

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: November 2011

Substance: Annatto extract color (pigment CAS # 1393-63-1)—water and oil soluble

Committee: Crops Livestock Handling Petition is for removal of Annatto extract color (pigment CAS # 1393-63-1)—water and oil soluble 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 type="checkbox"/> | No <input checked="" type="checkbox"/> | N/A <input type="checkbox"/> |

B. Substance Fails Criteria Category: 4 Comments: At this time, the Handling Committee believes that sufficient evidence exists that both forms, liquid and powdered, of organic annatto extract color are available. We understand that there may be applications where the forms available do not perform. We ask that handlers or certifiers who are aware of these applications provide written public comment for the fall 2011 NOSB meeting so they can be considered.

C. Proposed Annotation (if any): Current annotation is "Oil and Water Extracted." Proposed annotation is "Liquid and powdered forms." See committee comments at end of document for details_____

Basis for annotation: To meet criteria above: X Other regulatory criteria: _____ Citation: The Handling Committee is recommending an annotation change to include both forms of annatto extract color so that the NOSB has the flexibility to list one or the other should public comment be received that the forms of organic extract color that are available do not perform in all applications

D. Recommended Committee Action & Vote (State Actual Motion): Recommend changing the annotation of Annatto Extract Color from "Water and Oil Soluble" to "Liquid and Powdered Forms."

Motion by: Heinze Secounded: Dickson Yes: 6 No: 0 Absent: 1 Abstain: 0

Recommend removing Annatto color, with all annotations, from the National List §205.606

Motion by: Heinze Secounded: Dickson Yes: 6 No: 0 Absent: 1 Abstain: 0

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

1) Substance voted to be REMOVED as "allowed" on National List to § 205. 606 with Annotation (if any) Liquid and Powdered Forms

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. _____. Describe why material was rejected: _____

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:

Steve Demuri
Committee Chair

September 29, 2011
Date

NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? Substance – Annatto extract color (pigment CAS # 1393-63-1)—water and oil soluble

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 extract color (pigment CAS # 1393-63-1)—water and oil soluble

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		Material is manufactured by extraction from the annatto seed with either oil or water combined with physical agitation.
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			This is the natural source
5. Is there an organic substitute? [§205.600 b.1]	X			Organic forms of this material are available in the marketplace
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]		X		Not used for production
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X			This is the natural source
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]	X			This petition is for evaluation of commercial availability. See category 4.
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 extract color (pigment CAS # 1393–63–1)—water and oil soluble

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		Primary use is as a color. However use is not to recreate or improve color lost in processing but to provide consumers with a color with which they are familiar. For example, cheddar cheese is orange due to use of annatto.
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 extract color (pigment CAS # 1393-63-1)—water and oil soluble

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			Annatto extract color (pigment CAS # 1393-63-1)—water and oil soluble was added to the National List (Federal Register Vol. 72, #123, June 27, 2007). The NOSB recommended relisting at the October 2010 NOSB meeting: http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5088016&acct=nosb
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		<p>When annatto was originally listed public comment was received saying that organic annatto seeds were not available. Today organic seeds are available. However, annatto is used in both a liquid and powdered form. During the Sunset 2012 review of this material public comment was received, and supported by an informal market review by the NOSB Handling Committee, that the liquid form was available. Mixed public comment was received about the availability of the powdered form. At the time, removing one form but not the other could not be done during the sunset review process.</p> <p>This petition is for the removal of all forms from §205.606. The petitioner states that they have provided an organic liquid form for some time and have just recently, spring 2010, introduced a powdered form. The Handling Committee has conducted a second informal market survey and found that some, but not most, products (e.g., some brands of organic mac & cheese) that would be expected to be using the powdered form have switched to using organic annatto.</p> <p>At this time, the HC believes that sufficient evidence exists that both forms, liquid and powdered, of organic annatto extract color are available. We understand that there may be applications where the forms available do not perform. We ask that handlers or certifiers who are aware of these applications provide written public comment for the fall 2011 NOSB meeting so they can be considered.</p>
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		Quality of the organic annatto extract color has not been a question. The committee has no information indicating that organic forms of the material are not commercially available.
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		The petitioner states that there is sufficient supply of organic annatto seeds and both liquid and powdered organic annatto extract color to meet demand. The committee has no information to contradict this statement.

5. Does the industry information provided on material / substance non-availability as organic, include (but 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			The petition is from the supplier of organic annatto extract color.
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		