

**National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
Lycopene**

July 24 2012

Summary of Proposed Action:

Synthetic lycopene is currently used in organic infant formula. Under previous NOP policy regarding nutrient vitamins and minerals, an interpretation was made that synthetic ingredients such as lycopene were allowed without being added to the National List. Current NOP policy requires a specific addition to the National List. Lycopene is neither a vitamin nor a mineral. Lycopene is a carotenoid used as a dietary antioxidant and a color. Its petitioned use is not as a preservative or a color.

In 1995, the NOSB made the following recommendation in “The Use of Nutrient Supplementation in Organic Foods”.

Upon implementation of the National Organic Program, the use of synthetic vitamins, minerals, and/or accessory nutrients in products labeled as organic must be limited to that which is required by regulation or recommended for enrichment and fortification by independent professional associations.

The NOP did not include “accessory nutrients” in the final rule published in December 2000. Lycopene is not required by FDA or other regulation for infant formula. Neither the petition nor the Technical Review (TR) states that any independent professional association recommends it as an accessory nutrient at any specific level for enrichment or fortification. Neither the petition nor the TR presented definitive scientific information to conclude that lycopene is essential for addition to infant formula. The manufacturer notification to FDA of GRAS status (generally recognized as safe) for synthetic forms of lycopene for nutrient use does not include use in infant formula.

The human body does not produce Lycopene. However, depending on the amount of Lycopene consumed in the diet of lactating mothers, Lycopene appears in varying amounts in colostrum and breast milk. Lycopene is added to infant formula to make it more closely resemble breast milk. Levels of lycopene from natural sources in infant formulas are low. Natural and organic sources of lycopene are derived mainly from tomatoes. These sources also contain proteins from the originating plant that could be allergens. According to the petition, it is advisable to delay the introduction of potential allergens in infants less than 6 months old or even older for infants with allergy prone parents. There is no evidence that an allergy to tomatoes would produce allergic reactions to nonsynthetic lycopene, and the information in the TR hypothesized that allergic reactions to tomatoes are related to acidity and not specifically to lycopene.

The TR presented very little information on what alternatives are available in infant formula. Lycopene in breast milk is nonsynthetic. Natural and organic lycopene can be consumed in many foods, especially tomatoes, by lactating mothers. The TR states,

“The commercial use of nonsynthetic lycopene in infant formula, rather than synthetic lycopene, has not been reported, and no evidence indicating that nonsynthetic lycopene would act as a viable substitute for synthetic lycopene in infant formula has been identified.” Nonorganic agricultural lycopene for use as a coloring was rejected for addition to the National List by the NOSB in 2007 for lack of justification for not producing lycopene from organic sources. There is no allowance for synthetic lycopene in organic infant formula or other organic foods in European, Canadian or Japanese organic standards.

Synthetic crystalline lycopene, the petitioned material, involves the use of synthetic solvents dichloromethane and toluene in the extraction process. The TR states, “Synthetic lycopene may also contain residues of volatile solvents. However, no information has been identified to indicate that any reported residues of heavy metals or other contaminant in excess of FDA tolerances have been identified.” Information is presented on residual extracting solvents in the final product in a different form (not petitioned) of synthetic lycopene produced from *B. trispora* by the manufacturer Vitatene.

Evaluation Criteria

(Applicability noted for each category; Documentation attached)

(see “B” below)

Criteria Satisfied?

- | | |
|--|--|
| <ul style="list-style-type: none"> 1. Impact on Humans and Environment
<input type="checkbox"/> N/A 2. Essential & Availability Criteria
<input type="checkbox"/> N/A 3. Compatibility & Consistency
<input type="checkbox"/> N/A 4. Commercial Supply is Fragile or Potentially Unavailable
x
as Organic (only for § 205.606) | <ul style="list-style-type: none"> x <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes x <input type="checkbox"/> No <input type="checkbox"/> Yes x <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> |
|--|--|

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: Moved that Crystalline Lycopene be classified as a synthetic material.

Motion by: Zea Sonnabend Seconded by: Tracy Favre
Yes: 5 No: # Absent: 2 Abstain: # Recuse: #

Listing Motion: Moved that Crystalline Lycopene (CAS #502-65-8) for use in infant formula be added to the National List sec. 205.605(b).

Motion by: Jean Richardson

Seconded by: Harold Austin

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

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 checked="" 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: Not essential to or consistent with organic production.

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

July 24, 2012

NOSB Evaluation Criteria for Substances Added To the National List

Category 1. Adverse impacts on humans or the environment?

Substance: Lycopene

Question	Yes	No	N/A¹	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]		x		No specific information found with regard to use of volatile synthetic solvents to demonstrate no adverse effects.
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		x		No specific information found with regard to use of volatile synthetic solvents to demonstrate no adverse effects.
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	

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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			Self certified as GRAS but not for infant formula.
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		x		

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

NOSB Evaluation Criteria for Substances Added To the National List

Category 2. Is the Substance Essential for Organic Production?

Substance: Lycopene

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 and TR.
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		
4. Is there a natural source of the substance? [§205.600 b.1]	x			Foods high in lycopene, such as tomatoes.
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		
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	x			Agricultural sources, such as tomatoes.
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			Natural agricultural lycopenes.
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	x			Breast feeding.

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: Lycopene

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	Not a processing aid or adjuvant as referred to in 205.600(b)(2)
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:			x	
a. copper and sulfur compounds;			x	
b. toxins derived from bacteria;			x	
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?			x	
d. livestock parasiticides and medicines?			x	
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?			x	

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

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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: Lycopene**

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	
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			x	

production or destroy crops or supplies;				
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	