

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: March 2007

Substance: Annatto Color, Oil or Water Extracted

Committee: Crops Livestock Handling Petition is for inclusion of Annatto Color, Oil or Water Extracted 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 checked="" type="checkbox"/> | No <input 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 checked="" type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> |

B. Substance Fails Criteria Category: _____ **Comments:**

C. Proposed Annotation (if any): Organic Oil must be used for the oil extraction.

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

D. Recommended Committee Action & Vote (State Actual Motion): Recommend the inclusion of Annatto Color, Oil or Water Extracted, on the National List § 205.606.

Motion by: Julie Weisman Seconded: Andrea Caroe Yes: 2 No: 3 Absent: 0 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		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: Annotation is overly prescriptive. Material meets all criteria for listing on 205.606

4) Substance was recommended to be deferred because _____

_____ If follow-up needed, who will follow up _____ A friendly amendment can be made prior vote by the full Board to remove the annotation.

E. Approved by Committee Chair to transmit to NOSB:

Julie Weisman
Committee Chair

February 21, 2007
Date

NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? Substance – Annatto Color, Oil or Water Extracted

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		
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		
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 tolerances? [§205.600 b.5]		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 2. Is the Substance Essential for Organic Production? Substance – Annatto Color, Oil or Water
Extracted**

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		
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		
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 – Annatto Color, Oil or Water Extracted

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:				
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 - Annatto Color, Oil or Water Extracted

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			
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		Sensient petition
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		Sensient petition
5. Does the industry information provided on material / substance non-availability as organic, include (but 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			
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. Are there other issues which may present a challenge to a consistent supply?		X		