

# NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: March 2007

Substance: Color, Grape Skin Extract

Committee: Crops  Livestock  Handling  Petition is for: \_\_\_\_\_  
 on the National List § 205.

<b>A. Evaluation Criteria</b> (Applicability noted for each category; Documentation attached)	<b>Criteria Satisfied? (see B below)</b>
1. Impact on Humans and Environment	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input checked="" type="checkbox"/>
2. Essential & Availability Criteria	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input checked="" type="checkbox"/>
3. Compatibility & Consistency	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input checked="" 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: Petitioner did not provide credible information regarding the lack of supply of organic raw materials and the ability to process them as organic

**C. Proposed Annotation (if any):** \_\_\_\_\_

Basis for annotation: To meet criteria above: \_\_\_\_\_ Other regulatory criteria: \_\_\_\_\_ Citation: \_\_\_\_\_

**D. D. Recommended Committee Action & Vote (State Actual Motion):** Recommend Colors, Grape Juice for inclusion on

§ 205.606 of the National List

Motion by: Julie Weisman Seconded: Andrea Caroe Yes: 1 No: 4 Absent: 0 Abstain: 0

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

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: Petitioner did not provide credible information regarding the lack of supply of organic raw materials and the ability to process them as organic

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 Weisman  
Committee Chair

February 24, 2007  
Date

**NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST**

**Category 1. Adverse impacts on humans or the environment?**

**Substance - Color, Grape Skin Extract**

Question	Yes	No	N/A <sup>1</sup>	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]				
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]				
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]				
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]				
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]				
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]				
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]				
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]				
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]				
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]				
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]				
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]				
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]				

<sup>1</sup>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 - Color, Grape Skin Extract**

Question	Yes	No	N/A <sup>1</sup>	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]				
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)]				
3. Is the substance created by naturally occurring biological processes? [6502 (21)]				
4. Is there a natural source of the substance? [§205.600 b.1]				
5. Is there an organic substitute? [§205.600 b.1]		XX		IACM Petition p.8, “Commercial Availability Statement Research” describes that numerous suppliers of organic colors or organic grapes were contacted and none supplied organic grape skin extract. Petitioner does not address the specific obstacles to sourcing organic grape skins or developing certified operators to process them.
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]				
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]				
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]				
9. Is there any alternative substances? [§6518 m.6]				
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]				

<sup>1</sup>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 3. Is the substance compatible with organic production practices? Substance - Color, Grape Skin Extract**

Question	Yes	No	N/A <sup>1</sup>	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]				
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]				
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]				
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]				
5. Is the primary use as a preservative? [§205.600 b.4]				
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]		XX		This material is not used to replace color lost during processing, but to enhance color of finished product to meet consumer expectations.
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:				
a. copper and sulfur compounds;				
b. toxins derived from bacteria;				
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?				
d. livestock parasiticides and medicines?				
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?				

<sup>1</sup>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 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 - Colors Grape Skin Extract**

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?	XX			IACM Petition p.8 “ #12 Petition justification statement” and Colormaker Petition p. 1 # 3 “Intended Use” both describe that grape skin extract is necessary the formulation of organic processed food products to meet the visual appeal expectations of 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 <b>form</b> to fulfill an essential function in a system of organic handling?	XX			Petitioner (IACM) Petition p.8 “Commercial Availability Research” describes that numerous suppliers of organic colors or organic grapes were contacted and none supplied organic grape skin extract. Petitioner does not address the specific obstacles to sourcing organic grape skins or developing certified operators to process them.
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 <b>quality</b> to fulfill an essential function in a system of organic handling?				IACM Petition p.8 # 11 “Commercial Availability Research” makes reference to the inferior quality of organic grapes as an obstacle to supply. But neither back of this statement with evidence.
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 <b>quantity</b> to fulfill an essential function in a system of organic handling?	XX			See comment for Question 2. above.
5. Does the industry information provided on material / substance non-availability as organic, include ( but not limited to) the following:		XX		No information is given in either petition to indicate that regions production are a factor in limiting the supply of organic grape skin extract.
a. Regions of production (including factors such as climate and number of regions);				
b. Number of suppliers and amount produced;		XX		No specific information is given in either of the petitions regarding the number of suppliers of organic grapes or grape juice or the quantity produced.
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;		XX		No information is given in either of these petitions to indicate that weather-related events are a factor in supply of this material as organic.
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or		XX		No information is given in either of these petitions to indicate that trade-related events are a factor in supply of this material as organic.
e. Are there other issues which may present a challenge to a consistent supply?		XX		No information is given in either of these petitions to describing any factors which may present a challenge to are in supply of this material as organic.