

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: November 2008

Substance: Algae, Dumontiaceae, powdered

Committee: Crops Livestock Handling Petition is for: Inclusion on the National List § 205.606

A. Evaluation Criteria (Applicability noted for each category; Documentation attached) **Criteria Satisfied? (see B below)**

- | | | | |
|--|---|--|------------------------------|
| 1. Impact on Humans and Environment | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> |
| 2. Essential & Availability Criteria | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> | N/A <input type="checkbox"/> |
| 3. Compatibility & Consistency | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> |
| 4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606) | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> | N/A <input type="checkbox"/> |

B. Substance Fails Criteria Category: _____ **Comments:** As a photosynthesizing plant, this material could be eligible for listing on 606. However, this petition fails Category 2 and 4.

C. Proposed Annotation (if any): _____

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

D. Recommended Committee Action & Vote (State Actual Motion): For Inclusion of Algae, Dumontiaceae powder to § 205.606 of the National List

Motion by: Julie Weisman Seconded: Steve DeMuri Yes: 0 No: 4 Absent: 2 Abstain: 0

Crops		Agricultural	<input checked="" type="checkbox"/>	Allowed ¹	
Livestock		Non-Synthetic	<input type="checkbox"/>	Prohibited ²	
Handling	<input checked="" type="checkbox"/>	Synthetic	<input type="checkbox"/>	Rejected ³	<input checked="" type="checkbox"/>
No restriction		Commercially Un-Available as Organic ¹	<input checked="" type="checkbox"/>	Deferred ⁴	

1) Substance voted to be added as "allowed" on National List to § 205. _____ with Annotation (if any) _____

2) Substance to be added as "prohibited" on National List to § 205. _____ with Annotation (if any) _____

Describe why a prohibited substance: _____

3) Substance was rejected by vote for amending National List to § 205. 606 Describe why material was rejected: Petition does not address obstacles preventing this material from being produced in a certified organic form.

4) Substance was recommended to be deferred because _____

_____ If follow-up needed, who will

follow up _____

E. Approved by Committee Chair to transmit to NOSB:

Julie S. Weisman
Committee Chair

September 25, 2008
Date

NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? Substance - Algae, Dumontiaceae, powdered

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	
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		Petition p. 2, # 9 (c) describes manufacturing process, as follows: “ Dumontiaceae are photosynthesizing red algae which are indigenous to the Pacific coastal areas of North America for Alaska to Southern California....[and] is ethically wild-harvested from the ocean floor of the Pacific, it is then air dried and packaged.”
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		See # 2 above.
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		See # 2 above.
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		X		See # 2 above.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		See # 2 above.
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		See # 2 above.
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]		X		See # 2 above
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]		X		Petition p. 2, # 9 (d) cites several studies which demonstrate that Dumontiaceae algal extracts are non-toxic. It also states that such algae have been collected and consumed by humans for over 2500 years and are common ingredients in today in many foods, cosmetics and household products. There is research suggesting that Dumontiaceae extracts have anti-viral properties.
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 tolerances? [§205.600 b.5]			X	

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

Category 2. Is the Substance Essential for Organic Production? Substance - Algae, Dumontiaceae, powdered

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	
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	
3. Is the substance created by naturally occurring biological processes? [6502 (21)]			X	
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	
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			X	
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]		X		This IS a wholly natural product. There is no other natural anti-viral substitute product.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]	X			It is wild-harvested.
9. Is there any alternative substances? [§6518 m.6]		X		
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]		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.

Category 3. Is the substance compatible with organic production practices? Substance - Algae, Dumontiaceae, powdered

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	
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]	X			
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]	X			Petition p. 3, #12 “Petition Justification Statement” states that the substance is “sustainable[y] wild-harvested form the ocean in a manner which promotes continued reproduction which is consistent with sustainable agriculture.
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]			X	
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	
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:				
a. copper and sulfur compounds;		X		
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.

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 - Algae, Dumontiaceae, powdered**

Question	Yes	No	N/A	Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown)
1. <u>Is the comparative description provided</u> as to why the non-organic form of the material /substance is necessary for use in organic handling?	X			Petition includes an article which describes the health benefits of various ocean products. Dumontiaceae are specifically referred to as having viral-inhibiting properties. This effect from a non-drug source is desired by many consumers.
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 describes the review by their procurement department of trade journals and websites as having revealed no organic sources of this material. The material is described as being wild-harvested and does report any effort to encourage organic certification by the manufacturer or any obstacles which have become apparent to such certification.
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 provided on material / substance non-availability as organic, include (but not limited to) the following:		X		Petition states that this algae is indigenous to Pacific coastal areas of North America, but does not cite this as a factor which would limit a supply or organically certified Dumontiaceae.
a. Regions of production (including factors such as climate and number of regions);				
b. Number of suppliers and amount produced;		X		No information given
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		No information given.
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or		X		None indicated.
e. Are there other issues which may present a challenge to a consistent supply?		X		