

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: U

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

Committee Vote:

Moved:

Seconded:

Yes:

No:

Abstain:

Absent:

Recuse:

Statement of Recommendation: U . . .

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

Committee Vote:

Moved:

Seconded:

Yes:

No:

Abstain:

Absent:

Recuse:

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

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	<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	X	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:

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 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/A¹	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		

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: 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

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: 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:			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.

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. <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			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:			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 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.