HSE

Draft Assessment Report

Evaluation of Active Substances

Plant Protection Products

Prepared according to **Regulation (EC) 1107/2009**
as it applies in Great Britain

Metalaxyl-M

List of Endpoints

Great Britain

January 2024

Version History

Date	Reason for revision
February 2015	LoEP as published in the EFSA conclusion (EFSA Journal 2015; 13(3):3999) for the renewal of Metalaxyl-M, applicable to GB.
January 2024	GB Article 7 amendment assessment for the proposed removal of restriction of metalaxyl-M in GB.

Background

The approval of Metalaxyl-M was renewed on 01 June 2020 under Commission Implementing Regulation (EU) 2020/617. The endpoints adopted from the renewal review are applicable to Great Britain (GB), since the UK was an EU Member State at the time. The agreed endpoints for metalaxyl-M are provided for in the European Food Safety Authority (EFSA) conclusion on the peer review of the pesticide risk assessment of the active substance metalaxyl-M of (EFSA Journal 2015; 13(3):3999). The endpoints that have been amended as a result of the application to amend the approval conditions of metalaxyl-M in GB are clearly identified within this report.

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

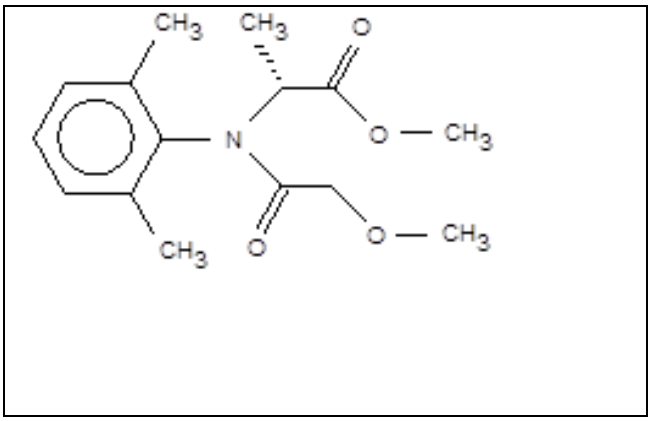
Active substance (ISO Common Name)	Metalaxyl-M(ISO-approved); Code CGA329351
Function (*e.g.* fungicide)	Fungicide

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

Chemical name (IUPAC)	methyl N-(methoxyacetyl)-N-(2,6-xylyl)-D-alaninate or methyl (R)-2-{[(2,6-dimethylphenyl)methoxyacetyl] amino}-propionate
Chemical name (CA)	N-(2,6-dimethylphenyl)-N-(methoxyacetyl)-D-alanine methyl ester
CIPAC No	580
CAS No	70630-17-0 (R)
EC No (EINECS or ELINCS)	n/a
FAO Specification (including year of publication)	-
Minimum purity of the active substance as manufactured	920g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	CGA72649 (max. content 0.5 g/kg) CGA363736 (max. content 1 g/kg) ~~CGA226048 (max content: OPEN)~~ ~~Open for other impurities~~
Molecular formula	$C_{15}H_{21}NO_4$
Molar mass	279.3 g/mol
Structural formula	

List of endpoints

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



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

Melting point (purity)	- 38.7°C (glass transition temperature) (97.2% pure)
Boiling point (purity)	not determinable due to thermal decomposition
Temperature of decomposition (purity)	approx. 270°C (97.2% pure)
Appearance (purity)	clear, pale yellow, viscous liquid with weak odour (97.2% pure)
	clear, light brown, viscous liquid with weak odour (95.2% pure)
Vapour pressure (temperature, purity)	3.3 10^{-3} Pa at 25°C (97.2% pure)
Henry's law constant (temperature)	3.5 10^{-5} Pa.m3/mol at 25°C (97.2% pure)
Solubility in water (temperature, purity and pH)	pure water : 26 g/l at 25°C (97.2% pure)
Solubility in organic solvents (temperature, purity)	no effect of pH at 25°C (95.2% pure) : n-hexane: 59 g/l toluene: completely miscible dichloromethane: completely miscible methanol: completely miscible n-octanol: completely miscible acetone: completely miscible ethyl acetate: completely miscible
Surface tension (concentration and temperature, purity)	57.6 - 57.8 mN/m (1 g/l) at 25°C (95.2% pure)
Partition coefficient (temperature, pH and purity)	log P_{OW} = 1.71 at 25°C (pH 7.6) (97.2%)
	No effect on pH
Dissociation constant (purity)	no pK_a in an accessible pH-range
UV/VIS absorption (max.) incl. ε (purity, pH)	266 nm (512 $l.mol^{-1}.cm^{-1}$) 274 nm (477 $l.mol^{-1}.cm^{-1}$) no absorption between 290 and 750 nm (97.2% pure)

Flammability (purity)	flash point : 179°C (1013 mbar) auto-ignition temperature : 410°C (95.2% pure)
Explosive properties (purity)	Not explosive (95.2% pure)
Oxidising properties (purity)	Not oxidising (92.3% pure)

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

Substance	Metalaxyl-M
Mandatory classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process as applicable in GB.	No Classification required
GB Authority proposal [1] for mandatory classification according to Regulation (EC) No 1272/2008 as applicable in GB:	No specific labelling or classification is proposed based on the measured physico-chemical properties of product A9873C

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

List of endpoints

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

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

Crop and/or situation (a)	Product name	For G Or I (b)	Pests or Group of pests controlled (c) (additionally: developmental stages of the pest or pest group)	Preparation Type (d-f)	Preparation Conc. a.i. (g/L) (i) 1)Fludioxonil 2)Metalaxyl-M 3)Sedexane	Application Method/ kind (f-h)	Application Timing/ Growth stages & season (j)	Application number min-max (k)	Application Interval between application (min)	Application rate per treatment ml product/ seed unit	Application rate per treatment Max g a.s /100kg seeds 1) Fludioxonil 2) Metalaxyl-M 3) Sedaxane	Application rate per treatment Max µg a.s./seed 1) Fludioxonil 2) Metalaxyl-M 3) Sedaxane	Application rate per treatment g a.s./ha max (l) 1) Fludioxonil 2) Metalaxyl-M 3) Sedaxane	PHI (days) (m)	Remarks
Beet (Sugar (BEAVA) and fodder (BEAVC) beet)	‘Vibrance SB’	I	Damping-off diseases (Pythium ultimum [PYTHUL], Pleospora betae/P betae [PLEOBJ], Thanatephorus cucumeris / Rhizoctonia solani [RHIZSO])	FS	1) 22.5 2) 14.4 3) 15.0	Seed Treatment	BBCH 00 Jan-Dec	1	n/a	33.3	1) 31.22 2) 19.98 3) 20.81	1) 7.49 2) 4.80 3) 5.00	1) 0.97 2) 0.62 3) 0.65	n/a	Seed unit: 100.000 seeds Seedling rate: 1 – 1.3 seed unit/ha TGW: 24-33 g/1000 seeds Slurry volume: 8-20L/100 kg seeds Max. 43.3 ml product/ha
		F				Sowing	BBCH 00 March-April								
		n.a				Transplanting	n/a								

(a) For crops, the GB and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure) (b) State if the use is outdoor, field use (F) or glass house (G) or indoor use (I). (c) *e.g.* biting and sucking insects, soil borne 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	(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 stages 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

List of endpoints

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

(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	(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

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

Crop and/or situation (a)	GB or Country For Import Tolerance	Product name	For 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.i. (i)	Method/ kind (f-h)	Timing / Growth stages & season (j)	number min-max (k)	Min interval between application (days)	kg a.s /hL min-max (l) 1) Metalaxyl-M 2) Cymoxanil 3) Fludioxonil	Slurry volume (ml/100kg) min-max	kg a.s./ha 1) Metalaxyl-M 2) Cymoxanil 3) Fludioxonil		
15	Combining Peas [PIBSS]	‘Wakil XL’	I	*Peronospora viciae, Ascochyta complex : Ascochyta pisi, Mycosphaerella pinodes, Phoma medicaginis var. Pinodella, Pythium spp.*			Seed Treatment	BBCH 00	1	1	1) 0.0339 2) 0.020 3) 0.010	3500/3500	1) 0.0678 2) 0.040 3) 0.020 Note: 0.095 kg/ha assumed for GB environmental exposure assessment for use on combining and vining peas	n/a	Seeding rate maximum 200 kg seeds/ha TGW: 250 g Use: Field Varieties of common pea
			F				Sowing	BBCH 00							
			n/a				Trans-planting	n/a							

List of endpoints

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

															(Pisum sativum) harvested when fully mature
17	Vining Peas [PIBSS]	'Wakil XL'	I F n/a	*Peronospora viciae, Ascochyta complex: Ascochyta pisi, Myco-sphaerella pinodes, Phoma medicaginis var. pinodella Pythium spp.,*			Seed Treatment Sowing Trans-planting	BBCH 00 BBCH 00 n/a	1	1	1) 0.0339/0.03015 2) 0.020/0.01778 3) 0.010/0.00889	3500/3500	1) 0.0763/0.0678 2) 0.0450/0.040 3) 0.0225/0.020 Note: 0.095 kg/ha assumed for GB environmental exposure assessment for use on combining and vining peas	n/a	Seeding rate: max-imum 225 kg seeds/ha TGW:min 225 g Use: Field Varieties of com-mon pea (Pisum sativum) harvested green for canning, freezing or market-ing fresh. Seeding density: 1000000 seeds/ha

Please note: Blue colour font is alternative dose expression

(a) For crops, the GB and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure) (b) State if the use is outdoor, field use (F) or glass house (G) or indoor use (I). (c) *e.g.* biting and sucking insects, soil borne insects, foliar fungi, weeds	(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).

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

(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	(j) Growth stages 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

List of endpoints

Identity, Physical/ Chemical Properties, Details of Uses, Further Information, Methods of Analysis

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)	GC with FID (sum of 2 enantiomers) + HPLC (chiral) with UV detection (separate enantiomers)
Impurities in technical a.s. (analytical technique)	GC with FID (organic by-products)
Plant protection product (analytical technique)	Metalaxyl-M : GC with FID (sum of 2 enantiomers) + HPLC (chiral) with UV detection (separate enantiomers)

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

Residue definitions for enforcement purposes

Food of plant origin	Metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers)
Food of animal origin	Not required
Honey	n/a
Soil	Metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers)
Sediment	
Water surface	Metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers)
drinking/ground	Metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers)
Air	Metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers)
Body fluids and tissues	n/a

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ)	parent compound (Metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers)): 1) QuECHERS multi-residue method: LOQ = 0.01 mg/kg for the 4 matrix types (tomato, dried bean, oilseed rape, potato, orange) 2) DFG S19 multi- residue method : LOQ = 0.01 mg/kg in high water matrix content (tomato, spinach)
Food/feed of animal origin (analytical technique and LOQ)	Not required
Honey (analytical technique and LOQ)	n/a
Soil (analytical technique and LOQ)	Metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers): LC-MS/MS (two mass transitions monitoring) : LOQ = 0.01 mg/kg (Method allows also the determination of CGA 62826 with a LOQ = 0.01 mg/kg)
Water (analytical technique and LOQ)	Metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers)) + CGA 62826 + CGA 108906: LC-MS/MS (two mass transitions monitoring) : LOQ = 0.05 µg/L for each component in surface, drinking and ground water
Air (analytical technique and LOQ)	Metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers): LC-MS/MS (two mass transitions monitoring): LOQ = 10 µg/m^3

Body fluids and tissues (analytical technique and LOQ)	not required as metalaxyl-M is not classified as toxic or highly toxic

Impact on Human and Animal Health

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

Rate and extent of oral absorption/systemic bioavailability	> 80% within 24 h based on comparison of excretion patterns after oral and i.v. administration of metalaxyl & bridging urinary excretion between metalaxyl and metalaxyl-M
Toxicokinetics	n/a
Distribution	Widely and evenly distributed
Potential for bioaccumulation	No potential for accumulation in fat (half-life 2.59 days).
Rate and extent of excretion	> 94 % excreted within 48 h, 48.2 (♂) – 59.3 (♀) % via urine and 46.2 (♂) –35.5 (♀) % via faeces (metalaxyl-M);71% (♂) - 65.8% (♀) via bile (metalaxyl-M within 24 h)
Metabolism in animals	Complete metabolism via ether demethylation, aromatic methyl oxidation, ester demethylation, hydroxylation meta position of phenyl ring to glucuronides and sulfates.
In vitro metabolism	n/a
Toxicologically relevant compounds (animals and plants)	Metalaxyl-M
Toxicologically relevant compounds (environment)	Metalaxyl-M ~~and metabolites CGA 62 826 and NOA409045~~

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

Rat LD_{50} oral Mouse LD_{50} Oral	667 mg/kg bw (males and females combined) Male : 953 mg/kg bw Female: 375 mg/kg bw Male : >1000 mg/kg bw Female: 500<LD50<1000 mg/kg bw	<u>Classification according to Regulation (EC) No 1272/2008:</u> Acute Toxicity Category 4, H302 (“Harmful if swallowed”)
Rat LD_{50}	> 2000 mg/kg bw	<u>Classification according to Regulation</u>

List of endpoints

Mammalian Toxicology

dermal		(EC) No 1272/2008: Not required
Rat LC_{50} inhalation	> 2.29 mg/L (4 hours exposure, nose-only)	Classification according to Regulation (EC) No 1272/2008: Not required
Skin irritation	Non-irritant (rabbit)	Classification according to Regulation (EC) No 1272/2008: Not required
Eye irritation	Severely Irritant (rabbit)	Classification according to Regulation (EC) No 1272/2008: Eye Dam, cat 1 H318 ("Causes serious eye damage")
Skin sensitisation	Maximisation of Bühler test: not sensitising	Classification according to Regulation (EC) No 1272/2008: Not required
Phototoxicity	(*state 'not required' or 'not phototoxic/probably phototoxic/phototoxic'*)	**n/a**

Target organ / critical effect	Rat: liver (hepatocyte hypertrophy, ↑ liver weight), reduced bwDog: liver (↑liver weight, ↑AP,↑ALT); blood (anaemia)
Relevant oral NOAEL	Overall Rat, 90-day: 17 mg/kg bw per day (metalaxyl & metalaxyl-M)Overall Dog, 90-day, 6-month, 1 & 2-year: 8 mg/kg bw per day (metalaxyl & metalaxyl-M)
Relevant dermal NOAEL	Rat, 21-day: 250 mg/kg bw per day, based on decreased bw gain at 1000 mg/kg bw per day (metalaxyl-M)
Relevant inhalation NOAEL	Not required

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

Weight of Evidence suggests no evidence for genotoxicity in-vivo

List of endpoints

Mammalian Toxicology

Long-term effects (target organ/critical effect)	Rat: liver (increased weight and ALT at top dose, testes atrophy) Mouse: ↓ bodyweight gain wk 11-30, liver cell fatty vacuolation
Relevant long-term NOAEL	9.4 mg/kg bw per day; 2-year rat study (metalaxyl)25 mg/kg bw per day; 18-month mouse study (metalaxyl)
Carcinogenicity (target organ, tumour type)	Metalaxyl-M is unlikely to pose a risk to humans
Relevant NOAEL for carcinogenicity	n/a
Reproduction target / critical effect	No reproductive effects or offspring's toxicity at parental toxic doses (↓bw gain, hepatomegaly and periportal fatty deposition)
Relevant parental NOAEL	21 mg/kg bw/d, (Metalaxyl)
Relevant reproductive NOAEL	96 mg/kg bw/d, (highest dose tested) (Metalaxyl)
Relevant offspring NOAEL	96 mg/kg bw/d, (highest dose tested) (Metalaxyl)
Developmental target / critical effect	<u>Rat (Metalaxyl):</u> Dams: mortality, clinical signs, ↓bw gain Pups: Ossification delay <u>Rat (Metalaxyl-M):</u> Dams: ↓bw gain and food consumption Pups: No effects <u>Rabbit (Metalaxyl):</u> Dams: Clinical signs, reduced bw gain, food consumption Pups: No effects
Relevant maternal NOAEL	Rat (Metalaxyl and Metalaxyl-M): 50 mg/kg bw/d Rabbit (Metalaxyl): 150 mg/kg bw/d
Relevant developmental NOAEL	Rat (Metalaxyl):

	250 mg/kg bw/d (ossification delay at 400 mg/kg bw/d) Rat (Metalaxyl-M): >250 mg/kg bw/d (highest dose tested) Rabbit (Metalaxyl): >300 mg/kg bw/d (highest dose tested)

Acute neurotoxicity	No data-not required
Repeated neurotoxicity	No data-not required
Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity)	No data-not required

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

Supplementary studies on the active substance (mechanism studies)	Metalaxyl is a weak inducer of CYP: In the liver, induction of CYP level, induction of PROD, ECOD, aminopyrine demethylase and UDP glucuronyl transferases activities. In kidneys: induction of aminopyrine demethylase activity. In lungs: induction of EROD.

List of endpoints

Mammalian Toxicology

Endocrine disrupting properties	EDSP (Metalaxyl) studies: considered negative In vitro: • Estrogen Receptor Binding (Rat Uterine Cytosol) • Estrogen Receptor Transcriptional Activation (Human Cell Line: HeLa-9903) • Androgen Receptor Binding (Rat Prostate Cytosol) • Human Recombinant Aromatase Assay • H295R Steroidogenesis Assay In vivo: • Uterotrophic Assay in Ovariectomized Rats • Hershberger Assay in Orchidectomised Rats • Male and female pubertal assay.

Studies performed on metabolites or impurities	Bridging study 28d oral, rat Metalaxyl / Metalaxyl-M: NOAEL = 50 mg/kg bw/d Metabolites of plants (P), environment (E), livestock (L), rat (R): (i) CGA 62 826 / NOA409045 (R-enantiomer of CGA 62 826; metalaxyl / metalaxyl-M acid, P,L,E, up to 5 % in R) -Acute, oral and dermal rat LD50> 2000 mg/kg bw -NOAEL 28-d oral rat study : 1000 mg/kg bw per day -Ames-test and gene mutation : negative -in-vitro clastogenicity: 22h –S9-mix, positive; 4h ±S9:negative -in-vivo clastogenicity and aneugenicity (micronucleus assay) : negative (ii)CGA 107 955(P,L,E, up to 20 % in R)Acute, oral rat LD50> 3000 mg/kg bw (iii)CGA 108 906(racemate) / SYN 546 520(R-enantiomer of CGA 108 906, P,L,E) -Acute, oral and dermal rat LD50> 2000 mg/kg bw -NOAEL 28-d rat study = 200 mg/kg bw per day -Ames-test and gene mutation : negative -in-vitro clastogenicity: negative (iv)CGA 67 868(=CGA 92 370) (P,L,E) -Ames-test and gene mutation : negative -in-vitro clastogenicity: negative Relevant impurity: CGA72649 (literature data)

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

	Medical data on Metalaxyl-M were submitted : No specific effects were observed in workers exposed to metalaxyl-M

Summary[2] (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)	0.08	Overall NOAEL from dog studies	100
Acute Reference Dose (ARfD)	0.5	Rat developmental study	100
Acceptable Operator Exposure Level (AOEL)	0.08	Overall NOAEL from dog studies	100*

* no correction needed regarding oral absorption

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

'Ridomil Gold WG' (38.8 g metalaxyl-M/kg and 640 g mancozeb/kg WG) 'Apron XL EC' (339 g metalaxyl-M/L, EC)	100% concentrate and dilution, default value ([1]) 25% (Apron XL EC) ([2]) 75% (Ridomil Gold WG) ([2]) ([1]): using the legally binding DG Sanco Guidance ([2]): using the new EFSA guidance (not of application at the time of EU-dossier submission)

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

Operators	% of AOEL (i) Ridomil-Gold MZ WG (application rate 0.097 kg a.s./ha) Tomato, hand-held <u>UK POEM</u> Without PPE: 647 % PPE (gloves during M/L): 191 % Tomato, Tractor mounted equipment <u>German model</u> Without PPE: 105 % PPE (gloves during M/L): 44 %

[2] If available include also reference values for metabolites

	UK POEM Without PPE: 753 % PPE (gloves during M/L): 57 % Grapes, Tractor mounted equipment German model Without PPE: 141 % PPE (gloves during M/L): 113 % UK POEM Without PPE: 1053 % PPE (gloves during M/L): 651 % (ii)Apron XL EC Sunflower seeds Seed TROPEX PPE (long-sleeved work jacket, long trousers and gloves during M/L, seed treatment and cleaning machinery) 366 % PPE (PPE above, adding respiratory protectionequipment (type FFP3) 226 % Spinach ad-hoc surrogate exposure study PPE (work trousers and work jacket, shirt and coverall during M/L, seed treatment and cleaning) 3.2 %
Workers	% of AOEL (iii)Ridomil-Gold MZ WG Tomato fields arms, body, legs covered 273 % hand, arms, body, legs covered 27 % Vineyards arms, body, legs covered491 % hand, arms, body, legs covered49 % (iv)Apron XL EC Sunflower and spinach seeds PPE (loading andsowing seeds)42 %

Bystanders and residents	% of AOEL (v)Ridomil-Gold MZ WG Bystanders UK Guidance Tomato fields:0.82 % Vineyards:28 % DE Guidance Tomato fields (adults)4.2 % Tomato fields (children)3.3 % Vineyards (adults)12.2 % Vineyards (children)9.5 % Residents UK Guidance (children) Tomato fields:4.1 % Vineyards:9.4 % DE Guidance Tomato fields (adults)*0.9 % Tomato fields (children)*1.4 % Vineyards (adults)*2 % Vineyards (children)*3 % (vi)Apron XL EC (seed treatment) Sunflower and spinach seed treatments2.8 % Sunflower and spinach seed loading/sowing0.4 %

*a maximum of 2 applications was considered while GAP mentions 3 applications (adding the 3rd application in the calculation would still result in a level of exposure below the AOEL).

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

Substance :	Metalaxyl-M
Mandatory classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process as applicable in GB:	-Acute Toxicity Category 4, H302 (“Harmful if swallowed”) -Eye Dam, cat 1, H318 (“Causes serious eye damage”)

List of endpoints

Mammalian Toxicology

GB Authority proposal [3] for mandatory classification according to Regulation (EC) No 1272/2008 as applicable in GB:	n/a

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

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)**
	Fruit	Tomatoes
	Root crops	Raddish, Sugar Beet
	Leafy crops	Lettuce
	Cereals/grass crops	Wheat
	n/a	
Rotational crops (metabolic pattern) **OECD Guideline 502**	**Crop groups**	**Crop(s)**
	Root/tuber crops	Raddish, Sugar Beet
	Leafy crops	Lettuce
	Cereal (small grain)	Wheat
Rotational crop and primary crop metabolism similar?	Yes	
Processed commodities (standard hydrolysis study) **OECD Guideline 507**	**Conditions**	
	Metalaxyl-M is stable under hydrolytic conditions representative for industrial processing, i.e. - pasteurisation (20 minutes at 90°C, pH 4); - boiling/brewing/baking (60 minutes at 100°C, pH 5); - sterilisation (20 minutes at 120°C, pH 6)	
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes	
Plant residue definition for enforcement (RD-Enf)	Metalaxyl and metalaxyl-M (metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers).	

List of endpoints

Residues

Plant residue definition for risk assessment (RD-RA)	Metalaxyl and metalaxyl-M (metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers).
Conversion factor (enforcement to risk assessment)	-

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)	
Animals covered	Goats, hens
Time needed to reach a plateau concentration in milk and eggs (days)	Milk: plateau reached immediately (feeding study duration 28 days) Eggs: possible that plateau had not been reached (residues continuously increasing along 4 days of dosing)
Animal residue definition for enforcement (RD-Enf) **OECD Guidance, series on pesticides No 31**	Not requiredfor the representative uses
Animal residue definition for risk assessment (RD-Enf)	Not requiredfor the representative uses
Conversion factor (enforcementto risk assessment)	n/a
Metabolism in rat and ruminant similar (Yes/No)	Yes
Fat soluble residues (Yes/No) **(FAO, 2009)**	No

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**	N/A
Field rotational crop study **OECD Guideline 504**	Following treatment of primary crops at maximal seasonal application rate (cf. GAP tomatoes: 300 g a.s./ha), residues of metalaxyl (sum of isomers) in edible parts of rotational/succeeding crops are expected to be below 0.05 mg/kg.

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

Plant products (Category)	Commodity	T (°C)	Stability (Month/Year)			
High water content	/	/	/	/	/	/
High oil content	/	/	/	/	/	/
High protein content	/	/	/	/	/	/
High starch content	/	/	/	/	/	/
High acid content	/	/	/	/	/	/

Residues of metalaxyl-M are stable during deep frozen storage (-20°C) for at least 24 months in commodities of plant origin from all four crop matrix categories. The ratio of the R- and S-enantiomers was constant over the storage period.

Total residues (determined as 2,6-dimethylaniline) of metalaxyl-M and CGA62826 appeared stable in muscle, liver, milk and eggs when stored at approximately –20°C for at least 21 months. In accordance with SANCO 7032/VI/95 rev.5 and OECD Technical Guideline 506 (2007), stability under those storage conditions can also be assumed for kidney and fat, although no storage stability testing was performed on these matrices.

List of endpoints

Residues

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

Commodity	**Outdoor/ Indoor** (a)	**Trial results relevant to the representative uses** (b)	**Recommendations/comments** (OECD calculations)	**MRL** proposals (mg/kg)	**HR** (mg/kg) (c)	**STMR** (mg/kg) (d)
Grapes	Outdoor	0.03;0.03;0.04;0.05;0.15; 0.16	Too small dataset (n=6) (**data gap**)	-	0.16	0.045
Tomatoes	Outdoor	<0.01 (2x); 0.02 (3x); 0.03;0.07; (0.02;<0.02)*	No apparent reason to consider 0.07 as an outlier; (*) overdosed trials (4 x 150 g a.s./ha); Some new trials gave residues >0.02 mg/kg, while in trials considered during MRL review (compliant with a more critical GAP), residues were always ≤ 0.02 mg/kg.	**0.1**	0.07	0.02
Spinach	Outdoor	<0.02 (3x)	No residue situation confirmed	**0.02**	<0.02	<0.02
Sunflower	Outdoor	<0.01 (2x); <0.02 (2x)	No residue situation confirmed	**0.02**	<0.02	<0.02

(a): Residues trials data relevant to the agricultural practices and climatic conditions in the UK, Indoor for glasshouse/protected crops. Country for an import tolerance.
(b): Residue levels in trials conducted according to GAPs reported in ascending order. When residue definitions for enforcement and risk assessment differ, **Enf/RA** differentiate data expressed according to the residue definition for **Enf**orcement and **R**isk **A**ssessment.
(c): **HR**: Highest residue, according to the residue for risk assessment, (within brackets when expressed according to the residue definition for enforcement: HR_{Enf})
(d): **STMR**: Supervised Trials Median Residue according to the residue definition risk assessment (within brackets when expressed according to the residue definition for enforcement: $STMR_{Enf}$)

List of endpoints

Residues

Inputs for animal dietary burden calculations

n/a: not applicable (no significant livestock dietary burden when solely considering the representative uses evaluated in the framework of renewal of the a.s. approval).

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

n/a: not applicable (no significant livestock dietary burden when solely considering the representative uses evaluated in the framewor renewal of the a.s. approval):

MRL calculations	**Ruminant**				**Pig/Swine**		**Poultry**		**Fish**	
Highest expected intake (mg/kg bw/d) (mg/kg DM for fish)	Beef cattle	No	Ram/Ewe	No	Breeding	No	Broiler	No	Carp	No
	Dairy cattle	No	Lamb	No	Finishing	No	Layer	No	Trout	No
							Turkey	No	Fish intake >0.1 mg/kg DM	
Intake >0.004 mg/kg bw	No		No		No		No		No	
Feeding study submitted	No		No		No		No		No	
Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and **N rates**	Level	Beef: N Dairy: N	Level	Lamb: N Ewe: N	Level	N rate Breed/Finish	Level	B or T: N Layer: N	Level	N rate Carp/Trout
	Estimated HR[(a)] at 1N	**MRL** proposals	Estimated HR[(a)] at 1N	**MRL** proposals	Estimated HR[(a)] at 1N	**MRL** proposals	Estimated HR[(a)] at 1N	**MRL** proposals	Estimated HR[(a)] at 1N	**MRL** proposals
Muscle	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Fat	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Meat[(b)]	n/a		n/a		n/a		n/a			
Liver	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a		
Kidney	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a		
Milk[(a)]	n/a	n/a	n/a	n/a						
Eggs							n/a	n/a		
Method of calculation[(c)]										

[(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

List of endpoints

Residues

(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.

List of endpoints

Residues

Summary of residues data according to the representative uses on raw agricultural commodities and feedingstuffs (Annex CA, point 6.3)

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
grapes	NEU (outdoor)	0.03;0.03;0.04;0.05;0.15; 0.16	Too small dataset (n=6) ***(data gap)***	-	0.16	0.045
	SEU (outdoor)	0.02 (2x); 0.03 (4x); 0.05 (2x); 0.06 (2x); 0.08; 0.13; 0.02; 0.44	No apparent reason to consider 0.44 as an outlier	**0.6**	0.44	0.04
tomatoes	NEU (outdoor)	<0.01 (2x); 0.02 (3x); 0.03;0.07; (0.02;<0.02)*	No apparent reason to consider 0.07 as an outlier; (*) overdosed trials (4 x 150 g a.s./ha); Some new trials gave residues >0.02 mg/kg, while in trials considered during MRL review (compliant with a more critical GAP), residues were always ≤ 0.02 mg/kg.	**0.1**	0.07	0.02
	SEU (outdoor)	<0.01 (2x); 0.01; 0.02 (2x); 0.03 (3x)		0.06	0.03	0.02
spinach	NEU (outdoor)	<0.02 (3x)	No-residue situation confirmed	**0.02***	<0.02	<0.02
	SEU (outdoor)	<0.02 (2x)	No-residue situation confirmed	0.02*	<0.02	<0.02
sunflower	NEU (outdoor)	<0.01 (2x); <0.02 (2x)	No-residue situation confirmed	**0.02***	<0.02	<0.02
	SEU (outdoor)	<0.02 (4x)	No-residue situation confirmed	0.02*	<0.02	<0.02

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17
(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the representative use

List of endpoints

Residues

(c) Highest residue

List of end points

Residues

List of endpoints

Residues

Conversion Factors (CF) for enforcementto risk assessment

n/a: not applicable (no significant livestock dietary burden when solely considering the representative uses evaluated in the framework of renewal of the a.s. approval):

Processing factors (Regulation (EU) N° 283/2013, Annex Part A, points 6.5.2 and 6.5.3)

Crop/ processed fraction	Number of trials [a]	Processing Factor (Pf)		Conversion Factor (CF_P) for RA[b]
		Individual values	Mean Pf	
Tomato: Washed fruit Wet pomace Dry pomace Juice Puree Canned fruit	4	0.63, 0.56, 0.43, 0.50, 2.13, 1.33, 2.43, 2.50, 10.50, 8.56, 12.14, 11.83, 0.63, 0.56, 0.57, 0.83, 2.00, 2.00, 2.71, 3.33, 0.38, 0.22, 0.29, 0.33	0.53 2.10 10.76 0.65 2.51 0.31	n/a
Grape / White wine: Must Wet pomace Dry pomace Stored white wine	2	0.65, 1.08, 0.38, 0.25, 1.57, 1.31, 0.95, 1.55, 3.35, 7.00, 4.57, 3.57, 0.52, 1.00, 0.33, 0.47	0.59 (0.86*) 1.35 4.62 0.58	n/a
Grape / Red wine Red wine Wet pomace Dry pomace Stored red wine		0.88, 1.22, 1.25, 0.80, 1.12, 1.74, 1.10, 0.95, 4.94, 6.61, 5.21, 3.58, 1.00, 1.30, 1.04, 0.58	1.04 1.23 5.09 0.98	n/a
Grape / Juice Wet pomace Dry pomace Pasteurised juice		2.08, 1.47, 0.53, 0.95, 6.04, 3.62, 3.50, 3.17, 1.98, 1.21, 0.27, 0.58	1.26 (1.77*) 4.08 1.01 (1.59*)	n/a
Grape / Raisin Raisins		3.20, 2.36, 2.40, 4.00	2.99	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 enforcement.

List of endpoints

Residues

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

Product code	Product	Crop	Existing GB MRL (mg/kg)	New or amended GB MRL (mg/kg)
A9642C	'Apron XL'	Table Grapes	2	No change
A9642C	'Apron XL'	Wine Grapes	1	No change
A9642C	'Apron XL'	Tomatoes	0.2	No change
A9642C	'Apron XL'	Spinach	0.05	No change
A9642C	'Apron XL'	Sunflower Seed	0.1	No change

* Indicates that the MRL is set at the limit of quantification/determination

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	Up to 2-33 % after 84 to 86 d, [^{14}C-phenyl label] (n[4]= 12)
Non-extractable residues after 100 days	Up to 14-73 % after 84 to 86 d, [^{14}C-phenyl label] (n[1]= 12)
Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)	NOA409045 : 6-72 % at 16-58 d (n=12) CGA67868 : 1-6 % at 7-28 d (n=12) SYN546520 : 1-4 % at 21-119 d (n=12) [14C-phenyl label]

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

Degradation pathway similar to the pathway under aerobic conditions, however at lower rate (study on metalaxyl).

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

No photodegradation was observed.

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	Aerobic conditions						
Soil type	X[5]	pH	t. °C / % MWHC	DT50 /DT90 (d)	DT_{50} (d) 20 °C pF2/10kPa[6]	Fit χ^2 error	Method of calculation
Gartenacker, loam ([redacted], 1996a)	-	7.25	20 °C / 40% MWHC	3.97 / 13.2	2.6[a]	3.66	SFO
Gartenacker, loam ([redacted], 1996a)	-	7.25	20 °C / 40% MWHC	5.73 / 19.0	3.75[a]	3.75	SFO

[4] n corresponds to the number of soils
[5] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.
[6] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

List of endpoints

Environmental fate and behaviour

Gartenacker, silt loam ([redacted] 2012a)	-	7.6	20 °C / pF2	3.3 / 10.9	3.3	3.3	SFO
Les Evouettes, silt loam ([redacted], 1994)	-	7.3	20 °C / 40% MWHC	3.90 / 13.0	2.38	7.31	SFO
Collombey, loamy sand ([redacted], 1995a)	-	7.4	20 °C / 40% MWHC	8.13 / 27.0	6.28	1.38	SFO
Birkenheide, sandy loam ([redacted], 2003a)	-	5.6	20 °C / 40% MWHC	26.4 / 87.6	22.5	2.70	SFO
Pappelacker, sandy loam ([redacted], 2003a)	-	7.5	20 °C / 40% MWHC	10.1 / 33.6	6.69	4.43	SFO
Marsillargues, silty clay ([redacted] 2012a)	-	8.0	20 °C / pF2	14.6 / 48.5	14.6	5.6	SFO
Gardner, sandy loam ([redacted] 2012a)	-	7.7	20 °C / pF2	8.2/27.3	8.2	6.5	SFO
18 Acres, sandy clay loam ([redacted] 2012a)	-	5.8	20 °C / pF2	3.8 / 12.7	3.8	4.5	SFO
San Miguel, sandy loam ([redacted] 2012a)	-	7.4	20 °C / pF2	73.1 / 243	73.1	2.3	SFO
median (n =10)					6.5	Median = Modelling endpoint for PECgw and PECsw	

[a] Values for similar soils (in this case Gartenacker) were averaged for the same year of sampling before calculating the overall geomean DT50

List of endpoints

Environmental fate and behaviour

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)

NOA409045	Aerobic conditions							
Soil type	X[1]	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. kdp/kf	DT_{50} (d) 20 °C pF2/10kPa[7]	Fit χ^2 error	Method of calculation
Gartenacker, loam ([redacted], 1996a)	-	7.25	20 °C / 40% MWHC	4.15 / 13.8	0.70 [a]	2.72[a]	9.04	SFO
Gartenacker, loam ([redacted], 1996a)	-	7.25	20 °C / 40% MWHC	15.5 / 51.4	0.72 [a]	10.2[a]	9.80	SFO
Gartenacker, silt loam ([redacted], 2012a)	-	7.6	20 °C / pF2	7.1 / 23.7	1	7.1	13.6	SFO
Birkenheide, sandy loam ([redacted], 2003a)	-	5.57	20 °C / 40% MWHC	96.6 / 321	0.66	82.3[b]	2.61	SFO
Birkenheide, sandy loam ([redacted], 2003c)	-	5.57	20 °C / 40% MWHC	69.4 / 230	-	59.1[b]	2.18	SFO
Pappelacker, sandy loam ([redacted], 2003a)	-	7.5	20 °C / 40% MWHC	7.88 / 26.2	0.83	5.22	10.3	SFO
Marsillargues, silty clay ([redacted] 2012a)	-	8.0	20 °C / pF2	161 / 536	0.78	161	8.8	SFO
Gardner, sandy loam ([redacted] 2012a)	-	7.7	20 °C / pF2	52.4 / 174	0.91	52.4	11.0	SFO
18 Acres, sandy clay loam ([redacted] 2012a)	-	5.8	20 °C / pF2	32.3 / 107	0.81	32.3	12.8	SFO

[7] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

List of endpoints

Environmental fate and behaviour

San Miguel, sandy loam ([redacted] 2012a)	-	7.4	20 °C / pF2	200 / 666	0.56	200	5.2	SFO
Geometric mean (n =8)						31.3 or 30.5 days	Geomean = Modelling endpoint for PECgw and PECsw As a result of a valid alternative calculation of geometric mean from this dataset, GB assessments may use a geometric mean DT50 value of 30.5 days	
Arithmetic mean (n = 8) formed from parent					0.783		Arithmetic mean = Modelling endpoint for PECgw and PECsw	

[a] Values for similar soils (in this case Gartenacker) were averaged for the same year of sampling before calculating the overall geomean DT50

[b] Values for similar soils (in this case Birkenheide) were averaged for the same year of sampling before calculating the overall geomean DT50

CGA67868	Aerobic conditions							
Soil type	X[1]	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k f	DT_{50} (d) 20 °C pF2/10kPa[8]	Fit χ^2 error	Method of calculation
Gartenacker, silt loam ([redacted], 2012a)	-	7.6	20 °C / pF2	1.6 / 5.4	0.53	1.6a	10.9	SFO
Gartenacker, silt loam ([redacted] 2012)	-	7.2	20 °C / pF2	2.1 / 6.8	-	2.1a	9.1	SFO
18 Acres, sandy loam ([redacted] 2012)	-	5.9	20 °C / pF2	2.6 / 8.7	-	2.6	5.6	SFO
Gardner, sandy loam ([redacted] 2012)	-	7.6	20 °C / pF2	4.9 / 16.2	-	4.9	3.3	SFO

[8] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

List of endpoints

Environmental fate and behaviour

Geometric mean/median (n = 3)				2.9 / 2.6	Geomean = Modelling endpoint for PECgw and PECsw
Arithmetic mean (n = 1) formed from NOA409045			0.53[b]		Modelling endpoint for PECgw and PECsw

[a] Values for similar soils (in this case Gartenacker) were averaged for the same year of sampling before calculating the overall geomean DT50
[b]kinetic formation fraction from NOA409045

SYN546520	Aerobic conditions							
Soil type	X[1]	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k f	DT_{50} (d) 20 °C pF2/10kPa[9]	Fit χ^2 error	Method of calculation
Gartenacker, silt loam ([redacted], 2012b)	-	7.4	20 °C / pF2	42.1 / 139.8	-	42.1	5.5	SFO
Marsillargues, silty clay ([redacted], 2012b)	-	8.1	20 °C / pF2	74.9 / 248.7	-	74.9	4.3	SFO
18 Acres, sandy clay loam ([redacted], 2012b)	-	6.2	20 °C / pF2	287.9 / 956.5	-	287.9	1.9	SFO
Geometric mean/median (n = 3)						96.8 / 74.9	Geomean = Modelling endpoint for PECgw and PECsw	
Arithmetic mean (n = 0) formed from NOA409045					-		Modelling endpoint for PECgw and PECsw	
Default formation fraction formed from NOA409045					0.47		Modelling endpoint for PECgw and PECsw (0.47 = 1 –ffm CGA67868)	
~~Formation fraction derived from inverse modelling~~					~~0.10~~			

[9] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

List of endpoints

Environmental fate and behaviour

Rate of degradation field soil dissipation studies for use as triggering endpoints (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)

FIELD TRIGGER ENDPOINTS								
Parent	Aerobic conditions; longest non-normalised DT_{50}							
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	X^5	pH	Depth (cm)	DT_{50} (d)	DT_{90} (d)	St. (χ^2)	Method of calculation
Sandy loam, bare ground (with sparse grass)	Elena (IT) (2383/97)	-	7.5	0-30	11.9	39.6	18.1	SFO
Silty clay loam, bare ground (with sparse grass)	Marsillargues (FR) (2036/98)	-	7.4	0-30	13.5	44.7	26.5	SFO
Silty clay loam, bare ground (with sparse grass)	Bastia di Rovolon (IT) (2027/99)	-	7.3	0-30	18.1	60.1	14.9	SFO
Loam, bare ground (with sparse grass)	Vouvry (CH) (2028/99)	-	7.4	0-30	4.6	15.3	12.5	SFO
Silty clay, bare ground (with sparse grass)	Vouvry (CH) (2029/99)	-	7.1	0-30	12.4	41.3	14.2	SFO
Loamy sand, bare ground (with sparse grass)	Sevilla (SP) (2057/99)	-	7.8	0-30	15.3	50.9	9.02	SFO
Loam, bare ground (with sparse grass)	Aimargues (FR) (2030/99)	-	7.4	0-30	30.9	102.6	11.4	SFO
Loamy sand, bare ground	Middelfart (DK) (gb 31099)	-	6.9	0-30	20.9	69.5	5.74	SFO
Loam, bare ground (with sparse grass)	Sept Saux (FR) (SYN-0734)	-	7.8	0-30	9.3	30.7	14.8	SFO
Silty loam, bare ground (with sparse grass)	Lower Saxony (DE) (T012218-05)	-	6.0	0-30	19.7	65.4	11.6	SFO
~~Geometric Mean/median (n=10)~~					~~14.1 / 14.4~~	~~46.7 / 47.8~~		
Maximum					30.9	102.6		

List of endpoints

Environmental fate and behaviour

FIELD TRIGGER ENDPOINTS								
NOA409045	Aerobic conditions; longest non-normalised DT_{50}							
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	X^5	pH	Depth (cm)	DT_{50} (d)	DT_{90} (d)	St. (χ^2)	Method of calculation
Sandy loam, bare ground (with sparse grass)	Elena (IT) (2383/97)	-	7.5	0-30	16.0	53.3	26.8	SFO
Silty clay loam, bare ground (with sparse grass)	Marsillargues (FR) (2036/98)	-	7.4	0-30	20.5	68.0	16.4	SFO
Silty clay loam, bare ground (with sparse grass)	Bastia di Rovolon (IT) (2027/99)	-	7.3	0-30	14.9	49.6	59.0	SFO
Loam, bare ground (with sparse grass)	Vouvry (CH) (2028/99)	-	7.4	0-30	5.8	19.2	25.7	SFO
Silty clay, bare ground (with sparse grass)	Vouvry (CH) (2029/99)	-	7.1	0-30	8.3	27.7	44.7	SFO
Loamy sand, bare ground (with sparse grass)	Sevilla (SP) (2057/99)	-	7.8	0-30	uncertain	uncertain	n.a	SFO
Loam, bare ground (with sparse grass)	Aimargues (FR) (2030/99)	-	7.4	0-30	15.9	52.8	20.7	SFO
Loamy sand, bare ground	Middelfart (DK) (gb 31099)	-	6.9	0-30	39.8	132.2	20.9	SFO
Loam, bare ground (with sparse grass)	Sept Saux (FR) (SYN-0734)	-	7.8	0-30	27.1	89.9	34.5	SFO
Silty loam, bare ground (with sparse grass)	Lower Saxony (DE) (T012218-05)	-	6.0	0-30	30.2	100	22.3	SFO
~~Geometric Mean/median (n=9)~~					~~17.1 / 16.0~~	~~56.6 / 53.3F~~		
Maximum					39.8	132.2		

List of endpoints

Environmental fate and behaviour

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

Rate of degradation in soil active substance, normalised geometric mean (if not pH dependent)	Not relevant, laboratory data only used for modelling for parent and metabolites
pH dependence (yes/no)	No

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

Soil accumulation and plateau concentration	Not relevant, accumulation consideration not triggered

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)

Degradation pathway similar to the pathway under aerobic conditions, however at lower rate. DT50lab (20°C, anaerobic): - not required.

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)

Degradation pathway similar to the pathway under aerobic conditions, however at lower rate. DT50lab (20°C, anaerobic): - not required.

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

No Photodegradation nor photolysis observed.

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	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Maryland, clay ([redacted], 1987)	2.82	5.9			8.01	283.8	1.16
Maryland, sand ([redacted], 1987)	0.53	6.5			0.157	29.6	0.795
Mississippi, loam ([redacted], 1987)	0.71	7.6			1.41	199.8	1.31
Collombey, sand ([redacted], 1978a)	1.28	7.8			0.43	33.6	0.83
Lakeland, sand ([redacted], 1978a)	0.696	6.3			0.48	69.0	0.79
Les Evouettes, loam ([redacted], 1978a)	2.09	6.1			0.87	41.6	0.77
Vetroz, sandy clay loam ([redacted], 1978a)	3.25	6.7			1.40	43.1	0.83
Mississippi, clay ([redacted], 1995)	1.33	7.0			7.61	570	1.45
Maryland, sand ([redacted], 1995)	0.348	5.4			0.0700	20	0.892
Washington, loam ([redacted], 1995)	1.51	7.0			1.30	86	1.05
Borstel, loamy sand ([redacted], 1999)	1.2	5.0			0.480	40.0	0.923
Pappelacker, loamy sand ([redacted], 1999)	1.1	7.6			0.318	28.9	0.900
Gartenacker, silt loam ([redacted], 1999)	2.08	7.3			0.644	31.0	0.908
Vetroz, silt loam ([redacted], 1999)	4.7	7.2			1.67	35.5	0.928
Illarsaz, silt loam ([redacted], 1999)	19.8	6.7			7.88	39.8	0.929
Birkenheide, sandy loam ([redacted], 2002)	0.84	5.57			0.339	40.4	0.963
Pappelacker, sandy loam ([redacted], 2002)	1.56	7.47			0.480	30.8	0.956
Gartenacker, silt loam ([redacted], 2002)	1.81	7.30			0.700	38.7	0.937
Vetroz, silt loam ([redacted], 2002)	1.77	7.70			0.717	40.5	0.934
Birkenheide, sandy loam ([redacted], 2001b)	0.94	5.65			0.372	39.6	0.92
Gartenacker, silt loam ([redacted], 2012a)	1.97	7.6			0.5	26	0.979
18 Acres, sandy clay loam ([redacted], 2012a)	3.19	5.8			0.9	29	0.910
Marsillargues, silty clay ([redacted], 2012a)	1.04	8			0.7	58	0.942

List of endpoints

Environmental fate and behaviour

Gardner, sandy loam ([redacted], 2012a)	2.84	7.7			1.9	67	0.923
Work Ranch, sandy loam ([redacted], 2012a)	2.44	7.4			1.3	52	0.954
Median (n=25)						40.0	0.93
Arithmetic mean (if not pH dependent) (n=25)						78.9	0.955
pH dependence, Yes or No			No				

Note: Kfoc values were obtained on racemic and R-enantiomer for Parent

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

Metabolite: NOA409045							
Soil Type	OC %	Soil pH	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Mississippi, clay ([redacted] 1996)	1.22	6.1			0.875	72	0.947
Maryland, sand ([redacted] 1996)	0.348	5.4			0.124	36	0.927
California, sandy loam ([redacted] 1996)	0.58	6.9			0.0175	3	0.867
Washington, loam ([redacted] 1996)	1.28	7.0			0.105	8	0.909
Arizona, clay loam ([redacted] 1996)	0.58	7.9			0.0992	17	0.929
Les Evouettes, loam ([redacted], 1994a)	1.4	5.5			0.3	22	0.91
Staffort, sandy loam ([redacted], 1998)	0.77	5.2			0.120	15.4	0.935
Gartenacker, loam ([redacted], 1998)	2.40	7.2			0.210	8.88	0.960
Vetroz, silt loam ([redacted], 1998)	4.39	7.1			0.440	9.94	0.956
Birkenheide, sandy loam ([redacted], 2001c)	0.84	5.57			0.131	15.6	0.907
Pappelacker, sandy loam ([redacted], 2001c)	1.56	7.47			0.139	8.9	0.940
Gartenacker, silt loam ([redacted], 2001c)	1.81	7.30			0.205	11.3	0.918
Vetroz, silt loam ([redacted], 2001c)	1.77	7.70			0.173	9.8	0.930
Birkenheide, sandy loam ([redacted], 2001d)	0.94	5.65			0.122	12.9	0.956
Arithmetic mean (if not pH dependent) (n=14)						17.9	0.928
Median (n=14)						12.1	
pH dependence (yes or no)			No				

Note: Kfoc values were obtained on racemic and R-enantiomer for metabolite NOA409045

List of endpoints

Environmental fate and behaviour

Metabolite: SYN546520							
Soil Type	OC %	Soil pH	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Gartenacker, silt loam ([redacted], 2012b)	2.7	7.2			0.1	3	1.131
18 Acres, sandy clay loam ([redacted], 2012b)	2.4	5.9			0.4	15	0.964
Seven springs, loamy sand ([redacted], 2012b)	0.5	5.8			0.2	41	0.951
Gardner, sandy loam ([redacted], 2012b)	2.7	7.6			0.1	2	1.366
Arithmetic mean-n=4						15.2	1.1
pH dependence (yes or no)					No		

Metabolite: CGA67868							
Soil Type	OC %	Soil pH	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Gartenacker, silt loam ([redacted], 2012c)	2.0	7.6			0.4	20	0.822
18 Acres, sandy clay loam ([redacted], 2012c)	3.2	5.5			0.5	16	0.879
Marsillargues, silty clay ([redacted], 2012c)	1.2	7.8			0.2	20	0.794
Gardner, sandy loam ([redacted], 2012c)	2.8	7.3			0.5	19	0.816
Madera, sandy loam ([redacted], 2012c)	0.7	6.9			0.1	20	1.169
Arithmetic mean (n=5)					19		0.896
pH dependence			No				

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	Metalaxyl, 200 mm rainfall, 2 days, 4 soils : 0.4-92% RR in the leachate
Aged residues leaching	Metalaxyl, 508 mm rainfall, 4 soils : 7.7-76.7% RR in the leachate Metalaxyl-M, 508 mm rainfall, 4 soils : 12.1-61.4% RR in the leachate

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	4 lysimeters, appl. rate: 330-365 g racemic metalaxyl/ha/season cropped with potato or vine: Concentration in the leachate of one year : metalaxyl : <0.01 to 0.05 µg/L CGA 62286 : 0.25-4.12 µg/L CGA108906 : 0.48-1.11 µg/L Field leaching studies received low weight in the final assessment.

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

Hydrolytic degradation of the active substance and metabolites > 10 %	(metalaxyl-M) No hydrolysis at any pH
	/
	/

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

Direct photolytic degradation of active substance and metabolites above 10 %	(metalaxyl-M) No photolysis
Quantum yield of direct phototransformation in water at Σ > 290 nm	/
Indirect photolytic degradation of active substance and metabolites above 10 %	/
Quantum yield of direct phototransformation in water at Σ > 290 nm	/

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

Readily biodegradable (yes/no)	(metalaxyl-M) No

Aerobic mineralisation in surface water (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.1)
Not submitted

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 Water (max in water 105.7% after 0d. Max sed 20.4% after 7d)						
				Whole system		Water		Sediment		
Water / sed system	pH water	pH sed	t. °C	$DegT_{50}$ /$DegT_{90}$	St. (r^2)	$DisT_{50}$ /$DisT_{90}$	St. (r^2)	$DisT_{50}$ /$DisT_{90}$	St. (r^2)	Method of Calculation
River	7.9	7.5	20	47.1/157	3.6	37.2/124	6.7	51.7/172	7.5	SFO
Pond	8.2	6.9	20	21.9/ 72.7	8.4	16.6/55.2	6.1	19.6/65.0	13	SFO
Geometric mean at 20°C[b)]				32.1/106.8	-	24.8/82.7	-	31.8/105.7	-	SFO

Metabolite CGA62826	Distribution (max in water 68.8% after 112 days. Max. sed 23.0% after 56 d) .									
Water / sediment system	pH water phase	pH sed	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)]				>1 year	-	-	-	-	-	-

Mineralisation and non extractable residues (from parent dosed experiments)					
Water / sediment system	pH water phase	pH sed	Mineralisation x % after n d. (end of the study).	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)
River	7.9	7.5	7.6% at 240 days	10.4% at 240 days	10.4% at 240 days
Pond	8.2	6.9	4.1% at 240 days	13.8% at 240 days	13.8% at 240 days

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

Vapour pressure	3.3×10^{-3} Pa at 25°C (97.2% pure)
Henry's law constant	3.5×10^{-5} $Pa.m^3/mol$ at 25°C (97.2% pure)
Direct photolysis in air	/
Photochemical oxidative degradation in air	DT_{50} = 4.8 of hours derived by the Atkinson model (AOP version 1.92) assuming 12h dark/ 12h light

List of endpoints

Environmental fate and behaviour

Volatilisation	from plant surfaces: 35% volatilization (after 24 h, glasshouse conditions) from soil: rate of volatilization (TRR) was calculated at 6-10 g/ha/day (35°C, 30l/h air flow (Note: 49% of the volatilized radioactivity was determined as metalaxyl, however the report does not provide total volatilized radioactivity)
Metabolites	/
PEC (air)	
Method of calculation	Not required : a.s. slightly volatile, short half-life

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: Metalaxyl-M, NOA409045 Surface water: Metalaxyl-M, NOA409045 Sediment: Metalaxyl-M, NOA409045 Groundwater: Metalaxyl-M, NOA409045, CGA67868 and SYN546520 Air: Metalaxyl-M

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

	See Ecotoxicology section

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

Soil	No Data
Surface water	No Data
Groundwater	In the studies performed in Europe that did include metalaxyl, no or only few detections of this compound were made. Where quantitatively reported, the concentrations found were < 0.1 µg/L. On the whole, the conclusion can be drawn that the uses of metalaxyl over the past 20 years have not led to more than occasional

	detections of metalaxyl in groundwater. Hardly ever did residues exceed 0.1 µg/L. Data from USA and Canada show that metalaxyl is detected in a limited number of wells at levels > 0.1 µg/L. These data reveal that applications at high rates (not intended for EU GAP) are susceptible to contaminate groundwater. A monitoring study carried out in France (2007-2011) was initiated to investigate the residues of metalaxyl-M and its metabolites NOA409045 and CGA108906 in groundwater throughout the major potato, vine, hop and strawberry growing regions of France. Surveys of the use were conducted in the confirmed or supposed recharge area of the wells. No quantifiable metalaxyl-M and CGA108906 residues (>0.05 µg/L) were determined in any of the groundwater samples. Quantifiable residues of NOA409045 were determined in 7 samples (2%) taken from 3 of the sites, in the range 0.05 to 0.08 µg/L. A Portuguese study (1999-2007) focussed on monitoring in vulnerable areas with widespread use of a variety of plant protection products. Among the 773 water samples which were analysed from 68 different sampling sites, only one sample contained a measurable residue of metalaxyl at high level (22 µg/L). It is assumed that this concentration was caused by point source contamination.
Air	No data

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

Note that metalaxyl-M is listed as the only ecotoxicologically relevant substance for soil (see Ecotoxicology section) and only initial PECsoil values are required for risk assessment. PECsoil values are not calculated for metabolites.

Product: Vibrance SB		
Parent	DT50 (d)	30.9 days
Method of calculation	Kinetics	SFO
	Field or Lab	representative worst case from field dissipation studies.
Application data	Crop	Sugar beet & fodder beet
	Application rate(s)	0.62g as/ha
	% plant interception	No crop interception (seed treatment)
	Number of applications	1
	Interval (d)	/
	Depth of soil layer	5cm
	Soil bulk density	1.5g/cm^3

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

Product: Wakil XL		
Parent	DT50 (d)	30.9 days
Method of calculation	Kinetics	SFO
	Field or Lab	representative worst case from field dissipation studies.
Application data	Crop	Combining and vining peas
	Application rate(s)	95g as/ha

List of endpoints

Environmental fate and behaviour

		% plant interception	No crop interception (seed treatment)	
		Number of applications	1	
		Interval (d)	/	
		Depth of soil layer	5cm	
		Soil bulk density	1.5g/cm^3	
PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.127	/	/	

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

Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance.

Product: Vibrance SB	
Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	For FOCUS gw modelling, values used – Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. Model(s) used: FOCUS PEARL 4.4.4 and FOCUS PELMO 5.5.3 Scenarios (list of names): see below Crop: Sugar beet Plant uptake for all substances: 0 Q_{10} : 2.58 *Metalaxyl-M* Molecular mass: 279.3 g/mol Geometric mean: DT_{50lab} : 6.5d (20°C, pF2). K_{foC}/K_{fOM}: median 40.0 / 23.2, $^1/_n$ Arithmetic Mean= 0.955 Solubility : 26000 mg/L (25°C) Vapour pressure: 0.0033 Pa (25°C) Formation fraction : not applicable *NOA409045* Molecular mass: 265.3 g/mol Geometric mean DT_{50lab} : 30.5d ~~31.3d~~ (20°C, pF2). K_{foC}/K_{fOM}: Arithmetic Mean 12.1 / 7.02 mL/g, $^1/_n$ Arithmetic mean = 0.928 Solubility: 265000 mg/L (25°C) Vapour pressure : $1x10^{-5}$ Pa (20°C) Formation fraction: 0.783 from metalaxyl-M Metabolite conversion factor for MACRO: 0.744 *SYN546520* Molecular mass: 295.3 g/mol

List of endpoints

Environmental fate and behaviour

	Geometric mean: DT_{50lab} : 96.8 d (20°C, pF2). K_{foC}/K_{fOM}: Arithmetic mean 15.2 / 8.82 mL/g, $^1/_n$ Arithmetic Mean = 1.1 Solubility: 265000 mg/L (25°C) Vapour pressure : $1x10^{-5}$ Pa (20°C) Formation fraction : 0.47 from NOA409045 Metabolite conversion factor for MACRO: Not used *CGA67868* Molecular mass: 193.2 g/mol Geometric mean DT_{50lab} : 2.9 d (20°C, pF2). K_{foC}/K_{fOM}: Arithmetic mean 19.0 / 11.0, $^1/_n$= 0.896 ~~0.9~~ Solubility: 45800 mg/L (25°C) Vapour pressure : $1x10^{-5}$ Pa (20°C) Formation fraction : 0.53 from NOA409045 Metabolite conversion factor for MACRO: Not used Note: The secondary metabolites CGA67868 and SYN546520 were not simulated in MACRO because CGA67868 was never predicted at >0.001 µg/L with PEARL and PELMO. In addition, SYN546520 is not a relevant metabolite and in the approval assessment modelling at higher doses predicted concentrations >10 µg/L.
Application rate	Application rate: 0.62 g a.s./ha Crop interception (%) : 0 No. of applications : 1 Interval : Not applicable Application type: Annual Time of application : Chateaudun: 25 March (MACRO Julian day 84) Hamburg: 1 April Kremsmunster: 1 April Okehampton: 10 April Seed treatment, residue placed at 5cm depth

Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance	
Product: Wakil XL	
Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	For FOCUS gw modelling, values used – Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. Model(s) used: FOCUS PEARL 4.4.4 and FOCUS PELMO 5.5.3 Scenarios (list of names): see below Crop: Peas Plant uptake for all substances: 0 Q_{10} : 2.58 *Metalaxyl-M* Molecular mass: 279.3 g/mol Geometric mean: DT_{50lab} : 6.5d (20°C, pF2). K_{fOC}/K_{fOM}: median 40.0 / 23.2, $^1/_n$ Arithmetic Mean= 0.955 Solubility : 26000 mg/L (25°C) Vapour pressure: 0.0033 Pa (25°C) Formation fraction : not applicable *NOA409045* Molecular mass: 265.3 g/mol Geometric mean DT_{50lab} : 30.5d ~~31.3d~~ (20°C, pF2). K_{fOC}/K_{fOM}: Arithmetic Mean 12.1 / 7.02 mL/g, $^1/_n$ Arithmetic mean = 0.928 Solubility: 265000 mg/L (25°C) Vapour pressure : $1x10^{-5}$ Pa (20°C) Formation fraction: 0.783 from metalaxyl-M Metabolite conversion factor for MACRO: 0.744 *SYN546520* Molecular mass: 295.3 g/mol Geometric mean: DT_{50lab} : 96.8 d (20°C, pF2). K_{fOC}/K_{fOM}: Arithmetic mean 15.2 / 8.82

List of endpoints

Environmental fate and behaviour

	mL/g, $^{1}/_{n}$ Arithmetic Mean = 1.1 Solubility: 265000 mg/L (25°C) Vapour pressure : 1x10^{-5} Pa (20°C) Formation fraction : 0.47 from NOA409045 Metabolite conversion factor for MACRO: 0.3891 *CGA67868* Molecular mass: 193.2 g/mol Geometric mean DT_{50lab} : 2.9 d (20°C, pF2). K_{fOC}/K_{fOM}: Arithmetic mean 19.0 / 11.0, $^{1}/_{n}$= 0.896 ~~0.9~~ Solubility: 45800 mg/L (25°C) Vapour pressure : 1x10^{-5} Pa (20°C) Formation fraction : 0.53 from NOA409045 Metabolite conversion factor for MACRO: 0.2871 Note: secondary metabolites CGA67868 and SYN546520 were simulated in MACRO due to higher dose
Application rate	Application rate: 95 g a.s./ha Crop interception (%) : 0 No. of applications : 1 Interval : Not applicable Application type: Annual Time of application : Chateaudun: 25 March (MACRO Julian day 84) Hamburg: 25 March Okehampton: 25 March Seed treatment, residue placed at 5cm depth

List of endpoints

Environmental fate and behaviour

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

FOCUS PEARL /Sugar beet

Scenario	Parent (µg/L)	Metabolite (µg/L)		
		NOA409045	CGA67868	SYN546520
Châteaudun	<0.001	0.018	<0.001	0.062
Hamburg	<0.001	0.020	<0.001	0.093
Kremsmünster	<0.001	0.012	<0.001	0.049
Okehampton	<0.001	0.011	<0.001	0.040

FOCUS PELMO / Sugar beet

Scenario	Parent (µg/L)	Metabolite (µg/L)		
		NOA409045	CGA67868	SYN546520
Châteaudun	<0.001	0.013	<0.001	0.074
Hamburg	<0.001	0.014	<0.001	0.066
Kremsmünster	<0.001	0.012	<0.001	0.051
Okehampton	<0.001	0.013	<0.001	0.039

FOCUS MACRO / Sugar beet

Scenario	Parent (µg/L)	Metabolite (µg/L)		
		NOA409045	CGA67868	SYN546520
Châteaudun	<0.001	0.007	Not calculated	Not calculated

FOCUS PEARL / Peas

Scenario	Parent (µg/L)	Metabolite (µg/L)		
		NOA409045	CGA67868	SYN546520
Châteaudun	<0.001	1.105	0.030	8.713
Hamburg	<0.001	4.809	0.142	14.642
Okehampton	<0.001	2.265	0.066	5.699

FOCUS PELMO / Peas

Scenario	Parent (µg/L)	Metabolite (µg/L)		
		NOA409045	CGA67868	SYN546520
Châteaudun	<0.001	0.727	0.019	7.019
Hamburg	<0.001	2.917	0.077	10.175
Okehampton	0.001	2.385	0.067	5.286

FOCUS MACRO / Peas

Scenario	Parent (µg/L)	Metabolite (µg/L)		
		NOA409045	CGA67868	SYN546520
Châteaudun	<0.001	0.754	<0.001	5.22

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

Note that metalaxyl-M is listed as the only ecotoxicologically relevant substance for surface water and sediment (see Ecotoxicology section). PECsw and PECsed values are not calculated for metabolites.

Calculation method	Spray drift: Not applicable (seed treatment) Drainflow: HSE Excel Calculator (first tier)
Parent input parameters	
Molecular mass (g/mol)	279.3
Crop uptake factor	Not required at 1st tier
Median Koc (mL/g)	40
Arithmetic mean 1/n	Not required at 1st tier
Geometric mean parent DT_{50}	Not required at 1st tier
$DisT_{50}$ water (d)	Not required at 1st tier
$DisT_{50}$ sediment (d)	Not required at 1st tier
Maximum in sediment (% AR)	20.4
Crop and application data	
Crop	Sugar beet / peas
Crop growth stage	BBCH 00
Canopy interception %	0
No. of applications	1
Application rate(s)	Sugar beet: 0.62 g a.s./ha Peas: 95 g a.s./ha

Drainflow - parent (tier 1)		
Use	PECsw (µg/L)	PECsed (µg/kg)
Sugar beet	0.091	0.085
Peas	13.885	13.073

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

PEC (air)

Method of calculation	Not required: a.s. slightly volatile, short half-life

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 (mg/kg bw/day)	End Point (mg/kg feed)
Birds				
Colinus virginianus	metalaxyl-M	Acute	1419	
Colinus virginianus	metalaxyl-M	Acute	981	
Geomean (*Colinus virginianus*)	metalaxyl-M	Acute	**1180**	
Anas platyrhynchos	metalaxyl	Acute	1466	
Colinus virginianus	RIDOMIL GOLD	Acute	3228	
LD_{50} (mix)	RIDOMIL GOLD	Acute	1924	
Colinus virginianus	metalaxyl-M	Short-term		> 5620
Coturnix coturnix japanica	metalaxyl	Short-term		> 10000
Colinus virginianus	metalaxyl	Short-term		> 10000
Anas platyrhynchos	metalaxyl	Short-term		> 10000
Colinus virginianus	metalaxyl-M	Long-term	84	900
Anas platyrhynchos	metalaxyl-M	Long-term	117	900
Colinus virginianus	metalaxyl	Long-term		900
Anas platyrhynchos	metalaxyl	Long-term	**24.6**	300
Mammals				
rat	metalaxyl-M	Acute	953 (male) **375** (female)	
rat	APRON	Acute	> 3000 (male) > 1000 < 3000 (female)	
rat	RIDOMIL GOLD	Acute	> 5000	
rat	CGA 62826	Acute	> 2000	
rat	CGA 108906	Acute	> 2000	
rat	metalaxyl	Long-term	**96**	
rat	CGA 62826	Long-term	1000	
rat	CGA 108906	Long-term	200	
Additional higher tier studies				

Supervised cage or field trials were conducted to support the avian risk assessment of the formulation APRON.

[redacted] (2006).

Utilisation of freshly drilled sunflower and maize fields in southern France by birds.

Surveys were carried out in freshly drilled maize and sunflower fields in southern France, to identify the observed birds to species level (qualitative assessment) and to determine the abundance, frequency of occurrence and dominance of the identified species (quantitative assessment).

The magpie, red-legged partridge, carrion crow and starling are the most common bird species found in freshly drilled sunflower fields in southern France. The most common bird species in freshly drilled maize fields are carrion crow, magpie, yellow-legged gull and starling. They are characterised by the largest figures for abundance, frequency of occurrence and dominance.

Fields adjacent to shrubs and hedges showed higher, but not significantly different abundances than fields bordered by other habitat types. Also, bird densities on headland parts of sunflower and maize fields were higher than on mainland areas, although this difference again was not statistically significant. The results calculated separately for maize and sunflower fields are similar regarding the common bird species. Hence, it seems justifiable to consider this type of habitat (freshly drilled plain surface) as comparable across the two crops, in terms of the use by birds.

Foraging was the most prevalent type of behaviour. 91.1% of all birds observed were foraging at the instant of observation. However, no information can be given about the type of food taken from drilled fields (e.g. seeds, arthropods and other invertebrates, weeds, harvest remains etc.).

[redacted]. (2008).

Exposure of Birds in Cereals in Germany in Spring – Attractiveness of Cereal Fields, Portion of Time and Diet Composition.

The study was conducted to identify relevant focal species for risk assessment in cereals. For the focal species identified an estimate was made by radio-tracking individual birds (including visual observations) to estimate proportion of diet obtained in cereal fields (PT estimate) and determined the proportion of different food types in the diet (PD estimates) by analysing faeces. The study was conducted in an agrarian landscape with a high proportion of cereal fields in the Hunsrueck region of western Germany. Ornithological observations (transect counts, scan sampling) confirmed that the skylark is the most abundant species on winter cereal fields in spring and also uses freshly drilled spring cereal fields as a foraging habitat. Eleven individually radio-tracked skylarks showed no particular preference to, or avoidance of, cereal fields compared to other crops but spent a significant amount of their 'potential foraging time' in winter cereal (BBCH 21 - 32) and in freshly sown spring cereal fields (BBCH ≤ 10). According to volume proportion analysis their diet mainly consisted of grass material and cereals, before spring cereals were drilled. Thereafter other plant material i.e. grass or cereal seeds and leaf remains made up the majority of the diet. Consumption of animal matter increased slightly during spring. For risk assessment purposes a value for portion of time (PT) spent potentially foraging in cereal fields for skylarks was calculated. For winter cereal fields in spring the PT value was 0.449 (44.9%), for freshly sown spring cereal fields 0.174 (17.4%).

[redacted]. (2012).

Fluodioxinil, Thiabendazole, Azoxystrobin and Metalaxyl-M - Dissipation of residues on treated maize seed and shoots.

Residue dissipation of fludioxinil, thiabendazole, azoxystrobin and metalaxyl-M was measured on treated maize seeds placed on the soil surface to refine exposure estimates for birds and mammals that might consume seeds. In addition, the shoots of seedlings emerging from drilled seed were analysed for thiabendazole and metalaxyl-M because both substances are systemic and may be eaten by bird and mammals.

Residues studies were replicated at 3 sites in the United Kingdom during 2011.

Samples of maize seed from the surface (protected and unprotected) were collected at 0, 1, 2, 4, 7, 10, 14 and 21 days. Protected seeds were sheltered from rain by a polythene film that was later shown to filter out most UV light (300-400nm).

Maize seed was drilled and allowed to emerge before sampling of the above ground plant shoots. Shoots were sampled at 7 time points to be representative of growth stages from emergence up to BBCH 15.

There was significant dissipation of fludioxinil, thiabendazole, azoxystrobin and metalaxyl-M on maize seeds placed on the soil surface.

There was initial uptake followed by dissipation of thiabendazole and metalaxyl-M in shoots of maize seedlings.

Dissipation was different for protected and unprotected seeds. Seed protection resulted from both rainfall and UV light (300-400nm).

[redacted] **N. (2012).** **The uptake of metalaxyl-M from treated seeds into the shoots of emerging seedlings.** The movement of metalaxyl-M from APRON treated sunflower seeds into newly emergent vegetative tissue was measured. The total seedling weight, root weight and above ground weight was also measured at regular intervals for the 21 days post-emergence. Over the 21-day observation period, spinach and sunflower shoots grow more rapidly than envisaged in the foliar dilution factor of 5 as outlined in the EFSA Guidance Document on Birds and Mammals. Furthermore only a small amount of the applied metalaxyl-M moves from the treated seed into the emergent vegetative tissue.
Studies investigating the acceptance of bait, granules or treated seeds by birds were conducted to support the avian risk assessment of the formulation APRON.
[redacted] **(1997).** **CGA329351 350 ES (A9642C) – Palatability and Dietary Toxicity to the Pheasant.** In a 14-day palatability and dietary toxicity test, adult pheasants, *Phasianus colchicus*, were given either treated seeds only, a choice of treated and untreated seeds, or untreated seeds only. Sunflower seeds treated with APRON, applied at a rate of 0.914 g metalaxyl-M/kg, are palatable and non-toxic to the pheasant, *Phasianus colchicus*.
[redacted] **(2004a).** **Untreated seeds: Seed selection by the house sparrow (*Passer domesticus*).** Under the conditions of the study house sparrow can be expected to consume significant amounts of wheat (small grain cereal), peas and cucumber seed if available on the soil surface. All other seeds tested, sugarbeet, oilseed rape, pepper, melon, carrot, lettuce, cotton, maize, soya and tomato can be considered unattractive or eaten in negligible amounts. These results were consistent with [redacted] (1999).
[redacted] **(2004b).** **Untreated seeds: Seed selection by the grey partridge (*Perdix perdix*).** Under the conditions of the study grey partridge can be expected to consume significant amounts of wheat (small grain cereal), oilseed rape and tomato seed if available on the soil surface. All other seeds tested, sugarbeet, pepper, cucumber, melon, carrot, lettuce, cotton, maize, soya and pea can be considered unattractive or eaten in negligible amounts. With the exception of peas, these results were consistent with [redacted] (1999).

Supervised cage or field trials were conducted to support the mammalian risk assessment of the formulation APRON.
[redacted] **(2006).** **Generic Field Monitoring of Mammals on Cereal Fields in Spring and Summer in Germany.** The study area comprised winter cereal fields in the region of Thale, Germany. Small mammal use of cereal fields was monitored by means of live-trapping. Three species were caught, wood mouse, common vole and yellow-necked mouse, but the latter species preferred off-field habitats. Individual wood mice and common voles were radio-tracked continuously from dusk till dawn (wood mice) and over 24 hours (common voles). From the telemetry data the portion of time/potential foraging time in cereal fields, the habitat preference (Jacob's index) and individual home ranges were calculated. No common voles and very few wood mice were found in cereal fields prior to BBCH growth stage 30. Radi-tracked wood mice spent most of their time in cereal fields from BBCH 30-90, with mean PT of around 0.88. For common vole, usage of cereal fields increased with growth stage, with a mean PT of 0.64 at BBCH 30-60 and mean PT of 0.94 at BBCH 70-90.
[redacted] **(2008).** **Generic field monitoring of mammals on freshly drilled summer cereals in Hunsrück, Germany.** Small mammals were live-trapped in summer cereals (spring sown barley) and surrounding non-cropped habitat in Germany. Woodmouse was identified as the focal species and radio-tracking provided a mean and 90th percentile PT value of 14.37 and 27.5, respectively.

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

Sunflower seed treatment 'Apron' at 6.1g a.s./ha

Indicator Species/ Category	Time scale	ETE	TER	Annex VI Trigger
Tier I – uptake via diet (Birds)				
Small Granivourous	Acute	305	3.9	10
Small Omnivorous	Acute	102	12	10
Small Granivourous	Long-term	162	0.15	5
Small Omnivorous	Long-term	53.9	0.46	5
Higher Tier refinement – uptake via diet (Birds)				
Skylark (FIR/bw = 0.17)	Acute	173	6.8	10
Skylark (FIR/bw = 0.17, PT = 0.418)	Long-term	38.3	0.64	5
Small omnivorous (FIR/bw = 0.5, dilution factor = 0.0036)	Long-term	1.83	13	5

List of endpoints

Ecotoxicology

Indicator Species/ Category	Time scale	ETE	TER	Annex VI Trigger
Small omnivorous (FIR/bw = 0.5, 21-day measured residues = 0.073 mg a.s./kg)	Long-term	0.0365	674	5
Tier I- update via drinking water (Birds)				
Not necessary (ratio of AReff to LD50 = 0.005 < 50, ratio of AReff to NOEC = 0.248 < 50)				
Tier I- secondary poisoning (Birds)				
Not necessary (log POW of metalaxyl-M (1.71) and metabolites < 3)				
Tier 1- Uptake via diet (mammals)				
Small omnivorous (seeds)	Acute	244	1.5	10
Small omnivorous (seedlings)	Acute	48.8	7.7	10
Small omnivorous (seeds)	Long-term	129	0.74	5
Small omnivorous (seedlings)	Long-term	25.9	3.7	5
Higher Tier Refinement- uptake via diet (Mammals)				
Small omnivorous (seeds) (FIR/bw = 0.14, DHF =1)	Acute	142	2.6	10
Small omnivorous (seedlings) (FIR/bw = 0.24, dilution factor = 0.062)	Acute	15.1	25	10
Small omnivorous (seedlings) (FIR/bw = 0.24, 1-day measured residues = 0.915 mg a.s./kg)	Acute	0.2196	1708	10
Wood mouse (seeds) (FIR/bw = 0.14, DHF = 1, PT = 0.51)	Long-term	38.5	2.5	5
Small omnivorous (seedlings) (FIR/bw = 0.24, dilution factor = 0.0036)	Long-term	0.88	96	5
Small omnivorous (seedlings) (FIR/bw = 0.24, 21-day measured residues = 0.073 mg a.s./kg)	Long-term	0.0175	5479	5
Tier I- Uptake via drinking water				
Not necessary (ratio of AReff to LD50 = 0.016 < 50, ratio of AReff to NOAEL = 0.064 < 50)				
Tier 1 – secondary poisoning (Mammals)				
Not necessary (log POW of metalaxyl-M (1.71) and metabolites < 3)				

1 in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)
2 for cereals indicate if it is early or late crop stage
3 If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance (e.g. many single species data), it should appear in this column.

Spinach seed treatment 'Apron' at 81.4g a.s./ha

Indicator Species/ Category	Time scale	ETE	TER	Annex VI Trigger
Tier I – uptake via diet (Birds)				
Small Granivourous	Acute	203	5.8	10
Small Omnivorous	Acute	67.8	17	10
Small Granivourous	Long-term	108	0.23	5
Small Omnivorous	Long-term	35.9	0.69	5
Higher Tier refinement – uptake via diet (Birds)				
Skylark (FIR/bw = 0.29)	Acute	197	6.0	10
Skylark (FIR/bw = 0.29, PT = 0.418)	Long-term	43.6	0.56	5
Small omnivorous (FIR/bw = 0.5, dilution factor = 0.0145)	Long-term	4.92	5	5
Small omnivorous (FIR/bw = 0.5, 21-day measured residues = 0.0050 mg a.s./kg)	Long-term	0.0050	4920	5
Tier I- update via drinking water (Birds)				
Not necessary (ratio of AReff to LD50 = 0.069 < 50, ratio of AReff to NOEC = 3.309 < 50)				
Tier I- secondary poisoning (Birds)				
Not necessary (log POW of metalaxyl-M (1.71) and metabolites < 3)				
Tier 1- Uptake via diet (mammals)				
Small omnivorous (seeds)	Acute	163	2.3	10
Small omnivorous (seedlings)	Acute	32.5	12	10
Small omnivorous (seeds)	Long-term	86.2	1.1	5
Small omnivorous (seedlings)	Long-term	17.2	5.6	5
Higher Tier Refinement- uptake via diet (Mammals)				
Wood mouse (seeds) (FIR/bw = 0.22, DHF = 1)	Acute	149	2.5	10
Wood mouse (seeds) (FIR/bw = 0.14, DHF = 1, PT = 0.51)	Long-term	40.3	2.4	5
Tier I- Uptake via drinking water (Mammals)				
Not necessary (ratio of AReff to LD50 = 0.217 < 50, ratio of AReff to NOAEL = 0.848 < 50)				
Tier 1 – secondary poisoning (Mammals)				
Not necessary (log POW of metalaxyl-M (1.71) and metabolites < 3)				

1 in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)
2 for cereals indicate if it is early or late crop stage
3 If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance (e.g. many single species data), it should appear in this column.

Tomato spray treatment 'Ridomol Gold' at 3 x 97g a.s./ha

Indicator Species/ Category	Time scale	DDD (mg/kg bw/day)	TER	Annex VI Trigger
Screening – uptake via diet (Birds)				
Small Granivourous	Acute	24.6	48	10
Small Omnivorous	Acute	431	4.5	10
Small Granivourous	Long-term	635	5.1	10
Small Omnivorous	Long-term	6.66	4	5
Tier I – uptake via diet (Birds)				
Small granivorous "finch" BBCH 10-49	Acute	67.1	29	10
Small granivorous "finch" BBCH ≥ 50	Acute	20.1	96	10
Small omnivorous "lark" BBCH 10-49	Acute	65.2	30	10
Small omnivorous "lark" BBCH ≥ 50	Acute	19.5	98	10
Small insectivorous "wagtail" BBCH 10-19	Acute	72.8	26	10
Small insectivorous "wagtail" BBCH ≥ 20	Acute	68.4	28	10
Frugivorous bird "crow" BBCH 71-89	Acute	156	12	10
Frugivorous bird "starling" BBCH 71-89	Acute	134	14	10
Small granivorous "finch" BBCH 10-49	Long-term	1.2	21	5
Small granivorous "finch" BBCH ≥ 50	Long-term	0.35	70	5
Small omnivorous "lark" BBCH 10-49	Long-term	1.1	22	5
Small omnivorous "lark" BBCH ≥ 50	Long-term	0.34	73	5
Small insectivorous "wagtail" BBCH 10-19	Long-term	1.2	21	5
Small insectivorous "wagtail" BBCH ≥ 20	Long-term	1.0	25	5
Frugivorous bird "crow" BBCH 71-89	Long-term	3.3	7.5	5

List of endpoints

Ecotoxicology

Indicator Species/ Category	Time scale	DDD (mg/kg bw/day)	TER	Annex VI Trigger
Frugivorous bird “starling” BBCH 71-89	Long-term	2.1	12	5
Higher tier refinement – uptake via diet (Birds)				
Not necessary				
Tier I- Uptake via drinking water (Birds)				
Not necessary (ratio of AR_{eff} to LD_{50} = 0.225 < 50, ratio of AR_{eff} to NOEC = 10.8 < 50)				
Tier I secondary poisioning (Birds)				
Not necessary (log POW of metalaxyl-M (1.71) and metabolites < 3)				
Screening- Uptake via diet (Mammals)				
Small herbivorous	Acute	21.2	18	10
Small herbivorous (based on mixture LD_{50})	Acute	370	7.9	10
Small herbivorous (based on formulation LD_{50})	Acute	546	9.2	10
Small herbivorous	Long-term	7.43	13	5
Tier I- Uptake via diet (Mammals)				
Small insectivorous “shrew” BBCH 10-19	Acute	20.6	142	10
Small insectivorous “shrew” BBCH ≥ 20	Acute	14.7	200	10
Small herbivorous “vole” BBCH 10-49	Acute	370	7.9	10
Small herbivorous “vole” BBCH ≥ 50	Acute	111	26	10
Small omnivorous “mouse” BBCH 10-49	Acute	46.7	63	10
Small omnivorous “mouse” BBCH ≥ 50	Acute	14.1	208	10
Frugivorous “rat” BBCH 71-89	Acute	123	24	10
Small herbivorous “shrew” BBCH 10-49 (deposition factor = 0.5)	Acute	185	16	10
Tier I- Uptake via drinking water (Mammals)				
Not necessary (ratio of AReff to LD50 = 0.709 < 50, ratio of AReff to NOAEL = 2.77 < 50)				
Tier 1 – secondary poisoning (Mammals)				
Not necessary (log POW of metalaxyl-M (1.71) and metabolites < 3)				

1 the exposure calculations for the combined active substances were based on an application rate of 1.697 kg total active substance/ha

2 in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)

List of endpoints

Ecotoxicology

3 for cereals indicate if it is early or late crop stage
4 If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance (e.g. many single species data), it should appear in this column.

Grapevine spray treatment 'Ridomol Gold' at 3 x 97g a.s./ha

Indicator Species/ Category	Time scale	DDD (mg/kg bw/day)	TER	Annex VI Trigger
Screening – uptake via diet (Birds)				
Small omnivorous	Acute	13.9	85	10
Small omnivorous (based on mixture LD_{50})	Acute	243	8	10
Small omnivorous (based on formulation LD_{50})	Acute	357	9	10
Small omnivorous	Long-term	3.60	7	5
Tier I – uptake via diet (Birds)				
Small insectivorous "Redstart" BBCH 10-19	Acute	69.7	28	10
Small insectivorous "Redstart" BBCH ≥ 20	Acute	65.4	29	10
Small granivorous "finch" BBCH 10-19	Acute	37.7	51	10
Small granivorous "finch" BBCH 20-39	Acute	31.6	61	10
Small granivorous "finch" BBCH ≥ 40	Acute	18.8	102	10
Small omnivorous "lark" BBCH 10-19	Acute	36.7	52	10
Small omnivorous "lark" BBCH 20-39	Acute	30.5	63	10
Small omnivorous "lark" BBCH ≥ 40	Acute	18.3	105	10
Frugivorous "Thrush/starling" ripening	Acute	73.6	26	10
Higher tier refinement – uptake via diet (Birds)				
Not necessary				
Tier I- Uptake via drinking water (Birds)				
Not necessary (ratio of AReff to LD50 = 0.217 < 50, ratio of AReff to NOEC = 10.4 < 50)				
Tier I secondary poisioning (Birds)				
Not necessary (log POW of metalaxyl-M (1.71) and metabolites < 3)				
Screening- Uptake via diet (Mammals)				
Small herbivorous	Acute	19.8	19	10

List of endpoints

Ecotoxicology

Indicator Species/ Category	Time scale	DDD (mg/kg bw/day)	TER	Annex VI Trigger
Small herbivorous (based on mixture LD_{50})	Acute	347	8.5	10
Small herbivorous (based on formulation LD_{50})	Acute	512	9.8	10
Small herbivorous	Long-term	6.69	14	5
Tier I- Uptake via diet (Mammals)				
Large herbivorous “lagomorph”BBCH 10-19	Acute	41.5	71	10
Large herbivorous “lagomorph”BBCH 20-39	Acute	34.6	85	10
Large herbivorous “lagomorph”BBCH ≥ 40	Acute	20.6	142	10
Small insectivorous “shrew” BBCH 10-19	Acute	19.3	152	10
Small insectivorous “shrew” BBCH ≥ 20	Acute	13.7	214	10
Small herbivorous ”vole” BBCH 10-19	Acute	208	14	10
Small herbivorous ”vole” BBCH 20-39	Acute	174	17	10
Small herbivorous ”vole” BBCH ≥ 40	Acute	104	28	10
Small omnivorous “mouse” BBCH 10-19	Acute	26.2	112	10
Small omnivorous “mouse” BBCH 20-39	Acute	21.9	134	10
Small omnivorous “mouse” BBCH ≥ 40	Acute	13.2	222	10
Tier I- Uptake via drinking water (Mammals)				
Not Necessary				
Tier 1 – secondary poisoning (Mammals)				
Not necessary (log POW of metalaxyl-M (1.71) and metabolites < 3)				

1 the exposure calculations for the combined active substances were based on an application rate of 1.697 kg total active substance/ha
2 in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)
3 for cereals indicate if it is early or late crop stage
4 If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance (e.g. many single species data), it should appear in this column.

List of endpoints

Ecotoxicology

Sugar and fodder beet seed treatment 'Vibrance SB' at 0.62 g a.s./ha

Indicator Species/ Category	Time scale	DDD	TER	Annex VI Trigger
Tier I – uptake via diet (Birds)				
Small granivourous - consumption of treated seeds with/as grit	Acute	6.07	194.46	10
Small omnivorous – consumption of emerged seedlings	Acute	19.98	59.06	10
Large herbivorous – consumption of emerged seedlings	Acute	11.99	98.43	10
Small granivourous - consumption of treated seeds with/as grit	Long-term	3.23	7.61	5
Small omnivorous – consumption of emerged seedlings	Long-term	19.98	**1.23**	5
Large herbivorous – consumption of emerged seedlings	Long-term	11.99	**2.05**	5
Higher Tier refinement – uptake via diet (Birds)				
Small omnivorous – consumption of emerged seedlings (revised residue value)	Long-term	2.81	8.75	5
Large herbivorous – consumption of emerged seedlings (revised residue value)	Long-term	1.68	14.64	5
Tier I- update via drinking water (Birds)				
Not necessary (ratio of AReff to LD50 = 0.0005 < 50, ratio of AReff to NOEC = 0.025 < 50)				
Tier I- secondary poisoning (Birds)				
Not necessary (log POW of metalaxyl-M (1.71) and metabolites < 3)				
Tier 1- Uptake via diet (mammals)				
Small omnivorous – consumption of emerged seedlings	Acute	9.59	39.1	10
Large herbivorous – consumption of emerged seedlings	Acute	15.98	23.46	10
Small omnivorous – consumption of emerged seedlings	Long-term	9.59	10.01	5

List of endpoints

Ecotoxicology

Indicator Species/ Category	Time scale	DDD	TER	Annex VI Trigger
Large herbivorous – consumption of emerged seedlings	Long-term	15.98	6.01	5
Tier I- Uptake via drinking water				
Not necessary (ratio of AReff to LD50 = 0.0017 < 50, ratio of AReff to NOAEL = 0.0065 < 50)				
Tier 1 – secondary poisoning (Mammals)				
Not necessary (log POW of metalaxyl-M (1.71) and metabolites < 3)				

Vining pea seed treatment 'Wakil XL' at 76.32 g a.s./ha

Indicator Species/ Category	Time scale	DDD	TER	Annex VI Trigger
Tier I – uptake via diet (Birds)				
Large granivourous - consumption of treated seeds	Acute	33.92	34.79	10
Small omnivorous – consumption of emerged seedlings	Acute	33.92	34.79	10
Large herbivorous – consumption of emerged seedlings	Acute	20.35	57.98	10
Large granivourous - consumption of treated seeds	Long-term	33.92	**0.73**	5
Small omnivorous – consumption of emerged seedlings	Long-term	33.92	**0.73**	5
Large herbivorous – consumption of emerged seedlings	Long-term	20.35	**1.21**	5
Higher Tier refinement – uptake via diet (Birds)				
Wood pigeon – consumption of treated seed scenario (refined FIR/bw = 0.074, PT = 0.17, TWA = 0.53)	Long-term	2.26	10.9	5
Wood pigeon – consumption of seedlings scenario (refined FIR/bw = 0.79, PT = 0.32, TWA = 0.53, initial residue = 1.09/7.12)	Long-term	0.146/ 0.954	168/ 25.8	5
Skylark – consumption of seedlings mixed diet scenario (refined FIR/bw = 0.48, PT = 0.879, TWA = 0.53, initial residue = 1.09/7.12)	Long-term	0.061/ 0.398	404/ 61.8	5

List of endpoints

Ecotoxicology

Indicator Species/ Category	Time scale	DDD	TER	Annex VI Trigger
Skylark – consumption of seedlings 100% diet scenario (refined FIR/bw = 0.55, PT = 0.879, TWA = 0.53, initial residue = 1.09/7.12)	Long-term	0.14/ 0.912	176/ 27	5
Tier I- update via drinking water (Birds)				
Not necessary (ratio of AReff to LD50 = 0.0065 < 50, ratio of AReff to NOEC = 3.1 < 50)				
Tier I- secondary poisoning (Birds)				
Not necessary (log POW of metalaxyl-M (1.71) and metabolites < 3)				
Tier 1- Uptake via diet (mammals)				
Small omnivorous - consumption of treated seeds	Acute	81.41	**4.61**	10
Small omnivorous – consumption of emerged seedlings	Acute	16.28	23.03	10
Large herbivorous – consumption of emerged seedlings	Acute	27.14	13.82	10
Small omnivorous - consumption of treated seeds	Long-term	81.41	**1.18**	5
Small omnivorous – consumption of emerged seedlings	Long-term	16.28	5.90	5
Large herbivorous – consumption of emerged seedlings	Long-term	27.14	**3.54**	5
Higher Tier Refinement- uptake via diet (Mammals)				
Wood mouse – consumption of treated seed scenario (refined FIR/bw = 0.21)	Acute	71.23	**5.26**	10
Wood mouse – consumption of treated seed scenario (refined FIR/bw = 0.21, PT = 0.51, TWA = 0.53)	Long-term	19.25	4.99	5
Large herbivorous – consumption of emerged seedlings (refined initial residue = 1.09/7.12)	Long-term	0.436/ 2.85	220/ 33.7	5
Tier I- Uptake via drinking water				
Not necessary (ratio of AReff to LD50 = 0.2 < 50, ratio of AReff to NOAEL = 0.8 < 50)				
Tier 1 – secondary poisoning (Mammals)				
Not necessary (log POW of metalaxyl-M (1.71) and metabolites < 3)				

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] (mg/L)
Laboratory tests				
Fish				
Acute Toxicity to Fish				
Oncorhynchus mykiss [redacted] (1994b)	Metalaxyl-M	96 hr (static)	Mortality, LC_{50}	> 100 mg/L (nom)
Oncorhynchus mykiss [redacted] *et al*. (1995a)	Metalaxyl-M	96 hr (static)	Mortality, LC_{50}	> 121 mg/L (nom)
Oncorhynchus mykiss [redacted] *et al.* (1991a)	CGA 62826 (NOA 409045)	96 hr (semi-static)	Mortality, LC_{50}	>100 mg/L (nom)
Oncorhynchus mykiss [redacted] *et al.* (1992a)	CGA67868	96 hr (semi-static)	Mortality, LC_{50}	> 98.9 mg/L (nom)
Oncorhynchus mykiss [redacted] (1994a)	CGA 108906 (SYN 546520)	96 hr (static)	Mortality, LC_{50}	>100 mg/L (nom)
Oncorhynchus mykiss [redacted] (1997)	APRON	96 hr (static)	Mortality, LC_{50}	> 100 mg/L (32 mg Metalaxyl-M/L)
Cyprinus carpio [redacted] (2005)	RIDOMIL GOLD	96 hr (static)	Mortality, LC_{50}	23 mg/L (0.87mg metalaxyl-M and 14mg mancozeb/L)
Oncorhynchus mykiss	Vibrance SB	96 hr (static)	Mortality, LC_{50}	21.97
Oncorhynchus mykiss	Wakil XL	96 hr (static)	Mortality, LC_{50}	11

List of endpoints

Ecotoxicology

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Chronic Fish Toxicity				
Oncorhynchus mykiss [redacted] (2000)	Metalaxyl-M	28 d (flow-through)	Growth NOEC	50 mg/L (nom)
Pimephales promelas [redacted] *et al*. (1980a)	Metalaxyl	30 d (flow-through)	Growth NOEC	9.1 mg/L (nom)
Oncorhynchus mykiss [redacted] (2000a)	CGA 62826 (NOA 409045)	28 d (flow-through)	Growth NOEC	100 mg/L (nom)
Aquatic Invertabrate				
Acute Toxicity to aquatic invertabrates				
Daphnia magna [redacted] (1994b)	metalaxyl-M	48 hr (static)	Mortality, EC_{50}	> 100 mg/L (nom)
Daphnia magna [redacted] *et al*. (1995b)	metalaxyl-M	48 hr (static)	Mortality, EC_{50}	> 113 mg/L (nom)
Crassostrea virginica [redacted] *et al*. (1995c)	metalaxyl-M	96 hr (flow-through)	Shell deposition, EC_{50}	9.7 mg/L (nom)
Mysidopsis bahia [redacted] (1989)	metalaxyl	96 hr (flow-through)	Mortality, EC_{50}	25 mg/L (nom)
Crassostrea virginica [redacted] (1989)	metalaxyl	96 hr (flow-through)	Shell deposition, EC_{50}	**5.6 mg/L (nom)**
Daphnia magna [redacted] *et al*. (1991b)	CGA 62826 (NOA 409045)	48 hr (static)	Mortality, EC_{50}	**852 mg/L (nom)**
Daphnia magna [redacted] *et al*. (1991c)	CGA 67868	48 hr (static)	Mortality, EC_{50}	**158 mg/L (nom)**
Daphnia magna [redacted] (1994a)	CGA 108906 (SYN 546520)	48 hr (static)	Mortality, EC_{50}	**> 100 mg/L (nom)**

List of endpoints

Ecotoxicology

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Daphnia magna [redacted] (1997a)	APRON	48 hr (static)	Mortality, EC_{50}	54.4 mg/L (17.56 mg metalaxyl-M/L)
Daphnia magna [redacted] *et al. (2005)*	RIDOMIL GOLD	48 hr (static)	Mortality, EC_{50}	**0.8 mg/L (**0.030mg metalaxyl-M and 0.48 mg mancozeb/L)
Daphnia magna	Vibrance SB	48 hr (static)	Mortality, EC_{50}	55.8
Daphnia magna	Wakil XL	48 hr (static)	Mortality, EC_{50}	47.9
Chronic toxicity to aquatic invertebrates				
Daphnia magna [redacted] (2000)	Metalaxyl-M	21 d (semi-static)	Reproduction, NOEC	25 mg/L (nom)
Daphnia magna	Metalaxyl-M	14 d (semi-static)	Reproduction, NOEC	1 mg/L
Daphnia magna [redacted] (2000a)	CGA 62826 (NOA 409045)	21 d (semi-static)	Reproduction, NOEC	100 mg/L (nom)
Algae				
Toxicity to Algae				
Desmodesmus subspicatus [redacted] (1994d)	metalaxyl-M	72 h (static)	Growth, E_bC_{50} Growth, E_rC_{50}	36 mg/L (nom) 103 mg/L
Desmodesmus subspicatus [redacted] (1995)	metalaxyl	72 h (static)	Growth, E_bC_{50}	46 mg/L (nom)
Scendesmus quadricauda	Metalaxyl-M	96 h (static)	Growth, E_rC_{50}	19.95
Desmodesmus subspicatus [redacted] *et al.* (1991d)	CGA 62826 (NOA 409045)	72 h (static)	Growth, E_bC_{50}	> 1000 mg/L (nom)

List of endpoints

Ecotoxicology

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Desmodesmus subspicatus [redacted] *et al*. (1992b)	CGA 67868	72 h (static)	Growth, E_bC_{50}	**195.4 mg/L (nom)**
Desmodesmus subspicatus [redacted] (1994c)	CGA 108906 (SYN 546520)	72 h (static)	Growth, E_bC_{50}	**74 mg/L (nom)**
Pseudokirchneriella subcapitata [redacted] (2011)	NOA 409045	72 h (static)	Growth, E_rC_{50} Growth, E_yC_{50} Growth, E_bC_{50}	81 mg/L 65.01 mg/L **63.25 mg/L (nom)**
Desmodesmus subspicatus [redacted] (1997b)	APRON	72 h (static)	Growth, E_rC_{50} Growth, E_bC_{50}	> 100 mg/L (32.28 mg Metalaxyl-M/L) 103 mg/L (33.25mg metalaxyl-M/L)
Pseudokirchneriella subcapitata [redacted] (2005)	RIDOMIL GOLD	96 h (static)	Growth, E_rC_{50} Growth, E_bC_{50}	0.248 mg/L (0.009mg Metalaxyl-M and 0.15 mg mancozeb/L) **0.102 mg/L** (0.004 mg metalaxyl-M and 0.062 mg mancozeb/L)
Higher Plant				
-				
Microcosm or mesocosm tests: not required				

1 indicate whether based on nominal (nom) or mean measured concentrations (mm). In the case of preparations indicate whether end points are presented as units of preparation or a.s.

Bioconcentration in fish (Annex Part A, point 8.2.2.3)

	Metalaxyl-M	Metabolite 1	Metabolite 2	Metabolite 3
$logP_{O/W}$	1.71	/	/	/
Steady-state bioconcentration factor (BCF)[1]	3.70	/	/	/
Annex VI Trigger for the bioconcentration factor	/	/	/	/
Clearance time (days) (CT_{50})	/	/	/	/
(CT_{90})	/	/	/	/
Level and nature of residues (%) in organisms after the 14 day depuration phase	/	/	/	/
Higher tier study				
Not required				

1 only required if log Po/w>3

Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex CP, point 10.2) – formulation APRON (A9642C)

Maximum PEC_{sw} values and TER values for metalaxyl-M – application to sunflowers at 6.1 g a.s./ha

Scenario	PEC global max (µg L)	PEC twa, 28d* (µg L)	fish acute	fish prolonged	Daphnia acute	Daphnia prolonged	Algae acute	Higher plant	Sed. dweller prolonged	Microcosm / Mesocosm
			O. mykiss	***O. mykiss***	***Crassostrea virginica***	***Daphnia magna***	***Desmodesmus subspicatus***	***Lemna* sp.**	***C. riparius***	
			LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	ErC_{50}	NOEC	NOEC
			> 100 mg/L	9.1 mg/L	5.6 mg/L	25 mg/L	36 mg/L	- µg/L	- µg/L	- µg/L
FOCUS Step 1	1.93	-	> 51813	4715	2902	12953	18653	-	-	-
FOCUS Step 2										
Annex VI Trigger*			100	10	100	10	10	10	10	5

* If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear as a footnote. E.g. if it is agreed during the risk assessment of mesocosm, that a trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval

Maximum PEC_{sw} values and TER values for NOA409045 – application to sunflowers at 6.1 g a.s./ha

List of endpoints

Ecotoxicology

Scenario	PEC global max (µg L)	PEC twa, 28d* (µg L)	fish acute	fish prolonged	Daphnia acute	Daphnia prolonged	Algae acute	Higher plant	Sed. dweller prolonged	Microcosm / Mesocosm
			O. mykiss	***O. mykiss***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Lemna* sp.**	***C. riparius***	
			LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	ErC_{50}	NOEC	NOEC
			> 100 mg/L	100 mg/L	852 mg/L	100 mg/L	63.25 mg/L	- µg/L	- µg/L	- µg/L
FOCUS Step 1	1.37	-	> 72993	72993	621898	72993	46168	-	-	-
FOCUS Step 2										
Annex VI Trigger*			100	10	100	10	10	10	10	5

* If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear as a footnote. E.g. if it is agreed during the risk assessment of mesocosm, that a trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval

Maximum PEC_{sw} values and TER values for CGA67868 – application to sunflowers at 6.1 g a.s./ha

Scenario	PEC global max (µg L)	PEC twa, 28d* (µg L)	fish acute	fish prolonged	Daphnia acute	Daphnia prolonged	Algae acute	Higher plant	Sed. dweller prolonged	Microcosm / Mesocosm
			O.	***O.***	***Daphnia***	***Daphnia***	***Desmod***	***Lemna***	***C.***	

List of endpoints

Ecotoxicology

			mykiss	***mykiss***	***magna***	***magna***	***esmus subspicatus***	**sp.**	***riparius***	
			LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	ErC_{50}	NOEC	NOEC
			> 98.9 mg/L	- mg/L	158 mg/L	- mg/L	195.4 mg/L	- µg/L	- µg/L	- µg/L
FOCUS Step 1	0.156	-	> 633974	-	1012821	-	1252564	-	-	-
FOCUS Step 2										
Annex VI Trigger*			100	10	100	10	10	10	10	5

* If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear as a footnote. E.g. if it is agreed during the risk assessment of mesocosm, that a trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval

Maximum PEC_{sw} values and TER values for SYN546520 – application to sunflowers at 6.1 g a.s./ha

Scenario	**PEC global max (µg L)**	**PEC twa, 28d* (µg L)**	**fish acute**	**fish prolonged**	**Daphnia acute**	**Daphnia prolonged**	**Algae acute**	**Higher plant**	**Sed. dweller prolonged**	**Microcosm / Mesocosm**
			O. mykiss	***O. mykiss***	***Daphnia magna***	***Daphnia magna***	***Desmodesmus subspicatus***	***Lemna* sp.**	***C. riparius***	

List of endpoints

Ecotoxicology

							tus			
			LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	ErC_{50}	NOEC	NOEC
			> 100 mg/L	- mg/L	> 100 mg/L	- mg/L	74 mg/L	- µg/L	- µg/L	- µg/L
FOCUS Step 1	0.116	-	> 862069	-	> 862069	-	637931	-	-	-
FOCUS Step 2										
Annex VI Trigger*			100	10	100	10	10	10	10	5

* If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear as a footnote. E.g. if it is agreed during the risk assessment of mesocosm, that a trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval

Maximum PEC_{sw} values and TER values for metalaxyl-M – application to spinach at 81.4 g a.s./ha

Scenario	**PEC global max (µg L)**	**PEC twa, 28d (µg L)**	**fish acute**	**fish prolonged**	**Daphnia acute**	**Daphnia prolonged**	**Algae acute**	**Higher plant**	**Sed. dweller prolonged**	**Microcosm / Mesocosm**
			O. mykiss	***O. mykiss***	***Crassostrea virginica***	***Daphnia magna***	***Desmodesmus subspicatus***	***Lemna* sp.**	***C. riparius***	
			LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	ErC_{50}	NOEC	NOEC
			> 100	9.1 mg/L	5.6 mg/L	25 mg/L	36 mg/L	- µg/L	- µg/L	- µg/L

			mg/L							
FOCUS Step 1	25.8	-	> 3876	353	217	969	1395	-	-	-
FOCUS Step 2										
Annex VI Trigger*			100	10	100	10	10	10	10	5

* If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear as a footnote. E.g. if it is agreed during the risk assessment of mesocosm, that a trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval

Maximum PEC_{sw} values and TER values for NOA409045 – application to spinach at 81.4 g a.s./ha

Scenario	**PEC global max (µg L)**	**PEC twa, 28d* (µg L)**	**fish acute**	**fish prolonged**	**Daphnia acute**	**Daphnia prolonged**	**Algae acute**	**Higher plant**	**Sed. dweller prolonged**	**Microcosm / Mesocosm**
			O. mykiss	***O. mykiss***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchenriella subcapitata***	***Lemna* sp.**	***C. riparius***	
			LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	ErC_{50}	NOEC	NOEC
			> 100 mg/L	100 mg/L	852 mg/L	100 mg/L	63.25 mg/L	- µg/L	- µg/L	- µg/L

List of endpoints

Ecotoxicology

FOCUS Step 1	18.3	-	> 5464	5464	46557	5464	3456	-	-	-
FOCUS Step 2										
Annex VI Trigger*			100	10	100	10	10	10	10	5

* If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear as a footnote. E.g. if it is agreed during the risk assessment of mesocosm, that a trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval

Maximum PEC_{sw} values and TER values for SYN546520 – application to spinach at 81.4 g a.s./ha

Scenario	PEC global max (µg L)	PEC twa, 28d* (µg L)	fish acute	fish prolonged	Daphnia acute	Daphnia prolonged	Algae acute	Higher plant	Sed. dweller prolonged	Microcosm / Mesocosm
			O. mykiss	***O. mykiss***	***Daphnia magna***	***Daphnia magna***	***Desmodesmus subspicatus***	***Lemna* sp.**	***C. riparius***	
			LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	ErC_{50}	NOEC	NOEC
			> 100 mg/L	- mg/L	> 100 mg/L	- mg/L	74 mg/L	- µg/L	- µg/L	- µg/L
FOCUS Step 1	1.54	-	> 64935	-	> 64935	-	48052	-	-	-

List of endpoints

Ecotoxicology

FOCUS Step 2									
Annex VI Trigger*	100	10	100	10	10	10	10	5	

* If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear as a footnote. E.g. if it is agreed during the risk assessment of mesocosm, that a trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval

Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex CP, point 10.2) – formulation RIDOMIL GOLD (A9651D)

Maximum PEC_{sw} values and TER values for metalaxyl-M – application to tomato at 3*97 g a.s./ha

Scenario	**PEC global max (µg L)**	**PEC twa, 28d* (µg L)**	**fish acute**	**fish prolonged**	**Daphnia acute**	**Daphnia prolonged**	**Algae acute**	**Higher plant**	**Sed. dweller prolonged**	**Microcosm / Mesocosm**
			O. mykiss	***O. mykiss***	***Crassostrea virginica***	***Daphnia magna***	***Desmodesmus subspicatus***	***Lemna* sp.**	***C. riparius***	
			LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	ErC_{50}	NOEC	NOEC
			> 100 mg/L	9.1 mg/L	5.6 mg/L	25 mg/L	36 mg/L	- µg/L	- µg/L	- µg/L
FOCUS Step 1	-	-	-	-	-	-	-	-	-	-

List of endpoints

Ecotoxicology

FOCUS Step 2									
Annex VI Trigger*	100	10	100	10	10	10	10	5	

* If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear as a footnote. E.g. if it is agreed during the risk assessment of mesocosm, that a trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval

Maximum PEC_{sw} values and TER values for NOA409045 – application to tomato at 3*97 g a.s./ha

Scenario	PEC global max (µg L)	PEC twa, 28d* (µg L)	fish acute	fish prolonged	Daphnia acute	Daphnia prolonged	Algae acute	Higher plant	Sed. dweller prolonged	Microcosm / Mesocosm
			O. mykiss	***O. mykiss***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchenriella subcapitata***	***Lemna* sp.**	***C. riparius***	
			LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	ErC_{50}	NOEC	NOEC
			> 100 mg/L	100 mg/L	852 mg/L	100 mg/L	63.25 mg/L	- µg/L	- µg/L	- µg/L
FOCUS Step 1	-	-	-	-	-	-	-	-	-	-
FOCUS Step 2										
Annex VI Trigger*			100	10	100	10	10	10	10	5

List of endpoints

Ecotoxicology

* If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear as a footnote. E.g. if it is agreed during the risk assessment of mesocosm, that a trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval

Maximum PEC_{sw} values and TER values for CGA67868 – application to tomato at 3*97 g a.s./ha

Scenario	PEC global max (µg L)	PEC twa, 28d* (µg L)	fish acute	fish prolonged	Daphnia acute	Daphnia prolonged	Algae acute	Higher plant	Sed. dweller prolonged	Microcosm / Mesocosm
			O. mykiss	***O. mykiss***	***Daphnia magna***	***Daphnia magna***	***Desmodesmus subspicatus***	***Lemna* sp.**	***C. riparius***	
			LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	ErC_{50}	NOEC	NOEC
			> 98.9 mg/L	- mg/L	158 mg/L	- mg/L	195.4 mg/L	- µg/L	- µg/L	- µg/L
FOCUS Step 1	-	-	-	-	-	-	-	-	-	-
FOCUS Step 2										
Annex VI Trigger*			100	10	100	10	10	10	10	5

* If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear as a footnote. E.g. if it is agreed during the risk assessment of mesocosm, that a trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval

Maximum PEC_{sw} values and TER values for SYN546520 – application to tomato at 3*97 g a.s./ha

Scenario	PEC global max (µg L)	PEC twa, 28d* (µg L)	fish acute	fish prolonged	Daphnia acute	Daphnia prolonged	Algae acute	Higher plant	Sed. dweller prolonged	Microcosm / Mesocosm
			O. mykiss	***O. mykiss***	***Daphnia magna***	***Daphnia magna***	***Desmodesmus subspicatus***	***Lemna* sp.**	***C. riparius***	
			LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	ErC_{50}	NOEC	NOEC
			> 100 mg/L	- mg/L	> 100 mg/L	- mg/L	74 mg/L	- µg/L	- µg/L	- µg/L
FOCUS Step 1	-	-	-	-	-	-	-	-	-	-
FOCUS Step 2										
North Europe	-	-	-	-	-	-	-	-	-	-
South Europe	3.08	-	> 32468	-	>32468	-	24026	-	-	-
Annex VI Trigger*			100	10	100	10	10	10	10	5

* If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear as a footnote. E.g. if it is agreed during the risk assessment of mesocosm, that a trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval

Maximum PEC_{sw} values and TER values for metalaxyl-M – application to vines at 3*97 g a.s./ha

Scenario	PEC global max (µg L)	PEC twa, 28d* (µg L)	fish acute	fish prolonged	Daphnia acute	Daphnia prolonged	Algae acute	Higher plant	Sed. dweller prolonged	Microcosm / Mesocosm
			O. mykiss	***O. mykiss***	***Crassostrea virginica***	***Daphnia magna***	***Desmodesmus subspicatus***	***Lemna* sp.**	***C. riparius***	
			LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	ErC_{50}	NOEC	NOEC
			> 100 mg/L	9.1 mg/L	5.6 mg/L	25 mg/L	36 mg/L	- µg/L	- µg/L	- µg/L
FOCUS Step 1	-	-	-	-	-	-	-	-	-	-
FOCUS Step 2										
North Europe	12.4	-	> 8065	734	452	2016	2903	-	-	-
South Europe	-	-	-	-	-	-	-	-	-	-
Annex VI Trigger*			100	10	100	10	10	10	10	5

* If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear as a footnote. E.g. if it is agreed during the risk assessment of mesocosm, that a trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval

Maximum PEC_{sw} values and TER values for NOA409045 – application to vines at 3*97 g a.s./ha

List of endpoints

Ecotoxicology

Scenario	PEC global max (µg L)	PEC twa, 28d* (µg L)	fish acute	fish prolonged	Daphnia acute	Daphnia prolonged	Algae acute	Higher plant	Sed. dweller prolonged	Microcosm / Mesocosm
			O. mykiss	***O. mykiss***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchenriella subcapitata***	***Lemna* sp.**	***C. riparius***	
			LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	ErC_{50}	NOEC	NOEC
			> 100 mg/L	100 mg/L	852 mg/L	100 mg/L	63.25 mg/L	- µg/L	- µg/L	- µg/L
FOCUS Step 1	-	-	-	-	-	-	-	-	-	-
FOCUS Step 2										
North Europe	16.7	-	> 5988	5988	51018	5988	3787	-	-	-
South Europe	-	-	-	-	-	-	-	-	-	-
Annex VI Trigger*			100	10	100	10	10	10	10	5

* If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear as a footnote. E.g. if it is agreed during the risk assessment of mesocosm, that a trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval

Maximum PEC_{sw} values and TER values for CGA67868 – application to vines at 3*97 g a.s./ha

Scenario	PEC global max (µg L)	PEC twa, 28d* (µg L)	fish acute	fish prolonged	Daphnia acute	Daphnia prolonged	Algae acute	Higher plant	Sed. dweller prolonged	Microcosm / Mesocosm
			O. mykiss	***O. mykiss***	***Daphnia magna***	***Daphnia magna***	***Desmodesmus subspicatus***	***Lemna* sp.**	***C. riparius***	
			LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	ErC_{50}	NOEC	NOEC
			> 98.9 mg/L	- mg/L	158 mg/L	- mg/L	195.4 mg/L	- µg/L	- µg/L	- µg/L
FOCUS Step 1	-	-	-	-	-	-	-	-	-	-
FOCUS Step 2										
North Europe	4.77	-	> 20734	-	33124	-	40964	-	-	-
South Europe	-	-	-	-	-	-	-	-	-	-
Annex VI Trigger*			100	10	100	10	10	10	10	5

* If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear as a footnote. E.g. if it is agreed during the risk assessment of mesocosm, that a trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval

Maximum PEC_{sw} values and TER values for SYN546520 – application to vines at 3*97 g a.s./ha

List of endpoints

Ecotoxicology

Scenario	PEC global max (µg L)	PEC twa, 28d* (µg L)	fish acute	fish prolonged	Daphnia acute	Daphnia prolonged	Algae acute	Higher plant	Sed. dweller prolonged	Microcosm / Mesocosm
			O. mykiss	***O. mykiss***	***Daphnia magna***	***Daphnia magna***	***Desmodesmus subspicatus***	***Lemna* sp.**	***C. riparius***	
			LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	ErC_{50}	NOEC	NOEC
			> 100 mg/L	- mg/L	> 100 mg/L	- mg/L	74 mg/L	- µg/L	- µg/L	- µg/L
FOCUS Step 1	-	-	-	-	-	-	-	-	-	-
FOCUS Step 2										
North Europe	8.24	-	> 12136	-	>12136	-	8981	-	-	-
South Europe	-	-	-	-	-	-	-	-	-	-
Annex VI Trigger*			100	10	100	10	10	10	10	5

* If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear as a footnote. E.g. if it is agreed during the risk assessment of mesocosm, that a trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval

Maximum PEC_{sw} values and PEC/RAC ratios for metalaxyl-M – seed treatment application to sugar and fodder beet at 0.62 g a.s./ha, exposure via drainage (first tier)

Scenario	PEC global max (µg L)	Fish acute	Fish prolonged	Daphnia acute	Daphnia prolonged	Algae acute	Higher plant	Sed. dweller prolonged	Microcosm / Mesocosm
		O. mykiss	*O. mykiss*	*Crassostrea virginica*	*Daphnia magna*	*S. quadricauda*	*Lemna* sp.	*C. riparius*	
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	ErC_{50}	NOEC	NOEC
Value		> 100 mg/L	9.1 mg/L	5.6 mg/L	1 mg/L	19.95 mg/L	- µg/L	- µg/L	- µg/L
Trigger		100	10	100	10	10	10	10	-
RAC		1000 µg/L	910 µg/L	56 µg/L	100 µg/L	1995 µg/L			
PEC/RAC ratio	0.091	<0.001	<0.001	0.016	<0.001	<0.001	-	-	-

Maximum PEC_{sw} values and PEC/RAC ratios for metalaxyl-M – seed treatment application to vining pea at 76.32 g a.s./ha, exposure via drainage (first tier)

Scenario	PEC global max (µg L)	Fish acute	Fish prolonged	Daphnia acute	Daphnia prolonged	Algae acute	Higher plant	Sed. dweller prolonged	Microcosm / Mesocosm
		O. mykiss	*O. mykiss*	*Crassostrea*	*Daphnia magna*	*S. quadrica*	*Lemna* sp.	*C. riparius*	

List of endpoints

Ecotoxicology

				virginica		***uda***			
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	ErC_{50}	NOEC	NOEC
Value		> 100 mg/L	9.1 mg/L	5.6 mg/L	1 mg/L	19.95 mg/L	- µg/L	- µg/L	- µg/L
Trigger		100	10	100	10	10	10	10	-
RAC		1000 µg/L	910 µg/L	56 µg/L	100 µg/L	1995 µg/L			
PEC/RAC ratio	13.885	<0.014	0.016	0.248	0.139	0.007	-	-	-

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

Species	Test substance	Acute Oral Toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
Honeybees	Metalaxyl-M	-	> 25.0
Honeybees	Metalaxyl-M	> 97.3	> 100
Honeybees	Metalaxyl	269	> 200
Honeybees	APRON	> 334 (form)	675 (form)
Honeybees	RIDOMIL GOLD	> 613 (form)	> 1471 (form)
Honeybees	Metalaxyl-M	-	> 25.0
Honeybees	Vibrance SB	> 1146 (form)	> 1000 (form)
Honeybees	Wakil XL	> 714 (form)	> 1000 (form)
Chronic laboratory tests			
Species	**Test substance**	**LDD50 (µg/bee/day)**	**NOED (µg/larva/ development period)**
Honeybees	A13947A	67.8 (form) 31 (a.s.)	-
Honeybees	A13947A	-	346.5 (form)* 157 (a.s.)*
Field or semi-field tests			
Not required			

*Study duration only 8 days and effects on development/emergence not investigated

Risk assessment for – sunflower seed treatment Apron at 6.1g a.s./ha

Test substance	Route	HQ	Annex VI Trigger
Metalaxyl-M	Contact	< 0.06	50
Metalaxyl-M	Oral	< 0.06	50

Risk assessment for – spinach, seed treatment Apron at 81.4g a.s./ha

Test substance	Route	HQ	Annex VI Trigger
Metalaxyl-M	Contact	< 0.81	50
Metalaxyl-M	Oral	< 0.84	50

List of endpoints

Ecotoxicology

Risk assessment for – tomato, spray treatment 'Ridomil Gold' at 3 x 97g a.s./ha

Test substance	Route	HQ	Annex VI Trigger
Metalaxyl-M	Contact	< 1.00	50
Metalaxyl-M	Oral	< 1.00	50
RIDOMIL GOLD	Contact	< 1.70	50
RIDOMIL GOLD	Oral	< 4.08	50

Risk assessment for – Grapevine, spray treatment 'Ridomil Gold' at 3 x 97g a.s./ha

Test substance	Route	HQ	Annex VI Trigger
Metalaxyl-M	Contact	< 1.00	50
Metalaxyl-M	Oral	< 1.00	50
RIDOMIL GOLD	Contact	< 1.70	50
RIDOMIL GOLD	Oral	< 4.08	50

Risk assessment for – sugar and fodder beet seed treatment Vibrance SB at 0.62 g a.s./ha

Test substance	Test design	Endpoint (µg/bee/d)	Exposure (µg/bee/d)	Factor of difference
Metalaxyl-M	Acute oral, adult	LD_{50} > 97.3	0.865	112
	Chronic oral, adult	LD_{50} = 31	0.865	35.8
	Chronic, oral, larva	NOED = 19.63*	0.0796	246

* Endpoint of 157 µg a.s./larva divided by 8 days (test duration) to derive the endpoint in µg a.s./larva/day

Risk assessment for – vining pea seed treatment Wakil XL at 76.32 g a.s./ha

Test substance	Test design	Endpoint (µg/bee/d)	Exposure (µg/bee/d)	Factor of difference
Metalaxyl-M	Acute oral, adult	LD_{50} > 97.3	0.865	112
	Chronic oral, adult	LD_{50} = 31	0.865	35.8
	Chronic, oral, larva	NOED = 19.63*	0.0796	246

* Endpoint of 157 µg a.s./larva divided by 8 days (test duration) to derive the endpoint in µg a.s./larva/day

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	Life Stage	Test Substance, Substrate and duration	End point	% effect	Trigger Value
Laboratory Tests (Tier I)					
Aleochara bilineata	10-14 day old adult females	treated sunflower seeds were applied to the surface of moistened quartz sand (2 seeds/arena of area 23.8 cm^2), 4 days of exposure	300 g APRON/100 kg seeds	< 50%	50%
Poecilus cupreus	2-10 week old adults	treated sunflower seeds were applied to the surface of moistened quartz sand (10 seeds/arena of area 155 cm^2), 14 days of exposure	300 g APRON/100 kg seeds	-	50%
Extended Laboratory tests (Tier II)					
Aleochara bilineata	1-7 day old adults	incorporation of the formulation into the soil, 28 days of exposure	100, 1000, 2000, 4000 and 6000 mL APRON/ha	No effects on mortality and reproduction > 50% were observed at 6000 mL APRON/ha which was the highest rate tested.	< 50%
Aphidius rhopalosiphi	<48 h old adult wasps	Dried residues on barley seedlings	213, 470, 1033, 2273 and 5000 mL Vibrance SB/ha	<50% effects on reproduction and mortality at 1033 mL Vibrance SB/ha	<50%

List of endpoints

Ecotoxicology

Typhlodromus pyri	<24 h old protonymphs	Dried residues on excised leaves	1.875, 3.75, 7.5, 15 and 30 L Vibrance SB/ha	<50% effects on reproduction and mortality at 15 L Vibrance SB/ha	<50%
Aleochara bilineata	1-7 day old adults	Soil incorporation	0.08, 0.16, 0.32, 0.64 and 1.28 mg Vibrance SB/kg soil d.w.	<50% effects on reproduction at 1.28 mg Vibrance SB/kg soil d.w.	<50%
Aphidius rhopalosiphi	<48 h old adult wasps	Dried residues on barley seedlings	64, 160, 400, 1000 and 2500 g Wakil XL/ha	<50% effects on reproduction and mortality at 400 g Wakil XL/ha	<50%
Typhlodromus pyri	<24 h old protonymphs	Dried residues on excised leaves	51.2, 128, 320, 800, 2000 and 5000 g Wakil XL/ha	<50% effects on reproduction and mortality at 800 g Wakil XL/ha	<50%
Aleochara bilineata	6 day old adults	Soil incorporation	150, 450, 1350, 4050 and 12150 g Wakil XL/ha	<50% effects on reproduction and mortality at 12150 g Wakil XL/ha (equivalent to 16.2 mg/kg soil d.w.)	<50%

List of endpoints

Ecotoxicology

Orius laevigatus	4-5 day old 2nd instar nymps	Dried residues on excised leaves	150, 450, 1350, 4050 and 12150 g Wakil XL/ha	<50% effects on reproduction and mortality at 12150 g Wakil XL/ha	<50%
Aleochara bilineata	2-5 day old adults	Dressed pea seeds, sand substrate	200 g Wakil XL/100 kg seed, sown at a rate of 300 kg seed/ha	<50% effects on reproduction at 200 g Wakil XL/kg seed (equivalent to 0.8 mg/kg soil d.w.)	<50%
Poecilus cupreus	18-20 day old adults	Dressed pea seeds, sand substrate	200 g Wakil XL/100 kg seed, sown at a rate of 300 kg seed/ha	<50% effects on reproduction at 200 g Wakil XL/kg seed (equivalent to 0.8 mg/kg soil d.w.)	<50%

First tier risk assessment for Tomato and Grapevine, spray treatment Ridomil Gold at 3x97g a.s./ha (in-field assessment based on Tier I data)

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger
RIDOMIL GOLD	*Typhlodromus pyri*	> 187.5	< 31	< 18	2

Tomato and Grapevine, spray treatment Ridomil Gold at 3x97g a.s./ha (in-field assessment based on Tier I data)

Test substance	Species	LR_{50} (g/ha)	In-field foliar		In-field soil	
			PER (g/ha)	Acceptable Risk	PER (g/ha)	Acceptable Risk

List of endpoints

Ecotoxicology

Test	Species	LR_{50}	In-field foliar		In-field soil	
RIDOMIL GOLD	*Aleochara bilineata*	> 7500	5750	Yes	3375	Yes
	Poecilus cupreus	> 7500	5750	Yes	3375	Yes
	Chrysoperla carnea	> 7000	5750	Yes	3375	Yes
	Coccinella septempuncata	> 7000	5750	Yes	3375	Yes

First tier risk assessment for Tomato Ridomil Gold at 3x97g a.s./ha (in-field assessment based on Tier I data)

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger
RIDOMIL GOLD	*Typhlodromus pyri*	> 187.5	< 0.62	< 2.1	2

First tier risk assessment for Grapevine Ridomil Gold at 3x97g a.s./ha (in-field assessment based on Tier I data)

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger
RIDOMIL GOLD	*Typhlodromus pyri*	> 187.5	< 0.76	< 2.1	2

Tomato and Grapevine, spray treatment Ridomil Gold at 3x97g a.s./ha (off-field assessment based on Tier I data)

Species	LR_{50} (g/ha)	Tomatoes				Grapevines			
		Height <50cm		Height >50cm		early		late	
		PER (g/ha)	Acceptable Risk	PER (g/ha)	Acceptable Risk	PER (g/ha)	Acceptable Risk	PER (g/ha)	Acceptable Risk
Aleochara bilineata	> 7500	116	Yes	397	Yes	143	Yes	397	Yes

List of endpoints

Ecotoxicology

Species	LR_{50}	Tomatoes				Grapevines			
Poecilus cupreus	> 7500	116	Yes	397	Yes	143	Yes	397	Yes
Chrysoperla carnea	> 7000	116	Yes	397	Yes	143	Yes	397	Yes
Coccinella septempunctata	> 7000	116	Yes	397	Yes	1473	Yes	397	Yes

[a]the $PER_{off\text{-}field}$ value is multiplied by the correction factor of 10 to account for the increased diversity in the off-crop environment

Tomato and Grapevine, spray treatment Ridomil Gold at 3x97g a.s./ha (off-field assessment based on Tier I data)

Species	Endpoint	Tomatoes				Grapevines			
		Height <50cm		Height >50cm		early		late	
		PER[a]	Acceptable Risk	PER[a]	Acceptable Risk	PER[a]	Acceptable Risk	PER[a]	Acceptable Risk
Typhlodromus pyri	ER_{50} > 64	58 (1 m)	Yes	199 (3 m)	No	71.5 (3 m)	Yes	199 (3 m)	Yes
		-	-	89 (5 m)	No	-	-	-	-
		-	-	29.4 (10 m)	Yes	-	-	-	-
Aphidius rhopalosiphi	ER_{50} > 7000	580 (1 m)	Yes	1985 (3 m)	Yes	715 (3 m)	Yes	1985 (3 m)	Yes
Aleochara bilineata	ER_{50} > 3750	58 (1 m)	Yes	199 (3 m)	Yes	71.5 (3 m)	Yes	199 (3 m)	Yes

[a]the $PER_{off\text{-}field}$ value is multiplied by the correction factor of 10 to account for the increased diversity in the off-crop environment

Field or Semi-field tests
Overall conclusion: The in-field PER values are less than the Tier II toxicity endpoints for predatory mites and beetles; however, residue decline data and field studies with predatory mites demonstrated recovery within the acceptable time frame. The off-field risk for *Aphidius rhopalosiphi* and *Aleochara bilineata* is acceptable. The off-field risk to *Typhlodromus pyri* is acceptable with a buffer zone of 10 m for tomatoes and of 3 m for grapevines.

In-field risk assessment for sugar and fodder beet seed treatment 'Vibrance SB' at 0.62 g a.s./ha

Test	Species	ER_{50} (mg/kg soil)	In-field soil

substance			PER (mg/kg soil)	Acceptable Risk
Vibrance SB	*Aleochara bilineata*	>1.28	0.06	Yes

In-field risk assessment for vining pea seed treatment 'Wakil XL' at 76.32 g a.s./ha

Test substance	Species	ER_{50} (mg/kg soil)	In-field soil	
			PER (mg/kg soil)	Acceptable Risk
Wakil XL	*Aleochara bilineata*	>16.2	0.747	Yes
	Aleochara bilineata	>0.8	0.747	Yes
	Poecilus cupreus	>0.8	0.747	Yes

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

Test organism	Test substance	Time scale	End point
Earthworms			
Eisenia fetida	metalaxyl-M	Acute 14 days	LC_{50} = 830 mg a.s./kg d.w.soil
Eisenia fetida	metalaxyl-M	Acute 14 days	LC_{50} > 1000 mg a.s./kg d.w.soil
Eisenia fetida	metalaxyl-M	Chronic 8 weeks	NOEC = 35.630 mg a.s./kg d.w.soil
Eisenia fetida	RIDOMIL GOLD	Acute	LC_{50} > 1000 mg/kg soil d.w. (0.98 mg metalaxyl-M and 15 mg mancozeb/kg soil d.w)
Eisenia fetida	APRON	Chronic	NOEC = 250 mg/kg soil d.w. (89 mg a.s./kg soil d.w.)
Eisenia fetida	RIDOMIL GOLD	Chronic	NOEC = 39.06 mg/kg soil d.w. (1.56 mg metalaxyl-M and 25 mg mancozeb/kg soil d.w)
Eisenia fetida	Vibrance SB	Chronic	EC_{10} = 13 mg/kg soil d.w. (corrected = 6.5 mg/kg soil d.w.)
Eisenia andrei	Wakil XL	Chronic	NOEC = 171 mg/kg soil d.w. (corrected = 85.5 mg/kg soil d.w.)
Eisenia fetida	Wakil XL	Chronic	NOEC = 6.66 mg/kg soil d.w. (corrected = 3.33 mg/kg soil d.w.)

List of endpoints

Ecotoxicology

Test organism	Test substance	Time scale	End point
Eisenia fetida	CGA 62826 (NOA 409045)	Acute	LC_{50} > 1000 mg/kg soil d.w.
Eisenia fetida	CGA 108906 (SYN 546520)	Acute	LC_{50} > 1000 mg/kg soil d.w.
Eisenia fetida	CGA 62826 (NOA 409045)	Chronic	NOEC = 500 mg/kg soil d.w.
Eisenia fetida	CGA 108906 (SYN 546520)	Chronic	NOEC = 500 mg/kg soil d.w.
Other soil macroorganisms			
Hypoaspis aculeifer	APRON	Chronic	EC_{10} = 16.6 mg a.s./kg soil d.w.
Hypoaspis aculeifer	Vibrance SB	Chronic	NOEC = 1000 mg/kg soil d.w. (corrected = 500 mg/kg soil d.w.)
Hypoaspis aculeifer	Wakil XL	Chronic	NOEC = 1000 mg/kg soil d.w. (corrected = 500 mg/kg soil d.w.)
Collembola			
Folsomia candida	metalaxyl-M	Chronic	NOEC = 125 mg a.s./kg soil d.w.
Folsomia candida	APRON	Chronic	NOEC = 250 mg/kg soil d.w. (89 mg a.s./kg soil d.w.)
Folsomia candida	RIDOMIL GOLD	Chronic	NOEC = 125 mg/kg soil d.w. (4.71 mg metalaxyl-M and 81 mg mancozeb/kg soil d.w)
Folsomia candida	Vibrance SB	Chronic	NOEC = 61 mg/kg soil d.w. (corrected = 30.5 mg/kg soil d.w.)
Folsomia candida	Wakil XL	Chronic	NOEC = 28.8 mg/kg soil d.w. (corrected = 14.4 mg/kg soil d.w.)
Soil micro-organisms			
Nitrogen mineralisation	metalaxyl-M	28 – 90 days	< 25 % effects at 6.6 mg/kg soil d.w.
Nitrogen mineralisation	RIDOMIL GOLD	28 days	< 25 % effects at 1.35 mg metalaxyl-M and 21.47 mg mancozeb/kg soil d.w.

List of endpoints

Ecotoxicology

Test organism	Test substance	Time scale	End point
Nitrogen mineralisation	Vibrance SB	28 days	< 25 % effects at 0.45 mg/kg soil d.w.
Nitrogen mineralisation	Wakil XL	28 days	< 25 % effects at 6 mg/kg soil d.w.
Nitrogen mineralisation	NOA 409045	28 days	< 25 % effects at 7.6 mg/kg soil d.w.
Nitrogen mineralisation	CGA 108906	28 days	< 25 % effects at 1.4 mg/kg soil d.w.
Carbon mineralisation	metalaxyl-M	28 – 90 days	< 25 % effects at 6.6 mg/kg soil d.w.
Carbon mineralisation	RIDOMIL GOLD	28 days	< 25 % effects at 1.35 mg metalaxyl-M and 21.47 mg mancozeb/kg soil d.w.
Carbon mineralisation	NOA 409045	28 days	< 25 % effects at 7.6 mg/kg soil d.w.
Carbon mineralisation	CGA 108906	28 days	< 25 % effects at 1.4 mg/kg soil d.w.
Field studies[2]			
Not required			

[1]To indicate whether the test substance was oversprayed/to indicate the organic content of the test soil (e.g. 5 % or 10 %).
[2] litter bag, field arthropod studies not included at 8.3.2/10.5 above, and earthworm field studies.
* Exposure via treated seed placed on soil surface

Toxicity/exposure ratios for soil organisms

Crop and application rate: sunflower, seed treatment APRON at 6.1 g a.s./ha

Test organism	Test substance	Time scale	Soil PEC[1]	TER	Trigger
Earthworms					
Eisenia fetida	metalaxyl-M	Acute	0.008	103750	10
Eisenia fetida	metalaxyl-M	Chronic	0.008	4454	5
Eisenia fetida	APRON	Chronic	0.026	9615	5
Eisenia fetida	NOA 409045	Acute	0.006	> 166667	10
Eisenia fetida	NOA 409045	Chronic	0.006	83333	5

List of endpoints

Ecotoxicology

Test organism	Test substance	Time scale	Soil PEC[1]	TER	Trigger
Other soil macroorganisms					
Hypoaspis aculeifer	APRON (a.s.)	Chronic	0.008	2075	5
Folsomia candida	Metalaxyl-M	Chronic	0.008	15625	5
Folsomia candida	APRON	Chronic	0.026	9615	5

[1]To be completed where first Tier triggers are breached
[2] Indicate which PEC soil was used (e.g. plateau PEC)

Toxicity/exposure ratios for soil organisms

Crop and application rate: spinach seed treatment APRON at 81.4 g a.s./ha

Test organism	Test substance	Time scale	Soil PEC[1]	TER	Trigger
Earthworms					
Eisenia fetida	metalaxyl-M	Acute	0.109	7615	10
Eisenia fetida	metalaxyl-M	Chronic	0.109	327	5
Eisenia fetida	APRON	Chronic	0.352	710	5
Eisenia fetida	NOA 409045	Acute	0.074	> 13514	10
Eisenia fetida	NOA 409045	Chronic	0.074	6757	5
Other soil macroorganisms					
Hypoaspis aculeifer	APRON (a.s.)	Chronic	0.109	152	5
Folsomia candida	Metalaxyl-M	Chronic	0.109	1147	5
Folsomia candida	APRON	Chronic	0.352	710	5

[1]To be completed where first Tier triggers are breached
[2] Indicate which PEC soil was used (e.g. plateau PEC)

Toxicity/exposure ratios for soil organisms

Crop and application rate: tomato seed treatment RIDOMIL GOLD at 3 x 97g a.s./ha

Test organism	Test substance	Time scale	Soil PEC[1]	TER	Trigger
Earthworms					
Eisenia fetida	metalaxyl-M	Acute	0.141	5887	10
Eisenia fetida	metalaxyl-M	Chronic	0.141	253	5
Eisenia fetida	RIDOMIL GOLD	Acute	1.670	> 599	10

List of endpoints

Ecotoxicology

Test organism	Test substance	Time scale	Soil PEC[1]	TER	Trigger
Eisenia fetida	RIDOMIL GOLD	Chronic	1.670	23	5
Eisenia fetida	NOA 409045	Acute	0.100	> 10000	10
Eisenia fetida	NOA 409045	Chronic	0.100	5000	5
Other soil macroorganisms					
Folsomia candida	Metalaxyl-M ‡	Chronic	0.141	887	5
Folsomia candida	RIDOMIL GOLD	Chronic	1.670	75	5

[1]To be completed where first Tier triggers are breached
[2] Indicate which PEC soil was used (e.g. plateau PEC)

Toxicity/exposure ratios for soil organisms

Crop and application rate: grapevine seed treatment RIDOMIL GOLD at 3 x 97g a.s./ha

Test organism	Test substance	Time scale	Soil PEC[1]	TER	Trigger
Earthworms					
Eisenia fetida	metalaxyl-M	Acute	0.134	6194	10
Eisenia fetida	metalaxyl-M	Chronic	0.134	266	5
Eisenia fetida	RIDOMIL GOLD	Acute	1.670	> 599	10
Eisenia fetida	RIDOMIL GOLD	Chronic	1.670	23	5
Eisenia fetida	NOA 409045	Acute	0.096	> 10417	10
Eisenia fetida	NOA 409045	Chronic	0.096	5208	5
Other soil macroorganisms					
Folsomia candida	Metalaxyl-M	Chronic	0.134	933	5
Folsomia candida	RIDOMIL GOLD	Chronic	1.670	75	5

Toxicity/exposure ratios for soil organisms

Crop and application rate: sugar beet seed treatment 'Vibrance SB' at 0.62 g a.s./ha

Test organism	Test substance	Time scale	Soil PEC	TER	Trigger
Earthworms					
Eisenia fetida	Metalaxyl-M	Chronic	0.001	35630	5
Eisenia fetida	Vibrance SB	Chronic	0.06	108	5
Other soil macroorganisms					
Folsomia candida	Metalaxyl-M	Chronic	0.001	125000	5
Folsomia candida	Vibrance SB	Chronic	0.06	508	5
Hypoaspis aculeifer	Metalaxyl-M	Chronic	0.001	16600	5
Hypoaspis aculeifer	Vibrance SB	Chronic	0.06	8333	5

Toxicity/exposure ratios for soil organisms

Crop and application rate: vining pea seed treatment 'Wakil XL' at 76.32 g a.s./ha

Test organism	Test substance	Time scale	Soil PEC	TER	Trigger
Earthworms					
Eisenia fetida	Metalaxyl-M	Chronic	0.127	281	5
Eisenia andrei	Wakil XL	Chronic	0.747	114	5
Eisenia fetida	Wakil XL	Chronic	0.747	9	5
Other soil macroorganisms					
Folsomia candida	Metalaxyl-M	Chronic	0.127	984	5
Folsomia candida	Wakil XL	Chronic	0.747	19	5
Hypoaspis aculeifer	Metalaxyl-M	Chronic	0.127	131	5
Hypoaspis aculeifer	Wakil XL	Chronic	0.747	669	5

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)

Preliminary Screening data

List of endpoints

Ecotoxicology

Most Sensitive Species	Test substance	ER_{50} (g/ha)[2] vegetative vigour	ER_{50} (g/ha)[2] emergence	Exposure[1] (g/ha)[2]	TER
Brassica napus, Avena fatua, Beta vulgaris, Zea mays, Glycine max, Allium cepa	RIDOMIL GOLD	ER_{50} > 4500 g/ha	ER_{50} > 4500 g/ha	200.5	acceptable

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

Test type/organism	Endpoint
Activated sludge	EC_{50} > 100 mg/L

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

Available monitoring data concerning adverse effect of the a.s.

Available monitoring data concerning effect of the PPP.

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

Compartment	
soil	Metalaxyl-M, CGA 62826 (R enantiomer of NOA 409045)
water	Metalaxyl-M, CGA 62826 (R enantiomer of NOA 409045)
sediment	Metalaxyl-M, CGA 62826 (R enantiomer of NOA 409045)
groundwater	Metalaxyl-M, CGA 62826 (R enantiomer of NOA 409045), CGA 67868, CGA 108906 (R enantiomer of SYN 546520)

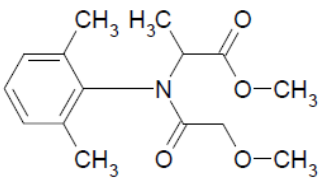
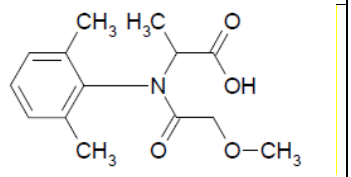
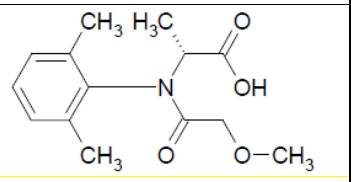
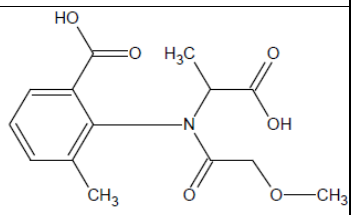
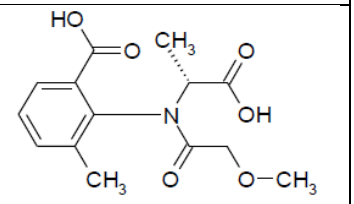
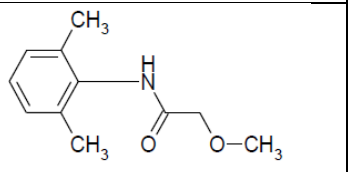
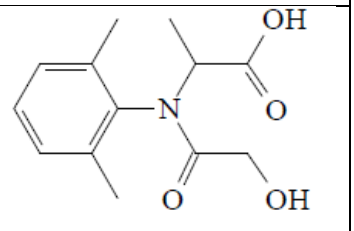
[1] metabolites are considered relevant when, based on the risk assessment, they pose a risk comparable or higher than the parent

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

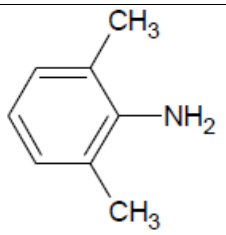
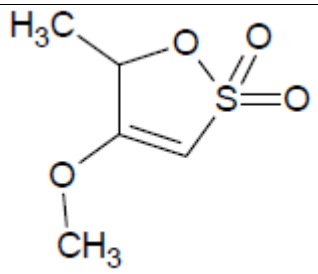
Substance	name
Mandatory classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process as applicable in GB:	
GB Authority proposal[10] for harmonised classification according to Regulation (EC) No 1272/2008 as applicable in GB:	

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

Used compounds code(s)

Code	IUPACname/SMILES notation	Structural formula
Metalaxyl CGA48988	methyl *N*-(methoxyacetyl)-*N*-2,6-xylyl-alaninate CC(N(C(=O)COC)c1c(C)cccc1C)C(=O)OC	
CGA62826	(RS)-2-[(2,6-Dimethyl-phenyl)-(2-methoxy-acetyl)-amino]-propionic acid CC(N(C(=O)COC)c1c(C)cccc1C)C(=O)O	
NOA409045	(R)-2-[(2,6-Dimethyl-phenyl)-(2-methoxy-acetyl)- amino]-propionic acid C[COOH](N(C(=O)COC)c1c(C)cccc1C)C(=O)O	
CGA108906	2-[((RS)-1-Carboxy-ethyl)-(2-methoxy-acetyl)-amino]-3-methyl-benzoic acid CC(N(C(=O)COC)c1c(C)cccc1C(=O)O)C(=O)O	
SYN546520	2-[((R)-1-Carboxy-ethyl)-(2-methoxy-acetyl)-amino]-3-methyl-benzoic acid C[C@@H](N(C(=O)COC)c1c(C)cccc1C(=O)O)C (=O)O	
CGA67868	N-(2,6-Dimethyl-phenyl)-2-methoxy-acetamide O=C(Nc1c(C)cccc1C)COC	
CGA107955	N-(2,6-dimethylphenyl)-N-(hydroxyacetyl)alanine CC(N(C(=O)CO)c1c(C)cccc1C)C(=O)O	

Appendix

CGA72649	2,6-dimethyl-phenylamine Cc1cccc(C)c1N	
CGA363736	4-methoxy-5-methyl-5H-[1,2]oxathiole 2,2-dioxide CC1OS(=O)(=O)C=C1OC	
CGA226048	1-methoxy-1-oxopropan-2-yl N-(2,6-dimethylphenyl)-N-(methoxyacetyl)alaninate CC(N(C(=O)COC)c1c(C)cccc1C)C(=O)OC(C)C(=O)OC