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Peer review of the pesticide risk assessment of the active substance laminarin

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Abstract

The conclusions of EFSA following the peer review of the initial risk assessments carried out by the competent authorities of the rapporteur Member State, the Netherlands, and co-rapporteur Member State, France, for the pesticide active substance laminarin are reported. The context of the peer review was that required by Commission Implementing Regulation (EU) No 844/2012. The conclusions were reached on the basis of the evaluation of the representative uses of laminarin as elicitor on apple, pear, vine, kiwi, green bean, lettuce, strawberry, tomato, cucurbits, aubergine and pepper. The reliable end points, appropriate for use in regulatory risk assessment, are presented. Missing information identified as being required by the regulatory framework is listed. Concerns are identified.

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Summary

Commission Implementing Regulation (EU) No 844/2012 (hereinafter referred to as 'the Regulation') lays down the procedure for the renewal of the approval of active substances submitted under Article 14 of Regulation (EC) No 1107/2009. The list of those substances is established in Commission Implementing Regulation (EU) No 686/2012. Laminarin is one of the active substances listed in Regulation (EU) No 686/2012.

In accordance with Article 1 of the Regulation, the rapporteur Member State (RMS), the Netherlands, and co-rapporteur Member State (co-RMS), France, received an application from Laboratoire Goëmar SAS for the renewal of approval of the active substance laminarin. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicant, the co-RMS (France), the European Commission and the European Food Safety Authority (EFSA) about the admissibility.

The RMS provided its initial evaluation of the dossier on laminarin in the renewal assessment report (RAR), which was received by EFSA on 22 April 2016. In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant, Laboratoire Goëmar SAS, for comments on 13 June 2016. EFSA also provided comments. In addition, EFSA conducted a public consultation on the RAR. EFSA collated and forwarded all comments received to the European Commission on 17 August 2016.

Following consideration of the comments received on the RAR, it was concluded that additional information should be requested from the applicant, and that EFSA should conduct an expert consultation in the areas of mammalian toxicology and environmental fate and behaviour.

In accordance with Article 13(1) of the Regulation, EFSA should adopt a conclusion on whether laminarin can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of laminarin as elicitor on apple, pear, vine, kiwi, green bean, lettuce, strawberry, tomato, cucurbits, aubergine and pepper, as proposed by the applicant. Full details of the representative uses can be found in Appendix A of this report.

Data were submitted to conclude that the representative uses of laminarin proposed at the European Union (EU) level result in a sufficient efficacy in inducing systemic resistance in plants against fungal diseases and bacteria.

Data gaps were identified in the area of identity, physical, chemical and technical properties and analytical methods for a final report of the 5-batch analysis including the results for heavy metals, for a shelf-life study of the formulation in the commercial packaging and final validation reports on the new analytical methods for the determination of laminarin and impurities in laminarin, for the method used in the new *Lemna* ecotoxicity study and enforcement method of laminarin in drinking water.

Laminarin did not exert any toxicity in the submitted studies and based on its chemical identity as polysaccharide the derivation of reference values was considered as not necessary. Consequently, a non-dietary risk assessment is not needed, either. Two data gaps were identified for the setting of acceptable levels of the relevant impurities (e.g. arsenic and iodine) in the technical specification, and for further demonstration of the representativeness of the batches used in the (eco)toxicological studies with regard to the technical specification, leading to a critical area of concern.

In the section of residues, a dietary risk assessment and maximum residue level (MRL) proposals for laminarin were not deemed necessary since toxicological reference values were not set for laminarin. However, the use of laminarin on crops may lead to relevant additional dietary exposure of consumers to arsenic and iodine in view of the multiple applications and the number of crops included in the representative uses. Therefore, a reliable assessment of the dietary exposure potential for arsenic and iodine residues related to the use of laminarin as a pesticide should be conducted, leading to a data gap and an assessment not finalised.

The information available on environmental fate and behaviour was sufficient to complete the required exposure assessment at the EU level with the notable exception that the potential for groundwater exposure could not be finalised. This has been identified as both a data gap and an assessment not finalised.

A data gap was identified in the ecotoxicology area to confirm the preliminary endpoint on *Lemna*.

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Background

Commission Implementing Regulation (EU) No 844/2012¹ (hereinafter referred to as 'the Regulation') lays down the provisions for the procedure of the renewal of the approval of active substances, submitted under Article 14 of Regulation (EC) No 1107/2009². This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States, the applicant(s) and the public on the initial evaluation provided by the rapporteur Member State (RMS) and/or co-rapporteur Member State (co-RMS) in the renewal assessment report (RAR), and the organisation of an expert consultation where appropriate.

In accordance with Article 13 of the Regulation, unless formally informed by the European Commission that a conclusion is not necessary, EFSA is required to adopt a conclusion on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 within 5 months from the end of the period provided for the submission of written comments, subject to an extension of an additional 3 months where additional information is required to be submitted by the applicant(s) in accordance with Article 13(3).

In accordance with Article 1 of the Regulation, the RMS, the Netherlands, and co-RMS, France, received an application from Laboratoire Goëmar SAS for the renewal of approval of the active substance laminarin. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicant, the co-RMS (France), the European Commission and EFSA about the admissibility.

The RMS provided its initial evaluation of the dossier on laminarin in the RAR, which was received by EFSA on 22 April 2016 (Netherlands, 2016).

In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant, Laboratoire Goëmar SAS, for consultation and comments on 13 June 2016. EFSA also provided comments. In addition, EFSA conducted a public consultation on the RAR. EFSA collated and forwarded all comments received to the European Commission on 17 August 2016. At the same time, the collated comments were forwarded to the RMS for compilation and evaluation in the format of a reporting table. The applicant was invited to respond to the comments in column 3 of the reporting table. The comments and the applicant's response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicant in accordance with Article 13(3) of the Regulation were considered in a telephone conference between EFSA and the RMS on 27 September 2016. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof, it was concluded that additional information should be requested from the applicant, and that EFSA should conduct an expert consultation in the areas of mammalian toxicology and environmental fate and behaviour.

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, including those issues to be considered in an expert consultation, were compiled by EFSA in the format of an evaluation table.

The conclusions arising from the consideration by EFSA, and as appropriate by the RMS, of the points identified in the evaluation table, together with the outcome of the expert consultation and the written consultation on the assessment of additional information, where these took place, 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 March–April 2017.

This conclusion report summarises the outcome of the peer review of the risk assessment of the active substance and the representative formulation, evaluated on the basis of the representative uses of laminarin as an elicitor by foliar spraying in apple, pear, vine, kiwi, green bean, lettuce, strawberry, tomato, cucurbits, aubergine and pepper, as proposed by the applicant.

¹ Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 252, 19.9.2012, p. 26–32.

² Regulation (EC) No 1107/2009 of 21 October 2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

A list of the relevant end points for the active substance and the formulation is provided in Appendix A.

In addition, a key supporting document to this conclusion is the peer review report (EFSA, 2017), which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The peer review report comprises the following documents, in which all views expressed during the course of the peer review, including minority views, where applicable, can be found:

- the comments received on the RAR;
- the reporting table (27 September 2017);
- the evaluation table (24 April 2017);
- the reports of the scientific consultation with Member State experts (where relevant);
- the comments received on the assessment of the additional information (where relevant);
- the comments received on the draft EFSA conclusion.

Given the importance of the RAR, including its revisions (Netherlands, 2017), and the peer review report, both documents are considered as background documents to this conclusion and thus are made publicly available.

It is recommended that this conclusion report and its background documents would not be accepted to support any registration outside the EU for which the applicant has not demonstrated that it has regulatory access to the information on which this conclusion report is based.

The active substance and the formulated product

Laminarin is the common name for (1→3)-β-D-glucan (IUPAC-IUB).

The representative formulated product for the evaluation was 'Vacciplant Fruits et Légumes', a soluble concentrate (SL) containing 45 g/L laminarin. There is no FAO specification available.

The representative uses evaluated as plant elicitor were spray applications on a wide range of crops, both field and glasshouse use. In particular, the representative uses were field applications by foliar spraying against various diseases in apple, pear, vine, kiwi, green bean, pumpkins, and field and glasshouse foliar spray applications in lettuce, strawberry, tomato, cucurbits, aubergine and pepper. Full details of the pathogens to be controlled in the specific crops of the Good Agricultural Practices (GAPs) can be found in the list of end points in Appendix A.

Data were submitted to conclude that the representative uses of laminarin proposed at the EU level result in a sufficient efficacy in inducing systemic resistance in plants against fungal diseases and bacteria following the guidance document SANCO/2012/11251-rev. 4 (European Commission, 2014).

Conclusions of the evaluation

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

The following guidance documents were considered in the production of this conclusion: SANCO/3029/99-rev. 4 (European Commission, 2000a), SANCO/3030/99-rev. 4 (European Commission, 2000b) and SANCO/825/00-rev. 8.1 (European Commission, 2010).

Laminarin is originated from a brown alga, *Laminaria digitata* and is produced as a technical concentrate (TK), containing 60 g/L (min. 50 g/L, max. 70 g/L) of laminarin. The proposed specification is based on batch data from industrial scale production. The minimum purity of the technical material (TC) is 860 g/kg on dry weight basis. There is no FAO specification available for laminarin. Arsenic and iodine were considered relevant impurities. It should be mentioned that a data gap was identified for the final report of the 5-batch analysis including the results for heavy metals, arsenic, iodine. Based on the final batch data, the specifications for the TC (on dry weight basis) and TK might have to be revised. As a consequence, the specification and the relevance of impurities are open (see Section 2).

A data gap was identified for a shelf-life study of the formulation in the commercial packaging. The main data regarding the identity of laminarin and its physical and chemical properties are given in Appendix A.

Data gaps were identified for additional validation data for some methods for the generation of pre-approval data required for the risk assessment (determination of the active substance and

impurities in the technical material and analytical method used in the new *Lemna* ecotoxicity study). Adequate method of analysis is available for the determination of the active substance in the representative formulation.

No residue definition for monitoring for plant, animal and environmental matrices (except groundwater) and for body fluids and tissues were proposed for laminarin, as a consequence, methods for monitoring purposes are not needed, except because of the legislation for groundwater. The need for methods for air and body fluids can be waived based on the considerations in Section 2. For groundwater, this remains open.

2. Mammalian toxicity

The toxicological profile of the active substance laminarin was discussed at the Pesticides Peer Review experts' meeting 151 (February, 2017) and assessed based on the following guidance documents: SANCO/221/2000-rev. 10-final (European Commission, 2003), SANCO/10597/2003-rev. 10.1 (European Commission, 2012), Guidance on dermal absorption (EFSA PPR Panel, 2012) and Guidance on the Application of the CLP Criteria (ECHA, 2015).

Laminarin is an extract from the brown alga *Laminaria digitata* which may contain heavy metals, arsenic and iodine (relevant impurities). Safe levels for arsenic and iodine in the technical specification cannot be determined on the basis of the information available. Considering also the data gap in Section 1 for the technical specification, the representativeness of the batches used in the toxicological studies cannot be concluded. Data gap and critical area of concern were identified.

To assess the toxicological profile of the active substance, the applicant submitted a limited but sufficient set of toxicity studies. Specific toxicokinetic studies were not submitted. Based on the peer-reviewed scientific literature, laminarin as a non-starch polysaccharide is metabolised in monogastric animals through gut's microbiota into short-chain fatty acids (SCFA) and is extensively excreted (approx. 90%). Due to the molecular size of laminarin, dermal or inhalation absorption is not expected. Due to the structure and natural origin of laminarin, an *in vitro* metabolism study was deemed unnecessary.

Laminarin is of low acute toxicity when administered orally (> 2,000 mg/kg body weight (bw)), dermally or by inhalation to rats. It is neither a skin or eye irritant, nor a skin sensitiser. For laminarin phototoxicity and photomutagenicity studies are not required. The results from an Ames test with laminarin were considered as equivocal. Considering the negative results in other genotoxicity studies (*in vitro* gene mutation test in L5178Y TK mouse lymphoma cells, *in vitro* chromosomal aberration assay in Chinese hamster ovary (CHO) cells and *in vivo* micronucleus test) and its chemical identity as a polysaccharide, it can be concluded that laminarin is unlikely to be genotoxic.

No toxic effects were observed in the short-term and developmental toxicity studies provided by the applicant. The no observed adverse effect level (NOAEL) for short- and long-term toxicity was set at 1,000 mg/kg bw per day. It was agreed that no further toxicity studies should be required.

Laminarin is not classified or proposed to be classified as carcinogenic category 2 and as toxic for reproduction category 2, in accordance with the provisions of Regulation (EC) No 1272/2008³ and, therefore, the conditions of the interim provisions of Annex II, Point 3.6.5 of Regulation (EC) No 1107/2009 concerning human health for the consideration of endocrine disrupting properties are not met. Based on the available toxicological data, no concern was raised for potential endocrine disruption properties for laminarin.

On the basis of the available data, it is considered unnecessary to set any toxicological reference values (acute reference dose (ARfD), acceptable daily intake (ADI), acceptable operator exposure level (AOEL) or acute acceptable operator exposure level (AAOEL)) for laminarin. This is in agreement with the approach taken during the first peer review evaluation (European Commission, 2004). As a consequence, the risk assessments for operators, workers, bystanders and residents are not triggered.

3. Residues

Metabolism studies with laminarin in plants were not provided, however based on peer reviewed scientific literature it could be demonstrated that β -1,3-linked glucan polymers are polysaccharides common to higher plants and that their endogenous enzymes such as β -1,3-glucanases are able to

³ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC with EEA relevance. OJ L 70, 16.3.2005, p. 1–16.

hydrolyse laminarin to lower oligosaccharides (laminaridextrins and laminaribiose) and monosaccharides (glucose). A number of studies investigated the use of laminarin as a feed additive and its impact on animal growth and health, while very little information is reported on the actual metabolism of laminarin in animals. Yet, it is reasonable to assume that animal exposure to laminarin is unlikely to lead to any residue in food of animal origin that could be of relevance for consumer safety. Since no ARfD and ADI were considered necessary for laminarin, a consumer risk assessment is not necessary with regard to laminarin residues.

It is not deemed necessary to establish maximum residue levels (MRLs) for laminarin. The inclusion of laminarin in Annex IV of Regulation (EC) No 396/2005⁴ as previously recommended in the reasoned opinion for first establishment of Annex IV by EFSA (2008), may be appropriate provided it can be demonstrated that the contents of impurities in the technical material, such as arsenic and iodine, and their potential residues on crops are not of relevance for consumers.

The use of laminarin on crops is expected to lead to additional dietary exposure of consumers to arsenic, taking into account the presence of arsenic in the formulated product (see Section 1) and the multiple applications on a number of crops according to the representative uses. With regard to the general dietary exposure of EU consumers to inorganic arsenic, the scientific report of EFSA (2014) concluded that 'there is little or no margin of exposure and the possibility of a risk to some consumers cannot be excluded'. Therefore, a reliable assessment of potential residue concentrations of arsenic in crops related to the use of laminarin as a pesticide and of the resulting dietary intake for livestock and consumers should be conducted when further data on the specification are available. In addition, it may also be necessary to assess the dietary exposure to iodine resulting from the use of laminarin as a pesticide to ensure that the tolerable limit for iodine dietary intake is not exceeded (data gap). Therefore, the consumer risk assessment is not finalised.

4. Environmental fate and behaviour

Laminarin was discussed in the Pesticides Peer Review experts' meeting 152 in February 2017. Laminarin (β -1,3-glucan polymers) was shown to be readily biodegradable in an OECD 301B guideline, ready biodegradability study (OECD, 1992). Following the ECHA (2016) guidance, this results in soil, water and sediment single first-order DT_{50} of 30, 15 and 300 days at the reference temperature of 12°C used by the REACH EUSES modelling framework. When normalised to the FOCUS modelling framework reference temperature of 20°C, usually used for pesticide exposure assessment using a Q10 of 2.58 (following EFSA, 2008), these soil, water and sediment single first-order DT_{50} become 14.1, 7.1 and 141.2 days, respectively. This means that laminarin can be considered to exhibit moderate soil persistence. Laminarin has a high water solubility (301.5 g/L at 23°C). A satisfactory measurement of laminarin adsorption to soil was not available, resulting in the experts of the Pesticides Peer Review 152 meeting identifying a data gap. Good evidence was presented from the peer-reviewed scientific literature to demonstrate that: the β -1,3-glucan polymers are present in the cell wall of microorganisms and plants and that β -1,3-glucanase enzymes that hydrolyse β -1,3-glucans to laminaridextrins and glucose are common in bacteria, fungi, algae, higher plants and molluscs.

The necessary surface water and sediment exposure assessments (predicted environmental concentrations (PEC) calculations) were carried out for laminarin, using the FOCUS (2001) step 1 and step 2 approach (version 1.1 of the Steps 1-2 in FOCUS calculator).

Reliable groundwater exposure assessments were not available, as satisfactory measurements of laminarin adsorption to soil were not available. This leads to a data gap and an assessment not finalised. The RMS provided illustrative FOCUS (2009) guidance compliant groundwater modelling using different quantitative structure–activity relationship (QSAR) estimated adsorption values for laminarin. When an adsorption value of 93.6 mL/g was used, none of the representative uses resulted in 80th percentile annual average recharge concentrations moving below 1 m being above 0.1 μ g/L. When an adsorption value of 0.0581 mL/g (calculated from the measured $\log K_{ow}$ of -1.6) was used in simulations, only the single scenario of Sevilla with the representative use with the lowest amount reaching the soil (use on lettuce, FOCUS crop simulated cabbage) was predicted to be below 0.1 μ g/L. At the other scenarios, representative uses resulted in concentrations predicted to be in the range 0.58–36.65 μ g/L. Molecular connectivity index QSAR, gave soil adsorption values for 3, 4 and 6 1,3-glucan chains of 93.6–248,900,000 mL/g with QSAR based on $\log K_{ow}$ being 0.0581–0.0000001468 mL/g (all estimated

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, p. 1–1355.

with EPISUITE KOCWIN v2.0). The experts at the Pesticides Peer Review 152 meeting considered that this QSAR tool could not be used to provide adsorption estimates for β -1,3-glucan polymers that would have any utility in informing a groundwater leaching assessment, as the EPISUITE tool clearly was not generating usable coherent adsorption estimates for such water-soluble polymers, i.e. this class of compounds did not appear to be within the applicability domain of the EPISUITE KOCWIN v2.0 tool.

The applicant provided appropriate information to address the effect of water treatment processes on the nature of the residues that might be present in surface water and groundwater, when surface water or groundwater are abstracted for drinking water. The conclusion of this consideration was that neither laminarin nor its transformation product glucose would be expected to undergo any substantial transformation due to oxidation at the disinfection stage of usual ozonation or chlorination water treatment processes.

The PEC in soil, surface water and sediment covering the representative uses assessed can be found in Appendix A of this conclusion.

5. Ecotoxicology

The risk assessment was based on the following documents: European Commission (2002a,b), SETAC (2001) and EFSA (2009).

Considering the data gap in Section 1 in relation to the technical specification, the representativeness of the batches used in the ecotoxicological studies cannot be concluded and the ecotoxicological relevance of levels for arsenic and iodine in the technical specification should be further considered. Data gap and critical area of concern identified.

On the basis of the available data, the acute and long-term risk to **birds** and **mammals** was considered as low for all representative uses. Since a reproductive endpoint for birds was not available, the risk assessment was based on weight-of-evidence using literature data, and a risk assessment was performed using the LD₅₀/10 as a surrogate.

On the basis of the available toxicity endpoints for fish, *Daphnia* and algae, the acute risk assessments to **aquatic organisms** was considered as low for all representative uses. No chronic studies were performed with laminarin on fish or aquatic invertebrates and no data were provided for aquatic plants. Literature data were presented demonstrating that the chronic risk to fish and invertebrates could be expected as low, even following repeated exposure. For the aquatic plants, the ongoing study, mentioned in the RAR, was not provided; therefore, a data gap was identified to confirm the preliminary endpoint from a range finding test.

The risk assessment to **honeybees** was performed by calculating the contact and oral hazard quotient (HQ) values, which indicated a low risk. Risk assessments, according to (EFSA, 2013) were not performed. Furthermore, chronic toxicity data and data on larvae were not available. Considering the nature of the substance, the rapid degradation in the environment and the plant metabolism along with the literature data provided, the risk to honeybees, bumblebees and solitary bees could be considered as low for all representative uses.

On the basis of the available data, the risk was considered low for **non-target arthropods, earthworms, soil macro- and microorganisms, terrestrial non-target plants** and organisms in **sewage treatment plants**.

With regard to the endocrine disruption potential, as discussed in Section 2, no concern was raised for potential endocrine disruption properties for laminarin.

6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments (Tables 1–4)

Table 1: Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Laminarin	Due to ready biodegradability, following ECHA (2016) guidance considered moderately persistent	Low risk

Table 2: Groundwater

Compound (name and/or code)	Mobility in soil	> 0.1 µg/L at 1 m depth for the representative uses ^(a)	Pesticidal activity	Toxicological relevance
Laminarin	Data gap	Data gap	Yes	Yes

(a): At least one FOCUS scenario or a relevant lysimeter.

Table 3: Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Laminarin	Low risk

Table 4: Air

Compound (name and/or code)	Toxicology
Laminarin	> 1.02 mg/L air per 4 h (maximum attainable concentration) – no classification required

7. Data gaps

This is a list of data gaps identified during the peer review process, including those areas in which 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 56 of Regulation (EC) No 1107/2009 concerning information on potentially harmful effects).

7.1. Data gaps identified for the representative uses evaluated

- Final report of the 5-batch analysis including the results for heavy metals, arsenic and iodine. Based on the results, the specifications for the TC (on dry weight basis) and TK may need to be revised (relevant for all representative uses evaluated; submission date proposed by the applicant: study in progress; see Sections 1 and 2).
- Shelf-life study of the formulation in the commercial packaging (relevant for all representative uses evaluated; submission date proposed by the applicant: study in progress; see Section 1).
- Final validation report on the new analytical methods for the determination of laminarin and impurities in laminarin (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 1).
- Final validation report on the analytical methods for the new study on the effect of the substance laminarin on *Lemna* (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 1).
- Enforcement method of laminarin in drinking water as a consequence of the legislation for groundwater (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Sections 1 and 4).
- Further evidence that the batches used in the toxicological and ecotoxicology studies are representative of the technical specification (still open) needs to be provided (relevant for all representative uses; submission data proposed by the applicant: unknown; see Sections 2 and 5).
- A reliable assessment of potential residues of arsenic and iodine on crops related to the use of laminarin as a pesticide and of the resulting dietary intake for livestock and consumers as well as further assessment of safe levels for arsenic and iodine in the technical specification (relevant for all representative uses; submission data proposed by the applicant: unknown; see Sections 1, 2, 3 and 5).
- A reliable estimation of soil adsorption or other approach that would provide an estimate of groundwater exposure was not available (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 4).
- An aerobic mineralisation in surface water study or information to demonstrate that contamination of open water (freshwater, estuarine and marine) will not occur was not available (although a data requirement, not needed for any of the representative uses evaluated when following the EU environmental exposure assessment guidance; submission date proposed by the applicant: unknown; see Section 4 of the evaluation table contained in the peer review report (EFSA, 2017)).
- The preliminary endpoint from a range-finding test on *Lemna* should be further confirmed (relevant for all representative uses; submission data proposed by the applicant: unknown; see Section 5).

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

No particular conditions are proposed for the representative uses evaluated.

9. Concerns

9.1. Issues that could not be finalised

An issue is listed as 'could not be finalised' if 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 in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in

Commission Regulation (EU) No 546/2011⁵ and if 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).

An issue is also listed as 'could not be finalised' if the available information is considered insufficient to conclude on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

- 1) The use of laminarin on crops may lead to relevant additional dietary exposure of consumers to heavy metals, arsenic and iodine and a reliable assessment of the exposure potential to these compounds is needed to be able to conclude on the consumer dietary risk assessment and to set, if possible, safe levels in the technical specification (see Sections 1, 2, 3 and 5).
- 2) The groundwater exposure assessment for parent laminarin could not be finalised, whilst a reliable estimate of soil adsorption potential (or any other approach for estimating potential for groundwater exposure) was not available (see Section 4).

9.2. Critical areas of concern

An issue is listed as a critical area of concern if there is enough information available to perform an assessment for the representative uses in line with the uniform principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011, and if this assessment does not permit the conclusion 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 if the assessment at a higher tier level could not be finalised due to lack of information, and if the assessment performed at a lower tier level does not permit the conclusion 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 if, in the light of current scientific and technical knowledge using guidance documents available at the time of application, the active substance is not expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

- 1) The batches used in the toxicological and ecotoxicity studies have not been sufficiently demonstrated to be representative of the final technical specification (still open). In addition,
- 2) Safe levels for heavy metals, arsenic and iodine in the technical specification currently cannot be determined on the basis of the information available (see Sections 2, 3 and 5).

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 Table 5.)

All columns are grey, as it was not possible to demonstrate that the technical material specification proposed (still open) was comparable to the material used in the testing that was used to derive the (eco) toxicological assessment.

⁵ Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.

Table 5: Overview of concerns

Representative use		Apple, pear, vine, kiwi, green bean, pumpkins (field)	Lettuce, strawberry, tomato, cucurbits, aubergine, pepper (field and glasshouse)
Operator risk	Risk identified		
	Assessment not finalised		
Worker risk	Risk identified		
	Assessment not finalised		
Resident/bystander risk	Risk identified		
	Assessment not finalised		
Consumer risk	Risk identified		
	Assessment not finalised	X ¹	X ¹
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		
Risk to aquatic organisms	Risk identified		
	Assessment not finalised		
Groundwater exposure to active substance	Legal parametric value breached		
	Assessment not finalised	X ²	X ²
Groundwater exposure to metabolites	Legal parametric value breached ^(a)		
	Parametric value of 10 µg/L ^(b) breached		
	Assessment not finalised		

Columns are grey if no safe use can be identified. The superscript numbers relate to the numbered points indicated in Sections 9.1 and 9.2. Where there is no superscript number, see Sections 2–6 for further information.

(a): When the consideration for classification made in the context of this evaluation under Regulation (EC) No 1107/2009 is confirmed under Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008.

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

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Abbreviations

AAOEL	acute acceptable operator exposure level
ADI	acceptable daily intake
AOEL	acceptable operator exposure level
ARfD	acute reference dose
bw	body weight
CAS	Chemical Abstracts Service
CFU	colony-forming units
CHO	Chinese hamster ovary
CLP	classification, labelling and packaging of substances and mixtures
DAR	draft assessment report
DT ₅₀	period required for 50% dissipation (define method of estimation)

ECHA	European Chemicals Agency
EEC	European Economic Community
EUSES	European Union System for the Evaluation of Substances
FAO	Food and Agriculture Organization of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	Good Agricultural Practice
HQ	hazard quotient
IUB	International Union of Biochemistry
IUPAC	International Union of Pure and Applied Chemistry
LD ₅₀	lethal dose, median; dosis letalis media
MRL	maximum residue level
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
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
PHI	pre-harvest interval
QSAR	quantitative structure–activity relationship
RAR	Renewal Assessment Report
REACH	Registration, Evaluation, Authorisation of Chemicals Regulation
RMS	rappporteur Member State
SCFA	short chain fatty acids
SL	soluble concentrate
SFO	single first-order
TC	technical material
TK	technical concentrate

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

Appendix A can be found in the online version of this output ('Supporting information' section):
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