

NOSB RECOMMENDED DECISION FORM

Form NOPLIST2. Full Board Transmittal to NOP

For NOSB Meeting: <u>MAY 2008</u>	Substance: <u>METHIONINE</u>																								
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? 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: . Basis for annotation: expiration date of October 1, 2010 To meet criteria above: <u>X</u> Criteria: _____ Other regulatory criteria: _____ Citation: _____																								
D. Final Board Action & Vote (State Actual Motion): Motion: HJK Second: KE JS amendment to 2011 1 st , 2 nd – SD- withdrawn Yes: 14 No: 0 Abstain: Absent: 1																									
<table border="1" style="margin-left: auto; margin-right: auto;"> <tr> <td>Agricultural</td> <td></td> <td>Nonagricultural</td> <td></td> <td>Crops</td> <td></td> </tr> <tr> <td>Synthetic</td> <td style="text-align: center;">√</td> <td>Not synthetic</td> <td></td> <td>Livestock</td> <td style="text-align: center;">√</td> </tr> <tr> <td>Allowed¹</td> <td style="text-align: center;">√</td> <td>Prohibited²</td> <td></td> <td>Handling</td> <td></td> </tr> <tr> <td>No restriction</td> <td></td> <td>Deferred⁴</td> <td></td> <td>Rejected³</td> <td></td> </tr> </table>		Agricultural		Nonagricultural		Crops		Synthetic	√	Not synthetic		Livestock	√	Allowed ¹	√	Prohibited ²		Handling		No restriction		Deferred ⁴		Rejected ³	
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Provide a summary narrative here or attach a more complete narrative, and attach the original committee recommendation that includes the evaluation criteria checklist: <u>To grow the market availability of natural alternatives to synthetic Methionine. Based on public presentations in Washington, DC (Nov. 2007) and La Crosse, WI (Upper Midwest Organic Farming Conference Feb. 2008), alternatives exist but need a few years to create sufficient supplies of naturally occurring methionine.</u>																									
2—substance to be added to “prohibited” paragraph of National List to § 205. _____ Describe why a prohibited substance: _____																									
3—substance was rejected by vote for amending National List to § 205. 603 Describe why material was rejected: <u>Original petition to remove the expiration date entirely was rejected by the Board unanimously. With this official vote, the material will still be on the list with a new expiration deadline of October 1, 2010. It is the intent of the Livestock Committee to stimulate further commercial development and management changes to provide methionine to poultry in a non-synthetic manner. This should be done in the most expeditious manner possible.</u>																									
4—substance was recommended to be deferred § 205. _____ Describe why deferred; if any follow-up is needed. If follow-up needed, who conducts follow-up _____																									
E. Approved by NOSB Chair to transmit to NOP <div style="display: flex; justify-content: space-between;"> Rigoberto Delgado June 20-2008 </div> <hr/> Chair _____ Date _____																									
F. NOP Action: Include in FR to amend National List: Return to NOSB Reason: _____ _____ <div style="text-align: right;">Date _____</div>																									

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;				
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	

**Livestock Committee
Minority Opinion
Methionine Recommendation, May 2008**

The following minority opinion suggests that there is no need to continue the allowance of synthetic Methionine for an additional two years for organic poultry production on the National List §205.603.

While the petition to remove the expiration date from the annotation does list immunological stress and reduced feathering as potential consequences of the absence of synthetic methionine supplementation, the actual data reported in the same petition does not show any of these as observed consequences.

The only potential consequence listed in the petition that is supported in the data submitted is a reduction in performance as measured in growth or egg production.

The petition further notes that amino acid requirements are directly tied to performance. An allowance within the industry for a reduced performance as being acceptable decreases the total methionine requirement and the need for synthetic methionine supplementation in the diet.

While the minority opinion agrees that methionine is an essential amino acid and required in the diet of poultry and all animals, the petitioner has not provided data that supports the necessity of supplementation of synthetic methionine, to provide total methionine at a level above the level provided by available organic livestock feeds, for any function except improvement of production parameters.

Therefore the listing of methionine only for poultry seems to be an allowance for organic poultry to more closely meet the performance expectations of conventional poultry production. This allowance has already been granted for six years via two subsequent listings of DL-methionine on §205.603 of three years each.

The lack of any real data that nothing but a decrease in performance will likely occur because of the removal of DL-methionine from the NL does not support the exemption for continued use of this substance for two more years.

If this exemption is allowed for an additional two years for poultry, then, since it appears to be essentially a substance to improve performance, there seems to be no support to limit this advantage to only the poultry sector of the organic livestock industry. Other omnivore and carnivore species would benefit from supplementation of synthetic methionine and even some herbivore livestock species have shown production benefits from synthetic methionine supplementation.

This minority opinion recommends either a) to vote to not relist synthetic DL-methionine and its analogs on the NL §205.603, or b) to amend the recommendation to remove the portion of the annotation limiting this performance benefit to the poultry sector of the organic livestock industry.