

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: Spring 2007

Substance: Color, Beta-Carotene from Carrots

Committee: Crops Livestock Handling Petition is for: Inclusion of Beta-Carotene

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 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. Recommended Committee Action & Vote (State Actual Motion): Recommend Colors, Beta-carotene for listing on §205.606

Motion by: Julie Weisman Seconded: Andrea Caroe Yes: 4 No: 1 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 | <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: 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 19, 2007
Date

NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? Substance - Color, Beta-Carotene from Carrots

| Question | Yes | No | N/A¹ | Documentation (TAP; petition; regulatory agency; other) |
|---|------------|-----------|------------------------|--|
| 1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2] | | | X | This is an agricultural product. |
| 2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3] | | | X | This is an agricultural product. |
| 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 | This is an agricultural product used as an ingredient in an organic processed food. It is no longer in the agro-ecosystem. |
| 7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5] | | | X | This is an agricultural product used as an ingredient in an organic processed food. It is no longer in the agro-ecosystem. |
| 8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2] | | | X | This is an agricultural product used as an ingredient in an organic processed food. It is no longer in the agro-ecosystem. |
| 9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2] | | | X | This is an agricultural product used as an ingredient in an organic processed food. It is no longer in the agro-ecosystem. |
| 10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4] | | X | | See #12, below. |
| 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 | | | Carrots are considered GRAS by the FDA (CFR 21 § 182.10) Color additives, in general, cannot, by definition qualify for GRAS status, as GRAS only applies to food additives. |
| 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 - Color, Beta-Carotene from Carrots

| 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 | This is an agricultural product. |
| 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 | This is an agricultural product. |
| 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 | Petitioned substance is from a natural source. |
| 5. Is there an organic substitute? [§205.600 b.1] | | XX | | |
| 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 | Petitioned substance is a wholly natural product. |
| 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 - Color, Beta-Carotene from Carrots

| 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] | | 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: | | | 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 | |

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 - Color, Beta-Carotene from Carrots

| 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 | | | Petition p.1 # 3 states that beta-carotene is necessary the formulation of organic processed food products to improve visual appeal. |
| 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? | | XX | | Petition presents no information describing inability to obtain material in appropriate form. |
| 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? | | XX | | |
| 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? | XX | | | Petition p.4 #12 "Petition Justification Statement" states there is an insufficient supply of organic carrots for use in producing natural colorants. No specific information is given to support this assertion. |
| 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); | | XX | | No information is given in this petition to indicate that regions production are a factor in limiting the supply of organic carrot juice color. |
| b. Number of suppliers and amount produced; | | XX | | No specific information is given in this petition regarding the number of suppliers of organic carrots 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 specific information is given in this petition regarding weather events which may limit the supply of of organic carrots. |
| d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or | | XX | | |
| e. Are there other issues which may present a challenge to a consistent supply? | | XX | | |