

Formal Recommendation
From: National Organic Standards Board (NOSB)
To: the National Organic Program (NOP)

Date: April 21, 2017

Subject: L-Methionine - petitioned

NOSB Chair: Tom Chapman

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: X

Guidance Statement:

Other:

Statement of the Recommendation:

The NOSB recommends that the petitioned material, L-Methionine, be added to the National List at §205.605(b) as petitioned: allowed in or on nutritionally complete enteral pediatric formulas labeled “organic” or “made with organic (specific ingredients)” with the annotation “for use in nutritionally complete pediatric enteral formulas based on soy protein”.

Rationale Supporting Recommendation:

L-Methionine is an essential amino acid, without which soy-based enteral pediatric formulas would be nutritionally deficient. The NOSB recommends the addition of L-Methionine so that organic soy-based enteral products may meet the nutritional requirements for protein. The Centers for Medicaid and Medicare, has defined nutritionally complete pediatric enteral formulas through the Healthcare Common Procedure Coding System (HCPCS).

NOSB Vote:

Classification Motion: Move to classify L-Methionine as petitioned, as non-agricultural, synthetic

Motion by: Tracy Favre

Seconded by: Harold V. Austin, IV

Yes: 15 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Listing Motion: Move to list L-Methionine at §205.605(b) as petitioned: allowed in or on nutritionally complete enteral pediatric formulas labeled “organic” or “made with organic (specific ingredients)” with the following annotation: “for use in nutritionally complete pediatric enteral formulas based on soy protein”.

Motion by: Tracy Favre

Seconded by: Jean Richardson

Yes: 15 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Motion Passed

**National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
L-Methionine**

January 17, 2017

Summary of Petition

Nature's One has petitioned for L-Methionine to be added to §605.205(b) as a synthetic, non-agricultural substance, allowed in or on nutritionally complete enteral pediatric formulas labeled "organic" or "made with organic (specific ingredients)" with the annotation, "for use in nutritionally complete pediatric enteral formulas based on soy protein".

Summary of Review:

L-Methionine is an essential amino acid, which cannot be synthesized by the human body. The material exists as a clear or white powder.

L-Methionine exists in a category around which there has been much controversy, specifically, the addition of synthetic nutrient vitamins and minerals and accessory nutrients on the National List.

In 1995, the National Organic Standards Board (NOSB) made the following recommendation in "The Use of Nutrient Supplementation in Organic Foods" (USDA, 2011) *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.* (2012 TR, lines 162-167)

Since that recommendation, the National Organic Program (NOP) published a proposed rule that clarifies a previous reference to FDA's 21 CFR 104.20 for nutrient vitamins and minerals, which indicates that L-Methionine would not be allowed under that provision. Hence the separate petition for its inclusion on the National List.

Nature's One has petitioned for the addition of L-Methionine to the National List at §205.605(b) with a very narrow annotation. The material was petitioned so that organic soy-based enteral products may meet the nutritional requirements for protein. While the FDA does not have specific requirements for enteral products, a sister agency, The Centers for Medicaid and Medicare, has defined nutritionally complete pediatric enteral formulas through the Healthcare Common Procedure Coding System (HCPCS). B4159 is the HCPCS for nutritionally complete pediatric enteral formulas based on soy protein.

Category 1: Classification

1. Substance is for: **Handling**

2. For HANDLING and LIVESTOCK use:
 - a. Is the substance **Agricultural** or **Non-Agricultural**?
Describe reasoning for this decision using NOP 5033-2 as a guide:

b. If the substance is **Non-agricultural**, is the substance ___ **Non-synthetic** or **X** **Synthetic**? Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [OFPA §6502(21)] If so, describe, using NOP 5033-1 as a guide:

3. For **LIVESTOCK**:

Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i)]; copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers; or (ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern?

Category 2: Adverse Impacts

1. What is the potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems? [§6518(m)(1)]
None identified. L-Methionine is a synthetic material petitioned for use in the formulation of enteral soy-based pediatric formulas and would have no impact on other materials used in organic farming systems.
2. What is the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment? [§6518(m)(2)].
Physiologically, methionine is required for nitrogen balance, cell metabolism, protein formation, and growth (Brosnan and Brosnan, 2006). (2012 TR lines 61-62).
The material breaks down into nitrogen oxides, carbon monoxide, sulfur oxides and carbon dioxide. (2012 TR lines 53-54).
3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)].
None identified. There are several processes used to manufacture L-Methionine. The most commonly used is an enzymatic process.
4. Discuss the effect of the substance on human health. [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)].
Methionine is an essential amino acid that cannot be synthesized by the body; thus, it is used primarily as a dietary supplement in humans and a feed additive in livestock. Physiologically, methionine is required for nitrogen balance, cell metabolism, protein formation, and growth (2012 TR, lines 60-62, Brosnan and Brosnan, 2006).
5. Discuss any effects the substance may have on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock. [§6518(m)(5)]
N/A. L-Methionine is a synthetic, manufactured and used in final product formulations.

6. Are there any adverse impacts on biodiversity? (§205.200)
N/A

Category 3: Alternatives/Compatibility

1. Are there alternatives to using the substance? Evaluate alternative practices as well as non-synthetic and synthetic available materials. [§6518(m)(6)].
As petitioned, there is no suitable alternative for L-Methionine in soy-based pediatric enteral formulas. L-Methionine is added to soy based formulas in order to meet protein requirements for pediatric formulas.
2. **For Livestock substances, and Nonsynthetic substances used in Handling:** In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]
N/A

Category 4: Additional criteria for synthetic substances used in Handling (does not apply to nonsynthetic or agricultural substances used in organic handling):

Describe how the petitioned substance meets or fails to meet each numbered criterion.

1. The substance cannot be produced from a natural source and there are no organic substitutes; (§205.600(b)(1)).
As petitioned, protein levels in organic soy-based formulas are insufficient without the addition of L-Methionine.
2. The substance's manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling; (§205.600(b)(2)).
Most L-methionine is produced from synthetic DL-methionine, and DL-methionine can be produced in following ways: In general, L-methionine is produced from DL-methionine via optical resolution or by enzymatic selection. Because much of the DL-methionine supply is synthesized using chemical methods, the L-methionine produced from it is also synthetic. While non-synthetic L-methionine can be produced by fermentation, there are no commercial sources available that use this method (Kumar and Gomes, 2005). (2012 TR lines 279-284)
3. The nutritional quality of the food is maintained when the substance is used, and the substance, itself, or its breakdown products do not have an adverse effect on human health as defined by applicable Federal regulations; (§205.600(b)(3)).
The nutritional quality of the food is deficient in soy-based enteral formulas without the addition of L-Methionine.

4. The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law; (§205.600(b)(4)). L-Methionine is for nutritional amendment only and does not improve flavors, colors, or nutritive value lost during processing.
5. The substance is listed as generally recognized as safe (GRAS) by the Food and Drug Administration (FDA) when used in accordance with FDA's good manufacturing practices (GMP) and contains no residues of heavy metals or other contaminants in excess of tolerances set by FDA; (§205.600(b)(5)) . Yes, L-Methionine is listed as GRAS. (2012 TR line 97).
6. The substance is essential for the handling of organically produced agricultural products. (§205.600(b)(6)) The addition of L-Methionine is essential for soy-based enteral formulas due to the need to supplement protein levels.
7. In balancing the responses to the criteria in Categories 2, 3 and 4, is the substance compatible with a system of sustainable agriculture [§6518(m)(7)] and compatible with organic handling? (see NOSB Recommendation, [Compatibility with Organic Production and Handling, April 2004](#))

Category 5: Additional criteria for agricultural substances used in Handling (review of commercial unavailability of organic sources): **N/A**

1. Is the comparative description as to why the non-organic form of the material /substance is necessary for use in organic handling provided?
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?
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?
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?
5. Does the industry information about unavailability include (but is not limited to) the following?:
Regions of production (including factors such as climate and number of regions);
 - a. Number of suppliers and amount produced;
 - b. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;

- c. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or
 - d. Other issues which may present a challenge to a consistent supply?
6. In balancing the responses to the criteria in Categories 2, 3 and 5, is the substance compatible with a system of sustainable agriculture [§6518(m)(7)] and compatible with organic handling? (see NOSB Recommendation, [Compatibility with Organic Production and Handling, April 2004](#))

Classification Motion:

Motion to classify L-Methionine as non-agricultural, synthetic.

Motion by: Tracy Favre

Seconded by: Harold Austin

Yes: 9 No: 0 Abstain: 0 Absent: 0 Recuse: 0

National List Motion:

Motion to add L-Methionine to §205.605(b), as petitioned: allowed in or on nutritionally complete enteral pediatric formulas labeled “organic” or “made with organic (specific ingredients)” with the annotation, “for use in nutritionally complete pediatric enteral formulas based on soy protein”.

Motion by: Tracy Favre

Seconded by: Jean Richardson

Yes: 9 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Approved by Lisa de Lima, Handling Subcommittee Chair, to transmit to NOP January 17, 2017