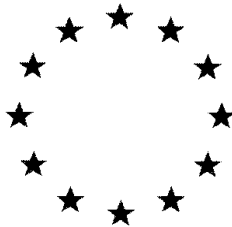


# **European Commission**



**VOLUME 1**

**Laminarin**

**Rapporteur Member State: The Netherlands**

**April 2016**

**Draft Re-Assessment Report and Proposed decision of the Netherlands  
prepared in the context of the possible renewal of laminarin under Regulation  
(EC) 1107/2009**

## Version history page

Date	Version history
April 2016	Initial RAR

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## **Volume 1**

### **Level 1**

#### **- *Laminarin* –**

**Statement of subject matter and purpose for which this report has been prepared and background information on the application**

## **1 Statement of subject matter and purpose for which this report has been prepared and background information on the application**

### **1.1 Context in which the draft assessment was prepared.**

#### **1.1.1 Purpose for which the draft assessment report was prepared**

This Renewal Assessment Report (RAR) is prepared for the renewal of the approval of the active substance laminarin. Laminarin is part of the AIR3 renewal programme for active substances (Commission Implementing Regulation (EU) No 844/2012).

No proposal for MRL setting is included in the RAR. Laminarin is currently included in Annex IV of Regulation (EC) No.396/2005 since October 2007 (Annex IV lists active substances for which maximum residue levels (MRLs) are not required). Since an ADI and/or an ARfD are not necessary, and since laminarin is a natural oligosaccharide, it is proposed to maintain the inclusion in Annex IV of Regulation (EC) No.396/2005.

Laminarin is currently not classified (<http://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/112828>).

No proposal for Classification & Labelling is included in the RAR.

#### **1.1.2 Arrangements between rapporteur Member State and co-rapporteur Member State**

The Netherlands – as Rapporteur Member State (RMS) – conducted the full evaluation and prepared the RAR for laminarin. The RAR was peer reviewed by co-RMS France.

#### **1.1.3 EU Regulatory history for use in Plant Protection Products**

Laminarin was already evaluated as new active substance by the former RMS Belgium. The main data submitted at that time was Goëmar SA.

Laminarin is approved since 1 April 2005 (Commission Directive 2005/3/EC). The current expiry date is 31 July 2017 (Commission Regulation (EU) No 1197/2012). The Review Report (Laminarin – SANCO/10488/04-rev.3) is dated 4 October 2004 and provides endpoints agreed during the first inclusion evaluation (Appendix II to the Review Report). No EFSA conclusion is available for laminarin. Laminarin is currently included in Annex IV of Regulation (EC) No.396/2005 since October 2007 (Annex IV lists active substances for which maximum residue levels (MRLs) are not required). Since an ADI and/or an ARfD are not necessary, and since laminarin is a natural oligosaccharide, it is proposed to maintain the inclusion in Annex IV of Regulation (EC) No.396/2005.

Laminarin is currently not classified (<http://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/112828>).

#### 1.1.4 Evaluations carried out under other regulatory contexts

Laminarin is not evaluated under the Biocidal Product Regulation (Regulation (EU) No 528/2012).

Laminarin is evaluated by the US EPA:

[https://iaspub.epa.gov/apex/pesticides/f?p=CHEMICALSEARCH:31:::NO:1,3,31,7,12,25:P3\\_XCHEMICAL\\_ID:2668](https://iaspub.epa.gov/apex/pesticides/f?p=CHEMICALSEARCH:31:::NO:1,3,31,7,12,25:P3_XCHEMICAL_ID:2668)

## 1.2 Applicant(s) information

### 1.2.1 Name and address of applicant(s) for approval of the active substance

Name: Laboratoire Goëmar SAS  
Address: Parc Technopolitain Atalante  
CS 41908  
35 435 Saint-Malo Cedex  
France

Contact:

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

### 1.2.2 Producers of the active substance

Laboratoire Goëmar SAS.

For more details, please refer to Volume 4.

### 1.2.3 Information relating to the collective provisions of dossiers

Not applicable. Laboratoire Goëmar SAS is the sole data submitter.

## 1.3 Identity of the active substance

### 1.3.1 Common name proposed or ISO-accepted and synonyms

Laminarin

### 1.3.2 Chemical name (IUPAC and CA nomenclature)

IUPAC: (1→3)-β-D-glucan  
(according to IUPAC-IUB Joint Commission on Biochemical Nomenclature)  
CA: - Laminaran

### 1.3.3 Producer's development code numbers

H11

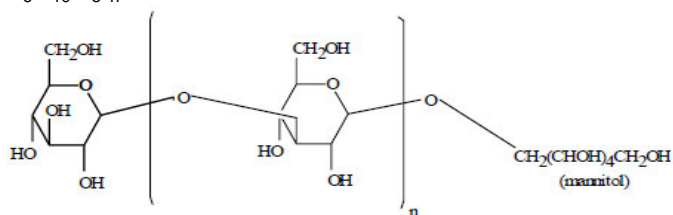
### 1.3.4 CAS, EC and CIPAC numbers

CAS: 9008-22-4  
EEC: 232-712-4 (EINECS)

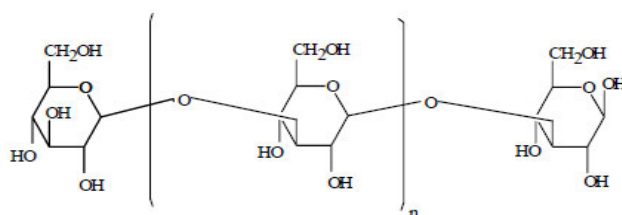
CIPAC: 671

### 1.3.5 Molecular and structural formulae, molecular mass

Molecular formula:  $(C_6H_{10}O_5)_n$   $n = 20$  to  $30$



M-series molecules



G-series molecules

Structural formula:

Molecular mass: 3240 – 4860 g/mol

### 1.3.6 Method of manufacture (synthesis pathway) of the active substance

Confidential information. Please refer to volume 4.

### 1.3.7 Specification of purity of the active substance in g/kg

860 g/kg

### 1.3.8 Identity and content of additives (such as stabilisers) and impurities

#### 1.3.8.1 Additives

None

#### 1.3.8.2 Significant impurities

Confidential information. Please refer to volume 4.

#### 1.3.8.3 Relevant impurities

None

### 1.3.9 Analytical profile of batches

Confidential information. Please refer to volume 4. A batch analysis study is currently ongoing.

## 1.4 Information on the plant protection product

### 1.4.1 Applicant

See 1.2.1.

### 1.4.2 Producer of the plant protection product

Confidential information. Please refer to volume 4.

### 1.4.3 Trade name or proposed trade name and producer's development code number of the plant protection product

Vacciplant Fruits et Légumes, Iodius 2 Cultures Spécialisées, Vacciplant, Vaxiplant SL.

### 1.4.4 Detailed quantitative and qualitative information on the composition of the plant protection product

#### 1.4.4.1 Composition of the plant product

Confidential information. Please refer to volume 4.

#### 1.4.4.2 Information on the active substances

### Pure active substance

<b>content of pure active substance :</b>	<b>45 g/L</b>	<b>4.24 % w/w</b>
Limits* :	40.5 – 49.5 g/L	3.82 – 4.66 % w/w

\* FAO limits +/-10%

### Technical active substance

During the process, the active substance is manufactured as a solution containing 60 g/L Laminarin active substance (min. 50 g/L, max. 70 g/L).

Once dried, the minimum purity of this active substance is 860 g/kg (86.0% w/w) on dry matter.

#### 1.4.4.3 Information on safeners, synergists and co-formulants

The product does not contain safeners and synergists. For co-formulant information, please refer to volume 4 (confidential information).

### 1.4.5 Type and code of the plant protection product

SL (soluble concentrate)

### 1.4.6 Function

Laminarin is an elicitor of the crop's self defence mechanisms.

### 1.4.7 Field of use envisaged

Agriculture. Field and Glasshouse use (F, G).



#### 1.4.8 Effects on harmful organisms

Laminarin is an elicitor of the crop's self-defence mechanisms and as such has no direct effect on harmful organisms. It stimulates the natural defences of the plant against pathogens, i.e. it enhances defence reactions which inhibit the development of the pathogens.

Laminarin will afford a systemic protection to the plant against pathogens like:

- fungi : *Bremia lactucae* on lettuce ; *Botrytis* sp, *Leveillula taurica* and *Pseudoperonospora cubensis* on vegetables and fruits *Botrytis cinerea*, *Diplocarpon earlianum*, , *Phytophthora cactorum* and *Podosphaera aphanis*, on strawberry ; *Gloeosporium* spp., *Podosphaera leucotricha*, *Venturia inaequalis* on apple trees ; *Erysiphe necator* on grapevine.
- bacteria : *Erwinia amylovora* on apple and pear trees, *Pseudomonas syringae* on tomato, *Pseudomonas syringae* pv. *actinidiae* on kiwi.

### 1.5 Detailed uses of the plant protection product (to be included for each preparation for which documentation was submitted).

#### 1.5.1 Details of representative uses

For details on the representative uses of the plant protection product Vacciplant Fruits et Légumes, please see Table 1.5.1-1.

Table 1.5.1-1 GAP table of representative uses

PPP (product name/code) Vacciplant Fruits et Légumes

active substance 1 Laminarin

active substance 2 -

Formulation type: SL

Conc. of as 1: 45 g/L

Conc. of as 2: -

safener not relevant

synergist not relevant

Conc. of safener: -

Conc. of synergist: -

Applicant: Laboratoires Goëmar SAS

Zone(s): central/southern/EU

professional use ☒non professional use ☒

Verified by MS: Yes northern/central/southern

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application			Application rate per treatment			PHI (days)	Remarks:
					Method / Kind	Timing / Growth stage of crop & season	Number / (min Interval Between Appli cations)	kg, L product / ha	g, kg as/ha	Water L/ha  min / max		
1	EU	Apple (MABSD)	F	Gloeosporium GLOESP  Powdery mildew <i>Podosphaera leucotricha</i> PODOLE  Scab	Foliar spraying	BBCH 11- 89 March to November	20 / (7 days)	Standard orchard 1 L/ha  LWA 0.67 L/ha	Standardorch ard 45 g a.s./ha  LWA 30.2 g as/ha	200 - 500	0	a)  Per season: 20  20 L/ha  Standard orchard in this case is 3 m tall, with a row distance of 4 m.

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application			Application rate per treatment			PHI (days)	Remarks:
					Method / Kind	Timing / Growth stage of crop & season	Number / (min Interval Between Appli cations)	kg, L product / ha	g, kg as/ha	Water L/ha  min / max		
				<i>Venturia inaequalis</i> VENTIN								
2	EU	Apple (MABSD)	F	Fire blight <i>Erwinia amylovora</i> EWIAM	Foliar spraying	BBCH 56- 89 April to November	7 / (10 days)	Standard orchard : 0.75 L/ha  LWA : 0.5 L/ha	Standard orchard : 33.8 g a.s./ha  LWA 22.5 g a.s./ha	500- 1000	0	a) Per season: 7  b) 5.25L/ha LWA: 3.5L/ha  c) Standard orchard in this case is 3 m tall, with a row distance of 4 m.
3	EU	Pear (PYUCO)	F	Fire blight <i>Erwinia amylovora</i> EWIAM	Foliar spraying	BBCH 56- 89 April to November	7 / (10 days)	Standard orchard : 0.75 L/ha  LWA : 0.5 L/ha	Standard orchard : 33.8 g a.s./ha  LWA 22.5 g a.s./ha	500- 1000	0	a) Per season: 7  b) 5.25L/ha LWA: 3.5L/ha  c) Standard orchard in this case is 3 m tall, with a row distance of 4 m.

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application			Application rate per treatment			PHI (days)	Remarks:
					Method / Kind	Timing / Growth stage of crop & season	Number / (min Interval Between Appli cations)	kg, L product / ha	g, kg as/ha	Water L/ha  min / max		
4	EU	Vine (VITVI)	F	Powdery mildew <i>Erysiphe necator</i> UNCINE	Foliar spraying	BBCH 11- 89 April to october	10 / (10 days)	2 L/ha	a) 90 g a.s./ha	100- 1000	0	a) Per season: 10 b)20L/ha
5	EU	Lettuce (LACSA)	F, G	Downy mildew <i>Bremia lactucae</i> BREMLA	Foliar spraying	BBCH 13- 49 January to December	per cycle: 6 per / 7 days season: 16 / ( 7 days)	2.5 L/ha	113 g a.s./ha	500- 1000	0	a)Per crop:6 Per season: 16 b)Per cycle: 15L/ha Per season:40L/ha
6	EU	Strawberry (FRASS)	F, G	Powdery mildew <i>Podosphaera aphanis</i> PODOAP	Foliar spraying	BBCH 12- 92 March to October	7 / (7 days)	Min : 0.75 l Max : 1 L/ha	45 g a.s./ha	300- 1000	0	a)Per crop : 7 Per season : 7 b) 7L/ha c) Min 0.75 L/ha Max 1L/ha
7	EU	Strawberry (FRASS)	F, G	Grey mould <i>Botrytis cinerea</i> BOTRCI  Leaf spot <i>Mycosphaerella fragariae</i> MYCOFR  Leaf scorch	Foliar spraying	BBCH 12- 92 February to Septembe r	7 / (5-7 days)	Min 1 L/ha Max 2 L/ha	Min 45 g a.s./ha Max 90 g a.s./ha	300- 1000	0	a)Per crop:7 Per season: 7 b)Min: 7L/ha Max: 14L/ha  c)Apply Vacciplant at 1 L/ha for water volume below 500 L/ha.

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application			Application rate per treatment			PHI (days)	Remarks:
					Method / Kind	Timing / Growth stage of crop & season	Number / (min Interval Between Appli cations)	kg, L product / ha	g, kg as/ha	Water L/ha  min / max		
				<i>Diplocarpon earliana</i> DIPCEA  Leather rot <i>Phytophthora cactorum</i> PHYTCC								Above 500 L/ha keep the product concentration at 0.2 L/hL .
8	EU	Tomato (LYPES)	F, G	Bacterial speck <i>Pseudomonas syringae</i> pv tomato PSDMTM	Foliar spraying	BBCH 10- 89 April to October	7 / (7 days)	Min 1 L/ha Max 2 L/ha	Min 45 g a.s./ha Max 90 g a.s./ha	500- 1300	0	a) Per crop:7 Per season: 7 b)Min: 7L/ha Max: 14L/ha c)
9	EU	Tomato (LYPES)	F, G	Grey mould <i>Botrytis cinerea</i> BOTRCI	Foliar spraying	BBCH 10- 89 January to December	7 /(7 days)	Min 1.5 L/ha Max 3 L/ha	Min 67.5 g a.s./ha Max 135 g a.s./ha	500- 1300	0	a) Per crop:7 Per season: 7 b)Min: 10.5L/ha Max: 21L/ha
10	EU	Tomato (LYPES)	F, G	Powdery mildew <i>Leveillula taurica</i> LEVETA	Foliar spraying	BBCH 10- 89 March to	7 / (7 days)	1 L/ha	45 g a.s./ha	500- 1300	0	a) Per crop:7 Per season: 7 b) 7 L/ha

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application			Application rate per treatment			PHI (days)	Remarks:
					Method / Kind	Timing / Growth stage of crop & season	Number / (min Interval Between Appli cations)	kg, L product / ha	g, kg as/ha	Water L/ha  min / max		
						December						
11	EU	Zucchini (CUUPG)	F, G	Powdery mildew <i>Leveillula taurica</i> LEVETA	Foliar spraying	BBCH 10- 89 January to December	6 / (5 days)	0.75 L/ha	33.8 g a.s./ha	100-500	0	a) Per crop: 6 Per season: 6 b) 4.5L/ha
12	EU	Pumpkins (CUUMA)	F	Powdery mildew <i>Leveillula taurica</i> LEVETA	Foliar spraying	BBCH 10- 89 January to December	6 / (5 days)	0.75 L/ha	33.8 g a.s./ha	100-500	0	a) Per crop:6 Per season: 6 b) 4.5L/ha
13	EU	Aubergine (SOLME) Pepper (CPSAN)	F, G	Grey mould <i>Botrytis cinerea</i> BOTRCI	Foliar spraying	BBCH 60- 89 February to October	7 / (7 days)	3 L/ha	135 g a.s./ha	500- 1300	0	a) Per crop :7 Per season: 7 b) 21L/ha c)
14	EU	Lettuce (LACSA)	F	Grey mould <i>Botrytis</i> sp. BOTRSP	Foliar spraying	BBCH 16- 49 January to December	7 / (7 days)	3 L/ha	135 g a.s./ha	750- 1000	0	a) Per crop: 7 Per season: 7 b) 21L/ha
15	EU	Greenbean (PHSVV)	F,	Grey mould <i>Botrytis</i> spp. BOTRSP	Foliar spraying	BBCH 51- 89 March to Septembe r	7 / (7 days)	3 L/ha	a) 135 g a.s./ha	800- 1300	0	a) Per crop: 7 Per season: 7 b) 21L/ha
16	EU	Cucurbits: Cucumber (CUMSA) Zucchini (CUUPG)	F, G	Grey mould <i>Botrytis</i> spp. BOTRSP	Foliar spraying	BBCH 60- 89 January to	7 / (7 days)	3 L/ha	135 g a.s./ha	800- 1300	0	a) Per crop: 7 Per season: 7 b) 21L/ha

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application			Application rate per treatment			PHI (days)	Remarks:
					Method / Kind	Timing / Growth stage of crop & season	Number / (min Interval Between Appli cations)	kg, L product / ha	g, kg as/ha	Water L/ha  min / max		
						December						
17	EU	Cucumber (CUMSA)	F, G	Downy mildew <i>Pseudoperonospora cubensis</i> PSPECU	Foliar spraying	BBCH 51- 89 January to December	7 / (7 days)	3 L/ha	135 g a.s./ha	800- 1300	0	a) Per crop: 7 Per season: 7 b) 21L/ha c)
18	EU	Kiwi (ATICH)	F	Bacterial canker <i>Pseudomonas syringae</i> pv. Actinidiae PSDMAK	Foliar spraying	BBCH 11- 95 March to November	7/(10 days)	2 L/ha	90 g a.s./ha	700- 1000	0	a) Per season: 7 b) 14L/ha

### 1.5.2 Further information on representative uses

Laminarin is intended to be used as an elicitor of the crop's self-defence mechanisms against pathogens on various crops. By inducing systemic resistance on plants, this allows protection during growth. Laminarin-based formulations are used alone or in combination with fungicides for the protection of crops against fungal diseases and bacteria.

Representative uses of plant protection products containing the active substance Laminarin comprise a wide range of crops, both Glasshouse (G) and Field (F) situations, using foliar application. Details on the exact pathogens to be controlled in the specific crops and situations is provided in the GAP ( Table 1.5.1-1).

The representative formulation containing the active substance Laminarin is Vacciplant Fruits et Légumes, containing 45g/L laminarin.

The timing of the applications varies between crops but it is used preventive in most of crops against target diseases. It allows to stimulate natural defenses of the plants and to alternate the mode of action in a fungicide program.

Vacciplant Fruits et Légumes is safe to all intended crops when it is used according to the label recommendations.

Moreover, Vacciplant Fruits et Légumes is quickly destroyed in the soil.

Therefore no negative effect on succeeding crop growth is anticipated. There is no minimum period for sowing/ planting succeeding/ replacement crops and limitation in the choice of succeeding/ replacement crops.

It can be concluded that Vacciplant Fruits et Légumes has no adverse effect on succeeding crops.

### 1.5.3 Details of other uses applied for to support the setting of MRLs for uses beyond the representative uses

Since laminarin is exempt from MRL setting, no other uses were applied for MRL setting.



#### 1.5.4 Overview on authorisations in EU Member States

The active substance Laminarin was discovered by GOEMAR Laboratories in 1993.

Vacciplant Fruits et Légumes was first developed for fire blight on apple and pear trees and powdery mildew on strawberry.

Later its use was extended to include a range of additional crops including tomato, lettuce, vine, zucchini, pumpkins.

Vacciplant Fruit et Légumes was first authorised in 2008 in France and Belgium.

It has since become widely authorised in European countries including Spain, Italy, Portugal, Greece, Switzerland, Poland, Denmark and Netherlands.

Authorisations for four commercial names (IODUS 2 Cultures Spécialisées / Vacciplant Fruits et Légumes / Vacciplant / Vaxiplant SL) have been achieved in Europe.

A full list of existing and pending authorisations is provided in Table 1.5.4-1 (Vacciplant Fruits et Légumes) and in Table 1.5.4-2 (Vacciplant Grandes Cultures).

Table 1.5.4-1 GAP TABLE OF EXISTING AND PENDING USES: Vacciplant Fruits et Légumes

GAP rev. 0, date: 2013-01-31

PPP (product name/code) Vacciplant Fruits et Légumes

active substance 1 Laminarin

active substance 2 not relevant

active substance not relevant

Formulation type: SL

Conc. of as 1: 45 g/L

Conc. of as 2: -

Conc. of as: -

safener none

synergist none

Conc. of safener: not relevant

Conc. of synergist: not relevant

Applicant: Laboratoires Goëmar SAS

Zone(s): central/southern/EU

professional use ☒non professional use ☒

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application			Min interval between applications	Application rate			PHI (days)	Remarks:  e.g. safener/synergist per ha  e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season		kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
1	BE, FR, NL  <i>Pending (Gloeosporium):</i> AT, BG, CZ, DE, ES, , IT, LU, PL, PT, RO, SI, SK, UK)	Apple (MABSD)	F	Gloeosporium Powdery mildew	Foliar spraying	BBCH 11-89	a) 1 b) 20	7 days	a) 1 L/ha b) 20 L/ha	a) 45 g a.s./ha b) 900 g a.s./ha	200 - 500	0	0.75 – 1 L/ha

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application			Min interval between applications	Application rate			PHI (days)	Remarks:  e.g. safener/synergist per ha  e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season		kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
2	BE, ES, FR, GR NL <i>Pending:</i> AT, BG, CZ, DE, ES, FR, IT, LU, , PL, PT, RO, SI, SK, UK)	Apple (MABSD)	F	Scab	Foliar spraying	BBCH 11-89	a) 1 b) 20	7 days	a) 1 L/ha b) 20 L/ha	a) 45 g a.s./ha b) 900 g a.s./ha	200 - 500	0	0.75 – 1 L/ha
3	BE, ES, FR, IT, NL, PT, GR	Apple (MABSD)	F	Fire blight	Foliar spraying	BBCH 56-89	a) 1 b) 7	10 days	a) 0.75 L/ha b) 5.25 L/ha	a) 33.8 g a.s./ha b) 236.3 g a.s./ha	500-1000	0 (IT: 5)	0.75 L/ha
4	BE, ES, FR, IT, NL, PT, GR	Pear (PYUCO)	F	Fire blight	Foliar spraying	BBCH 56-89	a) 1 b) 7	10 days	a) 0.75 L/ha b) 5.25 L/ha	a) 33.8 g a.s./ha b) 236.3 g a.s./ha	500-1000	0 (IT: 5)	0.75 L/ha
5	GR, FR <i>Pending:</i> ES, IT, PT	Vine (VITVI)	F	Powdery mildew	Foliar spraying	BBCH 11-89	a) 1 b) 10	10 days	a) 2 L/ha b) 20 L/ha	a) 90 g a.s./ha b) 900 g a.s./ha	100-1000	0	1.5 - 2 L/ha
6	GR, FR <i>Pending:</i> ES, IT, PT, BG	Lettuce (LACSA)	F, G	Downy mildew	Foliar spraying	BBCH 13-49	per cycle a) 6 per season b) 24	7 days	per cycle a) 2.5 L/ha b) 15 L/ha per season a) 2.5 L/ha b) 60 L/ha	per cycle a) 113 g a.s./ha b) 675 g a.s./ha per season a) 113 g a.s./ha b) 2700 g a.s./ha	500-1000	0	2.5 L/ha
7	BE, ES, FR, GR, IT, NL, PT	Strawberry (FRASS)	F, G	Powdery mildew	Foliar spraying	BBCH 12-92	a) 1 b) 7	7 days	a) 0.75 L/ha b) 5.25 L/ha	a) 33.8 g a.s./ha b) 236.3 g a.s./ha	300-1000	0 (IT: 5)	0.75 L/ha

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application			Min interval between applications	Application rate			PHI (days)	Remarks:  e.g. safener/synergist per ha  e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season		kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
8	PL <i>Pending :</i> AT, BE, CZ, DE, NL, UK	Strawberry (FRASS)	F, G	Powdery mildew Grey mould Leaf spot Leaf scorch Leather rot	Foliar spraying	BBCH 12-92	a) 1 b) 7	7 days	a) 1 L/ha b) 7 L/ha	a) 45 g a.s./ha b) 315 g a.s./ha	300-500	0	1 L/ha
9	<i>Pending:</i> BG, ES, FR, IT, PT	Strawberry (FRASS)	F, G	Grey mould	Foliar spraying	BBCH 57-89	a) 1 b) 7	7 days	a) 1 L/ha b) 7 L/ha	a) 45 g a.s./ha b) 315 g a.s./ha	300-1000	0	1 L/ha
10	DK	Strawberry (FRASS)	F, G	Grey mould	Foliar spraying	BBCH 57-89	a) 1 b) 7	5 days	a) 2 L/ha b) 14 L/ha	a) 90 g a.s./ha b) 630 g a.s./ha	300-1000	0	Apply Vacciplant at 1 L/ha for water volume below 500 L/ha. Above 500 L/ha keep the product concentration at 0.2 L/hL .
11	PL	Tomato (LYPES)	F	Bacterial speck	Foliar spraying	BBCH 10-89	a) 1 b) 7	7 days	a) 1.5 L/ha b) 10.5 L/ha	a) 67.5 g a.s./ha b) 473 g a.s./ha	600-800	0	1.5 L/ha
12	GR	Tomato (LYPES)	F	Bacterial speck Grey mould	Foliar spraying	BBCH 10-89	a) 1 b) 7	7 days	a) 2 L/ha b) 14 L/ha	a) 90 g a.s./ha b) 630 g a.s./ha	500-1300	0	2 L/ha
13	<i>Pending : ES</i>	Tomato (LYPES)	F	Grey mould	Foliar spraying	BBCH 10-89	a) 1 b) 7	7 days	a) 2 L/ha b) 14 L/ha	a) 90 g a.s./ha b) 630 g a.s./ha	500-1300	0	2 L/ha

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application			Min interval between applications	Application rate			PHI (days)	Remarks:  e.g. safener/synergist per ha  e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season		kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
14	GR <i>Pending: ES</i>	Tomato (LYPES)	F	Powdery mildew	Foliar spraying	BBCH 10-89	a) 1 b) 7	7 days	a) 1 L/ha b) 7 L/ha	a) 45 g a.s./ha b) 315 g a.s./ha	500-1300	0	1 L/ha
15	BE	Zucchini (CUUPG)	F	Powdery mildew	Foliar spraying	BBCH 10-89	a) 1 b) 6	5 days	a) 0.75 L/ha b) 4.5 L/ha	a) 33.8 g a.s./ha b) 203 g a.s./ha	100-500	0	0.75 L/ha
16	BE	Pumpkins (CUUMA)	F	Powdery mildew	Foliar spraying	BBCH 10-89	a) 1 b) 6	5 days	a) 0.75 L/ha b) 4.5 L/ha	a) 33.8 g a.s./ha b) 203 g a.s./ha	100-500	0	0.75 L/ha

F = Field ; G = Greenhouse ; I = Indoor

Table 1.5.4-2 GAP TABLE OF EXISTING AND PENDING USES: Vacciplant Grandes Cultures

GAP rev. 0, date: 2013-01-31

PPP (product name/code) Vacciplant Grandes Cultures

active substance 1 Laminarin

active substance 2 none

active substance none

safener none

synergist none

Applicant: Laboratoires Goëmar SAS

Zone(s): central/southern/EU

Formulation type: SL

Conc. of as 1: 37 g/L

Conc. of as 2: not relevant

Conc. of as: not relevant

Conc. of safener: not relevant

Conc. of synergist: not relevant

professional use ☒

non professional use ☐

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application			Min interval between applications	Application rate			PHI (days)	Remarks:  e.g. safener/synergist per ha  e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season		kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
1	FR	Wheat (TRZAX)	F	Septoria (SEPTTR)  Powdery mildew (ERYSGT)  Stimulation of plant natural defences	Foliar spraying	BBCH 30-89	a) 1 b) 3	7 days-	a) 1 L/ha b) 3 L/ha	a) 37 g a.s./ha b) 111 g a.s./ha	50-500	0	1 L/ha
2	UK	Wheat (TRZAX)	F	Septoria (SEPTTR)  Powdery mildew (ERYSGT)	Foliar spraying	BBCH 30-89	a) 1 b) 3	7 days	a) 1 L/ha b) 3 L/ha	a) 37 g a.s./ha b) 111 g a.s./ha	50-500	-	1 L/ha
3	FR	Barley (HORVX)	F	Helminthosporium (HELMSP)  Powdery mildew (ERYSGH)  Stimulation of plant natural defences	Foliar spraying	BBCH 30-89	a) 1 b) 3	7 days	a) 0.75 L/ha b) 2.25 L/ha	a) 27.8 g .a.s/ha b) 83.4 g .a.s/ha	50-500	-	0.75 L/ha

**Volume 1**

**Level 2**

**- *Laminarin* –**

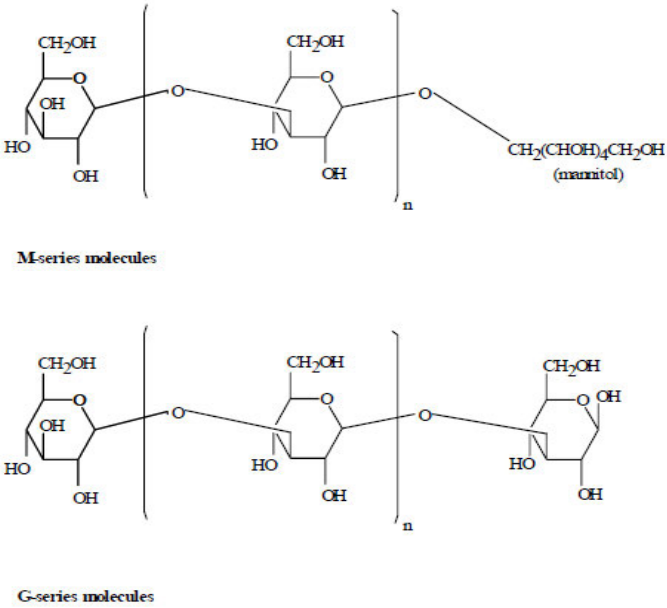
**Summary of active substance hazard and of product risk  
assessment**



## 2 Summary of active substance hazard of product risk assessment

### 2.1 Identity

#### 2.1.1 Summary of identity

ISO common name	Laminarin
IUPAC name	(1→3)-β-D-glucan (according to IUPAC-IUB Joint Commission on Biochemical Nomenclature)
CA name	Laminarin
CAS	9008-22-4
EEC no	232-712-4
CIPAC no	671
Molecular formula	$(C_6H_{10}O_5)_n$ n = 20 to 30
Structural formula	 <p>M-series molecules</p> <p>G-series molecules</p>
Molecular mass	3240 – 4860 g/mol

The minimum purity is 860g/kg (dry weight), which still needs to be confirmed. A batch analysis is currently ongoing and the representativeness of the tox and ecotox data still needs to be evaluated. The identity evaluation has therefore not yet been finalised.

### 2.2 Physical and chemical properties

#### 2.2.1 Summary of physical and chemical properties of the active substance

Pure Laminarin is a white to off-white crystal with a vapour pressure of  $< 2.6 \times 10^{-5}$  Pa. It is highly soluble in water at 301.5g/L and poorly soluble in most organic solvents. Its Henry's law constant is therefore  $< 3.45 \times 10^{-7}$  Pa.m<sup>3</sup>.mol<sup>-1</sup>, suggesting a low tendency to evaporate from water surfaces. Its log Pow of -1.6 suggests bioaccumulation will not occur. Laminarin does not dissociate within an

environmentally pH range, is not surface active and is not classified with regard to its physical and chemical properties.

#### 2.2.2 Summary of physical and chemical properties of the plant protection product

The representative product Vacciplant Fruits et Légumes is a pale brown viscous soluble concentrate (SL). It is not hazardous in the sense of its physical and chemical properties and does not need to be classified as flammable, self-heating, oxidising or explosive. The pH of the product is 3.7 with an acidity of 0.13% H<sub>2</sub>SO<sub>4</sub>. The viscosity shows a non-Newtonian correlation to the shear rates applied with a range of 150 to 5400 mPa.s at 20°C. The product is surface active with a surface tension of 33.5mN/m at 25°C. Its relative density is 1.047.

In 1L PE-EV containers, the product was stable for 2 weeks at 54°C. All relevant technical properties were investigated. The product does not foam and is sufficiently stable when diluted with water at the highest proposed in-use concentration.

A 2 year shelf-life study is not yet available and will be required. This data requirement can be addressed for the zonal authorization procedure of the product.

### 2.3 Data on application and efficacy

#### 2.3.1 Summary of effectiveness

It was already demonstrated in biological assessment dossiers submitted for Vacciplant Fruits et Légumes in Belgium (2008) that this product reached a level of control sufficient when applied as preventive treatment on fruits and vegetables crops against a wide range of various pathogens. Vacciplant Fruit et Légumes was first authorised in 2008 in France and Belgium.

#### 2.3.2 Summary of information on the development of resistance

Laminarin has no direct effect on the pathogen (it stimulates several pathways in the plant cell), the chance that resistance or cross-resistance could develop is considered to be low.

#### 2.3.3 Summary of adverse effect on treated crops

Laminarin is a stimulator of natural defences with a mode of action based on the activation of the defence processes of grown plants. The representative product, Vacciplant Fruits et Légumes is authorised in a number of member states. No negative effects are known.

#### 2.3.4 Summary of observations on other undesirable or unintended side-effects

Laminarin is a stimulator of natural defences with a mode of action based on the activation of the defence processes of plants. No negative effects are known for Laminarin-based formulations when they are used according to the label recommendations.

Moreover, the applicant states that Vacciplant Fruits et Légumes is quickly destroyed in the soil.

Therefore no negative effect on succeeding crop growth is anticipated. There is no minimum period for sowing/ planting succeeding/ replacement crops, with no limitation in the choice of succeeding/ replacement crops.

It can be concluded that Vacciplant Fruits et Légumes has no adverse effect on succeeding crops.

## **2.4 Further information**

### **2.4.1 Summary of methods and precautions concerning handling, storage, transport or fire**

Relevant information was reported. The substance does not require highly specific measures with regard to handling, storage, transport or fire.

### **2.4.2 Summary of procedures for destruction or decontamination**

Relevant information was reported. The substance does not require controlled pyrolysis and does not require highly specific procedures for decontamination.

### **2.4.3 Summary of emergency measures in case of an accident**

The following instructions are proposed:

- Avoid contact with the skin and eyes.
- Use individual protection.
- Limit and impound discharge.
- Prevent entry into drains, waters or soil.
- Do not water down. Collect with a neutral absorbent material and collect mechanically (sweep).
- Do not reintroduce into original container; treat as a waste.

## **2.5 Methods of analysis**

### **2.5.1 Methods used for the generation of pre-authorisation data**

No new methods for generation of pre-authorisation data were included in the renewal dossier. However, there are still some studies ongoing for which data will be required.

### **2.5.2 Methods for post control and monitoring purposes**

No methods for post control and monitoring purposes are required as these are not deemed necessary based on the risk assessment. No definition of the residue was set. The substance has an MRL exemption.

## **2.6 Effects on human and animal health**

## 2.6.1 Summary of absorption, distribution, metabolism and excretion in mammals

No specific ADME study has been conducted in mammals.

Laminarin, a linear  $\beta$  D-1, 3-linked glucan was extracted and purified from the brown alga *Laminaria digitata*.

Laminarins are cell wall components that are degraded by the colonic microflora in monogastric animals. The large bowel fermentation involves bacteria producing laminarinases, and B-glucosidases, which fully degrade the substrate into Short Chain Fatty Acids (SCFAs). SCFAs are absorbed and further metabolized before excretion into breath and flatus.

In plants, laminarin may undergo degradation by polysaccharide and oligosaccharide hydrolases leading to production of glucose. Fermentative production of SCFAs is the principal mechanism of intestinal digestion in ruminants.

## 2.6.2 Summary of acute toxicity

The results of the acute toxicity, irritation and sensitisation studies are presented in table 2.6.2-1 and 2.6.2-2.

Table 2.6.2-1 Summary of the acute toxicity studies

Test substance	Route	Species	LD <sub>50</sub> /LC <sub>50</sub>	Classification	Reference
Laminarin	oral	rat	>2000 mg/kg bw	None	1998a
Laminarin	dermal	rat	>1000 mg/kg bw	None	1998b; 2001d
Laminarin	inhalation	rat	>1.02 mg/L	None	1999

Table 2.6.2-2 Summary of the irritation and sensitisation studies

Test substance	Route	Species	Effect	Classification	Reference
Laminarin	Skin irritation	rabbit	non-irritant	None	1998a
Laminarin	Eye irritation	rabbit	non-irritant	None	1998b
Laminarin	Skin sensitisation, Maximisation	guinea pig	non-sensitising	None	1998c

## 2.6.3 Summary of short-term toxicity

For the short-term toxicity, two studies on rats, respectively for 28 days and 90 days, and one study on dogs for 90 days with daily oral administration of laminarin at 1000 mg/kg bw/d are available.

No mortality was observed. There was no change in body weights, in food and water consumptions and on organ weights. No clinical signs were noted and no macroscopic and microscopic changes were seen. There were no significant differences in haematology, blood clinical chemistry or urinalysis. As no sign of toxicity was observed, no target organ could be defined. Therefore in all three studies, the NOAEL was 1000 mg/kg bw/d.

Table 2.6.3-1 Summary of the short-term toxicity studies

Test substance	Duration, route	Species	NOAEL (mg/kg bw/d)	LOAEL (mg/kg bw/d)	Critical effects	Reference
Laminarin	oral, 4 weeks	rat	1000	>1000	No effects	(2000)
Laminarin	oral, 13 weeks	rat	1000	>1000	No effects	(2001a)
Laminarin	oral, 13 weeks	dog	1000	>1000	No effects	(2001b)

## 2.6.4 Summary of genotoxicity

In an *in vitro* study (Ames test), laminarin did not induce mutagenic activity in the four *Salmonella typhimurium* and the two *Escherichia coli* strains tested.

In a paper looking for anti-tumor activity of natural products (non GLP, non guideline), laminarin was tested in an anaphase-telophase test in CHO cells. No chromosomal damage was observed at any dose up to 100 µg/mL.

In an *in vivo* study (micronucleus test), laminarin did not induce damage to the chromosomes or the mitotic apparatus of mice bone marrow cells after two oral administrations, with a 24-hour interval, at 500, 1000 or 2000 mg/kg bw/d.

No genotoxic potential is expected with the active substance.

Table 2.6.4-1 *In vitro* genotoxicity studies

Test substance	Type of study		Result		Reference
	Indicator cells	Endpoint	without activation	with activation	
Laminarin	B: <i>S. typh.</i> TA 98 TA 100 TA 1535 TA 1537	point mut. point mut. point mut. point mut.	Negative Negative Negative Negative	Negative Negative Negative Negative	Marzin, 2000
	<i>E. coli</i> WP2 WPu uvrA	point mut. point mut.	Negative Negative	Negative Negative	

Table 6.4.3.2 *In vivo* genotoxicity studies



Test substance	Type of study		Result	Reference
	Species	Endpoint		
Laminarin	Mouse, Swiss Ico: OF1 (IOPS Caw) 5/sex/dose	Chromosomal aberration (bone marrow)	Negative	2001

#### 2.6.5 Summary of long-term toxicity and carcinogenicity

Due to the structure of laminarin, which can be considered as a storage carbohydrate similar to starch or glycogen, to the very high NOAELs observed in the 90-day studies on rats and dogs (absence of any treatment-related effect in two species), and to the recognition of *Laminaria digitata* as a human food, no long term toxicity study and no carcinogenicity study have been conducted. Moreover no mutagen effects were observed in both in vitro and in vivo studies.

Therefore, based on the favourable profile of laminarin, also known for its antioxidant properties, and in order to avoid useless tests in vertebrates, no long term toxicity study and no carcinogenicity study are deemed necessary.

#### 2.6.6 Summary of reproductive toxicity

##### Generational studies

Due to the structure of laminarin, which can be considered as a storage carbohydrate similar to starch or glycogen, to the very high NOAELs observed in the 90-day studies on rats and dogs (absence of any treatment-related effect in two species), to the favourable conclusions of both rat and rabbit developmental toxicity studies (absence of any treatment-related maternal or foetal effects in two species) and to the recognition of *Laminaria digitata* as a human food, no generational studies have been conducted. Moreover no mutagen effects were observed in both in vitro and in vivo studies.

Therefore, based on the favourable profile of laminarin, also known for its antioxidant properties, and in order to avoid useless tests in vertebrates, no generational study is deemed necessary.

##### Developmental toxicity studies

In two developmental toxicity studies in rats and rabbits, laminarin was administered at the limit dose 1000 mg/kg bw/d to females during the period of organogenesis, i.e. from Day 6 to Day 17 of pregnancy for rats and from Day 6 to Day 19 of pregnancy for rabbits respectively. The active substance was well tolerated since no major maternal toxicity and no external foetal abnormalities were reported.

For both species, the maternal and developmental NOAEL were 1000 mg/kg bw/d.

**Table 2.6.6-1 Summary of the reproduction and teratogenicity studies**

Test substance	Duration, route	Species	NOAEL (mg/kg bw/d)	LOAEL (mg/kg bw/d)	Critical effects	Reference

Laminarin	Oral developmental toxicity study	rat	1000	>1000	No effects	████████ 2001c
	Oral developmental toxicity study	rabbit	1000	>1000	No effects	████████ 2001e

#### 2.6.7 Summary of neurotoxicity

No such study has been conducted as the structure of laminarin is not similar or related to structures capable of inducing delayed neurotoxicity. Moreover, neurotoxicity tests and motor activity measurements were performed at the end of treatment during 28 and 90 day in the rat study and at the end of the 90-day dog study. These studies did not show changes attributable to treatment.

#### 2.6.8 Summary of further toxicological studies on the active substance

At this stage, no other toxicological study has been deemed necessary on the active substance or on metabolites, which would be smaller-sized oligo-saccharides or glucose itself.

#### 2.6.9 Summary of toxicological data on impurities and metabolites

At this stage, no other toxicological study has been deemed necessary on the active substance or on metabolites, which would be smaller-sized oligo-saccharides or glucose itself.

#### 2.6.10 Summary of medical data and information

Due to the very low acute and sub-chronic toxicity of laminarin, no special surveillance on manufacturing plant personnel will be undertaken.

#### 2.6.11 Toxicological end point for assessment of risk following long-term dietary exposure – ADI

Laminarin is a polysaccharide, which is devoid of acute toxicity. No specific effects / target organs were identified from the short-term toxicity studies performed in rat and dog. No developmental toxicity was observed in rats and rabbits. Laminarin is not genotoxic. As laminarin is degraded into glucose by plants, no residue will occur in plants. Since there is no risk for consumers from the use of laminarin as plant protection product, no ADI has been allocated for the Annex I inclusion, and no ADI is proposed now by the rapporteur.

Note: the applicant proposes to use the value of 1000 mg/kg bw/d for setting an ADI. Applying an assessment factor of 100 results in an ADI of 10mg/kg bw/d.

### 2.6.12 Toxicological end point for assessment of risk following acute dietary exposure – ARfD (acute reference dose)

Laminarin and its commercial preparations are of very low acute toxicity and no residues are expected on any food crop. Therefore no ARfD has been determined.

### 2.6.13 Toxicological end point for assessment of occupational, bystander and residents risks – AOEL

Laminarin is a polysaccharide and is devoid of acute toxicity. No specific effects/target organs were reported from the short-term toxicity studies performed in rat and dog. No developmental toxicity was observed in rats and rabbits. Laminarin is not genotoxic. A significant percutaneous absorption is excluded. The preparation is a solid, non-dusty, non-volatile granule. An inhalation risk is not expected. The allocation of an AOEL is considered not necessary, and no AOEL was set for the Annex I inclusion.

Note: the applicant proposes to use the value of 1000 mg/kg bw/d for setting an AOEL. Applying an assessment factor of 100, results in an AOEL of 10 mg/kg bw/d.

### 2.6.14 Summary of product and risk assessment

Exposures and risk assessments are specified in Table 2.6.14-1, 2.6.14-2 and 2.6.14-3.

**Table 2.3.6-1 Operator exposure and risk assessment, without PPE**

Application method	Model	Total systemic exposure (mg/kg bw/day) <sup>1</sup>	% of AOEL
Tractor-mounted sprayer, field crop	German model	0.02	<1
	UK POEM	0.13	1
Tractor-mounted sprayer, high crop	German model	0.02	<1
	UK POEM	0.21	2
Hand-held application, field crops	UK POEM	0.07	<1
Hand-held application, high crops	German model	0.04	<1
	UK POEM	0.14	1
Greenhouse	Dutch Greenhouse model	0.04	<1

<sup>1</sup> Systemic exposure based on dermal absorption of 10% for mixing and loading and 10% for application of Vacciplant Fruits et Légumes, and an AOEL of 10 mg/kg bw/d for the active substance laminarin.

**Table 2.3.6-2 Bystander and resident exposure and risk assessment**

Route	Estimated internal exposure (mg/day)	Systemic AEL (mg/day)	% AOEL
<i>Bystander (professional) exposure during application in representative crops according to EUROPOEM II</i>			



Adult	Total	0.158	600.00	0.03%
<i>Bystander exposure during application in representative crops according to the German guidance</i>				
Child	Total	0.0153	161.50	0.01%
Adult	Total	0.0724	600.00	0.01%
<i>Resident exposure during application in all representative crops according to the German guidance</i>				
Child	Total	0.0149	161.50	0.01%
Adult	Total	0.0261	600.00	<0.01%
<i>Bystander exposure during application in representative crops according to the UK guidance</i>				
Adult	Total	0.0095	600.00	<0.01%
<i>Resident exposure during application in representative crops according to the UK guidance</i>				
Child	Respiratory	0.0083	150.00	0.01%
	Dermal+Oral	0.0014	150.00	<0.01%

Table 2.3.6-3 Worker exposure and risk assessment

Application method	Model	Total systemic exposure (mg/kg bw/day) <sup>1</sup>	% of AOEL
Field, vines	EUROPOEM II	0.36	4
Greenhouse, tomato	EUROPOEM II	0.18	2

<sup>1</sup> Systemic exposure based on dermal absorption of 10% for mixing and loading and 10% for application of Vacciplant Fruits et Légumes, and an AOEL of 10 mg/kg bw/d for the active substance laminarin.

### Conclusions on risk assessments for operators, bystanders and workers

#### Operator

- Using the German model, safe uses were identified for operators, *without* PPE, for:
  - Mechanical downward spraying on lettuce, strawberry, tomato, zucchini, pumpkins, aubergine, pepper, greenbean, cucumber and kiwi
  - Mechanical upward spraying on apples, pear, vine, strawberry, tomato, aubergine, pepper, and kiwi
  - Manual upward spraying on apples, pear, vine, strawberry, tomato, aubergine, pepper, and kiwi
- Using UK-POEM, safe uses were identified for operators, *without* PPE, for:
  - Mechanical downward spraying on lettuce, strawberry, tomato, zucchini, pumpkins, aubergine, pepper, greenbean, cucumber and kiwi
  - Mechanical upward spraying on apples, pear, vine, strawberry, tomato, aubergine, pepper, and kiwi
  - Manual downward spraying on lettuce, strawberry, tomato, zucchini, pumpkins, aubergine, pepper, greenbean, cucumber and kiwi
  - Manual upward spraying on apples, pear, vine, strawberry, tomato, aubergine, pepper, and kiwi
- Using the Dutch-90<sup>th</sup> greenhouse model, safe uses were identified for operators, *without* PPE, for:
  - Manual spraying on lettuce, strawberry, tomato, aubergine, pepper, cucumber, zucchini

### *Bystander and residents*

Safe uses for bystanders and residents were identified for exposure during spraying on apples, pear, vine, lettuce, strawberry, tomato, zucchini, pumpkins, aubergine, pepper, greenbean, cucumber and kiwi, using EUROPOEM II, the German guidance paper and the UK PSD guidance document.

### *Worker*

Safe uses for workers *without* PPE were identified during re-entry exposure in apples, pear, vine, lettuce, strawberry, tomato, zucchini, pumpkins, aubergine, pepper, greenbean, cucumber and kiwi, using *the EUROPOEM II 2002 model (90<sup>th</sup> percentile)*.

## **2.7 Residues**

Laminarin is a natural oligosaccharide, therefore, the calculation of the TMDI is not relevant for this active substance because it is converted to (other) oligosaccharides and sugar. Since an ADI and/or ARfD are not necessary, since a risk assessment does not need to be performed, residue data are not submitted.

### 2.7.1 Summary of storage stability of residues

No stability of residue studies are available since residues in plants and animals are not relevant.

### 2.7.2 Summary of metabolism, distribution and expression of residues in plants, poultry, lactating ruminants, pigs and fish

Laminarin is a natural oligosaccharide composed of # 25 glucosyl units. It is therefore very close to many storage carbohydrates like starch and to constitutive carbohydrates like pectic substances or hemi-celluloses found ubiquitously in plants.

After application, laminarin will be submitted to a very quick degradation by the various carbohydrate hydrolases present during vegetative periods for the utilization of storage carbohydrates or during maturation of the fruits for the degradation of the constitutive polysaccharides.

In fact, the type of hydrolases specific to laminarin, called "laminarinase" or "laminarase" is found almost everywhere in the living world: bacteria, fungi, algae, higher plants and molluscs. In the case of plants, laminarinase is for instance found in bananas with a peak activity around climacteric or in bell pepper during ripening.

### 2.7.3 Definition of the residue

Since laminarin is exempt from MRL setting and a risk assessment is not necessary, a residue definition for monitoring and risk assessment is not proposed.

### 2.7.4 Summary of residue trials in plants and identification of critical GAP

Laminarin is currently included in Annex IV of Regulation (EC) No.396/2005 since October 2007 (Annex IV lists active substances for which maximum residue levels (MRLs) are not required). An ADI

and/or an ARfD are not necessary, therefore, a consumer risk assessment does not need to be performed and hence, residue trials are not required.

#### 2.7.5 Summary of feeding studies in poultry, ruminants, pigs and fish

No livestock feeding studies are available since residues in plants and animals are not relevant.

#### 2.7.6 Summary of effects on processing

No processing studies are available since residues in plants and animals are not relevant.

#### 2.7.7 Summary of residues in rotational crops

No rotational crop studies are available since residues in plants and animals are not relevant.

#### 2.7.8 Summary of other studies

No other studies were submitted.

#### 2.7.9 Estimation of the potential and actual exposure through diet and other sources

An ADI and/or an ARfD are not necessary for laminarin, therefore, a consumer risk assessment does not need to be performed and hence, residue trials are not required.

#### 2.7.10 Proposed MRLs and compliance with existing MRLs

Laminarin is currently included in Annex IV of Regulation (EC) No.396/2005 since October 2007 (Annex IV lists active substances for which maximum residue levels (MRLs) are not required). Since an ADI and/or an ARfD are not necessary, and since laminarin is a natural oligosaccharide, it is proposed to maintain the inclusion in Annex IV of Regulation (EC) No.396/2005.

#### 2.7.11 Proposed import tolerance and compliance with existing import tolerances

No import tolerances are proposed and they are not necessary, see above.

### 2.8 Fate and behaviour in the environment

#### 2.8.1 Summary of fate and behaviour in soil

Laminarin is a polysaccharide which leads to smaller-sized oligosaccharides and monosaccharides (glucose) after degradation. No other relevant metabolites, degradation or reaction products are expected to appear (Review Report for the active substance Laminarin, SANCO/10488/04-rev.3, 04/10/2004).

No study of degradation in soil is available. Laminarin is readily biodegradable. In the Technical Guidance Document on Risk Assessment, it is expected that a substance readily biodegradable has a DT50 in soil of 30 days.

#### 2.8.2 Summary of fate and behaviour in water and sediment

A study demonstrates that Laminarin is readily biodegradable (Review Report, 2004). It is expected that Laminarin (which is stable in sterile water) will be relatively stable in this non-sterile water, but will be readily degraded by the micro-organisms. Therefore no study has been conducted as the outcome would only depend on the equilibrium between the water phase and the soil phase.

In the Technical Guidance Document on Risk Assessment, it is expected that a substance readily biodegradable has a DT50 in water of 15 days.

#### 2.8.3 Summary of fate and behaviour in air

Laminarin has a very low vapour pressure ( $< 2.6 \times 10^{-5}$  Pa at 25°C) and a very low Henry's law constant ( $< 3.45 \times 10^{-7}$  Pa.m<sup>3</sup>.mol<sup>-1</sup> at 23-25°C). These values demonstrate that Laminarin has negligible volatility.

Laminarin is therefore not considered to be persistent in air and any residues in the atmosphere are expected to be rapidly degraded.

#### 2.8.4 Summary of monitoring data concerning fate and behaviour of the active substance, metabolites, degradation and reaction products

No monitoring data are required.

#### 2.8.5 Definition of the residue in the environment requiring further assessment

Definition of residue:

Soil: Laminarin

Surface water: Laminarin

Groundwater: Laminarin

Air: Laminarin

#### 2.8.6 Summary of exposure calculations and product assessment

##### Soil

Vacciplant Fruits et Légumes is a SL formulation containing 45 g/L Laminarin intended for use as an elicitor of the crop's self defence mechanisms on apples, pear, vine, lettuce, strawberry, tomato, zucchini, pumpkins, aubergine, pepper, greenbean, cucumber and kiwi.

**Table CP 9.1.3-4: Predicted Environmental Concentration of Laminarin soil after 16 applications of Vacciplant Fruits et Légumes to lettuce (PEC<sub>s</sub>)**

Days from last application or TWA period	PEC <sub>Soil,t</sub> (mg/kg)	PEC <sub>Soil,twa</sub> (mg/kg)
0	0.700	-
1	0.684	0.692
2	0.668	0.684
4	0.638	0.668
7	0.595	0.646
14	0.506	0.598
21	0.431	0.554
28	0.366	0.515
42	0.265	0.448
100	0.0694	0.273

### Groundwater

Due to the ready biodegradability of Laminarin and to its sensitivity to the attack from many bacteria strains in soil giving raise to glucose as transformation product, the chance that Laminarin will ever reach the ground water level can be considered very low. Consequently, no concern is expected for the groundwater.

### Surface water

**Table 9.2.5-04: Maximum initial PEC<sub>sw</sub>; orchards – 20\*45 g a.s./ha - 7-d interval**

Corresponding FOCUS scenario	Application window	Crop interception	Region	Step 1 1 global application		Step 2	
				PEC <sub>sw</sub> (µg/L)	PEC <sub>sed</sub> (µg/kg)	PEC <sub>sw</sub> (µg/L)	PEC <sub>sed</sub> (µg/kg)
Pome / stone fruit Early application	March – May	Minimal crop cover	N Europe	<b>388</b>	0.00	24.1 (5.83)	0.00 (0.00)
			S Europe			<b>38.2</b> (8.02)	0.00 (0.00)
	June – Sept	Minimal crop cover	N Europe			24.1 (5.83)	0.00 (0.00)
			S Europe			31.1 (6.92)	0.00 (0.00)
Pome / stone fruit Late application	March – May	Average crop cover	N Europe	347	0.00	14.5 (3.60)	0.00 (0.00)
			S Europe			<b>25.0</b> (5.24)	0.00 (0.00)
	June – Sept	Average crop cover	N Europe			14.5 (3.60)	0.00 (0.00)
			S Europe			19.7 (4.42)	0.00 (0.00)

(number in brackets refer to respective single application)

**Table 9.2.5-05: Maximum initial PEC<sub>sw</sub>; vines - 10\*90 g a.s./ha - 10-d interval**

Corresponding FOCUS scenario	Application window	Crop interception	Region	Step 1 1 global application		Step 2	
				PEC <sub>sw</sub> (µg/L)	PEC <sub>sed</sub> (µg/kg)	PEC <sub>sw</sub> (µg/L)	PEC <sub>sed</sub> (µg/kg)
Vines Early	March – May	Minimal crop cover	N Europe	308	0.00	15.8 (3.96)	0.00 (0.00)

	June – Sept	Minimal crop cover	S Europe			<b>30.2</b> (7.24)	0.00 (0.00)
			N Europe			15.8 (3.96)	0.00 (0.00)
			S Europe			23.0 (5.60)	0.00 (0.00)
Vines Late application	March – May	Average crop cover	N Europe	<b>324</b>	0.00	16.1 (4.74)	0.00 (0.00)
			S Europe			<b>28.0</b> (7.47)	0.00 (0.00)
	June – Sept	Average crop cover	N Europe			16.1 (4.74)	0.00 (0.00)
			S Europe			22.0 (6.10)	0.00 (0.00)

(number in brackets refer to respective single application)

**Table 9.2.5-06: Maximum initial PEC<sub>sw</sub>; leafy vegetables - 7\*135 g a.s./ha - 7-d interval**

Corresponding FOCUS scenario	Application window	Crop interception	Region	Step 1 1 global application		Step 2	
				PEC <sub>sw</sub> (µg/L)	PEC <sub>sed</sub> (µg/kg)	PEC <sub>sw</sub> (µg/L)	PEC <sub>sed</sub> (µg/kg)
Vegetables, leafy	March – May	Minimal crop cover	N Europe	<b>324</b>	0.00	29.8 (7.19)	0.00 (0.00)
			S Europe			57.8 (13.3)	0.00 (0.00)
	June – Sept	Minimal crop cover	N Europe			29.8 (7.19)	0.00 (0.00)
			S Europe			43.8 (10.3)	0.00 (0.00)
	Oct – Feb	Minimal crop cover	N Europe			<b>71.7</b> (16.4)	0.00 (0.00)
			S Europe			57.8 (13.3)	0.00 (0.00)

(number in brackets refer to respective single application)

**Table 9.2.5-07: Maximum initial PEC<sub>sw</sub>; fruiting vegetables - 7\*135 g a.s./ha - 7-d interval**

Corresponding FOCUS scenario	Application window	Crop interception	Region	Step 1 1 global application		Step 2	
				PEC <sub>sw</sub> (µg/L)	PEC <sub>sed</sub> (µg/kg)	PEC <sub>sw</sub> (µg/L)	PEC <sub>sed</sub> (µg/kg)
Vegetables, fruiting	March – May	Minimal crop cover	N Europe	<b>324</b>	0.00	29.8 (7.19)	0.00 (0.00)
			S Europe			57.8 (13.3)	0.00 (0.00)
	June – Sept	Minimal crop cover	N Europe			29.8 (7.19)	0.00 (0.00)
			S Europe			43.8 (10.3)	0.00 (0.00)
	Oct – Feb	Minimal crop cover	N Europe			<b>71.7</b> (16.4)	0.00 (0.00)
			S Europe			57.8 (13.3)	0.00 (0.00)

(number in brackets refer to respective single application)

## Air

Laminarin has negligible volatility and is considered not to be persistent in air. Any residues in the atmosphere are expected to be rapidly degraded. No PEC<sub>AR</sub> is relevant.

Other routes of exposure:

No other route of exposure are expected.

## 2.9 Effects on non-target species

### 2.9.1 Summary of effects on birds and other terrestrial vertebrates

#### Summary of toxicity data for birds and mammals

Species	Test type	Test substance	Toxicity	Reference
<b>Birds</b>				
Bobwhite quail	Acute oral	laminarin	LD <sub>50</sub> > 1700 mg/kg b.w <sup>1</sup>	██████████ (2002a)
Bobwhite quail	Short-term dietary	laminarin	LC <sub>50</sub> > 5 000 ppm	██████████ (2002b)
Surrogate for reproductive risk assessment			170 mg/kg bw/d	None
<b>Mammals</b>				
Rat	Acute oral	laminarin	LD <sub>50</sub> > 2000 mg/kg bw	██████████ (1998a)
Rat	Acute oral	Phyliq	LD <sub>50</sub> > 2000 mg/kg bw	██████████ (2000a)
Rat	90 day oral	laminarin	NOAEL = 1000 mg/kg bw/d <sup>2</sup>	██████████ (2001a)

<sup>1</sup> the purity of the test substance in this test was < 95% (85%), thus the RMS adjusted the nominal value to reflect the purity of the test substance

<sup>2</sup> this was also the NOEL for the developmental toxicity studies (rat and rabbit) and long-term study in dogs – no reproductive study was conducted.

As no reproductive toxicity data is available for birds, the RMS has performed a risk assessment using the LD<sub>50</sub>/10 as a surrogate. In addition, significant public literature is presented to support the fact that laminarin is non-toxic to birds even after longer term exposure (and indeed is used as a dietary supplement).

### 2.9.2 Summary of effects on aquatic organisms

#### Summary of toxicity data for aquatic organisms

Group	Species	Test substance	Time-scale	End point	Toxicity (mg a.s./L)	Reference
Fish	<i>O. mykiss</i>	Laminarin	96 h, semi-static	LC <sub>50</sub>	> 100	Review Report of Laminarin (SANCO/10488/04-rev.3)
	<i>Danio rerio</i>	Laminarin	96 h, semi-static	LC <sub>50</sub>	> 100	
	<i>Brachidanio rerio</i>	Vacciplant Fruits et Legumes	96 h (static)	LC <sub>50</sub>	> 4.8	██████████ (2008a)
Invertebrates	<i>Daphnia</i>	Laminarin	48 h,	EC <sub>50</sub>	> 100	Review Report of Laminarin

Group	Species	Test substance	Time-scale	End point	Toxicity (mg a.s./L)	Reference
	<i>magna</i>		semi-static			(SANCO/10488/04-rev.3
		Vacciplant Fruits et Legumes	48 h (static)	EC <sub>50</sub>	> 4.89	Servajean E. (2008b)
Algae	<i>S. capricornutum</i>	Laminarin	72 h	E <sub>r</sub> C <sub>50</sub> E <sub>b</sub> C <sub>50</sub>	> 100 > 100	Review Report of Laminarin (SANCO/10488/04-rev.3
	<i>Desmodesmus subspicatus</i>	Vacciplant Fruits et Legumes	72 h (static)	E <sub>y</sub> C <sub>50</sub> E <sub>r</sub> C <sub>50</sub>	> 4.8 <sup>1</sup> > 4.8	Servajean E. (2008c)
Aquatic plants	<i>L. gibba</i>	Laminarin	7 d	EC <sub>50</sub>	> 100 <sup>2</sup>	Allen R, 2015

<sup>1</sup> Since the test with the active substance failed one of the validity criterion, as a measure of conservativeness, the formulation endpoint is used in the risk assessment.

<sup>2</sup> preliminary value based on range-finding test. No final value available for use in risk assessment.

### 2.9.3 Summary of effects on arthropods

#### 2.9.3.1 Summary of effects on bees

##### Summary of laboratory data on adult bees (honeybees)

Test Item	Scenario	Endpoint	Reference
<b>Honeybees</b>			
laminarin	Acute oral	48 hr LD <sub>50</sub> = 118.6 µg a.s./bee	CA 8.3.1.1.1/01 Kling, 2000
	Acute contact	<b>48 hr LD<sub>50</sub> = 100 µg a.s./bee</b>	20001342/01-BLEU DAR, 2003

Endpoints highlighted in bold have been used in the risk assessment

#### 2.9.3.2 Summary of effects on arthropods other than bees

The table below gives an overview of the available toxicity data for non-target arthropods.

##### Summary of toxicity data for non-target arthropods: Tier 1 laboratory tests

Species	Exposed life stage	Study type old/new	Application rate [L/ha]	Corrected mortality [%] (LR <sub>50</sub> )	Sublethal effects [%]	Reference
<b>Phyliq*</b>						
<i>Typhlodromus pyri</i> Predatory mite	protonymphs	Tier 1 laboratory test Old: DAR	0, 0.1, 0.3, 1.0, 3.0, 10.0	<b>3.1 L or 114.7 g a.s.</b>	0	CA 8.3.2.1/01 Tessier, 2001a



**Summary of toxicity data for non-target arthropods: Tier 1 laboratory tests**

Species	Exposed life stage	Study type old/new	Application rate [L/ha]	Corrected mortality [%] (LR <sub>50</sub> )	Sublethal effects [%]	Reference
<i>Aphidius rhopalosiphi</i> Parasitoid	adult	Tier 1 laboratory test Old: DAR	0, 0.1, 0.3, 1.0, 3.0, 10.0	<b>&gt; 10 L or &gt; 370 g a.s.</b>	0	CA 8.3.2.1/02 Tessier, 2001b

Endpoints highlighted in bold have been used in the risk assessment.

\* since the formulation Phylig contains 37 g/L a.s., whereas the lead formulation Vacciplant fruit et legumes contains 45 g a.s./L (all other co-formulants being equivalent of of equally low toxicity), the risk assessment is performed according to g a.s./ha rather than L/ha.

## 2.9.4 Summary of effects on non-target soil meso- and macrofauna

**Summary of toxicity data for earthworms**

Species	Test substance	Test	Endpoint (mg a.s./kg soil)	Reference
<i>Eisenia fetida</i>	Laminarin	Reproduction toxicity	56 d-NOEC = <b>249</b>	Winkelmann G., 2015 CA 8.4.1

## 2.9.5 Summary of effects on soil nitrogen transformation

No studies were submitted, but considering the ubiquitous presence of laminarase in soil microorganisms and fungi, no effect on nitrogen transformation is expected.

## 2.9.6 Summary of effects on terrestrial non-target higher plants

The applicant submitted screening data, which was evaluated by the co-RMS, France, since it was only available in French. The screening data showed that there were low/no phytotoxic effects of laminarin on leek in an efficacy trial. Although screening data should be used with caution where concerns effects on non-target plants, considering the fact that laminarin is intended to elicit natural immunity in plants, no adverse effects on non-target plants are expected.

## 2.9.7 Summary of effects on other terrestrial organisms (flora and fauna)

No effects on other terrestrial organisms are expected, considering the relatively low toxicity profile of laminarin.

## 2.9.8 Summary of effects on biological methods for sewage treatment

The majority of bacteria contain laminarinases, thus, no effects on sewage treatment plants are expected. In addition, based on the intended use profile, exposure to sewage treatment plants is expected to be negligible.

## 2.9.9 Summary of product exposure and risk assessment

## 2.9.9.1 Risk assessment birds and other terrestrial vertebrates

The risk assessment of the active substance is presented below, based on the EFSA guidance document for risk assessment for birds and mammals (EFSA Journal 2009; 7(12):1438). The acute risk assessment for both birds and mammals showed a high margin of acceptability in the screening step:

**Acute Screening Step, Birds**

Indicator species	Small insectivorous	Small omnivorous	Small omnivorous
<b>Worst case Crop/scenario</b>	<b>kiwi</b>	<b>vineyard</b>	<b>vegetables</b>
Max. single application rate [kg a.s./ha]	0.090	0.090	0.135
Shortcut value	46.8	95.3	158.8
frequency	7	10	7
Interval [d]	10	10	7
Multiple application factor for 90 <sup>th</sup> percentile residue data (DT <sub>50</sub> = 10)	1.6	1.6	1.9
Daily dietary dose	6,7392	13,7232	40,7322
Endpoint (LD <sub>50</sub> ) [mg a.s./kg b.w.]	> 1700	> 1700	> 1700
TER	> 252	> 124	> 42
Trigger value [TER]	10	10	10
Refinement required	No	No	No

**Acute Screening Step, Mammals**

Indicator species	Small herbivorous	Small herbivorous
<b>Crop /scenario</b>	<b>Orchards/vineyard/vegetables</b>	<b>Strawberry</b>
Max. single application rate [kg a.s./ha]	0.135	0.090
Shortcut value	136.4	118.4
frequency	7	7
Interval [d]	7	5
Multiple application factor for 90 <sup>th</sup> percentile residue data (DT <sub>50</sub> = 10)	1.9	1.9
Daily dietary dose	34.9866	20.2464
Endpoint (LD <sub>50</sub> ) [mg a.s./kg b.w.]	> 2000	> 2000
TER	> 57.2	> 98.8
Trigger value [TER]	10	10
Refinement required	No	No

No chronic data in birds is available, but the literature (long-term feeding studies in chickens) suggests that the toxicity of laminarin to birds would be low. The surrogate risk assessment performed with the LD<sub>50</sub>/10 (170 mg/kg bw/d) passed in the screening step. The chronic risk to mammals also passed in the screening step with TERs significantly greater than the trigger value:

**Reproductive risk assessment screening step, mammals**

Indicator species	Small herbivorous	Small herbivorous
Crop /scenario	Orchards/vine/vegetables	strawberry
Max. single application rate [kg a.s./ha]	0.135	0.090
Shortcut value	72.3	48.3
frequency	7	7
Interval [d]	7	5
Multiple application factor for mean residue data (DT <sub>50</sub> = 10)	2.5	3.1*
f <sub>TWA</sub>	0.53	0.53
Daily dietary dose	12.9327	7.1421
Endpoint (NOEL) [mg a.s./kg b.w./d]	1000	1000
TER	77.3	140
Trigger value [TER]	5	5
Refinement required	No	No

**Risks to birds and mammals through drinking water***Leaf Scenario*

Since lettuce is a proposed use for Vacciplant Fruits et Legumes, the leaf scenario for small birds is applicable. The exposure from irrigation water or rain pooled in leaf whorls is calculated using the concentration in the spray ( $C_{\text{spray}}$ ) divided by 5.

The minimum water use for lettuce at 135 g a.s./ha is 750 L/ha. Thus the  $C_{\text{spray}} = 0.18$  g a.s./L. This value is divided by 5 to calculate the  $\text{PEC}_{\text{pool}}$  of 0.036 g a.s./L. This value is then multiplied by the drinking water intake for a small bird (0.46 L/kg bw/d), resulting in the  $\text{PEC}_{\text{dw}}$  of 0.017. Comparing this to the acute toxicity value of > 2000, results in a TER of > 100000. This is significantly greater than the trigger of 10. The risk to birds from water pooled in leaf whorls is considered negligible.

*Puddle Scenario*

According to the Guidance Document of EFSA (2009)<sup>1</sup>, due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by mammals, no specific calculations of exposure or TERs are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg b.w./d) does not exceed 50 in the case of less sorptive substances ( $K_{\text{oc}} < 500$  L/kg) or 3 000 in the case of more sorptive substances ( $K_{\text{oc}} \geq 500$  L/kg).

The worst-case scenario is to consider the maximum number of application and the maximum application rate to determine the worst-case effective application rate ( $\text{AR}_{\text{eff}}$ ). The  $\text{AR}_{\text{eff}}$  is calculated with the following formula:

$$\text{AR}_{\text{eff}} = \text{AR} * \text{MAF}_{\text{m}}$$

<sup>1</sup> EFSA Journal 2009; 7(12):1438. Risk assessment for birds and mammals.

with:

AR: application rate (g a.s./ha)

MAFm: MAF mean (= 2.6; 20 applications with a 7 d-minimal interval)

For the intended uses of Vacciplant Fruits et Légumes, the worst case scenario is to consider 20 applications at the maximum rate of 135 g a.s./ha. This leads to calculate an AReff of 351 g a.s./ha. The ratio of the effective application rate (351 g a.s./ha) to relevant endpoints (acute LD<sub>50</sub> of > 2 000 mg a.s./kg b.w./d. and NOAEL of 1000 mg a.s./kg b.w./d.) are 0.0176 and 0.351, respectively. Since these ratios are below 50 (and 3 000), no specific calculation of exposure of mammals through

### Risk of secondary poisoning

As the logP<sub>ow</sub> for laminarin is < 3 (-1.6), the risk to earthworm eating and fish-eating birds and mammals via secondary poisoning is considered to be negligible.

### Endocrine disruption

Laminarin is found in the diet of birds and mammals and is not expected to have endocrine disrupting properties.

#### 2.9.9.2 Risk assessment for aquatic organisms

Acute and chronic risk assessment was carried out using the initial PEC<sub>SW</sub> calculated with FOCUS Surface Water, Step 2, and the lowest available toxicity endpoints for algae, *Daphnia* and fish. No chronic data is available, though a study with higher aquatic plants is on-going. Therefore only the acute risk assessment was performed. In addition, no adequate algal toxicity studies with the active substance are available (only with the formulation). Nonetheless, the risk assessment performed with the formulation data showed no risk to algae at Step 2, thus a safe acute risk to aquatic life from the intended use pattern is expected.

Species	L(E)C <sub>50</sub> or NOEC	Pome fruit, early application Step 2	Vines, early application Step 2	Leafy and fruiting vegetables Step 2
	[µg as/L]	(PEC <sub>SW</sub> 38.2 µg/L)	(PEC <sub>SW</sub> 30.2 µg/L)	(PEC <sub>SW</sub> 71.7 µg/L)
<b>Acute</b>				
Algae	> 4800	> 125.7	> 158.9	> 66.9
Invertebrates	> 100000	> 2617	> 3311	> 1394
Fish	> 100000	> 2617	> 3311	> 1394
Aquatic plants	-	-	-	-

### Chronic Risk Assessment

No chronic studies were performed with laminarin on fish or invertebrates, however, considering the fact that plants are would be the most “sensitive species”, if a species group is likely to be sensitive to

laminarin, and considering the nature of the active substance, the chronic risk to aquatic life can be considered low.

Considering the fact that the co-formulant sodium methylparaben is present only at < 1% in the formulated product (0.22%), and the fact that the most sensitive species is invertebrates (and therefore different from the most sensitive species for laminarin) the RMS finds that the chronic risk to aquatic organisms from the formulated product can also be considered low.

Considering the low logP<sub>ow</sub> of laminarin, no bioaccumulation is expected.

### 2.9.9.3 Risk assessment for non-target arthropods

#### 2.9.9.3.1 Risk assessment for bees

The first tier risk assessment is based on the following endpoint: acute oral LD<sub>50</sub> 118.64 µg a.s./honeybee.

Procedures for risk assessment were in agreement with the recommendations in the Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC (Working Document Sanco/10329/2002 rev 2 final, 17 October 2002, referring to EPPO (EPPO 170 and EPPO 2002). EPPO 2002 was updated with EPPO 2010<sup>2</sup>.

Exposure is relevant for the field uses., as the crops (except lettuce) are attractive to honeybees (and other bees) for nectar and/or pollen collection. Also, bees may be present in the field to forage on flowering weeds and bees foraging in the off-field may be exposed via spray drift. Furthermore, other potential exposure routes include via honeydew, succeeding crops and guttation and other drinking water sources.

Crop	Exposure route	LD <sub>50</sub> [µg a.i./bee]	Application rate [g a.s./ha]	Hazard quotient HQ	Trigger	Refined risk assessment
lettuce	oral	>118.54	135	< 1.14	50	No
Lettuce	contact	> 100	135	< 1.35	50	No

Although the above first tier acute risk assessment demonstrates an acceptable risk to bees with large margins of safety, under Regulation (EC) No. 1107/2009, an acceptable chronic risk and risk to colony survival and development must also be demonstrated.

Since laminarin is quickly broken down to various natural polysaccharides, chronic exposure is not expected, nor is exposure to either laminarin nor these polysaccharides expected to have a deleterious effect on colony survival and development.

#### 2.9.9.3.2 Risk assessment for non-target arthropods other than bees

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<sup>2</sup> EPPO 2010: Environmental risk assessment scheme for plant protection products. Chapter 10: Honeybees. OEPP/EPPO, Bulletin OEPP/EPPO Bulletin 40, 323–331

The risk assessment for non-target arthropods has been conducted in line with the Terrestrial Guidance Document (SANCO/10329/2002).

The first tier in-field risk assessment with the worst-case crop (lettuce, tomato, aubergine, pepper, green bean, cucumber and zucchini) is shown below.

Crop	Max. number of Applications	GAP Application Rate [g a.s./ha]	PER <sub>in-field</sub> (g a.s./ha)	LR <sub>50</sub> (g a.s./ha)	In-field HQ	Trigger
<b><i>Aphidius rhopalosiphi</i></b>						
Lettuce, Tomato, Aubergine, Pepper, Greenbean, Cucumber, Zucchini	7	135	459	> 370	< 1.24	2
<b><i>Typhlodromus pyri</i></b>						
Lettuce, Tomato, Aubergine, Pepper, Greenbean, Cucumber, Zucchini	7	135	459	114.7	<b>4.0</b>	2

Since this resulted in an in-field risk to *T. pyri*, other uses were assessed:

Since this resulted in an in-field risk to *T. pyri*, other uses were assessed.

Crop	Max. number of Applications	GAP Application Rate [g a.s./ha]	PER <sub>in-field</sub> (g a.s./ha)	LR <sub>50</sub> (L PP/ha)	In-field HQ	Trigger
<b><i>Aphidius rhopalosiphi</i></b>						
Vine	10	90	315	> 370	< 0.85	2
Kiwi, strawberry	7	90	306		< 0.83	
Apple, early	20	45	157.5		< 0.43	
<b><i>Typhlodromus pyri</i></b>						
Vine	10	90	315	114.7	<b>2.75</b>	2
Kiwi, strawberry	7	90	306		<b>2.67</b>	
Apple, early	20	45	157.5		1.37	

The in-field risk from uses in apple, pear, zucchini and pumpkin show an acceptable risk to non-target arthropods. For all other uses a refined in-field risk assessment is required. Since the toxicity values for *T. pyri* were re-calculated from the test from the original Annex I inclusion by the RMS at the time of the initial review, the notifier did not expect the issue with *T. pyri*. To address this, the notifier has begun an extended laboratory test with *T. pyri* (expected completion mid-2016), however, the RMS notes that in the event that the Tier I trigger is not met, testing with two additional species is generally required. However, it might also be considered that laminarin is readily biodegradable (see CP B8), and subject to quick degradation by ubiquitously present laminarases (see section CA B7). Therefore,

although no measured  $DT_{50}$  value in plants (or other matrices) is available, the MAF values used in the risk assessment represent a worst-case, and it is unlikely that the true in-field PERs are at the levels presented in the risk assessment above. For example, if a MAF of 1.7 is assumed, all uses would be acceptable (use in lettuce, tomato, aubergine, pepper, green bean, cucumber and zucchini would show an HQ of 2.0). The RMS would appreciate the opinion of the MSs as to whether they consider further testing in additional species necessary.

All uses were safe in the off-field:

All uses were safe in the on field.

Crop	Max. number of Applications	GAP Application Rate [g a.s./ha]	PER <sub>off-field</sub> (g a.s./ha)	Correction factor	LR <sub>50</sub> (g a.s./ha)	Off-field HQ	Trigger
<b><i>Aphidius rhopalosiphi</i></b>							
Apple	20	45	3.50	10	> 370	< 0.09	2
Apple, Pear	7	33.75	2.60			< 0.09	2
Vine	10	90	1.97			< 0.05	2
Lettuce	16	112,5	0.599			< 0.02	2
Lettuce	7	135	0.739			< 0.02	2
Strawberry	7	90	0.493			< 0.01	2
Tomato	7	135	0.739			< 0.02	2
Zucchini, Pumpkins	6	33.75	0.177			< 0.005	2
Aubergine, Pepper, Greenbean, Cucumber, Zucchini	7	135	0.739			< 0.02	2
Kiwi	7	90	3.56			< 0.91	2
<b><i>Typhlodromus pyri</i></b>							
Apple	20	45	3.50	10	114.7	0.31	2
Apple, Pear	7	33.75	2.60			0.31	2
Vine	10	90	1.97			0.17	2
Lettuce	16	112,5	0.599			0.05	2
Lettuce	7	135	0.739			0.07	2
Strawberry	7	90	0.493			0.04	2
Tomato	7	135	0.739			0.07	2
Zucchini, Pumpkins	6	33.75	0.177			0.02	2

Crop	Max. number of Applications	GAP Application Rate [g a.s./ha]	PER <sub>off-field</sub> (g a.s./ha)	Correction factor	LR <sub>50</sub> (g a.s./ha)	Off-field HQ	Trigger
Aubergine, Pepper, Greenbean, Cucumber, Zucchini	7	135	0.739			0.07	2
Kiwi	7	90	3.56			0.61	2

#### 2.9.9.4 Risk assessment for non-target soil meso- and macrofauna

The risk assessment for soil meso- and macrofauna has been conducted in line with the Terrestrial Guidance Document (SANCO/10329/2002).

##### 2.9.9.4.1 Risk assessment earthworms

A risk assessment was performed for chronic toxicity to earthworms, using the maximum calculated PEC<sub>soil,ini</sub> (use in lettuce) of 0.7 mg/kg soil d.w.:

Active substance	Worst-case use	Number of applications	Maximum use rate [g a.s./ha]	Initial PEC <sub>s</sub> [mg a.s./kg]	NOEC [mg a.s./kg]	TER <sub>LT</sub>	Trigger
Laminarin	Lettuce	16	113	0.700	249	356	5

##### 2.9.9.4.2 Risk assessment for non-target soil meso- and macrofauna other than earthworms

According to the Guidance Document (SANCO/10329/2002) the risk for macro-organisms particularly addresses persistent active substances (DT<sub>90 field</sub> > 100 days). Testing is required where contamination of soil is possible, the DT<sub>90 field</sub> is between 100 and 365 days and the HQ for the standard arthropod species (*Typhlodromus* and *Aphidius*) > 2.

After application, laminarin will be rapidly degraded to smaller sized oligosaccharides and ultimately to glucose, which is naturally present in soil. Thus, a very low persistence is expected for laminarin.

Although the HQ for *T. pyri* was greater than 2, this is considered highly conservative, as it does not take into account the rapid dissipation of laminarin from plant surfaces. With this, and the rapid dissipation in soil in mind, the RMS does not consider further testing with soil macrofauna necessary.

#### 2.9.9.5 Risk assessment for soil nitrogen transformation

As Laminarin is expected to have a very short soil persistence, and as laminarinase is found in many micro-organisms (for more details, please see Point CA 8.5), no risk to soil non-target micro-organisms are to be expected from the applications of Vacciplant Fruits et Légumes in the field.

#### 2.9.9.6 Risk assessment for terrestrial non-target higher plants

Since only screening data was submitted, no quantitative risk assessment was performed. The RMS does not expect adverse effects on non-target plants following applications of laminarin according to the GAP.



## 2.10 Classification and labelling

Proposed classification according to Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures

CLP Annex I ref	Hazard class	Proposed classification	Proposed SCLs and/or M-factors	Current classification <sup>1)</sup>	Reason for no classification <sup>2)</sup>
2.1.	Explosives				
2.2.	Flammable gases				
2.3.	Flammable aerosols				
2.4.	Oxidising gases				
2.5.	Gases under pressure				
2.6.	Flammable liquids				
2.7.	Flammable solids				
2.8.	Self-reactive substances and mixtures				
2.9.	Pyrophoric liquids				
2.10.	Pyrophoric solids				
2.11.	Self-heating substances and mixtures				
2.12.	Substances and mixtures which in contact with water emit flammable gases				
2.13.	Oxidising liquids				
2.14.	Oxidising solids				
2.15.	Organic peroxides				
2.16.	Substance and mixtures corrosive to metals				
3.1.	Acute toxicity - oral				
	Acute toxicity - dermal				
	Acute toxicity - inhalation				
3.2.	Skin corrosion / irritation				
3.3.	Serious eye damage / eye irritation				
3.4.	Respiratory sensitisation				
3.4.	Skin sensitisation				
3.5.	Germ cell mutagenicity				
3.6.	Carcinogenicity				
3.7.	Reproductive toxicity				
3.8.	Specific target organ toxicity –single exposure				
3.9.	Specific target organ toxicity – repeated exposure				
3.10.	Aspiration hazard				
4.1.	Hazardous to the aquatic environment				
5.1.	Hazardous to the ozone layer				

<sup>1)</sup> Including specific concentration limits (SCLs) and M-factors

<sup>2)</sup> Data lacking, inconclusive, or conclusive but not sufficient for classification

**Labelling:**      Signal word: none  
                      Hazard statements: none  
                      Precautionary statements: none

**Proposed notes assigned to an entry:**

Notes in accordance with CLP Regulation, Annex VI, Section 1.1.3

**2.11    Relevance of metabolites in groundwater**

Not relevant.

**2.12    Consideration of isomeric composition in the risk assessment**

2.12.1   Identity and physical chemical properties

Identity evaluation has not yet been finalized.

2.12.2   Methods of analysis

Not relevant

2.12.3   Mammalian toxicity

Not relevant

2.12.4   Operator, Worker, Bystander and Resident exposure

Not relevant

2.12.5   Residues and Consumer risk assessment

2.12.6   Environmental fate

2.12.7   Ecotoxicology

**2.13    Residue definitions**

2.13.1   Definition of residues for exposure/risk assessment

**Food of plant origin:** not required

**Food of animal origin:** not required

**Soil:** Laminarin

**Groundwater:** Laminarin

**Surface water:** Laminarin

**Sediment:** Laminarin

**Air:** Laminarin

2.13.2 Definition of residues for monitoring

**Food of plant origin:** not required

**Food of animal origin:** not required

**Soil:** none

**Groundwater:** none

**Surface water:** none

**Sediment:** none

**Air:** none

F

## **Volume 1**

### **Level 3**

#### **- *Laminarin* -**

**Summary and consideration with respect to the approval  
criteria of Regulation (EC) No 1107/2009**

**Identification of data gaps, proposed conditions, risk  
management measures, issues that could not be finalized  
and critical areas of concern**

**Proposed decisions**

### 3 Proposed decision with respect to the application

#### 3.1 Background to the proposed decision

##### 3.1.1 Proposal on acceptability against the decision making criteria – Article 4 and Annex II of Regulation (EC) No 1107/2009

3.1.1.1 Article 4			
		Yes	No
i)	It is considered that Article 4 of Regulation (EC) No 1107/2009 is complied with. Specifically the RMS considers that authorisation in at least one Member State is expected to be possible for at least one plant protection product containing the active substance for at least one of the representative uses.	X	
3.1.1.2 Submission of further information			
		Yes	No
i)	It is considered that a complete dossier has been submitted	X	
ii)	It is considered that in the absence of a full dossier the active substance may be approved even though certain information is still to be submitted because: (a) the data requirements have been amended or refined after the submission of the dossier; or (b) the information is considered to be confirmatory in nature, as required to increase confidence in the decision.		Not applicable
3.1.1.3 Restrictions on approval			
		Yes	No
	It is considered that in line with Article 6 of Regulation (EC) No 1107/2009 approval should be subject to conditions and restrictions.		X
3.1.1.4 Criteria for the approval of an active substance			
Dossier			
		Yes	No
	It is considered the dossier contains the information needed to	X	No ADI, AOEL and ARfD necessary

	establish, where relevant, Acceptable Daily Intake (ADI), Acceptable Operator Exposure Level (AOEL) and Acute Reference Dose (ARfD).			
	<p>It is considered that the dossier contains the information necessary to carry out a risk assessment and for enforcement purposes (relevant for substances for which one or more representative uses includes use on feed or food crops or leads indirectly to residues in food or feed). In particular it is considered that the dossier:</p> <p>(a) permits any residue of concern to be defined;</p> <p>(b) reliably predicts the residues in food and feed, including succeeding crops</p> <p>(c) reliably predicts, where relevant, the corresponding residue level reflecting the effects of processing and/or mixing;</p> <p>(d) permits a maximum residue level to be defined and to be determined by appropriate methods in general use for the commodity and, where appropriate, for products of animal origin where the commodity or parts of it is fed to animals;</p> <p>(e) permits, where relevant, concentration or dilution factors due to processing and/or mixing to be defined.</p>	X		<p>Laminarin is a natural oligosaccharide, therefore, the calculation of the TMDI is not relevant for this active substance because it is converted to (other) oligosaccharides and sugar. Since an ADI and/or ARfD are not necessary, a consumer risk assessment does not need to be performed.</p> <p>Laminarin is currently included in Annex IV of Regulation (EC) No.396/2005 since October 2007 (Annex IV lists active substances for which maximum residue levels (MRLs) are not required).</p>
	It is considered that the dossier submitted is sufficient to permit, where relevant, an estimate of the fate and distribution of the active substance in the environment, and its impact on non-target species.	X		
<b>Efficacy</b>				
		Yes	No	
	It is considered that it has been established for one or more representative uses that the plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use is sufficiently effective.	X		It was already demonstrated in biological assessment dossiers submitted for Vacciplant Fruits et Légumes in Belgium (2008) that this product reached a level of control sufficient when applied as preventive treatment on fruits and vegetables crops against a wide range of various pathogens.. See also volume 1 level 2.
<b>Relevance of metabolites</b>				
		Yes	No	



	It is considered that the documentation submitted is sufficient to permit the establishment of the toxicological, ecotoxicological or environmental relevance of metabolites.	X		No (relevant) metabolites are formed in the environment
<b>Composition</b>				
		Yes	No	
	It is considered that the specification defines the minimum degree of purity, the identity and maximum content of impurities and, where relevant, of isomers/diastereo-isomers and additives, and the content of impurities of toxicological, ecotoxicological or environmental concern within acceptable limits.		X	A batch analysis is not yet available to confirm the existing specification.  Data on the composition of toxicological and ecotoxicological batches was provided, but a summary was not provided. The data could not yet be considered.
	It is considered that the specification is in compliance with the relevant Food and Agriculture Organisation specification, where such specification exists.			No FAO specification is available.
	It is considered for reasons of protection of human or animal health or the environment, stricter specifications than that provided for by the FAO specification should be adopted			No FAO specification is available.
<b>Methods of analysis</b>				
		Yes	No	
	It is considered that the methods of analysis of the active substance, safener or synergist as manufactured and of determination of impurities of toxicological, ecotoxicological or environmental concern or which are present in quantities greater than 1 g/kg in the active substance, safener or synergist as manufactured, have been validated and shown to be sufficiently specific, correctly calibrated, accurate and precise.			Methods of analysis for the substance as manufactured are available in the original dossier. However, an analysis of batches is currently ongoing, which may include additional validation data. The evaluation could therefore not be finalised.
	It is considered that the methods of residue analysis for the active substance and relevant metabolites in plant, animal and environmental matrices and drinking water, as appropriate, shall have been validated and shown to be sufficiently sensitive with respect to the levels of concern.	X		No methods are required.
	It is confirmed that the evaluation has been carried out in accordance with the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6) of Regulation 1107/2009.	X		
<b>Impact on human health</b>				
<b>Impact on human health - ADI, AOEL, ARfD</b>				

	Yes	No	
It is confirmed that (where relevant) an ADI, AOEL and ARfD can be established with an appropriate safety margin of at least 100 taking into account the type and severity of effects and the vulnerability of specific groups of the population.	X		No ADI, AOEL and ARfD necessary
<b>Impact on human health – proposed genotoxicity classification</b>			
	Yes	No	
It is considered that, on the basis of assessment of higher tier genotoxicity testing carried out in accordance with the data requirements and other available data and information, including a review of the scientific literature, reviewed by the Authority, <b>the substance SHOULD BE classified or proposed for classification</b> , in accordance with the provisions of Regulation (EC) No 1272/2008, <b>as mutagen category 1A or 1B</b> .		X	
<b>Impact on human health – proposed carcinogenicity classification</b>			
	Yes	No	
i) It is considered that, on the basis of assessment of the carcinogenicity testing carried out in accordance with the data requirements for the active substances, safener or synergist and other available data and information, including a review of the scientific literature, reviewed by the Authority, <b>the substance SHOULD BE classified or proposed for classification</b> , in accordance with the provisions of Regulation (EC) No 1272/2008, <b>as carcinogen category 1A or 1B</b> .		X	
ii) Linked to above classification proposal.  It is considered that exposure of humans to the active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.			
<b>Impact on human health – proposed reproductive toxicity classification</b>			
	Yes	No	



i)	It is considered that, on the basis of assessment of the reproductive toxicity testing carried out in accordance with the data requirements for the active substances, safeners or synergists and other available data and information, including a review of the scientific literature, reviewed by the Authority, <b>the substance SHOULD BE classified or proposed for classification</b> , in accordance with the provisions of Regulation (EC) No 1272/2008, <b>as toxic for reproduction category 1A or 1B.</b>		X	
ii)	Linked to above classification proposal.  It is considered that exposure of humans to the active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.			
<b>Impact on human health – proposed endocrine disrupting properties classification</b>				
		Yes	No	
i)	It is considered that <b>the substance SHOULD BE classified or proposed for classification</b> in accordance with the provisions of Regulation (EC) No 1272/2008, <b>as carcinogenic category 2 and toxic for reproduction category 2 and on that basis shall be considered to have endocrine disrupting properties</b>		X	
ii)	It is considered that <b>the substance SHOULD BE classified or proposed for classification</b> in accordance with the provisions of Regulation (EC) No 1272/2008, <b>as toxic for reproduction category 2 and in addition the RMS considers the substance has toxic effects on the endocrine organs and on that basis shall be considered to have endocrine disrupting properties</b>		X	
iii)	Linked to either i) or ii) immediately above.  It is considered that exposure of humans to the active substance, safener or synergist in a plant protection product,			

	under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.			
<b>Fate and behaviour in the environment</b>				
<b>Persistent organic pollutant (POP)</b>				
		Yes	No	
	It is considered that the active substance <b>FULFILS</b> the criteria of a persistent organic pollutant (POP) as laid out in Regulation 1107/2009 Annex II Section 3.7.1.		X	See level 2 section 2.8
<b>Persistent, bioaccumulative and toxic substance (PBT)</b>				
		Yes	No	
	It is considered that the active substance <b>FULFILS</b> the criteria of a persistent, bioaccumulative and toxic (PBT) substance as laid out in Regulation 1107/2009 Annex II Section 3.7.2.		X	See level 2 section 2.8
<b>Very persistent and very bioaccumulative substance (vPvB).</b>				
		Yes	No	
	It is considered that the active substance <b>FULFILS</b> the criteria of a a very persistent and very bioaccumulative substance (vPvB) as laid out in Regulation 1107/2009 Annex II Section 3.7.3.		X	See level 2 section 2.8
<b>Ecotoxicology</b>				
		Yes	No	
	It is considered that the risk assessment demonstrates risks to be acceptable in accordance with the criteria laid down in the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6) under realistic proposed conditions of use of a plant protection product containing the active substance, safener or synergist. The RMS is content that the assessment takes into account the severity of effects, the uncertainty of the data, and the number of organism groups which the active substance, safener or synergist is	X		



	expected to affect adversely by the intended use.			
	It is considered that, on the basis of the assessment of Community or internationally agreed test guidelines, the substance <b>HAS</b> endocrine disrupting properties that may cause adverse effects on non-target organisms.		X	There is no indication that laminarin has any endocrine disrupting properties.
	Linked to the consideration of the endocrine properties immediately above.  It is considered that the exposure of non-target organisms to the active substance in a plant protection product under realistic proposed conditions of use is negligible.			
	It is considered that it is established following an appropriate risk assessment on the basis of Community or internationally agreed test guidelines, that the use under the proposed conditions of use of plant protection products containing this active substance, safener or synergist:  — will result in a negligible exposure of honeybees, or  — has no unacceptable acute or chronic effects on colony survival and development, taking into account effects on honeybee larvae and honeybee behaviour.	X		Laminarin shows an acute HQ of < 1.35 µg/bee. Based on the physical/chemical nature of laminarin and the fact that it quickly breaks down into simple sugars, no chronic nor brood effects are expected.
<b>Residue definition</b>				
		Yes	No	
	It is considered that, where relevant, a residue definition can be established for the purposes of risk assessment and for enforcement purposes.	X		Laminarin is a natural oligosaccharide, for which no ARfD and/or ADI are required. It is exempt from MRL setting. Therefore, residue definitions are not required.
<b>Fate and behaviour concerning groundwater</b>				
		Yes	No	
	It is considered that it has been established for one or more representative uses, that consequently after application of the plant protection product consistent with realistic conditions on use, the predicted concentration of the active substance or of metabolites, degradation or reaction products in groundwater	X		Due to the ready biodegradability of Laminarin and to its sensitivity to the attack from many bacteria strains in soil giving raise to glucose, there is no chance that Laminarin, will ever reach the ground water level. Therefore there is no need to consider PECgw

	complies with the respective criteria of the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6) of Regulation 1107/2009.			
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3.1.2 Proposal – Candidate for substitution

Candidate for substitution			
		Yes	No
	It is considered that the active substance shall be approved as a candidate for substitution		X

## 3.1.3 Proposal – low risk active substance

Low-risk active substances			
	Yes	No	
<p>It is considered that the active substance <b>shall be considered of low risk.</b></p> <p>In particular it is considered that the substance <b>should NOT be classified or proposed for classification</b> in accordance with Regulation (EC) No 1272/2008 as at least one of the following:</p> <ul style="list-style-type: none"> <li>— carcinogenic,</li> <li>— mutagenic,</li> <li>— toxic to reproduction,</li> <li>— sensitising chemicals,</li> <li>— very toxic or toxic,</li> <li>— explosive,</li> <li>— corrosive.</li> </ul> <p>In addition it is considered that <b>the substance is NOT:</b></p> <ul style="list-style-type: none"> <li>— persistent (half-life in soil more than 60 days),</li> <li>— has a bioconcentration factor higher than 100,</li> <li>— is deemed to be an endocrine disrupter, or</li> <li>— has neurotoxic or immunotoxic effects.</li> </ul>	X		Laminarin meets all the criteria for low risk substances.

## 3.1.4 List of studies to be generated, still ongoing or available but not peer reviewed

Data gap	Relevance in relation to representative use(s)	Study status		
		No confirmation that study available or on-going.	Study on-going and anticipated date of completion	Study available but not peer-reviewed
3.1.4.1 Identity of the active substance or formulation				
Analysis of 5 representative batches, including methods and validation.	All		Ongoing, completion date unknown	
Clarification whether the plant at the former address (used for annex I listing) is still used for production of laminarin	All			
Summary of the composition of toxicologically and ecotoxicologically tested batches.	All			Data received, but a summary is missing. Data not yet considered by RMS.
3.1.4.2 Physical and chemical properties of the active substance and physical, chemical and technical properties of the formulation				
2 year storage data for the representative product is required		No confirmation study is ongoing		
3.1.4.3 Data on uses and efficacy				
No data gap				
3.1.4.4 Data on handling, storage, transport, packaging and labelling				
No data gap				

<b>3.1.4.5 Methods of analysis</b>				
See 3.1.4.1				
<b>3.1.4.6 Toxicology and metabolism</b>				
No data gap				
<b>3.1.4.7 Residue data</b>				
No data gap				
<b>3.1.4.8 Environmental fate and behaviour</b>				
No data gap				
<b>3.1.4.9 Ecotoxicology</b>				
No data gap				



## 3.1.5 Issue that could not be finalized

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, as laid out in Commission Regulation (EU) No 546/2011, 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).

Area of the risk assessment that could not be finalised on the basis of the available data	Relevance in relation to representative use(s)
Analysis of 5 representative batches, including methods and validation.	All
Summary of the composition of toxicologically and ecotoxicologically tested batches.	All

## 3.1.6 Critical areas of concern

An issue is listed as a critical area of concern:

- (a) where the substance does not satisfy the criteria set out in points 3.6.3, 3.6.4, 3.6.5 or 3.8.2 of Annex II of Regulation (EC) No 1107/2009 and the applicant has not provided detailed evidence that the active substance is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods, taking into account risk mitigation measures to ensure that exposure of humans and the environment is minimised, or
- (b) where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles, as laid out in Commission Regulation (EU) 546/2011, 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.

Critical area of concern identified	Relevance in relation to representative use(s)
None	

## 3.1.7 Overview table 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 3.3.1, has been evaluated as being effective, then 'risk identified' is not indicated in this table.)

All columns are grey as the material tested in the toxicological studies has not been demonstrated to be representative of the technical specification.

Representative use		Use "A" (X <sup>1</sup> )	Use "B" (X <sup>1</sup> )
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		
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 <sup>(a)</sup> breached		
	Assessment not finalised		
Comments/Remarks			

The superscript numbers in this table relate to the numbered points indicated within chapter 3.1.5 and 3.1.6. Where there is no superscript number, see level 2 for more explanation.

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

## 3.1.8 Area(s) where expert consultation is considered necessary

It is recommended to organise a consultation of experts on the following parts of the assessment report:

Area(s) where expert consultation is considered necessary	Justification
None	

**3.1.9 Critical issues on which the co-RMS did not agree with the assessment by the RMS**

Points on which the co-rapporteur Member State did not agree with the assessment by the rapporteur member state. Only the points relevant for the decision making process should be listed.

<b>Issue on which Co-RMS disagrees with RMS</b>	<b>Opinion of Co-RMS</b>	<b>Opinion of RMS</b>
None		

### 3.2 Proposed decision

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].

**3.3 Rational for the conditions and restrictions to be associated with the approval or authorisation(s), as appropriate**



## **Appendices**

### **Appendix 1    Guidance documents used in this assessment**

Guidances applicable at the time of submission of the additional dossier were used in this assessment.



**Appendix 2      Reference list**

Not applicable.