

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

Date:

Subject:

Chair:

The NOSB hereby recommends to the NOP the following:

Rulemaking Action:

Guidance Statement:

Other:

Statement of Recommendation: (Motion # 1)

Motion to classify Barley Beta Fiber as petitioned as agricultural

Rationale Supporting Recommendation (including consistency with OFPA and NOP):

As per the petition and Technical Report: Barley Beta Fiber and its constituents are non-synthetic when extracted by normal processing, including enzymatic hydrolysis.

Committee Vote:

Moved:

Seconded:

Yes:

No:

Abstain:

Absent:

Recuse:

Statement of Recommendation: (Motion # 2)

Failed

Motion to list Barley Beta Fiber on section 205.606 of the National List

Rationale Supporting Recommendation (including consistency with OFPA and NOP):

Upon review of the petition and the technical report, the Handling Subcommittee determined that Barley Beta Fiber does not satisfy evaluation criteria #2:

Essentiality & Availability.

Having considered the claim in the petition of the unique characteristics of the product the Subcommittee requested that interested members of the organic community comment on the supply, demand and specific qualities of the petitioned material in an effort to assess the degree to which there is an essential market need. Having received no strong support for this substance, the NOSB voted to not list Barley Beta Fiber on Section 205.606.

Committee Vote:

Moved: John Foster

Seconded: Jean Richardson

Yes: 3

No: 12

Abstain: 0

Absent: 0

Recuse: 0

**National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
Barley betafiber**

December 18, 2012

Summary of Proposed Action:

Barley betafiber is described in the petition as a “polysaccharide of unbranched, linear, mixed-linkage β -glucans” (Kolberg, 2011). Barley betafiber is described at 21 CFR 101.81(c)(2)(ii)(6) as a fraction of cellulase and alpha-amylase hydrolyzed whole grain barley.

Barley betafiber is defined by the FDA as “the ethanol precipitated soluble fraction of cellulase and alpha-amylase hydrolyzed whole grain barley. Barley betafiber is produced by hydrolysis of whole grain barley flour, as defined in paragraph (c)(2)(ii)(A)(5) of this section, with a cellulase and alpha-amylase enzyme preparation, to produce a clear aqueous extract that contains mainly partially hydrolyzed beta-glucan and substantially hydrolyzed starch. The soluble, partially hydrolyzed beta-glucan is separated from the insoluble material by centrifugation, and after removal of the insoluble material, the partially hydrolyzed beta-glucan soluble fiber is separated from the other soluble compounds by precipitation with ethanol. The product is then dried, milled and sifted. Barley betafiber shall have a beta-glucan soluble fiber content of at least 70 percent on a dry weight basis” [21 CFR 101.81(c)(2)(ii)(6)].

Barley β -glucan isolates such as barley betafiber enable food processors to incorporate the health benefits of barley in various foods without the problems created by whole grain barley in formulation (Fastnaught, 2009). The petition refers to it being used in a juice (Kolberg, 2011). Soluble barley betafiber is possible to use in other beverages (Zheng, et al., 2004). Other foods where barley betafiber has been added, at least experimentally if not commercially, include baked goods, pasta, ready-to-eat cereals, soups, stews, dairy products and meats (Newman and Newman, 2008; Fastnaught, 2009).

Barley is known to be a rich source of β -glucan. While most other grains have lower fiber in the endosperm than the whole grain, the soluble β -glucan in barley endosperm is comparable to that of whole grain (Henry, 1987). The variety “Prowashonupana” was identified in the early 1980s as a mutant hull-less waxy barley with a high β -glucan content (Eslick, 1981). The β -glucan in Prowashonupana is described as not soluble (WTARC, 2005). Other barley varieties selected for high soluble β -glucan content are Apollo and Wanubet (Yoon et al., 1995). The petitioned substance is described as new and at this time the only commercial products that use the petitioned substance are processed products that are not certified organic (Kolberg, 2011).

Nutritional fiber has a wide range of technical and functional effects on food (Dreher, 2001; Sharma et al., 2008; Cho, 2009). Naturally occurring β -glucans can be classified as *Soluble Fibers*, while added or isolated β -glucans are potential *Functional Fibers*. Soluble and functional fibers have similar activity, but isolated β -glucan extracts have a wide range of specific characteristics and functionality. Barley betafiber is distinguished by its low molecular weight (Zheng, et al., 2004). As discussed below, the primary health claim made related to the use of the petitioned substance is its ability to reduce the glycemic index of foods, help to maintain normal blood sugar levels, and lower cholesterol, decrease risk of diabetes, and “(potentially) promoting satiety” (Kolberg, 2011).

Consistent with the literature noted above, the petition claims specific properties of this barley beta fiber that are unique and currently unavailable in organic form to be used as dietary fiber additions in product formulations, specifically that the percentages and ratio of soluble to insoluble fiber are preferable from a product development standpoint. The petition also claims that the variety of barley used for this product is currently not grown in sufficient quantity to satisfy market demand.

The Handling Subcommittee reviewed the petition materials, considered the unique characteristics of the variety and product in the petition and reviewed the TR, which addressed the technical aspects of the material but not the market dynamics. The Subcommittee requests that interested members of the organic community comment on the supply, demand and specific qualities of the petitioned material in an effort to assess the degree to which there is an essential market need.

Evaluation Criteria

(Applicability noted for each category; Documentation attached)
“B” below)

Criteria Satisfied? (see

- | | | | |
|--|-------|-----------------------------|------------------------------|
| 1. Impact on Humans and Environment | x Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| 2. Essential & Availability Criteria | x Yes | x No | <input type="checkbox"/> N/A |
| 3. Compatibility & Consistency | x Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| 4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for § 205.606) | x Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |

Substance Fails Criteria Category: [] **Comments:**

Proposed Annotation (if any): none

Basis for annotation: To meet criteria above Other regulatory criteria Citation
 Notes:

Recommended Committee Action & Vote, including classification recommendation (state actual motion):

Classification Motion: Motion to classify barley beta fiber as petitioned as agricultural
 Motion by: John Foster Seconded by: Joe Dickson
 Yes: 8 No: 0 Absent: 0 Abstain: 0 Recuse: 0

Listing Motion:
 Motion by: John Foster Seconded by: Joe Dickson
 Yes: 7 No: 0 Absent: 0 Abstain: 1 Recuse: 0

Crops	<input type="checkbox"/>	Agricultural	x	Allowed¹	x
Livestock	<input type="checkbox"/>	Non-synthetic	<input type="checkbox"/>	Prohibited²	<input type="checkbox"/>
Handling	x	Synthetic	<input type="checkbox"/>	Rejected³	<input type="checkbox"/>
No restriction	<input type="checkbox"/>	Commercial unavailable as organic	x	Deferred⁴	<input type="checkbox"/>

¹Substance voted to be added as “allowed” on National List to § 205. with Annotation (if any):
 none

Approved by Subcommittee Chair to Transmit to NOSB
 John Foster, Subcommittee Chair December 18, 2012

NOSB Evaluation Criteria for Substances Added To the National List

Category 1. Adverse impacts on humans or the environment? Substance: Barley betafiber

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]		X		See TR-product is agricultural.
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		“
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		“
4. Does the substance contain List 1, 2 or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]			X	
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		X		“
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]			X	
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]			X	
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		“
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]		X		“
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4]		X		“
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		X		“
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]	X			“
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA	X			Small residual amounts are left in the product. TR states <2ppm lead.

tolerances? [§205.600 b.5]				
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¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Evaluation Criteria for Substances Added To the National List

Category 2. Is the Substance Essential for Organic Production?

Substance: Barley

betafiber

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]	X			Chemical reactions are occurring in the use of enzymes to break bonds. TR.
2. 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			There is a chemical separation of the fiber from the barley; that being said it is a normal component of the barley
3. Is the substance created by naturally occurring biological processes? [6502 (21)]	X			Natural in that it used enzymes; however the enzymes are not endogenous to the barley and are introduced. That being said, it is a normal biologic process.
4. Is there a natural source of the substance? [§205.600 b.1]			X	
5. Is there an organic substitute? [§205.600 b.1]		X		TR states that oat 70% β -glucan is available organically and not mentioned in the petition
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]		X		Not essential; however, it is an ingredient that will assist in providing for the overall health of the consumer.
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]			X	
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]	X			
9. Is there any alternative substances? [§6518 m.6]	X	X		There are other sources of fiber with β -glucans; but these have different properties and are not always functional in some types of products, beverages for example.
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]		X		

NOSB Evaluation Criteria for Substances Added To the National List

Category 3. Is the substance compatible with organic production practices?

Substance: Barley betafiber

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]	X			Consistent with most compatibility criteria
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]	X			Several other materials used in analogous capacities
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]			X	Not used in farming
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]	X			Increased due to the addition of heart healthy fiber
5. Is the primary use as a preservative? [§205.600 b.4]		X		
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]		X		Used for increased dietary fiber in foods
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:			X	
a. copper and sulfur compounds;				
b. toxins derived from bacteria;			X	
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?			X	
d. livestock parasiticides and medicines?			X	
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?			X	

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Evaluation Criteria for Substances Added To the National List

Category 4. Is the commercial supply of an agricultural substance as organic, fragile or potentially unavailable? [§6610, 6518, 6519, 205.2, 205.105 (d), 205.600 (c) 205.2, 205.105 (d), 205.600 (c)] **Substance: Barley betafiber**

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Is the comparative description provided as to why the non-organic form of the material /substance is necessary for use in organic handling?	X			Petition-pg 8
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			Petition Pg. 8—the variety grown for fiber production is not currently in organic production
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 appropriate quality to fulfill an essential function in a system of organic handling?	X			Petition Pg. 8
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			Petition Pg. 8
5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following:	X			See above
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			X	

hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;				
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or			X	
e. Are there other issues which may present a challenge to a consistent supply?	x			

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Recommendation