

**National Organic Standards Board
Handling Committee
Petitioned Material Proposal
Choline**

March 20, 2012

Summary of Proposed Action:

Choline is a synthetically made nutrient that also occurs naturally in food. It is considered by most regulatory bodies to be essential in non-milk-based infant formula and is required by the FDA for this purpose. It is permitted but not required to be added to milk-based infant formulas. All the organic infant formula brands that could be found through an internet search contain added choline, both milk-based and non-milk-based.

Choline has been petitioned for addition to adult food items as well as infant formula. There is no compelling reason to think that this is essential to handling organic food, although it is not harmful either. Therefore there are 2 proposed actions on choline. First, to add it to the National List for use in infant formula labeled organic or made with organic (). Second, to add it to the National List for use only in agricultural products other than infant formula labeled "made with organic (specified ingredients or food group(s))" and prohibited in agricultural products labeled "organic".

Allowing it in adult foods that are in the Made with organic category would allow such foods to highlight the fact they are fortified, while at the same time limiting the number of non-essential synthetics in organic processing.

Evaluation Criteria

(Applicability noted for each category; Documentation attached)
"B" below)

Criteria Satisfied? (see

1. Impact on Humans and Environment

☒ Yes ☐ No ☐ N/A

2. Essential & Availability Criteria

☒ Yes ☒ No ☐ N/A

3. Compatibility & Consistency

☒ Yes ☐ No ☐ N/A

4. Commercial Supply is Fragile or Potentially Unavailable
as Organic (only for § 205.606)

☐ Yes ☐ No ☒ N/A

Substance Fails Criteria Category: Essential Comments:

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.

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: Move that Choline as petitioned is synthetic.

Motion by: Zea Sonnabend

Seconded by: Harold Austin

Yes: # 5 No: # 0 Absent: # 1 Abstain: # 0 Recuse: # 0

Listing Motion: 1. Move to add Choline to the National List 205.605(b) for use in infant formula labeled 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 to the National List 205.605(b) for use only in agricultural products other than infant formula 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: # 0 Recuse: # 0

Crops	☐	Agricultural	☐	Allowed¹	☐
Livestock	☐	Non-synthetic	☐	Prohibited²	☐
Handling	☐	Synthetic	☐	Rejected³	☐
No restriction	☐	Commercial unavailable as organic	☐	Deferred⁴	☐

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:

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

March 20, 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		
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?		X		

[§6517c(1)(A)(i);6517(c)(2)(A)i]				
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		

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			
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			food sources are abundant, such as eggs, liver, wheat germ, lecithin, human milk.
5. Is there an organic substitute? [§205.600 b.1]	X	X		food sources can be organic but are not strictly substitutes in infant formula.
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]		X		all the products in the petition can be made without this substance, although it is required by the FDA in non-milk-based infant formula.
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X			For uses in adult food, the food is a substitute. In infant formula there is no natural substitute.
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	
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			breastfeeding. However in some circumstances breastfeeding is not feasible.

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			nutritional quality is improved.
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 is required by law for non-milk-based infant formula only.
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	Although this is considered a vitamin on product labels, it is not considered a vitamin by other entities.
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.

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		Other than for infant formula, there seems no compelling justification as to why choline should not be obtained from organic food sources.
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		same as above.
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);				
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	

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