

NOSB RECOMMENDED DECISION FORM

Form NOPLIST2. Full Board Transmittal to NOP

For NOSB Meeting: <u>April 2010</u>	Substance: <u>Methionine (action on petitioner's request)</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: The Livestock Committee rejects the petitioner's request on a number of levels. The pounds of MET requested represents the highest levels normally fed on a daily, per ton basis. Averaging the pounds fed over the life of the bird would allow even higher levels of MET to be fed at certain times, which is not the direction the committee wants to head. The approach of the MTF continues along the lines of finding a way to keep poultry confined yet still meet their needs for MET, rather than trying to find ways to adapt rations and housing to meet their nutritional needs. Different management practices and housing strategies are much preferred to purchased inputs in organic farming. High use levels of synthetic MET do not meet consumer expectations nor follow the principles of organic agriculture.	C. Proposed Annotation: _____ None _____ Basis for annotation: To meet criteria above: _____ Criteria: _____ Other regulatory criteria: _____ Citation: _____																								
D. Final Board Action & Vote (State Actual Motion): To amend 7 CFR § 205.603(d)(1) as follows: read DL-Methionine, DL-Methionine-hydroxy analog, and DL-Methionine hydroxyl analog calcium (CAS #-59-51-8; 63-68-3; 348-67-4)—for use only in organic poultry production until October 1, 2015, provided that the total amount of synthetic methionine in the diet remains below the following levels, calculated as the average pounds per ton of 100% synthetic methionine (MET) in the diet over the life of the bird: Laying chickens-4 pounds; broiler chickens-5 pounds; Turkeys and all other poultry-6 pounds.																									
Motion: Jeff Moyer; Second: Jennifer Hall Yes: 2 No: 12 Abstain: 0 Absent: 1																									
<table border="1" style="margin: auto; border-collapse: collapse;"> <tr> <td style="padding: 5px;">Agricultural</td> <td style="width: 20px;"></td> <td style="padding: 5px;">Nonagricultural</td> <td style="width: 20px;"></td> <td style="padding: 5px;">Crops</td> <td style="width: 20px;"></td> </tr> <tr> <td style="padding: 5px;">Synthetic</td> <td style="text-align: center;">X</td> <td style="padding: 5px;">Not synthetic</td> <td></td> <td style="padding: 5px;">Livestock</td> <td style="text-align: center;">X</td> </tr> <tr> <td style="padding: 5px;">Allowed¹</td> <td></td> <td style="padding: 5px;">Prohibited²</td> <td></td> <td style="padding: 5px;">Handling</td> <td></td> </tr> <tr> <td style="padding: 5px;">No restriction</td> <td></td> <td style="padding: 5px;">Deferred⁴</td> <td></td> <td style="padding: 5px;">Rejected³</td> <td style="text-align: center;">X</td> </tr> </table>		Agricultural		Nonagricultural		Crops		Synthetic	X	Not synthetic		Livestock	X	Allowed ¹		Prohibited ²		Handling		No restriction		Deferred ⁴		Rejected ³	X
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1—Substance voted to be added as “allowed” on National List on National List to § 205._____ with Annotation (if any): _____																									
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 <u>§ 205.603</u> . Describe why material was rejected: Material was rejected pending upcoming recommendation from the livestock committee to amend the petitioner's request based on information gathered during committee debate, public comment and industry input.																									
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 Chair: Daniel G. Giacomini Date: April 29, 2010																									
F. NOP Action: Include in FR to amend National List: Return to NOSB Reason: _____ Date: _____																									

**National Organic Standards Board
Livestock Committee
Synthetic Methionine Recommendation**

February 23, 2010

I. Introduction

The Methionine Task Force (MTF) has once again petitioned for the extension of the deadline for the use of Synthetic Methionine (DL-Methionine, DL-Methionine hydroxy analog, and DL-Methionine hydroxyl analog calcium; hereafter referred to as MET).

In a petition dated July 31, 2009 the MTF requested that **7CFR § 205.603(d)(1)** be amended as follows: DL-Methionine, DL-Methionine—hydroxy analog, and DL-Methionine—hydroxy analog calcium (CAS #–59–51–8; 63–68–3; 348–67–4)—for use only in organic poultry production until October 1, ~~2010~~ **2015, provided that the total amount of synthetic methionine in the diet remain below the following levels, calculated as the average pounds per ton of 100% synthetic methionine (MET) in the diet over the life of the bird:**

Laying chickens	4 pounds
Broiler chickens	5 pounds
Turkeys and all other poultry	6 pounds

II. Background

The July 31, 2009 petitioned represents the 4th petition involving MET, which was first petitioned for inclusion on the National List in 2001, with a Sunset date of October 2005. The next petition was on January 10, 2005, which requested a continued allowance of the use of MET without a Sunset Date. The NOSB, at the Spring 2005 meeting, granted an extension of the Sunset Date to October 1, 2008. There was also a request for a variance that would allow the feeding of non-organic feed for methionine research purposes; that request was not approved by the NOSB. Another petition was received on December 14, 2007 again requesting removal of the Sunset Date for MET on the National List. At the Spring 2008 meeting, the NOSB rejected the petition request, but recommended a new Sunset Date for MET of October 1, 2010. Which brings us to the current petition, which was received July 31, 2009, and requests a new Sunset Date for MET of October 1, 2015, along with specific allowances for the use of MET in different avian species.

III. Regulatory Framework

Amino acids do not appear on the list of synthetics that may be allowed according to the Organic Food Production Act (OFPA) 7 USC 6517(c)(1)(B)(i): EXEMPTION FOR PROHIBITED SUBSTANCES IN ORGANIC PRODUCTION AND HANDLING OPERATIONS.—The National List may provide for the use of substances in an organic farming or handling operation that are otherwise prohibited under this title only if—

(B) the substance---

(i) is used in production and contains an active synthetic ingredient in the following categories: 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;

IV. Discussion

Much of the pertinent information regarding MET remains the same, but a few points are worth repeating:

- a change in management strategies and practices, along with selection for suitable breeds and pastured poultry production, may lessen or eliminate the need for MET

- feed ingredients that provide natural methionine include soybeans, field peas, potato protein, dairy products and by-products, white corn gluten, fresh forage (pasture), insects, annelids, leeches, seed meals (flax, sunflower, and hemp), quinoa, alfalfa meal, earthworms, fish meal, kelp, crab meal, rice hull extract, pearl millet, sorghum, lobster shell meal, crab shell meal, oats, wheat, and barley. Although not currently allowed in organic production, organic bone, meat, and feather meals are excellent sources of methionine

- research on alternatives to MET remains incomplete, and a supply of viable alternatives does not presently exist

- the organic poultry industry claims that the use of MET remains necessary for the foreseeable future, and that MET is needed for maintenance, not growth or production maximization

- the organic poultry industry continues to grow faster than the supply of natural sources of methionine is developing

The Livestock Committee believes that the use of MET should cease. The committee does not think that the petitioner's request to amend the current annotation of Synthetic Methionine on § 205.603(d)(1) represents the best approach to achieve this goal.

V. Recommendation

The Livestock Committee recommends that

Material will still be on the National List, but with a new step down rate of use. The Livestock Committee hopes to stimulate further development and management changes in the organic poultry industry that will meet consumer expectations and organic principles. Along with the Animal Welfare Recommendation that was passed in November 2009, which will eventually include stocking rates for poultry, the committee believes these goals will be met.

The Livestock Committee and the NOSB will work in collaboration with the NOP if new information on MET or natural methionine becomes available.

VI. Committee vote

Moved: Dan Giacomini Second: Jeff Moyer
Yes – 5 No -- 0 Absent -- 3 Abstain -- 0

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: April 2010

Substance: Methionine (action on petitioner's request)

Committee: Crops Livestock Handling Petition is for: amending the annotation for Synthetic Methionine on the National List § 205.603 to read DL-Methionine, DL-Mehionine-hydroxy analog, and DL-Methionine hydroxyl analog calcium (CAS #-59-51-8; 63-68-3; 348-67-4)—for use only in organic poultry production until October 1, 2015, provided that the total amount of synthetic methionine in the diet remains below the following levels, calculated as the average pounds per ton of 100% synthetic methionine (MET) in the diet over the life of the bird: Laying chickens-4 pounds; broiler chickens-5 pounds; Turkeys and all other poultry-6 pounds.

A. Evaluation Criteria (Applicability noted for each category; Documentation attached)	Criteria Satisfied? (see B below)
4. Impact on Humans and Environment	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
5. Essential & Availability Criteria	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A <input type="checkbox"/>
6. Compatibility & Consistency	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A <input type="checkbox"/>
7. 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: 2 & 3 Comments: The Livestock Committee rejects the petitioner's request on a number of levels. The pounds of MET requested represents the highest levels normally fed on a daily, per ton basis. Averaging the pounds fed over the life of the bird would allow even higher levels of MET to be fed a certain times, which is not the direction the committee wants to head. The approach of the MTF continues along the lines of finding a way to keep poultry confined yet still meet their needs for MET, rather than trying to find ways to adapt rations and housing to meet their nutritional needs. Different management practices and housing strategies are much preferred to purchased inputs in organic farming. High use levels of synthetic MET does not meet consumer expectations nor follow the principles of organic agriculture.

C. Proposed Annotation (if any): _____

Basis for annotation: To meet criteria above: _____ Other regulatory criteria: _____ Citation: _____

D. Recommended Committee Action & Vote (State Actual Motion): to amend 7 CFR § 205.603(d)(1) as follows: read DL-Methionine, DL-Mehionine-hydroxy analog, and DL-Methionine hydroxyl analog calcium (CAS #-59-51-8; 63-68-3; 348-67-4)—for use only in organic poultry production until October 1, 2015, provided that the total amount of synthetic methionine in the diet remains below the following levels, calculated as the average pounds per ton of 100% synthetic methionine (MET) in the diet over the life of the bird: Laying chickens-4 pounds; broiler chickens-5 pounds; Turkeys and all other poultry-6 pounds.

Motion by: Dan Giacomini Seconded: Jeff Moyer Yes: 0 No: 5 Absent: 3 Abstain: 0

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 § 205. _____ 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. 603. Describe why material was rejected: As stated above, the Livestock Committee does not believe the petition represents the direction the organic poultry industry should move. We also reject the lifetime averaging use of the substance in calculating maximum allowed use.

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:

Kevin K. Engebart
Committee Chair

February 23, 2010
Date

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: April 2010

Substance: Methionine (Livestock Committee motion)

Committee: Crops Livestock Handling Petition is for: removal of the annotation date of October 1, 2010 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: 2 & 3 **Comments:** High use levels of synthetic MET does not meet consumer expectations nor follow the principles of organic agriculture. Different management practices and housing strategies are much preferred to purchased inputs in organic farming. Material will still be on the National List, but with a new step down rate of use. The Livestock Committee hopes to stimulate further development and management changes in the organic poultry industry that will meet consumer expectations and organic principles. Along with the Animal Welfare Recommendation that was passed in November 2009, which will eventually include stocking rates for poultry, the committee believes these goals will be met.

C. Proposed Annotation (if any): to amend 7 CFR § 205.603(d)(1) as follows: DL-Methionine, DL-Methionine-hydroxy analog, and DL-Methionine hydroxyl analog calcium (CAS #-59-51-8; 63-68-3; 348-67-4)—for use only in organic poultry production until October 1, 2012, at the following maximum levels per ton of synthetic methionine in the feed ration: Laying chickens – 4 pounds per ton; Broiler chickens – 5 pounds per ton; and Turkeys & all other poultry – 6 pounds per ton. After October 1, 2012 at the following maximum levels per ton: Laying and Broiler chickens – 2 pounds per ton; and Turkeys and all other poultry - 3 pounds per ton.

Basis for annotation: To meet criteria above: Other regulatory criteria: Citation: _____

To meet consumer expectations of organic poultry production, yet allow additional time for the development of natural alternatives to Synthetic Methionine.

D. Recommended Committee Action & Vote (State Actual Motion): to amend 7 CFR § 205.603(d)(1) as follows: DL-Methionine, DL-Methionine-hydroxy analog, and DL-Methionine hydroxy analog calcium (CAS #-59-51-8; 63-68-3; 348-67-4)—for use only in organic poultry production until October 1, 2012, at the following maximum levels per ton of synthetic methionine in the feed ration: Laying chickens – 4 pounds per ton; Broiler chickens – 5 pounds per ton; and Turkeys & all other poultry – 6 pounds per ton. After October 1, 2012 the following maximum levels per ton: Laying and Broiler chickens – 2 pounds per ton; and Turkeys and all other poultry - 3 pounds per ton.

Motion by: Dan Giacomini Seconded: Jeff Moyer Yes: 5 No: 0 Absent: 3 Abstain: 0

Crops		Agricultural		Allowed ¹	<input checked="" type="checkbox"/>
Livestock	<input checked="" type="checkbox"/>	Non-Synthetic		Prohibited ²	
Handling		Synthetic	<input checked="" type="checkbox"/>	Rejected ³	
No restriction		Commercially Un-Available as Organic ¹		Deferred ⁴	

1) Substance voted to be added as "allowed" on National List to § 205. _____ 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: _____

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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:

Kevin K. Engebart
Committee Chair

February 23, 2010
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			Methionine production process listed by EPA as a hazardous air pollutant (40 CFR 63.184). Potential for release of toxins into the environment . TAP p. 5
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		Substance degrades in water and neutralized by bacteria in water. 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		When fed to excess, methionine may cause deficiencies in other amino acids and induce toxicity, but use is well understood and unlikely to be misused. TAP p. 5
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		X		See 3. above
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		See 3. above
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		See 3. above
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]		X		See 3. above
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]		X		Essential in small amounts in the human diet, and sold over-the-counter as a dietary supplement. Used in medicine. TAP p. 6
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 - _____

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			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)]				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			Ongoing research to develop feedstuffs with a higher concentration of methionine. Also see 7. above
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			True outdoor access, alternative feeds & more diverse feed rations, different management and housing strategies. TAP & Petition various pages

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 - _____

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		Violates OFPA [7 USC 6517(c)(1)(B)(i)]. Amino acids do not appear on the list of synthetics allowed. The use of synthetic substances does not follow the principles of organic agriculture and is not consistent with organic farming and handling. TAP pgs. 1, 4, & 14
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]		X		TAP p. 1
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 - _____

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:			X	
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	