

**National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
Whole Algal Flour**

August 20, 2014

Summary of Proposed Action:

The Handling Subcommittee has reviewed the petition submitted by Solazyme, Inc. seeking permission to have Whole Algal Flour added to the National List of Approved Materials under §205.606 – Non-organically produced agricultural products allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

Whole Algal Flour is manufactured from, a microalgae by fermenting and harvesting cultures of a non-toxic strain of *Chlorella protothecoides*. The petitioner noted that algae is also a single-celled organism which could possibly place it on §205.605(a) – Non-agricultural (non-organic) substance (non-synthetic). It’s primary proposed use would be as 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 petition was received by the National Organic Program and forwarded to the NOSB’s Handling Sub-committee for petition review and consideration for listing. On January 14, 2014 the Handling Sub-committee received from the petitioner a response to several questions that they had concerning whole algal flour after the review of the original petition had been completed. Both the original petition dated September 6, 2013 and the supplemental dated January 21, 2014 contained a tremendous amount of information that was redacted because it was considered to be Confidential Business Information (CBI). This afforded the Subcommittee no opportunity to make a determination on the material or to complete its responsibility of looking at ancillary substances for the newly petitioned material.

Explanation of Motions: The Handling Subcommittee made the Classification Motion listed below because it could not determine whether the material was synthetic or non-synthetic based on the information provided. The Subcommittee made the Listing Motion shown below because it felt that they could not make a full determination due to the uncertainty created by the redaction of a large amount of Confidential Business Information (CBI). The Subcommittee also discussed the essentiality of this substance, since there are numerous alternatives available for use that are currently allowed, as stated in the petition. The Subcommittee could also not complete its due diligence assessing ancillary substances because of a lack of access to the appropriate information.

Evaluation Criteria (see attached checklist)

	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 checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A

Substance Fails Criteria Category: 2 (see attached checklist)

Subcommittee Action & Vote

Classification Motion: Move to classify Whole Algal Flour as non-synthetic.

Motion by: Harold Austin

Seconded by: John Foster

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

Listing Motion: Move to list Whole Algal Flour on section 205.606 (of the National List): non-organically produced agriculture products allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

Motion by: Harold Austin

Seconded by: John Foster

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

Approved by Harold Austin, Subcommittee Chair, to transmit to NOSB August 19, 2014

NOSB Evaluation Criteria for Substances Added To the National List

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		
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)]				Unable to determine due to CBI.
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);				We can't determine due to inability to establish what possible ancillary substances there might be in both the main substance and ancillary substances alike due to CBI

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§6518(m)(4), 205.600(b)(3)]				blackout.
7. Is the substance, and any ancillary substances, GRAS when used according to FDA's good manufacturing practices? [§205.600(b)(5)]				Unknown. 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 WAF to be GRAS, page 4 of the petition. Because there is so much CBI there is no logical way to determine this.
8. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 (b)(5)]				Unknown

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. It may belong on 205.606 non-organically grown agricultural product.
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			Made by fermentation process in a closed system. Process is CBI.
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)]				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		
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.
7. Is the substance essential for handling of organically produced agricultural products? [§205.600(b)(6)]		X		There currently are alternatives being used.
8. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]		X		
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			X	

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handling) that would make the substance unnecessary? [§6518(m)(6)]				
11. Have the ancillary substances associated with the primary substance been reviewed? Describe, along with any proposed limitations.		X		Ancillary substances are unknown at this time due to the huge amount of CBI within the materials petition. A decision on limitations can't be made because there is no possible way to determine what the ancillary substances in this material are. Also, by the petitioners own statement they add different things based upon the individual customer's needs.

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)]				Unknown
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			
4. Are the ancillary substances reviewed compatible with organic handling [?				We are not able to make that determination with the information provided. Petition contains too much CBI and the potential list of ancillary substances is not able to be determined, even with the supplemental information provided by the petitioner.
5. Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]				We are not able to make that determination with the information provided.
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.

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?:			X	
a. Regions of production (including factors such as climate and number of regions);				
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	