

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:

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
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)

Satisfied? (see "B" below)

- | | Criteria |
|--|---|
| 1. Impact on Humans and Environment No <input type="checkbox"/> N/A | X Yes <input type="checkbox"/> |
| 2. Essential & Availability Criteria No <input type="checkbox"/> N/A | <input type="checkbox"/> Yes X |
| 3. Compatibility & Consistency No <input type="checkbox"/> N/A | <input type="checkbox"/> Yes X |
| 4. Commercial Supply is Fragile or Potentially Unavailable No X <input type="checkbox"/> N/A as Organic (only for § 205.606) | <input type="checkbox"/> Yes <input type="checkbox"/> |

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:

| | | | | |
|---|---|---|--|---|
| 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 | | |

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:
L-Carnitine

| Question | Yes | No | N/A¹ | 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 trimethylamine. (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 |

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: 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: | | | X | |
| a. copper and sulfur compounds; | | | | |
| 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 | |

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

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 | | | 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 | |

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|--|--|--|---|--|
| 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 | |

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