Formal Recommendation
From: National Organic Standards Board (NOSB)
To: the National Organic Program (NOP)

Date: October 29, 2015

Subject: Classification of Laminarin

NOSB Chair: Jean Richardson

The NOSB hereby recommends to the NOP the following:

Rulemaking Action:

Guidance Statement:

Other: X

Statement of the Recommendation:

The NOSB classified laminarin as non-synthetic. Extraction of Laminarin, a brown seaweed petitioned as a disease control material was reviewed. The extraction is achieved by an acid-base reaction which results in a non-synthetic extract as described by the Draft Guidance for Classification of Materials (NOP 5033, section 4.6).

Rationale Supporting Recommendation (including consistency with OFPA and Organic Regulations):

The Crops Subcommittee provided analysis for the points in NOP 5033, section 4.6 as follows:

- *At the end of the extraction process, the material has not been transformed into a different substance via chemical change;*

  The TR indicates that laminarin is not changed in extraction.

- *The material has not been altered into a form that does not occur in nature; and*

  Laminarin does occur in nature

- *Any synthetic materials used to separate, isolate, or extract the substance have been removed from the final substance (e.g., via evaporation, distillation, precipitation, or other means) such that they have no technical or functional effect in the final product.*

  The reaction and filtration steps result in a purified laminarin in which the sodium and sulfate ions do not have a technical or functional effect. This is quite different than the listing for aquatic plant extracts that are classified as synthetic for crop production at 205.601(j)(1). In those the extracting agents such as potassium hydroxide does leave behind enough potassium

to have a functional effect as a fertilizer. In laminarin, neither the sodium (at 0.001%) nor the sulfate ions (at 0.0034%) have a functional effect for disease suppression

NOSB Vote:

Motion to classify laminarin as petitioned as non-synthetic
Motion by: Zea Sonnabend
Seconded by: Harold Austin
Yes: 9 No: 3 Abstain: 2 Absent: 0 Recuse: 0

Outcome: Motion passed.

arinNational Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal - Laminarin
June 23, 2015

Introduction
The NOSB received a petition for Laminarin, a seaweed extract for disease control that is EPA registered for that purpose. The NOSB Crops Subcommittee voted that it was non-synthetic by a vote of 5-2-0 and brought it to the full NOSB in the spring of 2014. The NOSB decided that there needed to be a Limited Scope Technical Review (TR) to clarify the whether the extraction and purification process resulted in a synthetic material, and to examine the environmental effects of seaweed harvest and processing. That TR was completed in May 2015.

Background
In the National Organic Program notes that accompanied the forwarded petition from June 3, 2013 they stated:

> In NOP's review of the eligibility of this petitioned substance for the National List, we reviewed the manufacturing process against the draft guidance on classification of materials (NOP 5033). Based on our preliminary review, this substance may be classified as nonsynthetic. We have moved this petition forward for NOSB review and final determination on the classification status for the following reasons:
>
> - The classification guidance is currently in draft form
> - Other aquatic plant extracts are classified as synthetic for crop production at 205.601(j)(1)
> - At this time, NOP is not aware of any products containing laminarin as an active ingredient that are approved by certifying agents or third-party material review organizations, such as EPA or OMRI

The draft Guidance on Classification of Materials was reviewed in the preparation of the TR and by the Crops Subcommittee (NOP 5033, section 4.6):

> **4.6 Extraction of Nonorganic Materials**
> Some materials are produced using manufacturing processes that involve separation techniques, such as the steam distillation of oil from plant leaves. Separation and extraction methods may include, but are not limited to, distillation, solvent extraction, acid-base extraction, and physical or mechanical methods (e.g., filtration, crushing, centrifugation, or gravity separation).
>
> For purposes of classification of a material as synthetic or nonsynthetic, a material may be classified as nonsynthetic (natural) if the extraction or separation technique results in a material that meets the following criteria:
>
> - At the end of the extraction process, the material has not been transformed into a different substance via chemical change;
> - The material has not been altered into a form that does not occur in nature; and
> - Any synthetic materials used to separate, isolate, or extract the substance have been removed from the final substance (e.g., via evaporation, distillation, precipitation, or other means) such that they have no technical or functional effect in the final product.

Discussion

Laminarin is a low molecular weight, bioactive polysaccharide. It does not have gelling or thickening properties like other algal polysaccharides, namely alginate and carrageenan. Laminarin was petitioned for addition to the National List for use as a pre-harvest pesticide to stimulate the plants' natural disease-defense mechanisms. Its ability to stimulate plant defenses is well documented. Laminarin has also been shown to enhance the biological control of crop pests by attracting parasitic wasps (2015 TR, lines 56-60).

Laminarin can be extracted by a number of different methods that are described in the TR under Evaluation Question #2 (2105 TR, lines 184 - 264). All of the processes use some physical methods such as grinding, filtration and centrifugation. Most of them use solvents such as alcohol or acid-base reactions to produce a purified extract. Table 2 in the TR (line 245) summarizes the methods. The claim in the petition that there is no modification to the chemical structure of the laminarin is supported by research cited in the TR (lines 249 - 259).

Evaluation Question #3 of the TR goes into the potential for residual sodium or sulfate to remain in the laminarin (lines 291 - 317). Several reasons are given why the calculations posed by the minority opinion of the NOSB crops subcommittee are not accurate. While there may be some ionic forms of sodium and sulfate ions, they would not react or precipitate as sodium sulfate (TR line 300-301). This is summed up by lines 316 and 317: "In all extraction scenarios, the literature does not suggest that the residual ions resulting from the acid-base reactions lend any technical or functional effect in the laminarin ingredient once it is completely extracted." Further the last point made in the TR on lines 382 to 388 states:

> "The EPA typically requires any component of a pesticide formula greater than or equal to 0.1% to be declared on the Confidential Statement of Formula (CSF), including impurities from acid-base reactions such as those described in this technical report. There can be no exceptions for listing on the CSF where 'Impurities of Toxicological Significance' are concerned (Pfiefer 2015). Based on theoretical calculations in Question 3, sulfate ions could conceivably comprise 0.0034% of a final commercial laminarin product, and sodium consists of .001%. Therefore, these residual by-products from the acid-base reaction would not likely be declared on the CSF, even as impurities."

The environmental impacts are discussed in Evaluation Question #6 of the Technical Report. (2015 TR, lines 319 - 388). The potential impacts are similar to many other non-synthetic inputs used in organic agriculture that are harvested or mined from the earth and sea. In France where the majority of the Laminaria is harvested, the production is highly regulated, but that information was not available for other locations which might have seaweed production.

Referring back to the bullet point in the Guidance on Classification of Materials 4.6 as quoted above, the subcommittee has this analysis:

• *At the end of the extraction process, the material has not been transformed into a different substance via chemical change;*

The TR indicates that laminarin is not changed in extraction.

• *The material has not been altered into a form that does not occur in nature; and*

Laminarin does occur in nature.

• *Any synthetic materials used to separate, isolate, or extract the substance have been removed from the final substance (e.g., via evaporation, distillation, precipitation, or other means) such that they have no technical or functional effect in the final product.*

The reaction and filtration steps result in a purified laminarin in which the sodium and sulfate ions do not have a technical or functional effect. This is quite different than the listing for aquatic plant extracts that are classified as synthetic for crop production at 205.601(j)(1). In those the extracting agents such as potassium hydroxide does leave behind enough potassium to have a functional effect as a fertilizer. In laminarin, neither the sodium (at 0.001%) nor the sulfate ions (at 0.0034%) have a functional effect for disease suppression.

Therefore the majority of the Crops Subcommittee believes that laminarin is non-synthetic and therefore is allowed without need to add it to the National List. A checklist is included here for only the sections covered in the Technical Report.

Evaluation Criteria (see attached checklist for criteria in each category)

	Criteria Satisfied?
1. Impact on Humans and Environment	☒ Yes ☐ No ☐ N/A
2. Essential & Availability Criteria	☒ Yes ☐ No ☐ N/A
3. Compatibility & Consistency	☒ Yes ☐ No ☐ N/A

Substance Fails Criteria Category: [ ] **Comments:** none

Subcommittee Action & Vote:

Motion to classify laminarin as petitioned as non-synthetic
Motion by: Zea Sonnabend
Seconded by: Harold Austin
Yes: 5 No: 0 Abstain: 0 Absent: Recuse: 0

Listing Motion:

Because laminarin was classified as non-synthetic it does not need to be added to the National List.

Approved by Zea Sonnabend, Subcommittee Chair, to transmit to NOSB August 25, 2015

NOSB Evaluation Criteria for Substances Added To the National List - Crops

Category 1. Adverse impacts on humans or the environment? Laminarin

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is there a probability of environmental contamination during use or misuse? [§6518(m)(3)]		X		
2. Is there a probability of environmental contamination during, manufacture or disposal? [§6518(m)(3)]		X		TR question 6, lines 319 - 388
3. Are there any adverse impacts on biodiversity? (§205.200)		X		Laminarin has also been shown to enhance the biological control of crop pests by attracting parasitic wasps (TR lines 59 - 60)
4. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517 (c)(1)(B)(ii)]		X		The formulation of Laminarin from the petitioner does contain inerts which have not been evaluated, but the active ingredient does not.
5. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]		X		
6. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]		X		
7. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		X		
8. Would the use of the substance be harmful to human health or the environment? [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)]		X		
9. Are there adverse biological and chemical interactions in the agro-ecosystem? [§6518(m)(5)]		X		
10. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)]		X		

NOSB Evaluation Criteria for Substances Added To the National List - Crops

Category 2. Is the Substance Essential for Organic Production? Substance: Laminarin

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]	X			
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]		X		
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]		X		See discussion above and TR evaluation Question #2 (lines 184 - 264)
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		
5. Is there a natural source of the substance? [§ 205.600(b)(1)]	X			
6. Is there an organic substitute? [§205.600(b)(1)]			X	
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]			X	
8. Are there any alternative substances? [§6518(m)(6)]	X			There are disease controls on the National List that are synthetic that may be alternatives, such as potassium bicarbonate and sulfur.
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]				Maybe some cultural management systems could minimize disease pressure, but there is no information yet on how well this works in an organic system because it has not been approved yet.