Appendix to:

EFSA (European Food Safety Authority), 2017. Conclusion on the peer review of the pesticide risk assessment of the active substance laminrin. EFSA Journal 2017;15(5):4836, 45 pp. doi:10.2903/j.efsa.2017.4836

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

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

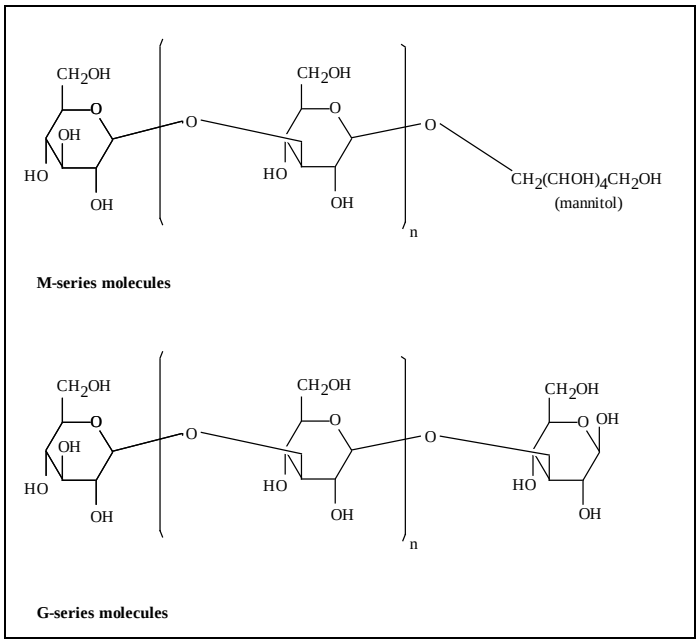
Active substance (ISO Common Name)	Laminarin (common name, not ISO)
Function (*e.g.* fungicide)	Elicitor of the self-defence mechanisms of crops

Rapporteur Member State	Netherlands
Co-rapporteur Member State	France

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

Chemical name (IUPAC)	(1→3)-β-D-glucan (according to IUPAC-IUB Joint Commission on Biochemical Nomenclature)
Chemical name (CA)	Laminarin
CIPAC No	671
CAS No	9008-22-4
EC No (EINECS or ELINCS)	232-712-4
FAO Specification (including year of publication)	Not available
Minimum purity of the active substance as manufactured	860 g/kg on dry matter (TC) 60 g/L (min. 50 g/L, max. 70 g/L) (TK)
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	As, I :open open for heavy metals
Molecular formula	$(C_6H_{10}O_5)_n$ n = 20 to 30
Molar mass	3240 – 4860 g/mol

Structural formula



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

Melting point (state purity)	Decomposes before melting
Boiling point (state purity)	Decomposes before boiling
Temperature of decomposition (state purity)	>200 °C (98%)
Appearance (state purity)	White to off-white crystals (98%)
Vapour pressure (state temperature, state purity)	< 2.6×10^{-5} Pa at 25°C (98%)
Henry's law constant (state temperature)	< 3.45×10^{-7} Pa m^3 mol^{-1} (23-25°C)
Solubility in water (state temperature, state purity and pH)	301.5 g/L at 23°C (98%) No pH dependence expected
Solubility in organic solvents (state temperature, state purity)	in g/L (98%) heptane <10 mg/L, expressed as glucose xylene <10 mg/L, expressed as glucose 1,2-dichloroethane <10 mg/L, expressed as glucose methanol 60 mg/L, expressed as glucose acetone 21 mg/L, expressed as glucose ethylacetate <10 mg/L, expressed as glucose
Surface tension (state concentration and temperature, state purity)	72.2 mN/m at 20.2°C (1g/L) (98%) Not a surface active material
Partition coefficient (state temperature, pH and purity)	log P_{OW} = -1.6 (pH 4, 7 and 9) (98%)
Dissociation constant (state purity)	No dissociation within an environmentally relevant pH range.
UV/VIS absorption (max.) incl. ε (state purity, pH)	At pH 1.9: λ_{max} = 264 nm; ε = 245 to 294 $L.mol^{-1}.cm^{-1}$ At pH 7.0: λ_{max} = 260 nm; ε = 242 to 290 $L.mol^{-1}.cm^{-1}$ At pH 11.8: λ_{max} = 258 nm; ε = 264 to 317 $L.mol^{-1}.cm^{-1}$
Flammability (state purity)	Not flammable in the sense of Reg (EC) 1272/2008 Self-ignition >420°C (both 90% pure)
Explosive properties (state purity)	Not explosive (theoretical consideration)
Oxidising properties (state purity)	Not oxidising (theoretical consideration)

Summary of representative uses evaluated, for which all risk assessments needed to be completed (*name of active substance or the respective variant*)
(Regulation (EU) N° 284/2013, Annex Part A, points 3, 4)

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group) (c)	Preparation		Application			Interval between application (min)	Application rate per treatment			PHI (days) (m)	Remarks: a) max. no. of applications per crop and season b) Max product rate per season c) Additional remarks
					Type (d-f)	Conc. a.s. (i)	Method / Kind (f-h)	range of growth stages & season (j)	number min-max (k)		kg, L product / ha	Water L/ha min / max	g, kg as/ha (l)		
Apple (MABSD)	EU	Vacciplant Fruits et Légumes	F	Gloeosporium GLOESP Powdery mildew *Podosphaera leucotricha* PODOLE Scab *Venturia inaequalis* VENTIN	SL	45 g/L	Foliar spraying	BBCH 11-89 March to November	20	7 days	Standard orchard: 1 L/ha 0.67 L/ha	200 - 500	Standard orchard: 45 g a.s./ha 30.2 g as/ha	0	a)Per season: 20 b)20 L/ha c)Standard orchard in this case is 3 m tall, with a row distance of 4 m.
Apple (MABSD)	EU	Vacciplant Fruits et Légumes	F	Fire blight *Erwinia amylovora* EWIAM	SL	45 g/L	Foliar spraying	BBCH 56-89 April to November	7	10 days	Standard orchard : 0.75 L/ha 0.5 L/ha	500-1000	Standard orchard : 33.8 g a.s./ha 22.5 g a.s./ha	0	a) Per season: 7 b) 5.25L/ha 3.5L/ha c) Standard orchard in this case is 3 m tall, with a row distance of 4 m.
Pear (PYUCO)	EU	Vacciplant Fruits et Légumes	F	Fire blight *Erwinia amylovora* EWIAM	SL	45 g/L	Foliar spraying	BBCH 56-89 April to November	7	10 days	Standard orchard : 0.75 L/ha 0.5 L/ha	500-1000	Standard orchard : 33.8 g a.s./ha 22.5 g a.s./ha	0	a) Per season: 7 b) 5.25L/ha 3.5L/ha c) Standard orchard in this case is 3 m tall, with a row distance of 4 m.

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group) (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks: a) max. no. of applications per crop and season b) Max product rate per season c) Additional remarks
					Type (d-f)	Conc. a.s. (i)	Method / Kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg, L product / ha	Water L/ha min / max	g, kg as/ha (l)		
Vine (VITVI)	EU	Vacciplant Fruits et Légumes	F	Powdery mildew *Erysiphe necator* UNCINE	SL	45 g/L	Foliar spraying	BBCH 11-89 April to october	10	10 days	2 L/ha	100-1000	a) 90 g a.s./ha	0	a) Per season: 10 b)20L/ha
Lettuce (LACSA)	EU	Vacciplant Fruits et Légumes	F, G*	Downy mildew *Bremia lactucae* BREMLA	SL	45 g/L	Foliar spraying	BBCH 13-49 January to December	per cycle: 6 season: 16	7 days 7 days	2.5 L/ha	500-1000	113 g a.s./ha	0	a)Per crop:6 Per season: 16 b)Per cycle: 15L/ha Per season:40L/ha
Strawberry (FRASS)	EU	Vacciplant Fruits et Légumes	F, G*	Powdery mildew *Podosphaera aphanis* PODOAP	SL	45 g/L	Foliar spraying	BBCH 12-92 March to October	7	7 days	Min : 0.75 l Max : 1 L/ha	300-1000	45 g a.s./ha	0	a)Per crop : 7 Per season : 7 b) 7L/ha c) Min 0.75 L/ha Max 1L/ha
Strawberry (FRASS)	EU	Vacciplant Fruits et Légumes	F, G*	Grey mould *Botrytis cinerea* BOTRCI Leaf spot *Mycosphaerella fragariae* MYCOFR Leaf scorch *Diplocarpon earliana* DIPCEA Leather rot *Phytophthora cactorum* PHYTCC	SL	45 g/L	Foliar spraying	BBCH 12-92 February to September	7	5-7 days	Min 1 L/ha Max 2 L/ha	300-1000	Min 45 g a.s./ha Max 90 g a.s./ha	0	a)Per crop:7 Per season: 7 b)Min: 7L/ha Max: 14L/ha c)Apply Vacciplant at 1 L/ha for water volume below 500 L/ha. Above 500 L/ha keep the product concentration at 0.2 L/hL .
Tomato (LYPES)	EU	Vacciplant Fruits et Légumes	F, G*	Bacterial speck *Pseudomonas syringae* pv tomato PSDMTM	SL	45 g/L	Foliar spraying	BBCH 10-89 April to October	7	7 days	Min 1 L/ha Max 2 L/ha	500-1300	Min 45 g a.s./ha Max 90 g a.s./ha	0	a) Per crop:7 Per season: 7 b)Min: 7L/ha Max: 14L/ha
Tomato	EU	Vacciplant	F,	Grey mould	SL	45 g/L	Foliar	BBCH 10-89	7	7 days	Min 1.5 L/ha	500-1300	Min 67.5 g	0	a) Per crop:7

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group) (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks: a) max. no. of applications per crop and season b) Max product rate per season c) Additional remarks
					Type (d-f)	Conc. a.s. (i)	Method / Kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg, L product / ha	Water L/ha min / max	g, kg as/ha (l)		
(LYPES)		Fruits et Légumes	G*	*Botrytis cinerea* BOTRCI			spraying	January to December			Max 3 L/ha		a.s./ha Max 135 g a.s./ha		Per season: 7 b)Min: 10.5L/ha Max: 21L/ha
Tomato (LYPES)	EU	Vacciplant Fruits et Légumes	F, G*	Powdery mildew *Leveillula taurica* LEVETA	SL	45 g/L	Foliar spraying	BBCH 10-89 March to December	7	7 days	1 L/ha	500-1300	45 g a.s./ha	0	a) Per crop:7 Per season: 7 b) 7 L/ha
Courgette (CUUPG)	EU	Vacciplant Fruits et Légumes	F, G*	Powdery mildew *Leveillula taurica* LEVETA	SL	45 g/L	Foliar spraying	BBCH 10-89 January to December	6	5 days	0.75 L/ha	100-500	33.8 g a.s./ha	0	a) Per crop: 6 Per season: 6 b) 4.5L/ha
Pumpkins (CUUMA)	EU	Vacciplant Fruits et Légumes	F	Powdery mildew *Leveillula taurica* LEVETA	SL	45 g/L	Foliar spraying	BBCH 10-89 January to December	6	5 days	0.75 L/ha	100-500	33.8 g a.s./ha	0	a) Per crop:6 Per season: 6 b) 4.5L/ha
Aubergine (SOLME) Pepper (CPSAN)	EU	Vacciplant Fruits et Légumes	F, G*	Grey mould *Botrytis cinerea* BOTRCI	SL	45 g/L	Foliar spraying	BBCH 60-89 February to October	7	7 days	3 L/ha	500-1300	135 g a.s./ha	0	a) Per crop :7 Per season: 7 b) 21L/ha c)
Lettuce (LACSA)	EU	Vacciplant Fruits et Légumes	F	Grey mould *Botrytis* sp. BOTRSP	SL	45 g/L	Foliar spraying	BBCH 16-49 January to December	7	7 days	3 L/ha	750-1000	135 g a.s./ha	0	a) Per crop: 7 Per season: 7 b) 21L/ha
Greenbean (PHSVV)	EU	Vacciplant Fruits et Légumes	F	Grey mould *Botrytis* spp. BOTRSP	SL	45 g/L	Foliar spraying	BBCH 51-89 March to September	7	7 days	3 L/ha	800-1300	a) 135 g a.s./ha	0	a) Per crop: 7 Per season: 7 b) 21L/ha
Cucurbits: Cucumber (CUMSA) Zucchini (CUUPG)	EU	Vacciplant Fruits et Légumes	F, G*	Grey mould *Botrytis* spp. BOTRSP	SL	45 g/L	Foliar spraying	BBCH 60-89 January to December	7	7 days	3 L/ha	800-1300	135 g a.s./ha	0	a) Per crop: 7 Per season: 7 b) 21L/ha
Cucumber (CUMSA)	EU	Vacciplant Fruits et Légumes	F, G*	Downy mildew *Pseudoperonospora cubensis* PSPECU	SL	45 g/L	Foliar spraying	BBCH 51-89 January to December	7	7 days	3 L/ha	800-1300	135 g a.s./ha	0	a) Per crop: 7 Per season: 7 b) 21L/ha
Kiwi (ATICH)	EU	Vacciplant Fruits et Légumes	F	Bacterial canker *Pseudomonas syringae* pv. Actinidiae	SL	45 g/L	Foliar spraying	BBCH 11- March to November	7	10 days	2 L/ha	700-1000	90 g a.s./ha	0	a) Per season: 7 b) 14L/ha

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group) (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks: a) max. no. of applications per crop and season b) Max product rate per season c) Additional remarks
					Type (d-f)	Conc. a.s. (i)	Method / Kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg, L product / ha	Water L/ha min / max	g, kg as/ha (l)		
				PSDMAK											

*Greenhouse uses include both permanent and semi-permanent/open structures.

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

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

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

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s /hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
MRL Application (according to Article 8.1(g) of Regulation (EC) No 1107/2009)															
Not applicable, inclusion in Annex IV of Reg (EC) 396/2005															

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

Further information, Efficacy

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

It was already demonstrated in biological assessment dossiers submitted for Vacciplant Fruits et Légumes in Belgium (2008) that this product reached a level of control sufficient when applied as preventive treatment on fruits and vegetables crops against a wide range of various pathogens. For further information see also Volume 1 level 1: 1.5.4 Overview on authorisations in EU Member States (Netherlands, 2017). The representative uses of the GAP are supported.

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

The representative uses of the GAP are supported, no negative effects are known.

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

No undesirable or unintended side-effects on adjacent or succeeding crops are known when the product is applied as indicated on the label. The representative uses of the GAP are supported.

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

Soil metabolites triggering groundwater exposure assessment were not identified so the provision of screening data was not triggered.

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)	Open, awaiting batch analysis data
Impurities in technical a.s. (analytical technique)	Open, awaiting batch analysis data
Plant protection product (analytical technique)	IC

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

Residue definitions for monitoring purposes

Food of plant origin		Not required
Food of animal origin		Not required
Soil		No residue definition proposed
Sediment		No residue definition proposed
Water	surface	No residue definition proposed
	drinking/ground	Laminarin
Air		No residue definition proposed
Body fluids and tissues		No residue definition proposed

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Not required
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Not required
Soil (analytical technique and LOQ)	Not required, no residue definition proposed
Water (analytical technique and LOQ)	Open for groundwater
Air (analytical technique and LOQ)	Not required, no residue definition proposed
Body fluids and tissues (analytical technique and LOQ)	Not required, no residue definition proposed

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

Substance	Laminarin
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended][1]:	No current harmonised classification.
Peer review proposal [2] for harmonised classification according to Regulation (EC) No 1272/2008:	None

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

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

Impact on Human and Animal Health

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

Rate and extent of oral absorption/systemic bioavailability	Very limited absorption (<0.5%)
Toxicokinetics	No specific ADME study available. Not required.
Distribution	Limited to the gastrointestinal tract and the liver
Potential for bioaccumulation	No evidence for accumulation
Rate and extent of excretion	Degradation products rapidly and extensively excreted (approx. 90%) via breath and flatus
Metabolism in animals	Extensively metabolised into short chain fatty acids via colonic microbiota fermentation
In vitro metabolism	No data - not required
Toxicologically relevant compounds (animals and plants)	None: laminarin is a polysaccharide of glucose and mannitol
Toxicologically relevant compounds (environment)	None: laminarin is a polysaccharide of glucose and mannitol

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

Rat LD_{50} oral	> 2000 mg/kg bw	
Rat LD_{50} dermal	> 5000 mg/kg bw	
Rat LC_{50} inhalation	> 1.02 mg/L air /4h (*head-nose only; maximum attainable concentration*)	
Skin irritation	Non-irritant	
Eye irritation	Non-irritant	
Skin sensitisation	Non-sensitising (*M&K test*)	
Phototoxicity	No data - not required	

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

Target organ / critical effect	Rat: no effects Dog: no effects	
Relevant oral NOAEL	90-day, dog: 1000 mg/kg bw per day 90-day rat: 1000 mg/kg bw per day	
Relevant dermal NOAEL	No data - not required	
Relevant inhalation NOAEL	No data - not required	

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

In vitro studies	Ames test: equivocal Gene mutation in mouse lymphoma: negative Chromosome aberration in CHO cells (public literature): negative	
In vivo studies	Micronucleus: negative	
Photomutagenicity	not required	

Potential for genotoxicity	Laminarin is unlikely to be genotoxic	

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

Long-term effects (target organ/critical effect)	No data - not required	
Relevant long-term NOAEL	No data - not required	
Carcinogenicity (target organ, tumour type)	No data - not required	
Relevant NOAEL for carcinogenicity	No data - not required	

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

Reproduction toxicity

Reproduction target / critical effect	No data - not required	
Relevant parental NOAEL	No data - not required	
Relevant reproductive NOAEL	No data - not required	
Relevant offspring NOAEL	No data - not required	

Developmental toxicity

Developmental target / critical effect	Rat: Maternal toxicity: no effects Developmental toxicity: no effects Rabbit: Maternal toxicity: no effects Developmental toxicity: no effects	
Relevant maternal NOAEL	Rat: 1000 mg/kg bw per day (highest dose tested) Rabbit: 1000 mg/kg bw per day (highest dose tested)	
Relevant developmental NOAEL	Rat: 1000 mg/kg bw per day (highest dose tested) Rabbit: 1000 mg/kg bw per day (highest dose tested)	

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

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	No data - not required
Endocrine disrupting properties	No data - not required
Studies performed on metabolites or impurities	No data - not required

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

Due to the nature of the active substance no medical surveillance is carried out.

Summary[3] (Regulation (EU) N°1107/2009, Annex II, point 3.1 and 3.6)	Value (mg/kg bw (per day))	Study	Uncertainty factor
Acceptable Daily Intake (ADI)	Not required	-	-
Acute Reference Dose (ARfD)	Not required	-	-
Acceptable Operator Exposure Level (AOEL)	Not required	-	-
Acute Acceptable Operator Exposure Level (AAOEL)	Not required	-	-

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

Representative formulation	No data – not required

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

Operators	No exposure assessment was deemed necessary, as the substance does not present a toxicological concern and is a natural polysaccharide
Workers	No exposure assessment was deemed necessary, as the substance does not present a toxicological concern and is a natural polysaccharide
Bystanders and residents	No exposure assessment was deemed necessary, as the substance does not present a toxicological concern and is a natural polysaccharide

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

Substance :	laminarin
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended][4] :	No current harmonised classification.
Peer review proposal [5] for harmonised classification according to Regulation (EC) No 1272/2008:	None

[3] If available include also reference values for metabolites
[4] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.
[5] It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.

Residues in or on treated products food and feed

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

Primary crops (Plant groups covered) **OECD Guideline 501**	**Crop groups**	**Crop(s)**	**Application(s)**	**DAT** (days)
	Fruit crops	-	-	-
	Root crops	-	-	-
	Leafy crops	-	-	-
	Cereals/grass crops	-	-	-
	Pulses/Oilseeds	-	-	-
	Miscellaneous	-	-	-
	No plant metabolism studies submitted, not required			

Rotational crops (metabolic pattern) **OECD Guideline 502**	**Crop groups**	**Crop(s)**	**PBI** (days)	**Comments**
	Root/tuber crops	-	-	
	Leafy crops	-	-	
	Cereal (small grain)	-	-	
	Other	-	-	
Rotational crop and primary crop metabolism similar?	No rotational crop metabolism studies submitted, not required			

Processed commodities (standard hydrolysis study) **OECD Guideline 507**	**Conditions**				
	20 min, 90°C, pH 4	-	-	-	-
	60 min, 100°C, pH 5	-	-	-	-
	20 min, 120°C, pH 6	-	-	-	-
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Standard hydrolysis studies were not conducted, not required.				

Plant residue definition for monitoring (RD-Mo) **OECD Guidance, series on pesticides No 31**	Not required
Plant residue definition for risk assessment (RD-RA)	Not required
Conversion factor (monitoring 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**	**Animal**	**Dose** (mg/kg bw/d)	**Duration** (days)	**N rate/comment**
	Laying hen	-	-	-
	Goat/Cow	-	-	-
	Pig	-	-	-
	Fish	mg/kg DM	-	-

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

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**	No confined rotational crop studies submitted, not required
Field rotational crop study **OECD Guideline 504**	No field rotational crop studies submitted, not required

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

OECD Guideline 506

Plant products (Category)	Commodity	T (°C)	Stability (Month/Year)			
High water content	-	-	-	-	-	-
High oil content	-	-	-	-	-	-
High protein content	-	-	-	-	-	-
High starch content	-	-	-	-	-	-
High acid content	-	-	-	-	-	-
No storage stability studies submitted, not required						
Animal	**Animal commodity**	**T (°C)**	**Stability** (Month/Year)			
			-	-	-	-
-	Muscle	-	-	-	-	-
-	Liver	-	-	-	-	-
-	Kidney	-	-	-	-	-
-	Milk	-	-	-	-	-
-	Egg	-	-	-	-	-
No storage stability studies submitted, not required						

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

Crop	**Region/ Indoor** (a)	**Residue levels** (mg/kg) **observed in the supervised residue trials relevant to the supported GAPs** (b)	**Recommendations/comments** (OECD calculations)	**MRL** proposals (mg/kg)	**HR** (mg/kg) (c)	**STMR** (mg/kg) (d)
No supervised residue trials submitted, not required						

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

Inputs for animal burden calculations

Feed commodity	Median dietary burden		Maximum dietary burden	
	(mg/kg)	Comment	(mg/kg)	Comment
Not relevant	-	-	-	-

Residues from livestock feeding studies (Regulaton (EU) N° 283/2013, Annex Part A, points 6.4.1, 6.4.2, 6.4.3 and 6.4.4)

OECD Guideline 505 and OECD Guidance, series on pesticides No 73

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

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

STMR calculations	**Ruminant**				**Pig/Swine**		**Poultry**		**Fish**	
Median expected intake (mg/kg bw/d) (mg/kg DM for fish)	Beef cattle	-	Ram/Ewe	-	Breeding	-	Broiler	-	Carp	-
	Dairy cattle	-	Lamb	-	Finishing	-	Layer	-	Trout	-
							Turkey	-		
Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and **N rates**	Level	Beef: N Dairy: N	Level	Lamb : N Ewe: N	Level	N rate Breed/Finish	Level	B or T: N Layer: N	Level	N rate Carp/Trout
	Mean level in feeding level	Estimated **STMR**[(b)] at 1N	Mean level in feeding level	Estimated **STMR**[(b)] at 1N	Mean level in feeding level	Estimated **STMR**[(b)] at 1N	Mean level in feeding level	Estimated **STMR**[(b)] at 1N	Mean level in feeding level	Estimated **STMR**[(b)] at 1N
Muscle	-	-	-	-	-	-	-	-	-	-
Fat	-	-	-	-	-	-	-	-	-	-
Meat[(a)]	-	-	-	-	-	-	-	-	-	-
Liver	-	-	-	-	-	-	-	-	-	-
Kidney	-	-	-	-	-	-	-	-	-	-
Milk	-	-	-	-	-	-	-	-	-	-
Eggs	-	-	-	-	-	-	-	-	-	-
Method of calculation[(c)]										

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

Conversion Factors (CF) for monitoring to risk assessment

Not relevant

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

OECD Guideline 508 and OECD Guidance, series on testing and assessment No 96

Crop (RAC)/Edible part or Crop (RAC)/Processed product	Number of studies[a]	Processing Factor (PF)		Conversion Factor (CF_P) for RA[b]
		Individual values	Median PF	
No studies submitted, not required				

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

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

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

ADI	Not required
TMDI according to EFSA PRIMo	Not required
NTMDI, according to (to be specified)	Not required
IEDI (% ADI), according to EFSA PRIMo	Not required
NEDI (% ADI), according to (to be specified)	Not required
Factors included in the calculations	
ARfD	Not required
IESTI (% ARfD), according to EFSA PRIMo	Not required
NESTI (% ARfD), according to (to be specified)	Not required
Factors included in IESTI and NESTI	

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

Since laminarin is a natural oligosaccharide and an ADI and/or ARfD are not necessary, it is proposed to maintain the MRL exemption through the inclusion in Annex IV of Regulation (EC) 396/2005, provided it can be demonstrated that consumer exposure to iodine and arsenic will be acceptable. (assessment pending data gap)

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

Environmental fate and behaviour

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

Mineralisation after 100 days	No study submitted, not required. Laminarin is a polysaccharide which leads to smaller-sized oligosaccharides and monosaccharides (glucose) after degradation
Non-extractable residues after 100 days	No study submitted, not required.
Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)	Laminarin is a polysaccharide which leads to smaller-sized oligosaccharides and monosaccharides (glucose) after degradation. No other relevant metabolites, degradation or reaction products are expected to occur.

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

Mineralisation after 100 days	No study submitted, not required.
Non-extractable residues after 100 days	No study submitted, not required.
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	No relevant metabolites, degradation or reaction products are expected to occur.

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

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Laminarin has a low molar absorption coefficient (ε = 160 dm3.mol-1.cm-1), no photo degradation is expected to occur. No metabolites.
Mineralisation at study end	No study submitted, not required.
Non-extractable residues at study end	No study submitted, not required.

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

Parent	**Dark aerobic conditions**					
Soil type	**pH**	**t. °C / % MWHC**	**DT_{50} /DT_{90} (d)**	**DT_{50} (d) 20 °C pF2/10kPa[a)]**	**St. (χ^2)**	**Method of calculation**
no study, not required	-	12	30 (default)[1]	14.1 (default)[2]		

[1] ECHA (2016), Guidance on information requirements and Chemical Safety Assessment Chapter R.16: Environmental exposure assessment (version 3.0, February 2016), for readily biodegradable substance.

[2] Normalised value with Q10 of 2.58 from 12°C

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

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	no study, not required

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

Parent	Soil photolysis				
Soil type	pH	t. °C / % MWHC	DT_{50} / DT_{90} (d) calculated at 50ºN	St. (χ^2)	Method of calculation
no study, not required	-	-	-	-	-

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

Parent							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
no study, Data gap	-	-	-	-	-	-	-

[a)] Measured in [medium to be stated, usually calcium chloride solution or water]
*Only relevant after implementation of the published EFSA guidance.

Mobility in soil column leaching active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Column leaching	no study, not required

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

Lysimeter/ field leaching studies	no study, not required

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

Hydrolytic degradation of the active substance and metabolites > 10 %	pH 4: stable at 20 °C less than 10% degradation
	pH 7: stable at 20 °C less than 10% degradation
	pH 9: stable at 20 °C less than 10% degradation

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

Photolytic degradation of active substance and metabolites above 10 %	stable due to its low molar absorption coefficient
Quantum yield of direct phototransformation in water at Σ > 290 nm	not relevant

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

Readily biodegradable (yes/no)	Yes. (based on the available study)

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

Parent										
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed [a]	t. °C[b]	DT_{50} /DT_{90} whole sys. (suspended sediment test)		St. (χ^2)	DT_{50} /DT_{90} Water (pelagic test)		St. (χ^2)	Method of calculation
				At study temp	Normalised to *x* °C[c]		At study temp	Normalised to 12 °C[c]		
Data Gap	-	-	-	-	-	-	-	-	-	-

[a] Measured in [medium to be stated, usually calcium chloride solution or water]
[b] Temperature of incubation=temperature that the environmental media was collected or std temperature of 20°C
[c] Normalised using a Q10 of 2.58

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 / 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
no study, not required	-	-	12° C	-	-	15*	-	300*	-	-

* A value of 15 days at 12°C could be considered here, based upon the ECHA (2016) Guidance on information requirements and Chemical Safety Assessment Chapter R.16: Environmental exposure assessment (version 3.0, February 2016),. Values for readily biodegradable substances. Normalised using a Q10 of 2.58 to FOCUS reference conditions (20°C) the water DT50 is 7.1 days and sediment DT50 is 141.2 days.

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

Direct photolysis in air	Not studied - no data requested
Photochemical oxidative degradation in air	0.044 days (AOPWIN v.1.92) assuming a hydroxyl radical concentration of $1.5x10^6$ OH/cm^3
Volatilisation	from plant surfaces: -
	from soil: -
Metabolites	none

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	Soil:Laminarin Surface water:Laminarin

(toxicology and ecotoxicology) and or requiring consideration for groundwater exposure	Sediment: Laminarin Ground water: Laminarin Air: Laminarin

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

	See section 5, Ecotoxicology

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

Soil (indicate location and type of study)	no monitoring data available, not required
Surface water (indicate location and type of study)	no monitoring data available, not required
Ground water (indicate location and type of study)	no monitoring data available, not required
Air (indicate location and type of study)	no monitoring data available, not required

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

Parent Method of calculation	DT_{50} (d): 30 days Kinetics: not applicable Field or Lab: not relevant
Application data	Crop: lettuce Depth of soil layer: 5cm Soil bulk density: 1.5g/cm^3 % plant interception: 25% Number of applications: 16 Interval (d): 7 Application rate(s): 113 g a.s./ha

$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		n.c.		0.700	
Short term	24h	n.c.	n.c.	0.684	0.692
	2d	n.c.	n.c.	0.668	0.684
	4d	n.c.	n.c.	0.638	0.668
Long term	7d	n.c.	n.c.	0.595	0.646
	28d	n.c.	n.c.	0.366	0.515
	50d	n.c.	n.c.	0.265	0.448
	100d	n.c.	n.c.	0.069	0.273
Plateau concentration		n.r.			

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

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	Calculations using a reliable soil adsorption measurement were not available. Data gap.
Application rate	-

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

Parent Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: v1.1 Molecular weight 3240-4860 (g/mol): K_{OC}/K_{OM} (mL/g): 93.6/54.3 (QSAR Koc Values MCI methods) DT_{50} soil (d): 30 days (default) DT_{50} water/sediment system (d): 15 d (default) DT_{50} water (d): 15 d (ECHA guidance) DT_{50} sediment (d): 300 d (ECHA guidance) Crop interception (%): minimal crop cover
Parameters used in FOCUSsw step 3 (if performed)	not calculated
Application rate	Crop and growth stage: orchards/ vines/ fruiting vegetables BBCH 11-89; leafy vegetables BBCH 16-49 Number of applications: orchards 20; vines 10; vegetables 7 Interval (d): orchards/vegetables 7; vines 10 Application rate(s): orchards 45 g a.s./ha; vines 90 g a.s./ha; vegetables 135 g a.s./ha Application window: Orchards and vines: March-May, June-Sept, Oct-Feb; vegetables (leafy/fruiting) March-May, June-Sept, Oct-Feb, Minimal crop cover, Average crop cover

FOCUS STEP 1 Scenario orchards early	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0	354.3051		249.6444	
	1	343.7913	349.0482	321.7887	285.7165
	2	342.9979	346.2214	321.0461	303.5669
	4	341.4166	344.2140	319.5659	311.9362
	7	339.0583	342.5092	317.3585	314.7325
	14	333.6186	339.4202	312.2670	314.7692
	21	328.2663	336.5919	307.2572	313.0979
	28	322.9998	333.8504	302.3278	311.0199
	42	312.7189	328.5108	292.7049	306.5101
	50	306.9918	325.5245	287.3443	303.8711
	100	273.4986	307.7237	255.9947	287.6194

FOCUS STEP 1 Scenario orchards late	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0	313.8891		249.6444	
	1	307.9426	310.9158	288.2342	268.9393
	2	307.2319	309.2514	287.5690	278.4204
	4	305.8154	307.8873	286.2432	282.6630
	7	303.7030	306.5462	284.2660	283.7732
	14	298.8306	303.9032	279.7054	282.8764
	21	294.0364	301.4111	275.2180	281.0695
	28	289.3190	298.9762	270.8026	279.0532
	42	280.1102	294.2141	262.1832	274.8587
	50	274.9802	291.5458	257.3815	272.4453
	100	244.9795	275.6185	229.3008	257.7581

FOCUS STEP 2 Scenario orchards early minimal crop cover March-May	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0	22.4854		20.6856	
	1	21.1508	21.8181	19.8498	20.2677
	2	20.2962	21.2708	19.0478	19.8582
	4	18.6892	20.3776	17.5397	19.0721
	7	16.5142	19.1794	15.4984	17.9699
	14	12.3730	16.7628	11.6120	15.7168
	21	9.2703	14.7581	8.7001	13.8404
	28	6.9457	13.0819	6.5184	12.2698
	42	3.8990	10.4803	3.6592	9.8307
	50	2.8032	9.3349	2.6308	8.7566
	100	0.3565	5.2608	0.3346	4.9351
Southern EU	0	34.9995		32.3717	
	1	33.0997	34.0496	31.0637	31.7177
	2	31.7624	33.2403	29.8087	31.0770
	4	29.2476	31.8662	27.4485	29.8467
	7	25.8437	30.0011	24.2541	28.1218
	14	19.3631	26.2260	18.1720	24.5959
	21	14.5075	23.0910	13.6152	21.6594
	28	10.8696	20.4690	10.2010	19.2015
	42	6.1017	16.3989	5.7264	15.3845
	50	4.3869	14.6067	4.1171	13.7035
	100	0.5579	8.2319	0.5236	7.7232

FOCUS STEP 2 Scenario orchards Early minimal crop cover June-September	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0	22.4854		20.6856	
	1	21.1508	21.8181	19.8498	20.2677
	2	20.2962	21.2708	19.0478	19.8582
	4	18.6892	20.3776	17.5397	19.0721

FOCUS STEP 2 Scenario orchards Early minimal crop cover June-September	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	7	16.5142	19.1794	15.4984	17.9699
	14	12.3730	16.7628	11.6120	15.7168
	21	9.2703	14.7581	8.7001	13.8404
	28	6.9457	13.0819	6.5184	12.2698
	42	3.8990	10.4803	3.6592	9.8307
	50	2.8032	9.3349	2.6308	8.7566
	100	0.3565	5.2608	0.3346	4.9351
Southern EU	0	28.7425		26.5286	
	1	27.1253	27.9339	25.4568	25.9927
	2	26.0293	27.2556	24.4282	25.4676
	4	23.9684	26.1219	22.4941	24.4594
	7	21.1789	24.5903	19.8762	23.0459
	14	15.8680	21.4944	14.8920	20.1563
	21	11.8889	18.9245	11.1576	17.7499
	28	8.9076	16.7754	8.3597	15.7356
	42	5.0003	13.4396	4.6928	12.6076
	50	3.5951	11.9708	3.3739	11.2300
	100	0.4572	6.7463	0.4291	6.3291

FOCUS STEP 2 Scenario orchards Early minimal crop cover Oct - Feb	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0	41.2565		38.2148	
	1	39.0742	40.1654	36.6707	37.4427
	2	37.4954	39.2251	35.1891	36.6863
	4	34.5267	37.6104	32.4030	35.2340
	7	30.5085	35.4120	28.6319	33.1978
	14	22.8581	30.9576	21.4521	29.0354
	21	17.1261	27.2575	16.0727	25.5689
	28	12.8315	24.1625	12.0422	22.6673
	42	7.2030	19.3581	6.7600	18.1614
	50	5.1787	17.2426	4.8602	16.1770
	100	0.6586	9.7174	0.6181	9.1172
Southern EU	0	34.9995		32.3717	
	1	33.0997	34.0496	31.0637	31.7177
	2	31.7624	33.2403	29.8087	31.0770
	4	29.2476	31.8662	27.4485	29.8467
	7	25.8437	30.0011	24.2541	28.1218
	14	19.3631	26.2260	18.1720	24.5959
	21	14.5075	23.0910	13.6152	21.6594
	28	10.8696	20.4690	10.2010	19.2015
	42	6.1017	16.3989	5.7264	15.3845
	50	4.3869	14.6067	4.1171	13.7035
	100	0.5579	8.2319	0.5236	7.7232

FOCUS STEP 1 Scenario vines early	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0	274.8111		249.6444	
	1	273.2806	274.0458	255.7906	252.7175
	2	272.6499	273.5055	255.2003	254.1064
	4	271.3929	272.7632	254.0237	254.3590
	7	269.5182	271.7737	252.2691	253.8389
	14	265.1942	269.5621	248.2218	252.0394
	21	260.9396	267.3951	244.2395	250.1014
	28	256.7533	265.2565	240.3211	248.1448
	42	248.5810	261.0527	232.6718	244.2551
	50	244.0285	258.6919	228.4106	242.0599
	100	217.4047	244.5761	203.4908	228.8854

FOCUS STEP 1 Scenario vines late	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0	290.7981		249.6444	
	1	287.4609	289.1295	269.0634	259.3539
	2	286.7975	288.1293	268.4425	264.0534
	4	285.4753	287.1326	267.2049	265.9383
	7	283.5034	285.9993	265.3592	266.0852
	14	278.9550	283.6112	261.1019	264.6550
	21	274.4797	281.3112	256.9130	262.7706
	28	270.0761	279.0514	252.7912	260.7896
	42	261.4798	274.6192	244.7451	256.7752
	50	256.6910	272.1326	240.2628	254.4907
	100	228.6857	257.2757	214.0498	240.6973

FOCUS STEP 2 Scenario Vines early minimal crop cover March-May	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0	14.2341		13.2456	
	1	13.5435	13.8888	12.7104	12.9780
	2	12.9963	13.5793	12.1969	12.7158
	4	11.9673	13.0279	11.2312	12.2124
	7	10.5745	12.2694	9.9241	11.5067
	14	7.9228	10.7278	7.4355	10.0639
	21	5.9361	9.4461	5.5709	8.8624
	28	4.4475	8.3738	4.1740	7.8567
	42	2.4966	6.7089	2.3431	6.2949
	50	1.7950	5.9758	1.6846	5.6071
	100	0.2283	3.3678	0.2142	3.1601
Southern EU	0	26.9754		25.1439	
	1	25.7094	26.3424	24.1280	24.6360
	2	24.6706	25.7662	23.1531	24.1383
	4	22.7173	24.7251	21.3200	23.1827
	7	20.0735	23.2877	18.8388	21.8430
	14	15.0398	20.3629	14.1147	19.1043
	21	11.2684	17.9304	10.5752	16.8234
	28	8.4427	15.8950	7.9234	14.9143
	42	4.7393	12.7349	4.4478	11.9496

FOCUS STEP 2 Scenario Vines early minimal crop cover March-May	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	50	3.4074	11.3433	3.1978	10.6439
	100	0.4334	6.3929	0.4067	5.9988

FOCUS STEP 2 Scenario Vines early minimal crop cover June-September	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0	14.2341		13.2456	
	1	13.5435	13.8888	12.7104	12.9780
	2	12.9963	13.5793	12.1969	12.7158
	4	11.9673	13.0279	11.2312	12.2124
	7	10.5745	12.2694	9.9241	11.5067
	14	7.9228	10.7278	7.4355	10.0639
	21	5.9361	9.4461	5.5709	8.8624
	28	4.4475	8.3738	4.1740	7.8567
	42	2.4966	6.7089	2.3431	6.2949
	50	1.7950	5.9758	1.6846	5.6071
	100	0.2283	3.3678	0.2142	3.1601
Southern EU	0	20.6047		19.1948	
	1	19.6264	20.1156	18.4192	18.8070
	2	18.8335	19.6728	17.6750	18.4270
	4	17.3423	18.8765	16.2756	17.6976
	7	15.3240	17.7786	14.3814	16.6748
	14	11.4813	15.5454	10.7751	14.5841
	21	8.6022	13.6883	8.0731	12.8429
	28	6.4451	12.1344	6.0487	11.3855
	42	3.6180	9.7219	3.3954	9.1222
	50	2.6012	8.6596	2.4412	8.1255
	100	0.3308	4.8803	0.3105	4.5794

FOCUS STEP 2 Scenario Vines early minimal crop cover Oct-Feb	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0	33.3460		31.0931	
	1	31.7924	32.5692	29.8368	30.4650
	2	30.5078	31.8597	28.6313	29.8495
	4	28.0924	30.5737	26.3644	28.6678
	7	24.8230	28.7968	23.2961	27.0111
	14	18.5983	25.1805	17.4543	23.6244
	21	13.9345	22.1725	13.0774	20.8039
	28	10.4402	19.6557	9.7981	18.4430
	42	5.8607	15.7479	5.5002	14.7769
	50	4.2136	14.0271	3.9544	13.1623
	100	0.5359	7.9054	0.5029	7.4181
Southern EU	0	26.9754		25.1439	
	1	25.7094	26.3424	24.1280	24.6360
	2	24.6706	25.7662	23.1531	24.1383

FOCUS STEP 2 Scenario Vines early minimal crop cover Oct-Feb	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	4	22.7173	24.7251	21.3200	23.1827
	7	20.0735	23.2877	18.8388	21.8430
	14	15.0398	20.3629	14.1147	19.1043
	21	11.2684	17.9304	10.5752	16.8234
	28	8.4427	15.8950	7.9234	14.9143
	42	4.7393	12.7349	4.4478	11.9496
	50	3.4074	11.3433	3.1978	10.6439
	100	0.4334	6.3929	0.4067	5.9988

FOCUS STEP 1 Scenario Vegetables,	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0	288.7406		262.1266	
	1	287.1122	287.9264	268.7370	265.4318
	2	286.4496	287.3536	268.1168	266.9293
	4	285.1290	286.5712	266.8807	267.2138
	7	283.1595	285.5306	265.0373	266.6756
	14	278.6166	283.2063	260.7852	264.7905
	21	274.1467	280.9294	256.6013	262.7562
	28	269.7485	278.6825	252.4846	260.7015
	42	261.1626	274.2658	244.4482	256.6159
	50	256.3796	271.7854	239.9713	254.3098
	100	228.4082	256.9551	213.7901	240.4693

FOCUS STEP 2 Scenario Vegetables, leafy and fruiting minimal crop cover March - May	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0	26.6942		24.8697	
	1	25.4290	26.0616	23.8649	24.3673
	2	24.4016	25.4885	22.9006	23.8750
	4	22.4696	24.4571	21.0875	22.9299
	7	19.8546	23.0346	18.6333	21.6047
	14	14.8758	20.1413	13.9608	18.8959
	21	11.1455	17.7352	10.4599	16.6399
	28	8.3506	15.7219	7.8369	14.7516
	42	4.6877	12.5962	4.3993	11.8192
	50	3.3703	11.2197	3.1630	10.5278
	100	0.4286	6.3232	0.4023	5.9334
Southern EU	0	51.5225		48.0553	
	1	49.1361	50.3293	46.1137	47.0845
	2	47.1508	49.2363	44.2505	46.1333
	4	43.4176	47.2506	40.7470	44.3070
	7	38.3646	44.5053	36.0048	41.7465
	14	28.7442	38.9166	26.9761	36.5122
	21	21.5362	34.2679	20.2115	32.1530
	28	16.1357	30.3782	15.1432	28.5043
	42	9.0579	24.3387	8.5007	22.8381

FOCUS STEP 2 Scenario Vegetables, leafy and fruiting minimal crop cover March - May	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	50	6.5123	21.6791	6.1117	20.3427
	100	0.8282	12.2180	0.7773	11.4649

FOCUS STEP 2 Scenario Vegetables, leafy and fruiting minimal crop cover June -Sep	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0	26.6942		24.8697	
	1	25.4290	26.0616	23.8649	24.3673
	2	24.4016	25.4885	22.9006	23.8750
	4	22.4696	24.4571	21.0875	22.9299
	7	19.8546	23.0346	18.6333	21.6047
	14	14.8758	20.1413	13.9608	18.8959
	21	11.1455	17.7352	10.4599	16.6399
	28	8.3506	15.7219	7.8369	14.7516
	42	4.6877	12.5962	4.3993	11.8192
	50	3.3703	11.2197	3.1630	10.5278
	100	0.4286	6.3232	0.4023	5.9334
Southern EU	0	39.1084		36.4625	
	1	37.2825	38.1955	34.9893	35.7259
	2	35.7762	37.3624	33.5756	35.0042
	4	32.9436	35.8538	30.9172	33.6184
	7	29.1096	33.7700	27.3191	31.6756
	14	21.8100	29.5290	20.4684	27.7041
	21	16.3408	26.0016	15.3357	24.3965
	28	12.2432	23.0501	11.4901	21.6279
	42	6.8728	18.4675	6.4500	17.3287
	50	4.9413	16.4494	4.6373	15.4352
	100	0.6284	9.2706	0.5898	8.6991

FOCUS STEP 2 Scenario Vegetables, leafy and fruiting minimal crop cover Oct - Feb	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0	63.9366		59.6481	
	1	60.9896	62.4631	57.2381	58.4431
	2	58.5254	61.1103	54.9255	57.2624
	4	53.8916	58.6474	50.5767	54.9956
	7	47.6197	55.2406	44.6906	51.8173
	14	35.6784	48.3043	33.4838	45.3204
	21	26.7316	42.5343	25.0873	39.9096
	28	20.0283	37.7063	18.7963	35.3806
	42	11.2430	30.2100	10.5514	28.3475

FOCUS STEP 2 Scenario Vegetables, leafy and fruiting minimal crop cover Oct - Feb	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	50	8.0833	26.9088	7.5861	25.2501
	100	1.0280	15.1653	0.9648	14.2307
Southern EU	0	51.5225		48.0553	
	1	49.1361	50.3293	46.1137	47.0845
	2	47.1508	49.2363	44.2505	46.1333
	4	43.4176	47.2506	40.7470	44.3070
	7	38.3646	44.5053	36.0048	41.7465
	14	28.7442	38.9166	26.9761	36.5122
	21	21.5362	34.2679	20.2115	32.1530
	28	16.1357	30.3782	15.1432	28.5043
	42	9.0579	24.3387	8.5007	22.8381
	50	6.5123	21.6791	6.1117	20.3427
	100	0.8282	12.2180	0.7773	11.4649

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

Method of calculation	not relevant

Ecotoxicology

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

Species	Test substance	Time scale	End point	Toxicity (mg/kg bw per day)
Birds				
Bobwhite quail	a.s.	Acute	LD_{50}	> 1700
	Preparation	Acute	LD_{50}	None submitted or required
	a.s.	Long-term	LD_{50}/10	> 170
	a.s.	Long-term	NOEC/NOAEC/NOAEL	None submitted.
Mammals				
Rat	a.s.	Acute	LD_{50}	> 2000
Rat	Preparation	Acute	LD_{50}	> 2000
Rat	a.s.	Long-term 90 day oral	NOAEL	1000
Endocrine disrupting properties (Annex Part A, points 8.1.5) *None.*				
Additional higher tier studies (Annex Part A, points 10.1.1.2): *None.*				
Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3): *None.*				

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

Lettuce, tomato, zucchini, pumpkin, eggplant, cucumber, strawberry, green bean at 135 g a.s./ha [x 7 applications]

Vineyard at 90 g a.s./ha [x 10 applications]

Kiwi (orchards) at 90 g a.s./ha [7 applications]

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Screening Step (Birds)					
All vegetables	Small omnivorous	Acute	40.7322	> 42	10
All vegetables	Small omnivorous	Long-term	11.5911	> 14.7	5
All vineyard	Small omnivorous	Acute	13.7232	> 124	10
All vineyard	Small omnivorous	Long-term	3.71106	>45.8	5
All kiwi (orchard)	Small insectivorous	Acute	6.7392	> 252	10
All kiwi (orchard)	Small insectivorous	Long-term	1.73628	>97.9	5
Screening Step (Mammals)					
All orchards, vegetables, vines	Small herbivorous	Acute	34.9866	> 57.2	10
All orchards, vegetables, vines	Small herbivorous	Long-term	12.9327	77.5	5
All strawberry	Small herbivorous	Acute	20.2464	> 98.8	10
All strawberry	Small herbivorous	Long-term	7.1421	140	5
Risk from bioaccumulation and food chain behaviour (*Not relevant – logKow = -1.6)*					
Risk from consumption of contaminated water					

Scenarios	**Indicator or focal species**	**Time scale**	**PEC_{dw}xDWR**	**TER**	**Trigger**
Leaf scenario	Birds	acute	0.017	> 100000	5
Puddle scenario, Screening step 1)Application rate (351 g a.s./ha)/1700 mg/kg bw <50, TER calculation not needed. 2)Application rate (351 g a.s./ha)/2000 mg/kg bw <3000, TER calculation not needed.					

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

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

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Laboratory tests				
Fish				
O. mykiss	a.s.	Acute 96 hr (semi-static)	Mortality, LC_{50}	> 88 mg a.s./$L_{(mm)}$

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Danio rerio	a.s.	Acute 96 hr (semi-static)	Mortality, LC_{50}	**> 71.3 mg a.s./$L_{(mm)}$**
Brachidanio rerio	Preparation*	Acute 96 hr (static)	Mortality, LC_{50}	> 103.9 mg prep./L (> 4.8 mg a.s./$L_{(mm)}$)
Aquatic invertebrates				
Daphnia magna	a.s.	48 h (semi-static)	Mortality, EC_{50}	> 100 mg a.s./$L_{(nom)}$
Daphnia magna	Preparation*	48 h (static)	Mortality, EC_{50}	> 103 mg prep./L (> 4.89 mg a.s./L $_{(mm)}$)
Sediment-dwelling organisms				
No data presented or required.				
Algae				
Desmodesmus subspicatus	Preparation*	72 h (static)	Growth rate: E_rC_{50} (NOEC) Biomass: E_bC_{50} (NOEC)	> 100 mg prep./L (> 4.8 mg a.s./L $_{(mm)}$) > 100 mg prep./L (> 4.8 mg a.s./L $_{(mm)}$)
Higher plant				
Lemna gibba	a.s.	(static, or semi-static or flow-through)	Fronds number, EC_{50} (NOEC) Frond area/fresh weight/dry weight, E_rC_{50} (NOEC)	Only a preliminary (range-finding) test is available indicating a value of > 100 mg a.s./$L_{(nom)}$
Potential endocrine disrupting properties (Annex Part A, point 8.2.3) *None.*				

* The stability of the test item in water was checked by appropriate analytical verification of the test solutions at test initiation and at test completion. This is not expected to have had an effect on the outcome of the test nor the endpoints derived.

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

Bioconcentration in fish (Annex Part A, point 8.2.2.3)

	Active substance	Metabolite1	Metabolite2	Metabolite3
$logP_{O/W}$	-1.6			

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

$FOCUS_{sw}$ step 1-2 - TERs for laminarin – leafy and fruiting vegetables at 135 g a.s./ha x 7 applications

Scenario	PEC global max (µg L)	fish acute	Aquatic invertebrates	Algae	Higher plant
		All tested	*Daphnia magna*	*All tested*	*Lemna gibba*
		LC_{50}	EC_{50}	EC_{50}	EC_{50}
		71300 µg/L	100000 µg/L	4800 µg/L	µg/L
FOCUS Step 1	354.3	> 201.32	> 282.5	> 13.6	(Data gap)
FOCUS Step 2					
North Europe	63.94	> 1116	> 1564	> 75.1	
South Europe	51.52	> 1385	> 1941	> 93	
Trigger		100	100	10	10

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

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

Species	Test substance	Time scale/type of endpoint	End point	toxicity
Apis mellifera	a.s.	Acute	Oral toxicity (LD_{50})	> 118.64 µg/bee
Apis mellifera	a.s.	Acute	Contact toxicity (LD_{50})	> 100 µg/bee
Apis mellifera	Preparation	Acute	Oral toxicity (LD_{50})	> 35.22 µg/bee
Apis mellifera	Preparation	Acute	Contact toxicity (LD_{50})	> 103.5 µg/bee

Risk assessment for – lettuce at 135 g a.s./ha x 7 applications

Species	Test substance	Risk quotient	HQ/ETR	Trigger
Apis mellifera	a.s., preparation	HQcontact	<3.83	50

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

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Toxicity
Typhlodromus pyri	Preparation	Mortality, LR_{50} Reproduction, ER_{50}	114.7 g/ha > 370 g/ha
Aphidius rhopalosiphi	Preparation	Mortality, LR_{50} Reproduction, ER_{50}	> 370 g/ha > 370 g/ha

First tier risk assessment for – lettuce at 135 g a.s./ha x 7 applications

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1] (1m)	Trigger
Phyliq	*Typhlodromus pyri*	114.7	**4.0**	0.07	2
Phyliq	*Aphidius rhopalosiphi*	> 370	< 1.24	< 0.02	2

[1]indicate distance assumed to calculate the drift rate

Extended laboratory tests, aged residue tests

Species	Life stage	Test substance, substrate	Time scale	Dose (g/ha)[1,2]	End point	% effect[3]	ER_{50}
Typhlodromus pyri	protonymph	Vacciplant (S1672aa / ARD 0707, content of active ingredient	14 day	18.5 46.3 115.7 289.3 723.2 1808	Mortality	11.7 ± 12.6 3.33 ± 2.89 6.67 ± 2.89	> 1808 g a.s./ha

Species	Life stage	Test substance, substrate	Time scale	Dose (g/ha)[1,2]	End point	% effect[3]	ER_{50}
		45.2 g/L (batch number: 15070885)				5.00 ± 5.00 11.7 ± 12.6 46.7 ± 12.6	
					Reproduction	-25.3 6.60 2.98 30.6 29.1 97.3	792 g a.s./ha

[1] indicate whether initial or aged residues
[2] for preparations indicate whether dose is expressed in units of a.s. or preparation
[3] indicate if positive percentages relate to adverse effects or not

Risk assessment for – Lettuce, Tomato, Aubergine, Pepper, Greenbean, Cucumber, Zucchini at 135 g a.s./ha x 7 based on extended lab test or aged residue tests

Species	ER_{50} (g/ha)	In-field rate	Off-field rate[1]
Typhlodromus pyri	792	459	See above.

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

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

Test organism	Test substance	Application method of test a.s./ OM[1]	Time scale	End point	Toxicity
Earthworms					
	a.s.	Soil incorporation 10% OM	Chronic	Growth, reproduction, behaviour	NOEC 262 mg a.s./kg d.w.soil EC_{10}, EC_{20} could not be calculated as there were no significant effects up to the highest tested dose

Nitrogen transformation	a.s. preparation		Laminarin is quickly degraded by soil micro-organisms which contain laminarase. No effect on microbial soil processes is expected.

Toxicity/exposure ratios for soil organisms

Lettuce at 135 g a.s./ha x 7 applications

Test organism	Test substance	Time scale	Soil PEC_{ini}	TER	Trigger
Earthworms					
Eisenia	a.s.	Chronic	0.700	356	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)

Screening data

Screening data show that a deleterious effect on non-target plants is not expected up to a level > 1.5 L/ha (45 g laminarin/L formulation). Therefore no effect on non-target plants is expected from the proposed uses of 'Vacciplant Fruit et Legumes'.

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

Test type/organism	end point
Activated sludge	Sludge microorganisms contain laminarase, therefore no effect on sludge microorganisms is expected.

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

Compartment	
soil	Ecotoxicologically relevant laminarin, for monitoring none.
water	Ecotoxicologically relevant laminarin, for monitoring none.
sediment	Ecotoxicologically relevant laminarin, for monitoring none.
groundwater	laminarin

[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	laminarin
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended][6]:	No current harmonised classification.
Peer review proposal[7] for harmonised classification according to Regulation (EC) No 1272/2008:	None

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

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

Abbreviations

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

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

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

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

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