

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 Lutein as petitioned (CAS 127-40-2) as synthetic

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

The petitioner claims that the method of Lutein extraction would make it a non-synthetic material. However, based on the petitioner's public testimony that saponification (esterification or de-esterification) is a process involving the use of multiple solvents and is part of the formulation process, which was confirmed in the technical report, the NOSB recommends the listing of Lutein (CAS 127-40-2) as a synthetic. (Technical Evaluation Report April 26, 2012).

Committee Vote:

Moved:

Seconded:

Yes:

No:

Abstain:

Absent:

Recuse:

Statement of Recommendation: (Motion # 2)

Failed

Motion to list Lutein (CAS 127-40-2) on 205.605(b) for use in infant formula only, using approved organic delivery ingredients on the National List section 205.605(b): Non-agricultural (non-organic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

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

While Lutein is not listed by the FDA under 21 CFR 104.20(d)(3), nor is it required by FDA in infant formula at 21 CFR §107.100 or §107.10, it is currently in use by organic handlers. Public comment was split, with approximately half in favor of listing Lutein, and half not in favor. Supporters cited benefits for eye and neural health in infants, however, the NOSB did not find it to be essential or required by FDA for any use.

Committee Vote:

Moved: Harold Austin

Seconded: Jean Richardson

Yes: 6

No: 9

Abstain: 0

Absent: 0

Recuse: 0

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

July 17, 2012

Summary of Proposed Action:

Lutein (commonly referred to as xanthophyll) is a carotenoid, is related to beta-carotene. It is a strong antioxidant, as well as a natural pigment. Lutein is present in many vegetables such as: spinach, kale, broccoli, and green peas. The petitioned Lutein is derived from dried food grade marigolds. This is the primary source of Lutein used as a coloring agent, food and livestock feed additive, and as a nutritional supplement. Lutein comprises the macular pigment of the eye and is found in the lens. It acts as a filter to blue light and serves an important role in eye health. All Lutein must be acquired through ones diet and cannot be synthesized by the body.

The primary source of Lutein for young infants is from human breast milk. The level of Lutein in human breast milk will vary depending on the dietary intake of Lutein rich vegetables by the infant's mother. This will vary in different parts of the world due to cultural dietary eating habits. Cow milk or soy based infant formulas would need to be fortified with Lutein to equal the amounts normally found in human breast milk.

This ingredient is not listed by the FDA under 21 CFR 104.20(d)(3).

The petitioner has requested their product listed as **Lutein- derived from marigold: (*Tagetes erecta*), and meeting the "Lutein" monograph established by the U.S. Pharmacopeia ("USP")** (when mixed with organic delivery ingredients including organic corn or safflower oil, and organic sugar and starch) as a listed substance pursuant to 7CFR 205.606, on the National List of Allowed and Prohibited Substances in the category of "Non-organically produced agricultural products allowed as ingredients in or on processed products labeled as 'organic'". They are requesting to list two specific uses of Lutein : (1) In organically labeled Infant Formula, (2) In organically labeled foods. The current petitioned source of Lutein is currently being used in organic handling. Because Lutein falls into the "*accessory nutrients*" category and was not one of the substances listed in 21CFR 104.20(d)(3) it is being petitioned for inclusion to the list of allowed substances. Because the actual method of producing Lutein is Confidential Business Information (CBI), the sub-committee could not verify that Lutein would be considered non-synthetic. Therefore the recommendation for classification of Lutein as petitioned is synthetic.

The Handling Sub-Committee was split on the listing of Lutein for use in infant formula. The basis of those voting in favor of listing it was that it currently is being used in some organic infant formulas and secondly because of the role it plays in the eye health of infants (and adults). Those on the sub-committee opposed to listing Lutein believe it is not a mandated additive by FDA for infant formula, did not have enough information in

the CBI version of the petition to determine it to be non-synthetic, it does not appear to be “essential” since it is in some brands and not in others, and there appear to be viable non-synthetic alternatives such as whey protein and microalgae sources. The rationale behind the sub-committee choosing not to include the petitioners request for the second proposed listing, for use in organically labeled foods, is based on the fact that there are currently several alternatives available as a food additive. There are also many natural and organic sources available for adults to obtain Lutein through their diet.

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

Substance Fails Criteria Category: [2] **Comments:** This substance has not been deemed to be essential by the FDA regulations for use in fortification of infant formulas.

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: Lutein (CAS 127-40-2) as petitioned as a synthetic.

Motion by: Harold Austin

Seconded by: Jean Richardson

Yes: # 7 No: # 0 Absent: # 0 Abstain: # 0 Recuse: # 0

Listing Motion: To add Lutein (CAS 127-40-2) to the National List 205.605(b) for use in infant formula only. Lutein using approved organic delivery ingredients.

Motion by: Harold Austin

Seconded by: John Foster

Yes: # 3 No: # 4 Absent: # 0 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	x	Rejected³	x
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: This substance has not been deemed to be essential by the FDA regulations for use in fortification of infant formulas.

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, Subcommittee Chair

July 17, 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/A¹	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]		X		Does require large amounts of land mass to produce. Solvents used during process of extraction could pose a potential threat to the environment. TR lines 502-512
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		Solvent storage tanks could be a potential hazard. TR lines 516-519
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		

Handling:Lutein

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		There is some speculation that it may play a role in Autism and ADHDD. No scientific support of these claims were found. TR lines 539-543
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			While the substance is not listed as GRAS, the petitioner has received several non-objection responses from the FDA for the use of Lutein, as petitioned. TR lines 416-433
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:

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			Solvents (hexane, isopropyl alcohol, etc) are used during the two step extraction process. TR lines 326-329
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			The petitioner claims that it uses a process similar to that used in the manufacture of Pectin or Lecithin- unbleached. TR lines 373-378 mention this claim. The TR lines 384-389
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			Human breast milk. Green vegetables such as spinach, kale, broccoli, and green peas.
5. Is there an organic substitute? [§205.600 b.1]	X			Powdered Lutein processed from green vegetables can be made, but the amount needed to equal the marigold source is not feasible in handling and food processing. Beta-carotene would be an alternate source as a coloring agent. Green vegetables and human breast milk.
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. The TR (lines 120-122) also mentions skim milk powder and whey protein.
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?	X			The TR (lines 120-122) indicates that skim milk powder and whey

[§6518 m.6]				protein are possible sources of Lutein. The TR (lines 360-371) discusses obtaining lutein from microalgae, which may be a truly non-synthetic source and appears to be feasible, although not in commercial production at this time.
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:

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			It can be used as a color additive, but the primary petition purpose is as a nutritional additive.
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		

Handling:Lutein

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. <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: a. Regions of production (including factors such as climate and number of			X	

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	

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