

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

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|---|--|---|----------|-------------------------|----------|----------------------|--|-----------|----------|---------------|--|-------------------------|--|----------|--|-----------|----------|-----------------------|----------|----------------|--|---|--|-----------------------|--|
| For NOSB Meeting: May 2008 | Substance: METHIONINE (action on petitioners' request) | | | | | | | | | | | | | | | | | | | | | | | | |
| Committee: Crops Livestock X Handling | | | | | | | | | | | | | | | | | | | | | | | | | |
| Petition is for: removal of the annotation date of October 1, 2008 for Synthetic Methionine on the National List § 205.603 | | | | | | | | | | | | | | | | | | | | | | | | | |
| A. Evaluation Criteria (Applicability noted for each category; Documentation attached) Criteria Satisfied? (see B below) | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Impact on Humans and Environment | Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> | | | | | | | | | | | | | | | | | | | | | | | | |
| 2. Essential & Availability Criteria | Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A <input type="checkbox"/> | | | | | | | | | | | | | | | | | | | | | | | | |
| 3. Compatibility & Consistency | Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A <input type="checkbox"/> | | | | | | | | | | | | | | | | | | | | | | | | |
| 4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606) | Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input checked="" type="checkbox"/> | | | | | | | | | | | | | | | | | | | | | | | | |
| B. Substance Fails Criteria Category: <u>2 & 3</u> Comments: Rations that supply adequate naturally occurring methionine appear to exist, especially if poultry have true access to the outdoors (pasture); management practices are preferred to off farm inputs in organic agriculture. Synthetic methionine is used primarily to increase growth rates and production, not only to maintain health. | | | | | | | | | | | | | | | | | | | | | | | | | |
| C. Proposed Annotation (if any): _____ Basis for annotation: To meet criteria above: _____ Other regulatory criteria: _____ Citation: _____ | | | | | | | | | | | | | | | | | | | | | | | | | |
| D. Recommended Committee Action & Vote (State Actual Motion): Motion (1) Petitioner's Request : Remove the annotation date of October 1, 2008 for synthetic methionine on the National List 205.603 Motion (1) by: Kevin Engelbert Seconded by Tina Ellor Yes: 0 No: 5 Absent: 2 Abstain: 0 | | | | | | | | | | | | | | | | | | | | | | | | | |
| <table border="1" style="border-collapse: collapse; margin: auto;"> <tr> <td style="padding: 2px;">Crops</td> <td style="padding: 2px;"></td> <td style="padding: 2px;">Agricultural</td> <td style="padding: 2px;"></td> <td style="padding: 2px;">Allowed¹</td> <td style="padding: 2px;"></td> </tr> <tr> <td style="padding: 2px;">Livestock</td> <td style="padding: 2px; text-align: center;">X</td> <td style="padding: 2px;">Non-Synthetic</td> <td style="padding: 2px;"></td> <td style="padding: 2px;">Prohibited²</td> <td style="padding: 2px;"></td> </tr> <tr> <td style="padding: 2px;">Handling</td> <td style="padding: 2px;"></td> <td style="padding: 2px;">Synthetic</td> <td style="padding: 2px; text-align: center;">X</td> <td style="padding: 2px;">Rejected³</td> <td style="padding: 2px; text-align: center;">X</td> </tr> <tr> <td style="padding: 2px;">No restriction</td> <td style="padding: 2px;"></td> <td style="padding: 2px;">Commercially Un-Available as Organic¹</td> <td style="padding: 2px;"></td> <td style="padding: 2px;">Deferred⁴</td> <td style="padding: 2px;"></td> </tr> </table> | | Crops | | Agricultural | | Allowed ¹ | | Livestock | X | Non-Synthetic | | Prohibited ² | | Handling | | Synthetic | X | Rejected ³ | X | No restriction | | Commercially Un-Available as Organic ¹ | | Deferred ⁴ | |
| Crops | | Agricultural | | Allowed ¹ | | | | | | | | | | | | | | | | | | | | | |
| Livestock | X | Non-Synthetic | | Prohibited ² | | | | | | | | | | | | | | | | | | | | | |
| Handling | | Synthetic | X | Rejected ³ | X | | | | | | | | | | | | | | | | | | | | |
| No restriction | | Commercially Un-Available as Organic ¹ | | Deferred ⁴ | | | | | | | | | | | | | | | | | | | | | |
| 1) Substance voted to be added as "allowed" on National List to with Annotation (if any) _____ 2) Substance to be added as "prohibited" on National List to § 205. _____ with Annotation (if any) _____ Describe why a prohibited substance: _____ 3) Substance was rejected by vote for amending National List to § 205. _____ Describe why material was rejected: <u>Rations that supply adequate naturally occurring methionine appear to exist, especially if poultry have true access to the outdoors (pasture); management practices are preferred to off farm inputs in organic agriculture. Synthetic methionine is used primarily to increase growth rates and production, not only to maintain health.</u> 4) Substance was recommended to be deferred because _____ _____ If follow-up needed, who will follow up _____ | | | | | | | | | | | | | | | | | | | | | | | | | |
| E. Approved by Committee Chair to transmit to NOSB: Hubert Karreman March 14, 2008 Committee Chair Date | | | | | | | | | | | | | | | | | | | | | | | | | |

NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? Substance - Methionine

| Question | Yes | No | N/A ¹ | 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 | | Potential for release of highly toxic substances during manufacturing, including hydrogen cyanide, methane, ammonia, and acrolein, in the form of air pollution. TAP p. 5 |
| 3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i] | | X | | Rapidly degraded in water and neutralized by bacteria in the soil TAP p. 11 |
| 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 | X | | Most toxic of all amino acids. Petition p. 15 Excessive feeding may cause deficiencies in other amino acids and induce toxicity, but rates of inclusion are well understood. TAP p. 5,21 |
| 6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5] | | X | | See 3 |
| 7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5] | | X | | See 3 |
| 8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2] | | X | | See 3 |
| 9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2] | | X | | See 3 |
| 10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4] | | X | | Appears to present no human health problems. Well utilized by poultry. Used in medicine. TAP p. 11 |
| 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.

Category 2. Is the Substance Essential for Organic Production? Substance - Methionine

| 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 | | | May be isolated from naturally occurring sources, produced from genetically engineered organisms, or entirely synthesized by a wide number of processes. TAP p. 3 |
| 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 | | | One method uses propylene, hydrogen sulfide, methane, and ammonia. Another uses acrolein and methyl mercaptan in the presence of a catalyst. TAP p. 3 |
| 3. Is the substance created by naturally occurring biological processes? [6502 (21)] | | X | | TAP p. 3 |
| 4. Is there a natural source of the substance? [§205.600 b.1] | | | X | |
| 5. Is there an organic substitute? [§205.600 b.1] | | | X | |
| 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 | | | Fish meal, kelp, crab meal, insects, earthworms, seed meals, dairy products and by-products, rice hull extract, pearl millet, sorghum, crab shell meal, lobster shell meal, white corn gluten, potato protein, barley, oats, wheat, flax meal, annelids, leeches, fresh green forage, field peas, quinoa TAP & Petition various pages |
| 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 | | | See 7 |
| 10. Is there another practice that would make the substance unnecessary? [§6518 m.6] | X | | | Slower growing breeds, more diverse feed rations, use of alternative feeds, true outdoor access and other management strategies. TAP & Petition |

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

Category 3. Is the substance compatible with organic production practices? Substance - Methionine

| 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 | | Use of synthetic substances not compatible with organic farming and handling, and does not follow the principles of organic agriculture TAP p. 14 |
| 3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7] | | X | | Natural sources are allowed and are more compatible. TAP |
| 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 | | | Sulfur. TAP p. 3 |
| 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.

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 - Methionine

| Question | Yes | No | N/A | Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown) |
|--|-----|----|-----|---|
| 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 | |
| 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 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 | |