NOP Compliance and Enforcement Branch
Agricultural Marketing Service
United States Department of Agriculture
1400 Independence Avenue, S.W.
Mail Stop 0268, Room 2648-S
Washington, D.C. 20250-0268

November 10, 2014

Dear Mr. McEvoy,

We ask that your office investigate possible violations of the National Organic Program standards by Nurture, Inc.

Nurture, Inc. introduced a new product, called "Happy Tot Organic Toddler Milk," in October 2014. The product is marketed to children aged 12-24 months. The organic standards require that products sold as "organic" must be produced and handled without the use of nonagricultural substances, except as provided in section 205.605 (the "National List"). The ingredients in Happy Baby Organic Toddler Milk that do not appear on the National List are ascorbyl palmitate, beta carotene, choline chloride, inositol, taurine and l-carnitine.

These ingredients were all petitioned to be added to the National List. Four of the six petitions were rejected in their entirety, and two of the six petitions were approved only for use in infant formula or medical nutritional enteral products and have not been added to the National List by the USDA.

Ingredients rejected by the NOSB

- **Ascorbyl palmitate**: This material does not appear on the National List. It was petitioned to be added to the National List as a synthetic preservative for use in organic infant formula. The National Organic Standards Board voted on October 17, 2012 and rejected the petition.

- **Beta carotene**: Like ascorbyl palmitate, beta carotene was petitioned to be added to the National List as a synthetic preservative for use in organic infant formula. The National Organic Standards Board voted on October 17, 2012 and rejected the petition.

- **Taurine**: This material does not appear on the National List. Taurine was petitioned to be added to the National List. On October 16, 2012, the National Organic Standards Board voted and rejected the petition.

- **L-carnitine**: This material does not appear on the National List. L-carnititne was petitioned to be added to the National List. On October 16, 2012, the National Organic Standards Board voted and rejected the petition.

Ingredients approved by the NOSB with restrictions, and not yet added to the National List by the USDA

- **Choline chloride:** This material does not appear on the National List. The material was petitioned to be added to the National List, and the National Organic Standards Board voted on May 25, 2012 to add choline chloride to the National List "for use in infant formula and medical nutritional enteral products labeled organic or made with organic (specified ingredients or food groups)." The USDA has not added choline chloride to the National List, and the NOSB has not approved its use in organic products other than infant formula and medical nutritional enteral products. We do not believe Happy Baby's "toddler milk" is either an infant formula or medical nutritional enteral product.

- **Inositol**: Like choline, inositol does not appear on the National List. The material was petitioned to be added to the National List, and the National Organic Standards Board voted on May 25, 2012 to add inositol to the National List "for use in infant formula and medical nutritional enteral products labeled organic or made with organic (specified ingredients or food groups)." The USDA has not added inositol to the National List, and the NOSB has not approved its use in organic products other than infant formula and medical nutritional enteral products. The USDA has not added inositol to the National List, and the NOSB has not approved its use in organic products other than infant formula and medical nutritional enteral products. We do not believe Happy Baby "toddler milk" is either an infant formula or medical nutritional enteral product.

Please note that the four synthetic nutrients (choline, inositol, taurine and l-carnitine) do not appear on 21 CFR 104.20, Nutritional Quality Guidelines for Foods. We believe they therefore also do not qualify to be added to organic foods under the "Nutrients vitamins and minerals, in accordance with 21 CFR 104.20" listing on the National List.

Given that the National Organic Standards Board specifically rejected four of the six synthetic materials for use in organic foods and did not approve two of the six for use in foods other than infant formula and medical nutritional enteral products, we ask that your office investigate these possible violations of the national organic standards.

Sincerely,

Urvashi Rangan, Ph.D.
Executive Director
Food Safety and Sustainability Center, Consumer Reports

Charlotte Vallaeys
Senior Policy Analyst
Food Safety and Sustainability Center, Consumer Reports

INGREDIENTS: ORGANIC SKIM MILK POWDER, ORGANIC VEGETABLE OILS (PALM OR PALM OLEIN, SOY, COCONUT, HIGH OLEIC (SAFFLOWER OR SUNFLOWER)), ORGANIC GLUCOSE SYRUP SOLIDS, ORGANIC MALTODEXTRIN, LESS THAN 1%: MORTIERELLA ALPINA OIL*, CRYPTHECODINIUM COHNII OIL**, MIXED TOCOPHEROL CONCENTRATE, ORGANIC SOY LECITHIN, VITAMIN A PALMITATE, VITAMIN D (CHOLECALCIFEROL), VITAMIN E (dl-ALPHA TOCOPHERYL ACETATE), VITAMIN K (PHYTONADIONE), ASCORBYL PALMITATE, BETA-CAROTENE, THIAMINE HYDROCHLORIDE, RIBOFLAVIN, PYRIDOXINE HYDROCHLORIDE, CYANOCOBALAMIN, NIACINAMIDE, FOLIC ACID, CALCIUM PANTOTHENATE, BIOTIN, ASCORBIC ACID, CHOLINE CHLORIDE, INOSITOL, CALCIUM CARBONATE, CALCIUM HYDROXIDE, CALCIUM PHOSPHATE, CUPRIC SULFATE, FERROUS SULFATE, MAGNESIUM CHLORIDE, MANGANESE SULFATE, POTASSIUM BICARBONATE, POTASSIUM CHLORIDE, POTASSIUM IODIDE, POTASSIUM PHOSPHATE, SODIUM CITRATE, SODIUM SELENITE, ZINC SULFATE, TAURINE, L-CARNITINE. **CONTAINS MILK, SOY, AND COCONUT INGREDIENTS.**

* A SOURCE OF ARACHIDONIC ACID (ARA)
** A SOURCE OF DOCOSAHEXAENOIC ACID

shine organic toddler milk: milk drink

Our Happy Tot Grow & Shine Organic is formulated to support your toddler during this vital time in his or her life with organic non-GMO ingredients and specific nutrition for continued development. Our Happy Tot blend provides support for Brain & Eye, Immune System, and Growth & Development – to ensure that your toddler has what it takes to Grow & Shine!

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

Date: October 17, 2012

Subject: Petition to add ascorbyl palmitate (CAS 137-66-6) to section 205.605(b)

Chair: Barry Flamm

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: ☐ Petition Failed

Guidance Statement: ☐

Other: ☐

Statement of Recommendation: (Motion # 1) Passed

Motion to classify ascorbyl palmitate as petitioned (CAS 137-66-6) as synthetic.

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

Ascorbyl palmitate as petitioned is synthetic.

Committee Vote:

Moved: Nick Maravell

Seconded: Jean Richardson

Yes: 15 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Statement of Recommendation: (Motion # 2) Failed

Motion to add Ascorbyl palmitate (CAS 137-66-6) to the National List section 205.605(b) for use as a preservative in infant formula.

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

Ascorbyl palmitate (AP) is not required by the FDA or other regulation to be added to infant formula. Permitted alternatives exist, including fat soluble ones, but none have been evaluated for use in infant processed foods. AP is a synthetic preservative and should not be added to the National List under restriction of 205.600(b)(4).

Committee Vote:

Moved: Nick Maravell

Seconded: Jean Richardson

Yes: 4 No: 11 Abstain: 0 Absent: 0 Recuse: 0

National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
Ascorbyl Palmitate

August 14, 2012

Summary of Proposed Action:
Ascorbyl palmitate (AP) is a synthetic ester of ascorbic acid and palmitic acid used in infant formula as a preservative. FDA lists it as GRAS. Ascorbyl Palmitate has antioxidant properties, but, as the TR states " it remains inconclusive whether or not the body actually utilizes ascorbic acid that is metabolized from AP".

Ascorbyl palmitate has some advantages as a food preservative because it is fat soluble and very slightly water soluble. AP synergistically improves the effectiveness of other preservatives, such as tocopherols, to protect fats and oils from rancidity and prevent rancid flavor. It is used in cosmetics, animal feeds and margarine to reduce rancidity (Petition page 2). Synthetic AP is currently used in infant formula to stabilize DHA and ARA edible oils. AP, DHA, and ARA are not required by FDA to be added to infant formula.

Use of AP for stabilizing edible oils raises the issue of a lack of an established policy on "other ingredients." In December 2011 the NOSB approved use of DHA from Algal Oil and ARA from Fungal Oil, and specifically did not approve all the "other ingredients" (which included AP) for broad use in organic food. Approval was specific and explicitly not precedent setting, applying only to the petitioned formulations of DHA and ARA.

Organic alternatives to Ascorbyl palmitate exist, especially rosemary extract and tocopherols. Synthetic tocopherols are also an alternative on the National List if organic rosemary extracts are not suitable. The Petition asserts that tocopherols are currently used in infant formulas, but have limited function without AP. Another alternative is to shorten shelf life date.

Agricultural organic alternatives to AP have not been evaluated for use in infant formula. The TR states, "Other organic agricultural fat-soluble antioxidants which may be potential alternative preservatives include, but are not limited to, alpha-tocopherol (vitamin E), beta-carotene, alpha-lipoic and dihydrolipoic acids, and ubiquinone. … Like ascorbyl palmitate, ubiquinone and dihydrolipoic acid can function as synergistic antioxidants to regenerate tocopherols. No information was found to indicate whether or not these other fat-soluble antioxidants have been tested as alternatives to ascorbyl palmitate as preservatives in food or cosmetics, or are readily available for commercial use in processed foods."

According to the petitioner, certain organic alternative preservatives (carnosic acid from rosemary extract) could have effects harmful to pregnant mothers and unknown side effects in infants. No scientific data has been presented to show adverse effects or the

relative degree of efficacy of using rosemary extract in infant formula. However, the NOSB recommendation approving DHA Algal Oil and ARA Fungal Oil recognized that rosemary extract was included in both materials. It must be noted that the Petition (page 7) states “for infant formula rosemary extracts are not a suitable option” and further states that “rosemary extracts have not been tested and accepted for use in infant formula” and it is “not prudent to use these substances in food for young infants” (Petition, page 8).

As reported by the Journal of the European Food Safety Authority (June 2008), a study in rats found no effect of rosemary extract on fetus development or on the ability of the fetus to reach full term. However, this same scientific opinion states, “The toxicological data on the rosemary extracts are insufficient to establish a numerical ADI [Acceptable Daily Intake], because the toxicity data set does not provide reproductive toxicity studies or a long term study. On the other hand, the existing data, including the absence of effects in the 90-day studies on reproductive organs and lack of genotoxicity, do not give reason for concern.”

Ascorbyl palmitate, as petitioned for use in “organic” infant formula, is not used to fortify food or add nutritional value.

AP is not listed for use as a preservative in organic infant formula in European, Canadian or Japanese standards. In European standards it appears that AP as vitamin C is permitted in organic infant formula to the extent it is required by infant formula directives on vitamins (although, as noted above, data is inconclusive on actual potential absorption of ascorbic acid from AP).

According to the TR, AP does not have significant adverse impacts on the environment or on human health, although it is noted in the Petition (page 5) that high levels of ascorbic acid increase oxalic acid production and excretion with potential for oxalate bladder stones.

Evaluation Criteria

(Applicability noted for each category; Documentation attached)	**Criteria Satisfied? (see “B” below)**		
1. Impact on Humans and Environment	x☐ Yes	☐ No	☐ N/A
2. Essential & Availability Criteria	☐ Yes	x☐ No	☐ N/A
3. Compatibility & Consistency	☐ Yes	x☐ No	☐ N/A
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for § 205.606)	☐ Yes	☐ No	x☐ N/A

Substance Fails Criteria Category: [2 &3] **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: Ascorbyl palmitate (CAS 137-66-6) is synthetic.
Motion by: Nick Maravell Seconded by: Jean Richardson
Yes: 6 No: 0 Absent: 1 Abstain: 0 Recuse: 0

Listing Motion: To add Ascorbyl palmitate (CAS 137-66-6) to the National List sec 205.605(b) for use as a preservative in infant formula.
Motion by: Nick Maravell Seconded by: Jean Richardson
Yes: 0 No: 6 Absent: 1 Abstain: 0 Recuse: 0

Crops	☐	**Agricultural**	☐	**Allowed[1]**	☐
Livestock	☐	**Non-synthetic**	☐	**Prohibited[2]**	☐
Handling	x☐	**Synthetic**	x☐	**Rejected[3]**	x☐
No restriction	☐	**Commercial unavailable as organic**	☐	**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 § 205.605(b). Describe why material was rejected: Ascorbyl palmitate (AP) is not required by FDA or other regulation to be added to infant formula. Permitted alternatives exist, including fat soluble ones, but none have been evaluated for use in infant processed foods. Objections to organic rosemary abstract are not supported by scientific data. DHA and ARA, already added to list, contain rosemary extracts. AP is a synthetic preservative and should not be added to the National List under restriction of 205.600(b)(4).
[4]Substance 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 8/14/12

NOSB Evaluation Criteria for Substances Added To the National List

Category 1. Adverse impacts on humans or the environment? Substance: Ascorbyl palmitate

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		TR
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		x		
3. Is the substance harmful to the environment and biodiversity? [§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		
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		
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]		x		
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4]	x			At high doses ascorbic acid increases oxalic acid production and excretion with potential for oxalate bladder stones (Petition, page 5)
11. Is there an adverse effect on human health as defined by		x		

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]	x			
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		x		

[1]If 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: Ascorbyl palmitate

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			Petition; TR lines 227-234
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		Not the petitioned material.
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		
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]		x		Shorter shelf life of product
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	x			Natural alternatives, such as rosemary oil and extracts, for addition to infant formula have not been evaluated.
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			Tocopherols, derived from vegetable oils, and "only when rosemary extracts are not a suitable alternative" TR lines 124-125
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	x			Breast feeding.

[1]If 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: Ascorbyl palmitate

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		TR (lines 317-318) states AP "is used as a preservative, which includes the prevention of off-flavors or bad odors during shelf life of product".
5. Is the primary use as a preservative? [§205.600 b.4]	x			Petition and TR state; "The primary function of ascorbyl palmitate is as a preservative" (TR line 301)
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			Primary use is to prevent "development of off-flavors or bad odors that would otherwise occur over time" (TR line 303)
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: 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	

[1]If 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 Ascorbyl palmitate**

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
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	
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: a. Regions of production (including factors such as climate and number of regions);			x	
b. Number of suppliers and			x	

amount 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;			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	

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

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

Date: October 17, 2012

Subject: Petition to add beta carotene to §205.605(b) for use in infant formula

Chair: Barry Flamm

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: ☐ Petition Failed

Guidance Statement: ☐

Other: ☐

Statement of Recommendation: (Motion # 1) Passed

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: Tracy Favre

Seconded: Colehour Bondera

Yes: 15 No: 0 Abstain: 0 Absent: 0 Recuse: 0

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: Tracy Favre

Seconded: Harold Austin

Yes: 1 No: 14 Abstain: 0 Absent: 0 Recuse: 0

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)	**Criteria Satisfied? (see "B" below)**
1. Impact on Humans and Environment	X Yes ☐ No ☐ N/A
2. Essential & Availability Criteria	X Yes X No ☐ N/A
3. Compatibility & Consistency	X Yes ☐ No ☐ N/A
4. Commercial Supply is Fragile or Potentially Unavailable	☐ Yes X No ☐ N/A
as Organic (only for § 205.606)	

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	☐	**Agricultural**	☐	**Allowed**[1]	☐
Livestock	☐	**Non-synthetic**	☐	**Prohibited**[2]	☐
Handling	**X**	**Synthetic**	☐	**Rejected**[3]	**X**
No restriction	☐	**Commercial unavailable as organic**	☐	**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. . Describe why material was rejected: The committee was reluctant to approve the addition of a synthetic material that was not absolutely necessary.

[4]Substance 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

[1]If 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	

[1]If 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: 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,			X	

row covers, and equipment cleaners?				

[1]If 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. Is the comparative description provided 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	

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

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

Date: October 16, 2012

Subject: Petition to add Taurine to 205.605(b) on the National List

Chair: Barry Flamm

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: ☐ Petition Failed

Guidance Statement: ☐

Other: ☐

Statement of Recommendation: (Motion # 1) Passed

Motion to classify Taurine as petitioned (CAS # 107-35-7) as synthetic

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

Taurine is a b-amino-sulfone created by chemical processes (Technical Report, 2011, lines 23 and 262)

Committee Vote:

Moved: Jean Richardson

Seconded: Colehour Bondera

Yes: 15 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Statement of Recommendation: (Motion # 2) Failed

Motion to list Taurine as petitioned (CAS # 107-35-7) at 205.605 (b)

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

The petitioned use does not fit into any of the allowable uses of synthetics in 7 USC Section 6517, and its use fails the criteria for essentiality and compatability with organic and sustainable agriculture. The NOSB recommends against approving the petition

Committee Vote:

Moved: Jean Richardson

Seconded: Tracy Favre

Yes: 1 No: 14 Abstain: 0 Absent: 0 Recuse: 0

National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
Taurine

July 3, 2012

Summary of Proposed Action:

Taurine is a compound that is synthesized in the body from methionine and cysteine metabolism. While not technically an amino acid it is more accurately classified as a B-amino sulfone. It is found in animal protein such as seafood, beef and chicken and nearly absent from vegetarian foods. The synthetic form has been petitioned for use in infant formula because insufficient taurine could result in subpar fat digestion and absorption in infants.

Taurine is not required under the FDA in 21 CFR 104.20(d)(3), 107.100 or 107.10. Taurine can be made or extracted from non-synthetic sources, although apparently available only in small amounts at this time. Although essential for cats and thus added to cat pet food, taurine is considered a non-essential human dietary supplement.

The Handling Sub-committee is not recommending addition of Taurine to the National List.

Evaluation Criteria

(Applicability noted for each category; Documentation attached) **(see "B" below)**	**Criteria Satisfied?**
1. Impact on Humans and Environment	x☐ Yes ☐ No ☐ N/A
2. Essential & Availability Criteria	☐ Yes X No ☐ N/A
3. Compatibility & Consistency	☐ Yes X No ☐ N/A
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for § 205.606)	☐ Yes ☐ No X N/A

Substance Fails Criteria Category: [2] **Comments:**
This substance is not deemed essential by FDA regulations for fortification of infant formula

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: Taurine (CAS# 107-35-7) as petitioned is synthetic.
Motion by: Jean Richardson Seconded by: Joe Dickson
Yes: 4 No: 0 Absent: 3 Abstain: 0 Recuse: 0

Listing Motion: To add Taurine (CAS 107-35-7) to the National List 205.605 b for use in infant formula only.

Motion by: Seconded by:
Yes: 0 No: 4 Absent: 3 Abstain: 0 Recuse: 0

Crops	☐	**Agricultural**	☐	**Allowed**[1]	☐
Livestock	☐	**Non-synthetic**	☐	**Prohibited**[2]	☐
Handling	X	**Synthetic**	X	**Rejected**[3]	X
No restriction	☐	**Commercial unavailable as organic**	☐	**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. . Describe why material was rejected:
[4]Substance 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 July 3, 2012

NOSB Evaluation Criteria for Substances Added To the National List

Category 1. Adverse impacts on humans or the environment? Substance: Taurine

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		Inasmuch as the TR addressed this issue there does not appear to be adverse environmental effects
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		
3. Is the substance harmful to the environment and biodiversity? [§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		
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?		X		

Handling:Taurine

[§6518 m.2]				
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]		X		
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4]		X		None cited in TR
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	X		TR Line 290 "taurine is not listed as GRAS.."
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		X		

[1]If 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: Taurine

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			There are non-synthetic ways to manufacture taurine (TR lines 264-268) much of the taurine used is created by commercial chemical processes (TR lines 262-263)
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		
3. Is the substance created by naturally occurring biological processes? [6502 (21)]	X	X		Taurine is extracted from natural sources (TR 264-268) but only in small quantities
4. Is there a natural source of the substance? [§205.600 b.1]	X			Abundant in animal protein in food sources, and in human breast milk.
5. Is there an organic substitute? [§205.600 b.1]	X			Organic food
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			Human breast milk
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			Human breast milk
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			Breast feeding

[1] If 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: Taurine

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		Because the substance could be obtained from organic foods the synthetic dietary supplement fortification is not compatible with organic handling
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		Taurine is a non-essential dietary supplement (TR), lack of which "could result in subpar fat digestion and absorption by infants" (Petition, page 4, paragraph 4)
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		
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: 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	

[1]If 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: Taurine**

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
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			Provided, but not detailed.
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: 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	

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

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

Date: October 17, 2012

Subject: Petition to add L-carnitine to §205.605 (b) for infant formula

Chair: Barry Flamm

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: ☐ Petition Failed

Guidance Statement: ☐

Other: ☐

Statement of Recommendation: (Motion # 1) Passed

Motion to classify L-Carnitine [CAS #541-15-1] as petitioned as synthetic.

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

L-carnitine occurs naturally in food, but the form being petitioned is synthetic.

Committee Vote:

Moved: Zea Sonnabend

Seconded: Tracy Favre

Yes: 15 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Statement of Recommendation: (Motion # 2) Failed

Motion to add L-Carnitine [CAS #541-15-1] as petitioned to the National List 205.605 (b)--for use in infant formula only.

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

L-Carnitine [CAS #541-15-1] is not deemed essential by FDA regulations for the fortification of infant formula.

Committee Vote:

Moved: Zea Sonnabend

Seconded: Colehour Bondera

Yes: 6 No: 9 Abstain: 0 Absent: 0 Recuse: 0

National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
L-Carnitine

June 19, 2012

Summary of Proposed Action:
L-Carnitine is a compound that is synthesized in the body from the amino acids lysine and methionine. These amino acids are abundant in foods such as beans, avocado and red meat. The synthetic form has been petitioned for use in infant formula because soy-based formulas contain very low levels of carnitine, and infants are less able to synthesize carnitine for themselves. Cow's milk formulas also can be low in carnitine because the milk is diluted in the formula.

Unlike some other ingredients petitioned for infant formula, carnitine is not required under the FDA in 21 CFR 104.20, 107.100 or 107.10 as clarified in the NOP proposed rule on Nutrient Vitamins and Minerals. Also it appears that carnitine would be feasible to make or extract from non-synthetic sources, although that is not commercially done at this time. For these reasons the Handling Sub-committee is not recommending to add synthetic L-carnitine to the National List.

Evaluation Criteria

(Applicability noted for each category; Documentation attached)	**Criteria Satisfied? (see "B" below)**
1. Impact on Humans and Environment	X Yes ☐
No ☐ N/A	
2. Essential & Availability Criteria	☐ Yes X
No ☐ N/A	
3. Compatibility & Consistency	☐ Yes X
No ☐ N/A	
4. Commercial Supply is Fragile or Potentially Unavailable	☐ Yes ☐
No X ☐ N/A	
as Organic (only for § 205.606)	

Substance Fails Criteria Category: [2] **Comments:**
This substance is not deemed to be essential by FDA regulations for the fortification of infant formula.

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: L-Carnitine [CAS #541-15-1] as petitioned is synthetic.
Motion by: Zea Sonnebend Seconded by: Harold Austin
Yes: # 5 No: # 0 Absent: # 1 Abstain: # 0 Recuse: #0

Listing Motion: To add L-Carnitine [CAS #541-15-1] to the National List 205.605 (b)--for use in infant formula only.
Motion by: John Foster Seconded by: Harold Austin
Yes: # 2 No: # 3 Absent: # 1 Abstain: # 0 Recuse: #0

Crops	☐	**Agricultural**	☐	**Allowed[1]**	☐
Livestock	☐	**Non-synthetic**	☐	**Prohibited[2]**	☐
Handling	**x**	**Synthetic**	**x**	**Rejected[3]**	**x**
No restriction	☐	**Commercial unavailable as organic**	☐	**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. Describe why material was rejected: It appears that carnitine would be feasible to make or extract from non-synthetic sources, although that is not commercially done at this time.

Approved by Committee Chair to Transmit to NOSB

John Foster, Committee Chair June 19, 2012

NOSB Evaluation Criteria for Substances Added To the National List

Category 1. Adverse impacts on humans or the environment? Substance: L-Carnitine

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		
2. Is there environmental contamination during manufacture,		X		

use, misuse, or disposal? [§6518 m.3]				
3. Is the substance harmful to the environment and biodiversity? [§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		
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		
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); 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			may be self identified. See TR Evaluation question #4 (lines 350 - 363)
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		X		

[1]If 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: L-Carnitine

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			while there are non-synthetic ways to manufacture it, most in use for supplementation is synthesized from epichlorhydrine or trimethlamine. (TR lines 285-287)
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		
3. Is the substance created by naturally occurring biological processes? [6502 (21)]	X	X		it can be produced by "biosynthetic or fermentative methods" (TR lines 294-295) but it is not clear if these would be considered non-synthetic. It appears from the TR discussion for Evaluation questions #1 and #2, that non-synthetic production would be possible but is not commercially done in the US at this time.
4. Is there a natural source of the substance? [§205.600 b.1]	X			abundant in food and human breast milk.
5. Is there an organic substitute? [§205.600 b.1]	X			organic food
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			human breast milk
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]		X		
9. Is there any alternative	X			human breast milk

substances? [§6518 m.6]				
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			breast feeding

[1]If 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: L-Carnitine

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		since the substance could be obtained from organic foods, the synthetic fortification is not compatible with organic handling.
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		
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: 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,			X	

insect traps, sticky barriers, row covers, and equipment cleaners?				

[1]If 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**

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
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			provided but not convincing.
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: a. Regions of production (including factors such as			X	

climate and number of regions);				
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	

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

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

Date: **May 25, 2012**

Subject: **Petition to add Choline to § 205.605(b) of the National List**

Chair: **Barry Flamm**

The NOSB hereby recommends to the NOP the following:

Rulemaking Action **___x_____**
Guidance Statement **_____**
Other **_____**

Statement of the Recommendation (Including Recount of Vote):

Classification Motion: Move that Choline chloride (CAS 67-48-1) and Choline bitartrate (CAS 87-67-2) are synthetic. (don't have vote count)

Moved: Zea Sonnabend **Second:** Jean Richardson
Yes: 15 **No: 0** **Abstain: 0** **Absent: 0** **Recusal: 0**

Listing Motion: **1**. Move to add Choline chloride (CAS 67-48-1) and Choline bitartrate (CAS 87-67-2) to the National List 205.605(b) for use in infant formula and medical nutritional enteral products labeled organic or made with organic (specified ingredients or food group(s))
Vote: 11 yes, 4 no, 0 abstain, 0 absent, 0 recuse

Rationale Supporting Recommendation (including consistency with OFPA and NOP):
Consistent with OFPA and NOP policies, this petitioned substance was determined to be synthetic and only approved for infant formula as mandated by the FDA. The substance is deemed essential in infant formula by regulating authorities but the NOSB committee does not feel it is essential to supplement it for adults.

Committee Vote-Classification:
Moved: Zea Sonnabend **Second:** Jean Richardson
Yes: 15 **No: 0** **Abstain: 0** **Absent: 0** **Recusal: 0**

Committee Vote-Listing:

Moved: Zea Sonnabend **Second:** Jean Richardson

Yes: 11 **No: 4** **Abstain: 0** **Absent: 0** **Recusal: 0**

Choline Amendment

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

Classification Motion: Move that Choline chloride (CAS # 67-48-1) and Choline bitartrate (CAS # 87-67-2) are synthetic.
Motion by: Zea Sonnabend Seconded by: Harold Austin
Yes: # 5 No: # 0 Absent: # 1 Abstain: # Recuse: #

Listing Motion: **1**. Move to add Choline chloride (CAS # 67-48-1) and Choline bitartrate (CAS # 87-67-2) to the National List 205.605(b) for use in infant formula **and medical nutritional enteral products** labelled organic or made with organic (specified ingredients or food group(s))
Motion by: Zea Sonnabend Seconded by: Harold Austin
Yes: # 5 No: # 0 Absent: # 1 Abstain: # Recuse: #

Listing Motion: **2**. Move to add Choline chloride (CAS # 67-48-1) and Choline bitartrate (CAS # 87-67-2) to the National List 205.605(b) for use only in agricultural products other than infant formula **and medical nutritional enteral products** labeled "made with organic (specified ingredients or food group(s))" and prohibited in agricultural products labeled "organic".
Motion by: Zea Sonnabend Seconded by: Tracy Favre
Yes: # 5 No: # 0 Absent: # 1 Abstain: # Recuse: #

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

Date: **May 25, 2012**

Subject: **Petition to add Inositol §205.605(b) of National List**

Chair: **Barry Flamm**

The NOSB hereby recommends to the NOP the following:

Rulemaking Action **___x_____**
Guidance Statement **_____**
Other **_____**

Statement of the Recommendation (Including Recount of Vote):

Classification Motion: Move that inositol (CAS 87-89-8 (myo-inositol) and 6917-35-7 (non-specific isomer) are synthetic. (
Vote: 15 yes 0 no Abstain: 0 Absent: 0 Recusal: 0

Listing Motion: **1**. Move to add inositol (CAS 87-89-8 (myo-inositol) and 6917-35-7 (non-specific isomer) to the National List §205.605(b) for use in infant formula and medical nutritional enteral products labeled organic or made with organic (specified ingredients or food group(s))
Vote: 10 yes 5 no Abstain: 0 Absent: 0 Recusal: 0

Rationale Supporting Recommendation (including consistency with OFPA and NOP):
Consistent with OFPA and NOP policies, this petitioned substance was determined to be synthetic and only approved for infant formula as mandated by the FDA. See also attached recommendation.

Committee Vote-Classsification:
Moved: John Foster **Second:** Joe Dickson
Yes: 15 **No: 0** **Abstain: 0** **Absent: 0** **Recusal: 0**

Committee Vote-Listing:
Moved: John Foster **Second:** Joe Dickson
Yes: 10 **No: 5** **Abstain: 0** **Absent: 0** **Recusal: 0**

National Organic Standards Board
Handling Committee
Petitioned Material Proposal
Inositol

May 25, 2012

Summary of Proposed Action:
Inositol is an important biologic compound that serves numerous biologic functions/roles including but not limited to the following: a structural component of cell membranes, messenger molecules in reactions/processes, assist in overall muscle function and cell growth. Inositol may be formed endogenously using glucose as a substrate or it may be obtained by the human body through dietary sources. In addition to the aforementioned roles, inositol has been found to influence fat accumulation within the liver/intestines, control triacyglycerol and esterified cholesterol levels, and impact insulin resistance. Due to its association with these biologic processes/conditons, inositol is often marketed as a dietary supplement for those with these afflictions. The category of dietary supplements in the United States are not required to be regulated by the FDA in order to assure the validity and safety of using a substance to treat conditions, and as long as no health claims are made on the supplement they may be sold to American consumers without restrictions.

Inositol is found naturally in many foods which include fruits, beans, grains, seeds, and nuts. Another notable source of inositol is human breast milk which has been found to contain high concentrations of inositol (1500-4000 mM/L) as stated in the March 2012 Tap review. The FDA list inositol as Generally Recognized as Safe (GRAS) for human consumption by the under 21 CFR 184.1370 and also mandates that all infant formulas sold in the United States must contain a minimum 4mg/ 100 kilocalories of inositol in order to assure infants fed solely on formula sources acquire adequate nutrition to grow as successfully as breast-fed infants.

Commercial production of inositol is often obtained from hydrolysis and acidification that begins from the corn/rice steeping process by using the phytic acid extracted from the corn/rice, and then using this phytic acid in one of several different chemical processes that ultimately results in isolating inositol. Additional methods also include utilization of microbial byproducts and processes (yeast); however these reactions are also dependent on synthetic reactions, or reactions that would not normally occur in nature to produce the final product of isolated inositol. Therefore, while inositol is a natural compound, the methods by which we can obtain commercial quantities of inositol are synthetic.

The Handling Committee, based on public comment received at the Spring 2012 meeting amended the previously recommended proposal to include CAS numbers and to allow for the use of the substance in medical applications as specified in the annotation.

Evaluation Criteria

(Applicability noted for each category; Documentation attached)	**Criteria Satisfied? (see "B" below)**		
1. Impact on Humans and Environment	Ⅹ Yes	☐ No	☐ N/A
2. Essential & Availability Criteria	Ⅹ Yes	☐ No	☐ N/A
3. Compatibility & Consistency	Ⅹ Yes	☐ No	☐ N/A
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for § 205.606)	☐ Yes	☐ No	Ⅹ N/A

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

Proposed Annotation (if any):

Basis for annotation: Ⅹ To meet criteria above ☐ Other regulatory criteria ☐ Citation
Notes:

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

Classification Motion: Move that inositol as petitioned (CAS Numbers: 87-89-8 (myo-inositol) 6917-35-7 (non-specific isomer) is synthetic.

Motion by: John Foster Seconded by: Joe Dickson
Yes: # 6 No: # 0 Absent: # 0 Abstain: # 0 Recuse: # 0

Listing Motion: **1**. Move to add inositol (CAS Numbers: 87-89-8 (myo-inositol) 6917-35-7 (non-specific isomer) to the National List 205.605(b) for use in infant formula and medical nutritional enteral products labelled organic or made with organic (specified ingredients or food group(s))

Motion by: John Foster Seconded by: Joe Dickson
Yes: # 6 No: # Absent: # 0 Abstain: # Recuse: #

Listing Motion: **2**. Move to add inositol (CAS Numbers: 87-89-8 (myo-inositol) 6917-35-7 (non-specific isomer) to the National List 205.605(b) for use only in agricultural products other than infant formula and medical nutritional enteral products labeled "made with organic (specified ingredients or food group(s))" and prohibited in agricultural products labeled "organic".

Motion by: John Foster Seconded by: Joe Dickson
Yes: # 6 No: # Absent: # 0 Abstain: # Recuse: #

Crops	☐	**Agricultural**	☐	**Allowed**[1]	X
Livestock	☐	**Non-synthetic**	☐	**Prohibited**[2]	☐
Handling	x	**Synthetic**	X	**Rejected**[3]	☐
No restriction	☐	**Commercial unavailable as organic**	☐	**Deferred**[4]	☐

[1]Substance voted to be added as "allowed" on National List to § 205.605 with Annotation (if any):

As noted above.

[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. Describe why material was rejected:

[4]Substance 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 May 25, 2012

NOSB Evaluation Criteria for Substances Added To the National List

Category 1. Adverse impacts on humans or the environment? Substance:

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		TR 3/9/12

2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		x		TR 3/9/12
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]		x		TR 3/9/12
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		
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		
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]			x	
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		

[1]If 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:

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			
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			May be obtained through yeast hydrolysis
3. Is the substance created by naturally occurring biological processes? [6502 (21)]	x			Yes, but can also be made synthetically
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		
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]	x			Yes, but only for infant formula as req in 21 CFR 107.100
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		Mass production is via synthetic pathways. Could be produced using organic yeast to provide organic inositol
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		

[1] If 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:

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]		x		Nutritive, but not replacing nutrients
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: 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		

[1]If 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

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
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	
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			x	

supply?				

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