

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

Date: April 27, 2016

Subject: Petition to add Oat Beta Glucan at §205.606

NOSB Chair: Tracy Favre

The NOSB hereby recommends to the NOP the following:

Rulemaking Action:

Guidance Statement:

Other: X

Statement of the Recommendation:

The NOSB recommends that the petitioned material, oat beta glucan, not be added to the National List at §205.606.

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

The NOSB determined that the petitioned material, oat beta glucan failed the evaluation criteria of essentiality & availability. The Board found no compelling reason why an organic version of the petitioned substance could not be produced.

NOSB Vote:

Classification Motion: Move to classify oat beta glucan as agricultural

Motion by: Lisa de Lima

Seconded by: Ashley Swaffar

Yes: 15 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Listing Motion: Move to list oat beta glucan at §205.606

Motion by: Lisa de Lima

Seconded by: Jean Richardson

Yes: 0 No: 15 Abstain: 0 Absent: 0 Recuse: 0

Motion Failed

**National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal - Oat Beta Glucan
January 19, 2016**

Summary of Proposed Action:

Oat beta glucan is being petitioned by manufacturer Tate & Lyle for addition at §205.606, as a natural component of oats, an agricultural commodity. According to the petition the substance is isolated through a simple process of grinding, enzyme treatment, water extraction and drying. No synthetic chemical additions or solvents are used in the manufacturing process being petitioned. The only additives used in producing oat beta glucan are water and enzymes. Specifically, the enzyme is food-grade alpha-amylase and non-GMO per GRAS self-determination. In addition to the beta glucan, dextrins and gluco-oligosaccharides are found in the final product, which is in powder form.

Due to oat beta glucan's high soluble fiber content, bland flavor and minimal impact at low use levels, it's used to supplement fiber content in processed foods including biscuits, cakes, breads, cereals, bars, soups, and smoothies. Other common names for oat beta glucan include oat bran soluble fiber, oat fiber, oat soluble fiber, and oat bran fiber.

Overall, oat beta glucan appears to have no significant negative impacts on human health. There have been studies that show the positive effect of the substance on lowering cholesterol and modulating blood glucose.

The petition concludes that since oat beta glucan is used in handling, and not crop production, it has no effect on soil, crops, or livestock. The subcommittee however would like to point out that according to the USDA pesticide data program there are 7 pesticide residues found on conventionally grown oats.

The petition states that currently there is no source of organic oat beta glucan, despite organic oats and organics oat bran being widely available in the U.S. and Canada. Additionally the petition claims that in Nordic countries, where a large amount of oat beta glucan is manufactured, organic oats and organic oat bran quantities are limited. The petition goes on to state that if the demand for organic oat beta glucan was to increase, the Nordic manufacturing facilities could purchase organic oats and organic oat bran from the U.S. The petitioner thought this scenario was unlikely to happen soon due to the undetermined demand for oat beta glucan in organic form and that it would be more likely to happen if the use of non-organic beta glucan in organic foods was successful first.

The handling subcommittee would like to point out that the global market is the universe of supply, non-commercial availability is not dependent upon geographical location. The subcommittee sees no reason why oat beta glucan could not be manufactured organically. In fact, the manufacturer Garuda International used to produce organic oat beta glucan but stopped doing so due to low demand.

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

1. Impact on Humans and Environment
2. Essential & Availability Criteria
3. Compatibility & Consistency
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for §205.606)

Criteria Satisfied?

- | | | |
|------------------------------|-----------------------------|------------------------------|
| X Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| <input type="checkbox"/> Yes | X No | <input type="checkbox"/> N/A |
| X Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| <input type="checkbox"/> Yes | X No | <input type="checkbox"/> N/A |

Substance Fails Criteria Category: 2- Essentiality and Availability. **Comments:** The Subcommittee felt that there were alternatives currently available and alternative sources for which these petitioned needs could be met.

Subcommittee Action & Vote, including classification proposal (state actual motion):

Classification Motion: Move to classify Oat Beta Glucan as agricultural

Motion by: Lisa de Lima

Seconded by: Ashley Swaffar

Yes: 4 No: 0 Abstain: 0 Absent: 2 Recuse: 0

Listing Motion: Move to list Oat Beta Glucan at §205.606 of the National List

Motion by: Lisa de Lima

Seconded by: Jean Richardson

Yes: 0 No: 4 Abstain: 0 Absent: 2 Recuse: 0

Approved by Harold V. Austin IV, Handling Subcommittee Chair, to transmit to NOSB January 19, 2016

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

Category 1. Adverse impacts on humans or the environment? Oat beta glucan

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Are there adverse effects on the environment, or is there a probability of environmental contamination during use or misuse of the substance? [§205.600(b)(2), [§6518(m)(3)]	x	x		Produced from non-organic oat, which according to the USDA pesticide data program, can contain 7 pesticide residues.
2. Are there adverse effects on the environment or is there a probability of environmental contamination during manufacture or disposal of the substance? [§6518(m)(3)]		x		
3. Are there any adverse impacts on biodiversity? (§205.200)		x		
4. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517 (c)(1)(B)(ii)]		x		

5. Is there undesirable persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		x		
6. Are there any harmful effects on human health from the main substance or the ancillary substances that may be added to it? [§6517(c)(1)(A)(i); 6517 (c)(2)(A)(i); §6518(m)(4), 205.600(b)(3)]		x		
7. Is the substance, and any ancillary substances, GRAS when used according to FDA's good manufacturing practices? [§205.600(b)(5)]	x			
8. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 (b)(5)]		x		

Category 2. Is the Substance Essential for Organic Production? Oat beta glucan

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		
4. Is the substance created by naturally occurring biological processes? [§6502(21)]	x			Yes, natural because it uses enzymes.
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		Currently no. Former producer of organic oat beta glucan stopped producing due to low demand.
7. Is the substance essential for handling of organically produced agricultural products? [§205.600(b)(6)]		x		
8. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]	x	x		Currently no, but could be made from organic oats
9. Are there any alternative substances? [§6518(m)(6)]	x	x		Yes, but petition claims they are unpalatable
10. Is there another practice (in farming or handling) that would make the substance unnecessary? [§6518(m)(6)]			x	

11. Have the ancillary substances associated with the primary substance been reviewed? Describe, along with any proposed limitations.			x	No ancillaries reported in the petition
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Category 3. Is the substance compatible with organic handling practices? Oat beta glucan

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]	x			
2. Is the manner of the substance's use, manufacture, and disposal compatible with organic handling? [§205.600(b)(2)]	x			
3. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]			x	Not used in farming
4. Are the ancillary substances reviewed compatible with organic handling [?]			x	Not ancillary substances identified in petition
5. Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]	x			
6. Is the primary use as a preservative? [§205.600(b)(4)]		x		Primary use is to increase fiber
7. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law)? [§205.600(b)(4)]		x		Primary use is to increase fiber

Category 4. Is the commercial supply of an organic agricultural substance fragile or potentially unavailable? [§6610, 6518, 6519, §205.2, § 205.105(d), §205.600(c)] Oat Beta Glucan

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the comparative description as to why the non-organic form of the material /substance is necessary for use in organic handling provided?	x			Page 4 of the petition
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate form to fulfill an essential function in a system of organic handling?	x	x		Page 12 of the petition gives their justification.
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the	x			Page 12 petition

appropriate quality to fulfill an essential function in a system of organic handling?				
4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate quantity to fulfill an essential function in a system of organic handling?	x			Page 12 petition
5. Does the industry information about unavailability include (but is not limited to) the following?:		x		
a. Regions of production (including factors such as climate and number of regions);				
b. Number of suppliers and amount produced;	x			
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;		x		
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or		x		
e. Other issues which may present a challenge to a consistent supply?				