

Formal Recommendation
From: National Organic Standards Board (NOSB)
To: the National Organic Program (NOP)

Date:

Subject:

Chair:

The NOSB hereby recommends to the NOP the following:

Rulemaking Action:

Guidance Statement:

Other:

Statement of Recommendation: (Motion # 1)

Motion to classify Beta Carotene as petitioned as synthetic.

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

Beta Carotene, as petitioned, is synthetic.

Committee Vote:

Moved:

Seconded:

Yes:

No:

Abstain:

Absent:

Recuse:

Statement of Recommendation: (Motion # 2)

Failed

Motion to add Beta-Carotene as petitioned to 205.605(b) for use in infant formula.

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

Beta Carotene is not required for inclusion in infant formula, therefore the committee had concerns regarding the addition of a synthetic material that is not absolutely necessary. Further, the ingredient was petitioned for use as an anti-oxident, with the primary function of stabilizing the lipids in the formula, and therefore acting as a preservative. This provided further disincentive to list the synthetic.

Committee Vote:

Moved:

Seconded:

Yes:

No:

Abstain:

Absent:

Recuse:

**National Organic Standards Board
 Handling Subcommittee
 Petitioned Material Proposal
 Synthetic Beta-Carotene**

August 7, 2012

Summary of Proposed Action:

1. Petitioned for inclusion on 205.605(b) synthetic, non-agricultural addition to “organic” and “made with organic” ingredients
2. The synthetic version is what is being petitioned but there are natural versions of the ingredient on the market. Commercial availability may be a limiting factor.
3. The petition mentions for use in infant formula as a nutritional supplement and to prevent lipid components in the formula from going rancid (preservative) and as a colorant.
4. Beta-Carotene is necessary for proper development of retinas, and acts as an anti-oxidant, and in some cases as preservative.
5. Is considered GRAS as a food additive for nutrition. As a food colorant, it is exempt from certification (colors are not considered GRAS).
6. B-C can be manufactured from a variety of processes including wholly chemical, from natural sources including fungi and algae, but these methods typically use toxic solvents.
7. BASF is a key manufacturer of the ingredient
8. Commercially available manufacturing process utilizes toxic solvents and/or solvents that pose environmental risk to aquatic species if released.
9. One method of manufacture uses relatively benign solvent made from soy and corn feedstuffs.
10. Only one method from natural dehydrated carrots was discussed.
11. B-C is not required for inclusion in infant formula, therefore the committee had concerns regarding the addition of a synthetic material that is not absolutely necessary.

Evaluation Criteria

(Applicability noted for each category; Documentation attached)

Satisfied? (see “B” below)

	Criteria
1. Impact on Humans and Environment No <input type="checkbox"/> N/A	X Yes <input type="checkbox"/>
2. Essential & Availability Criteria No <input type="checkbox"/> N/A	X Yes X
3. Compatibility & Consistency No <input type="checkbox"/> N/A	X Yes <input type="checkbox"/>
4. Commercial Supply is Fragile or Potentially Unavailable No <input type="checkbox"/> N/A as Organic (only for § 205.606)	<input type="checkbox"/> Yes X

Substance Fails Criteria Category: [] **Comments:**

Proposed Annotation (if any):

Basis for annotation: To meet criteria above Other regulatory criteria

Citation

Notes:

Recommended Committee Action & Vote, including classification recommendation (state actual motion):

Classification Motion: Classify Beta-Carotene as petitioned as synthetic

Motion by: Tracy Favre

Seconded by: Harold Austin

Yes: # 5 No: # 0 Absent: #2 Abstain: # 0 Recuse: # 0

Listing Motion: Add Beta-Carotene as petitioned to 205.605(b) for use in infant formula.

Motion by: Tracy Favre Seconded by: Joe Dickson

Yes: # 0 No: # 5 Absent: # 2 Abstain: # 0 Recuse: # 0

Crops	<input type="checkbox"/>	Agricultural	<input type="checkbox"/>	Allowed¹	<input type="checkbox"/>
Livestock	<input type="checkbox"/>	Non-synthetic	<input type="checkbox"/>	Prohibited²	<input type="checkbox"/>
Handling	<input checked="" type="checkbox"/>	Synthetic	<input type="checkbox"/>	Rejected³	<input checked="" type="checkbox"/>
No restriction	<input type="checkbox"/>	Commercial unavailable as organic	<input type="checkbox"/>	Deferred⁴	<input type="checkbox"/>

¹Substance voted to be added as “allowed” on National List to § 205. with Annotation (if any):

²Substance to be added as “prohibited” on National List to § 205. with Annotation (if any):

Describe why a prohibited substance:

³Substance was rejected by vote for amending National List to § 205. . Describe why material was rejected: The committee was reluctant to approve the addition of a synthetic material that was not absolutely necessary.

⁴Substance was recommended to be deferred because
If follow-up needed, who will follow up:

Approved by Committee Chair to Transmit to NOSB

John Foster, Committee Chair

August 7, 2012

NOSB Evaluation Criteria for Substances Added To the National List

Category 1. Adverse impacts on humans or the environment?

Substance: Synthetic Beta-Carotene

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	X		Potential exists for environmental damage due to solvents used in the extraction process, which are toxic to aquatic life
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]	X	X		The solvents used in the manufacturing process are not easily biodegraded and must be properly recycled, leading to potential for improper disposal or spillage. Under proper recycling there is no environmental contamination.
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]	X	X		Could be harmful should solvents used in manufacturing be improperly disposed of
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]				Information not available
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]	X	X		See comments above regarding potential for environmental contamination
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]	X	X		See comments above regarding potential for environmental contamination
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. Are there any harmful effects on human health? [§6517 c (1)(A)(i);	X	X		Some studies have linked beta-Carotene with increases in lung

6517 c(2)(A)i; §6518 m.4]				cancer of smokers, but generally the effects of the ingredient are considered beneficial
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]	X	X		See comments above
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]	X			When considered as a nutritional additive, when as a colorant GRAS is not applicable
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]	X	X		The FDA has established residue limits for heavy metals but there is no evidence that contamination exists in the ingredient

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Evaluation Criteria for Substances Added To the National List

Category 2. Is the Substance Essential for Organic Production?

Substance: Synthetic Beta-Carotene

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			Per both the petition and TR, the ingredient is considered synthetically manufactured
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	X		The most common formulation of the petitioned ingredient is wholly synthetic and is manufactured using a Confidential method, however there are other methods using solvent extraction from naturally occurring sources
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		The petitioned material is Synthetic Beta-Carotene
4. Is there a natural source of the substance? [§205.600 b.1]	X			Beta-Carotene is widely available in red, orange and yellow fruits and vegetables, leafy greens, some types of fungus and algae
5. Is there an organic substitute? [§205.600 b.1]	X	X		Beta-Carotene can be extracted from plants using environmentally benign solvents from fermented corn and soybean feedstocks, but it is not clear whether this process would be considered organic
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]	X	X		As a nutritional additive, Beta-Carotene has unique anti-oxidant and preservative properties, but the use as a color additive could be replaced with alternatives such as organic annatto.
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X			Naturally derived Beta-Carotene is an alternate source, although commercial viability is an issue
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]	X			Beta-Carotene may be produced by extraction from some fungi and algae using solvents
9. Is there any alternative substances? [§6518 m.6]	X	X		Organic annatto could be used as a replacement for color additive, but would not address the anti-

				oxidant and preservative properties of Beta-Carotene
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.

NOSB Evaluation Criteria for Substances Added To the National List

Category 3. Is the substance compatible with organic production practices?

Substance: Synthetic Beta-Carotene

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		Synthetic Beta-Carotene is wholly synthetic manufactured from chemical compounds
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			Beta-Carotene is used as a nutritional substance as a precursor to Vitamin A
5. Is the primary use as a preservative? [§205.600 b.4]	X	X		Beta-Carotene is used as both a preservative of lipids (in infant formula, for instance) but also as nutritional supplement
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			A use of Beta-Carotene is as a coloring agent but the ingredient has other uses as described above
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;				
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,			X	

row covers, and equipment cleaners?				
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¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Evaluation Criteria for Substances Added To the National List

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: Name Synthetic Beta-Carotene**

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
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		Neither the TR nor petition makes it clear as to why synthetic Beta-Carotene is necessary over natural
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			There is some discussion that there is only one naturally derived substitute that is commercially available.
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	

b. Number of suppliers and amount produced;	X	X		Two suppliers are mentioned but no quantities are listed
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	X	
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or		X	X	
e. Are there other issues which may present a challenge to a consistent supply?			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.