

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: November 2008

Substance: Algae, Chlorella, powder

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, it fails to meet criteria in 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 the addition of Algae, Chlorella Powder to § 205.606

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		Prohibited ²	
Handling	<input checked="" type="checkbox"/>	Synthetic		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 did not mention the existence of certified organic chlorella and did not address why the certified organic material is not adequate for the petitioner's use.

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, Chlorella powder

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 , #5 describes that this algae is cultivated in tanks. Furthermore, Page 3 # 12, "Petition Justification Statement" describes these tanks as "hermetically-sealed."
3. Is the substance harmful to the environment? [§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		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		
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		Petition p. 2, #9 states that "Chlorella is a naturally-occurring biodegradable non-toxic plant."
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]		X		Petition p.2, #9 (c) states "[t]here are no toxic chemicals used to cultivate or process this plant therefore environmental impact is negligible."
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	(N/A – But, in fact, Petition p. 2 #9 (d) states that "Chlorella" contains "most vitamins needed in human nutrition.")
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]			X	(N/A – But petitioner included a letter from the FDA informing recipient that [chlorella] is not GRAS (meaning no one has applied for that status, as yet.)
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]			X	(N/A – Not when tank-grown. Chlorella has a well-documented tendency to absorb heavy metals when it occurs naturally in freshwater, brackish and marine environments)

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 2. Is the Substance Essential for Organic Production? Substance - Algae, Chlorella powder

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.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]	X			Certified organic Chlorella is currently on the market
9. Is there any alternative substances? [§6518 m.6]	X			Other certified organic vitamins sources such as flax seed.
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, Chlorella powder

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			
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:		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.

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, Chlorella 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 p. 3, #12 “Petition Justification Statement” describes that currently most chlorella cultivated is a “hard-shell” variety the nutrients of which are “bio-unavailable to humans.”
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		Evaluator’s research reveals at least one commercial producer of certified organic chlorella. Petitioner makes no reference to this producer and gives no indication as to why currently-available organic chlorella cannot be used.
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		None indicated (Probably not applicable)
a. Regions of production (including factors such as climate and number of regions);		X		Petition is glaring in it’s omission of at least one known producer of certified organic chlorella.
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		None indicated (Probably not applicable)
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or		X		None indicated (Probably not applicable)
e. Are there other issues which may present a challenge to a consistent supply?		X		None indicated