

**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 L-Methionine as petitioned on 205.605(b) as synthetic, non-agricultural.

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

L-Methionine, as petitioned, is a wholly synthetic manufactured ingredient.

**Committee Vote:**

Moved:

Seconded:

Yes:

No:

Abstain:

Absent:

Recuse:

**Statement of Recommendation: (Motion # 2)**

Passed

Motion to list L Methionine as petitioned for inclusion on 205.605(b). For use only in infant formula made with soy-based protein.

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

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 (Brosnan and Brosnan, 2006). A number of soy-based baby formulas are supplemented with L-methionine because soy formula (unlike milk-based formula or breast milk) does not provide adequate levels of methionine to ensure adequate growth, nitrogen balance, and plasma albumin concentrations (Agostoni et al., 2006). Therefore L-Methionine is required in soy based infant formulas in order to meet FDA requirements for protein quality at 21 CFR 107.100 (f). The Handling subcommittee recommends approval, acknowledging the fact that if L-Methionine is not added to soy formula there would be no organic soy based formula. The group discussed the fact that protein is the essential building block and there does not seem to be an alternate source of non-milk protein available in commerce for use for infant formula.

**Committee Vote:**

Moved:

Seconded:

Yes:

No:

Abstain:

Absent:

Recuse:

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

**July 3, 2012**

**Summary of Proposed Action:**

The Team Leader for Infant Formula Regulation at FDA provided information about the need for L-Methionine in soy based formulas in order to meet requirements for protein quality at 21 CFR 107.100 (f) . Subcommittee members have reservations about approving synthetic L Methionine, because toxic solvents are used in extraction process. However the subcommittee recommends approval, acknowledging the fact that if L-Methionine is not added to soy formula there would be no organic soy based formula. The group discussed the fact that protein is the essential building block and there does not seem to be an alternate source of non-milk protein available in commerce for use for infant formula.

**Additional comments:** The Handling Subcommittee would welcome public comment about alternatives.

**Evaluation Criteria**

(Applicability noted for each category; Documentation attached)

**Satisfied? (see "B" below)**

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

**Substance Fails Criteria Category:** [ ] **Comments:**

**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:** Motion to list L-Methionine on 205.605(b) as synthetic, non-agricultural.

Motion by: TF

Seconded by: HA

Yes: # 6 No: # 0 Absent: # 1 Abstain: #0 Recuse: #0

**Listing Motion:** Motion to list L Methionine for inclusion on 205.605(b). For use only in infant formula and medical nutritional enteral products labeled organic or made with organic (specified ingredients or food group(s)) soy-based protein.

Motion by: TF

Seconded by: HA

Yes: # 6 No: # 0 Absent: # 1 Abstain: # 0 Recuse: #0

<b>Crops</b>	<input type="checkbox"/>	<b>Agricultural</b>	<input type="checkbox"/>	<b>Allowed<sup>1</sup></b>	<b>X</b>
<b>Livestock</b>	<input type="checkbox"/>	<b>Non-synthetic</b>	<input type="checkbox"/>	<b>Prohibited<sup>2</sup></b>	<input type="checkbox"/>
<b>Handling</b>	<b>X</b>	<b>Synthetic</b>	<b>X</b>	<b>Rejected<sup>3</sup></b>	<input type="checkbox"/>
<b>2No restriction</b>	<input type="checkbox"/>	<b>Commercial unavailable as organic</b>	<b>X</b>	<b>Deferred<sup>4</sup></b>	<input type="checkbox"/>

<sup>1</sup>Substance voted to be added as “allowed” on National List to § 205.605(b) with Annotation (if any): For use in or on processed infant formula labeled as “organic” or “made with organic ingredients”. Annotated: For use only in formula made with isolated soy-based protein.

<sup>2</sup>Substance to be added as “prohibited” on National List to § 205. with Annotation (if any):

Describe why a prohibited substance:

<sup>3</sup>Substance was rejected by vote for amending National List to § 205. . Describe why material was rejected:

<sup>4</sup>Substance 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: L-Methionine

Question	Yes	No	N/A <sup>1</sup>	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]	X	X		Yes, manufacture of synthetic L-Methionine typically is obtained from a precursor DL-Methionine, which uses Cyanide, considered an extremely toxic and volatile chemical. Inadvertent release of Cyanide has happened and has caused environmental damage.
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]	X	X		Yes, see above comment.
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]	X			Continued use of synthetically manufactured L-Methionine has the potential to delay the development of naturally obtained sources, including aquatic sources
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			Over supplementation of L-Methionine has shown to have detrimental effect on the uptake of other critical amino acids
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		X		L-Methionine breaks down fairly quickly in the environment and is therefore not considered a risk to soil or water health.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		See above comments
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		X		

concentration of the material or breakdown products in environment? [§6518 m.2]				
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4]	X	X		Over supplementation of L-Methionine is hepatotoxic, causing fatty deposits in the liver. Normal supplementation has not shown detrimental effects, and is, in fact, an essential amino acid.
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		

<sup>1</sup>If 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-Methionine**

Question	Yes	No	N/A <sup>1</sup>	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]	X	X		Both synthetic and non-synthetic methods exist, but only the synthetic method is commercially available.
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	X		The manufacture of L-Methionine can be accomplished from natural materials, however, only the completely synthetic methods are commercially viable.
3. Is the substance created by naturally occurring biological processes? [6502 (21)]	X			L-Methionine is an essential amino acid that is obtained in the human diet from meat, dairy and some grains. The human body is not able to synthesize it.
4. Is there a natural source of the substance? [§205.600 b.1]	X			See above
5. Is there an organic substitute? [§205.600 b.1]	X			Yes, but not commercially viable at this time.
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			It may be obtained from natural, whole food sources.
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	X		Cow's milk, meat and some grains are sources, but for soy-based formulas, L-methionine is not available in sufficient amounts to meet the dietary requirements of infants.
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			Breastfeeding would eliminate the need for soy-based formulas

## NOSB Evaluation Criteria for Substances Added To the National List

### Category 3. Is the substance compatible with organic production practices?

**Substance: L-Methionine**

Question	Yes	No	N/A <sup>1</sup>	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]		X		Previous TAP and TR indicate that the synthetic manufacture of L-methionine is not considered 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	X	Petitioned use is for soy-based infant formula only, but is not consistent with organic farming.
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			In fact, this is the only justification for inclusion of L-methionine in soy-based formulas
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 in order to bring nutrient contents of soy-based formula up to milk-based formulas and mother's milk.
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:	X			This is a sulfur-based amino acid.
a. toxins derived from bacteria;			X	
b. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?			X	
c. livestock parasiticides and medicines?			X	
d. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?			X	

## 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 L-Methionine**

Question	Yes	No	N/A <sup>1</sup>	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 <b>form</b> 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 <b>quality</b> to fulfill an essential function in a system of organic handling?		X		Quality of the substance has not been discussed, rather the commercial availability of the organic version
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 <b>quantity</b> 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 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	X	Not provided but not relevant to manufacture.
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or		X	X	Same as above
e. Are there other issues which may present a challenge to a consistent supply?	X			Only as related to organic and non-synthetic versions of L-Methionine

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