Appendix to:

EFSA (European Food Safety Authority), 2017. Conclusion on the peer review of the pesticide risk assessment of the active substance methoxyfenozide. EFSA Journal 2017;15(8):4978, 30 pp. doi:10.2903/j.efsa.2017.4978

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

Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

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

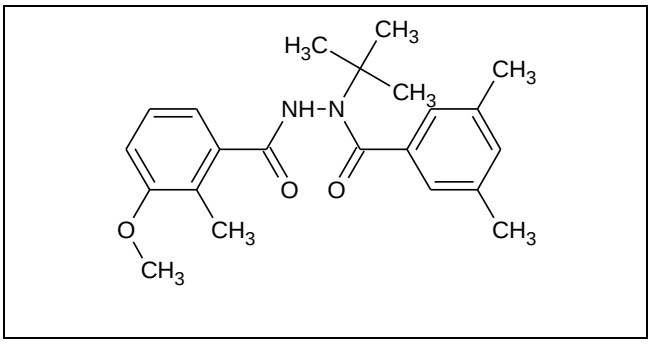
Active substance (ISO Common Name)	Methoxyfenozide (Codes used prior to the common name methoxyfenozide: RH-2485 (RH2485), RH-112485 (RH-112,485))
Function (*e.g.* fungicide)	Insecticide

Rapporteur Member State	UK
Co-rapporteur Member State	Slovakia

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

Chemical name (IUPAC)	*N-tert*-butyl- *N'*-(3-methoxy-*o*-toluoyl)-3,5-xylohydrazide
Chemical name (CA)	3-methoxy-2-methylbenzoic acid 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl)hydrazide
CIPAC No	656
CAS No	161050-58-4
EC No (EINECS or ELINCS)	605-245-2
FAO Specification (including year of publication)	None
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	butylhydrazine (RH-84078/RH-99838/ *TBZ*) at level <0.001 g/kg Open for others.
Molecular formula	$C_{22}H_{28}N_2O_3$
Molar mass	368.47 g/mol

Structural formula



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

Melting point (state purity)	184.8-188.9 °C (low melting form) 206.0-207.9°C (high melting form) (99.8%)
Boiling point (state purity)	The test substance decomposes at 262.9-264.8 °C without boiling (99.7%)
Temperature of decomposition (state purity)	262.9-264.8 °C
Appearance (state purity)	White powder (97.6%)
Vapour pressure (state temperature, state purity)	$<1.33 \times 10^{-5}$ Pa (at 25, 35 and 45 °C, 99.8%)
Henry's law constant	$<1.64 \times 10^{-4}$ Pa m^3 mol^{-1} at 20 °C
Solubility in water (state temperature, state purity and pH)	3.3 mg/L in unbuffered de-ionised water at 20°C ± 0.5 °C (99.6%)
Solubility in organic solvents (state temperature, state purity)	Solvent — g/L at 20 °C (98.5%) methanol — 115 acetone — 69 xylene — 0.6 1,2-dichloroethane — 28 ethyl acetate — 21 heptane — 0.03 1-octanol — 15
Surface tension (state concentration and temperature, state purity)	58 mN/m at 20 °C (90 % saturated solution, 99.4%)
Partition coefficient (state temperature, pH and purity)	log P_{OW} = 3.72 ± 0.04 in unbuffered water at 24.7±1.4°C (99.0%)
Dissociation constant (state purity)	pKa = 12.20 (99.7%)
UV/VIS absorption (max.) incl. ε (state purity, pH)	Solution: 96 µg/mL in methanol (99.9% purity) λ_{max} (nm); ε (L mol^{-1} cm^{-1}) 216 ; 12,819 (pH7) 280; 2,503 (pH7) 290 ; 1,561(pH7) 216 ; 12,881 (pH<2) 279 ; 2,916 (pH<2) 290 ; 1,912 (pH<2) 225 ; 11,312 (pH>10) 276 ; 2,937 (pH>10) 290 ; 1,548 (pH>10) No UV absorption maxima > 290 nm:
Flammability (state purity)	Not highly flammable (98.2%)
Explosive properties (state purity)	Not explosive (98.2%)

Oxidising properties (state purity)	Not oxidising (98.5%)

Summary of representative uses evaluated, for which all risk assessments needed to be completed (*methoxyfenozide*)
(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)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	Method kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between applications (min)	g as/hl min max	water l/ha min max	g as/ha min max		
Table grapes	SZ	GF-837	F	POLYBO, CLYSAM, SPARPI	SC	240	Broadcast Foliar	BBCH 71-85 May to Sep	1	NA	5.8 - 120	80 - 1000	58 - 96	7	
Wine grapes	SZ	GF-837	F	POLYBO, CLYSAM, SPARPI	SC	240	Broadcast Foliar	BBCH 71-85 May to Sep	1	NA	5.8 - 120	80 - 1000	58 - 96	14	
Table grapes	CZ	GF-837	F	POLYBO, CLYSAM, SPARPI	SC	240	Broadcast Foliar	BBCH 71-85 May to Sep	1	NA	3.6 - 48	200 - 1600	58 - 96	7	
Wine grapes	CZ	GF-837	F	POLYBO, CLYSAM, SPARPI	SC	240	Broadcast Foliar	BBCH 71-85 May to Sep	1	NA	3.6 - 48	200 - 1600	58 - 96	14	
Maize	SZ, CZ	GF-837	F	PYRUNU, SESANO	SC	240	Broadcast Foliar	BBCH 51-75 May to Sep	1	NA	9.6 - 144	100 - 1000	96 - 144	28	
Sweet corn	SZ, CZ	GF-837	F	PYRUNU, SESANO	SC	240	Broadcast Foliar	BBCH 51-75 May to Sep	1	NA	9.6 - 144	100 - 1000	96 - 144	7	
Fruiting	SZ	GF-837	F	SPODSP,	SC	240	Broadcast	BBCH 51-87	1	NA	6.4 -	200 -	96 - 144	1	

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	Method kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between applications (min)	g as/hl min max	water l/ha min max	g as/ha min max		
vegetables – Solanaceae – Tomatoes, Peppers, Aubergines				loopers, PYRUNU, HELIAR			Foliar	May to Sep			72	1500			
Fruiting vegetables – Solanaceae – Tomatoes, Peppers, Aubergines	EU	GF-837	G	SPODSP, loopers, PYRUNU, HELIAR	SC	240	Broadcast Foliar	BBCH 51-87 Feb to Nov	1	NA	6.4 - 72	200 - 1500	96 - 144	1	
Leaf vegetables – Lettuce and other salad plants including Brassicacea – Lamb's lettuce, Lettuce, Cress, Land cress, Rocket, Rucola, Red	SZ	GF-837	F	SPODSP, HELIAR	SC	240	Broadcast Foliar	BBCH 41-49 May to Sep	1	NA	9.6 - 40	300 - 1000	96 - 120	3	

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	Method kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between applications (min)	g as/hl min max	water l/ha min max	g as/ha min max		
mustard, Leaves and sprouts of Brassica spp., including turnip greens, others															
Leaf vegetables – Spinach & similar (leaves)	SZ	GF-837	F	SPODSP, HELIAR	SC	240	Broadcast Foliar	BBCH 41-49 May to Sep	1	NA	9.6 - 40	300 - 1000	96 - 120	3	
Leaf vegetables – Herbs	SZ	GF-837	F	SPODSP, HELIAR	SC	240	Broadcast Foliar	BBCH 41-49 May to Sep	1	NA	9.6 - 40	300 - 1000	96 - 120	3	

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

(a) For crops, the EU and Codex classification (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 suckling insects, soil born insects, foliar fungi, weeds

(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989

(f) All abbreviations used must be explained

(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench

(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used must be indicated

(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**

(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

(k) Indicate the minimum and maximum number of application possible under practical conditions of use

(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha

Crop and/or situation (a)	**Member State or Country**	**Product name**	**F G or I** (b)	**Pests or Group of pests controlled** (c)	**Formulation**		**Application**				**Application rate per treatment**			**PHI** (days) (l)	**Remarks:** (m)
					Type (d-f)	Conc. of as (i)	Method kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between applications (min)	g as/hl min max	water l/ha min max	g as/ha min max		

(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 (*methoxyfenozide*)

Regulation (EC) N° 1107/2009 Article 8.1(g))

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

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	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)		
MRL Application (according to Article 8.1(g) of Regulation (EC) No 1107/2009)															
Vine leaves	SEU	GF-837 Runner	F	POLYBO, CLYSAM, SPARPI	SC	240	Broad cast Foliar	BBCH 71-85	1	n.a.	0.0096	1000	0.096	10	Grape leaves is not a representative use of methoxyfenozide. Application rate is specified in terms of the concentration of the spray solution.
Sweet corn	NEU	GF-837 Runner	F	PYRUNU, SESANO	SC	240	Broad cast Foliar	BBCH 51-75	1-3	28	0.0144 – 0.144	100 - 1000	0.144	7	Sweet corn is a representative use of methoxyfenozide, but at a less critical GAP (1 application). The residue trials available were conducted in compliance with this more critical GAP of 3 applications.

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and sucking insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(j) Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of applications possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

Further information, Efficacy

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

Sufficient information has been provided on the effectiveness of methoxyfenozide for the representative uses.

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

Sufficient information has been provided to establish there are no adverse effects for the representative uses.

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

Sufficient information has been provided to establish there are no undersirable effects for the representative uses.

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

	RH-131154 (M08)
Activity against target organism	No

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 (254 nm)
Impurities in technical a.s. (analytical technique)	HPLC-UV (254 nm)
Plant protection product (analytical technique)	Methoxyfenozide: HPLC-UV (220 nm) Relevant impurities: *tert*-butylhydrazine –GS-NPD

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		Methoxyfenozide
Food of animal origin		Methoxyfenozide
Soil		Methoxyfenozide
Sediment		Methoxyfenozide, M08 (pending), M14 (pending)
Water	surface	Methoxyfenozide
	drinking/ground	Methoxyfenozide
Air		Methoxyfenozide
Body fluids and tissues		Methoxyfenozide

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	HPLC-MS/MS (LOQ: 0.01 mg/kg) Orange (high acid), apple (high water), oilseed rape seed (high oil), wheat grain (dry). Also validated for honey.
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	HPLC-MS/MS (LOQ: 0.01 mg/kg)
Soil (analytical technique and LOQ)	HPLC-MS/MS Methoxyfenozide: LOQ 0.01 mg/kg RH-117236 (M14): LOQ 0.01 mg/kg RH-131154 (M08): LOQ 0.01 mg/kg
Water (analytical technique and LOQ)	HPLC-MS/MS Methoxyfenozide: LOQ 0.05 µg/L RH-117236 (M14): LOQ 0.05 µg/L RH-131154 (M08): LOQ 0.05 µg/L
Air (analytical technique and LOQ)	HPLC-MS/MS Methoxyfenozide: LOQ 2.79 µg/m^3
Body fluids and tissues (analytical technique and LOQ)	Body fluids HPLC-MS/MS Methoxyfenozide: LOQ 0.05 mg/L

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

Substance	Methoxyfenozide
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]:	Not classified
Peer review proposal [2] for harmonised classification according to Regulation (EC) No 1272/2008:	No classification proposed

[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.

Section 2 Mammalian Toxicology
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	About 60-70% within 72h in the rat (biliary excretion taken into account) following a single gavage dose of 10 mg/kg bw The value for oral absorption chosen for calculation of the AOEL was 60%. Pre-treatment of animals with methoxyfenozide in the diet for 2 weeks did not appreciably alter the absorption, distribution or elimination findings
Toxicokinetics	The maximum concentrations of radioactivity in blood and plasma were observed 15 to 30 minutes post-dose. Peak blood levels were not proportional to the dose level administered. Elimination of ^{14}C-label from plasma followed a biphasic pattern.
Distribution	Widely distributed. Highest absorbed levels after 15 min to 2 h in the liver. Highest levels after 5 days also chiefly in liver.
Potential for bioaccumulation	No evidence for accumulation
Rate and extent of excretion	The majority of the administered dose was excreted in faeces (c.90%) and to a lesser extent in the urine (c.5-10%). There was significant biliary excretion.
Metabolism in animals	The metabolism of methoxyfenozide was rapid and extensive (a total of 31 metabolites, of which 25 were identified). Mostly, the main part of the methoxyfenozide molecule remained intact, ie the dibenzoyl-tert-butylhydrazine structure) was present in most metabolites.
In vitro metabolism	No data, data gap identified
Toxicologically relevant compounds (animals and plants)	Parent and metabolites M14 and its conjugates (M115 and M40). M24 and conjugates and M16.
Toxicologically relevant compounds (environment)	Parent and M08

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

Rat LD_{50} oral	LD_{50} > 5000 mg/kg bw	
Rat LD_{50} dermal	LD_{50} > 5000 mg/kg bw	
Rat LC_{50} inhalation	LC_{50} > 4.3 mg/l (4h, nose only, maximum achievable concentration)	
Skin irritation	Non-irritant	
Eye irritation	Non-irritant	
Skin sensitisation	Non-sensitiser in submitted study (M &K)	

Phototoxicity	Not required	

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

Target organ / critical effect	Rats, dogs: Liver (increased weight, hypertrophy), hemopoietic system (haemolytic anaemia) Mouse: reduced body weight gain.	
Relevant oral NOAEL	2-week, dog: 18 mg/kg bw per day 1-year, dog: 9.8 mg/kg bw per day 90-day, rat: 69 mg/kg bw per day 90-day, mouse: 428 mg/kg bw per day	
Relevant dermal NOAEL	>1000 mg/kg bw per day 28-day rat	
Relevant inhalation NOAEL	No data - not required.	

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

In vitro studies	Ames test (OECD TG 471): Negative. Mammalian Cell Gene Mutation Test (OECD TG 476): Negative Mammalian Chromosome Aberration Test (OECD TG 473): Negative.	
In vivo studies	Micronucleus Test (OECD TG 474): Negative	
Photomutagenicity	Not required	
Potential for genotoxicity	Methoxyfenozide 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: Liver (increased weight, hypertrophy), hemopoietic system (haemolytic anaemia), thyroid (hypertrophy) Mouse: no effects.	
Relevant long-term NOAEL	80-90 week, rat:10.2 mg/kg bw per day 18-months, mouse: Highest dose tested 1020 mg/kg bw per day	
Carcinogenicity (target organ, tumour type)	Rat: thyroid C-cell adenoma and hepatocellular adenoma. Mouse: No tumours considered to be substance related.	H351 Carc. 2
Relevant NOAEL for carcinogenicity	2-year, rat: 10.2 mg/kg bw per day 18-month, mouse: Highest dose tested 1020 mg/kg bw per day	

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

Reproduction toxicity

Reproduction target / critical effect	Parental toxicity: Reduced bodyweight gain and liver effects (increased weight, hepatocellular hypertrophy and vacuolation, pigment in Kupffer cells). Reproductive toxicity: no adverse effect observed in rat 2-generation study Offspring's toxicity: No effects	
Relevant parental NOAEL	153 mg/kg bw per day	
Relevant reproductive NOAEL	1552 mg/kg bw per day	
Relevant offspring NOAEL	1552 mg/kg bw per day	

Developmental toxicity

Developmental target / critical effect	Rat: No evidence of substance-related adverse effects up to limit dose Rabbit: No evidence of substance-related adverse effects up to limit dose	
Relevant maternal NOAEL	Rat: 1000 mg/kg bw per day Rabbit: 1000 mg/kg bw per day	
Relevant developmental NOAEL	Rat: 1000 mg/kg bw per day Rabbit: 1000 mg/kg bw per day	

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

Acute neurotoxicity	NOAEL (acute neurotoxicity rat) > 2000 mg/kg bw	
Repeated neurotoxicity	NOAEL (90-day neurotoxicity rat) >1318 mg/kg bw per day	
Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity)	-	

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

Supplementary studies on the active substance	Effects on liver enzymes and thyroid function The Notifier provided a study on the effect of methoxyfenozide on liver enzymes and thyroid function in rats and liver enzymes at doses relevant to the relevant carcinogenicity studies. Significant increases in microsomal protein and cytochrome P-450 were seen in the rat as well as increased pentoxyresorufin O-dealkylase, and ethoxycoumarin O-dealkylase. In the mouse significant increases in CYP2B and CYP3A contents. Immunotoxicity The Sheep Red Blood Cell Assay demonstrated that methoxyfenozide did not cause a treatment-related decrease in the primary immune response to SRBCs in female rats up to a limit dose of 1000 mg/kg bw per day.
Endocrine disrupting properties	No additional testing of endocrine disrupting properties was performed. However no substance-related adverse reproductive and/or developmental effects were seen in a multigeneration study in rats up to a dose in excess of the limit dose for such a study or in a developmental toxicity study in rats with doses up to the limit dose. Similarly, in a developmental study in rabbits, also using doses up to the limit dose, there were no clear substance-related adverse findings. Indications of a possible effect on sexual maturation and differentiation at the top dose in the rat multigeneration study, and in the rabbit developmental study, are not considered to be substance related. However during the Pesticides Peer Review Meeting 159 (06-09 June 2017) experts agreed that more data (level 2 and level 3 studies according to OECD conceptual framework) are needed in the light of the observed effects on thyroid such as changes in thyroid weight sometimes correlating with follicular cell hypertrophy and C-cell adenomas. A data gap was identified for endocrine disrupting potential. RMS disagreed with such proposal.
Studies performed on metabolites or impurities	**Metabolite M14** Ames test (OECD TG 471): Negative. Mammalian Cell Gene Mutation Test (OECD TG 476): Negative Mammalian Chromosome Aberration Test (OECD TG 473): Negative. **Metabolite M08** Ames test (OECD TG 471): Negative. Mammalian Cell Gene Mutation Test (OECD TG 476): Negative Mammalian Chromosome Aberration Test (OECD TG 473): Negative.

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

Production of Methoxyfenozide has been undertaken at one site since 1998, and to date, on average, 44 personnel have been directly involved in production. All personnel are offered a health program, consisting of an annual physical examination and blood screen, and more extensive testing at 3 and 5 years. No specific abnormalities were detected from the health screening over these years deemed attributable to methoxfenozide exposure.

For the general population and end users in the USA and Canada, the Notifier has records of 15 reports of possible human exposure and adverse effects to methoxyfenozide between 2005 and current date. Of these, 13 were reported as minor or asymptomatic. One reported as moderate – a truck driver reported headaches with respiratory irritation and dyspnoea after a crop sprayer dumped a considerable amount of product plus cotton seed oil onto the cab of his truck. The driver was evaluated in hospital and no specific findings were noted.

Summary[3] (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)	0.1	rat, 2-year	100
Acute Reference Dose (ARfD) [(a)]	0.1	1 year dog study supported by the 2-week dog study	100
Acceptable Operator Exposure Level (AOEL) [(a)]	0.06[(b)]	1 year dog study supported by the 2-week dog study	100
Acute Acceptable Operator Exposure Level (AAOEL)	0.06[(b)]	1 year dog study supported by the 2-week dog study	100

(a)Reference values different from previously set by European Commission (2004).
(b)Including correction for limited oral absorption/bioavailability (60 %).

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

Representative formulation (GF-837; 240 g/litre; WP)	Concentrate (251.9 g/L) : **0.5%** Field dilution I (1.58 g/L) : **8%** Field dilution II (0.16 g/L) : **4%** Based on a 240 g/litre suspension concentrate formulation (in vitro human data) considered similar to GF-837.

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

Operators	Use: grapes, tractor mounted broadcast air assisted sprayer, application rate 0.096 kg a.s/ha % of the AOEL German model Without PPE: 17% UK POEM (500 L/ha model) Without PPE: 91%
	Use: maize/sweetcorn and vegetables, tractor mounted field crop boom sprayer, application rate 0.144 kg a.s/ha % of the AOEL German model Without PPE: 12% UK POEM With gloves during all operations: 23%

(a) [3] If available include also reference values for metabolites

	Use: grapes and vegetables , hand-held application (outdoor), application rate 0.096 kg a.s/ha % of the AOEL German model Without PPE: 11% UK POEM With gloves during all operations and coveralls during application: 55%
	Use: fruiting vegetables, hand-held application (indoor), application rate 0.144 kg a.s/ha % of the AOEL EUROPOEM Without PPE: Knapsack sprayer 37%
Workers	EUROPOEM II worker re-entry model Without PPE: Maize 10% Sweet-corn 38% Grapes (outdoor) 52% Vegetables (outdoor) 19% Fruiting vegetables (indoor) 45%
Bystanders and residents	Spray drift (based on surrogate data) Tractor mounted field crop boom sprayer <1% Tractor mounted broadcast air assisted sprayer 10% Vapour (based on surrogate data) 6% and 14% of the AOEL for an adult and a child respectively. Drift fallout (based on published drift data and EPA SOPs) Tractor mounted field crop boom sprayer <1% Tractor mounted broadcast air assisted sprayer <1%

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

Substance :	Methoxyfenozide
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] :	Not listed in Annex VI

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

Peer review proposal [5] for harmonised classification according to Regulation (EC) No 1272/2008:	Carc. 2 H351 "Suspected of causing cancer"

(c) [5] It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.

Section 3 Residues

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	Apples	2 x 1.1 kg a.s./ha[1] (33 days interval)	0, 7, 14 and 36
	Grapes	2 x 1.12 kg a.s./ha[2] (28 days interval)	27
Root crops	-	-	-
Leafy crops	-	-	-
Cereals/grass crops	Rice	2 x 0.6 kg a.s./ha (B-ring/t-butyl) (36 days interval) 0.6 kg a.s./ha + 0.31 kg as/ha (A-ring)	14, 31, 62
Pulses/Oilseeds	Cotton	2 x 1.1 kg a.s./ha[3] (31 days interval)	7, 14, 21
Miscellaneous	-	-	-

[1] - Mixture of non-labelled, ^{13}C- carbonyl- and A-ring (^{14}C-methoxyphenyl) labelled methoxyfenozide
[2] - t-butyl labelled [^{14}C]/ [^{13}C]methoxyfenozide
[3] - ^{14}C-methoxyfenozide, separately labelled in the A-ring, B-ring and t-butyl site

Rotational crops (metabolic pattern)
OECD Guideline 502

Crop groups	Crop(s)	PBI (days)	Comments
Root/tuber crops	White radish	31, 91, 364	3 x 0.75 kg a.s./ha of ^{14}C-methoxyphenyl-, ^{14}C-dimethylphenyl- or ^{14}C-t-butyl-labelled methoxyfenozide – Bare soil application
Leafy crops	Mustard	31, 91, 364	
Cereal (small grain)	Wheat	31, 91, 364	
Other	-	-	

Rotational crop and primary crop metabolism similar?

Yes

Although the metabolism of methoxyfenozide in rotational crops is more extensive, it proceeds in similar pathways as in primary plants.

Open for M08 (see data gap).

Processed commodities(4) (standard hydrolysis study)
OECD Guideline 507

Conditions	
20 min, 90°C, pH 4	Methoxyfenozide residues considered stable under these conditions.
60 min, 100°C, pH 5	
20 min, 120°C, pH 6	

Residue pattern in processed commodities similar to residue pattern in raw commodities?

Yes

[4]: The need for additional data to address the nature of the residues at processing will be revised pending upon the finalization of the residue definition for risk assessment in plants.	
Plant residue definition for monitoring (RD-Mo) **OECD Guidance, series on pesticides No 31**	Methoxyfenozide
Plant residue definition for risk assessment (RD-RA)	Primary crops: Methoxyfenozide Rotational crops: Methoxyfenozide plus M14 and its conjugates (M15 and M40), expressed as methoxyfenozide – provisional.
Conversion factor (monitoring to risk assessment)	Open for rotational crops

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	1 x 50 mg/kg feed	7	38 N
	Goat	A-ring: 2.21 B-ring: 1.76 t-butyl: 1.72	7	42 N 33 N 33 N
	Pig	N/A		Not required
	Fish	N/A		Not required
	^{14}C-methoxyfenozide, separately labelled in the A-ring (methoxyphenyl ring), B-ring (dimethylphenyl ring) and t-butyl site. N/A: Not applicable			

Time needed to reach a plateau concentration in milk and eggs (days)	Not observed for eggs and milk over the 7 days dosing period.
Animal residue definition for monitoring (RD-Mo) **OECD Guidance, series on pesticides No 31**	Methoxyfenozide
Animal residue definition for risk assessment (RD-RA)	Methoxyfenozide, M24 (free and conjugated-M26) and M16, expressed as methoxyfenozide – provisional
Conversion factor (monitoring to risk assessment)	Open
Metabolism in rat and ruminant similar (Yes/No)	Yes
Fat soluble residues (Yes/No) **(FAO, 2009)**	Yes

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

Confined rotational crop study (Quantitative aspect) **OECD Guideline 502**	Methoxyfenozide was found to be extensively degraded in all crop parts and was observed mainly in mustard leaves and radish leaves and root but was never detected or at negligible levels in wheat forage, straw and grain. M15 was found to be a major compound of the total residues in mustard leaves, radish leaves/roots and in wheat forage and straw. M40 was also identified at significant levels in wheat forage only whilst M14 accounted for significant levels in wheat straw and grain.
Field rotational crop study **OECD Guideline 504**	US trials: 5x0.45 kg a.s./ha on lettuce (cover crop) (PBI: 7 days) analysing for methoxyfenozide, M14 and M15 in different crop categories. EU trial: 2x0.144 kg a.s./ha-Bare soil treatment (PBIs: 30, 60, 120, 270 days) analysing for methoxyfenozide only in lettuce, radish leaves/root, rape seed and wheat grain/straw.

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)
			Methoxyfenozide
High water content	Apples	-20	12
	Tomatoes	-20	12
High oil content	Cotton seed	-20	23.5
	Corn (maize) Oil	-10	6
High protein content	Beans, dry	<-20	11
	Peas, dry	<-20	14
High starch content	Maize grain	-20	13
High acid content	Oranges	-18	15
	Grapes		

Animal	**Animal commodity**	**T** (°C)	**Stability** (Month)	
			Methoxyfenozide	M16
Cow	Muscle	-20	5.5	N/A
Cow	Liver	-20	9	2 weeks
Cow	Kidney	-20	9	9
Cow	Milk	-20	3.5	N/A

N/A: Not applicable

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

Crop	Region/ Indoor (a)	Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs (b)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (d)
Representative uses						
Table Grapes (7 day PHI)	NEU	0.08, 0.12, 2 x 0.14, 0.19		0.4	0.19	0.14
Wine Grapes (14 day PHI)		0.02, 0.08, 0.12, 2 x 0.14, 0.19, 0.20	7 trials to support representative use on a major crop in the NEU. 1 additional trial required.	0.4 (provisional)	0.20	0.14
Table Grapes (7 day PHI)	SEU	0.039, 0.040, 0.049, 0.10, 0.20, 0.25	6 trials to support representative use on a major crop in the SEU. 2 additional trials required.	0.5 (provisional)	0.25	0.075
Wine Grapes (14 day PHI)		0.024, 0.069, 0.13, 0.14, 0.17, 0.20, 0.21	7 trials to support representative use on a major crop in the SEU. 1 additional trial required.	0.4 (provisional)	0.21	0.14
Tomatoes	Indoor	Unscaled residues: 0.019, 0.023, 0.038, 0.043, 0.05, 0.07, 0.11, 0.128 Scaled residues: 0.018, 0.023, 0.029, 0.033, 0.048, 0.070, 0.079, 0.125	Possible extrapolation to aubergines. Proportionality concept was applied to the whole residue dataset.	0.2	0.125	0.041
	SEU	Unscaled residues: 0.055, 0.075, 0.084, 0.13 Scaled residues: 0.039, 0.057, 0.062, 0.101	4 trials to support representative use on a major crop in the SEU. 4 additional trials required – Possible extrapolation to aubergines. Proportionality concept was applied to the whole residue dataset.	0.2 (provisional)	0.101	0.060
Peppers	Indoor	Unscaled residues: 0.058, 0.079, 0.12, 0.14, 0.139, 0.17, 0.25, 0.201 Scaled residues: 0.058, 0.077, 0.086, 0.096, 0.133, 0.138, 0.188, 0.201	Proportionality concept was applied to the whole residue dataset.	0.4	0.201	0.115

Crop	Region/ Indoor (a)	Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs (b)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (d)
	SEU	Unscaled residues: 0.15, 0.26, 0.29, 0.4 Scaled residues: 0.12, 0.19, 0.23, 0.29	4 trials to support representative use on a major crop in the SEU. 4 additional trials required. Proportionality concept was applied to the whole residue dataset.	0.7 (provisional)	0.29	0.21
Sweet corn	NEU	0.02, 0.031, 0.033, 0.044	Residue trials to support the representative NEU GAP on sweet corn not available. The representative NEU use is covered by residue trials on sweet corn submitted in the framework of the MRL application.	0.1	0.044	0.032
	SEU	-	No trials conducted in accordance with the representative SEU GAP are available. 4 residue trials compliant with the representative SEU use on sweet corn are requested.	-	-	-
Maize	NEU+SEU	8 x <0.01	NEU and SEU datasets combined.	0.01*	0.01	0.01
Maize stover (rest of plant)	NEU	0.055, 0.199, 0.220, 0.372	Data taken from "rest of plant" samples at harvest (PHI *ca*. 27-29 days)		0.372	0.21
	SEU	0.355, 0.932, 1.674, 5.65	Data taken from "rest of plant" samples at harvest (PHI *ca*. 27-29 days)		5.650	1.3
Lettuces and salad plants (except escaroles/broad-leaved endives), Herbs and edible flowers, Spinaches and similar leaves	SEU	0.52, 0.62, 0.80, 0.92, 2 x 1, 1.7, 2.6	8 residue trials on lettuces, "open leaf" varieties to support the representative uses. Possible extrapolation to other salad plants (except escaroles/broad-leaved endives), herbs and edible flowers and spinaches and similar leaves.	4.0	2.6	0.96
MRL application						
Grape leaves and	SEU	1.0, 4.6, 5.7, 12		30	12	5.15

Crop	Region/ Indoor (a)	Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs (b)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (d)
similar species						
Sweet corn	NEU	0.02, 0.031, 0.033, 0.044		0.1	0.044	0.032
Summary of the data on formulation equivalence OECD Guideline 509						
Crop	**Region**	**Residue data** (mg/kg)	**Recommendations/comments**			
N/A – All trials were conducted using the same formulation type (SC) as the representative formulation.						
Summary of data on residues in pollen and bee products (Regulation (EU) No 283/2013, Annex Part A, point 6.10.1)						
Product(s)	**Region**	**Residue data** (mg/kg)	**Recommendations/comments**			
Data gap: Residues of methoxyfenozide in pollen and bee products cannot be excluded and further information is requested.						

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

Inputs for animal burden calculations

Feed commodity	Median dietary burden		Maximum dietary burden	
	(mg/kg)	Comment	(mg/kg)	Comment
Representative uses				
Maize grain	0.01		0.01	
Maize stover	1.3		5.65	Data taken from "rest of plant" samples at harvest (PHI *ca*. 27-29 days).

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	0.041	Ram/Ewe	0.000	Breeding	0.032	Broiler	0.001	Carp	N/A
	Dairy cattle	0.053	Lamb	0.000	Finishing	0.000	Layer	0.001	Trout	N/A
							Turkey	0.001	Fish intake >0.1 mg/kg DM	
Intake >0.004 mg/kg bw	Yes		No		Yes		No		No	
Feeding study submitted	Yes		No		No		No		Not requested as methoxyfenozide residues in maize grain are <0.01 mg/kg.	
Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and **N rates**	Level 0.760	Beef: 18.5 N Dairy: 14.4 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	0.000	0.01*	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Fat	0.003	0.01*	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Meat[(b)]	0.000		N/A		N/A		N/A			
Liver	0.002	0.01*	N/A	N/A	N/A	N/A	N/A	N/A		
Kidney	0.001	0.01*	N/A	N/A	N/A	N/A	N/A	N/A		
Milk[(a)]	0.000	0.01*	N/A	N/A						
Eggs							N/A	N/A		
Method of calculation[(c)]	Ln		N/A		N/A		N/A		N/A	

[(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	0.010	Ram/Ewe	0.000	Breeding	0.007	Broiler	0.001	Carp	N/A
	Dairy cattle	0.012	Lamb	0.000	Finishing	0.000	Layer	0.001	Trout	N/A
							Turkey	0.001		
Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and **N rates**	Level 0.760	Beef: 78.3N Dairy: 61N	Level N/A	Lamb : N Ewe: N	Level N/A	N rate Breed/Finish	Level N/A	B or T: N Layer: N	Level N/A	N rate Carp/Trout
	Mean level in feeding level	Estimated **STMR**[(b)] at 1N	Mean level in feeding level	Estimated **STMR**[(b)] at 1N	Mean level in feeding level	Estimated **STMR**[(b)] at 1N	Mean level in feeding level	Estimated **STMR**[(b)] at 1N	Mean level in feeding level	Estimated **STMR**[(b)] at 1N
Muscle	0.000	0.000	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Fat	0.007	0.000	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Meat[(a)]	0.001	0.000	N/A	N/A	N/A	N/A	N/A	N/A		
Liver	0.023	0.000	N/A	N/A	N/A	N/A	N/A	N/A		
Kidney	0.000	0.000	N/A	N/A	N/A	N/A	N/A			
Milk	0.000	0.000	N/A	N/A						
Eggs							N/A	N/A		
Method of calculation[(c)]	Ln		N/A		N/A		N/A		N/A	

[(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.

[(5)]: Validity of the ruminant feeding study is pending upon the outcome of the data gap identified for further information on the validation data of the analytical method for the determination of M16 residues in animal.matrices.

Conversion Factors (CF) for monitoring to risk assessment

Open for plant and animal matrices.

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[c]	
Representative uses				
Oranges/pulp	3	<0.4, <0.3, <0.2	<0.3	N/A
Oranges/marmalade	3	0.8, 0.5, 0.24	0.5	N/A
Oranges/juice	2	<0.05, <0.05	<0.05	N/A
Apples/fruit, washed	3	0.6, 0.7, 0.8	0.7	N/A
Apples/juice	3	<0.4, <0.4, <0.5	<0.4	N/A
Apples/sauce	3	0.4, <0.5, 0.5	0.5	N/A
Apples/pomace, wet	3	2, 2.3, 2.3	2.3	N/A
Apples/pomace, dried	3	7, 7.5, 8.1	7.5	N/A
Wine grapes / juice	2	<0.4, <0.3	<0.35	N/A
Wine grapes / must	6	<0.3, <0.3, 0.3, <0.4, 1.7, 1.3	0.35	N/A
Wine grapes / wine[d]	4 (red wine) 4 (white wine)	<0.3 (R), <0.4 (W), 0.3 (W), <0.2 (R), 0.4 (R), <0.3 (W), 0.4 (R), 1.3, (W)	0.35	N/A
Table grapes / juice	2	<0.1, <0.2	<0.15	N/A
Table grapes / raisins	3	2.1, 2.4, 3.0	2.4	N/A
Tomato / fruit, washed	4	<0.4, <0.6, 0.4, 0.6	0.5	N/A
Tomato / fruit, peeled	4	<0.2, 0.2, <0.4, <0.4	0.3	N/A
Tomato / preserve	4	<0.4, 0.3, <0.4, 0.2	0.35	N/A
Tomato / paste	4	1.7, 3.4, 3.0, 2.2	2.6	N/A
Tomato / juice	4	<0.4, 0.4, 0.4, 0.3	0.4	N/A
Tomato / pomace, wet	1	3.6	3.6	N/A

[a]: Studies with residues in the RAC at or close to the LOQ should be disregarded (unless concentration).
[b]: When the residue definition for risk assessment differs from the residue definition for monitoring.
[c]: Processing factors with '<' were used to derive the median processing factors where there were insufficient data to derive the processing factors without reliance on these 'uncertain' factors; however, where possible, greater reliance was placed on the individual processing factor values without '<'.
[d]: (R) = red wine; (W) = white wine.

Consumer risk assessment (Regulation (EU) N° 283/2013, Annex Part A, point 6.9)[6]

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

ADI	0.1 mg/kg bw per day
TMDI according to EFSA PRIMo	Highest TMDI: 4.2 % ADI (WHO Cluster diet B)
IEDI (% ADI), according to EFSA PRIMo	Not relevant

Factors included in the calculations	N/A
ARfD	0.1 mg/kg bw
IESTI (% ARfD), according to EFSA PRIMo	Highest IESTI:70% ARfD (Lettuce, DE child)
Factors included in IESTI and NESTI	N/A

Consumer risk assessment limited to the representative uses

ADI	0.1 mg/kg bw per day
TMDI according to EFSA PRIMo	Highest TMDI: 4.2 % ADI (WHO Cluster diet B)
IEDI (% ADI), according to EFSA PRIMo	Not relevant
Factors included in the calculations	N/A
ARfD	0.1 mg/kg bw
IESTI (% ARfD), according to EFSA PRIMo	Highest IESTI:70% ARfD (Lettuce, DE child)
Factors included in IESTI and NESTI	N/A

(6): The consumer dietary risk assessment is regarded as not finalised for the products of plant and animal origin.

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

Code[(a)]	Commodity/Group	MRL (mg/kg)
Plant commodities		
Representative uses		
0151010	Table grapes	0.5 (provisional)
0151020	Wine grapes	0.4 (provisional)
0231010	Tomatoes	0.2 (Indoor)
	Tomatoes	0.2 (outdoor) (provisional)
0231030	Aubergines	0.2 (Indoor)
	Aubergines	0.2 (outdoor) (provisional)
0231020	Sweet Peppers/Bell peppers	0.4 (Indoor)
	Sweet Peppers/Bell peppers	0.7 (outdoor) (provisional)
0234000	Sweet corn	0.1 (provisional)
0251000	Lettuces and salad plants, except escaroles/broad-leaved endives	4

0252000	Spinaches and similar leaves	4
0256000	Herbs and edible flowers	4
0500030	Maize	0.01*
MRL application		
0253000	Grape leaves and similar species	30
0234000	Sweet corn	0.1
Animal commodities		
1011000	Swine tissues	Open
1012000	Bovine tissues	Open
1013000	Sheep tissues	Open
1014000	Goat tissues	Open
1016000	Poultry tissues	Open
1020000	Milk	Open
1030000	Birds eggs	Open

(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005
(b): MRLs proposed at the LOQ, should be annotated by an asterisk (*) after the figure.

Section 4 Environmental fate and behaviour

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	*0.9-3.6* % after 120 d, A- ring label (n= 4) at 25ºC *2.6* % after 120 d, B-ring label (n= 4) at 25ºC *2.7* % after 120 d, t- label (n= 4) at 25ºC 3.5-24.25 % after 119 d, A-ring label (n= 4) at 20ºC
Non-extractable residues after 100 days	12-27% after 120 d, A- ring label (n= 4) at 25ºC 26% after 120 d, B-ring label (n= 4) at 25ºC 24% after 120 d, t- label (n= 4) at 25ºC 9.6-24.1% after 119 d, A-ring label (n= 4) at 20ºC
Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)	*RH-131154 (M08)* A-ring label *Range:* 0.64 - 15.83 %. Maximum 15.83 % at 120 d (n=10)

A-ring label = methoxymethylbenzoyl-phenyl-UL-^{14}C label , B-ring label = [3,5-dimethylbenzoyl-phenyl-UL-14C], t- label = label on tertiary butyl group.

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

Mineralisation after 100 days	5.9-6.0 % after 120 d after system flooding, (n= 1, replicate sampling) A-ring and B-ring label
Non-extractable residues after 100 days	*12.7-13.0* % after 120 d after system flooding, (n= 1) A-ring and B-ring label
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	*RH-131154 (M08)* *Máximum 9.4* % at 21 d after system flooding (n= 1) B-ring label *RH-117236 (M14)* *Maximum 8.8* % at 120 d after system flooding (n= *1*) B-ring label (not considered in the risk assessment as formed at a very late timepoint)

A-ring label = methoxymethylbenzoyl-phenyl-UL-^{14}C label , B-ring label = [3,5-dimethylbenzoyl-phenyl-UL-14C]

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 novel photolytic metabolites were identified.
Mineralisation at study end	*0.61* % after 30 d, [^{14}C]-B-ring-label (n=1)

Non-extractable residues at study end	*7.39* % after 30 d, [^{14}C]-B ring label (n= 1)

B-ring label = [3,5-dimethylbenzoyl-phenyl-UL-14C]

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

Parent	Dark aerobic conditions						
Soil type	*USDA texture*	pH[a)] in $CaCl_2$	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
Hoefchen am Hohenseh	Silt Loam	6.4	20 /62.8	125.4 / 417	125.4	2.81	SFO
Laacherhof AIIIa	Loam	6.2	20 /43.7	87.2 / 290	81.0	2.36	SFO
Laacherhof AXXa	Sandy Loam	5.7	20 /48.9	347.9 / 1160	347.9	1.98	SFO
Laacherhof Wurmwiese	Sandy Loam	5.0	20 /59.4	208.2 / 692	208.2	2.20	SFO
Bagnolo	Clay Loam	7.25	20/ 67.91	199 / 661	195	1.8	SFO
Hoefchen	Silt Loam	6.25	20/66.37	656 / 2180	537	1.7	SFO
Laacherhof	Sandy Loam	6.01	20/48.37	841 / 2790	841	1.5	SFO
Negroni	Clay Loam	7.30	20/72.93	599 / 1990	519	5.6	SFO
Agrifoglio	Sandy Loam	7.41	20/40.59	453 / 1500	453	1.4	SFO
Emstek	Loamy Sand	5.98	20/50.76	1910 / 6340	1000*	1.0	SFO
Thurston	Sandy Clay Loam	7.27	20/74.46	268 / 890	268	2.6	SFO
Wellesbourne	Sandy Loam	6.21	20/49.80	439 / 1460	439	1.0	SFO
Marsonnas	Silt Loam	4.98	20/57.21	1381 / 4590	1000*	1.2	SFO
Fresne	Silt Loam	5.90	20/50.44	514 / 1710	375	1.0	SFO
California**	Clay loam		25/ 75% FMC at 1/3 bar	313/1.04x10^3	491.1	2.74	SFO
Ohio**	Loamy sand		25/ 75% FMC at 1/3 bar	460/1.53x10^3	721.7	2.52	SFO

Georgia**	Loamy sand		25/ 75% FMC at 1/3 bar	211/701	331.1	5.14	SFO
Texas**	Clay loam		25/ 75% FMC at 1/3 bar	385/1.28X10^3	604.1	5.79	SFO
Geometric mean (if not pH dependent)					392.0		
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

* Default maximum

**Data from days 0-120 only, since microbial decline was accepted as the cause for decreased degradation over longer time periods. Initially the soils from California, Ohio, Georgia and Texas were not included in the generation of the geomean DT_{50} and therefore a value of 362.3 d was utilised in tier I of groundwater modelling.

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)

RH-131154 (M08)	Dark aerobic conditions precursor from which the f.f. was derived was *methoxyfenozide*							
Soil type	*USDA texture*	pH[a)] in water	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	DT_{50} (d) 20 °C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
Hoefchen am Hohenseh	Silt Loam	6.6	20 /62.8	49.6/ 164.83	0.459	49.6	11.17	SFO
Laacherhof AIIIa	Loam	6.6	20 /43.7	30.8/ 102.24	0.385	28.6	5.8	SFO
Laacherhof AXXa	Sandy Loam	6.0	20 /48.9	42.2/ 140.04	0.524	42.2	16.59	SFO
Laacherhof Wurmwiese	Sandy Loam	5.3	20 /59.4	38.1/ 126.67	0.877	38.1	8.70	SFO
Bagnolo				73.1	0.6345	71.7		
Agrigfolio				1000	1	1000*		
Thurston				1000	1	1000*		
Fresne				1000	1	1000*		
Geometric mean (if not pH dependent)						141.8		
Arithmetic mean					0.73			
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

*moisture correction not required

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).	*USDA soil type*	pH[a)] in $CaCl_2$	Depth (cm)**	DT_{50} (d) actual	DT_{90}(d) actual	St. (χ^2)	DT_{50} (d) Norm[b)].	Method of calculation
Emstek (Bare*)	Germany	Sandy Loam	5.57	40	206.0	685.0	5.3	206.0	SFO
Negroni (Bare)	Italy	Loam	7.77	40	17.2	911.0	11.79	938.6***	DFOP
Agrifolio (Bare)	Italy	Sandy Loam	7.89	40	4.3	429.0	7.96	190.0***	HS
Wellesbourne (Bare)	United Kingdom	Sandy Loam	6.25	50	166.0	963.0	6.71	343.0***	HS
Hofchen (Bare)	Germany	Silt Loam	6.47	40	109.0	363.0	5.68	109.0	SFO
Laacherhof (Bare)	Germany	Sandy Loam	6.47	30	88.3	293.0	9.06	88.3	SFO
Geometric mean (if not pH dependent)								222.5	
pH dependence					No				

b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7, values are DegT50matrix
* Trial terminated early due to excessive lichen and moss formation after day120.
**including depths for which values related to LOD and LOQ were included in the kinetics assessment
***based on slow phase kinetics

Met 1		No metabolites were recorded in field studies

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

Soil accumulation and plateau concentration	Plateau concentration of *0.219* mg/kg reached after 12 years Based on 2 applications of 120g/ha to leafy vegetables with 70 day interval and using the longest non-normalised DT_{50} field of 470days, soil depth of 5cm and soil density of 1.5g/cm^3.

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	*USDA texture*	pH(0.01 M $CaCl_2$)]	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C[b)]	St. (χ^2)	Method of calculation
Laacherhof AIIIa	Loam	6.2)	20ºC /*	496/ >1000	496	1.97	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

* System was flooded

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	No metabolite transformation rates were determined. Metabolite RH-131154 was formed at larger quantities in the aerobic studies, and the rate of degradation in aerobic lab studies is shown above. Metabolite RH-117236 was not formed in excess of 5% in the anaerobic study until after 93 days of system flooding. It was considered unlikely that such a prolonged period of flooding would occur during cultivation.

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

Methoxyfenozide	Soil photolysis					
Soil type	*UK classification*	pH[a)]	t. °C / % MWHC	DT_{50} / DT_{90} (d) calculated at 40°N	St. (χ^2)	Method of calculation
Ohio	Loamy sand	6.9	25°C/ 9.8% moisture at 1/3 bar	173d/	R^2 =0.82	First order extrapolation beyond the study (30 days)

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

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

Parent							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
California	1.56	6.9			4.2	267	1.00
Minnesota	2.85	7.9			6.2	219	0.94
Newtown	1.05	7.0			3.8	365	1.06
BBA 2.2	2.48	6.0			5.0	200	0.93
Laacher Hof A2	0.86	8.1			2.7	314	1.00
Laacher Hof A20a	1.8	7.0			6.0	331	0.95
Soil LUFA-Speyer	0.64	7.6			2.0	318	1.00
Bagnolo	1.04	7.3			1.43	138	0.914
Hoefchen	1.51	6.3			3.16	209	0.911
Laacherhof	1.04	6.0			2.49	239	0.889
Agrifoglio	0.62	7.4			1.66	269	0.937
Emstek	1.84	6.0			5.36	291	0.849
Thurston	1.76	7.3			2.33	132	0.895
Wellesbourne	1.17	6.2			2.32	198	0.90
Marsonnas	0.75	5.0			1.53	204	0.92
Fresne	1.0	5.9			1.63	163	0.91

Geometric mean (if not pH dependent)	2.87	231	
Arithmetic mean (if not pH dependent)			0.938
pH dependence	No		

a) Measured in calcium chloride solution

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

RH-131154 (M08)							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
AXXA	2.1	6.2			0.348	17	0.76
Hoefchen	2.4	6.6			0.378	16	0.87
Wurmweise	1.6	5.1			0.348	22	0.86
Hanscheiderhof	2.2	5.3			0.604	27	0.93
Geometric mean (if not pH dependent)					0.408	20	
Arithmetic mean (if not pH dependent)							0.86
pH dependence			No				

a) Measured in calcium chloride solution

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	Column leaching studies with the active substance are not required.

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

Column leaching	Column leaching studies with the metabolites of methoxyfenozide are not required.

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

Lysimeter/ field leaching studies	Not required.

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

Hydrolytic degradation of the active substance and metabolites > 10 %	pH 5: At 25ºC, with 30 days incubation, no significant degradation of a.s. detected. No metabolites detected.
	pH 7: At 25ºC, with 30 days incubation, no significant degradation of a.s. detected. No metabolites detected.
	pH 9: At 25ºC, with 30 days incubation, no significant degradation of a.s. detected. No metabolites detected.

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 %	Sterile aqueous photolysis: Light comparable to natural summer sunlight in New Jersey, 40ºN. DT_{50} : *2166d* *Metabolites:* *M08 (RH-131154) maximum 0.56% A.R.* *Two further metabolites both below 0.4% A.R.* Photolysis in Pond water: Light comparable to natural summer sunlight in New Jersey, 40ºN. DT50: 77d Seven minor metbolites observed with mean values at each time point below 5% A.R. The metabolites were not identified.
Quantum yield of direct phototransformation in water at Σ > 290 nm	Mean value: 1.91 x10 $^{-3}$ mol · Einstein $^{-1}$

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

Readily biodegradable (yes/no)	No data submitted, substance considered not readily biodegradable

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)

Methoxyfenozide									
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 12°C[c]		At study temp	Normalised to x °C[c]		
Natural pond water	7.4		21.2 ±2	Mineralisation did not exceed 1%, Two minor metabolites were formed both below 1% during the 60 days study. It was not feasible to determine degradation rates						
Natural pond water	7.8		21.2 ±2	Mineralisation did not exceed 1%, Two minor metabolites were formed both below 1% during the 60 days study. It was not feasible to determine degradation rates						

[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

Metabolite	No metabolites were found above 1%

[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 <1 % after 61 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)
Natural pond water	7.4		<1% after 61 days	n/a note that aqueous phase was never below 93.9%	
Natural pond water	7.8		<1% after 61 days		

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 (e.g. max in water 91.1 after 0d. Max. sed 68.25 % after 91 d)									
Water / sediment system	pH water phase	pH sed in $CaCl_2$	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
Honniger weiher (Loam)	7.9	5.7	20 ± 1	159.1 /528.6	1.6	8.6/28.6	17.9	223.1/741.1	3.8	SFO
Angler weiher (Loamy sand)	7.7	6.6	20 ± 1	273.5 /908.7	1.1	19.3/64.0	23.0	359.1/1193	2.0	SFO
Geometric mean at 20°C[b)]				208.6						

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

RH-117236 (M14)	Distribution (e.g. max in water 5.02% after 60 d. Max. sed 12.62 % after 91 d). Max in total system 15.75 % after 91 days,									
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
Geometric mean at 20°C[b)]				1000		1000		1000		Default values

[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 n d. (end of the study).	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)
Texas	9.13	5.7	5.94% (365d)	9.61% (270d)	7.67% (365d)
California	8.89	5.4	4.94% (365d)	43.82% (270d)	43.20% (365)
Honniger Weiher	7.9	5.0 (in water)	1.7% (120d)	26.1% (120d)	26.1% (120d)
Angler Weiher	7.7	7.1 (in water)	2.9% (120d)	17.2% (90d)	17.1% (120d)

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

Direct photolysis in air	Not studied - no data requested.
Photochemical oxidative degradation in air	DT_{50} of *3.3* hours derived by the Atkinson model. OH (*12 h*) concentration assumed = $1.5x10^6$.
Volatilisation	from plant surfaces (BBA guideline): *<5* % after *24*

	hours
	from soil surfaces (BBA guideline): *negligible after x24 hours*
Metabolites	No information available

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

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure	Soil: Methoxyfenozide, RH-131154 (M08) Surface water: Methoxyfenozide, RH-131154 (M08), RH-117236 (M14) Sediment: Methoxyfenozide, RH-131154 (M08), RH-117236 (M14) Ground water: Methoxyfenozide, RH-131154 (M08) Air: Methoxyfenozide by default

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)	No data relied upon
Surface water (indicate location and type of study)	No data relied upon
Ground water (indicate location and type of study)	No data relied upon
Air (indicate location and type of study)	No data relied upon

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

Parent Method of calculation	DT_{50} (d): *470* days Kinetics: *SFO* Field: *longest non-normalised field DT_{50}.*
Application data	Crop: Leafy veg Depth of soil layer: *5cm* Soil bulk density: *1.5g/cm^3* % plant interception: 70 Interval (d): *70* Application rate(s): Leafy Veg: 1 or 2 x *120* g a.s./ha (1 application per successive crop)

$PEC_{(s)}$
(mg/kg)

	1 application per year		2 applications per year, 2 successive crops	
DAT	Leafy veg	Leafy veg	Leafy veg*	Leafy veg*
	PECs, Actual	PECs, TWA	PECs, Actual	PECs, TWA
0	0.048	0.048	0.091	0.091
1	0.048	0.048	0.091	0.091
2	0.048	0.048	0.091	0.091
4	0.048	0.048	0.091	0.091
7	0.048	0.048	0.090	0.091
14	0.047	0.048	0.089	0.090
21	0.047	0.047	0.089	0.090
28	0.046	0.047	0.088	0.089
50	0.045	0.046	0.085	0.088
100	0.041	0.045	0.079	0.085

* 70 day interval. DAT= Days after treatment, C.I. = crop interception, TWA = Time weighted average.

PECsoil Plateau concentration (Using the longest non-normalised field DT_{50} of 470days)

Crop	Application rate (g/ha)	Number of applications per year	Crop interception (%)	Steady state mg/kg	Peak occurrence mg/kg	Time to reach peak (years)
Maize	144	1	75	0.067	**0.115**	10
Leafy veg	120	1	70	0.067	**0.115**	10
Leafy veg	120	2 (70d interval)	70	0.142	**0.219**	12
Vines	96	1	75	0.077	0.045	10
Fruiting veg	144	1	80	0.054	0.092	11

Metabolite RH 131154 (M08) Method of calculation	Molecular weight relative to the parent: 1.08
Application data	Application rate assumed: *assumed RH-131154 is*

formed at a mean maximum of 15.83 % of the applied dose

Maximum Single application: 24.7 g/ha to maize (based on 144g a.s./ha, to be modelled using 75% crop interception)

Multiple application: 41.1g*/ha (calculation based on total dose approach of 2x120ga.s./ha to leafy veg*, to be modelled *using 70% crop interception)*

PECsoil accumulation based on DT50soil of 1000 days

Crop	Methoxyfenozide Application Rate (g/ha)	RH-131154 (M08) application rate	Crop interception (%)	PECsoil initial (mg/Kg)	PECsoil accumulation peak value (mg/kg)
Vine	1 x96	16.4	75	0.005	0.024
Maize/Corn	1x144	24.7	75	0.008	0.037
Fruiting vegetables	1x144	24.7	80	0.007	0.029
Leafy vegetables	1x120	20.5	70	0.008	0.036
Leafy vegetables	2x 120 (70 day interval)	41.1 (total dose approach)	70	**0.016**	**0.071**

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: PELMO v5.5.3, PEARL v 4.4.4 A tiered modelling scheme was assessed using a range of standard and time dependent sorption (TDS) parameterised. The following Tiers were evaluated: *Tier I : Laboratory DT_{50} with batch sorption Koc input parameterisation* *Tier II: Laboratory DT_{50} with lab time dependent sorption input parameterisation* *Tier III: Field DT_{50} with batch sorption Koc input parameterisation* *Tier IV: Field DT_{50} with field derived sorption Koc input parameterisation.* **Inputs/results not presented as approach utilised by the Notifier not accepted by the UK RMS.** *Tier V: Field DT_{50} with lab time dependent sorption input parameterisation* Crop: OUTDOOR: Vines, Maize, Fruiting Vegetables, Leafy Vegetables GREENHOUSE: Fruiting Vegetables Crop uptake factor: 0 Water solubility (mg/L): 3.3 at pH 7 and 20°C Vapour pressure: 1.3 x 10^{-5} Pa at 20°C 1/n (arithmetic mean batch sorption): 0.938 (all Tiers) **Tier I : Laboratory DT_{50} with batch sorption Koc input parameterisation** DT50 soil lab geomean (days): 362.3 d* Kfoc/Kfom ml/g (geomean batch sorption value, *n = 16*): 231/134 **Tier III: Field DT_{50} with batch sorption Koc input parameterisation** DT50 soil (k1 fast phase field geomean): 37.3 d DT50 soil (k2 slow phase field geomean): 222.5 d Kfoc/Kfom ml/g (geomean batch sorption value *n = 16*) 231/134 1/n 0.938 Metabolite RH-131145 (M08) DT_{50} soil Maximum mean: 141.8d

	formation in soil 15.83% Transformation rate (k) to M08 fast phase 0.0136 slow phase . 0.0023 Transformation rate (k) to CO_2 fast phase 0.0050 slow phase 0.0008 **GREENHOUSE** Crop uptake factor: 0 DT50 soil lab geomean (days): 225 days (field geomean). Note, as safe use was demonstrated, this modelling was not repeated with the revised geomean field DT_{50} of 222.5 days. Kf_{OC}/Kfom: 231/134. 1/n (arithmetic mean batch sorption): 0.938 PEARL (v4.4.4) was parameterised according to the EFSA guidance on assessment of risk to the environment from the use of plant protection products on protected crops. The default Piacenza scenario crop parameterisation for tomato was used with emergence and harvest dates changed to reflect those detailed in the example EFSA greenhouse scenario with consequent changes to the crop growth stages. A weather file specific to the Piacenza scenario which modifies the standard FOCUSgw Piacenza scenario weather file using data presented in the guidance document. Metabolites: **RH-131154 (M-08)** Crop: Crop uptake factor: 0 Water solubility (mg/L): 3.3 at pH 7 and 20°C Vapour pressure: 1.3 x 10^{-5} Pa at 20°C Kinetic formation fraction: 0.73 DT50 soil lab geomean (days): 41.8 Kf_{OC}/Kfom: 20/11.6. 1/n (arithmetic mean batch sorption): 0.86 The groundwater exposure modelling for glasshouse uses has not been re-run with the updated input parameters for the parent and the metabolite RH-131154 (M-08) as the RMS considers that the outdoor uses modelled in the previous section are protective of the glasshouse use.
Application rate	

	Crop	Application rate (g/ha)	Number of applications per year	Application Timing BBCH	Effective Soil Loading (g a.s./ha)	Application Date
OUTDOOR	Vines	96	1	71-85	24.0	1 Aug (aprox 60 days before harvest)
	Maize	144	1	51-75	36	50 days after emergence
	Fruiting veg (tomato)	144	1	51-87	28.8	40 days after emergence
	Leafy Veg (cabbage)	120	1	41-49	36	50 days after emergence
	Leafy veg (cabbage)	120	2 (70d interval)	41-49 multi-cropping	2 x 36	50 & 120 days after emergence
GREEN-HOUSE	Fruiting veg	144	1	51-87	28.8	18 Feb – 21 Aug

* Subsequent to this modelling four additional soils were included in the generation of the Lab soil DT_{50}. This resulted in the geomean value changing to 392.0 d. However, since it was clearly demonstrated that the groundwater assessment had to progress beyond Tier I, the modelling was not repeated with this new value.

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

Tier I Results: Laboratory DT_{50} with batch sorption Koc input parameterisation, modelled using PELMO v5.5.3. (See footnote under table above)

METHOXYFENOZIDE					
Scenario	Vines	Maize	Fruiting Veg (tomato)	Leafy Veg (cabbage)	Leafy veg (cabbage) X 2
Chateaudun	1.429	1.865	1.447	-	3.674
Hamburg	1.441	2.185	-	2.136	4.732
Jokioinen	-	-	-		-
Kremsmunster	1.307	1.893	-	-	3.622
Okehampton	-	1.824	-	1.561	-
Piacenza	1.024	1.353	1.328	1.13	-
Porto	0.678	1.192	0.959	1.19	2.642
Sevilla	0.794	0.301	0.231	0.444	1.042
Thiva	0.321	1.581	0.998	1.243	-

RH131154 (M08)					
Scenario	**Vines**	**Maize**	**Fruiting Veg (tomato)**	**Leafy Veg (cabbage)**	**Leafy veg (cabbage) X 2**
Chateaudun	0.493	0.738	0.56	0.636	1.490
Hamburg	0.616	0.988		1.025	2.281
Jokioinen	-	-	-	0.800	-
Kremsmunster	0.484	0.746		0.682	1.483
Okehampton	-	0.720		-	-

Piacenza	0.303	0.525	0.508	-	-
Porto	0.255	0.502	0.392	0.471	1.017
Sevilla	0.345	0.209	0.189	0.280	0.689
Thiva	**0.096**	0.569	0.357	0.463	-

Tier III Results: Field DT_{50} with batch sorption Koc input parameterisation

METHOXYFENOZIDE PEARL v.4.4.3				
Scenario	**Vines**	**Maize**	**Fruiting Veg (tomato)**	**Leafy Veg (cabbage)**
Chateaudun	0.366	0.413	0.313	0.324
Hamburg	0.324	0.613	-	0.474
Jokioinen	-	-	-	0.206
Kremsmunster	0.244	0.414	-	0.354
Okehampton	-	0.516	-	-
Piacenza	0.322	0.464	0.316	-
Porto	0.187	0.281	0.204	0.256
Sevilla	0.252	***0.037***	***0.036***	***0.049***
Thiva	0.273	0.387	0.211	0.189
METHOXYFENOZIDE PELMO v.5.5.3				
Scenario	**Vines**	**Maize**	**Fruiting Veg (tomato)**	**Leafy Veg (cabbage)**
Chateaudun	0.313	0.277	0.195	0.264
Hamburg	0.305	0.415	-	0.400
Jokioinen	-	-	-	0.159
Kremsmunster	0.271	0.351	-	0.331
Okehampton	-	0.392	-	-
Piacenza	0.237	0.356	0.244	-
Porto	***0.085***	0.225	0.176	0.248
Sevilla	***0.099***	***0.020***	***0.012***	***0.030***
Thiva	***0.028***	0.265	0.138	0.136

The groundwater modelling was repeated for M08 using; the revised soil M08 geomean DT_{50} of 141.8 days and the methoxyfenozide geomean soil DT_{50} of 222.5 days slow phase as a worst case as well as the revised formation fraction of 0.73. Although new PECgw values for methoxyfenozide were produced from this modelling they were not included as they did not take into account the fast and slow phase transformation rates which are worst-case for the parent.

RH131154 (M-08) PEARL v.4.4.4				
Scenario	**Vines**	**Maize**	**Fruiting Veg (tomato)**	**Leafy Veg (cabbage)**
Chateaudun	3.657	5.081	4.761	5.003
Hamburg	2.983	7.246	-	5.972
Jokioinen	-	-	-	4.666
Kremsmunster	2.126	4.248	-	4.005
Okehampton	-	3.632	-	-
Piacenza	3.967	5.623	4.243	-
Porto	1.636	2.708	2.298	2.542
Sevilla	3.163	3.477	2.887	3.536
Thiva	4.596	7.478	4.888	3.504
RH131154 (M-08) PELMO v.5.5.3				
Scenario	**Vines**	**Maize**	**Fruiting Veg (tomato)**	**Leafy Veg (cabbage)**
Chateaudun	3.276	4.649	3.638	4.501
Hamburg	2.926	5.326	-	4.901
Jokioinen	-	-	-	3.906
Kremsmunster	2.508	4.299	-	3.996
Okehampton	-	3.054	-	-
Piacenza	2.026	2.586	3.000	-
Porto	0.868	2.166	1.808	2.095
Sevilla	2.196	2.704	2.774	3.006
Thiva	0.487	5.411	3.679	2.718

GREENHOUSE USE RESULTS: Applications of methoxyfenozide to fruiting vegetables as simulated with the constructed Piacenza greenhouse scenario.

Application date	Methoxyfenozide PECgw (µg/L)	RH-131154 (M08) PECgw (µg/L)
18 February	0.0788	0.0919
18 March	**0.0829**	**0.0939**
1 April	0.0794	0.0894
1 May	0.0684	0.0779
1 June	0.0599	0.0702
1 July	0.0566	0.0683
1 August	0.0542	0.0685
21 August	0.0545	0.0704

Note that this modelling is based on a methoxyfenozide soil DT_{50} of 225 days and has not been re-run with the revised DT_{50} value of 222.5 days; but the UK RMS considers that the amounts leached would decrease as a

result of the changed endpoint. Therefore the results in can be considered to be a worst case assessment of leaching.

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: FOCUS surface water STEP 1 and 2 v2.1 Molecular weight (g/mol): 368.5 K_{OC}/K_{OM} (mL/g): 231/134 DT_{50} soil (d): 225days (field normalised value) Note revised field geomean of 222.5 days should be used in future assessments by MS. Remodelling with the revised value of 222.5 was not conducted. DT_{50} water/sediment system (d): 208.6d DT_{50} water (d): 1000d DT_{50} sediment (d): 1000d Crop interception (%): *full canopy* Modelled using whole system DT_{50} for water and default value for sediment compartment.
Parameters used in FOCUSsw step 3 (if performed)	Version control no.'s of FOCUS software: SWASH v3.1 TOXWA v3.3.1 PRZM v3.1.1 MACRO v4.4.2 Water solubility (mg/L): 3.3mg/L (20°C) Vapour pressure: $1.33x10^{-5}$ Pa at 20°C Kom/Koc (mL/g): 231/134 1/n: (Freundlich exponent general or for soil, susp. solids or sediment respectively) 0.938 Q10=2.58, Walker equation coefficient 0.7 Crop uptake factor: 0.0
Application rate	Crop and growth stage: Vines BBCH 71-85 Number of applications: 1 Application rate(s): 96 g a.s./ha Application window: May-Sept* *late spray drift selected for vines* Crop and growth stage: Maize BBCH 51-75 Number of applications: 1 Application rate(s): 144 g a.s./ha Application window: May –Sept* Crop and growth stage: Fruiting vegetables BBCH 51-87 Number of applications: 1 Application rate(s): 144 g a.s./ha

Application window: May-Sept*

Crop and growth stage: Leafy vegetables BBCH 41-49
Number of applications: 1 or 2
Interval (d): 70d
Application rate(s): 120 g a.s./ha
Application window: May- Sept*

**Note: The application window relative to growth stage did not always coincide with May-Sept. Therefore at STEP 3 a comprehensive approach was taken to cover all potential application windows i.e. those relative to both calendar timings AND growth stages.*

FOCUS STEP 1 Scenario	Application	Max. PEC_{SW} (µg/L)	TWA PEC_{SW} 7 day	TWA PEC_{SW} 21 day	Max. PEC_{SED} (µg/kg dw)	TWA PEC_{SED} 7 day	TWA PEC_{SED} 21 day
Vine	1 x 96 g/ha	27.03	26.17	25.54	60.85	60.02	58.86
Maize	1 x 144g/ha	38.02	36.84	36.43	86.82	85.94	84.08
Fruiting vegetables	1 x 144 g/ha	38.02	37.30	36.43	86.82	85.94	84.08
Leafy vegetables	1 x 120 g/ha	31.68	31.08	30.36	72.35	71.61	70.07
Leafy vegetables	2 x 120 g/ha (70 day interval)	63.37	62.16	60.72	144.70	143.23	140.14

FOCUS STEP 2 Scenario	Application	Max. PEC_{SW} (µg/L)	TWA PEC_{SW} 7 day	TWA PEC_{SW} 21 day	Max. PEC_{SED} (µg/kg)	TWA PEC_{SED} 7 day	TWA PEC_{SED} 21 day
Vine NEU	1 x 96 g/ha	3.58	3.41	3.39	7.87	7.85	7.81
Vine SEU	1 x 96 g/ha	5.03	4.86	4.83	11.22	11.19	11.13
Maize NEU	1 x 144g/ha	2.91	2.82	2.80	6.51	6.50	6.47
Maize SEU	1 x 144g/ha	4.72	4.63	4.60	10.70	10.67	10.62
Fruiting vegetables NEU	1 x 144 g/ha	3.27	3.18	3.16	7.35	7.33	7.30
Fruiting vegetables SEU	1 x 144 g/ha	5.45	5.35	5.32	12.37	12.34	12.28
Leafy vegetables NEU	1 x 120 g/ha	2.73	2.65	2.64	6.13	6.11	6.08
Leafy vegetables SEU	1 x 120 g/ha	4.54	4.46	4.44	10.31	10.28	10.24
Leafy vegetables NEU	2 x 120 g/ha (70 day interval)	4.85	4.72	4.69	10.91	10.88	10.83
Leafy vegetables SEU	2 x 120 g/ha (70 day interval)	8.12	7.99	7.94	18.46	18.42	18.33

NEU = Northern EU, SEU = Southern EU

STEP 3 PECsw (µg/L) for Vines with different application windows

Scenario	May1st-July 15th (µg/L)*	July 15th-September 30th (µg/L)*	window relative to earliest BBCH code	window relative to latest BBCH code

			71 (µg/L)*	85 (µg/L)*
D6 (Ditch)	1.65 (SD)	1.65 (SD)	1.65 (SD)	1.65 (SD)
R1 (Pond)	0.06 (SD)	0.06 (SD)	0.06 (SD)	0.06 (SD)
R1 (Stream)	1.18 (SD)	1.18 (SD)	1.21 (SD)	1.21 (SD)
R2 (Stream)	1.61 (SD)	1.62 (SD)	1.62 (SD)	1.62 (SD)
R3 (Stream)	1.69 (SD)	1.70 (SD)	1.73 (R)	1.70 (SD)
R4 (Stream)	1.19 (SD)	1.21 (SD)	1.21 (SD)	1.79 (R)

*Event resulting in global maximum PECsw: SD = spray drift, D= drainflow, R= runoff.

STEP 3 PECsw (µg/L) for Maize with different application windows

Scenario	May1st-July 15th (µg/L)*	July 15th-September 30th (µg/L)*	window relative to earliest BBCH code 51 (µg/L)*	window relative to latest BBCH code 75
D3 (Ditch)	0.88 (SD)	0.84 (SD)	0.86 (SD)	-
D4 (Pond)	2.20 (D)	1.32 (D)	1.86 (D)	-
D4 (Stream)	2.00 (D)	1.15 (D)	1.79 (D)	-
D5 (Pond)	1.40 (D)	0.66 (D)	0.65 (D)	-
D5 (Stream)	0.96 (D)	0.74 (SD)	0.74 (SD)	-
D6 (Ditch)	1.03 (D)	1.78 (D)	1.01 (D)	-
R1 (Pond)	0.11 (R)	0.04 (R)	0.15 (R)	-
R1 (Stream)	1.97 (R)	0.97 (R)	2.80 (R)	-
R2 (Stream)	1.41 (R)	0.70 (SD)	0.70 (SD)	-
R3 (Stream)	4.12 (R)	2.86 (R)	3.25 (R)	-
R4 (Stream)	4.34 (R)	3.04 (R)	2.20 (R)	-

- Modelling was not performed because the suggested dates for the latest BBCH code fell within the may-September window

*Event resulting in global maximum PECsw: SD = spray drift, D= drainflow, R= runoff.

STEP 3 PECsw (µg/L) for Fruiting veg with different application windows

Scenario	May1st-July 15th (µg/L)*	July 15th-September 30th (µg/L)*	window relative to earliest BBCH code 51 (µg/L)*	window relative to latest BBCH code 87 (µg/L)*
D6 (Ditch)	1.14 (D)	3.42 (D)	1.13 (D)	-
R2 (Stream)	1.17 (R)	0.81 (SD)	0.92 (R)	-
R3 (Stream)	4.09 (R)	2.77 (R)	2.46 (R)	-
R4 (Stream)	4.41 (R)	4.64 (R)	1.98 (R)	-

- Modelling was not performed because the suggested dates for the latest BBCH code fell within the may-September window

*Event resulting in global maximum PECsw: SD = spray drift, D= drainflow, R= runoff.

STEP 3 PECsw (µg/L) for Leafy veg with different application windows

Scenario	May1st-July 15th (µg/Kg)	July 15th-September 30th (µg/Kg)	window relative to earliest BBCH code 41 (µg/Kg)	window relative to latest BBCH code 49 (µg/Kg)
D3 (Ditch) 1st	0.87 (SD)	#	0.84 (SD)	-
D3 (Ditch) 2nd	#	0.88 (SD)	0.83 (SD)	0.82 (SD)
D4 (Pond)	1.94 (D)	#	1.66 (D)	1.64 (D)
D4 (Stream)	1.38(D)	#	1.38 (D)	1.49 (D)
D6 (Ditch)	#	3.31 (D)	3.70 (D)	4.35 (D)
R1 (Pond) 1st	0.10 (R)	#	0.23 (R)	-
R1 (Pond) 2nd	#	0.06 (R)	0.08 (R)	0.16 (R)
R1 (Stream) 1st	1.43 (R)	#	1.78 (R)	-
R1 (Stream) 2nd	#	0.77 (R)	0.85 (R)	1.70 (R)
R2 (Stream) 1st	0.80 (R)	#	0.80 (R)	-
R2 (Stream) 2nd	#	0.84 (R)	0.68 (SD)	0.67 (SD)
R3 (Stream) 1st	2.49 (R)	#	1.26 (R)	-

R3 (Stream) 2nd	#	2.69 (R)	2.34 (R)	-
R4 (Stream) 1st	2.66 (R)	#	2.91 (R)	-
R4 (Stream) 2nd	#	3.04 (R)	2.79 (R)	-

- Modelling was not performed because the suggested dates for the latest BBCH code fell within the may-September window

Modelling was not performed in this window because either a successive crop scenario was modelled in which case the 1st crop was in the May-July window and the 2nd crop was in the July-September window, or because the model only simulated one crop in the scenario and the crops growth stage as per the FOCUS sw guidance was more suited to either May-July, or July- September window.

*Event resulting in global maximum PECsw: SD = spray drift, D= drainflow, R= runoff.

STEP 3 PECsed (µg/Kg) for Vines with different application windows

Scenario	May1st-July 15th (µg/Kg)	July 15th-September 30th (µg/Kg)	window relative to earliest BBCH code 71 (µg/Kg)	window relative to latest BBCH code 85 (µg/Kg)
D6 (Ditch)	1.52	1.56	1.55	1.583
R1 (Pond)	0.16	0.15	0.15	0.154
R1 (Stream)	0.13	0.08	0.14	0.143
R2 (Stream)	0.21	0.11	0.11	0.298
R3 (Stream)	0.22	0.33	0.62	0.401
R4 (Stream)	0.30	0.27	0.34	0.645

STEP 3 PECsw (µg/Kg) for Maize with different application windows

Scenario	May1st-July 15th (µg/Kg)	July 15th-September 30th (µg/Kg)	window relative to earliest BBCH code 51 (µg/Kg)	window relative to latest BBCH code 75 (µg/Kg)
D3 (Ditch)	1.54	0.96	1.112	-
D4 (Pond)	9.85	6.16	7.893	-
D4 (Stream)	3.45	2.15	2.748	-
D5 (Pond)	7.03	3.44	3.432	-
D5 (Stream)	1.83	0.88	0.877	-
D6 (Ditch)	1.80	2.21	1.482	-
R1 (Pond)	0.33	0.17	0.389	-
R1 (Stream)	0.46	0.22	0.789	-
R2 (Stream)	0.45	0.48	0.475	-
R3 (Stream)	1.02	1.23	1.381	-
R4 (Stream)	1.39	1.00	0.698	-

- Modelling was not performed because the suggested dates for the latest BBCH code fell within the may-September window

STEP 3 PECsw (µg/Kg) for Fruiting veg with different application windows

Scenario	May1st-July 15th (µg/Kg)	July 15th-September 30th (µg/Kg)	window relative to earliest BBCH code 51 (µg/Kg)	window relative to latest BBCH code 87 (µg/Kg)
D6 (Ditch)	2.04	3.47	1.974	-
R2 (Stream)	0.43	0.51	0.643	-
R3 (Stream)	1.02	1.06	1.003	-
R4 (Stream)	1.41	1.24	0.628	-

- Modelling was not performed because the suggested dates for the latest BBCH code fell within the may-September window

STEP 3 PECsw (µg/Kg)for Leafy veg with different application windows

Scenario	May1st-July 15th	July 15th-September	window relative to	window relative to

	(µg/Kg)	30th (µg/Kg)	earliest BBCH code 41 (µg/Kg)	latest BBCH code 49 (µg/Kg)
D3 (Ditch) 1st	1.29	#	0.940	-
D3 (Ditch) 2nd	#	1.40	0.728	0.588
D4 (Pond)	10.12	#	7.912	7.517
D4 (Stream)	3.86	#	2.912	2.772
D6 (Ditch)	#	5.46	3.351	4.571
R1 (Pond) 1st	0.30	#	0.680	-
R1 (Pond) 2nd	#	0.21	0.717	0.549
R1 (Stream) 1st	0.37	#	0.350	-
R1 (Stream) 2nd	#	0.25	0.319	0.375
R2 (Stream) 1st	0.35	#	0.952	-
R2 (Stream) 2nd	#	0.49	0.293	0.248
R3 (Stream) 1st	0.66	#	0.210	-
R3 (Stream) 2nd	#	1.02	0.270	-
R4 (Stream) 1st	0.87	#	0.943	-
R4 (Stream) 2nd	#	0.99	0.920	-

- Modelling was not performed because the suggested dates for the latest BBCH code fell within the may-September window

Modelling was not performed in this window because either a successive crop scenario was modelled in which case the 1st crop was in the May-July window and the 2nd crop was in the July-September window, or because the model only simulated one crop in the scenario and the crops growth stage as per the FOCUS sw guidance was more suited to either May-July, or July- September window.

Metabolite *RH-117236 (M14)*	Molecular weight:354.5
Parameters used in FOCUSsw step 1 and 2	Soil or water metabolite: water metabolite Koc/Kom (mL/g): No Koc was available, therefore both 10 and 10,000 were assessed DT_{50} soil (d): *1000day default value* DT_{50} water/sediment system (d): 1000d DT_{50} water (d):1000d DT_{50} sediment (d):1000d Crop interception (%): *full canopy* Maximum occurrence observed (% molar basis with respect to the parent) Total Water and Sediment: 15.75% Soil: *0.01% (default value for modelling purposes)*
Parameters used in FOCUSsw step 3 (if performed)	Not performed
Application rate	Crop and growth stage: Vines BBCH 71-85 Number of applications: 1 Application rate(s): 96 g a.s./ha Application window: May-Sept *late spray drift selected for vines* Crop and growth stage: Maize BBCH 51-75 Number of applications: 1 Application rate(s): 144 g a.s./ha Application window: May -Sept Crop and growth stage: Fruiting vegetables BBCH 51-87 Number of applications: 1

	Application rate(s): 144 g a.s./ha Application window: May-Sept Crop and growth stage: Leafy vegetables BBCH 41-49 Number of applications: 1 or 2 Interval (d): 70d Application rate(s): 120 g a.s./ha Application window: May- Sept
Main routes of entry	

Metabolite RH-117236 PECsw/PECsed Values based on Koc of 10 ml/g

Values based on Koc of 10 ml/g	Max. PEC_{SW} (µg/L)*	TWA PEC_{SW} 7 day (µg/L)	TWA PEC_{SW} 21 day (µg/L)	Max. PEC_{SED} (µg/kg dw)	TWA PEC_{SED} 7 day (µg/kg dw)	TWA PEC_{SED} 21 day (µg/kg dw)
Vine (1x96g/ha)						
NEU / SEU STEP 1	0.39	0.39	0.38	0.04	0.04	0.04
NEU STEP 2	0.39	0.39	0.38	0.04	0.04	0.04
SEU STEP 2	0.39	0.38	0.38	0.04	0.04	0.04
Maize (1x144g/ha)						
NEU/ SEU STEP 1	0.21	0.20	0.20	0.02	0.02	0.02
NEU STEP 2	0.20	0.20	0.20	0.02	0.02	0.02
SEU STEP 2	0.20	0.20	0.20	0.02	0.02	0.02
Fruiting vegetables (1 x 144g/ha)						
NEU /SEU STEP 1	0.21	0.20	0.20	0.02	0.02	0.02
NEU STEP 2	0.20	0.20	0.20	0.02	0.02	0.02
SEU STEP 2	0.20	0.20	0.20	0.02	0.02	0.02
Leafy vegetables (1x120g/ha)						
NEU / SEU STEP 1	0.17	0.17	0.17	0.02	0.02	0.02
NEU STEP 2	0.17	0.17	0.16	0.02	0.02	0.02
SEU STEP 2	0.17	0.17	0.16	0.02	0.02	0.02
Leafy vegetables (2x120g/ha) 70 day interval						
NEU / SEU STEP 1	0.34	0.34	0.34	0.03	0.03	0.03
NEU STEP 2	0.29	0.29	0.28	0.03	0.03	0.03
SEU STEP 2	0.29	0.29	0.28	0.03	0.03	0.03

*See calculation below the following table, for the maximum PECsw value.

Metabolite RH-117236 PECsw/PECsed Values based on Koc of 10,000 ml/g

Values based on Koc of 10,000 ml/g	Max. PEC_{SW} (µg/L)*	TWA PEC_{SW} 7 day (µg/L)	TWA PEC_{SW} 21 day (µg/L)	Max. PEC_{SED} (µg/kg dw)	TWA PEC_{SED} 7 day (µg/kg dw)	TWA PEC_{SED} 21 day (µg/kg dw)
Vine (1x96g/ha)						
NEU / SEU Step1	0.39	0.05	0.04	2.74	2.54	2.65
NEU Step2	0.39	0.08	0.05	2.71	2.70	2.69
SEU Step2	0.39	0.08	0.05	2.71	2.70	2.69
Maize (1x144g/ha)						
NEU/ SEU Step1	0.20	0.03	0.02	1.43	1.33	1.39
NEU Step2	0.20	0.04	0.02	1.40	1.39	1.39
SEU Step2	0.20	0.04	0.02	1.40	1.39	1.39
Fruiting vegetables (1 x 144g/ha)						
NEU /SEU Step1	0.20	0.03	0.02	1.43	1.33	1.39
NEU Step2	0.20	0.04	0.02	1.40	1.39	1.39
SEU Step2	0.20	0.04	0.02	1.40	1.40	1.39
Leafy vegetables (1x120g/ha)						
NEU / SEU Step1	0.17	0.02	0.02	1.19	1.11	1.16
NEU Step2	0.17	0.04	0.02	1.16	1.16	1.16
SEU Step2	0.17	0.04	0.02	1.17	1.16	1.16
Leafy vegetables (2x120g/ha) 70day interval						
NEU / SEU Step1	0.33	0.05	0.03	2.39	2.21	2.31
NEU Step2	0.16	0.04	0.03	2.01	2.00	1.99
SEU Step2	0.16	0.04	0.03	2.01	2.00	2.00

*Due to RH-117236 being a water metabolite only, the RMS also determined a PECsw based on the maximum parent PECsw value adjusted for the molecular weight correction and maximum occurrence of RH-117236. This gave a PECsw value of **0.83µg/L**. The UK RMS considers this value to be the appropriate value to use in the risk assessment.

Metabolite RH-131154 (M08)	Molecular weight:398.5
Parameters used in FOCUSsw step 1 and 2	Soil or water metabolite: soil and water Koc/Kom (mL/g): 20/11.6 DT_{50} soil (d): *141.8 d(geomean normalised lab value)* DT_{50} water/sediment system (d): *1000d* DT_{50} water (d): 1000d DT_{50} sediment (d): 1000d Crop interception (%): *full canopy* Maximum occurrence observed (% molar basis with respect to the parent) Total Water and Sediment: 2.43% Soil: *15.83%*
Parameters used in FOCUSsw step 3 (if performed)	Not performed

Application rate	Crop and growth stage: Vines BBCH 71-85 Number of applications: 1 Application rate(s): 96 g a.s./ha Application window: May-Sept *late spray drift selected for vines* Crop and growth stage: Maize BBCH 51-75 Number of applications: 1 Application rate(s): 144 g a.s./ha Application window: May -Sept Crop and growth stage: Fruiting vegetables BBCH 51-87 Number of applications: 1 Application rate(s): 144 g a.s./ha Application window: May-Sept Crop and growth stage: Leafy vegetables BBCH 41-49 Number of applications: 1 or 2 Interval (d): 70d Application rate(s): 120 g a.s./ha Application window: May- Sept
Main routes of entry	

	Max. PECsw (µg/L)	TWA PECsw 7 day	TWA PECsw 21 day	Max. PECsed (µg/kg dw)	TWA PECsed 7 day	TWA PECsed 21 day
Vine (1x96g/ha)						
NEU / SEU Step1	5.36	5.34	5.32	1.07	1.07	1.06
NEU Step2	0.34	0.34	0.33	0.07	0.07	0.07
SEU Step2	0.65	0.65	0.65	0.13	0.13	0.13
Maize (1x144g/ha)						
NEU/ SEU Step1	8.04	8.02	7.98	1.61	1.60	1.60
NEU Step2	0.43	0.43	0.42	0.09	0.08	0.08
SEU Step2	0.82	0.82	0.81	0.16	0.16	0.16
Fruiting vegetables (1 x 144g/ha)						
NEU /SEU Step1	8.04	8.02	7.98	1.61	1.60	1.60
NEU Step2	0.51	0.50	0.50	0.10	0.10	0.10
SEU Step2	0.98	0.97	0.97	0.19	0.19	0.19
Leafy vegetables (1x120g/ha)						
NEU / SEU Step1	6.70	6.68	6.65	1.34	1.34	1.33
NEU Step2	0.42	0.42	0.42	0.08	0.08	0.08
SEU Step2	0.81	0.81	0.81	0.16	0.16	0.16
Leafy vegetables (2x120g/ha) 70 day interval						
NEU / SEU Step1	**13.4**	13.36	13.3	**2.68**	2.67	2.66
NEU Step2	**0.72**	0.72	0.71	**0.14**	0.14	0.14
SEU Step2	**1.39**	1.39	1.38	**0.28**	0.28	0.28

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

Method of calculation	Vapour pressure <1.33x10^{-5} Pa, water solubility 3.3 mg/l, calculated Henry's law constant <1.64x10^{-4} Pa m^3 mol and calculated dimensionless Henry's Law coefficient at 20°C <6.7 x 10^{-8}, indicate that methoxyfenozide exhibits low volatility and has the potential for only very slight volatility from aqueous solutions / soil water. A theoretical Atkinson calculation of the potential for photo-oxidation of methoxyfenozide in the upper atmosphere led to a DT_{50} value in the upper atmosphere of 3.3 hours.

PEC

Maximum concentration	N/A

Section 5 Ecotoxicology

Ecotoxicology

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

Species	Test substance	Time scale	End point	Toxicity (mg/kg bw per day)
Birds				
Bobwhite quail *(Colinus virginianus*)	a.s.	Acute	LD_{50}	**>2250**
Bobwhite quail *(Colinus virginianus)*	Preparation RH112,485 2F	Acute	LD_{50}	>2250 mg/kg bw formulation (>531 mg/kg bw a.s.)
	Metabolite 1	Acute	LD_{50}	
Bobwhite quail (*Colinus virginianus*)	a.s.	Short-term dietary	LC_{50} NOEC	>5620 ppm a.s. 5620 ppm a.s.
Mallard duck (*Anas platyrhynchos*)	a.s.	Short-term dietary	LC_{50} NOEC	>5620 ppm a.s. 562 ppm a.s.
Bobwhite quail *(Colinus virginianus*)	a.s.	Long-term	LD_{50}/10	> 225 mg a.s./kg bw
Bobwhite quail (*Colinus virginianus*)	a.s.	Long-term	NOEC	1000 ppm a.s., i.e. NOEL = **82.7** mg a.s./kg b.wt./d.
Mallard duck (*Anas platyrhynchos*)	a.s.	Long-term	NOEC	1000 ppm a.s., i.e. NOEL = 138 mg/kg bw/d
Mammals				
Rat	a.s.	Acute	LD_{50}	**>5000** mg/kg bw
Mouse	a.s.	Acute	LD50	**>5000** mg/kg bw
Rat	Preparation GF-837	Acute	LD_{50}	>5000 mg/kg bw* (i.e. >1167[1] mg a.s./kg bw)
Mouse	Preparation GF-837	Acute	LD_{50}	LD_{50} >5000 mg/kg bw
Mouse	Metabolite M14	Acute	LD_{50}	> 5000 mg /kg bw

Rat	a.s.	Long-term *[for first tier risk assessment]*	NOAEL	2000 ppm (**153** mg/kg bw/day in males; 181 mg/kg bw/day in females)
Endocrine disrupting properties (Annex Part A, points 8.1.5) Considering the available information, it is unlikely that methoxyfenozide is an endocrine disruptor for fish via the estrogenic, androgenic and steroidogenic modalities. An amphibian metamorphosis assay was available which did not provide any evidence of endocrine activity or potential endocrine related adverse effects via the thyroid modality. Pending on the data gap in Section 2, further consideration of the endocrine potential of methoxyfenozide via the thyroid modality may be needed. No firm conclusion could be drawn for birds.				
Additional higher tier studies (Annex Part A, points 10.1.1.2): *[To be provided if the tier 1 risk assessment fails]*				
Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3): *[To provide available data]*				

* Maximum dose tested
[1] Converted to a.s. accounting for the purity of 23.35% methoxyfenozide for the lot tested in the study.

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

[Vineyard] at [0.096] g a.s./ha [x 1 number of applications]

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Screening Step (Birds)					
All	Small omnivorous bird	Acute	9.15	>246	10
All	Small omnivorous bird	Long-term	1.98	41.8	5
Tier 1 (Mammals)					
BBCH ≥ 40	Large herbivorous mammal "lagomorph"	Long-term	0.17	900	5
BBCH ≥ 20	Small Insectivorous mammal "shrew"	Long-term	0.097	1577	5
Application crop directed BBCH ≥ 40	Small herbivorous mammal "vole	Long-term	1.1	139	5
Application crop directed BBCH ≥ 40	Small omnivorous mammal "mouse"	Long-term	0.12	1275	5

Risk from consumption of contaminated water

Scenarios	**Indicator or focal species**	**Time scale**	**PEC_{dw}xDWR**	**TER**	**Trigger**
Leaf scenario	Birds	acute	-	-	5

Puddle scenario, Screening step

1)Application rate (g a.s./ha)/relevant endpoint <50 (koc<500 L/kg), TER calculation not needed

Maize, fruiting and leafy vegetables] at [0.144] g a.s./ha [x 1 number of applications]

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Screening Step (Birds)					
All	Small omnivorous bird	Acute	22.9	>98.3	10

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
All	Small omnivorous bird	Long-term	4.95	16.7	5
Tier 1 (Mammals)					
Maize BBCH ≥ 20	Small insectivorous mammal "shrew"	Long-term	0.15	1020	5
Maize BBCH ≥ 40	Small herbivorous mammal "vole	Long-term	1.38	111	5
Maize BBCH ≥ 40	Small omnivorous mammal "mouse"	Long-term	0.15	1020	5
Fruiting vegetables Fruit stage BBCH 71-89	Frugivorous mammal "rat"	Long-term	1.92	79.7	5
Fruiting vegetables BBCH ≥ 20	Small insectivorous mammal "shrew"	Long-term	0.15	1020	5
Fruiting vegetables BBCH ≥ 50	Small herbivorous mammal "vole	Long-term	1.66	92.2	5
Fruiting vegetables BBCH ≥ 50	Small omnivorous mammal "mouse"	Long-term	0.18	850	5
Leafy vegetables BBCH ≥ 20	Small insectivorous mammal "shrew"	Long-term	0.12	1275	5
Leafy vegetables BBCH 40-49	Small herbivorous mammal "vole	Long-term	4.6	33.3	5
Leafy vegetables All season	Large herbivorous mammal "lagomorph"	Long-term	0.91	168.1	5
Leafy vegetables BBCH 10-49	Small omnivorous mammal "mouse"	Long-term	0.5	306	5

Risk from bioaccumulation and food chain behavior

Methoxyfenozide

Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Earthworm-eating birds	Long-term	3.175	48	5
Earthworm-eating mammals	Long-term	3.871	40	5
Fish-eating birds	Long-term	0.1108	1381	5
Fish-eating mammals	Long-term	0.099	1545	5

Metabolite RH-117236*

Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Fish-eating birds	Long-term	0.000665	124432	5
Fish-eating mammals	Long-term	0.000594	25777	5

Risk from consumption of contaminated water

Scenarios	**Indicator or focal species**	**Time scale**	**PEC_{dw}xDWR**	**TER**	**Trigger**
Leaf scenario	Birds	acute	80 x 0.46	> 61.14	5

Puddle scenario, Screening step
1)Application rate (g a.s./ha)/relevant endpoint <50 (koc<500 L/kg), TER calculation not needed

*In the absence of toxicity data on metabolite RH-117236, this metabolite was considered as 10 times more toxic than the parent compound.

Risk assessment for metabolite RH-117236* (worst case- Maize, Fruiting and Leafy vegetables)				
Indicator or focal species	Time scale	DDD** (mg/kg bw per day)	TER	Trigger
Small omnivorous bird	acute	2.10	107	5
Small omnivorous bird	Long-term	0.453	18.3	10
Small herbivorous mammal	acute	1.8	278	5
Small herbivorous mammal	Long-term	0.506	30.2	10

*In the absence of toxicity data on metabolite RH-117236, this metabolite was considered as 10 times more toxic than the parent compound.
** the BCF value from the parent compound was used in the assessment

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

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Laboratory tests				
Fish				
Oncorhynchus mykiss (rainbow trout)	Methoxyfenozide	Acute 96 hr (flow through)	Mortality, LC_{50}	> 4.2 mg a.s./$L_{(mm)}$
Lepomis macrochirus (bluegill sunfish)	Methoxyfenozide	Acute 96 hr (flow through)	Mortality, LC_{50}	> 4.3 mg a.s./$L_{(mm)}$
Cyprinus carpio (Common carp)	Methoxyfenozide	Acute 96 hr (static renewal)	Mortality, LC_{50}	> 4.9 mg a.s./$L_{(nom)}$
Pimephales promelas (Fathead minnow)	Methoxyfenozide	Acute 96 hr (flow through)	Mortality, LC_{50}	> 3.8 mg a.s./$L_{(mm)}$
Cyprinodon variegatus (sheephead minnow)	Methoxyfenozide	Acute 96 hr (flow through)	Mortality, LC_{50}	**> 2.8** mg a.s./$L_{(mm)}$

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Oncorhynchus mykiss (rainbow trout)	Preparation RH112,485 2F[2]	Acute 96 hr (flow-through)	Mortality, LC_{50}	>130 * (i.e. >30.7 mg a.s./L) (nom)
Lepomis macrochirus (bluegill sunfish)	Preparation RH112,485 2F[2]	Acute 96 hr (flow-through)	Mortality, LC_{50}	>130 * (i.e. >30.7 mg a.s./L) (nom)
Pimephales promelas (fathead minnow)	Methoxyfenozide	33 d Chronic (28d post hatching) (static)	Growth, development NOEC	2.4 mg a.s./L (mm)
Cyprinodon variegatus (Sheepshead minnow)	Methoxyfenozide	32 d Chronic (28d post hatching) (static)	Growth, development NOEC	2.6 mg a.s./L (mm)
Pimephales promelas (fathead minnow)	Methoxyfenozide	262 d, Chronic (full life-cycle) (flow-through)	Growth, reproduction NOEC	**0.53** mg a.s./L (mm)
Aquatic invertebrates				
Daphnia magna (water flea)	Methoxyfenozide	Acute 48 hr (flow through)	Mortality, EC_{50}	3.7 mg a.s./L (mm)
Daphnia magna (water flea)	Preparation RH2485 SC 240[2]	Acute 48 hr (static)	Mortality, EC_{50}	>420 * (i.e. >100 mg a.s./L) (nom)
Daphnia magna (water flea)	Methoxyfenozide	21 d chronic (flow through)	Reproduction, NOEC	**0.39** mg a.s./L (mm)
Sediment-dwelling organisms				
Chironomus riparius (Midge)	Methoxyfenozide	Acute 48 hr (static)	Mortality, EC_{50}	0.257 mg a.s./L (mm)
Chironomus riparius (Midge)	Methoxyfenozide	28 d chronic (static)	NOEC	0.018 mg a.s./L (nom) (spiked water)
Chironomus riparius (Midge)	Methoxyfenozide	28 d chronic (static)	NOEC EC10	**0.0065** mg a.s./L (measured day 0) (spiked water) 0.010 mg a.s./L
Chironomus riparius (Midge)	Metabolite RH-131154	Acute 48 hr (static)	Mortality, EC_{50}	71 mg a.s./L (nom)

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Chironomus riparius (Midge)	Metabolite RH-117236	28 d chronic (static)	NOEC	**0.1** mg a.s./$L_{(nom)}$ (spiked water)
Algae				
Higher plant				
No data submitted.				

Further testing on aquatic organisms

Applicant has carried out and submitted a mesocosm study that assessed the toxicity of GF-837 – Jenkins (2014). Overall, it is considered that the exposure in the mesocosm study is appropriate for use in risk assessment. On the basis of the assessment carried out by the RMS and CoRMS, the NOEC is considered to be **10** µg a.s./L and this is based on the effects on Coenagrionidae larvae. However, there are concerns regarding the high variability of certain species and the low numbers of other species, and therefore it is proposed that an assessment factor of 3 is applied to the NOEC, hence the regulatory acceptable concentration (RAC) is **3.3** µg a.s./L.

It is noted that this study was not considered as sufficient to address the risk to sediment dwellers.

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

Test organism	**Test substance**	**Timescale (test type)**	**Endpoint**	**Toxicity value (mg test substance /L)**
Fathead minnow (*Pimephales promelas*)	Methoxyfenozide	21 d, Short term, (reproduction), (Flow-through)	NOEC	0.0962 * (mm)
African clawed frog (*Xenopus laevis*)	Methoxyfenozide	21 d, (flow-through)	NOEC	0.0747 * (mm)

***** maximum concentration tested

Considering the available information, it is unlikely that methoxyfenozide is an endocrine disruptor for fish via the estrogenic, androgenic and steroidogenic modalities. An amphibian metamorphosis assay was available which did not provide any evidence of endocrine activity or potential endocrine related adverse effects via the thyroid modality. Pending on the data gap in Section 2, further consideration of the endocrine potential of methoxyfenozide via the thyroid modality may be needed. No firm conclusion could be drawn for birds.

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

[2] The formulation 'RH 112, 485 2F' and RH-2485 240SC are considered to be equivalent to 'GF-837' (formulation details are given in Volume 4 , Section C.1.3.).

Bioconcentration in fish (Annex Part A, point 8.2.2.3)

	Methoxyfenozide	Metabolite RH-117236 (M14)
$logP_{O/W}$	3.72	3.24
Steady-state bioconcentration factor (BCF) (total wet weight/normalised to 5% lipid content)	11 mL/g	20*
Uptake/depuration kinetics BCF (total wet weight/normalised to 5% lipid content)		
Annex VI Trigger for the bioconcentration factor		

Clearance time (days) (CT_{50})	0.31	
(CT_{90})	1.0	
Level and nature of residues (%) in organisms after the 14 day depuration phase	15% whole fish	

* Software versions used were BCF model (CAESAR) 2.1.14, BCF model (Meylan) 1.0.3, BCF model (KNN/Read-Across) 1.1.0

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

FOCUS$_{sw}$ step 1-3 - TERs for Methoxyfenozide – vine at 1 x 96 g a.s./ha

Scenario	PEC global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates	Aquatic invertebrates prolonged	Sed. dweller prolonged	Microcosm / Mesocosm
		Cyprinodon variegatus	*Pimephales promelas*	*Daphnia magna*	*Chironomus riparius*	*Daphnia magna*	*Chironomus riparius*	
		LC_{50} > 2800	NOEC = 530	EC_{50} > 3700	EC_{50} = 257	NOEC = 390	NOEC = 6.5	NOEC = 3.3
		µg/L	µg/L	µg/L	µg/L	µg/L	µg/L	µg/L
FOCUS Step 1	27.03	>103	19.6	>137	9.5	14.4	**0.24**	-
FOCUS Step 2								
North Europe Single	3.58	-	-	-	**71.8**	-	**1.8**	-
South Europe Single	5.03	-	-	-	**51.1**	-	**1.3**	-
FOCUS Step 3								
D6/ ditch	1.65	-	-	-	156	-	**3.9**	2
R1 / pond	0.06	-	-	-	4283	-	108	-
R1 / stream	1.21	-	-	-	212	-	**5.4**	2.7
R2 / stream	1.62	-	-	-	159	-	**3.9**	2.0
R3 / stream	1.73	-	-	-	148	-	**3.7**	1.9
R4 / stream	1.788	-	-	-	144	-	**3.63**	1.8
Trigger		100	10	100	100	10	10	1

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

FOCUS$_{sw}$ step 1-3 - TERs for Methoxyfenozide – maize at 1 x 144 g a.s./ha

Scenario	PEC global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates	Aquatic invertebrates prolonged	Sed. dweller prolonged	Microcosm / Mesocosm
		Cyprinodon variegatus	*Pimephales promelas*	*Daphnia magna*	*Chironomus riparius*	*Daphnia magna*	*Chironomus riparius*	
		LC_{50} > 2800	NOEC = 530	EC_{50} > 3700	EC_{50} = 257	NOEC = 390	NOEC = 6.5	NOEC = 3.3
		µg/L	µg/L	µg/L	µg/L	µg/L	µg/L	µg/L
FOCUS Step 1	38.02	**>73.6**	13.9	**>97.3**	**6.7**	10.3	**0.17**	-
FOCUS Step 2								
North Europe Single	2.91	>962	-	>1271	**88.3**	-	**2.2**	-
South Europe Single	4.72	> 593	-	> 784	**54.4**	-	**1.4**	-
FOCUS Step 3								
D3 / ditch	0.88	-	-	-	292	-	**7.4**	3.8
D4 / pond	2.2	-	-	-	117	-	**2.9**	1.5
D4 / stream	2.00	-	-	-	128	-	**3.2**	1.7
D5 / pond	1.4	-	-	-	184	-	**4.6**	2.4
D5 / stream	0.96	-	-	-	268	-	**6.8**	3.4
D6/ ditch	1.78	-	-	-	144	-	**3.7**	1.9
R1 / pond	0.148	-	-	-	1736	-	44	-
R1 / stream	2.798	-	-	-	**92.1**	-	**2.3**	1.2
R2 / stream	1.41	-	-	-	182	-	**4.6**	2.3
R3 / stream	4.12	-	-	-	**62.4**	-	**1.6**	**0.8**
R4 / stream	4.34	-	-	-	**59.2**	-	**1.5**	**0.8**
Trigger		100	10	100	100	10	10	1

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

FOCUS$_{sw}$ step 1-3 - TERs for Methoxyfenozide – fruiting vegetables at 1 x 144 g a.s./ha

Scenario	PEC global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates	Aquatic invertebrates prolonged	Sed. dweller prolonged	Microcosm / Mesocosm
		Cyprinodon variegatus	*Pimephales promelas*	*Daphnia magna*	*Chironomus riparius*	*Daphnia magna*	*Chironomus riparius*	
		LC_{50} > 2800	NOEC = 530	EC_{50} > 3700	EC_{50} = 257	NOEC = 390	NOEC = 6.5	NOEC = 3.3
		µg/L	µg/L	µg/L	µg/L	µg/L	µg/L	µg/L
FOCUS Step 1	38.02	**>73.6**	13.9	**>97.3**	**6.7**	10.3	**0.17**	-
FOCUS Step 2								
North Europe Single	3.27	>856	-	>1131	**78.6**	-	**2.0**	-
South Europe Single	5.45	> 513	-	> 679	**47.2**	-	**1.2**	-
FOCUS Step 3								
D6/ ditch	3.42	-	-	-	**75.1**	-	**1.9**	**0.96**
R2 / stream	1.17	-	-	-	219	-	**5.5**	2.8
R3 / stream	4.09	-	-	-	**62.8**	-	**1.6**	**0.8**
R4 / stream	4.64	-	-	-	**55.4**	-	**1.4**	**0.7**
Trigger		100	10	100	100	10	10	1

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

FOCUS$_{sw}$ step 1-3 - TERs for Methoxyfenozide – leafy vegetables at 1 x 120 g a.s./ha

Scenario	PEC global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates	Aquatic invertebrates prolonged	Sed. dweller prolonged	Microcosm / Mesocosm
		Cyprinodon variegatus	*Pimephales promelas*	*Daphnia magna*	*Chironomus riparius*	*Daphnia magna*	*Chironomus riparius*	
		LC_{50} > 2800	NOEC = 530	EC_{50} > 3700	EC_{50} = 257	NOEC = 390	NOEC = 6.5	NOEC = 3.3
		µg/L	µg/L	µg/L	µg/L	µg/L	µg/L	µg/L
FOCUS Step 1	31.68	**>88.4**	16.7	>117	**8.1**	12.3	**0.21**	-
FOCUS Step 2								
North Europe Single	2.73	>1026	-	-	**94.1**	-	**2.4**	-
South Europe Single	4.54	> 617	-	-	**56.6**	-	**1.43**	-
FOCUS Step 3								
D3 / ditch	0.87	-	-	-	295	-	**7.5**	3.8
D4 / pond	1.94	-	-	-	132	-	**3.4**	1.7
D4 / stream	1.488	-	-	-	173	-	**4.4**	2.2
D6/ ditch	4.353	-	-	-	**59.0**	-	**1.5**	**0.76**
R1 / pond	0.23	-	-	-	1117	-	28	-
R1 / stream	1.779	-	-	-	144	-	**3.6**	1.8
R2 / stream	0.803	-	-	-	320	-	**8.1**	4.1
R3 / stream	2.49	-	-	-	103	-	**2.6**	1.3
R4 / stream	2.906	-	-	-	**88.4**	-	**2.2**	1.1
Trigger		100	10	100	100	10	10	1

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

FOCUS$_{sw}$ step 1 - TERs for metabolites RH-131154 (M08), RH-117236 (M14) – vine at 1 x 96 g a.s./ha

Metabolite	RH-131154 (M08)	RH-117236 (M14)
Species	*Chironomus riparius*	*Chironomus riparius*
	EC_{50} = 71000	NOEC = 100
	µg/L	µg/L
Scenario		
FOCUS Step 1 PEC global max (µg L)	5.36	0.83
TER	13246	120
Trigger	100	10

FOCUS$_{sw}$ step 1 - TERs for metabolites RH-131154 (M08), RH-117236 (M14) – maize and fruiting vegetables at 1 x 144 g a.s./ha

Metabolite	RH-131154 (M08)	RH-117236 (M14)
Species	*Chironomus riparius*	*Chironomus riparius*
	EC_{50} = 71000	NOEC = 100
	µg/L	µg/L
Scenario		
FOCUS Step 1 PEC global max (µg L)	8.04	0.83
TER	8831	120
Trigger	100	10

$FOCUS_{sw}$ step 1 - TERs for metabolites RH-131154 (M08), RH-117236 (M14) – leafy vegetables at 1 x 120 g a.s./ha

Metabolite	RH-131154 (M08)	RH-117236 (M14)
Species	*Chironomus riparius*	*Chironomus riparius*
	EC_{50} = 71000	NOEC = 100
	µg/L	µg/L
Scenario		
FOCUS Step 1 PEC global max (µg L)	6.70	0.83
TER	10597	120
Trigger	100	10

$FOCUS_{sw}$ step 1 - TERs for metabolites RH-131154 (M08), RH-117236 (M14) – leafy vegetables at 2 x 120 g a.s./ha

Metabolite	RH-131154 (M08)	RH-117236 (M14)
Species	*Chironomus riparius*	*Chironomus riparius*
	EC_{50} = 71000	NOEC = 100
	µg/L	µg/L
Scenario		
FOCUS Step 1 PEC global max (µg L)	13.4	0.83
TER	5298	120
Trigger	100	10

Appendix

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 PART REFLECTS THE NEW EFSA GD ON BEES WHICH HAS NOT YET BEEN TAKEN NOTE BY EC. THIS WAS BECAUSE OF DIFFERENCES BETWEEN THE DATA REQUIREMENTS AND THE MORE DETAILED APPROACHES PROPOSED BY THE NEW EFSA GD ON BEES.

Species	Test substance	Time scale/type of endpoint	Endpoint	toxicity
Apis mellifera	a.s., Methoxyfenozide	Acute, 72h	Oral toxicity (LD_{50})	>2000 µg a.s./bee
Apis mellifera	RH-2485 240 SC	Acute, 48h		>289 µg form/bee >68.8 µg a.s./bee
Apis mellifera	a.s., Methoxyfenozide	Acute, 48h	Contact toxicity (LD_{50})	>100 µg a.s./bee
Apis mellifera	RH-2485 240 SC	Acute, 48h		>200 µg form/bee >47.6 µg a.s. /bee
	a.s.,	Chronic*	10 d-LC50	µg/bee/day
	preparation	Chronic*		
	a.s.,	Bee brood development*	NOEClarvae	µg/larva/developmental period
	preparation	Bee brood development*		
	a.s.,	Sub-lethal effects (behavioural and reproductive)*	NOEC hypopharyngeal glands	
	preparation	Sub-lethal effects (behavioural and reproductive)*		

* No study submitted – data point address via the use of bee brood studies and field studies.

Potential for accumulative toxicity: Not determined
Honey bee brood feeding (acc. to Oomen *et a*l., 1992): A study using RH-2485 SC 240 was carried based on Oomen *et al* (1992). Three free-flying honey bee colonies were fed with 1 litre of commercial syrup containing 0.04% 'RH-2485 240 SC'. All traps were examined daily for dead adults, larvae and pupae for the duration of the study. Dead larvae and pupae were examined for specific symptoms known to be caused by insect growth regulators (eg. white eye rims and malformations) in the laboratory. No dead bees were found in the feeding bowls. No behavioural abnormalities occurred during the checks in none of the colonies. Normal brood development was seen in the untreated and the 'RH-2485 240 SC' hives. 86% of eggs and 85% of larvae in hives treated with 'RH-2485 240 SC' successfully developed to adult stage compared to 80% of eggs and 89% of larvae in untreated hives. It was concluded that under the conditions of the study a concentration of 0.04% did not result in any adverse effects on brood development. An additional study was conducted using the Oomen *et al* methodology, colonies were each administered with 6.25, 12.5, 25, 50, 100 mg methoxyfenozide/colony. Measured concentrations were: 5.01, 10.1, 21.8 and 45.8

mg/kg were used. Exposure was to the a.s. only. Colonies in the control group were each dosed with one litre of untreated sucrose solution (containing 1% acetone; as was used in the methoxyfenozide doses). The study was conducted under natural field conditions. The 1 litre of sucrose solution in each colony was consumed in 3-4 days. Overall survival in marked cells from the methoxyfenozide treatments was 76.8-85.5% in the five dose levels, compared with 85.3% in controls. Pupae from cells marked as eggs and young larvae in the 25 and 50 mg a.s./colony treatments were slightly lighter (statistically significant) than those of the control, but no adverse effect was observed in the highest dose level (100 mg a.s./colony). In the dead bee traps, no significant adult or pupal mortality was observed at any dose level (there were occasional peaks associated with robbing due to poor forage availability at this time of year). No adverse effects were observed in any treatment group. Two colonies in the 50 mg a.s./colony group and one in the control group became queenless, and this is reflected in the mean levels of brood in these groups. These were re-queened at the end of the brood assessment period. Overwintering of the colonies was assessed in March 2012. There was no effect on overwintering success of the methoxyfenozide-dosed colonies compared with the controls. There were no long-term adverse effects on adult bees, brood or on colony development or overwintering following direct feeding of honeybee colonies with methoxyfenozide at up to and including 100 mg/colony delivered in a 1 L sucrose solution.

Semi-field test (Cage and tunnel test): A study was carried out according to EPPO 170 on *Phacelia* and used RH-2485 240SC at the 0.8 L/ha. On the basis of the study, it was concluded that RH-2485 240 SC does not have harmful effect on honey bees and brood development when applied at its maximum recommended use rate of 0.8 L/ha.

A further study was carried out according to EPPO 170 in *Phacelia* at the rate of 0 (control), 48 g a.s. in 400 L water/ha = 207.79 g product/ha (corresponding to 519 mg product/L), 480 g a.s. in 400 L water/ha = 2077.9 g product/ha (corresponding to 5.19 g product/L) and 960 g a.s. in 400 L water/ha = 4155.8 g product/ha (corresponding to 10.39 g product/L). Due to issues with the control and the fact that it was replaced during the study, the study is not considered to be robust and hence can only be used in a qualitative manner.

A semi-field study was carried out to investigate the residues in honey bee products and larvae. The study was conducted using *Phacelia* and GF-837 and was based on EPPO 170.

Following an application of GF-837 to flowering *Phacelia* during bee flight at 144 g a.s./ha, samples of pollen and nectar from foragers were taken at 1, 2, and 6 DAA. Nectar from colonies was sampled at 7 DAA only. Results in terms of measured concentrations of methoxyfenozide are given below.

- Highest measured residue for an individual sample:

Pollen from forager bees:	2.751 mg/kg
Nectar from forager bees:	0.035 mg/kg
Nectar from combs:	<0.00011 mg/kg
Larvae from combs:	0.053 mg/kg

- Highest mean measured residue in pollen and nectar from forager bees and in larvae from the combs:

Pollen from forager bees:	2.263 mg/kg
Nectar from forager bees:	0.022 mg/kg
Larvae from combs:	0.029 mg/kg

The study was not designed to assess effects of methoxyfenozide on the colonies and their development (there was only one replicate in the control, compared with four test item replicates), but the parameters which were assessed showed no obvious differences between the condition of the colonies from the control and test item treated tunnels. It should be noted that the study was not considered to be sufficiently robust and has only be used in a qualitative manner.

Field test A field study was carried out using GF-837 at the rate of 210 g a.s./ha on almond trees in the USA. The main aim of the study was to determine residues in honey bees and honey bee products. There were no effects on the condition of honey bee colonies following application of methoxyfenozide at 209.8 or 192.5 g a.s./ha during flowering of almond orchards, during bee flight/foraging.
Residues in the test samples were analysed to be in the range <0.005 to 9.42 mg/kg. Residues in all matrices declined relatively rapidly in the period after application. An overview of the highest measured residues in the different matrices is provided below.

- Highest measured residue for an individual sample (for field trial samples):

Pollen from flower:	6.43 mg/kg
Pollen from forager bees:	9.42 mg/kg
Nectar from forager bees:	0.794 mg/kg
Pollen from combs:	3.87 mg/kg
Larvae from combs:	0.021 mg/kg

- Highest mean measured residue:

Pollen from flower:	6.433 mg/kg
Pollen from forager bees:	6.359 mg/kg
Nectar from forager bees:	0.339 mg/kg
Pollen from combs:	1.508 mg/kg
Larvae from combs:	0.013 mg/kg

It should be noted that due to issues with the residues found in samples before application and the fact that there was observed high variation between residue analysis in pollen at two tested sites, the study is not considered to be robust and hence can only be used in a qualitative manner.

A further field study was carried on which used pome fruit applied at the rate of 142 g a.s./ha. **i**n this study, honeybee colonies were exposed to methoxyfenozide treatment during full flowering of a 3 ha apple orchard in Northern Italy at a rate of 142.4 g a.s./ha. Foraging by worker bees occurred during and shortly after application. There were no effects by the test item on: brood development, colony development, observed, adult mortality, and return rate of foragers to the colony.

The residues data gathered during the study are summarised below as methoxyfenozide concentrations.

- Highest measured residue for an individual sample:

	GF-837 tretment	**Control**
Forager bees (without pollen)	1.949 mg/kg	- -
Pollen from forager bees	6.663 mg/kg	- -
Pollen from colonies (bee bread)	4.043 mg/kg	0.231 mg/kg
Nectar from forager bees	0.096 mg/kg	- -
Nectar from colonies	0.028 mg/kg	0.006 mg/kg
Larvae from colonies	0.012 mg/kg	<LOQ
Harvested honey	<LOQ *	<LOQ

- - only bees from the treatment orchard were analysed
* three colonies swarmed (i.e. colonies 2/1, 2/6 and 2/9) and could not be harvested
LOQ <0.005 mg/kg

- Individual values at 1 DAA (n=2) and highest mean measured residue at 3 DAA (n=7) in pollen and nectar from forager bees:

Pollen from forager bees (1 DAA):	2.091 and 6.663 mg/kg
Pollen from forager bees (3 DAA):	1.736 mg/kg
Nectar from forager bees (1 DAA):	0.022, 0.032 mg/kg
Nectar from forager bees (3 DAA):	0.054 mg/kg

It should be noted that due to the potential reliability of the study, it is not considered to be robust and hence can only be used in a qualitative manner.

Risk assessment for maize and sweet corn at 144 g a.s./ha g a.s./ha once per year

Species	Test substance	Risk quotient	HQ/ETR	Trigger
Apis mellifera	RH-2485 240 SC	HQcontact	<3.03	50
Apis mellifera	RH-2485 240 SC	HQoral	<2.09	50

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
Aphidius rhopalosiphi	RH 2485 SC 240	Mortality, LR_{50}	LR_{50} >0.8 L/ha* (i.e. >192 g a.s./ha) Adult mortality (%): Control = 3.3% Formulation = 10.0% Mummies/female: control 13.0 0.8 l/ha 9.1 70% parasitisation compared to control
Additional species			
Pardosa sp.	RH 2485 SC 240	ER_{50}	ER_{50} >0.8 L/ha* (i.e. >192 g a.s./ha) Mortality (%): Control = 5 Formulation = 5 Feeding of treated spiders 33% greater than control
Orius laevigatus	RH 2485 SC 240	ER_{50}	ER_{50} >0.8 L/ha* (i.e. >192 g a.s./ha) Exposure phase mortality: Control = 15% Formulation = 33% (corrected value 22%) Reproduction (eggs/female): control 31.8 0.8 l/ha 61.3 Egg hatching (%): control 79.3 0.8 l/ha 78.8

Extended laboratory tests, aged residue tests

Species	Life stage	Test substance, substrate	Time scale	Dose (g/ha)	End point	% effect	ER_{50}
Aphidius rhopalosiphi	adult	RH 2485 SC 240	48 hr exposure and 12 days fecundity assessment	0 and 192 g a.s./ha	Mortality Repro	Adult mortality (%): 0 0 Mummies/female: Control = 12.3% Formulation = 10.9 89% parasitisation compared to control	ER_{50} >0.8 L/ha* (i.e. >192 g a.s./ha)
Trichogramma cacoeciae	adult	RH 2485 SC 240	7 days	0, 2x0.8 l/ha with 10 day interval	Mortality and parasitisation	Adult survival: 100% 100% 166% parasitisation compared to control	ER_{50} >0.8 L/ha* (i.e. >192 g a.s./ha)
Trichogramma cacoeciae	adult	RH 2485 SC 240	10 days exposure	0, 0.16 L/ha	Mortality and parasitisation	Adult emergence: 80% 86% 89% parasitisation compared to control	ER_{50} >38.4 g/ha*
Typhlodromus pyri		RH 2485 SC 240		0 and 192 g a.s./ha	Mortality Repro	No effects >50% on fecundity and fertility	ER_{50} >192 g a.s./ha

Species	Life stage	Test substance, substrate	Time scale	Dose (g/ha)	End point	% effect	ER_{50}
Typhlodromus pyri	adults	RH 2485 SC 240	18 days	0, 4x0.4 l/ha with 10 day interval	Mortality and repro	Mortality: Control = 13.8% Formulation = 17.5% Eggs per female 67% relative to control. Larvae per female 73% relative to control. Larvae per egg 105% relative to control	>4x96 g a.s./ha with 10 day interval
Chrysoperla carnea	larvae	RH 2485 SC 240	105 days	control 3 x 0.4 l/ha with 10 day interval	Mortality Repro	Adult emergence from pupae: 86% 74% Eggs/female 82% relative to control Egg hatch 102% relative to control	ER_{50} >3× 0.4 L/ha* (i.e. >3× 96 g a.s./ha), 10-d interval
*Poecilus cupreus**	larvae	Intrepid 2F and Methoxyfenozide	45-days	0 (control), 0.064, 0.64 and 1.28 mg a.s./kg soil	Mortality Repro	No effects >50% on body weight and emergence	LR50 = >1.28 mg a.s./kg soil and >5.54 mg formn/kg soil
*Typhlodromus pyri**	proton ymphs	Intrepid 2F	14-days	0 (control), 4000, 2000 and 200 mL product/ha (nominally 960, 480 and 48 g a.s./ha)	Mortality Repro	-53% on fecundity +21% on fecundity	*Day 0 residues*: LR_{50} >4 L/ha i.e. >960 g a.s./ha *Day 7 residues*: LR_{50} >4 L/ha

Species	Life stage	Test substance, substrate	Time scale	Dose (g/ha)	End point	% effect	ER_{50}
Stethorus punctillum	larvae	Intrepid 2F	7-days	0 (control), 48, 480 and 960 g a.s./ha	Mortality Repro	50.1% mortality No effects >50% on fecundity and fertility	*Day 0 residues*: LR_{50} = 4 L/ha* (i.e. = 960 g a.s./ha) *Day 7 residues*: LR_{50} >4 L/ha*

* multiple rate test

Risk assessment

Species	ER_{50} (g/ha)	In-field rate	Off-field rate[1]
Assessment not considered relevant due to the mode of action of methoxyfenozide and the fact that it is needs to be ingested.			

[1]indicate distance assumed to calculate the drift rate and if 3D or 2D.

Semi-field tests
-
Field studies
Typhlodromus pyri : at most -26.2% difference in number of mites per 25 leaves from control at 4× 0.4 L RH-2485 SC250 /ha (i.e. >4× 96 g a.s./ha), 10/15-d interval
Typhlodromus pyri : at most -22% difference in number of mites per 25 leaves from control at 4× 0.4 L RH-2485 SC250 /ha (i.e. >4× 96 g a.s./ha), 10/11-d interval
Additional specific test
Community of arthropods in apple orchard: NOEC = 2× 144 g a.s./ha (as GF-837), 30-d interval. the following key points were noted: **Pitfall traps:** there were no overall adverse effects of either treatment, noting that some species/groups were present, in both treatments and the control, at low numbers. **Visual assessment:** no overall adverse effects of either treatment, i.e. numbers were in line with treatment. **Yellow water traps**: there were no overall adverse effects of either treatment, noting that some species/groups were present, in both treatments and the control, at low numbers. **Inventory sampling:** there were no overall adverse effects of either treatment, noting that some species/groups were present, in both treatments and the control, at low numbers. Data gap Further information to address the risk to sensitive life stages of non-target arthropods in-field and off-field and further information to address the off-field risk to Lepidoptera

Effects on non-target soil meso- and macro fauna; effects on soil nitrogen transformation (Regulation (EU) N° 283/2013, Annex Part A, points 8.4, 8.5, and Regulation (EU) N° 284/2013 Annex Part A, points 10.4, 10.5)

Test organism	Test substance	Application method of test a.s./ OM[1]	Time scale	End point	Toxicity
Earthworms					
Eisenia andrei	RH 2485 SC 240:	Artificial soil with 10% peat content, test item mixed into artificial soil	Chronic	Reproduction, 56 d	NOEC = 2.04 mg a.s./kg dry soil*
Eisenia foetida	RH-131154 (M08)	Artificial soil with 10% peat content, test item mixed into artificial soil	Chronic	Reproduction, 56 d	NOEC = 20 mg/kg dry soil*
Other soil macroorganisms					
Folsomia candida	Methoxyfenozide	Artificial soil with 10% peat content, test item mixed into artificial soil	Chronic	Reproduction, 28 d	NOEC = 0.64 mg/kg dry soil*
	GF-837	(5% peat in test soil) test item mixed into artificial soil	Chronic	Reproduction, 28 d	NOEC = 20.48 mg a.s./kg dry soil*
	RH-131154 (M08)	(5% peat in test soil) test item mixed into artificial soil	Chronic	Reproduction, 28 d	NOEC = 20 mg/kg dry soil*
Hypoaspis aculeifer	RH-131154 (M08)	(5% peat in test soil) test item mixed into artificial soil	Chronic	Reproduction, 14 d	NOEC = 1000 mg/kg dry soil*

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

*Toxicity endpoints have been amended by a factor of 2.

Higher tier testing (e.g. modelling or field studies)

Nitrogen transformation	Methoxyfenozide		<25% effects at (Day 28) 1.96 kg/ha* (i.e. 2.61 mg/kg dry soil)
	GF-837	dose equivalent to 3.75 kg product/ha (= 0.9 kg a.s./ha)	<25% effects at (Day 28) 3.75 kg/ha* (i.e. 5 mg/kg dry soil) (i.e. 1.18 mg a.s./kg dry soil)
	RH-131154 (M08)	Dose 2: 5 mg RH-131154/kg soil dry weight	<25% effects at (Day 28) 5 mg/kg dry soil

Toxicity/exposure ratios for soil organisms

Test organism	Test substance	Time scale	Soil PEC[1]		TER	Trigger
Earthworms						
Eisenia andrei	RH 2485 SC	Chronic	Maize Vines Fruiting veg Leafy veg	0.115 0.219 0.045 0.092	17.7 9.3 45.3 22.2	5
Eisenia foetida	RH-131154	Chronic	Vine Maize Fruiting veg Leafy veg Leafy veg (total dose)	0.005 0.008 0.007 0.008 0.016	4000 2500 4000 2500 1250	5
Eisenia foetida	RH-131154	Chronic	Maximum accumulated PEC	0.071	281	5
Other soil macroorganisms						
Folsomia candida	GF-837	Chronic	Maize Vines Fruiting veg Leafy veg	0.115 0.077 0.092 0.219	178 266 222.6 93.5	5
Folsomia candida	RH-131154	Chronic	Maize Vines Fruiting veg Leafy veg	0.008 0.005 0.007 0.016	2500 4000 2857 1250	5
Folsomia candida	RH-131154	Chronic	Maximum accumulated PEC	0.071	281	5
Hypoaspis	RH-131154	Chronic	Maize	0.008	125000	5

Test organism	Test substance	Time scale	Soil PEC[1]		TER	Trigger
aculeifer			Vines Fruiting veg Leafy veg	0.005 0.007 0.016	200000 142857 62500	

[1]indicate which PEC soil was used (e.g. plateau PEC)

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

Screening data

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

Laboratory dose response tests

Species	Test substance	ER_{50} (g/ha)[2] vegetative vigour	ER_{50} (g/ha)[2] emergence	Exposure[1] (g/ha)[2]	TER	Trigger
Maize/sweet corn and fruiting vegetables	RH 2485 SC 240	5 monocots + 6 dicots ER_{50} >1000 g a.s./ha NOER = 1000 g a.s./ha	5 monocots + 6 dicots ER_{50} >1000 g a.s./ha NOER = 1000 g a.s./ha	3.99	>250	5
Leaf Vegetable	RH 2485 SC 240	5 monocots + 6 dicots ER_{50} >1000 g a.s./ha NOER = 1000 g a.s./ha	5 monocots + 6 dicots ER_{50} >1000 g a.s./ha NOER = 1000 g a.s./ha	2.77	>301	5
Grapes	RH 2485 SC 240	5 monocots + 6 dicots ER_{50} >1000 g a.s./ha NOER = 1000 g a.s./ha	5 monocots + 6 dicots ER_{50} >1000 g a.s./ha NOER = 1000 g a.s./ha	8.02	>129	5
Extended laboratory studies: No study presented Semi-field and field test: No study presented						

[1] explanation of how exposure has been estimated should be provided (e.g. based on Ganzelmeier drift data)
[2] for preparations indicate whether dose is expressed in units of a.s. or preparation

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	EC50 >10000mg a.s./l.
Pseudomonas sp	

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

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

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 (methoxyfenozide)
water	Parent (methoxyfenozide)
sediment	Parent (methoxyfenozide)
groundwater	Parent (methoxyfenozide)

[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	Methoxyfenozide
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][6]:	-
Peer review proposal[7] for harmonised classification according to Regulation (EC) No 1272/2008:	Aquatic Acute 1 and Aquatic Chronic 1-(Acute M-factor 10; Chronic M-factor 1)

[6] 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.

[7] 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.

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