FORMAL RECOMMENDATION BY THE
NATIONAL ORGANIC STANDARDS BOARD (NOSB)
TO THE NATIONAL ORGANIC PROGRAM (NOP)

Date: **__March 18, 2005_____**

Subject: **_Renewal of DL-Methionine on National List until October 1, 2008___**

Chair: **____Jim Riddle**_____
(sign)

Recommendation

The NOSB hereby recommends to the NOP the following:

Rulemaking Action:	____X____
Guidance Statement:	_____
Other:	_____

Statement of the Recommendation (including Recount of Vote)**:**

The NOSB recommends the use of synthetic methionine in organic poultry production be extended to October 1, 2008 to provide time for thorough research to be completed. This recommendation follows inclusion allowances provided in 205.603 Synthetic substances allowed for use in organic livestock production as (d) feed additives.

NOSB vote: 11 yes, 0 no, 2 abstain, 1 recuse

The NOSB recommends that the petitioners' request for a research variance for the feeding of non-organic feed alternatives to poultry that would be labeled and sold as "organic" be rejected.

NOSB vote: 13 yes, 0 no, 0 abstain, 1 recuse

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

Rationale for the positions taken by the Board explained in the DL-Methionine final recommendation form and decision sheets.

Response by the NOP:

NOSB Livestock Committee - Synthetic Methionine Recommendation

Draft 1-30-05

Background:

A petition has been submitted to the NOP requesting that the use of synthetic methionine in poultry diets be extended past the current sunset date of October 1, 2005. The basic arguments presented by the petitioners include:

> Research on organic alternatives to synthetic methionine is incomplete. Projects in progress show promise but more time is needed to assure science is sound. No clear solution is available at the present time.
>
> Even if science had identified viable organic alternatives to synthetic methionine, they would not yet be available in sufficient quantity.
>
> Sufficient dietary levels of methionine are a necessity for organic poultry production from an economic, animal health/welfare, and environmental standpoint.
>
> Methionine is not a growth promoter. It is a necessary dietary requirement essential to maintain the health of poultry.
>
> Feed ingredients that provide methionine include soybeans, field peas, white corn gluten, potato protein, seed meals (sunflower, flax, and hemp), quinoa, alfalfa meal, fresh pasture, and casein. Insects and earthworms are also rich in methionine.
>
> Research into natural methionine production through extraction and fermentation continues. A natural source of methionine feed additive would be allowed according to current National Organic Program standards.
>
> Production systems and cultural practices, including selection of breeds and pastured poultry production, may obviate the need for synthetic methionine. Research projects are underway to examine alternative feed sources, alternative production systems, and alternative breeds.

The Livestock Committee concurs with the petitioners that it is desirable to eliminate the use of synthetic methionine from the organic poultry industry. We support continued intense and good faith research efforts to eliminate synthetic methionine from organic poultry diets.

Recommendation:

After careful consideration and discussion of the merits of the petition, the NOSB Livestock Committee recommends the use of synthetic methionine in organic poultry production be extended to October 1, 2008 to provide time for thorough research on organic alternatives to be completed. This recommendation follows inclusion allowances provided in 205.603 Synthetic substances allowed for use in organic livestock production (d) as feed additives.

A temporary variance petition for the allowance of the use of non-organic feed ingredients in organic poultry production for research purposes was also submitted by the petitioners. The requested variance would allow the feeding of non-organic feed ingredients for research purposes. The variance would require approval by NOP, be limited to trials of 1,000 birds or less, require immediate and full disclosure of research findings, and expire October 1, 2008. If the variance is granted, the birds would be able to be labeled and sold as "organic." The Livestock Committee recommends that this request be rejected. This Committee cannot support a request to feed non-organic feed to birds that would be labeled and sold as "organic."

Committee vote:

6 yes, 0 no, 2 absent

EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? Substance Synthetic 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	See Footnote # 1 below.
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]	X			Some air pollution is caused by the manufacturing process. (EPA, TAP)
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		Substance is "rapidly degraded in water; metabolized by bacteria in sediments." (TAP)
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]		X		Methionine is a List 4 Inert. (EPA)
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		X		Use of the substance is "well understood, unlikely to be misused, misformulated, or cause detrimental interactions or results." (TAP)
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		X		See Question # 3 and # 5 above.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		See Question # 3 and # 5 above.
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		See Question # 3 and # 5 above.
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]		X		See Question # 3 and # 5 above.
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]		X		No human health implications. Common dietary supplement. Used in medicine. Not detectable in poultry meat or eggs. (TAP)
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]			X	See Footnote # 1 below.
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]			X	See Footnote # 1 below.
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]			X	See Footnote # 1 below.

[1]If 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 Synthetic 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			Chemically synthesized from the combination of nitrogen, carbon and sulfur compounds. (TAP)
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		Methionine may be isolated from naturally occurring sources, produced from genetically engineered organisms, or entirely synthesized by a wide number of processes. D- and L-methionine (DL-methionine) are usually produced entirely by chemical methods. 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		See Question # 1 above. (Produced naturally by plants and bacteria, for example in the rumen of cows, sheep, etc.) (TAP)
4. Is there a natural source of the substance? [§205.600 b.1]			X	See Footnote # 1 below.
5. Is there an organic substitute? [§205.600 b.1]			X	See Footnote # 1 below.
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			X	See Footnote # 1 below.
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X			There are feed ingredients that contain higher levels of natural methionine relative to other feed ingredients. See TAP and Livestock Committee Recommendation for a listing of several of these. (TAP, Livestock Committee Recommendation)
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]		X		Substance is not used in handling and is synthetic.
9. Is there any alternative substances? [§6518 m.6]	X			Research is ongoing examining the feasibility of alternative feed ingredients. See Question 7 above.
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			Research may provide information relative to other practices that would make synthetic methionine unnecessary. Slower growing breeds, alternative feed ingredients, other management and housing strategies may eliminate the need for synthetic methionine supplementaion. (TAP, Livestock Committee Recommendation)

[1]If 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 Synthetic 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	See Footnote # 1 below.
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]	X	X		Proper nutrition is the cornerstone of organic livestock production. In terms of animal welfare, animal health, and minimizing environmental impact, synthetic methionine is consistent with organic farming principles. The substance causes no chemical modification of poultry products and organic quality of products remains intact. (TAP, Livestock Committee Recommendation)
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]	X	X		Natural sources of methionine are allowed according to current National Organic Program standards, and are more compatible with a system of sustainable agriculture than synthetic forms. Feed ingredients that provide methionine include soybeans, field peas, white corn gluten, potato protein, seed meals (sunflower, flax, and hemp), fish meal, crab meal, yeast, quinoa, alfalfa meal, fresh pasture, and casein. Insects and earthworms are also rich in methionine. Compatible production systems and cultural practices, including selection of breeds, alternative feeds, and pastured poultry production, may obviate the need for synthetic methionine in the future.
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]			X	See Footote # 1 below.
5. Is the primary use as a preservative? [§205.600 b.4]			X	See Footote # 1 below.
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	See Footote # 1 below.
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: a. copper and sulfur compounds;	X			Synthetic methionine and natural methionine both contain sulfur. (TAP)
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		

[1]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 RECOMMENDED DECISION

Form NOPLIST2. Full Board Transmittal to NOP

For NOSB Meeting: February 28 – March 3, 2005	Substance: Synthetic Methionine

A. Evaluation Criteria (Documentation attached; committee recommendation attached)

	Criteria Satisfied?
1. Impact on humans and environment	Yes No ☐ (see B below)
2. Availability criteria	Yes No ☐ (see B below)
3. Compatibility & consistency	Yes No ☐ (see B below)

B. Substance fails criteria?

Criteria category: _____

Comments:

C. Proposed Annotation: Allowed until October 2008 to allow research on natural sources of methionine to be completed._____

_____

Basis for annotation:

To meet criteria above: ____ Criteria: _____

Other regulatory criteria: ____ Citation:_____

D. Final Board Action & Vote: Motion by: _____ Second:_____

Agricultural

Nonagricultural

Crops

Synthetic X

Not synthetic

Livestock X

Allowed[1] X

Prohibited[2]

Handling

No restriction

Deferred4

Rejected[3]

Vote:

Yes: _____

No: _____

Abstain: _____

1—substance voted to be added as “allowed” on National List

Annotation: Allowed until October 2008 to allow research on natural sources of methionine to be completed.

_____

_____

2—substance to be added to "prohibited" paragraph of National List

Describe why a prohibited substance:_____

_____

3—substance was rejected by vote for amending National List

Describe why material was rejected:_____

_____

4-substance was recommended to be deferred

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:

_____ _____

Dave Carter, NOSB Chair Date

F. NOP Action: Include in FR to amend National List: ☐

Return to NOSB ☐ Reason: _____

_____ _____

Richard H. Mathews, Program Manager Date

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: February 28 – March 3, 2005	Substance: Synthetic Methionine

Committee: Crops ☐ Livestock ☐ Handling ☐

A. Evaluation Criteria (Documentation attached; committee recommendation attached)

		Criteria Satisfied?
4.	Impact on humans and environment	Yes No ☐ (see B below)
5.	Availability criteria	Yes No ☐ (see B below)
6.	Compatibility & consistency	Yes No ☐ (see B below)

B. Substance fails criteria?

Criteria category: _____

Comments:

C. Proposed Annotation: Allowed until October 2008 to allow research on natural sources of methionine to be completed._____

_____

Basis for annotation:

To meet criteria above: ____ Criteria: _____

Other regulatory criteria: ____ Citation:_____

D. Recommended Committee Action & Vote: Motion by: _____

Seconded:_____

Agricultural

Nonagricultural

Crops

Synthetic X

Not synthetic

Livestock X

Allowed[1] X

Prohibited[2]

Handling

No restriction

Deferred4

Rejected[3]

Vote:

Yes: _____

No: _____

Abstain: _____

1—substance voted to be added as “allowed” on National List
Annotation: Allowed until October 2008 to allow research on natural sources of methionine to be completed.
_____

_____
2—substance to be added to “prohibited” paragraph of National List
Describe why a prohibited substance:_____

_____
3—substance was rejected by vote for amending National List
Describe why material was rejected:_____

_____
4-substance was recommended to be deferred
Describe why deferred; if follow-up is needed. If follow-up needed, who will follow up_____

_____

E. Approved by Committee Chair to transmit to NOSB:

_____ _____
Committee Chair Date