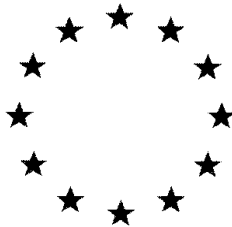


European Commission



VOLUME 3 – Annex B (AS)

Laminarin

B.7 Residue

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

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B.7 Residue data

In the original DAR the following was presented:

The formulation Phylig SL (containing 37 g laminarin/l) is applied at the rate of 37 g a.s./l, on cereals (wheat, barley and rice) once a year, at an early growth stage between full tillering and the 1 cm-ear stage (BBCH 29-30) when the ear is not apparent.

The toxicological evaluation showed that Laminarin (B-1,3 linked glucans) 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 no ADI has been allocated by the RMS.

In plants, laminarin may undergo degradation by polysaccharide and oligosaccharide hydrolases leading to production of glucose. In consequence, there is no possibility to define a residue as such, as it would have to be glucose itself and no plant metabolism studies are necessary to re-enforce that statement.

In ruminants, fermentative production of short chain of fatty acids (which are further metabolized before excretion into breath and flatus) is the principal mechanism of intestinal digestion and further livestock metabolism studies are not necessary.

Therefore, no residue of biological significance will occur in plants and in animals and it can be stated that there is no risk for consumers from the use of laminarin as plant protection product.

Conclusion:

As no residues in plants and animals are relevant and as the establishment of an ADI is not necessary, the estimates of the potential and actual exposure through diet and other means do not have to be calculated.

The representative products for renewal are different from the product in the original DAR, and the supported uses now include cereals, and a number of fruits, vegetables and fruiting vegetables. See Vol 1.

The conclusion for the renewal under Regulation (EC) 1107/2009 remains the same, residues of laminarin in plants and animals are not relevant and therefore, studies were not submitted. Since and ADI and/or an ARfD are not necessary, a consumer risk assessment does not need to be conducted and residue studies are not required.

B.7.1 Storage stability of residues

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

B.7.2 Metabolism, distribution and expression of residues

No metabolism studies were conducted since residues in plants and animals are not relevant.

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.

B.7.3 Magnitude of residue trials in plants

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.

B.7.4 Feeding studies

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

B.7.5 Effects of processing

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

B.7.6 Residues in rotational crops

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

B.7.7 Other studies

No other studies were submitted.

B.7.7.1 Effect on the residue level in pollen and bee products

No studies on the effect on residue levels in bee products and nectar were conducted since residues in plants and animals are not relevant.

B.7.8 References relied on

A literature search was not carried out for laminarin for residues. Since studies are not required considering the properties of laminarin, RMS does not request a literature search to be conducted.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
No data are submitted.							