

**Formal Recommendation by the
National Organic Standards Board (NOSB)
to the National Organic Program (NOP)**

Date: December 2, 2011

Subject: Petition for Annotation Change for Beta-carotene extract color, derived from carrots (CAS# 1393-63-1) on National List § 205.606

Chair: Tracy Miedema

The NOSB hereby recommends to the NOP the following:

Rulemaking Action X

Statement of the Recommendation (Including Recount of Vote):

The NOSB recommended by a vote of 14 yes, zero no and zero absent to change the annotation for Beta-carotene extract color, derived from carrots (CAS# 1393-63-1) to beta-carotene extract color, derived from carrots or algae (CAS#7235-40-7)

Rationale Supporting Recommendation (including consistency with OFPA and NOP):

A petition to change the annotation for Beta-Carotene Extract Color was reviewed by the NOSB at the November 2011 meeting. A summary of the Handling committee's recommendation is attached.

Beta-carotene extract color derived from carrots was originally recommended for listing on the National List section §205.606 in 2007 by the NOSB because of evidence that specific varieties of carrots/growing conditions were required to produce the color and none were available in organic form. Subsequently the NOSB has recommended that an annotation be added to the broad listing of colors, derived from agricultural products on §205.606. The added annotation change was "Must not be produced using synthetic solvents and carrier systems or any artificial preservative." The petition stated, and was supported by the Technical Review, that beta-carotene from carrots can only be extracted with synthetic solvents making it not commercially available for use in organic products. The beta-carotene derived from algae can be produced to meet the annotation.

Three public comments were received supporting the committee's recommendation. None were received that did not support the recommendation.

The NOSB voted unanimously to change the annotation for beta-carotene extract color.

NOSB Vote:

Moved: Steve DeMuri		Second: Katrina Heinze		
Yes: 14	No: 0	Abstain: 0	Absent: 0	Recusal: 0

NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment?

Substance - Color, Beta-carotene

extract, derived from carrots

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		Technical Review lines 531-545: "Production of beta-carotene from (algae) will surpass synthetic as well as other natural sources due to microalgae sustainability of production and their renewable nature."
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		Technical Review lines 531-545: "Production of beta-carotene from (algae) will surpass synthetic as well as other natural sources due to microalgae sustainability of production and their renewable nature."
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		Naturally present in variety of agricultural products
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 #11 below
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		X		Technical Review lines 136-140: Recognized as GRAS by FDA. Certification of the color not needed to protect human health
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]	X			Technical Review lines 136-140, 385-416: Recognized as GRAS by FDA.
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		X		Technical Review lines 485-492

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
 extract, derived 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		<p>Petition: Beta-carotene is produced from natural strains of the algae <i>D. salina</i> and is extracted from the algae using carbon dioxide, ethanol, or vegetable oil.</p> <p>Technical Report lines 243-248: Other extraction solvents that can be used to extract beta-carotene from algae are carbon dioxide, acetone, methanol, propan-2-ol, hexane, ethanol, and vegetable oil. Note that a previous NOSB recommendation (http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5088018&acct=nosb) recommended an annotation be added to the broad listing of colors, derived from agricultural products on §205.606. The added annotation change was “Must not be produced using synthetic solvents and carrier systems or any artificial preservative.”</p> <p>Full description of manufacturing, derived from algae, is listed in Technical Review lines 325-346. The TR also describes synthetic sources of beta-carotene. These are not the subject of this petition.</p>
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		Beta-carotene is extracted from the algae
3. Is the substance created by naturally occurring biological processes? [6502 (21)]	X			Beta-carotene produced by strains of algae (petition and TR)
4. Is there a natural source of the substance? [§205.600 b.1]			X	Petitioned material is from a natural source
5. Is there an organic substitute? [§205.600 b.1]		X		Beta-carotene derived from carrots was originally recommended for listing by the NOSB (see transcripts from Spring 2007 meeting) because of evidence that specific varieties of carrots/growing conditions were required to produce the color and none were available in organic form. This petition goes on (see question #1 above) to say that the color derived from carrots is not available in organic form because of the solvents that would be used for extraction.
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]	X			Petitioner states that color is used to make products meet consumer expectations.
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]			X	Petitioned material is from a natural source
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]	X			Material is being petitioned for listing on §205.606. See category 4.
9. Is there any alternative		X		Beta-carotene extract derived from carrots is currently

substances? [§6518 m.6]				<p>listed on §205.606. The petition is to add an annotation to also list beta-carotene extracted from algae. The petitioner states that beta-carotene extracted from carrots is not commercially available because use of synthetic solvents is required. The Technical Review supports that statement (lines 257-262, 353-355).</p> <p>Technical Review states that annatto color may be used as an alternate in some applications.</p>
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 extract, derived 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			Use of colors in organic handling is fairly common. There are other colors on §205.606
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]	X			Not used in farming. Use of colors in organic handling is fairly common
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]			X	This is an agricultural product used as an ingredient in an organic processed food. It is not used in agriculture.
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]	X			Nutritional quality of food not affected by use of color.
5. Is the primary use as a preservative? [§205.600 b.4]		X		Use is as a color in handling products
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		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	Petitioned material is not for use in production
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 agricultural substance inconsistently or not commercially available as organic?

Substance - Color, Beta-carotene extract, derived from carrots

Question	Yes	No	N/A	Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown)
1. Is the comparative description provided as to why the non-organic form of the material /substance is necessary for use in organic handling?	X			The petitioner states that beta-carotene extracted from carrots is not commercially available because use of synthetic solvents is required. The Technical Review supports that statement (lines 257-262, 353-355).
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	
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	
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);			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			See response to question #1.