich isotherm exponent) 0.83 (arithmetic mean, n = 5) Q10=2.58, Walker equation coefficient 0.7 Crop uptake factor: 0.0 (default value for non-systemic compounds)
Application rate	Crop and growth stage: vines, strawberries, tomatoes (for application dates and growth stages please refer to study report No. WP13101, Peeters, 2016b) Number of applications: 1 for vines, 1-2 for strawberries and tomatoes Interval (d): for application dates please refer to study report No. WP13101, Peeters, 2016b Application rate(s): 600 g a.s./ha for vines, 400 g a.s./ha for strawberries and tomatoes Application window: Grapevines: 1. First possible summer application after maximum leaf

area development 2. Last possible autumn application 21 days before harvest date Strawberries: 1. Last possible spring application 1 day before harvest date 2. Last possible summer application 1 day before harvest date Tomatoes 1. Last possible summer application 1 day before harvest date

* Geometric mean DT50 of 90.6 d derived by pooling laboratory and field data should be used for future simulations.

FOCUS Step for **vines**	**summer application**	Water		Sediment	
		Global max. (µg/L)	TWAC 7d (µg/L)	Global max. (µg/kg)	TWAC 7d (µg/kg)
1	all	93.90	73.37	916.2	850
2	Northern Europe	16.06	10.75	131.9	120.5
2	Southern Europe	16.35	13.84	165.4	151.2
3	D6 – ditch (D6d)	10.28	7.446	18.61	17.62
	R1 – pond (R1p)	0.367	0.329	1.550	1.547
	R1 – stream (R1s)	7.333	0.151	0.656	0.483
	R2 – stream (R2s)	10.11	0.154	0.814	0.516
	R3 – stream (R3s)	10.63	0.565	2.711	1.659
	R4 – stream (R4s)	7.537	0.258	1.394	0.929
4 20 m no-spray buffer zone	D6 – ditch (D6d)	0.821	0.626	1.851	1.756
	R1 – pond (R1p)	0.128	0.118	0.593	0.592
	R1 – stream (R1s)	0.700	0.019	0.105	0.078
	R2 – stream (R2s)	0.963	0.016	0.081	0.058
	R3 – stream (R3s)	1.003	0.058	0.280	0.194
	R4 – stream (R4s)	0.723	0.059	0.307	0.211

FOCUS Step for **vines**	**autumn application**	Water		Sediment	
		Global max. (µg/L)	TWAC 7d (µg/L)	Global max. (µg/kg)	TWAC 7d (µg/kg)
1	all	93.90	73.37	948.3	850.0
2	Northern Europe	22.29	19.40	232.4	212.4
2	Southern Europe	19.32	16.62	198.9	181.8
3	D6 – ditch (D6d) R1 – pond (R1p) R1 – stream (R1s) R3 – stream (R3s)	10.28 0.366 7.538 10.63	7.451 0.329 0.226 0.661	18.79 1.872 1.171 5.617	17.82 1.871 0.777 4.636
4 20 m no-spray buffer zone	D6 – ditch (D6d) R1 – pond (R1p) R1 – stream (R1s) R3 – stream (R3s)	2.127 0.127 0.719 0.999	0.619 0.117 0.023 0.157	1.847 0.711 0.118 0.862	1.755 0.711 0.089 0.683

FOCUS Step for **strawberries**	**multiple spring applications**	Water		Sediment	
		Global max. (µg/L)	TWAC 7d (µg/L)	Global max. (µg/kg)	TWAC 7d (µg/kg)
1	all	111.1	92.49	1.22×10^3	1.08×10^3
2	Southern Europe	25.26	23.08	285.1	260.5
3	D6 – ditch (D6d) R2 – stream (R2s) R3 – stream (R3s) R4 stream (R4s)	2.223 1.909 3.427 6.186	0.426 0.130 0.460 1.528	2.497 17.44 2.482 10.36	2.015 15.12 2.134 8.318
4 20 m vegetated buffer zone	D6 – ditch (D6d) R2 – stream (R2s) R3 – stream (R3s) R4 - stream (R4s)	0.320 0.247 0.809 1.460	0.115 0.030 0.106 0.360	0.546 1.019 0.500 1.963	0.527 0.876 0.420 1.548

FOCUS Step for **strawberries**	**single spring application**	Water		Sediment	
		Global max. (µg/L)	TWAC 7d (µg/L)	Global max. (µg/kg)	TWAC 7d (µg/kg)
1	all	55.57	46.24	610.8	541.2
2	Southern Europe	13.59	12.38	152.5	139.6
3	D6 – ditch (D6d) R2 – stream (R2s) R3 – stream (R3s) R4 - stream (R4s)	2.536 2.208 2.349 3.011	0.484 0.064 0.260 0.806	2.104 10.37 1.474 6.053	1.645 9.036 1.264 4.927
4 20 m vegetated buffer zone	D6 – ditch (D6d) R2 – stream (R2s) R3 – stream (R3s) R4 - stream (R4s)	0.189 0.227 0.428 0.710	0.061 0.015 0.057 0.191	0.321 0.592 0.270 1.061	0.311 0.513 0.221 0.845

FOCUS Step for **strawberries**	**multiple summer applications**	Water		Sediment	
		Global max. (µg/L)	TWAC 7d (µg/L)	Global max. (µg/kg)	TWAC 7d (µg/kg)
1	all	111.1	92.49	1.22×10^3	1.08×10^3
2	Northern Europe	14.21	12.75	155.1	143.5
3	Southern Europe	19.92	18.09	222.3	203.9
3	D3 – ditch (D3d)	2.212	0.319	1.794	1.361

	D4 – pond (D4p)	0.121	0.111	1.033	1.033
	D4 – stream (D4s)	1.716	0.089	0.348	0.306
	D6 – ditch (D6d)	3.109	2.019	6.863	6.523
	R1 – pond (R1p)	0.524	0.489	3.947	3.945
	R1 - stream (R1s)	3.196	0.364	8.961	7.560
4 20 m vegetated buffer zone	D3 – ditch (D3d)	0.151	0.025	0.157	0.126
	D4 – pond (D4p)	0.098	0.092	0.765	0.765
	D4 – stream (D4s)	0.357	0.089	0.344	0.301
	D6 – ditch (D6d)	0.464	0.154	0.622	0.592
	R1 – pond (R1p)	0.131	0.122	0.953	0.952
	R1 - stream (R1s)	0.754	0.084	0.766	0.609

FOCUS Step for **strawberries**	**single summer application**	Water		Sediment	
		Global max. (µg/L)	TWAC 7d (µg/L)	Global max. (µg/kg)	TWAC 7d (µg/kg)
1	all	55.57	46.24	610.7	541.1
2	Northern Europe	7.646	6.820	82.57	76.70
2	Southern Europe	10.62	9.599	117.5	108.1
3	D3 – ditch (D3d)	2.527	0.347	1.479	1.082
	D4 – pond (D4p)	0.087	0.077	0.505	0.504
	D4 – stream (D4s)	1.791	0.032	0.134	0.117
	D6 – ditch (D6d)	2.551	1.811	4.687	4.399
	R1 – pond (R1p)	0.447	0.408	2.226	2.223
	R1 - stream (R1s)	1.733	0.360	8.948	7.485
4 20 m vegetated buffer zone	D3 – ditch (D3d)	0.188	0.029	0.130	0.102
	D4 – pond (D4p)	0.039	0.036	0.338	0.338
	D4 – stream (D4s)	0.181	0.032	0.132	0.116
	D6 – ditch (D6d)	0.196	0.148	0.444	0.417
	R1 – pond (R1p)	0.108	0.098	0.572	0.571
	R1 - stream (R1s)	0.413	0.083	0.736	0.585

FOCUS Step for **tomatoes**	**multiple summer applications**	Water		Sediment	
		Global max. (µg/L)	TWAC 7d (µg/L)	Global max. (µg/kg)	TWAC 7d (µg/kg)
1	all	111.1	92.49	1.22×10^3	1.08×10^3
2	Southern Europe	11.36	10.08	121.5	113.3
3	D6 – ditch (D6d)	2.191	0.163	0.820	0.562
	R2 – stream (R2s)	1.939	0.126	36.78	34.91
	R3 – stream (R3s)	3.450	0.807	9.734	7.644
	R4 - stream (R4s)	5.336	0.645	5.154	3.628
4 20 m vegetated buffer zone	D6 – ditch (D6d)	0.520	0.085	0.426	0.362
	R2 – stream (R2s)	0.188	0.029	2.016	1.922
	R3 – stream (R3s)	0.824	0.194	1.052	0.781
	R4 - stream (R4s)	1.271	0.148	1.007	0.695

FOCUS Step for **tomatoes**	**single summer application**	Water		Sediment	
		Global max. (µg/L)	TWAC 7d (µg/L)	Global max. (µg/kg)	TWAC 7d (µg/kg)
1	all	55.57	46.24	610.7	541.1
2	Southern Europe	6.160	5.430	65.13	59.51
3	D6 – ditch (D6d)	2.499	0.153	0.737	0.492
	R2 – stream (R2s)	2.243	0.046	18.44	17.56
	R3 – stream (R3s)	2.358	0.338	5.743	4.806

	R4 - stream (R4s)	2.448	0.325	2.461	1.804
4 20 m vegetated buffer zone	D6 – ditch (D6d) R2 – stream (R2s) R3 – stream (R3s) R4 - stream (R4s)	0.186 0.232 0.365 0.583	0.024 0.010 0.081 0.071	0.129 0.992 0.539 0.462	0.110 0.950 0.440 0.334

Metabolite **No major metabolites**

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

Method of calculation	No study available, Atmospheric exposure resulting from other routes of exposure such as dust deposition, amenity use or indirect exposure of surface water via a sewage treatment plant (STP) after application of the plant protection product in storage rooms, is not anticipated in accordance with the uses of the Frupica® WP formulation in agricultural crops as proposed. Therefore, further information is not required or provided.

PEC

Maximum concentration	No data

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				
Mallard duck *Anas platyrhynchos*	a.s.	Acute	LD_{50}	> 2250 mg a.s./kg bw
Bobwhite quail *Colinus virginianus*	a.s.	Acute	LD_{50}	> 2250 mg a.s./kg bw
Bobwhite quail *Colinus virginianus*	a.s.	Long-term	LD_{50}/10	225.0 mg a.s./kg bw/day
Bobwhite quail *Colinus virginianus*	a.s.	Long-term	NOEC	100 mg a.s./kg bw/day
Mammals				
Mouse	a.s.	Acute	LD_{50}	> 5000 mg a.s./kg bw
Rat	a.s.	Acute	LD_{50}	> 5000 mg a.s./kg bw
Mouse	Preparation	Acute	LD_{50}	> 5000 mg form./kg bw (= 2650 mg a.s./kg bw)
Rat	Preparation	Acute	LD_{50}	> 5000 mg form./kg bw (= 2650 mg a.s./kg bw)
Rabbit	a.s.	Long-term	NOAEL	10 mg a.s./kg bw/day
Rat	a.s.	Long-term	NOAEL	93 mg/kg bw/day
Endocrine disrupting properties (Annex Part A, points 8.1.5) For the ecotoxicological assessments, no other data were available to address the potential endocrine activity of mepanipyrim. Pending on the outcome of the data gap in Section 2, further ecotoxicological tests might be necessary to address the potential endocrine disrupting properties of mepanipyrim.				

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

The applicant provided residue studies in grapevines, strawberry and tomato. From these studies, the highest measured residue value on the fruit, measured directly after the last application, was derived for each crop. The measured residue data on tomato could potentially be used to refine the long-term risk assessment for frugivorous mammals in tomato. The number of studies available (n=9) was however not considered sufficient to override the residue dataset from the EFSA Guidance Document (n = 86). Therefore, the RUD value for tomato could not be refined.

Based on data available from literature, the common vole (*Microtus arvilis*) was initially identified as focal species for small herbivorous mammals in grapevines, strawberry and tomato. However, at Pesticides Peer Review Meeting 154, the experts agreed that the available information is not sufficient for supporting the selection of the common vole as a specific focal species in these crops. A refinement based on biological parameters specific for the common vole (e.g. PD or PT refinements) could not be used in the risk assessment.

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

No additional data available for mepanipyrim.

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

Grapevines at BBCH 77-89, 1 x 600 g a.s./ha

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Screening Step (Birds)					
All	Small omnivorous bird	Acute	57.18	>39.3	10
All	Small omnivorous bird	Long-term	12.37	8.1	5
Screening Step (Mammals)					
All	Small herbivorous mammal	Acute	81.84	>61.1	10
All	Small herbivorous mammal	Long-term	22.99	**0.43**	5
Tier 1 (Mammals)					
BBCH ≥ 40	Large herbivorous mammal "lagomorph"	Long-term	1.05	9.5	5
BBCH ≥ 20	Small insectivorous mammal "shrew"	Long-term	0.60	16.6	5
BBCH ≥ 40	Small herbivorous mammal "vole"	Long-term	6.90	**1.4**	5
BBCH ≥ 40	Small omnivorous mammal "mouse"	Long-term	0.73	13.7	5
Higher tier (Mammals): -					

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	0.266	375	5
Earthworm-eating mammals	Long-term	0.325	30.7	5
Fish-eating birds	Long-term	0.13	775 [a]	5
Fish-eating mammals	Long-term	0.12	86.7 [a]	5
Higher tier : not required				

Risk from consumption of contaminated water

Scenarios	Indicator or focal species	Time scale	PEC_{dw}xDWR	TER	Trigger
Leaf scenario	Birds	acute	Not relevant		5

Puddle scenario, Screening step 1)Application rate (g a.s./ha)/relevant endpoint <50 (koc<500 L/kg), TER calculation not needed 2)Application rate (g a.s./ha)/relevant endpoint <3000 (koc≥500 L/kg), TER calculation not needed					
Puddle scenario	Birds	acute	Not needed	Case 2 (<0.27)	10
Puddle scenario	Mammals	acute	Not needed	Case 2 (<0.12)	10
Puddle scenario	Birds	Long-term	Not needed	Case 2 (6.0)	5
Puddle scenario	Mammals	Long-term	Not needed	Case 2 (60)	5

[a] *TER value calculated based on a BCF of 980, which was not normalized to 5% lipid content, as it was derived from a study where the lipid content was not measured.*

Strawberries at BBCH 60-89, 2 x 400 g a.s./ha (interval 7 days) (both indoor and outdoor use)

Growth stage	**Indicator or focal species**	**Time scale**	**DDD (mg/kg bw per day)**	**TER**	**Trigger**
Screening Step (Birds)					
All	Small omnivorous bird	Acute	88.93	>25.3	10
All	Small omnivorous bird	Long-term	21.98	**4.5**	5
Tier 1 (Birds)					
BBCH ≥ 40	Small omnivorous bird "lark"	Long-term	1.49	67.0	5
BBCH 61-89	Frugivorous bird "starling"	Long-term	4.55	22.0	5
BBCH ≥ 20	Small insectivorous bird "wagtail"	Long-term	3.29	30.4	5
Screening Step (Mammals)					
All	Small herbivorous mammal	Acute	66.30	> 75.4	10
All	Small herbivorous mammal	Long-term	16.38	**0.61**	5
Tier 1 (Mammals)					
BBCH ≥ 20	Small insectivorous mammal "shrew"	Long-term	0.64	15.5	5
BBCH ≥ 40	Small herbivorous mammal "vole"	Long-term	9.80	**1.0**	5
BBCH ≥ 40	Large herbivorous mammal "lagomorph"	Long-term	1.93	5.2	5
BBCH ≥ 40	Small omnivorous mammal "mouse"	Long-term	1.05	9.5	5
Higher tier (Mammals): -					

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	0.460	217	5
Earthworm-eating mammals	Long-term	0.561	17.8	5
Fish-eating birds	Long-term	0.21	484 [a]	5
Fish-eating mammals	Long-term	0.18	54.2 [a]	5
Higher tier : not required				

Risk from consumption of contaminated water

Scenarios	**Indicator or focal species**	**Time scale**	**PEC_{dw}xDWR**	**TER**	**Trigger**
Leaf scenario	Birds	acute	Not relevant		5

Puddle scenario, Screening step 1)Application rate (g a.s./ha)/relevant endpoint <50 (koc<500 L/kg), TER calculation not needed 2)Application rate (g a.s./ha)/relevant endpoint <3000 (koc≥500 L/kg), TER calculation not needed					
Puddle scenario	Birds	acute	Not needed	Case 2 (<0.36)	10
Puddle scenario	Mammals	acute	Not needed	Case 2 (<0.16)	10
Puddle scenario	Birds	Long-term	Not needed	Case 2 (8.0)	5
Puddle scenario	Mammals	Long-term	Not needed	Case 2 (80)	5

[a] *TER value calculated based on a BCF of 980, which was not normalized to 5% lipid content, as it was derived from a study where the lipid content was not measured.*

Tomatoes at BBCH 61-89, 2 x 400 g a.s./ha (interval 7 days) (both indoor and outdoor use)

Growth stage	**Indicator or focal species**	**Time scale**	**DDD (mg/kg bw per day)**	**TER**	**Trigger**
Screening Step (Birds)					
All	Small omnivorous bird	Acute	88.93	>25.3	10
All	Small omnivorous bird	Long-term	21.98	**4.5**	5
Tier 1 (Birds)					
BBCH 71-80	Frugivorous bird "crow"	Long-term	10.85	9.2	5
BBCH ≥ 50	Small granivorous bird "finch"	Long-term	1.15	86.7	5
BBCH ≥ 50	Small omnivorous bird "lark"	Long-term	1.12	89.3	5
BBCH 71-80	Frugivorous bird "starling"	Long-term	7.02	14.2	5
BBCH ≥ 20	Small insectivorous bird "wagtail"	Long-term	3.29	30.4	5
Screening Step (Mammals)					
All	Small herbivorous mammal	Acute	76.38	>65.5	10
All	Small herbivorous mammal	Long-term	24.52	**0.41**	5
Tier 1 (Mammals)					
BBCH 71-89	Frugivorous mammal "rat"	Long-term	3.17	**3.16**	5
BBCH ≥ 20	Small insectivorous mammal "shrew"	Long-term	0.64	15.5	5
BBCH ≥ 50	Small herbivorous mammal "vole"	Long-term	7.36	**1.4**	5
BBCH ≥ 50	Small omnivorous mammal "mouse"	Long-term	0.78	12.8	5
Higher tier (Mammals): -					

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	0.575	174	5
Earthworm-eating mammals	Long-term	0.701	14.3	5
Fish-eating birds	Long-term	0.21	484 [a]	5
Fish-eating mammals	Long-term	0.18	54.2 [a]	5
Higher tier : not required				

Risk from consumption of contaminated water

Scenarios	**Indicator or focal species**	**Time scale**	**PEC_{dw}xDWR**	**TER**	**Trigger**
Leaf scenario	Birds	acute	Not relevant		5

Puddle scenario, Screening step 1)Application rate (g a.s./ha)/relevant endpoint <50 (koc<500 L/kg), TER calculation not needed 2)Application rate (g a.s./ha)/relevant endpoint <3000 (koc≥500 L/kg), TER calculation not needed					
Puddle scenario	Birds	acute	Not needed	Case 2 (<0.36)	10
Puddle scenario	Mammals	acute	Not needed	Case 2 (<0.16)	10
Puddle scenario	Birds	Long-term	Not needed	Case 2 (8.0)	5
Puddle scenario	Mammals	Long-term	Not needed	Case 2 (80)	5

[a] *TER value calculated based on a BCF of 980, which was not normalized to 5% lipid content, as it was derived from a study where the lipid content was not measured.*

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

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

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Laboratory tests				
Fish				
Rainbow trout (*Oncorhynchus mykiss*)	Mepanipyrim	Acute 96 h (static)	Mortality, LC_{50}	> 0.74 mg a.s./L (mm)
Rainbow trout (*Oncorhynchus mykiss*)	Frupica 50 WP	Acute 96 h (static)	Mortality, LC_{50}	> 0.67 mg a.s./L (mm)
Rainbow trout (*Oncorhynchus mykiss*)	Mepanipyrim	Chronic 28 d (flow-through)	Growth, NOEC	0.029 mg a.s./L (mm)
Rainbow trout (*Oncorhynchus mykiss*)	Mepanipyrim	Chronic 91 d (flow-through)	Larval survival, NOEC Growth, EC_{50} Growth, EC_{20} Growth, EC_{10}	0.051 mg a.s./L (mm) 0.130 mg a.s./L (mm) 0.046 mg a.s./L (mm) 0.027 mg a.s./L (mm)
Fathead minnow (*Pimephales promelas*)	Mepanipyrim	Chronic 32 d (semi-static)	Development, NOEC	0.51 mg a.s./L (mm)
Aquatic invertebrates				
Daphnia magna	Mepanipyrim	Acute 48 h (static)	Mortality, EC_{50}	0.63 mg a.s./L (mm)
Daphnia magna	Frupica 50 WP	Acute 48 h (static)	Mortality, EC_{50}	0.48 mg a.s./L (mm)

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Daphnia magna	Mepanipyrim	Chronic 21 d (flow-through)	Development, NOEC Development, EC_{50} Development, EC_{20} Development, EC_{10}	0.031 mg a.s./L (mm) 0.277 mg a.s./L (mm) 0.206 mg a.s./L (mm) 0.176 mg a.s./L (mm)
Sediment-dwelling organisms				
Midge *(Chironomus riparius)*	Mepanipyrim	Chronic 28 d (spiked water, static)	NOEC	4.67 mg a.s./kg dry sediment (im) (3.28 mg a.s./L (im))
Algae				
Green microalgae (*Pseudokirchneriella subcapitata*)	Mepanipyrim	Chronic 72 h (static)	Growth rate: E_rC_{50} E_rC_{20} E_rC_{10} $NOEC_r$ Yield: E_yC_{50} E_yC_{20} E_yC_{10} $NOEC_y$	 2.74 mg a.s./L (mm) 1.53 mg a.s./L (mm) 1.13 mg a.s./L (mm) 0.363 mg a.s./L (mm) 1.52 mg a.s./L (mm) 1.04 mg a.s./L (mm) 0.86 mg a.s./L (mm) 0.363 mg a.s./L (mm)

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Green microalgae (*Pseudokirchneriella subcapitata*)	Frupica 50 WP	Chronic 72 h (static)	Growth rate: E_rC_{50} E_rC_{20} E_rC_{10} $NOEC_r$ Yield: E_yC_{50} E_yC_{20} E_yC_{10} $NOEC_y$	 2.49 mg a.s./L (mm) 0.89 mg a.s./L (mm) 0.53 mg a.s./L (mm) 0.041 mg a.s./L (mm) 0.75 mg a.s./L (mm) 0.21 mg a.s./L (mm) 0.11 mg a.s./L (mm) 0.041 mg a.s./L (mm)
Further testing on aquatic organisms *Not needed*				
Potential endocrine disrupting properties (Annex Part A, point 8.2.3) Based on the specific long-term *in vivo* studies reported in the DRAR there are no indications that mepanipyrim has endocrine-specific effects on fish. However, pending on the outcome of the data gap in Section 2, further ecotoxicological tests might be necessary to address the potential endocrine disrupting properties of mepanipyrim.				

[1] ($_{nom}$) nominal concentration; ($_{mm}$) mean measured concentration; ($_{im}$) initial measured concentration prep.: preparation; a.s.: active substance

Bioconcentration in fish (Annex Part A, point 8.2.2.3)

	Mepanipyrim
$logP_{O/W}$	3.28
Steady-state bioconcentration factor (BCF) (total wet weight/normalised to 5% lipid content)	280*
Uptake/depuration kinetics BCF (total wet weight/normalised to 5% lipid content)	-
Annex VI Trigger for the bioconcentration factor	-
Clearance time (days) (CT_{50})	-
(CT_{90})	-
Level and nature of residues (%) in organisms after the 14 day depuration phase	-
Higher tier study *Not needed*	

* based on total ^{14}C. As the study from which this bioconcentration factor was derived was performed in accordance with a previous version of OECD Test Guideline 305, the lipid content of the fish tissue was not measured. It was therefore not possible to normalize the bioconcentration factor to 5% lipid content.

Regulatory acceptable concentrations for the most sensitive aquatic organisms

Mepanipyrim				
	Most sensitive species group	**Endpoint**	**Assessment factor**	**RAC**
Acute effect assessment	Aquatic invertebrates	EC_{50} = 0.48 mg a.s./L	100	0.0048 mg a.s./L
Chronic effect assessment	*Chironomus riparius*	NOEC = 4.67 mg a.s./kg	10	0.467 mg a.s./kg
	Fish	EC_{10} = 0.027 mg a.s./L	10	0.0027 mg a.s./L

Comparison of the RAC for the most sensitive aquatic organisms with FOCUS $PEC_{SW/SED}$ values (Regulation (EU) N° 284/2013, Annex Part A, point 10.2)

$FOCUS_{sw}$ step 1-4 – Comparison of RACs and PEC_{SW}/PEC_{SED} for mepanipyrim – Grapevines at BBCH 77-89, 1 x 600 g a.s./ha (outdoor use)

Step	Scenario	$RAC_{SW,CH}$ (µg a.s./L)	Max PEC_{SW} (µg a.s./L)	$RAC_{SED,CH}$ (µg a.s./kg)	Max PEC_{SED} (µg a.s./kg)
1	Europe	2.7	**93.90**	46.7	**948.3**
2	Northern Europe		**22.29**		**232.4**
	Southern Europe		**19.32**		**198.9**
3	D6 ditch		**10.28**		18.79
	R1 pond		0.367		1.872
	R1 stream		**7.538**		1.171
	R2 stream		**10.11**		0.814
	R3 stream		**10.63**		5.617
	R4 stream		**7.537**		1.394
4	D6 ditch		2.127		1.851
	R1 pond		0.128		0.711
	R1 stream		0.719		0.118
	R2 stream		0.963		0.081
	R3 stream		1.003		0.862
	R4 stream		0.723		0.307

Notes: Step 4 mitigation was 20 m no-spray buffer; values in bold exceed the relevant RAC, indicating an unacceptable risk

$FOCUS_{sw}$ step 1-4 – Comparison of RACs and PEC_{SW}/PEC_{SED} for mepanipyrim – Strawberries at BBCH 60-89, 2 x 400 g a.s./ha (interval 7 days) (outdoor use)

Step	Scenario	$RAC_{SW,CH}$ (µg a.s./L)	Max PEC_{SW} (µg a.s./L)	$RAC_{SED,CH}$ (µg a.s./kg)	Max PEC_{SED} (µg a.s./kg)
1	Europe	2.7	**111.1**	46.7	**1220**
2	Northern Europe		**14.21**		**155.1**
	Southern Europe		**25.26**		**285.1**
3	D3 ditch		2.527		1.794
	D4 pond		0.121		1.033
	D4 pond		1.791		0.348
	D6 ditch		**3.109**		6.863
	R1 pond		0.524		3.947
	R1 stream		**3.196**		8.961
	R2 stream		2.208		17.44
	R3 stream		**3.427**		2.482
	R4 stream		**6.186**		10.36
4	D3 ditch		0.188		0.157
	D4 pond		0.098		0.765
	D4 pond		0.357		0.344
	D6 ditch		0.464		0.622
	R1 pond		0.131		0.953
	R1 stream		0.754		0.766
	R2 stream		0.247		1.019
	R3 stream		0.809		0.500
	R4 stream		1.460		1.963

Notes: Step 4 mitigation was 20 m no-spray buffer and vegetated filter strip; values in bold exceed the relevant RAC, indicating an unacceptable risk

FOCUS$_{sw}$ step 1-4 – Comparison of RACs and PEC$_{SW}$/PEC$_{SED}$ for mepanipyrim – Tomatoes at BBCH 61-89, 2 x 400 g a.s./ha (interval 7 days) (outdoor use)

Step	Scenario	RAC$_{SW,CH}$ (µg a.s./L)	Max PEC$_{SW}$ (µg a.s./L)	RAC$_{SED,CH}$ (µg a.s./kg)	Max PEC$_{SED}$ (µg a.s./kg)
1	Europe	2.7	**111.1**	46.7	**1220**
2	Northern Europe		NA		NA
	Southern Europe		**11.36**		**121.5**
3	D6 ditch		2.499		0.820
	R2 stream		2.243		36.38
	R3 stream		**3.450**		7.743
	R4 stream		**5.336**		5.154
4	D6 ditch		0.520		0.426
	R2 stream		0.232		2.016
	R3 stream		0.824		1.052
	R4 stream		1.271		1.007

Notes: NA = not applicable; Step 4 mitigation was 20 m no-spray buffer and vegetated filter strip; values in bold exceed the relevant RAC, indicating an unacceptable risk

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

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

Species	Test substance	Time scale/type of endpoint	End point	toxicity
Honeybee (*Apis mellifera*)	Mepanipyrim	Acute, adult toxicity	Oral toxicity (LD_{50})	> 50 µg a.s./bee
Honeybee (*Apis mellifera*)	Mepanipyrim	Acute, adult toxicity	Contact toxicity (LD_{50})	> 100 µg a.s./bee
Honeybee (*Apis mellifera*)	Frupica 50 WP	Acute, adult toxicity	Oral toxicity (LD_{50})	> 100 µg a.s./bee
Honeybee (*Apis mellifera*)	Frupica 50 WP	Acute, adult toxicity	Contact toxicity (LD_{50})	> 80 µg a.s./bee
Honeybee (*Apis mellifera*)	Mepanipyrim	Chronic (10d), adult toxicity	LDD50	> 60.2 µg a.s./bee/day
Honeybee (*Apis mellifera*)	Mepanipyrim	Chronic (7d), larval toxicity	NOEL	155 µg/larva/ developmental period
Bumblebee (*Bombus terrestris*)	Mepanipyrim	Acute, adult toxicity	Oral toxicity (LD_{50})	> 100 µg a.s./bee
Bumblebee (*Bombus terrestris*)	Mepanipyrim	Acute, adult toxicity	Contact toxicity (LD_{50})	> 100 µg a.s./bee

Potential for accumulative toxicity: *not assessed*
Semi-field test (Cage and tunnel test) *None*
Field tests *None*

Risk assessment for bees according to SANCO/10329/2002 (acute risk) for Grapevines at BBCH 77-89, 1 x 600 g a.s./ha

(covers the acute risk to bees following the use (both indoor and outdoor) in Strawberries at BBCH 60-89, 2 x 400 g a.s./ha and the use in Tomatoes at BBCH 61-89, 2 x 400 g a.s./ha)

Species	Test substance	Risk quotient	HQ/TER	Trigger
Honeybee (*Apis mellifera*)	Mepanipyrim	HQ_{oral}	< 12	≥ 50
Honeybee (*Apis mellifera*)	Mepanipyrim	$HQ_{contact}$	< 6	≥ 50
Honeybee (*Apis mellifera*)	Frupica 50 WP	HQ_{oral}	< 6	≥ 50
Honeybee (*Apis mellifera*)	Frupica 50 WP	$HQ_{contact}$	< 7.5	≥ 50

Risk assessment for bees according to EFSA (2013)

for Grapevines at BBCH 77-89, 1 x 600 g a.s./ha, Strawberries (indoor and outdoor) at BBCH 60-89, 2 x 400 g a.s./ha (interval 7 days), and Tomatoes (indoor and outdoor) at BBCH 61-89, 2 x 400 g a.s./ha (interval 7 days)

Acute contact exposure of adult honeybees – screening step

Test substance	Crop	Application rate (g a.s./ha)	LD_{50} (µg a.s./bee)	HQ	Trigger value
Mepanipyrim	Vineyard	600	> 100	< 6.0	85
	Strawberries [1]	400	> 100	< 4.0	42
	Fruiting Vegetables [1]	400	> 100	< 4.0	42
Frupica 50 WP	Vineyard	600	>80	< 7.5	85
	Strawberries [1]	400	> 80	< 5.0	42
	Fruiting Vegetables [1]	400	> 80	< 5.0	42

[1]*Both indoor and outdoor use*

Acute and chronic oral exposure of adult honeybees and honeybee larvae – screening step

Type of assessment	Test substance	Crop	Application rate (kg a.s./ha)	SV	Endpoint	ETR	Trigger value
Acute oral exposure adult bees	Mepanipyrim	Vineyard[1]	0.6	10.6	> 50 µg a.s./bee	< 0.12	0.2
		Strawberries[2]	0.4	7.6		< 0.06	0.2
		Strawberries[3]	0.4	10.6		< 0.08	0.2
		Fruiting Vegetables[2]	0.4	7.6		< 0.06	0.2
		Fruiting Vegetables[3]	0.4	10.6		< 0.08	0.2
	Frupica 50 WP	Vineyard[1]	0.6	10.6	> 100 µg a.s./bee	< 0.06	0.2
		Strawberries[2]	0.4	7.6		< 0.03	0.2
		Strawberries[3]	0.4	10.6		< 0.04	0.2
		Fruiting Vegetables[2]	0.4	7.6		< 0.03	0.2
		Fruiting Vegetables[3]	0.4	10.6		< 0.04	0.2
Chronic oral exposure adult bees	Mepanipyrim	Vineyard[1]	0.6	10.6	> 60.2 µg a.s./bee/day	**< 0.106**	0.03
		Strawberries[2]	0.4	7.6		**< 0.050**	0.03
		Strawberries[3]	0.4	10.6		**< 0.070**	0.03
		Fruiting Vegetables[2]	0.4	7.6		**< 0.050**	0.03
		Fruiting Vegetables[3]	0.4	10.6		**< 0.070**	0.03
Chronic oral exposure larvae	Mepanipyrim	Vineyard[1]	0.6	6.1	155 µg a.s./ larvae per developmental period	0.024	0.2
		Strawberries[2]	0.4	4.4		0.011	0.2
		Strawberries[3]	0.4	6.1		0.016	0.2
		Fruiting Vegetables[2]	0.4	4.4		0.011	0.2
		Fruiting Vegetables[3]	0.4	6.1		0.016	0.2

[1]*Sideward spray application;* [2]*Outdoor use – Downward spray application;* [3]*Indoor use – Sideward spray application*

Chronic oral exposure of adult honeybees – Tier 1

Crop	Scenario	BBCH	Appl. rate (kg a.s./ha)	Ef	SV	twa	Endpoint (µg a.s./bee/day)	ETR	Trigger value
Vineyard[1]	Treated crop	≥ 70	0.6	1	0	0.72	>60.2	0.000	0.03
	Weeds	≥ 70		0.3	2.9	0.72		< 0.006	
	Field	≥ 70		0.027	2.9	0.72		< 0.001	

	margin								
	Adjacent crop	≥ 70		0.0143	5.8	0.72		< 0.001	
	Succeeding crop	≥ 70		1	0.54	0.72		< 0.004	
Strawberries, outdoor[2]	Treated crop	40-69	0.4	1	5.8	0.72	> 60.2	< **0.039***	0.03
		≥ 70		1	0	0.72		0.000	
	Weeds	40-69		0.4	2.9	0.72		< 0.006	
		≥ 70		0.4	2.9	0.72		< 0.006	
	Field margin	40-69		0.0092	2.9	0.72		0.000	
		≥ 70		0.0092	2.9	0.72		0.000	
	Adjacent crop	40-69		0.0033	5.8	0.72		0.000	
		≥ 70		0.0033	5.8	0.72		0.000	
	Succeeding crop	40-69		1	0.54	0.72		< 0.003	
		≥ 70		1	0.54	0.72		< 0.003	
Strawberries, indoor[1]	Treated crop	40-69	0.4	1	8.2	0.72	> 60.2	< 0.039	0.03
		≥ 70		1	0	0.72		0.000	
	Weeds	40-69		0.4	2.9	0.72		< 0.006	
		≥ 70		0.4	2.9	0.72		< 0.006	
	Field margin	40-69		0.0092	2.9	0.72		0.000	
		≥ 70		0.0092	2.9	0.72		0.000	
	Adjacent crop	40-69		0.0033	5.8	0.72		0.000	
		≥ 70		0.0033	5.8	0.72		0.000	
	Succeeding crop	40-69		1	0.54	0.72		< 0.003	
		≥ 70		1	0.54	0.72		< 0.003	
Fruiting vegetables, outdoor[2]	Treated crop	50-69	0.4	1	0.92	0.72	> 60.2	< 0.004	0.03
		≥ 70		1	0	0.72		0.000	
	Weeds	50-69		0.3	2.9	0.72		< 0.004	
		≥ 70		0.3	2.9	0.72		< 0.004	
	Field margin	50-69		0.0092	2.9	0.72		0.000	
		≥ 70		0.0092	2.9	0.72		0.000	
	Adjacent crop	50-69		0.0033	5.8	0.72		0.000	
		≥ 70		0.0033	5.8	0.72		0.000	
	Succeeding crop	50-69		1	0.54	0.72		< 0.003	
		≥ 70		1	0.54	0.72		< 0.003	
Fruiting vegetables, indoor[1]	Treated crop	50-69	0.4	1	0.06	0.72	> 60.2	0.000	0.03
		≥ 70		1	0	0.72		0.000	
	Weeds	50-69		0.3	2.9	0.72		< 0.004	
		≥ 70		0.3	2.9	0.72		< 0.004	
	Field margin	50-69		0.0092	2.9	0.72		0.000	
		≥ 70		0.0092	2.9	0.72		0.000	
	Adjacent crop	50-69		0.0033	5.8	0.72		0.000	
		≥ 70		0.0033	5.8	0.72		0.000	
	Succeeding crop	50-69		1	0.54	0.72		< 0.003	
		≥ 70		1	0.54	0.72		< 0.003	

[1]*Sideward spray application;* [2]*Downward spray application*

** Despite the trigger was slightly breached, EFSA concluded a low risk based on the fact that the ETR was calculated with an unbounded LDD_{50} and that only 4% effect was seen at the highest tested dose. More details about the rationale for this decision are included in the evaluation table.*

Risk assessment for contaminated water

Risk assessment for guttation water						
Type of assessment	Crop	Water consumption (µL)	PEC (µg/µL)	Endpoint	ETR	Trigger
Acute oral	Vineyard[1]	11.4	0.0031	> 50 µg	0.0007	0.2

exposure adult bees	Strawberries[2]	11.4	0.0031	a.s./bee	0.0007	0.2
	Fruiting Vegetables[2]	11.4	0.0031		0.0007	0.2
Chronic oral exposure adult bees	Vineyard[1]	11.4	0.00167	> 60.2 µg a.s./bee/day	0.0003	0.03
	Strawberries[2]	11.4	0.00167		0.0003	0.03
	Fruiting Vegetables[2]	11.4	0.00167		0.0003	0.03
Chronic oral exposure larvae	Vineyard[1]	111	0.00223	155 µg a.s./ larvae per development al period	0.0016	0.2
	Strawberries[2]	111	0.00223		0.0016	0.2
	Fruiting Vegetables[2]	111	0.00223		0.0016	0.2
Risk assessment for contaminated surface water						
Type of assessment	Crop	Water consumption (µL)	PEC (µg/µL)	Endpoint	ETR	Trigger
Acute oral exposure adult bees	Vineyard[1]	11.4	0.000094	> 50 µg a.s./bee	2.1×10^{-5}	0.2
	Strawberries[2]	11.4	0.00011		2.5×10^{-5}	0.2
	Fruiting Vegetables[2]	11.4	0.00011		2.5×10^{-5}	0.2
Chronic oral exposure adult bees	Vineyard[1]	11.4	0.000094	> 60.2 µg a.s./bee/day	1.8×10^{-5}	0.03
	Strawberries[2]	11.4	0.00011		2.1×10^{-5}	0.03
	Fruiting Vegetables[2]	11.4	0.00011		2.1×10^{-5}	0.03
Chronic oral exposure larvae	Vineyard[1]	111	0.000094	155 µg a.s./ larvae per development al period	6.7×10^{-5}	0.2
	Strawberries[2]	111	0.00011		8.0×10^{-5}	0.2
	Fruiting Vegetables[2]	111	0.00011		8.0×10^{-5}	0.2

[1]*Sideward spray application;* [2]*Downward spray application*

Acute contact exposure of adult bumblebees – screening step

Test substance	Crop	Application rate (g a.s./ha)	LD_{50} (µg a.s./bee)	HQ	Trigger value
Mepanipyrim	Vineyard	600	> 100	< 6.0	14
	Strawberries [1]	400	> 100	< 4.0	7
	Fruiting Vegetables [1]	400	> 100	< 4.0	7

[1]*For both outdoor and indoor application*

Acute oral exposure of adult bumblebees – screening step

Type of assessment	Test substance	Crop	Application rate (kg a.s./ha)	SV	Endpoint	ETR	Trigger value
Acute oral exposure adult bees	Mepanipyrim	Vineyard[1]	0.6	13.3	> 100 µg a.s./bee	< **0.080**	0.036
		Strawberries[2]	0.4	11.2		< **0.045**	0.036
		Strawberries[3]	0.4	13.3		< **0.053**	0.036
		Fruiting Vegetables[2]	0.4	11.2		< **0.045**	0.036
		Fruiting Vegetables[3]	0.4	13.3		< **0.053**	0.036

[1]*Sideward spray application;* [2]*Outdoor use - Downward spray application;* [3]*Indoor use – Sideward spray application*

Acute oral exposure of adult bumblebees – Tier 1

Crop	**Scenario**	**BBCH**	**Appl. rate (kg a.s./ha)**	**Ef**	**SV**	**Endpoint (µg a.s./bee)**	**ETR**	**Trigger value**
Vineyard[1]	Treated crop	≥ 70	0.6	1	0	> 100	0.000	0.036
	Weeds	≥ 70		0.3	6.5		< 0.0117	
	Field	≥ 70		0.027	6.5		< 0.0011	

	margin							
	Adjacent crop	≥ 70		0.0143	11.2		< 0.0010	
	Succeeding crop	≥ 70		1	0.9		< 0.0054	
Strawberries outdoor[2]	Treated crop	40-69	0.4	1	11.2	> 100	< **0.0448***	0.036
		≥ 70		1	0		0.0000	
	Weeds	40-69		0.4	6.5		< 0.0104	
		≥ 70		0.4	6.5		< 0.0104	
	Field margin	40-69		0.0092	6.5		< 0.0002	
		≥ 70		0.0092	6.5		< 0.0002	
	Adjacent crop	40-69		0.0033	11.2		< 0.0001	
		≥ 70		0.0033	11.2		< 0.0001	
	Succeeding crop	40-69		1	0.9		< 0.0036	
		≥ 70		1	0.9		< 0.0036	
Strawberries indoor[1]	Treated crop	40-69	0.4	1	13.3	> 100	< **0.0532***	0.036
		≥ 70		1	0		0.0000	
	Weeds	40-69		0.4	6.5		< 0.0104	
		≥ 70		0.4	6.5		< 0.0104	
	Field margin	40-69		0.0092	6.5		< 0.0002	
		≥ 70		0.0092	6.5		< 0.0002	
	Adjacent crop	40-69		0.0033	11.2		< 0.0001	
		≥ 70		0.0033	11.2		< 0.0001	
	Succeeding crop	40-69		1	0.9		< 0.0036	
		≥ 70		1	0.9		< 0.0036	
Fruiting vegetables outdoor[2]	Treated crop	50-69	0.4	1	2.3	> 100	< 0.0092	0.036
		≥ 70		1	0		0.0000	
	Weeds	50-69		0.3	6.5		< 0.0078	
		≥ 70		0.3	6.5		< 0.0078	
	Field margin	50-69		0.0092	6.5		< 0.0002	
		≥ 70		0.0092	6.5		< 0.0002	
	Adjacent crop	50-69		0.0033	11.2		< 0.0001	
		≥ 70		0.0033	11.2		< 0.0001	
	Succeeding crop	50-69		1	0.9		< 0.0036	
		≥ 70		1	0.9		< 0.0036	
Fruiting vegetables indoor[2]	Treated crop	50-69	0.4	1	0.15	> 100	< 0.0006	0.036
		≥ 70		1	0		0.0000	
	Weeds	50-69		0.3	6.5		< 0.0078	
		≥ 70		0.3	6.5		< 0.0078	
	Field margin	50-69		0.0092	6.5		< 0.0002	
		≥ 70		0.0092	6.5		< 0.0002	
	Adjacent crop	50-69		0.0033	11.2		< 0.0001	
		≥ 70		0.0033	11.2		< 0.0001	
	Succeeding crop	50-69		1	0.9		< 0.0036	
		≥ 70		1	0.9		< 0.0036	

[1]*Sideward spray application;* [2]*Downward spray application*

** Despite the trigger was slightly breached, EFSA concluded a low risk based on the fact that the ETR was calculated with an unbounded LD_{50} and that 0% effect was seen at the highest tested dose. More details about the rationale for this decision are included in the evaluation table.*

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

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Toxicity
Typhlodromus pyri	Frupica 50 WP	Mortality, LR_{50} Reproduction, ER_{50}	> 1000 g a.s/ha > 1000 g a.s./ha
Aphidius rhopalosiphi	Frupica 50 WP	Mortality, LR_{50} Reproduction, ER_{50}	> 1000 g a.s./ha 250 g a.s./ha
Additional species			
Poecilus cupreus	Frupica 50 WP	Mortality, LR_{50} Reproduction, ER_{50}	> 1400 g a.s./ha > 1400 g a.s./ha
Chrysoperla carnea	Frupica 50 WP	Mortality, LR_{50} Reproduction	> 500 g a.s./ha 35.9% reduction in reproductive successs at 500 g a.s./ha
Coccinella septempunctata	Frupica 50 WP	Mortality Reproduction	47.7% higher larval mortality compared to controlat 500 g a.s./ha 54.99 % reduction in reproduction success compared to control at 500 g a.s./ha
Trichogramma cacoeciae	Frupica 50 WP	Reproduction	96% reduction in parasitation capacity compared to control at 500 g a.s./ha

First tier risk assessment for Grapevines at BBCH 77-89, 1 x 600 g a.s./ha / Strawberries (indoor and outdoor) at BBCH 60-89, 2 x 400 g a.s./ha (7 day interval) / Tomatoes (indoor and outdoor) at BBCH 61-89, 2 x 400 g a.s./ha (7 day interval)

(the highest in-field and off-field PER values were used to calculate the HQ values to cover all the proposed uses)

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger
Frupica 50 WP	*Typhlodromus pyri*	> 1000	< 0.68	< 0.048	2
Frupica 50 WP	*Aphidius rhopalosiphi*	> 1000	< 0.68	< 0.048	2
Frupica 50 WP	*Poecilus cupreus*	> 1400	< 0.49	< 0.034	2
Frupica 50 WP	*Chrysoperla carnea*	> 500	< 1.36	< 0.096	2

[1]a distance of 3 m was assumed to calculate the drift rate for the use in grapevines, and a distance of 1 m was assumed for the use in strawberries and tomatoes

Extended laboratory tests, aged residue tests

Species	Life stage	Test substance, substrate	Time scale	Dose (g/ha)	End point	% effect[1]	ER_{50}
Aphidius rhopalosiphi	Adult	Frupica 50 WP, Vine leaves	48h of exposure	606 g a.s./ha and 2 x 404 g a.s./ha; fresh and 7d aged residues	Mortality, reproduction	At 606 and 2 x 404 g a.s./ha: <25% mortality on fresh residues and < 10% on 7d aged residues; reduction in parasitation capacity < 35% both on fresh and 7d aged residues	-
Chrysoperla carnea	Larvae and adults	Frupica 50 WP, Vine leaves	3 weeks of exposure	45 g a.s./ha, 600 g a.s./ha and 2 x 400 g a.s./ha; fresh and 7d aged residues	Mortality, reproduction	At 45, 600 and 2 x 400 g a.s./ha (0 and 7 d residues on vine leaves): mortality <15% in all treatments; >16.2 eggs/female/day with hatching success >83.8% in all treatments (≤15% reduction compared to control)	-
Coccinella septempunctata	Larvae and adults	Frupica 50 WP, Vine leaves	3 weeks of exposure	45 g a.s./ha, 600 g a.s./ha and 2 x 400 g a.s./ha; fresh and 7d aged residues	Mortality, reproduction	At 45, 600 and 2 x 400 g a.s./ha (0 and 8 d residues on vine leaves): mortality ≤30% in all treatments; >5 eggs/female/day with hatching success >69.5% in all treatments (<35% reduction compared to control)	-

[1] Positive percentages relate to adverse effects

Semi-field tests
A semi-field test was performed with *Aphidius rhopalosiphi* adults, on treated strawberry plants. The adult wasps were exposed for 96h to either fresh or 14 day aged residues of mepanipyrim following treatment with Frupica 50 WP. The plants were treated with either 45 g a.s./ha, 600 g a.s./ha or 2 x 400 g a.s./ha. Results: At 45, 600 and 2 x 400 g a.s./ha (0 and 14d residues on strawberries): <30% reduction in parasitation capacity (no reduction on 14d aged residues); no behavioural effects
Field studies
A field test was performed with *Typhlodromus pyri* (mobile stages), on treated vine plants. The mites were exposed for 57 days to residues of mepanipyrim following a treatment with Frupica 50 WP at 600 g a.s./ha. Results: the number of mites per leaf 7 days after treatment reduced to 57% of control levels, to 77% after 21 days and to 88% after 57 days.
Additional specific test

None

Risk assessment for – Grapevines at BBCH 77-89, 1 x 600 g a.s./ha / Strawberries at BBCH 60-89, 2 x 400 g a.s./ha (7 day interval) (both indoor and outdoor) / Tomatoes at BBCH 61-89, 2 x 400 g a.s./ha (7 day interval) (both indoor and outdoor), based on extended lab tests, aged residue tests, semi-field and field tests.

As the effects observed in the extended lab tests, aged residue tests, semi-field and field tests were below the 50% threshold of ESCORT II at application rates covering the intended application rates in grapevines, strawberry and tomato, the risk to non-target arthropods can be considered acceptable.

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					
Earthworm (*Eisenia fetida*)	Frupica 50 WP	Mixed with soil as a solution / 10%	Chronic	Reproduction	NOEC = 230 mg prep./kg d.w.soil (= 113 mg a.s/kg d.w. soil) $NOEC_{CORR}$ = 115 mg prep./kg d.w.soil (= 56.5 mg a.s/kg d.w. soil)
Other soil macroorganisms					
Folsomia candida	Mepanipyrim	Mixed with soil as a solution / 5%	Chronic	Mortality: Reproduction:	LC_{10} = 73.52 mg a.s./kg d.w. soil $LC_{10, CORR}$ = 36.76 mg a.s./kg d.w. soil LC_{20} = 341.79 mg a.s./kg d.w. soil $LC_{20, CORR}$ = 170.90 mg a.s./kg d.w. soil NOEC = 104.98 mg a.s./kg d.w. soil $NOEC_{CORR}$ = 52.49 mg a.s./kg d.w. soil EC_{10} = 67.69 mg a.s./kg d.w. soil $EC_{10, CORR}$ = 33.85 mg a.s./kg d.w. soil EC_{20} = 131.90 mg a.s./kg d.w. soil $EC_{20, CORR}$ = 65.95 mg

Test organism	Test substance	Application method of test a.s./ OM[1]	Time scale	End point	Toxicity
					a.s./kg d.w. soil NOEC = 58.35 mg a.s./kg d.w. soil $NOEC_{CORR}$ = 29.18 mg a.s./kg d.w. soil
Hypoaspis aculeifer	a.s.	Mixed with soil as a solution / 5%		Reproduction	NOEC = 1000 mg a.s./kg soil d.w. $NOEC_{CORR}$ = 500 mg a.s./kg soil d.w.

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

Higher tier testing (e.g. modelling or field studies); *None*

Nitrogen transformation	Mepanipyrim	Maximum tested rate of 5.2 mg a.s./kg d.w. soil; sandy loam soil	6.96 % effect at day 21 at 5.2 mg a.s./kg d.w.soil *[In line with the OECD test guideline the endpoint should be based on nitrogen transformation rate and not nitrogen levels*]
	Mepanipyrim	Maximum tested rate of 3.335 mg a.s./kg d.w. soil; sandy loam and clay loam soil	Sandy loam soil: 20.2% effect at day 28 at 3.335 mg a.s./kg d.w. soil Clay soil : 14.2 % effect at day 70 at 3.335 mg a.s./kg d.w. soil
	Frupica 50 WP	Maximum tested rate of 2.7 mg a.s./kg d.w. soil; Sandy loam soil	5.55 % effect at day 81 at 2.7 mg a.s./kg d.w.soil

Toxicity/exposure ratios for soil organisms

Grapevines at BBCH 77-89, 1 x 600 g a.s./ha

Test organism	Test substance	Time scale	Soil PEC[1]	TER	Trigger
Earthworms					
Eisenia fetida	Frupica 50 WP	Chronic	0.252	224	5
Other soil macroorganisms					
Folsomia candida	Mepanipyrim	Chronic	0.252	115.8	5
Hypoaspis aculeifer	Mepanipyrim	Chronic	0.252	1984	5

[1]maximum PEC soil was used

Strawberries at BBCH 60-89, 2 x 400 g a.s./ha (7 day interval) (both indoor and outdoor use)

Test organism	Test substance	Time scale	Soil PEC[1]	TER	Trigger
Earthworms					
Eisenia fetida	Frupica 50 WP	Chronic	0.434	130	5
Other soil macroorganisms					
Folsomia candida	Mepanipyrim	Chronic	0.434	67.22	5
Hypoaspis aculeifer	Mepanipyrim	Chronic	0.434	1152	5

[1]maximum PEC soil was used

Tomatoes at BBCH 61-89, 2 x 400 g a.s./ha (7 day interval) (both indoor and outdoor use)

Test organism	Test substance	Time scale	Soil PEC[1]	TER	Trigger
Earthworms					
Eisenia fetida	Frupica 50 WP	Chronic	0.217	260	5
Other soil macroorganisms					
Folsomia candida	Mepanipyrim	Chronic	0.217	134.45	5
Hypoaspis aculeifer	Mepanipyrim	Chronic	0.217	2304	5

[1]maximum PEC soil was used

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 provided as ER_{50} tests are available

Laboratory dose response tests

Species	Test substance	ER_{50} (g/ha)[2] vegetative vigour	ER_{50} (g/ha)[2] emergence	Exposure[1] (g/ha)[2]	TER	Trigger
Zea mais *(maize)*, Allium cepa (onion), **Brassica napus** (oilseed rape), **Cucumis sativa** (cucumber), **Helianthus annuus** (sunflower), **Phaseolus vulgaris *(bean*)**	Frupica 50 WP	> 780.96	> 780.96	1) 48.12 2) 11.08 3) 11.08	1) 16.2 2) 70.5 3) 70.5	5
Extended laboratory studies: *None* Semi-field and field test: *None*						

Note: 1) For the use in grapevines; 2) for the use in strawberry (both indoor and outdoor); 3) for the use in tomato (both indoor and outdoor)

[1] Exposure has been estimated based on Ganzelmeier drift data with a standard drift distance of 1 meter for Strawberry and Tomato and 3 meters for Grapevines

[2] dose is expressed as g a.s./ha

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
Pseudomonas sp	No data available

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

No 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	Parent (mepanipyrim)
water	Parent (mepanipyrim)
sediment	Parent (mepanipyrim)
groundwater	Parent (mepanipyrim)

[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	Mepanipyrim
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended][11]:	H400 H410
Peer review proposal[12] for harmonised classification according to Regulation (EC) No 1272/2008:	Category Acute 1 | Endpoint: 0.63 mg/L [48h EC50 Daphnia magna] H400 (M-factor = 1) Category chronic 1 | Endpoint: 0.027 mg/L [Chronic NOEC Oncorhynchus mykiss] H410 (M-factor = 1)

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

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

Abbreviations

1/*n*	slope of Freundlich isotherm
λ	wavelength
ε	decadic molar extinction coefficient
a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AAOEL	acute acceptable operator exposure level
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
AUC	area under the blood concentration/time curve
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstracts Service
CFU	colony-forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticides Analytical Council Limited
CL	confidence limits
Cmax	concentration achieved at peak blood level
DAA	days after application
DAT	days after treatment
DDD	daily dietary dose
DM	dry matter
DT_{50}	period required for 50% dissipation (define method of estimation)
DT_{90}	period required for 90% dissipation (define method of estimation)
dw	dry weight
EbC_{50}	effective concentration (biomass)
EC_{50}	effective concentration
ECHA	European Chemicals Agency

EEC	European Economic Community
EMDI	estimated maximum daily intake
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
ETR	exposure toxicity ratio
ETR_{acute}	exposure toxicity ratio for acute exposure
ETR_{larvae}	exposure toxicity ratio for chronic exposure
ETR_{larvae}	exposure toxicity ratio for larvae
ETR_{HPG}	exposure toxicity ratio for effects on honeybee hypopharygeal glands
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	Time-weighted average factor
FAO	Food and Agriculture Organization of the United Nations
FID	flame ionisation detector
FIR	food intake rate
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	Good Agricultural Practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly known as International Group of National Associations of Manufacturers of Agrochemical Products; GIFAP)
GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathione
Hb	haemoglobin
Hct	haematocrit
HPLC	high-pressure liquid chromatography or high-performance liquid chromatography
HPLC-MS	high-pressure liquid chromatography–mass spectrometry
HPG	hypopharygeal glands
HQ	hazard quotient
$HQ_{contact}$	hazard quotient for contact exposure
HR	hazard rate
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
iv	intravenous

JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{doc}	organic carbon linear adsorption coefficient
K_{Foc}	Freundlich organic carbon adsorption coefficient
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC-MS	liquid chromatography–mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LDD_{50}	lethal dietary dose; median
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mm	millimetre (also used for mean measured concentrations)
mN	milli-newton
MRL	maximum residue level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water-holding capacity
NESTI	national estimated short-term intake
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NPD	nitrogen–phosphorus detector
OECD	Organisation for Economic Co-operation and Development
OM	organic matter content
Pa	pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air

PEC_{gw}	predicted environmental concentration in groundwater
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure–activity relationship
r^2	coefficient of determination
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SMILES	simplified molecular-input line-entry system
SPG	specific protection goal
SSD	species sensitivity distribution
STMR	supervised trials median residue
$t_{1/2}$	half-life (define method of estimation)
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
Tmax	time until peak blood levels achieved
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid-stimulating hormone (thyrotropin)
TWA	time-weighted average
UDS	unscheduled DNA synthesis
UF	uncertainty factor

UV	ultraviolet
W/S	water/sediment
w/v	weight per unit volume
w/w	weight per unit weight
WBC	white blood cell
WG	water-dispersible granule
WHO	World Health Organization