

March 26, 2014

National Organic Standards Board Spring 2014 Meeting San Antonio, TX

## Re. CS: Laminarin

These comments are submitted on behalf of Beyond Pesticides. Beyond Pesticides, founded in 1981 as a national, grassroots, membership organization that represents community-based organizations and a range of people seeking to bridge the interests of consumers, farmers and farmworkers, advances improved protections from pesticides and alternative pest management strategies that reduce or eliminate a reliance on pesticides. Our membership and network span the 50 states and groups around the world.

Beyond Pesticides supports the minority view that laminarin must be classified as a synthetic substance if it is extracted as described in the petition. In the case of laminarin, sulfuric acid is added during the extraction process. It is neutralized with sodium hydroxide in a later step. While the reaction of sulfuric acid and sodium hydroxide neutralizes the acid, thus "removing" that <u>effect</u>, it does not remove the sulfuric acid. Sodium is also added. The sulfur, as sodium sulfate, remains. No later step in the process removes the sodium sulfate, and the majority does not claim it does. It is the remaining material at levels that are of technical concern or that have technical effect that requires the classification of this material as a synthetic. Removal is not the same thing as eliminating the function while creating an added substance in the material.

Unfortunately, there is some uncertainty about which classification guidelines to use. The NOSB has adopted classification guidelines, and the NOP has proposed draft guidelines that are still incomplete. In the following, the important difference between the two is that according to the NOSB guidelines, a substance is synthetic if there are **significant** residues of a synthetic added during extraction, while according to the draft NOP guidelines, a substance is synthetic if any synthetic added during extraction is **not removed so that it has no technical or functional effect**. A key defect in both of these sets of guidelines is the failure to define the critical terms "significant" and "technical or functional effect."

In the case of laminarin, there is a residue of two synthetic substances added during extraction. Is that residue "significant"? Does it have a "technical or functional effect"? The minority performed some calculations estimating the residues of <u>added</u> sulfate at 624 parts per million (ppm) and <u>added</u> sodium at 299 ppm. The uncertainties in the calculation make it likely that these are <u>underestimates</u>.

While the majority is correct in stating that the technical/functional effect of acidity has been removed, it has not addressed the effects of the additions of sulfate and sodium in removing the acidity. We believe that these concentrations are significant within the laminarin. Like the minority, we do not claim that they would be a significant addition to the crop plants. We do not know what other technical or functional effects the sulfate and sodium might have on laminarin. Are they preservatives?

Sodium sulfate is used as a viscosity modifying agent in cosmetics. The scientific literature review *Safety Assessment of Inorganic Sulfates as Used in Cosmetics* performed by Cosmetic Ingredient Review<sup>1</sup> (CIR) states that sodium sulfate is used as a viscosity-control agent. Does the concentration found in laminarin perform this effect? Table 3 of the CIR report (attached) indicates that the answer is "yes."

## Why do we care about the classification of laminarin?

Laminarin is extracted from seaweed. It is also found in fungi. It works by amplifying natural plant defenses. Why, then, should we care whether there is a small residue of synthetic that causes laminarin to be classified as synthetic?

- 1. Determining as nonsynthetic substances formulated with high levels of sulfuric acid resulting in high levels of sulfate sets a bad precedent for future synthetic-nonsynthetic decisions.
- 2. With no Board oversight of materials deemed nonsynthetic, given USDA's new position that NOSB recommendations are only binding for synthetic materials –and no assurance of NOP consultation—decisions such as these are critical to Board oversight and compliance with the Organic Foods Production Act (OFPA). For instance, if the Board wanted to designate a material natural with an annotation that certain formulations are not allowed, USDA's announced policy would not require that annotation to be attached to the 602 listing.

## Concerns about laminarin that can be addressed with a synthetic classification.

Given that we believe laminarin as described in the petition is a synthetic material, the Board should be aware that there are health concerns that we believe deserve some consideration. With the benefit of a technical review, these issues could be addressed and the public could be assured of the material's acceptability under OFPA standards.

<sup>&</sup>lt;sup>1</sup> Cosmetic Ingredient Review, 2013. *Safety Assessment of Inorganic Sulfates as Used in Cosmetics*, <a href="http://www.cirsafety.org/sites/default/files/inorgs032014slr.pdf">http://www.cirsafety.org/sites/default/files/inorgs032014slr.pdf</a> (The 2013 Cosmetic Ingredient Review Expert Panel members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; Curtis D. Klaassen, Ph.D.; Daniel C. Liebler, Ph.D.; Ronald A Hill, Ph.D. James G. Marks, Jr., M.D.; Ronald C. Shank, Ph.D.; Thomas J. Slaga, Ph.D.; and Paul W. Snyder, D.V.M., Ph.D. The CIR Director is Lillian J. Gill, D.P.A. This report was prepared by Wilbur Johnson, Jr., M.S., Senior Scientific Analyst and Bart Heldreth, Ph.D., Chemist.)

As we all know, "natural" does not mean safe. One of the most toxic pesticides we know – the predator poison sodium fluoroacetate or 1080— occurs naturally as an anti-herbivore metabolite in various plants.

Laminarin acts by increasing the concentration of anti-herbivore and anti-fungal metabolites in plants. Although humans do not consume the species containing 1080, we do consume plants that contain compounds that would be toxic in larger quantities and whose relatives are considered poisonous. Solanaceous plants, including tomatoes, potatoes, and eggplants, with relatives poisonous nightshades, are examples. Some people are more sensitive than others to the toxic components in the Solanaceae.

These points lead us to question whether laminarin might result in levels of exposure to plant-defensive chemicals that would prove toxic to consumers. Might it also result in levels of exposure that are toxic to pollinators? The petition considers the toxicity of laminarin *per se*, but not the toxic properties induced in plants as they might affect humans, pollinators, or other non-target organisms. The issue of the toxicity induced by laminarin is one that would be considered by the NOSB in a decision to list laminarin as a synthetic input, but is not considered in this decision. Not only do we believe that the manufacturing process qualifies this material as a synthetic material, there are sufficient issues of health and safety that the Board should evaluate as it moves forward in determining whether this material should be recommended for allowance in organic production.

Therefore, we urge you to vote to classify laminarin as synthetic.

Thank you for your consideration of these comments.

Sincerely,

Terry Shistar, Ph.D. Board of Directors

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Attachment: Table 3 from Cosmetic Ingredient Review, 2013. Safety Assessment of Inorganic Sulfates as Used in Cosmetics

**Table 3**. Current Frequency and Concentration of Use According to Duration and Type of Exposure. **Sodium Sulfate Zinc Sulfate** 

Sodium Suitate			Zilic Sullate	
# of Uses		Conc. (%)	# of Uses	Conc. (%)
		Exposure Type		
Eye Area	11	0.000046-0.0064	NR	NR
Incidental Ingestion	NR	0.00015-0.83	NR	0.05
Incidental Inhalation- Sprays	38	0.00015-2	10	NR
Incidental Inhalation- Powders	34	0.005	10	NR
Dermal Contact	272	0.00001-96.8	45	0.057-1
Deodorant (underarm)	2	0.0001-0.0027	NR	NR
Hair - Non-Coloring	76	0.00095-2	16	0.44
Hair-Coloring	209	1-2.7	NR	NR
Nail	11	0.001-9.1	NR	NR
Mucous Membrane	190	0.00015-96.8	2	0.057
<b>Baby Products</b>	7	0.29	NR	NR
		Duration of Use		
Leave-On	74	0.00001-9.1	23	0.07-1
Rinse off	458	0.00015-8	30	0.057
Diluted for (bath) Use	42	0.14-96.8	NR	NR
Totals/Conc. Range	612	0.00001-96.8	63	0.057-1

NR = Not Reported; Totals = Rinse-off + Leave-on Product Uses;

Note: Because each ingredient may be used in cosmetics with multiple exposure types, the sum of all exposure type uses may not equal the sum total uses.

Note: the calculated concentration of sulfate in laminarin is approximately 624 ppm = 0.000624.