

# NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: **May 2008**

Substance: **Caramel Color**

Committee: Crops  Livestock  Handling  Petition is for: Inclusion of Caramel Color 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 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 checked="" type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/>            |

**B. Substance Fails Criteria Category:** \_\_\_\_\_ **Comments:** \_\_\_\_\_

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

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

**D. Recommended Committee Action & Vote (State Actual Motion): Inclusion of Caramel Color on the National List § 205.606**

Motion by: Joe Smillie Seconded: Katrina Heinze Yes: 0 No: 6 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>	X
No restriction		Commercially Un-Available as Organic <sup>1</sup>		Deferred <sup>4</sup>	

1) Substance voted to be added as "allowed" on National List to § 205.606 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: **Cost of production was a major reason of the petition, and committee rejected that as a basis.**

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

March 31, 2008  
Date

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

**Category 1. Adverse impacts on humans or the environment? Substance - Caramel Color**

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]		X		Product is produced from sugar ( agricultural commodity)
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		Agricultural Product used as ingredient in food products and no longer in eco-system
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		Agricultural Product used as ingredient in food products and no longer in eco-system
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		Agricultural Product used as ingredient in food products and no longer in eco-system
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		Agricultural Product used as ingredient in food products and no longer in eco-system
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]		X		Agricultural Product used as ingredient in food products and no longer in eco-system
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		

<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 - Caramel Color**

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)]		X		Sugar is the only ingredient and is caramelized
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			See above
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			Not in same form & quality
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	Not synthetic
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]			X	

<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 - Caramel Color**

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]			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		It has a color effects but not because it was lost in processing
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;		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		

<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 - Caramel Color**

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			The petitioner, a manufacturer who makes organic caramel color, can't make enough organic forms that are needed for specific production needs
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?	X			<p>Petitioner is an organic caramel manufacturer and cannot make all forms organic</p> <p>Many applications can't use organic formulations due to acidity and other requirements</p> <p>Comment was made by petitioner that producing all organic forms is "cost prohibitive". Cost cannot be a factor in the consideration of commercial availability</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 <b>quality</b> 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 <b>quantity</b> to fulfill an essential function in a system of organic handling?		X		Quantity is not an issue
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			Also phoned the major producer of organic caramel and they confirmed petitioner information
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			Complicated specifications for different types of reactions