CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance sea-algae extract[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Sea-algae extract is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004[3], as amended by Commission Regulation (EC) No 1095/2007[4].

Sea-algae extract was included in Annex I to Directive 91/414/EEC on 1 September 2009 pursuant to Article 24b of the Regulation (EC) No 2229/2004 (hereinafter referred to as 'the Regulation'), and has subsequently been deemed to be approved under Regulation (EC) No 1107/2009[5], in accordance with Commission Implementing Regulation (EU) No 540/2011[6], as amended by Commission Implementing Regulation (EU) No 541/2011[7]. In accordance with Article 25a of the Regulation, as amended by Commission Regulation (EU) No 114/2010[8], the European Food Safety Authority (EFSA) is required to deliver by 31 December 2012 its view on the draft review report submitted by the European Commission in accordance with Article 25(1) of the Regulation. This review report was established as a result of the initial evaluation provided by the designated rapporteur Member State in the Draft Assessment Report (DAR). The EFSA therefore organised a peer review of the DAR. The conclusions of the peer review are set out in this report.

Italy being the designated rapporteur Member State submitted the DAR on sea-algae extract in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 28 November 2007. The peer review was initiated on 18 June 2008 by dispatching the DAR to the notifier the Seaweed Task Force and on 24 February 2011 to the Member States for consultation and comments. Following consideration of the comments received on the DAR, it was concluded that there was no need to conduct an expert consultation and EFSA should deliver its conclusions on sea-algae extract.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of sea-algae extract as a plant growth regulator on beans, as proposed by the notifier. Full details of the representative uses can be found in Appendix A to this report.

[1] On request from the European Commission, Question No EFSA-Q-2009-00289, issued on 6 December 2011.
[2] Correspondence: pesticides.peerreview@efsa.europa.eu
[3] OJ L 379, 24.12.2004, p.13
[4] OJ L 246, 21.9.2007, p.19
[5] OJ L 309, 24.11.2009, p.1
[6] OJ L 153, 11.6.2011, p.1
[7] OJ L 153, 11.6.2011, p.187
[8] OJ L 37, 10.2.2010, p.12

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In the area of identity, physical/chemical/technical properties and methods of analysis the following Annex II data gaps were identified: melting point, boiling point, temperature of decomposition, vapour pressure, Henry's law constant, spectra, solubility in water, solubility in organic solvents, octanol-water partition co-efficient, hydrolysis, photolysis, quantum yield and dissociation constant. For the formulations low temperature stability, dilution stability before and after accelerated storage, and shelf-life studies were identified as data gaps.

Data gaps were identified in the mammalian toxicology section regarding information on the uses allowing to waive toxicological studies for the species *Macrocystis integrifolia*, and for medical data on the three species *Ascophyllum nodosum, Laminaria digitata* and *Macrocystis integrifolia*.

No areas of concern or data gaps were identified in the residue section.

No areas of concern or data gaps were identified in the environmental fate and behaviour section.

The risk to birds and mammals and to aquatic organisms was assessed as low. However, a data gap was identified for further data and risk assessment for algae from an additional taxonomic group and for aquatic plants. Moreover, it was noted that the composition of the batches of the formulations used in the aquatic tests did not comply with the representative batches. A data gap was also identified for a risk assessment for honeybees referring to one of the representative uses where exposure of bees could occur. Further data gaps were identified for non-target arthropods, earthworms, soil macro- and micro-organisms and terrestrial non-target plants. The extent of the risk to these non-target organisms could not be assessed.

KEY WORDS

Sea-algae extract, peer review, risk assessment, pesticide, plant growth regulator

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BACKGROUND

Sea-algae extract is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004[9], as amended by Commission Regulation (EC) No 1095/2007[10].

Sea-algae extract was included in Annex I to Directive 91/414/EEC on 1 September 2009 pursuant to Article 24b of the Regulation (EC) No 2229/2004 (hereinafter referred to as 'the Regulation'), and has subsequently been deemed to be approved under Regulation (EC) No 1107/2009[11], in accordance with Commission Implementing Regulation (EU) No 540/2011[12], as amended by Commission Implementing Regulation (EU) No 541/2011[13]. In accordance with Article 25a of the Regulation, as amended by Commission Regulation (EU) No 114/2010[14] the European Food Safety Authority (EFSA) is required to deliver by 31 December 2012 its view on the draft review report submitted by the European Commission in accordance with Article 25(1) of the Regulation (European Commission, 2008). This review report was established as a result of the initial evaluation provided by the designated rapporteur Member State in the Draft Assessment Report (DAR). The EFSA therefore organised a peer review of the DAR. The conclusions of the peer review are set out in this report.

Italy being the designated rapporteur Member State submitted the DAR on sea-algae extract in accordance with the provisions of Article 22(1) of the Regulation, which was received by the EFSA on 28 November 2007 (Italy, 2007). The peer review was initiated on 18 June 2008 by dispatching the DAR to the notifier the Seaweed Task Force and on 24 February 2011 to the Member States for consultation and comments. In addition, the EFSA conducted a public consultation on the DAR. The comments received were collated by the EFSA and forwarded to the RMS for compilation and evaluation in the format of a Reporting Table. The notifier was invited to respond to the comments in column 3 of the Reporting Table. The comments and the notifier's response were evaluated by the RMS in column 3 of the Reporting Table.

The scope of the peer review was considered in a telephone conference between the EFSA, the RMS, and the European Commission on 20 June 2011. On the basis of the comments received and the RMS' evaluation thereof it was concluded that there was no need to conduct an expert consultation.

The outcome of the telephone conference, together with EFSA's further consideration of the comments is reflected in the conclusions set out in column 4 of the Reporting Table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, and the additional information to be submitted by the notifier, were compiled by the EFSA in the format of an Evaluation Table.

The conclusions arising from the consideration by the EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table, were reported in the final column of the Evaluation Table.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in November 2011.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses as a plant growth regulator on beans, as proposed by the notifier. A list of the relevant end points for the active substance as well as the formulation is provided in Appendix A. In addition, a key supporting document to this conclusion is the Peer Review Report, which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting

[9] OJ L 379, 24.12.2004, p.13
[10] OJ L 246, 21.9.2007, p.19
[11] OJ L 309, 24.11.2009, p.1
[12] OJ L 153, 11.6.2011, p.1
[13] OJ L 153, 11.6.2011, p.187
[14] OJ L 37, 10.2.2010, p.12

phase to the conclusion. The Peer Review Report (EFSA, 2011) comprises the following documents, in which all views expressed during the course of the peer review, including minority views, can be found:

- the comments received on the DAR,
- the Reporting Table (21 June 2011),
- the Evaluation Table (1 December 2011),
- the comments received on the assessment of the points of clarification,
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR including its addendum (compiled version of September 2011 containing all individually submitted addenda (Italy, 2011)) and the Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

The materials being considered are sea-algae extracts; there are no IUPAC or ISO names for these materials. These are aqueous extracts of one or more of the species *Ascophyllum nodosum*, *Laminaria digitata* and *Macrocystis integrifolia* of the orders *Fucales* and *Laminariales* of the class *Phaeophyceae* (brown seaweeds). The sea-algae used as the starting material is of food grade quality.

The representative formulated products for the evaluation were 'Kelpgrow', 'Agrocean base', 'Stimplex', 'Althia' and 'Algaegreen'.

The representative uses evaluated are outdoor spray applications to beans as a plant growth regulator. Full details of the representative uses can be found in the list of end points in Appendix A.

CONCLUSIONS OF THE EVALUATION

1. Identity, physical/chemical/technical properties and methods of analysis

The following guidance document was followed in the production of this conclusion: SANCO/3030/99 rev.4 (European Commission, 2000).

Acceptable marker compound specifications were provided for all of the extracts. It is noted that no information was given on the level of microbial contamination and the mechanism for the control of such contamination, or its possible increase on storage.

The following Annex II data points were not sufficiently addressed: melting point, boiling point, temperature of decomposition, vapour pressure, Henry's law constant, spectra, solubility in water, solubility in organic solvents, octanol-water partition co-efficient, hydrolysis, photolysis, quantum yield and dissociation constant. These can be addressed with a reasoned case.

The main data regarding the identity of the extracts and their physical and chemical properties are given in Appendix A.

For all plant protection products the following data gaps were identified: low temperature stability, dilution stability before and after accelerated storage, and shelf-life studies.

Methods of analysis for residues are not required due to the nature of these extracts. A method of analysis for body fluids and tissues is not required as the extracts are not classified as toxic or very toxic.

2. Mammalian toxicity

Sea-algae extracts do not have a toxic mode of action and do not present a toxicological concern by themselves. As sea-algae are harvested in a variable natural environment where contaminants of toxicological concern such as heavy metals, toxins produced as secondary metabolites from blue-green algae or cyanobacteria, and pathogens are potentially present, the toxicological assessment assumes that the manufacturing process ensures the production of a food grade quality of the extract.

Sea-algae extracts are also used as herbal remedies, however no information has been submitted on their (beneficial or adverse) effects and therefore a data gap was identified for medical data.

Based on the nature of sea-algae extract from the species *Ascophyllum nodosum* and *Laminaria digitata* used as seaweed meal in animal and human nutrition, and in health food tablets or gelatine capsules, all toxicological data requirements are waived for these two species. Toxicological reference values are not required and no quantitative risk assessment for operators, workers or bystanders was conducted considering the risk, if any, to be negligible. A data gap has been identified for information on the uses related to the species *Macrocystis integrifolia* that would allow to waive toxicological

information also on this species. However, it is expected that the species *Macrocystis integrifolia* would also be used in human nutrition.

3. Residues

To assess the consumer risk from the representative uses of sea-algae extract the assessment was conducted by comparison of the exposure arising from the use as a plant protection product with the exposure arising from consumption of the plant itself. The assessment presumes that the sea-algae extract used will be free of potentially harmful contaminants such as marine toxins, heavy metals or pathogens.

Consumption data of aquatic plants for EU countries can be extracted from the respective WHO cluster diets B, E, F and D (WHO, 2006), and range from 0.1 to 30.8 g/person/day. Having regard to the single application and the representative dose rate, it is considered unlikely that any pre-existing daily dietary exposure of humans to aquatic plants would be significantly increased by the use of sea-algae extract as a plant protection product.

No areas of concern or data gaps are identified. No MRL is proposed; sea-algae extract could be considered as a candidate for Annex IV of Commission Regulation (EC) No 396/2005[15].

4. Environmental fate and behaviour

The sea-algae extract products are all aqueous extracts (cell contents) of one or more of the species *Ascophyllum nodosum*, *Laminaria digitata* and *Macrocystis integrifolia*. No information or experimental data on these algal products were submitted in the dossier. However, it is considered that algae and algal products, used as soil supplements, are readily transformed to elements naturally present in the environment. Therefore, when the formulations containing sea-algae extracts are applied to bean plants, they are expected to degrade resulting in a low potential for longer term impact on the environment. However, as the exposure of soil and natural surface water systems might be expected to be low but cannot be completely excluded, initial PEC for the product in soil and surface water via drift have been estimated and were included in an Addendum (Italy, 2011). Although the method of calculation for PECsw is not completely clear, the EFSA considers that the available values are conservative and can be considered acceptable. These PEC are included in appendix A.

5. Ecotoxicology

For the environmental risk assessments the following documents were considered: European Commission 2002a and 2002b, and EFSA, 2009.

No toxicity studies were available for **birds** therefore no quantitative risk assessments were performed. Considering other available information, such as the fact that seaweed products are routinely used in poultry-feeding, and the available toxicological end points for mammals, it was concluded that the risk to birds from the use of sea-algae extract as a pesticide, based on the representative uses, is low. This was further supported by the available risk assessment for wild mammals that indicated low risk to **non-target terrestrial vertebrates** other than birds.

Risk assessments for **aquatic organisms,** based on the available acute data for fish, daphnia and algae with the formulations and considering a spray drift exposure of the aquatic environment, resulted in a low risk. It was noted that the composition of the batches of formulations used in the aquatic tests did not comply with the representative batches. No data for long-term toxicity were available. However, considering the nature and the composition of the products, the available toxicity data and the representative uses of these products, no assessments were considered to be necessary for long-term scale. However, a data gap has been identified for further data and risk assessment for algae from an additional taxonomic group, and for aquatic plants considering that sea-algae extracts are plant growth regulators.

[15] OJ L 70, 16.3.2005, p. 16

No toxicity data or risk assessments for **honeybees** were available. However, based on the representative uses, four out of the five formulations are applied only when attractive crops or flowers are not present in the field. Therefore the exposure of bees was considered to be negligible for these uses. However, this is not the case for the representative use with the formulation 'Agrocean Base' that can be applied also in later growth stages when the presence of other attractive crops or flowering weeds cannot be excluded, therefore a data gap has been identified for a risk assessment for honeybees for the case(s) when bees can be exposed.

No reliable data or risk assessments were available for **non-target arthropods**, **earthworms**, **soil macro- and micro- organisms** or for **terrestrial non-target plants**. Considering the facts that no data are available, the composition of the formulations contains several compounds, some of which are plant hormones, and that the mode of action was not fully clarified, the extent of the risk to these non-target organisms could not be assessed. Therefore relevant data gaps were identified for the assessments for these issues.

The risk to **biological methods for sewage treatments** was considered as low.

6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments

6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Sea-algae extract	No data, not required	No data were available. Data gap.

6.2. Ground water

Compound (name and/or code)	Mobility in soil	>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
Sea-algae extract	No data, not required	No data, not required	Not applicable	No	The risk to aquatic organisms was assessed as low. Data gap was identified for further data and assessments for algae from an additional taxonomic group, and for aquatic plants.

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Sea-algae extract	The risk to aquatic organisms was assessed as low. Data gap was identified for further data and assessments for algae from an additional taxonomic group, and for aquatic plants.

6.4. Air

Compound (name and/or code)	Toxicology
Sea-algae extract	No data - not required

7. List of studies to be generated, still ongoing or available but not peer reviewed

This is a complete list of the data gaps identified during the peer review process, including those areas where a study may have been made available during the peer review process but not considered for procedural reasons (without prejudice to the provisions of Article 7 of Directive 91/414/EEC concerning information on potentially harmful effects).

- Melting point, boiling point, temperature of decomposition, vapour pressure, Henry's law constant, spectra, solubility in water, solubility in organic solvents, octanol-water partition co-efficient, hydrolysis, photolysis, quantum yield and dissociation constant. These can be addressed with a reasoned case (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)

- For all formulations low temperature stability (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)

- For all formulations dilution stability before and after accelerated storage (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)

- For all formulations a shelf-life study (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1)

- Medical data on sea-algae extracts from the three species *Ascophyllum nodosum*, *Laminaria digitata* and *Macrocystis integrifolia* (relevant for all representative uses evaluated; submission date proposed by the notifier: some data were provided in Reporting Table point 2(6), however according to Commission Regulation (EC) No 1095/2007 new information cannot be considered in the peer review; see section 2)

- Information on the uses of the species *Macrocystis integrifolia* that would allow to waive toxicological information (relevant for the representative use with the formulation "Kelpgrow"; submission date proposed by the notifier: indications were provided in Reporting Table point 2(7), however according to Commission Regulation (EC) No 1095/2007 new information cannot be considered in the peer review; see section 2)

- Additional data and risk assessments for algae from an other taxonomic group and for aquatic plants (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 5)

- Risk assessment for honeybees for the case(s) when bees can be exposed (relevant for the representative use with the formulation 'Agrocean Base'; submission date proposed by the notifier: unknown; see section 5)

- Risk assessment for non-target arthropods (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 5)

- Risk assessment for non-target soil organisms (such as earthworms, soil macro- and micro-organisms) (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 5)

- Risk assessment for terrestrial non-target plants (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 5)

8. Particular conditions proposed to be taken into account to manage the risk(s) identified

- The toxicological assessment assumes that the manufacturing process ensures a food grade quality of sea-algae extracts.

9. Concerns

9.1. Issues that could not be finalised

An issue is listed as an issue that could not be finalised where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the Uniform Principles of Annex VI to Directive 91/414/EEC and where the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

1. The extent of the risk to honeybees for the representative use with the formulation 'Agrocean Base' when the treated area is potentially attractive to bees

2. The extent of the risk to non-target arthropods

3. The extent of the risk to non-target soil organisms

4. The extent of the risk to non-target terrestrial plants

9.2. Critical areas of concern

An issue is listed as a critical area of concern where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles of Annex VI to Directive 91/414/EEC, and where this assessment does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

None.

9.3. Overview of the concerns identified for each representative use considered

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in section 8, has been evaluated as being effective, then 'risk identified' is not indicated in this table.)

Representative use		Outdoor spray applications to beans as a plant growth regulator	
		Max. application rate of 2 L formulated product/ha ('Kelpgrow', 'Stimplex', 'Althia', 'Algaegreen')	Max. application rate of 2.5 L formulated product/ha ('Agrocean Base')
Operator risk	Risk identified		
	Assessment not finalised		
Worker risk	Risk identified		
	Assessment not finalised		
Bystander risk	Risk identified		
	Assessment not finalised		
Consumer risk	Risk identified		
	Assessment not finalised		
Risk to wild non target terrestrial vertebrates	Risk identified		
	Assessment not finalised		
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified		
	Assessment not finalised	X[2,3,4]	X[1,2,3,4]
Risk to aquatic organisms	Risk identified		
	Assessment not finalised		
Groundwater exposure active substance	Legal parametric value breached		
	Assessment not finalised		
Groundwater exposure metabolites	Legal parametric value breached		
	Parametric value of 10µg/L[(a)] breached		
	Assessment not finalised		
Comments/Remarks			

The superscript numbers in this table relate to the numbered points indicated in sections 9.1 and 9.2. Where there is no superscript number see sections 2 to 6 for further information.

(a): Value for non relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003

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APPENDICES

APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

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

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

Active substance (ISO Common Name) ‡	Sea-algae extract (No ISO common name available)
Function (*e.g.* fungicide)	Plant growth regulator
Rappporteur Member State	Italy

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	Not applicable
Chemical name (CA) ‡	Not applicable
CIPAC No ‡	Not applicable
CAS No ‡	Not applicable
EC No (EINECS or ELINCS) ‡	Not applicable
FAO Specification (including year of publication) ‡	Not applicable
Minimum purity of the active substance as manufactured (g/kg) ‡	See Appendix B – Detailed specification of the marker compounds in the formulations
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	None.
Molecular formula‡	Not applicable
Molecular mass‡	Not applicable
Structural formula‡	Not applicable

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	Data gap
Boiling point (state purity) ‡	Data gap
Temperature of decomposition (state purity)	Data gap
Appearance (state purity) ‡	From solution to cream, colour from bright yellow to dark brown.
Vapour pressure (state temperature, state purity) ‡	Data gap
Henry's law constant (Pa m^3 mol^{-1}) ‡	Data gap
Solubility in water (g/l or mg/l, state temperature, state purity and pH) ‡	Data gap
Solubility in organic solvents (in g/l or mg/l, state temperature, state purity and pH) ‡	Data gap
pH	From 2.61 to 7.86
Kinematic viscosity	From 1.33 to 300-500 mm^2/s
Relative density (state purity)	From 1.032 to 1.109
Surface tension ‡	From 23.05 to 70.5 mN/m
Partition co-efficient (log P_{OW}) (state temperature, pH and purity) ‡	Data gap
Dissociation constant (state purity) ‡	Data gap
Acidity / Alkalinity	From 0.97% H_2SO_4 to 0.1% NaOH
Persistent foaming	No foam
Stability after storage for 14 days at 54° C	The products are stable
Stability after storage for other periods and/or temperatures	After accelerate storage stability test it can be concluded that the storage stability for other periods and/or temperatures is not required since the sea-algae extract is not heat sensitive.
UV/VIS absorption (max.) incl. ε (state purity, pH)‡	Data gap
Flammability ‡ (state purity)	Acceptable case provided
Explosive properties ‡ (state purity)	Acceptable case provided
Oxidising properties ‡ (state purity)	Acceptable case provided

Summary of representative uses evaluated (*sea-algae extract*)

Crop and/or situation (a)	Country	Product name (sponsor)	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg a.s./hL min max	water (L/ha) min max	kg a.s./ha min max		
BEAN	FRANCE	KELPGROW (Asfaleia)	F	-	SL	--	spray	Growth stage 5 BBCH	1	-	-	-	2 litres of formulated product	Not necessary	-
BEAN	FRANCE	AGROCEAN BASE (Agrimer)	F	-	SL	--	spray	At any stage; avoid the blossoming stage of the culture	1	-	-	-	2 - 2.5 litres of formulated product	Not necessary	-
BEAN	FRANCE	STIMPLEX (Acadian)	F	-	SL	--	spray	Growth stage 5 BBCH	1	-	-	-	2 litres of formulated product	Not necessary	-
BEAN	FRANCE	ALTHIA (Goemar)	F	-	SL	--	spray	Growth stage 5 BBCH	1	-	-	-	2 litres of formulated product	Not necessary	-
BEAN	FRANCE	ALGAEGREEN (OGT)	F	-	SL	--	spray	Growth stage 5 BBCH	1	-	-	-	2 litres of formulated product	Not necessary	-

Remarks:

(a) For crops, Codex (or other, *e.g.* EU) classifications should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (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) GCPF Codes - GIFAP Technical Monograph No. 2, 1989
(f) All abbreviations 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 plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of applications possible under practical conditions of use must be provided
(l) PHI – minimum pre-harvest interval
(m) Remarks may include: Extent of use/ economic importance/restrictions

Methods of Analysis

Analytical methods for the active substance (Annex IIA, point 4.1)

The active substance can not be identified but three markers common to all extracts have been selected.

Technical a.s. (principle of method)	Not applicable
Impurities in technical a.s. (principle of method)	Not applicable
Plant protection product (principle of method)	Three markers have been identified: **Mannitol:** anion exchange chromatography coupled with the high sensitive pulsed amperometric detection (HPAE-PAD). **Fucose containing polymers (fucoidans):** Gibbons method (M.N. Gibbons – The determination of methylpentoses. Analyst, 1955, 80: 267-276) after precipitation by ethanol and re-dissolution by 30g/L $CaCl_2$ HCl 0.5 M solution. **Alginic acids and alginates:** metahydroxidiphenyl method with precipitation by 30 g/L $CaCl_2$ solution in ethanol and further dilution in sodium tetraborate solution.

Analytical methods for residues (Annex IIA, point 4.2)

The extracts are used as animal and/or human feed or herbal remedies and therefore there is no additional risk to consumers from any residues that may possibly occur as a result of the use as a plant protection product Therefore, no residue data requirements need to be fulfilled and no residue method is required.

Residue definitions for monitoring purposes

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Not required
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Not required
Soil (principle of method and LOQ)	Not required
Water (principle of method and LOQ)	Not required
Air (principle of method and LOQ)	Not required
Body fluids and tissues (principle of method and LOQ)	Not required

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
Water (analytical technique and LOQ)	Not required
Air (analytical technique and LOQ)	Not required
Body fluids and tissues (analytical technique and LOQ)	Not required

Classification and proposed labelling with regard to physical and chemical data (Annex IIA, point 10)

	RMS/peer review proposal
Active substance	None

Impact on Human and Animal Health

Sea-algae extracts are all aqueous extracts (cell contents) of one or more of the species *Ascophyllum nodosum*, *Laminaria digitata* and *Macrocystis integrifolia* of the Orders *Fucales* and *Laminariales* of the Class *Phaeophyceae* (Brown Seaweeds).

These species have a non-toxic mode of action and are non-toxic by themselves; they are used as animal and/or human feed or herbal remedies and therefore there is no additional risk to consumers from any residues that may possibly occur as a result of the use as a plant protection product. It is concluded, therefore, that toxicological data requirements do not need to be fulfilled.

Absorption, distribution, excretion and metabolism (toxicokinetics) (Annex IIA, point 5.1)

Rate and extent of oral absorption ‡	No data - not required
Distribution ‡	No data - not required
Potential for accumulation ‡	No data - not required
Rate and extent of excretion ‡	No data - not required
Metabolism in animals ‡	No data - not required
Toxicologically relevant compounds ‡ (animals and plants)	No data - not required
Toxicologically relevant compounds ‡ (environment)	No data - not required

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	> 2000 mg/kg bw	
Rat LD_{50} dermal ‡	> 2000 mg/kg bw	
Rat LC_{50} inhalation ‡	No data - not required	
Skin irritation ‡	Non-irritant	
Eye irritation ‡	Non-irritant	
Skin sensitisation ‡	Non-sensitising (M & K)	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	No data - not required	
Relevant oral NOAEL ‡	No data - not required	
Relevant dermal NOAEL ‡	No data - not required	
Relevant inhalation NOAEL ‡	No data - not required	

Genotoxicity ‡ (Annex IIA, point 5.4)

No data - not required	

Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect ‡	No data - not required	
Relevant NOAEL ‡	No data - not required	
Carcinogenicity ‡	No data - not required	

Reproductive toxicity (Annex IIA, 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 ‡	No data - not required	
Relevant maternal NOAEL ‡	No data - not required	
Relevant developmental NOAEL ‡	No data - not required	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data - not required	
Repeated neurotoxicity ‡	No data - not required	
Delayed neurotoxicity ‡	No data - not required	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	No data
Studies performed on metabolites or impurities ‡	No data

Medical data ‡ (Annex IIA, point 5.9)

No data, data required.

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	No data - not required	-	-
AOEL ‡	No data - not required	-	-
ARfD ‡	No data - not required	-	-

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulations (Kelpgrow, Althia, Agrocean Base, Stimplex, Algaegreen)	No data - not necessary

Exposure scenarios (Annex IIIA, point 7.2)

Operator	No exposure assessment was deemed necessary, as the substance does not present a toxicological concern. Exposure to consumers already exists, as sea-algae extracts are food-grade.
Workers	No exposure assessment was deemed necessary, as the substance does not present a toxicological concern. Exposure to consumers already exists, as sea-algae extracts are food-grade.
Bystanders	No exposure assessment was deemed necessary, as the substance does not present a toxicological concern. Exposure to consumers already exists, as sea-algae extracts are food-grade.

Classification and proposed labelling with regard to toxicological data (Annex IIA, point 10)

	RMS/peer review proposal
Sea algae extracts	No classification required.

Residues

The extracts are used as animal and/or human feed or herbal remedies and therefore there is no additional risk to consumers from any residues that may possibly occur as a result of the use as a plant protection product is expected. Therefore, the definition of residues is not requested and no ADI is proposed.

Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	Not required
Rotational crops	Not required
Metabolism in rotational crops similar to metabolism in primary crops?	Not required
Processed commodities	Not required
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not required
Plant residue definition for monitoring	Not required
Plant residue definition for risk assessment	Not required
Conversion factor (monitoring to risk assessment)	Not required

Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	Not required
Time needed to reach a plateau concentration in milk and eggs	Not required
Animal residue definition for monitoring	Not required
Animal residue definition for risk assessment	Not required
Conversion factor (monitoring to risk assessment)	Not required
Metabolism in rat and ruminant similar (yes/no)	-
Fat soluble residue: (yes/no)	-

Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

-

Stability of residues (Annex IIA, point 6 introduction, Annex IIIA, point 8 introduction)

-

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

	Ruminant	Poultry	Pig
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)			
Potential for accumulation (yes/no):			
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)			
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices : Mean (max) mg/kg		
Muscle			
Liver			
Kidney			
Fat			
Milk			
Eggs			

Summary of residues data according to the representative uses on raw agricultural commodities and feedingstuffs (Annex IIA, point 6.3, Annex IIIA, point 8.2)

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)

(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
(c) Highest residue

Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	Not required
TMDI (according to WHO European Diet) (% ADI)	Not required
TMDI (% ADI) according to national (to be specified) diets	
IEDI (WHO European Diet) (% ADI)	
NEDI (specify diet) (% ADI)	Not required
Factors included in IEDI and NEDI	Not applicable
ARfD	Not required
IESTI (% ARfD)	
NESTI (% ARfD) according to national (to be specified) large portion consumption data	
Acute exposure (% ARfD)	Not applicable

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Crop/process/processed product	Number of studies	Processing factors		Amount transferred (%)
		Transfer factor	Yield factor	

Proposed MRLs (Annex IIA, point 6.7, Annex IIIA, point 8.6)

Crop or Crop Group	Proposed MRLs
Beans	No MRL proposed. Candidate for Annex IV of Commission Regulation (EC) No 396/2005

Fate and Behaviour in the Environment

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)

Mineralization after 100 days ‡	No data submitted
Non-extractable residues after 100 days ‡	No data submitted
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	No data submitted

Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation ‡

Mineralization after 100 days	No data submitted
Non-extractable residues after 100 days	No data submitted
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	No data submitted

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	No data submitted

Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Laboratory studies:

Parent	Aerobic conditions: no data submitted

Field studies ‡

Parent	Aerobic conditions: no data submitted

Soil accumulation and plateau concentration ‡	No data submitted

Laboratory studies ‡

Parent	Anaerobic conditions: no data submitted

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡ no data submitted

Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Column leaching ‡	No data submitted
Aged residues leaching ‡	No data submitted
Lysimeter/ field leaching studies ‡	No data submitted

PEC (soil)

Parent Method of calculation	No valid DT_{50} could be determined due the nature of the active ingredient.
Application data	Crop: bean Depth of soil layer: 5 cm Soil bulk density: 1.5 g/ml % plant interception: no crop interception Number of applications: single application Application rate(s): max. 2500 g a.s./ha

Summary of initial PEC_s

Formulation/ compound	Crop	Number of applications	Maximum use rate [g product/ha]	Crop interception [%]	Effective soil exposure rate [g/ha]	PEC_S [mg/kg]
ALTHIA (Goemar)	Bean	1	2000	0	2000	2.667
AGROCEAN BASE (Agrimer)	Bean	1	2500	0	2500	3.333
STIMPLEX (Acadian)	Bean	1	2000	0	2000	2.667
KELPGROW (Asfaleia)	Bean	1	2000	0	2000	2.667
ALGAEGREEN (OGT)	Bean	1	2000	0	2000	2.667

Route and rate of degradation in water (Annex IIA, point 7.2.1)

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	No data submitted
	No data submitted
	No data submitted
Photolytic degradation of active substance and metabolites above 10 % ‡	No data submitted
Quantum yield of direct phototransformation in water at Σ > 290 nm	No data submitted
Readily biodegradable ‡ (yes/no)	No data submitted

Degradation in water / sediment

Parent	No data submitted

PEC (surface water) (Annex IIIA, point 9.2.3)

Parameters used	The PECsw for all products were calculated using the Rautman spray-drift equation*, assuming a water depth of 0.3 m, vegetables (height > 50 cm) as crop.

Formulation/ compound	Crop	Number of applications	Maximum use rate [g product/ha]	PEC_{sw} [µg/L]			
				3m	5m	10m	15m
ALTHIA (Goemar)	Bean	1	2000	53.467	24.133	8.200	4.333
AGROCEAN BASE (Agrimer)	Bean	1	2500	66.833	30.167	10.250	5.417
STIMPLEX (Acadian)	Bean	1	2000	53.467	24.133	8.200	4.333
KELPGROW (Asfaleia)	Bean	1	2000	53.467	24.133	8.200	4.333
ALGAEGREEN (OGT)	Bean	1	2000	53.467	24.133	8.200	4.333

* the version of the Rautman spray-drift equation used in PECsw calculations is not available; however, results can be considered conservative and are acceptable.

Residues requiring further assessment

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure.	Soil: sea-algae extract Surface water: sea-algae extract Sediment: sea-algae extract Ground water: sea-algae extract Air: sea-algae extract

Monitoring data, if available (Annex IIA, point 7.4)

Soil (indicate location and type of study)	No data available
Surface water (indicate location and type of study)	No data available
Ground water (indicate location and type of study)	No data available
Air (indicate location and type of study)	No data available

Points pertinent to the classification and proposed labelling with regard to fate and behaviour data

Candidate for R 53 in the absence of data on ready biodegradability.

Ecotoxicology

Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Species	Test substance	Time scale	End point (mg/kg bw)	End point (mg/kg feed)
Birds ‡				
No data available				
Mammals ‡				
Rat	Althia	Acute	LD_{50} >2000 mg/kg bw (oral and dermal)	
	Agrocean Base	Acute	LD_{50} >2000 mg/kg bw (oral and dermal)	
	Stimplex (pH 4)	Acute	LD_{50} >2000 mg/kg bw (oral and dermal)	
	Stimplex (pH 8)	Acute	LD_{50} >2000 mg/kg bw (oral and dermal)	
	Kelpgrow	Acute	LD_{50} >2000 mg/kg bw (oral and dermal)	
	Algaegreen	Acute	LD_{50} >2000 mg/kg bw (oral and dermal)	
Additional higher tier studies ‡				
No data available – not required				

Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

Crop and application rate: Bean (BBCH 5)
Kelpgrow, Stimplex Althia, Algaegreen: 2 kg formulated product/ha, Agrocean base (at any crop stage): 2.5 kg formulated product/ha

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Tier 1 (Birds)				
No data available				
Higher tier refinement (Birds)				
No data available				
Tier 1 (Mammals)				
Small omnivorous mammal[1)]	Acute	5.7 [2)]	> 17.5	10
	Long-term	Not relevant		5

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Higher tier refinement (Mammals)				
	Acute	Not relevant		10
	Long-term	Not relevant		5

[1)] for crops treated at BBCH < 10 the generic focal species is a small omnivorous mammal with a shortcut 90th percentile RUD = 14.3 (Table I.2, (Annex I of guidance document EFSA, 2009)

[2)] the figure refers to DDD; $DDD_{single\ application)}$= application rate x shortcut value = 0.4 kg dw a.s./ha x 14.3 = 5.7.

Worst-case acute mammal toxicity (expressed as dry matter content of the formulation) is LD_{50} > 100 mg dw a.s./kg bw/day (Althia).

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Group	Test substance	Time-scale	Endpoint	Toxicity (mg preparation /L $_{nom}$)
Laboratory tests				
Fish				
Oncorhynchus mykiss	Althia	96 h	96 h NOEC (mortality)	> 100 mg/L
Danio rerio	Agrocean Base	96 h	96 h NOEC (mortality)	> 100 mg/L
Danio rerio	Stimplex (pH 4)	96 h	96 h NOEC (mortality)	> 100 mg/L
Danio rerio	Stimplex (pH 8)	96 h	96 h NOEC (mortality)	> 100 mg/L
Danio rerio	Kelpgrow	96 h	96 h NOEC (mortality)	> 100 mg/L
Aquatic invertebrates				
Daphnia magna	Althia	48 h	48 h NOEC (immobility)	> 100 mg/L
Daphnia magna	Agrocean Base	48 h	48 h NOEC (immobility)	> 100 mg/L
Daphnia magna	Stimplex (pH 4)	48 h	48 h NOEC (immobility)	> 100 mg/L
Daphnia magna	Stimplex (pH 8)	48 h	48 h NOEC (immobility)	> 100 mg/L
Daphnia magna	Kelpgrow	48 h	48 h NOEC (immobility)	> 100 mg/L
Sediment dwelling organisms				
No data available – not required				
Algae				
Scenedesmus subspicatus	Althia	72 h	72 h EC10 (biomass and growth rate)	> 100 mg/L
Pseudokirchneriella subcapitata	Agrocean Base	72 h	72 h EC10 (biomass and growth rate)	> 100 mg/L
Pseudokirchneriella subcapitata	Stimplex (pH 4)	72 h	72 h EC10 (biomass and growth rate)	> 30 mg/L
Pseudokirchneriella subcapitata	Stimplex (pH 8)	72 h	72 h EC10 (biomass and growth rate)	> 30 mg/L
Pseudokirchneriella subcapitata	Kelpgrow	72 h	72 h EC10 (biomass and growth rate)	> 100 mg/L

Pseudokirchneriella subcapitata	Algaegreen	72 h	72 h EC10 (biomass and growth rate)	> 30 mg/L
Higher plants				
No data available –Data gap				
Microcosm or mesocosm tests				
No data available – not required				

Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

Crop and application rate: Bean (BBCH 5) Kelpgrow, Stimplex, Althia, Alagegreen: 2 kg formulated product/ha, Agrocean base (at any crop stage): 2.5 kg formulated product/ha

Test substance	Organism	Toxicity end point (mg/L)	Time scale	PEC_i*	TER	Annex VI Trigger
Althia	Fish		Acute	53.47	> 1870	100
Althia	Aquatic invertebrates		Acute	53.47	> 1870	100
Althia	Algae		Chronic	53.47	> 1870	10
Agrocean Base	Fish		Acute	66.83	> 1496	100
Agrocean Base	Aquatic invertebrates		Acute	66.83	> 1496	100
Agrocean Base	Algae		Chronic	66.83	> 1496	10
Stimplex	Fish		Acute	53.47	> 1870	100
Stimplex	Aquatic invertebrates		Acute	53.47	> 1870	100
Stimplex	Algae		Chronic	53.47	> 561	10
Kelpgrow	Fish		Acute	53.47	> 1870	100
Kelpgrow	Aquatic invertebrates		Acute	53.47	> 1870	100
Kelpgrow	Algae		Chronic	53.47	> 1870	10
Algaegreen	Algae		Chronic	53.47	> 561	10
a.s.	Higher plants		Chronic	Data gap	-	10
a.s.	Sediment-dwelling organisms		Chronic	Not available	Not relevant	10

* Global maximum PEC (µg/L) due to the spray drift (3m).

Bioconcentration				
	Active substance	Metabolite1	Metabolite2	Metabolite3
$logP_{O/W}$	No data available			

Bioconcentration				
Bioconcentration factor (BCF)	No data available - not required			
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				

Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
a.s.	No data available	No data available
formulation	No data available	No data available
Field or semi-field tests		
No data available		

Hazard quotients for honey bees (Annex IIIA, point 10.4)

Test substance	Route	Hazard quotient	Annex VI Trigger
a.s.	Contact	Not relevant	50
a.s.	oral	Not relevant	50
formulation	Contact	Not relevant*	50
formulation	oral	Not relevant*	50

*: data gap for the use with the formulation Agrocean base for the case(s) when bees can be exposed.

Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Effect (LR_{50} g/ha)
Typhlodromus pyri ‡		Mortality	No data available
Aphidius rhopalosiphi ‡		Mortality	No data available

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field	Trigger
	Typhlodromus pyri	No data available	data gap	data gap	2

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field	Trigger
	Aphidius rhopalosiphi	No data available	data gap	data gap	2

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)	End point	% effect	Trigger value
				No data available		50 %

Field or semi-field tests: no reliable data are available

Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA points 8.4 and 8.5. Annex IIIA, points, 10.6 and 10.7)

Test organism	Test substance	Time scale	End point
Earthworms			
No data available			
Other soil macro-organisms			
No data available			
Collembola			
No data available			
Soil micro-organisms			
No data available			
Field studies			
No data available			

Data gap is identified to address the risk for soil organisms (earthworms, soil macro- and micro- organisms).

Toxicity/exposure ratios for soil organisms

Test organism	Test substance	Time scale	Soil PEC	TER	Trigger
Earthworms					
Eisenia foetida	a.s. ‡			data gap	10
Other soil macro-organisms					
Soil mite	a.s. ‡			data gap*	
	formulation				
	Metabolite 1				
Collembola	a.s. ‡			data gap*	
	formulation				

Test organism	Test substance	Time scale	Soil PEC	TER	Trigger
	Metabolite 1				

*: the relevant data gap is a general data gap to address the risk for soil organisms

Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)

Preliminary screening data

No data available

Laboratory dose response tests

Most sensitive species	Test substance	ER_{50} $(g/ha)^2$ vegetative vigour	ER_{50} (g/ha) emergence	Exposure (g/ha)	TER	Trigger
No data available - data gap						

Additional studies (e.g. semi-field or field studies)

No data available

Effects on biological methods for sewage treatment (Annex IIA 8.7)

Test type/organism	End point
Activated sludge	No data available

Ecotoxicologically relevant compounds (consider parent and all relevant metabolites requiring further assessment from the fate section)

Compartment	
soil	sea-algae extracts
water	sea-algae extracts
sediment	sea-algae extracts
groundwater	sea-algae extracts

Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

	RMS/peer review proposal
Active substance	No classification is proposed

APPENDIX B - DETAILED SPECIFICATION OF THE MARKER COMPOUNDS IN THE FORMULATIONS

ACADIAN

Sea-algae Extract of *Ascophyllum nodosum* (STIMPLEX)

Table 1 Summary of the specification for STIMPLEX based on wet weight analysis

	Proposed Specification g/kg
Mannitol	6.0
Fucoidans	19.0
Alginic acids	24.0
Water and unidentified components	Up to 1000

Table 2 Summary of the specification for STIMPLEX based on dry weight analysis

	Proposed Specification g/kg
Mannitol	30.0
Fucoidans	99.0
Alginic acids	124.0

AGRIMER

Sea-algae Extract of *Laminaria digitata* (AGROCEAN BASE)

Table 3 Summary of the specification for AGROCEAN BASE based on wet weight analysis

	Proposed Specification g/kg
Mannitol	18.0
Fucoidans	3.5
Alginic acids	18.0
Water and unidentified components	Up to 1000

Table 4 Summary of the specification for AGROCEAN BASE based on dry weight analysis

	Proposed Specification g/kg
Mannitol	166.0
Fucoidans	34.0
Alginic acids	166.5

ASFALEIA

Sea-algae Extract of *Macrocystis integrifolia* (KELPGROW)

Table 5 Summary of the specification for KELPGROW based on wet weight analysis

	Proposed Specification g/kg
Mannitol	6.0
Fucoidans	2.0
Alginic acids	1.5
Water and unidentified components	Up to 1000

Table 6 Summary of the specification for KELPGROW based on dry weight analysis

	Proposed Specification g/kg
Mannitol	191.0
Fucoidans	67.0
Alginic acids	23.5

GOËMAR

Sea-algae Extract of *Laminaria digitata* and *Ascophyllum nodosum* (ALTHIA)

Table 7 Summary of the specification for ALTHIA based on wet weight analysis.

	Proposed Specification g/kg
Mannitol	7.3
Fucoidans	2.8
Alginic acids	1
Water and unidentified components	Up to 1000

Table 8 Summary of the specification for ALTHIA based on dry weight analysis.

	Proposed Specification g/kg
Mannitol	147
Fucoidans	55.5
Alginic acids	18.5

OILEAN GLAS

SEA ALGAE EXTRACT of Ascophyllum sp. (ALGAEGREEN)

Table 9 Summary of the specification for ALGAEGREEN base on wet weight analysis

	Proposed Specification g/kg
Mannitol	6.0
Fucoidans	3.0
Alginic acids	6.0
Water and unidenfied components	Up to 1000

Table 10 Summary of the specification for ALGAEGREEN base on dry weight analysis

	Proposed Specification g/kg
Mannitol	140.0
Fucoidans	38.0
Alginic acids	77.0

ABBREVIATIONS

1/n	slope of Freundlich isotherm
λ	wavelength
ε	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
µg	microgram
µm	micrometer (micron)
a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
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
cm	centimetre
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT_{50}	period required for 50 percent disappearance (define method of estimation)
DT_{90}	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC_{50}	effective concentration (biomass)
EC_{50}	effective concentration
ECHA	European Chemical Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
FIR	Food intake rate
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram
GAP	good agricultural practice

GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathion
h	hour(s)
ha	hectare
Hb	haemoglobin
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HQ	hazard quotient
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting on 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
kg	kilogram
K_{Foc}	Freundlich organic carbon adsorption coefficient
L	litre
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
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mg	milligram
mL	millilitre
mm	millimetre
mN	milli-newton
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
NESTI	national estimated short-term intake
ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration

NOEL	no observed effect level
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 ground water
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
pH	pH-value
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})
ppp	plant protection product
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
SL	soluble concentrate
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
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WBC	white blood cell
WHO	World Health Organisation
wk	week
yr	year