

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

Date: April 2015

Subject: Petition to add Whole Algal Flour at §205.605(a)

NOSB Chair: Jean Richardson

The NOSB hereby recommends to the NOP the following:

Rulemaking Action:

Guidance Statement:

Other: X

Statement of the Recommendation (Motion #1):

Motion to classify Whole Algal Flour (WAF) as non-synthetic, passed.

Statement of the Recommendation (Motion #2):

Motion to add Whole Algal Flour at §205.605(a) - Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” (a) Nonsynthetics allowed, failed.

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

Based on mixed public comment and the information provided in the petition, the NOSB determined that Whole Algal flour, while non-synthetic, is not essential to organic handling and is inconsistent with fundamental organic principles. As such, it would not meet the expectations of organic consumers, handlers, or others within the organic community.

Committee Vote:

Motion to classify Whole Algal Flour (WAF) as non-synthetic.

Motion by: Harold Austin

Seconded by: Jean Richardson

Yes: 14 No: 0 Absent: 1 Abstain 0 Recuse: 0

Motion passed

Motion to add Whole Algal Flour at §205.605(a) - Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” (a) Nonsynthetics allowed

Motion by: Harold Austin

Seconded by: Jean Richardson

Yes: 0 No: 14 Absent: 1 Abstain: 0 Recuse: 0

Motion failed

**National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal - Whole Algal Flour
January 6, 2015**

Summary of Proposed Action:

The Handling Subcommittee (HS) has again reviewed the petition and additional information submitted by Solazyme, Inc. seeking permission to have Whole Algal Flour (WAF) added to the National List of Approved Materials. (This material was referred back to the Handling Subcommittee at the Louisville National Organic Standards Board (NOSB meeting). The Handling Subcommittee proposes to recommend adding WAF to the National List at §205.605(a) - Nonagricultural (non-organic) substance (non-synthetic) allowed. Originally, the Handling Subcommittee considered adding WAF to the National List under §205.606 – Nonorganic agricultural products allowed as an ingredient in or on processed product; however, our discussion and further considerations during the original proposal presentation to the full Board at the NOSB meetings (specifically, at the October 2014 NOSB Fall meeting in Louisville led us to determine §205.606 is not the appropriate place to list this material. To be consistent with other materials already listed and to follow the guidelines of the Draft Decision Tree, the Handling Subcommittee decided this material belongs on §205.605(a) rather than on §205.606.

Background: Whole Algal Flour is manufactured from, a microalgae by fermenting and harvesting cultures of a non-toxicogenic strain of *Chlorella protothecoides*. The petitioner originally proposed listing this material on §205.606 yet noted that algae is also a single-celled organism, and as such, we could place it on §205.605(a). Its primary proposed use would be: a whole food ingredient used as either a partial replacement for food ingredients that provide dietary fat and/or protein such as cream, milk, eggs/egg yolks, and/or butter or shortening in baked goods, beverages, dairy and egg products, sauces, gravies, margarines, salad dressings and soups, or as an added ingredient for texture and mouth feel enhancement.

On September 6, 2013, the National Organic Program received the original petition and forwarded it to the NOSB's Handling Subcommittee for petition review and consideration for listing. On January 14, 2014, the Handling Subcommittee received a supplement from the petitioner: a response to questions that the HS had concerning whole algal flour after our review of the original petition. Both the original petition and the supplemental information contained confidential business information, requiring redaction. The redacted information made it difficult for the Handling Subcommittee to thoroughly review this material and its ancillary substances.

During the 30day public comment period prior to the NOSB's October 2014 fall meeting in Louisville, the petitioner provided additional information to the Handling Subcommittee. This information clarified some points of concern. Additionally, the petitioner (and others) provided more information and questions to the NOSB during oral public presentation and questions,. There were 14 written public comments submitted for whole algal flour; While Six commenters opposed listing whole algal flour on §205.606, eight supported adding whole algal flour to that Section. Those opposed were concerned with: 1) the amount of information withheld as confidential business information; 2) the fermentation process (as a whole, not just this material); 3) excluded methods, using a synthetic material to replace already existing organic alternatives; and 4) ancillary substances. Those that supported adding whole algal flour to the National List stated that it would not replace organic substances currently being used but give

handlers an alternative – to make a finished product that can provide a healthier organic product – a nonallergenic, vegan option. Materials used currently could be partially replaced by whole algal flour; this replacement could help to reduce calories, fat, saturated fat, and cholesterol while not impacting taste, mouth feel, or end product quality.

Discussion:

The petitioner provided the Handling Subcommittee (during written public comment and their oral comments) answers to several areas of concern that they had previously had. The HS resolved the concerns related to ancillary substances, especially the Subcommittee's requirement of a due diligence review even though some of the information was redacted. The two ancillary substances used are antioxidants: tocopherols and ascorbic acid; both are currently listed on the National List at §205.605(b). Consequently, the NOSB's ancillary substance review of a petitioned material is complete.

Another concern was the manufacturing process via fermentation and the media used during the process. A detailed list of those materials used in the fermentation growth medium was provided. This list was very typical of substances normally used in the fermentation process of other materials currently allowed on the National List. The petitioner provided two examples of two materials currently on the National List at §205.605 that are also products of fermentation; these are: Gellan gum at §205.605(a) and Xanthan gum at §205.605(b)

The petitioner also assured the Subcommittee and the full Board that no excluded methods were used by them to manufacture whole algal flour. This, together with the materials used in their manufacturing process, would be subject to review by their certifier at each annual inspection, and as it reviews their Organic System Plan during certification renewal.

Regarding essentiality, the Handling Subcommittee discussed whether or not this material is essential to organic handling. Part of the original discussion was based on the belief that this material would replace currently used "organic" materials (organic milk, eggs, cream, etc.) or practices. While that is partially true, it is not the petitioner's reason for seeking to add Whole Algal Flour to the National List. The primary reason is to provide handlers with an option, so that they might be able to provide those organic consumers with allergen concerns to eggs and/or dairy products, an alternative choice of a non-allergenic option to their finished goods. It would also help provide an alternative to those looking for a vegetarian or vegan alternative in organic consumer goods. Is there currently an alternative for this material based on its intended use? The answer is no. Does this material offer something to a handler currently not accessible to their manufacturing process? The answer is possibly. Could this material be considered essential to a handler to formulate a lower in calorie, low fat, vegan, or a non-allergenic alternative to what is currently being manufactured? The answer could then be considered possibly yes. While there will be differences of opinion, we must look at what this material could provide the organic community if it were listed, versus the consequences if it is not allowed.

The Handling Subcommittee has decided that Whole Algal Flour is not essential to organic handling. The Subcommittee also recognizes that this use is inconsistent with the basic fundamental principles of organics and, as such, would not meet the expectations of organic consumers, handlers, or others within the organic community.

Explanation of Motions: During the October 2014 Fall meeting in Louisville, a classification motion was not voted on by the Subcommittee due to the redacted information pertaining to the manufacturing process and ancillary substances. Once the petitioner provided additional

information 1) this issue was reconsidered and brought to a proper vote by the Subcommittee, and 2) we decided to add whole algal flour to the National List at §205.605(a) instead of at §205.606 as originally proposed in the listing motion. The motion is presented below.

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

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

Substance Fails Criteria Category: 2, 3

Comments: During its discussion about whole algal flour, particularly whether or not it should be added to the National List, the Handling Subcommittee decided the following: it is not essential to organic handling and it is inconsistent with basic organic principles (replacing organic materials currently being used with this product).

Subcommittee Action & Vote

Classification Motion: Move to classify Whole Algal Flour (WAF) as non synthetic.

Motion by: Harold Austin

Seconded by: Jean Richardson

Yes: 5 No: 0 Absent: 3 Abstain 0 Recuse: 0

Listing Motion: Move to add Whole Algal Flour at §205.605(a) – Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” (a) Nonsynthetics allowed

Motion by: Harold Austin

Seconded by: Jean Richardson

Yes: 0 No: 6 Absent: 2 Abstain: 0 Recuse: 0

Proposed Annotation (if any): none

Approved by Harold Austin, Handling Subcommittee Chair, to transmit to NOSB, January 6, 2015

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

Category 1. Adverse impacts on humans or the environment? Substance: Whole Algal Flour

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		It would not appear that there would be any adverse effects on the environment from the use or misuse of this material.
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		It would not appear that there would be any adverse effects to the environment from the manufacture or disposal of this substance.
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			Page 6 and 7 of the petition for whole algal flour states that on June 7, 2013 the FDA issued a No Questions letter (GRN 469) for whole algal flour. The petitioner has self-affirmed whole algal flour to be GRAS, page 4 of the petition. The two declared ancillary substances used in whole algal flour (as stated in the petitioner's written public comments dated October 6, 2014) were mixed tocopherol and ascorbic acid (both of these materials are currently listed on the National List at §205.605(b).
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?

Whole Algal Flour

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]		X		Petitioner claims that it should be classified as a microorganism and is nonagricultural.
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]		X		Made by fermentation process in a closed system.
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		Goes through fermentation and has either potassium hydroxide or sodium hydroxide added to adjust the pH. (both are on the national list).
4. Is the substance created by naturally occurring biological processes? [§6502(21)]	X			Fermentation has been considered to be a natural process.
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			Organic milk, cream, eggs/egg yolks are currently being used and others. But, these do not serve the same as the intended purpose of whole algal flour.
7. Is the substance essential for handling of organically produced agricultural products? [§205.600(b)(6)]	X	X		There currently are alternatives being used. It could be considered essential, if it were considered that it can help to provide an alternative to currently used organic materials to provide a non-allergen/vegan alternative to those organic consumers needing an alternative choice.
8. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]		X		There could be wholly natural substitutes for this product, in part. But, for the intended use of this material there would not be a wholly natural substitute product currently available.
9. Are there any alternative substances? [§6518(m)(6)]	X			There are substances currently on the National List of Approved Substances that are being used such as: starch products, some of the gums, hydrocolloids, to name just a few.
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			In the petitioners written public comments (October 6, 2014) they identified two ancillary substances used in the production of whole algal flour; those were: mixed tocopherol and ascorbic acid, both are listed on the National List at §205.605(b).
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Category 3. Is the substance compatible with organic handling practices? Whole Algal Flour

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			It is consistent with other materials currently allowed in organic handling and also currently on the National List.
3. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]	X			
4. Are the ancillary substances reviewed compatible with organic handling?	X			The ancillary substances were reviewed and found to be compatible with organic handling. The two ancillary substances identified are both currently on the National List.
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		
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		The primary use is to reduce and replace substances currently being used to help reduce fat content, improve texture and mouth feel in some products. The substance is used to provide a non-allergenic and vegan alternative to materials currently used in organic handling.

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)] **Whole Algal Flour**

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			There currently is not an organic form of this substance available on the market for use in organic handling.
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			
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	
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	
5. Does the industry information about unavailability include (but is not limited to) the following? a. Regions of production (including factors such as climate and number of regions);			X	
b. Number of suppliers and amount produced;			X	Unknown
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?			X	