National Organic Standards Board Meeting

Best Western InnTowner | Madison, Wisconsin

October 25 – 28, 2010

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National Organic Standards Board Meeting

Best Western InnTowner | Madison, Wisconsin

October 25 – 28, 2010

October 25, 2010 | October 26, 2010 | October 27, 2010 | October 28, 2010

Monday, October 25, 2010

8:00 a.m.	**Call to Order** ***Dan Giacomini, Chairperson*** – Approval of Agenda – Announcements – Introductions – NOSB Mission
8:15 a.m.	**Secretary's Report** ***Tina Ellor, Secretary*** – Acceptance of April 2010 Meeting Transcripts and Voting Results as Official Record
8:30 a.m.	**National Organic Program Report** ***Miles McEvoy, Deputy Administrator*** **National Organic Program**
9:30 a.m.	**USDA Organic Agriculture Report** ***Mark Lipson*** **Organic Coordinator, USDA**
10:00 a.m.	**Break**
10:15 a.m.	**Public Comments**
12:30 p.m.	**Lunch**
1:30 p.m.	**Public Comments (continued)**
3:30 p.m.	**Break**
3:45 p.m.	**Public Comments (continued)**
5:30 p.m.	**Recess**

Tuesday, October 26, 2010

8:00 a.m.	**NOSB Materials Review Process Update** ***Katrina Heinze, Materials Committee Chairperson***

Tuesday, October 26, 2010 (continued)

8:30 a.m. **NOSB Committee Presentations and Discussions**

Crops Committee
Tina Ellor, Chairperson

Petitioned Materials Recommendations

- Ethylene Glycol | PDF
- Ethylene DDS | PDF
- Tall Oils | PDF
- TetraMethyl-decyne-diol | PDF

Reaffirm Prior Sunset 2012 Recommendations on § 205.601 & § 205.602 | PDF

Sunset 2012 Recommendations on § 205.601 | PDF

- EPA List 4–Inerts of Minimal Concern | PDF
- Chlorine materials (calcium hypochlorite, chlorine dioxide, sodium hypochlorite) | Deferred
- Copper materials (copper sulfate and fixed coppers) | Deferred

Corn Steep Liquor Recommendation | PDF

10:00 a.m. **Break**

10:15 a.m. **Livestock Committee**
Kevin Engelbert, Chairperson

Petitioned Material Recommendation

- Formic acid | PDF

Reaffirm Prior Sunset 2012 Recommendations on § 205.603 & § 205.604 | PDF

Sunset 2012 Recommendations on § 205.603 | PDF

- Aspirin
- Chlorine materials (calcium hypochlorite, chlorine dioxide, sodium hypochlorite)
- Copper sulfate
- Alcohols (ethanol, isopropanol)
- Furosemide
- Glucose
- Glycerine
- Magnesium sulfate
- EPA List 4–Inerts of Minimal Concern

Apiculture Recommendation | PDF

Animal Healthcare Products / Clarifying § 205.238(c)(2) Recommendation | PDF

Stocking Rates Discussion Document | PDF

Animal Handling, Transit, and Slaughter Discussion Document | PDF

Tuesday, October 26, 2010 (continued)

11:30 p.m.	**Lunch**
12:30 p.m.	**NOSB Committee Presentations and Discussions (continued)**

Handling Committee
Steve DeMuri, Chairperson

Petitioned Materials Recommendations

- Yeast (petition to move from § 205.605 to § 205.606) | PDF
- Pectin (low-methoxy - petition to move from § 205.605 to § 205.606) | PDF
- Glucosamine hydrochloride | PDF
- Hops (petition to remove) | PDF

Reaffirm Prior Sunset 2012 Recommendations
§ 205.605(a) | PDF **§ 205.605(b)** | PDF **§ 205.606** | PDF

Reconsider Prior Sunset 2012 Recommendation - Glycerides (Mono and Di) | PDF

Colors Annotation Recommendation | PDF

Sunset 2012 Recommendations on § 205.605(a)

- Flavors | PDF
- Magnesium sulfate | PDF
- Yeast | PDF

Sunset 2012 Recommendations on § 205.605(b)

- Chlorine materials | PDF
- Ferrous sulfate | PDF
- Pectin (low-methoxy) | PDF
- Phosphoric acid | PDF
- Silicon dioxide | PDF
- Sodium citrate | PDF
- Sodium hydroxide | PDF
- Sodium phosphates | PDF
- Sulfur dioxide | PDF

Sunset 2012 Recommendations on § 205.606

- Colors (18) | PDF
- Annatto Extract | PDF
- Fructo-oligosaccharides | PDF
- Hops | PDF
- Inulin | PDF
- Pectin (high-methoxy) | PDF
- Cornstarch | PDF
- Whey protein | PDF

Nutrient Vitamins and Minerals Discussion Document | PDF

Tuesday, October 26, 2010 (continued)

2:30 p.m.	**Break**
2:45 p.m.	**Materials Committee** ***Katrina Heinze, Chairperson*** **Nanotechnology Guidance Document** | PDF **Materials Classification Oral Update**
3:30 p.m.	**Compliance, Accreditation, and Certification Committee** ***Joe Smillie, Chairperson*** **"Made With" Organic Claim Recommendation** | PDF **Limitations of § 205.101(b) Recommendation** | PDF
4:00 p.m.	**Policy Development Committee** ***Barry Flamm, Chairperson*** **NOSB Policy and Procedure Manual Recommendations** – Section IV: Establishing ad-hoc committees | PDF – Section V: NOP/NOSB Collaboration | PDF – Section VIII: Recommendation on sunset review policy | PDF **NOSB New Member Guide Update Recommendation** | PDF
4:40 p.m.	**Recess**

Wednesday, October 27, 2010

8:00 a.m.	**Public Comments**
9:15 a.m.	**Break**
9:30 a.m.	**Public Comments (continued)**
10:45 a.m.	**Break**
11:00 a.m.	**Public Comments (continued)**
12:30 p.m.	**Lunch**
1:30 p.m.	**Public Comments (continued)**
3:15 p.m.	**Break**
3:30 p.m.	**Public Comments (continued)**
5:00 p.m.	**Recess**

Thursday, October 28, 2010

8:00 a.m. **NOSB Consideration and Vote on Committee Action Items**

Crops Committee
Tina Ellor, Chairperson

Petitioned Materials Recommendations

- Ethylene glycol
- Ethylene DDS
- Tall oils
- TetraMethyl-decyne-diol

Reaffirm Prior Sunset 2012 Recommendations on § 205.601 & § 205.602

Sunset 2012 Recommendations on § 205.601

- EPA List 4–Inerts of Minimal Concern
- Chlorine materials (calcium hypochlorite, chlorine dioxide, sodium hypochlorite)
- Copper materials (copper sulfate and fixed coppers)

Corn Steep Liquor Recommendation

9:15 a.m. **Break**

9:30 a.m. **Livestock Committee**
Kevin Engelbert, Chairperson

Petitioned Material Recommendation

- Formic acid

Reaffirm Prior Sunset 2012 Recommendations on § 205.603 and § 205.604

Sunset 2012 Recommendations on § 205.603

- Aspirin
- Chlorine materials (calcium hypochlorite, chlorine dioxide, sodium hypochlorite)
- Copper sulfate
- Alcohols (ethanol, isopropanol)
- Furosemide
- Glucose
- Glycerine
- Magnesium sulfate

Apiculture Recommendation

Animal Healthcare Products / Clarifying § 205.238(c)(2) Recommendation

11:00 a.m. **Break**

Thursday, October 28, 2010 (continued)

11:15 a.m. **Handling Committee**
Steve DeMuri, Chairperson

Petitioned Materials Recommendations

- Yeast (petition to move from § 205.605 to § 205.606)
- Pectin (low-methoxy)
- Glucosamine hydrochloride
- Hops (petition to remove)

Reaffirm Prior Sunset 2012 Recommendations on § 205.605(a), § 205.605(b), and § 205.606

Reconsider Prior Sunset 2012 Recommendation on Glycerides (Mono and Di)

Colors Annotation Recommendation

12:00 p.m. **Lunch**

1:00 p.m. **Handling Committee**
Steve DeMuri, Chairperson

Sunset 2012 Recommendations on § 205.605(a)

- Flavors
- Magnesium sulfate
- Yeast

Sunset 2012 Recommendations on § 205.605(b)

- Chlorine materials
- Ferrous sulfate
- Pectin (low-methoxy)
- Phosphoric acid
- Silicon dioxide
- Sodium citrate
- Sodium hydroxide
- Sodium phosphates
- Sulfur dioxide

Sunset 2012 Recommendations on § 205.606

- Colors (19)
- Fructo-oligosaccharides
- Hops
- Inulin
- Pectin (high-methoxy)
- Cornstarch
- Whey protein

1:45 p.m. **Break**

Thursday, October 28, 2010 (continued)

2:00 p.m.	**Materials Committee** ***Katrina Heinze, Chairperson***
	Nanotechnology Guidance Document
2:45 p.m.	**Compliance, Accreditation, and Certification Committee** ***Joe Smillie, Chairperson***
	"Made With" Organic Claim Recommendation
	Limitations of § 205.101(b) Recommendation
3:05 p.m.	**Break**
3:20 p.m.	**Policy Development Committee** ***Barry Flamm, Chairperson***
	NOSB Policy and Procedure Manual Recommendations – Section IV: Establishing ad-hoc committees – Section V: NOP/NOSB Collaboration – Section VIII: Recommendation on sunset review policy
	NOSB New Member Guide Update Recommendation
3:50 p.m.	**Committee Workplans**
4:45 p.m.	**Selection of NOSB Officers and Committee Chairs**
5:15 p.m.	**Other Business and Closing Remarks**
5:30 p.m.	**Adjourn**

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: __October 2010_____ **Substance:** __Ethylene Glycol

Committee: **Crops X** **Livestock ☐** **Handling ☐** **Petition is for:** To add Ethylene Glycol to the National List § 205.601

A. Evaluation Criteria (Applicability noted for each category; Documentation attached) **Criteria Satisfied? (see B below)**

1. Impact on Humans and Environment — Yes No X N/A ☐
2. Essential & Availability Criteria — Yes ☐ No X N/A ☐
3. Compatibility & Consistency — Yes ☐ No X N/A ☐
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606) — Yes ☐ No ☐ N/A X

B. Substance Fails Criteria Category: 1,2,3___ Comments: __Material is a synthetic with many alternative materials and practices that may be employed and was previously listed on EPA's list 3 inerts.

Proposed Annotation (if any): _____
Basis for annotation: To meet criteria above: _____ Other regulatory criteria: _____ Citation:_____

C. Recommended Committee Action & Vote, including classification recommendation (State Actual Motion):
Ethylene Glycol be classified as synthetic for crop production_____

Classification of the material: Synthetic ___5____ Non- synthetic_____0_____ Absent:____2___ Abstain __0__

Motion by: ___Keven Englebert____ Seconded:__Tina Ellor_____

D. Recommended Committee Action & Vote (State Actual Motion): _Motion is to add Ethylene Glycol to the National List §205.601.

Motion by: _Jeff Moyer_ *Seconded:*_*Tina_Ellor*_ *Yes:* __*0*___ *No:* __*6*___ *Absent:* ___*1*____ *Abstain:* _____

Crops	X	Agricultural		Allowed[1]	
Livestock		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.__601_____with Annotation (if any) _____
_____

2) Substance to be added as "prohibited" on National List to § 205.__601_____with Annotation (if any) _____

_____

Describe why a prohibited substance:_____

_____

3) Substance was rejected by vote for amending National List to § 205. ___601___Describe why material was rejected: Material was rejected for reasons listed above and on the attached forms – alternatives already exist on the national list and practices that make this material unnecessary exist._____

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:

____Tina Ellor_____ **_____July 26, 2010_____**
Committee Chair **Date**

NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? **Substance -** _ Ethylene Glycol

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**			TR lines 208 – 238 Millions of gallons enter the environment through general manufacture and use. This includes entry to surface water and soil.
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]	**X**			TR lines 252 – 299 Lethal to fish, volatilizes into the air and is highly mobile in soil.
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]	**X**			Ethylene glycol is being petitioned as an inert and was listed on the EPA list 3.
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]	**X**			TR lines 303 – 336 Several materials already on the national list of allowed synthetics have the potential for interaction
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]	**X**			TR lines 341 - 348 Ethylene Glycol has been designated an air pollutant and has the ability to persist in the environment for several weeks.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]	**X**			TR lines 353 – 386 Terrestrial animals are most susceptible yet are least likely to be exposed. Soil microbes are most likely to be exposed but are less susceptible.
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]	**X**			TR lines 391 – 426 Ethylene Glycol is toxic to humans but is not listed as a carcinogen.
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]	X			TR lines 431 – 445 Yes, Ethylene Glycol is highly mobile in the soil and breaks down at various rates depending on temperature and is broken down by microorganisms.
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]	**X**			TR lines 450 – 468 Toxic to humans
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**	

[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 – Ethylene Glycol

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			TR lines 176 - 189
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			TR lines 195 – 195 There are no natural sources of this material
3. Is the substance created by naturally occurring biological processes? [6502 (21)]	X	X		TR lines 200 – 203 While ethylene glycol can be released into the soil by naturally occurring processes; however there are no natural processes that are of commercial use.
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			TR lines 473 – 482 Both ethyl alcohol and isopropyl alcohol, already listed on the national list can be used as a substitute for this material.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]			X	
9. Are there any alternative substances? [§6518 m.6]	X			TR lines 487 – 512 Many materials are already listed.
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			TR lines 518 – 547 There are many cultural practices such as crop rotations, sanitation, mechanical cultivation, flaming, and use of materials already on the list to name a few.

[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 - Ethylene Glycol

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		It is a synthetic and there are many substitute materials and alternative practices that can be employed.
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	
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: 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		

[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 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 - _Ethylene Glycol_____

Question	Yes	No	N/A	Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown)
1. Is the comparative description provided 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	

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: Fall 2010

Substance: (S, S)-Ethylenediaminedisuccinic acid (EDDS)

Committee: **Crops** ☒ **Livestock** ☐ **Handling** ☐ **Petition is for:** **adding** (S, S)-Ethylenediaminedisuccinic acid (EDDS) **on the National List § 205.601**

A. Evaluation Criteria (Applicability noted for each category; Documentation attached)

	Criteria Satisfied? (see B below)		
1. Impact on Humans and Environment	Yes ☐	No ☒	N/A ☐
2. Essential & Availability Criteria	Yes ☐	No ☒	N/A ☐
3. Compatibility & Consistency	Yes ☐	No ☒	N/A ☐
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606)	Yes ☐	No ☐	N/A ☒

B. Substance Fails Criteria Category: 1, 2, 3 **Comments:** Material is synthetic with alternative materials available. There are concerns surrounding the environmental impact of its manufacture and use as well it's compatibility and consistency with organic agriculture. See checklist for details.

C. Proposed Annotation (if any): _____

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

D. Recommended Committee Action & Vote, including classification recommendation (State Actual Motion):
EDDS be classified as a synthetic for organic crop production_____

Classification of the material: Synthetic ___5____ Non- synthetic___0_____ Absent:___2_____ Abstain __0___

Motion by: Kevin Englebert Seconded: Tina Ellor

Recommended Committee Action & Vote List EDDS on National List § 205.601 for use in organic crop production.

Motion by: Kevin Englebert Seconded: Jeff Moyer *Yes: 0___ No: _5___ Absent: _2_____ Abstain: _0___*

Crops	X	Agricultural		Allowed[1]	
Livestock		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. 601_____Describe why material was rejected: Adverse effects on humans and the environment,, not compatable with organic production and alternatives are available._____

4) Substance was recommended to be deferred because _____

If follow-up needed, who will follow up _____

F. Approved by Committee Chair to transmit to NOSB:

Tina Ellor **August 16, 2010**

Committee Chair **Date**

EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? Substance: EDDS

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	TR pages 7-9: One of the major reactants used in making EDDS is EDB, which has many adverse effects. "In the petition, no information was given whether dibromoethane, one of the two major chemicals for manufacturing (S,S)EDDS, would be completely converted to the end-product of (S,S)EDDS. If the conversion is not 100%, no information was given whether the un-reacted dibromoethane would be mixed with the end-product of (S,S)EDDS or mixed with by-products." Lines.351-444 History on the hazards of EDB
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]	X			TR page 8: **"What happens to 1,2-dibromoethane when it enters the environment?** It moves into the environment from manufacturing use and leaks at waste sites. It moves into the environment from manufacturing use and leaks at waste sites. When released, it quickly moves to air and will evaporate from surface water and soil to the air. It dissolves in water and will move through soil into the groundwater. Small amounts remain attached to soil particles. It breaks down slowly in air (over 4-5 months), more quickly in surface water (2 months), and hardly at all in groundwater. It is not expected to build up in plants or animals."
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]	X			TR page 10: Direct evidence/data are still limited.
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			Chelating agents interact with a wide range of metals and could conceivably create imbalances and/or deficiencies.

6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]	X			TR page 10: Direct evidence/data are still limited. No TR on dibromoethane, breakdown products are not known.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]	X			TR page 10: Direct evidence/data are still limited.
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]	X			TR page 10: Direct evidence/data are still limited.
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]	X			TR page 11: "Although the labeled part of (S,S)EDDS decomposed to CO_2 gas, that did not necessarily assure that the unlabeled part also decomposed to CO_2 gas since that part was not directly measured. Therefore, (S,S)EDDS as a whole compound might decompose rapidly, but the breakdown products might not be totally inorganic. The breakdown products of the unlabeled part of (S,S)EDDS may still need to be clarified. The potentially unbroken part is originated from 1,2-dibromoethane, a substance banned by US EPA in 1984 for most kinds of uses."
10. Is there any harmful effect on human health? [§6517 c (1)(A) (i) ; 6517 c(2)(A)I; §6518 m.4]	X			TR page 11: "(S,S)-EDDS is considered to be of low toxicity by US EPA. US FDA approved the use of (S,S)-EDDS in food-contacting paper or paperboards." However, it is unknown how much unreacted EDB might be present. MSDS page 3: Slightly irritating to skin, eyes, and respiratory system.
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]			X	TR page 4: The U.S. Environmental Protection Agency (EPA) established the exemption from the requirement of a tolerance for residues of (S,S)-EDDS when used as an inert ingredient sequestrant or chelating agent in pesticide formulations applied to growing crops only under 40 CFR Part 180.920 (EPA-HQ-OPP-2008-0250; FRL-8362-4; effective November 14, 2008). TR page 11: US FDA approved the use of (S,S)-EDDS in food-contacting paper or paperboards. Petition p 8: The agency's [FDA's] final ruling was a "Finding of No Significant Impact" (FONSI) when EDDS was present at no more than 0.31% b weight of the dry fiber of food-contact paper and paperboard."
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]			X	TR page 11: US FDA approved the use of (S,S)-EDDS in food-contacting paper or paperboards.
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]			X	TR, Petition (exempt from tolerance)

[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: EDDS

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			TR lines 278-292
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		TR lines 299-302. Not extracted from naturally occurring plant, animal, or mineral sources.
3. Is the substance created by naturally occurring biological processes? [6502 (21)]	X	X		The chemical process is noted above; however, lines 307-313 describes production from bacteria as an alternative.
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			Jay Feldman: Could be considered? Use of distilled or deionized water to eliminate interference of metals in the mixture. TR page 6. "In a laboratory experiment, EDDS was produced by bacteria at a rate of 20 grams per liter in fermentations of *Amycolatopsis orientalis* with feeding solution of glycerol (major component), glutamic acid an urea (major component), phosphates (minor) an Fe(III)citric acid (trace)."
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]			X	
9. Are there any alternative substances? [§6518 m.6]	X			TR page 11: as a chelating agent, EDTA not as an active ingredient but still as an inert.
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			TR page 11: Several alternative cultural methods to using pesticides (or the petitioned material) were cited in the petition (page 20 – 21 of the petition): biological controls, barrier controls, repellent controls, traps, hand picking, and cultural controls.

[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: EDDS

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, and biodiversity? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]		X		TR: Manufacture involves highly toxic reactants. No need established.
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]		X		TR page 11: breakdown products not all known. Unknown interactions with desirable metals in soils.
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: 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		

[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 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 -** EDDS

Question	Yes	No	N/A	Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown)
1. Is the comparative description provided 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	

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: October 2010	Substance: Tall Oil CAS# 8002-26-4

Committee: Crops X Livestock ☐ Handling ☐ Petition is for: Distillated Tall Oil to be included on the National List § 205.601

A. Evaluation Criteria (Applicability noted for each category; Documentation attached) **Criteria Satisfied? (see B below)**

1. Impact on Humans and Environment — Yes No **X** N/A ☐
2. Essential & Availability Criteria — Yes ☐ No **X** N/A ☐
3. Compatibility & Consistency — Yes No **X** N/A ☐
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606) — Yes ☐ No ☐ N/A **X**

B. Substance Fails Criteria Category: 1, 2, and 3; Comments: Even though Tall Oil is being petitioned as an inert, it also has insecticidal properties so the committee felt that it failed the environmental impact category. There are alternatives; therefore the committee does not feel it was essential, and the committee determined that it is not compatible or consistent with organic or sustainable agriculture.

C. Proposed Annotation (if any): _____

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

D. Recommended Committee Action & Vote, including classification recommendation (State Actual Motion):
__Tall Oil be classified as synthetic for crop production_____

Classification of the material: Synthetic ___6____ Non- synthetic_____0_____ Absent:____1___ Abstain __0__

Motion by: Keven Englebert; Seconded: Tina Ellor

Recommended Committee Action & Vote (State Actual Motion): To add Tall oil to the national list § 205.601 as a synthetic for use in crop production.

Motion by: Kevin Englebert; Seconded: Jeff Moyer Yes: 0; No: 6; Absent: 1; Abstain: 0;

Crops	**X**	Agricultural		Allowed[1]	
Livestock		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 § 205.601__Describe why material was rejected:__Substance has insecticidal properties despite being petitioned as an inert. The CC felt that it failed categories 1, 2, and 3: adverse environmental impacts, non-essential, and inconsistent with organic and sustainable agriculture.

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:

Tina Ellor **September 9, 2010**
Committee Chair **Date**

NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? **Substance –** Tall Oil

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	TR lines 194-208—environmental contamination associated with the Kraft papermaking process.
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]	X			TR lines 194-208—environmental contamination associated with the Kraft papermaking process.
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]	X	X		No: TR lines 220-250—low concern for potential risk Yes: TR lines 157-167 and 331-341. Tall oil has insecticidal properties.
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]	X			It was (is?) on the EPA List 3 Inert Substances of Unknown Toxicity
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		X		TR lines 256-278
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]	X	X		No: TR lines 283-341 Yes: TR lines 157-167 and 331-341. Tall oil has insecticidal properties. Insecticidal activity cause unintentional adverse biological interactions.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]	X	X		No: TR lines 346-412 Yes: TR lines 157-167 and 331-341. Tall oil has insecticidal properties. The insecticidal properties may be detrimental to soil organisms, especially insects.
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]	X			TR lines 417-431—Tall oil rosin may cause dermal sensitivity
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]		X		TR lines 436-457
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4]		X		TR lines 462-481
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	Tall oil is GRAS as an indirect food additive (*Handbook of Preservatives* by Ash and Ash, Synapse Information Resources 2004, page 555) and http://edocket.access.gpo.gov/cfr_2008/aprqtr/21cfr186.1557.htm
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]			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.

Category 2. Is the Substance Essential for Organic Production? Substance – Tall Oil

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			TR lines 129-146
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			TR lines 172-181
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		TR lines 186-189. It is an extract of trees, which are natural products, but it is not clear whether tall oil would exist in nature without the pulping and extraction process.
4. Is there a natural source of the substance? [§205.600 b.1]			X	TR 186-189—Tall oil products are materials extracted from wood pulp, especially pine tree wood, which is a renewable natural resource. During the process of pulping coniferous trees to make paper, sodium salts of chemicals (tall oil soaps) occurring naturally in the trees are produced as a co-product. When acidulated, this soap becomes Crude Tall Oil (US EPA, 2009).
5. Is there an organic substitute? [§205.600 b.1]			X	Vegetable oil TR line 500.
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			TR lines 486-491—animal tallow, terpene extracts from soft woods
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			TR lines 496-501, 486-491. Vegetable oils, white mineral oils
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			TR lines 506-511

[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 – Tall Oil

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		TR lines 157-167 and 331-341. Tall oil has insecticidal properties although it is being petitioned as an inert. Because of it's unintentional effects on non-target insects and therefore biodiversity, the CC felt that it is incompatible with organic farming.
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]		X		TR lines 157-167 and 331-341. Tall oil has insecticidal properties although it is being petitioned as an inert. Because of it's unintentional effects on non-target insects and therefore biodiversity, the CC felt that it is incompatible with sustainable agriculture.
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: 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		

[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 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 – Tall Oil

Question	Yes	No	N/A	Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown)
1. Is the comparative description provided 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	

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: Fall 2010 | **Substance:** 2,4,7,9-Tetramethyl–5–decyne -4,7-diol

Committee: Crops ☒ Livestock ☐ Handling ☐ **Petition is for:** adding 2,4,7,9-Teramethyl -5-decyne-4,7-diol **on the National List § 205.601**_____

A. Evaluation Criteria (Applicability noted for each category; Documentation attached) **Criteria Satisfied? (see B below)**

1. Impact on Humans and Environment — Yes ☐ No ☒ N/A ☐
2. Essential & Availability Criteria — Yes ☐ No ☒ N/A ☐
3. Compatibility & Consistency — Yes ☐ No ☒ N/A ☐
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606) — Yes ☐ No ☐ N/A ☒

B. Substance Fails Criteria Category: 1, 2, 3 **Comments:** According to the TR material is not allowed for use in organic crop production by either EU. **or Codex. See following evaluation.**_____

C. Proposed Annotation (if any): _____

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

D. Recommended Committee Action & Vote, including classification recommendation (State Actual Motion):
To aprove 2,4,7,9-Teramethyl-decyne-4,7-diol to 205.601(m) of the National List

Classification of the material: Synthetic ___X___ Non- synthetic_____ Absent:_____ Abstain _____

Motion by: Jeff Moyer Seconded: Tina Ellor Yes: __1___ No: _5____ Absent: _1_____ Abstain: _____

Crops	X	Agricultural		Allowed[1]	
Livestock		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. 601_____Describe why material was rejected: Adverse effects on humans and the environment, not compatable with organic production and alternatives are available._____

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:

_____ _____

Committee Chair **Date**

EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? Substance: Tetramethyl decyne diol

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			TAP lines 133-149: Trace amounts appear to be released to the environment via air and water. Potential concern from run off from fields after treatment.
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]	X			TAP lines 169-172: slightly toxic to fish and aquatic invertebrates and moderately toxic to aquatic plants. Has long half lives. Lines 184-5: Has ability to persist in the enviroment and interact with other chemicals and organic substances. Line 204: may have dertimental physiological effects on soil, organisms, crops or livestock.
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1) (B)(ii); 205.601(m)2]	X			List 3 Inerts of unknown toxcity.List 3 now obsolete.
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]	X			See 3 above. Also TAP lines 198-99, if solubilized in an organic solvent, there may be additional concerns about adverse effeects on the agro ecosystem.
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]	X			See 5 above.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]	X			TAP line 204
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]	X			TAP lines 204-297
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]	X			TAP lines 184-185
10. Is there any harmful effect on human health? [§6517 c (1)(A) (i) ; 6517 c(2)(A)I; §6518 m.4]	X			TAP lines 312-329: severely irritating to eyes, mildly irritating to skin, inhalation may cause headache, drowsiness, or other effects to the central nervous system.
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]	X	X		TAP lines 72-82, Petition:Has 3 EPA exemptions from the requirement of a tolerance when not more than 2.5% of the pesticide formulation.
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]		X		Not approved by FDA as a food additive.
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		X		TAP, Petition

[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: Tetramethyl

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is there a natural source of the substance? [§205.600 b.1]			X	TAP lines 122-123,128.
2. Is there an organic substitute? [§205.600 b.1]			X	TAP 332-340: There are non-synthetic sapponins and microbial wetting agents on OMRI list.
3. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			X	TAP 332-340, 342-371: alternatives are available.
4. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]			X	Possibly. See TAP lines 332-340
5. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]			X	
6. Is there any alternative substances? [§6518 m.6]	X			TAP lines 345-371: could use synethics already listed in 205.601
7. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			TAP lines 376-405: alternative practices such as bio controls, cultural measures(crop rotation, cover crops, sanitation,mowing,weeding,flame, pruning, mulches, others) natural substances, resistent varieties.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]				Duplicate question
9. Is there any alternative substances? [§6518 m.6]				Duplicate question
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]				Duplicate question

[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: Tetramethyl

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, and biodiversity? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]		X		TAP: Wide range of known and potential adverse effects to biodiversity and agro ecosystem.
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]		X		TAP line 184: Material is not readily biodegradable with ability to persist in the environment thus is not compatible with sustainable agriculture.
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: 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		

[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 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. Is the comparative description provided as to why the non-organic form of the material /substance is necessary for use in organic handling?				
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?				
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?				
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?				
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);				
b. Number of suppliers and amount produced;				
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;				
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or				
e. Are there other issues which may present a challenge to a consistent supply?				

National Organic Standards Board
Crops Committee
Reaffirmation of Spring 2010 Meeting Votes
on Sunset 2012 Recommendation

July 14, 2010

Committee Summary

At the Spring 2010 NOSB Meeting, the Crops Committee recommended, and the NOSB passed, a recommendation involving fifty-four (54) listings of Sunset materials on § 205.601 and seven (7) listings of Sunset materials on § 205.602 (included below). The public comment period for the spring recommendations did not close until after the meeting was completed; therefore, the Crops Committee agreed to determine if any of those comments warranted a change in our recommendation. No evidence was presented to justify changing our recommendations, and therefore, in accordance with the current Sunset process rules, the Crops Committee recommends the vote stands.

Committee Recommendations

The Crops Committee recommends that the votes at the spring 2010 Meeting on Sunset Recommendations – 2012 stand as recorded.

Committee Vote:

Motion: Jeff Moyer Second: Kevin Engelbert
Yes: 6 No: 0 Abstain: 0 Absent: 1

Tina Ellor, Chair

List: § 205.601 Synthetic substances allowed for use in organic crop production.

Category Use

(a) As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems.

Committee Summary

In reviewing these materials for sunset, the Crops Committee used historical information in the form of TR's, past committee and board recommendations, prior public testimony and comment, transcripts of past NOSB board meetings, and prior committee deliberations to make this recommendation. The Federal Register notice of the sunset of these materials has not been posted as of the final deadline for committee review to be included on the agenda of the April 2010 NOSB meeting. Public comments subsequent to this recommendation will be taken into consideration for the final board vote.

Committee Recommendation(s)

The Crops Committee recommends the renewal of the following materials:

(4) Hydrogen peroxide.

(7) Soap-based algicide/demossers.

The Crops Committee recommends deferring the vote on the following materials until updated technical information is obtained:

(a) As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems.

(1) Alcohols.

(i) Ethanol.
(ii) Isopropanol.

(2) Chlorine materials— *Except,* That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

(i) Calcium hypochlorite.
(ii) Chlorine dioxide.
(iii) Sodium hypochlorite.

Motion: Jeff Moyer Second: Kevin Engelbert
Yes: 6; No: 0 Absent: 1 Abstain: 0

List: § 205.601 Synthetic substances allowed for use in organic crop production.

Category Use

(b) As herbicides, weed barriers, as applicable.

Committee Summary

In reviewing these materials for sunset, the Crops Committee used historical information in the form of TR's, past committee and board recommendations, prior public testimony and comment, transcripts of past NOSB board meetings, and prior committee deliberations to make this recommendation. The Federal Register notice of the sunset of these materials has not been posted as of the final deadline for committee review to be included on the agenda of the April 2010 NOSB meeting. Public comments subsequent to this recommendation will be taken into consideration for the final board vote.

Committee Recommendation

The Crops Committee recommends the renewal of the following materials in this use category:

(1) Herbicides, soap-based—for use in farmstead maintenance (roadways, ditches, right of ways, building perimeters) and ornamental crops.

Based on changes in coating and manufacturing technologies of paper and cardboard and plastic and the introduction into the market place of possible alternatives, the Crops Committee recommends deferring relisting decisions of the following until updated technical information is obtained:

(2) Mulches.

(i) Newspaper or other recycled paper, without glossy or colored inks.
(ii) Plastic mulch and covers (petroleum-based other than polyvinyl chloride (PVC)).

Motion: Jeff Moyer Second: Kevin Engelbert
Yes: 6; No: 0 Absent: 1 Abstain: 0

List: § 205.601 Synthetic substances allowed for use in organic crop production.

Category Use

(c) As compost feedstocks—Newspapers or other recycled paper, without glossy or colored inks.

Committee Summary and Recommendation

Based on changes in coating and manufacturing technologies of paper and cardboard and the introduction into the market place of possible alternatives, the Crops Committee recommends deferring relisting decisions of the following until updated technical information is obtained:

(c) As compost feedstocks—Newspapers or other recycled paper, without glossy or colored inks.

List: § 205.601 Synthetic substances allowed for use in organic crop production.

Category Use

(d) As animal repellents—Soaps, ammonium—for use as a large animal repellant only, no contact with soil or edible portion of crop.

Committee Summary

In reviewing these materials for sunset, the Crops Committee used historical information in the form of TR's, past committee and board recommendations, prior public testimony and comment, transcripts of past NOSB board meetings, and prior committee deliberations to make this recommendation. The Federal Register notice of the sunset of these materials has not been posted as of the final deadline for committee review to be included on the agenda of the April 2010 NOSB meeting. Public comments subsequent to this recommendation will be taken into consideration for the final board vote.

Committee Recommendation

The Crops Committee recommends the renewal of the following materials:

(d) As animal repellents—Soaps, ammonium—for use as a large animal repellant only, no contact with soil or edible portion of crop.

Motion: Jeff Moyer Second: Kevin Engelbert
Yes: 6; No: 0 Absent: 1 Abstain: 0

List: § 205.601 Synthetic substances allowed for use in organic crop production.

Category Use

(3) As insecticides (including acaricides or mite control).

Committee Summary

In reviewing these materials for sunset, the Crops Committee used historical information in the form of TR's, past committee and board recommendations, prior public testimony and comment, transcripts of past NOSB board meetings, and prior committee deliberations to make this recommendation. During committee discussions for the relisting of sulfur issues regarding the purity of sulfur used came up. At the May 2009 NOSB meeting, the Board recommended adding on farm generation of sulfurous acid to the National List using 99% purity elemental sulfur. The Crops Committee would like to see the same purity standard be extended to other sulfur use categories. In discussing Boric Acid, taking into consideration changes in the industry in terms of application technologies; the committee would like to see a change considered in the current annotation to read 'in lures and baited traps only for structural pest control, not direct contact with organic food or crops. The committee would be interested inaddressing a petition to that effect and to public comment regarding this change. The Federal Register notice of the sunset of these materials has not been posted as of the final deadline for committee review to be included on the agenda of the April 2010 NOSB meeting. Public comments subsequent to this recommendation will be taken into consideration for the final board vote.

Committee Recommendation

The Crops Committee recommends the renewal of the following materials:

(1) Ammonium carbonate—for use as bait in insect traps only, no direct contact with crop or soil.

(2) Boric acid—structural pest control, no direct contact with organic food or crops.

(4) Elemental sulfur.

(5) Lime sulfur—including calcium polysulfide.

(6) Oils, horticultural—narrow range oils as dormant, suffocating, and summer oils.

(7) Soaps, insecticidal.

(8) Sticky traps/barriers.

(9) Sucrose octanoate esters (CAS #s—42922–74–7; 58064–47–4)—in accordance with approved labeling.

Motion: Jeff Moyer Second: Kevin Engelbert
Yes: 6; No: 0 Absent: 1 Abstain: 0

List: § 205.601 Synthetic substances allowed for use in organic crop production.

Category Use

(f) As insect management. Pheromones.

Committee Summary and Recommendation

There are many more pheromone products on the market than when pheromones last received technical review. The crops committee recommends deferring voting on this material until updated technical information on delivery systems, all chemicals used; and manufacture, use, and disposal issues is obtained.

(f) As insect management. Pheromones.

List: § 205.601 Synthetic substances allowed for use in organic crop production.

Category Use

(g) As rodenticides.

Committee Summary and Recommendation

The committee recommends deferring a board vote on these materials until updated technical information is obtained:

(1) Sulfur dioxide—underground rodent control only (smoke bombs).

(2) Vitamin D_3.

List: § 205.601 Synthetic substances allowed for use in organic crop production.

Category Use

(i) As plant disease control.

Committee Summary: In reviewing these materials for sunset, the Crops Committee used historical information in the form of TR's, past committee and board recommendations, prior public testimony and comment, transcripts of past NOSB board meetings, and prior committee deliberations to make this recommendation. During committee discussions for the relisting of sulfur issues regarding the purity of sulfur used came up. At the May 2009 NOSB meeting, the Board recommended adding on farm generation of sulfurous acid to the National List using 99% purity elemental sulfur. The Crops Committee would like to see the same purity standard be extended to other sulfur use categories. The Federal Register notice of the sunset of these materials has not been posted as of the final deadline for committee review to be included on the agenda of the April 2010 NOSB meeting. Public comments subsequent to this recommendation will be taken into consideration for the final board vote.

Committee Recommendation: The Crops Committee recommends the renewal of the following materials:

(3) Hydrated lime.

(4) Hydrogen peroxide.

(5) Lime sulfur.

(6) Oils, horticultural, narrow range oils as dormant, suffocating, and summer oils.

(8) Potassium bicarbonate.

(9) Elemental sulfur.

The EPA has recently reviewed copper containing compounds and the Crops Committee wanted to review that information before further deliberating on the relisting of Fixed Coppers and Copper Sulfate. There have been advances in development of alternatives for antibiotic use in control of fire blight and the crops committee felt it necessary to have updated technical information on alternative treatments to Streptomycin before completing the review of this material for sunset. The committee recommends deferring board vote on the following materials until updated technical information can be obtained:

(1) Coppers, fixed—copper hydroxide, copper oxide, copper oxychloride, includes products exempted from EPA tolerance, *Provided,* That, copper-based materials must be used in a manner that minimizes accumulation in the soil and shall not be used as herbicides.

(2) Copper sulfate—Substance must be used in a manner that minimizes accumulation of copper in the soil.

(10) Streptomycin, for fire blight control in apples and pears only.

Motion: Jeff Moyer Second: Kevin Engelbert
Yes: 6; No: 0 Absent: 1 Abstain: 0

List: § 205.601 Synthetic substances allowed for use in organic crop production.

Category Use

(j) As plant or soil amendments.

Committee Summary

In reviewing these materials for sunset, the Crops Committee used historical information in the form of TR's, past committee and board recommendations, prior public testimony and comment, transcripts of past NOSB board meetings, and prior committee deliberations to make this recommendation. During committee discussions for the relisting of sulfur issues regarding the purity of sulfur used came up. At the May 2009 NOSB meeting, the Board recommended adding on farm generation of sulfurous acid to the National List using 99% purity elemental sulfur. The Crops Committee would like to see the same purity standard be extended to other sulfur use categories. In discussing micronutrients, taking into consideration their large use, the committee would like to see the adoption of an annotation to ensure full assessments and analysis to establish the specific need for these materials, with attention to the site's existing soil fertility program, natural fertilization practices, and alternative nonsynthetic materials. The Federal Register notice of the sunset of these materials has not been posted as of the final deadline for committee review to be included on the agenda of the

April 2010 NOSB meeting. Public comments subsequent to this recommendation will be taken into consideration for the final board vote.

Committee Recommendation

The Crops Committee recommends the renewal of the following materials:

(1) Aquatic plant extracts (other than hydrolyzed)—Extraction process is limited to the use of potassium hydroxide or sodium hydroxide; solvent amount used is limited to that amount necessary for extraction.

(2) Elemental sulfur.

(3) Humic acids—naturally occurring deposits, water and alkali extracts only.

(6) Micronutrients—not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Soil deficiency must be documented by testing.

(i) Soluble boron products.
(ii) Sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt.

(7) Liquid fish products—can be pH adjusted with sulfuric, citric or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5.

(8) Vitamins, B_1, C, and E.

The Crops Committee recommends deferring voting on the following materials pending updated technical information:

(4) Lignin sulfonate—chelating agent, dust suppressant, floatation agent.

(5) Magnesium sulfate—allowed with a documented soil deficiency.

Motion: Jeff Moyer Second: Kevin Engelbert
Yes: 6; No: 0 Absent: 1 Abstain: 0

List: § 205.601 Synthetic substances allowed for use in organic crop production.

Category Use

(k) As plant growth regulators. Ethylene gas—for regulation of pineapple flowering.

Committee Summary

In reviewing these materials for sunset, the Crops Committee used historical information in the form of TR's, past committee and board recommendations, prior public testimony and comment, transcripts of past NOSB board meetings, and prior committee deliberations to make this recommendation. The Federal Register notice of the sunset of these materials has not been posted as of the final deadline for committee review to be included on the agenda of the April 2010 NOSB meeting. Public comments subsequent to this recommendation will be taken into consideration for the final board vote.

Committee Recommendation

The Crops Committee recommends the deferral of the following materials pending updated technical review on alternatives:

(k) As plant growth regulators. Ethylene gas—for regulation of pineapple flowering.

List: § 205.601 Synthetic substances allowed for use in organic crop production.

Category Use

(l) As floating agents in postharvest handling.

Committee Summary

In reviewing these materials for sunset, the Crops Committee used historical information in the form of TR's, past committee and board recommendations, prior public testimony and comment, transcripts of past NOSB board meetings, and prior committee deliberations to make this recommendation. The Federal Register notice of the sunset of these materials has not been posted as of the final deadline for committee review to be included on the agenda of the April 2010 NOSB meeting. Public comments subsequent to this recommendation will be taken into consideration for the final board vote. There was a lot of discussion about these materials during the last sunset cycle and the current Crops Committee felt that updated technical information on use, alternatives, and disposal issues would be helpful in informing the decision whether to relist these materials.

(1) Lignin sulfonate.

(2) Sodium silicate—for tree fruit and fiber processing.

List: § 205.601 Synthetic substances allowed for use in organic crop production.

Category Use

(m) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

Committee Summary

The NOP currently maintains an outdated classification listing for inerts used in pesticides under the old EPA list 4 and list 3 classifications. As of 2006 this EPA classification no longer exists and has been replaced by the new EPA classification lists 40CFR 180. The NOP issued the following statement on September 6, 2007 documenting the position of the program regarding the changes made by EPA to their List 3 and 4 inerts

The National Organic Program (NOP) regulations currently allow inert ingredients which appear on the Environmental Protection Agency (EPA) List 4A – Minimal Risk Inert Ingredients and List 4B – Other ingredients for which EPA has sufficient information to reasonably conclude that the current use pattern in pesticide products will not adversely affect the public health or the environment – as ingredients in pesticides allowed in organic production operations. These lists were maintained and managed by EPA.

EPA has been reassessing exemptions from tolerances for inert ingredients in pesticide products to ensure that they meet the safety standard established by the Food Quality Protection Act (FQPA). FQPA requires the reassessment of inert ingredient tolerances and tolerance exemptions that were in place prior to August 3, 1996. EPA completed their reassessments in 2006.

Committee Recommendation

Pending further guidance development by the this committee specifically in a document before the board at the April 2010 meeting titled ‘Guidance Recommendation on Inerts in Pesticides Allowed for use in Organic Agriculture’, the Board, and the NOP, the Crops Committee recommends deferring this material.

(1) EPA List 4—Inerts of Minimal Concern.

List: § 205.602 Nonsynthetic substances prohibited for use in organic crop production.

Category Use

The following nonsynthetic substances may not be used in organic crop production:

Committee Summary

In reviewing these materials for sunset, the Crops Committee used historical information in the form of TR's, past committee and board recommendations, prior public testimony and comment, transcripts of past NOSB board meetings, and prior committee deliberations to make this recommendation. The consensus of this committee was that we could find no compelling evidence that taking these materials off of the prohibited list would be beneficial for organic production or viewed at all favorably by organic consumers. The Federal Register notice of the sunset of these materials has not been posted as of the final deadline for committee review to be included on the agenda of the April 2010 NOSB meeting. Public comments subsequent to this recommendation will be taken into consideration for the final board vote.

Committee Recommendation

The committee recommends renewal of the following materials:

(a) Ash from manure burning.
(b) Arsenic.
(d) Lead salts.
(e) Potassium chloride—unless derived from a mined source and applied in a manner that minimizes chloride accumulation in the soil.
(f) Sodium fluoaluminate (mined).
(h) Strychnine.
(i) Tobacco dust (nicotine sulfate).

Based on the controversial nature of Sodium Nitrate and the lack of international harmonization of standards regarding this material, the committee recommends deferring the following pending more up to date technical information:

(g) Sodium nitrate—unless use is restricted to no more than 20% of the crop's total nitrogen requirement; use in spirulina production is unrestricted until October 21, 2005.

Motion: Jeff Moyer Second: Kevin Engelbert
Yes: 6; No: 0 Absent: 1 Abstain: 0

National Organic Standards Board
Crops Committee
2012 Sunset Recommendation
EPA List 4—Inerts of Minimal Concern

September 9, 2010

List: §205.601 Synthetic substances allowed for use in organic crop production.
(m)As synthetic ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient inaccordance with any limitations on the use of such substances.

(1) EPA List 4—Inerts of Minimal Concern

Committee Summary

Following the recommendation of the Board at the Spring 2010 meeting regarding these materials, it is recommended that we re-list EPA List 4 inerts pending review by the program of inerts individually and as a class of materials. To allow these materials to sunset at this point would be to disruptive to the industry.

Committee Recommendations

The Crops Committee recommends the continued listing of EPA List 4—Inerts of Minimal Concern on 205.601 Synthetics substances allowed for use in organic crop production.

Committee Vote

Motion: Jeff Moyer Second: Tina Ellor
Yes: 4 No: 2 Abstain: 0 Absent: 1

Minority Opinion

Given the statutory responsibility of the NOSB to evaluate allowable substances on the National List, including inert ingredients in pesticides, it is critical that the now defunct EPA *inert* ingredient listing process, on which the Board relied, be replaced as soon as possible by a new system of review, based on a collaboration between EPA, NOP and the NOSB. It is the minority opinion of the Crops Committee that a blanket five-year relisting of List 4 *inert* ingredients under the Sunset Review process is much too long because of the widespread use of these ingredients in product formulations and the current reliance on a now non-existent review process.

As is recognized by EPA and the guidance recommendation adopted by the NOSB at its April 2010 meeting, so-called inert ingredients—including those in products for use in organic systems—are not biologically and chemically inert. They may act as solvents, emulsifiers, synergists, or even active pesticidal ingredients. As we have seen from EPA's previous

delisting of numerous List 4 *inerts*, the review of these chemicals is not a static process, and listings are subject to change based on updated reviews, new science, and better understanding. Therefore, the NOSB must insist on an expeditious process to implement the inert ingredient guidance document adopted by the Board at its April 2010 meeting. It is the strong minority view of the Committee that the best way to express the Board's sense of urgency in upholding the legitimacy of its materials review process is to limit the time frame for relisting on the NL those chemicals previously on List 4 to three years. It is our hope and desire that the setting of a reasonable yet firm time frame will help to elevate the importance of this issue and move implementation ahead in the most expeditious fashion.

Barry Flamm and Jay Feldman

Respectfully submitted,
Tina Ellor, Chair
Crops Committee

National Organic Standards Board
Crops Committee
Corn Steep Liquor
Synthetic/Nonsynthetic Determination

September 9, 2010

Introduction

Corn Steep Liquor is a byproduct of the corn wet milling process. This material has been considered non-synthetic in the past by stakeholders including accredited certifying agents (ACAs) and the Organic Materials Review Institute (OMRI). It has been used as a nonsynthetic input mostly in liquid fertilizer formulations for organic crop production. Corn steep liquor was recently reevaluated by OMRI using the NOSB's 2005 clarifications regarding the classification of synthetic and nonsynthetic substances. OMRI concluded that CSL should be classified as synthetic based on the use of sulfur dioxide during processing. A new clarification was passed by the NOSB in November of 2009 which is the clarification that the CC used in their determination.

Background

In an action memorandum dated April 23, 2010, the National Organic Program (NOP) requested that the National Organic Standards Board (NOSB) review the process for corn steep liquor (CLS) concerning its classification as synthetic or nonsynthetic as an input for crop production for the Fall 2010 NOSB meeting. In considering this request, the CC asked the following questions of S&T:

1. Does the change to the molecule occur to any significant degree under the conditions typically found (temp, pH, form of sulfur present, etc.) in the manufacture of this product? What is the classification of this chemical change if there is a change? For example is it breaking the bond so the protein goes from insoluable to soluble? Is the physical orientation changed versus the chemical structure in terms of molecules – the name of the chemical formula is identical but the rotation is changed?

2. If so (and only if so), does the physical re-orientation of the atoms in the bond constitute a ***chemical*** change, or merely a structural change with no change in chemistry?

3. What other materials made from this process that are currently on the National List would be effected if we determine that this process causes a chemical change sufficient to be designated synthetic? And in addition to that, what products that are currently on the list that use these materials would be affected? (i.e. liquid fertilizers that use Corn Steep Liquor and other materials like starch that may be used in fertilizer or pesticide formulations)

4. Can CSL be made without the use of prohibited substances? Are there other materials that are more benign that can be used to make CSL?

5. Are there other permitted materials that could be used instead of CSL in it's current use?

The Technical Review received in February of 2010, while not answering these questions directly, was deemed adequate to go forward with discussions of synthetic/non-synthetic determination for CSL. This determination was discussed over the course of a number of CC weekly meetings.

Relevant areas in the Rule

In crop production, nonsynthetic substances are allowed unless listed on the NL §205.602, while synthetic substances are prohibited unless listed on the NL §205.601.
OFPA defines **Synthetic** is defined as "*a substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from a naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes*" (§2103 (21)) and **Nonsynthetic (natural)** is defined as "*a substance that is derived from mineral, plant, or animal matter and does not undergo a synthetic process as defined in section 6502 (21) of the Act (7 U.S.C. 6502(21)). For the purposes of this part, nonsynthetic is used as a synonym for natural as the term used in the Act*" (§205.2 Terms defined).

Chemical change is defined by the November 2009 recommendation as "*an occurrence whereby the identity of a substance is modified, such that the resulting substance possesses a different distinct identity (see related definition of "substance).* As discussed by the MWG in their recommendation, chemical change is "an event in which one substance becomes one or more difference substances." Chemical change would not necessarily include processes like ion-exchange or pH adjustment if the final material was not a different substance from the initial substance. For clarity, a definition of substance is included in the recommendation as well: *Substance* An element, molecular species, or chemical compound that possesses a distinct identity (e.g., having a separate Chemical Abstract Service (CAS) number, Codex International Numbering System (INS) number, or FDA or other agency standard of identity).

Discussion

The CC voted to classify CSL as synthetic based on the use of a non-allowed synthetic; sulfur dioxide, in the corn wet milling process. The majority of the CC felt that the sulfur dioxide use broke disulfide bonds during the steeping process prior to the lactic acid fermentation and that a significant amount of sulfur dioxide remained in the final product. The consensus of the majority was that any non-allowed synthetic used in the process of manufacturing a material makes that material synthetic. By this determination, other products of the wet corn milling process would also have to be reassessed as to their synthetic/nonsynthetic determination as well as other input into organic crop production.

Recommendation

The Crops Committee recommends that Corn Steep Liquor produced with synthetic materials not allowed for organic processing such as sulfur dioxide be classified as a synthetic.

Committee Vote

Motion: Consider CSL to be synthetic
Motion: Jeff Moyer Second: Kevin Engelbert
Yes: 4 No: 2 Abstain: 0 Absent: 1

Minority opinion

This minority opinion argues that the NOSB should determine Corn Steep Liquor (CSL) to remain classified as nonsynthetic. Such a decision would allow its continued use as an input to liquid fertilizers common in organic crop production systems.

1. Identity of CSL is unchanged by use of SO2 as a pH buffering processing aid.

First and foremost, after many years of careful deliberation by the Materials Working Group, the NOSB, the NOP, and many interested individuals in the organic community and industry, the following definition of chemical change was adopted by a supermajority of the NOSB in April 2010 through discussion of Classification of Materials:

> Chemical Change--An occurrence whereby the identity of a substance is modified, such that the resulting substance possesses a different distinct identity (see related definition of “substance”)

The minority understands that some in the majority disagree with the definition adopted by the NOSB in April, but to disregard the definition adopted under due process in one’s analysis is inappropriate. In deliberations of the Crops Committee, only the minority referenced the linchpin of identity in its decision making process. The vocal majority voiced the leading rationale that a material’s contact with a synthetic renders the whole material synthetic. The minority considers this rationale to be inaccurate, inconsistent, and unrealistic.

There was no evidence indicating that that the identity—that which makes the subject in question unique in its behavior, character, or function—of corn steep liquor as used is any different with or without SO2 as a processing aid. The behavior, character and function of the two are indistinguishable and on that basis alone, CSL remains non-synthetic.

Corn starch has previously been accepted by NOSB, using the exact same steeping process as CSL. In the 1995 TAP Review for native cornstarch, reviewer Richard Theuer stated that “sulfur dioxide is used as a ‘temporary’ preservative to avoid putrification of soaked corn. Later, fermentation inhibits putrefactive organisms.” Dr. Theuer’s recommendation was that cornstarch be classified as nonsynthetic. That same year, the NOSB determined that the SO2 used in corn starch production was a processing aid. Synthetic processing aids used in food

have not been determined to render agricultural products synthetic. If CSL was to be considered synthetic, then this decision would contradict how a handling material is listed on the National List.

CSL has a long history of safe use as an added source of nutrition in animal feed, in fermentation processes, and in antibiotic production. It is not a significant source of water or air pollution. Due to the fact that CSL is composed of proteins, amino acids, carbohydrates, organic acids (such as lactic acid), vitamins, minerals and water, no environmental contamination would be expected. These components are all readily utilized by animals and microorganisms. In fact, CSL is a nutrient rich product that has been safely used as a component in livestock feed, fertilizers, and soil conditioners for many years.

Furthermore, if the proposal that CSL should be considered to be synthetic is attributed to the sulfur dioxide used as a processing aid in the corn wet milling process, one should note that it is generally agreed that the SO2 action occurs in the endosperm protein matrix of the corn kernel, not in the steepwater. There is compelling evidence that the proteins that the SO2 allegedly alters are insoluble, thus are not a part of the CSL. The level of SO2 remaining in the final CSL product is insignificant. General analysis of corn steep liquor reports the SO2 in CSL from 0.0009 – 0.015 (Liggett and Koffler, 1948). For use in organic crop production, the CSL is typically blended with other approved materials or used as a compost feedstock, which would further reduce the already insignificant levels of SO2 to be non-detectable.

Inconsistent technical opinion

Many inconsistencies exist in the technical documentation regarding the roles that sulfur dioxide (SO2) and lactic acid play during the corn wet milling process.

One of the most common claims—claims that precipitated the NOP request for the NOSB to review this material at all—is that the starch is released from the protein matrix due to the addition of SO2, disrupting the disulfide cross-links. Several technical papers accept this, the majority citing Watson, 1984 as their reference.

However, there is also compelling documentation that the protein matrix is broken down not by SO2, but by lactic acid or endogenous enzymatic action. In these cases, the function of the SO2 is not to break the disulfide bonds, but to prevent the growth of putrefactive microorganisms and to activate proteases already present in the kernels.

The corn wet milling process is not well understood. This is evidenced by the contradictory findings and summaries of the various scientific studies and technical papers that are currently available, and specifically noted by the Technical Evaluation Report Compiled by the Technical Services Branch for the USDA National Organic Program. With respect to the wet milling process, it confirms in lines 192 and 193 that “It is a complicated process of chemical and biochemical reactions that, despite the long history of the wet-milling industry, are still not fully understood.” This is far from conclusive or even suspicious.

2. Majority rationale runs counter to past precedent and common sense, blurring the lines between classification and allowability

Wheat grass may be used as an input to an organic farm, regardless of whether it was produced organically or otherwise; its non synthetic status is not in question and likely has far more notorious residues on it than a trace amount of sulfur. That same wheat grass may not be used to make organic wheat grass juice or fed or organic livestock because the wheat grass is not organic, but that is an issue of allowability, not of classification. Even conventional wheat grass is non-synthetic.

Sugar and molasses are produced with allowed synthetic inputs and processing aids (e.g. calcium hydroxide, CO2, ion exchange resins, etc.) and never are those considered synthetic. Organic sugar is produced with calcium hydroxide and is clarified with ion exchange technology that exposes it to synthetic resins, but we do not consider organic sugar synthetic, regardless of whether that sugar is added to a fertilizer, added to a feed mix, or to organic cookie dough. The majority opinion's rational fails on this point.

Organic fruits and vegetables are frequently dumped into chlorinated water in most pack sheds and many processors. Is this produce considered synthetic because of this contact with a synthetic processing aid? Of course not; the majority opinion's rational fails on this point. If the rinds and skins are synthetic, then they would cease being able to be given to organic livestock operations for feed or to compost manufacturers because they would be synthetic inputs that would lead to decertification of livestock or would turn all compost made with them to synthetic compost.

Newspapers are considered synthetic under the NOP, yet they are allowed to be used in the manufacturing of compost for organic farms. The newspapers are considered synthetic, yet the compost is not (otherwise that compost would not be allowed on an organic farm). Again, the majority opinion's rationale fails on this point.

There are hundreds more examples to be found in this regard. As an organic community, we have already made this decision, and the minority opinion argues, have made it correctly. If that were the case, if the majority rationale carries the day, then the vast majority of organic farm inputs derived from agricultural by products would be lost to use by organic farms.

A closing comment

The purpose of soaking corn in water is to soften corn kernels so that starch can be separated from protein in order to further process the corn into other products including oil, cornstarch and corn gluten. Corn steep liquor (CSL) is a food waste from the corn wet milling process and contains an insignificant amount of the processing aid, sulfur dioxide or SO2, and includes other plant nutrients derived only from what was in the corn to begin with.

CSL was classified as a non-synthetic input in the fertilizer manufacturing community since well before the advent of the NOP. OMRI's sudden reversal of its assessment occurred without the benefit of the NOSB's definition of chemical change approved in April of 2010, which is provided below, and, in the minority opinion's view, has blurred the lines of classification and allowability.

CSL is not presently applied to crops or soil directly. It is blended with other natural ingredients in liquid fertilizer formulations and may be used as a feedstock in compost. Both uses further reduce the already insignificant amount of the processing aid, sulfur dioxide or SO2. The resulting fertilizer products are not harmful to soil or micro-organisms and provide nutrient rich material; and it is not used to supply sulfur to soil or crops. This fertilizer, like all other plant derived, simply processed crop by products contain numerous nutrients and other beneficial natural compounds.

The action of the SO2 in the countercurrent (traditional) corn wet milling process does not render CSL synthetic; the SO2 provides a buffering action to allow lactic acid fermentation to triumph over putrefaction.

Definitions

Chemical Change--An occurrence whereby the identity of a substance is modified, such that the resulting substance possesses a different distinct identity (see related definition of "substance")

Substance--An element, molecular species, or chemical compound that possesses a distinct identity (For example, a distinct identity may be demonstrated through the material having a separate Chemical Abstract Service (CAS) number (in some cases the same material may have multiple CAS numbers), Codex International Numbering System (INS) number, or FDA or other agency standard of identity).

Nonsynthetic (natural)--A substance that is derived from mineral, plant, or animal matter and does not undergo a synthetic process as defined in section 6502(21) of the Act (7 U.S.C. 6502(21)). For the purposes of this part, Nonsynthetic is used as a synonym for natural as the term is used in the Act.

Synthetic--A substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes.

Processing aid. (1) Substance that is added to a food during the processing of such food but is removed in some manner from the food before it is packaged in its finished form;
(2) a substance that is added to a food during processing, is converted into constituents normally present in the food, and does not significantly increase the amount of the constituents naturally found in the food; and
(3) a substance that is added to a food for its technical or functional effect in the processing but is present in the finished food at insignificant levels and does not have any technical or functional effect in that food.

Minority opinion: John Foster and Tina Ellor

NOSB COMMITTEE RECOMMENDATION
Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: Fall 2010 | **Substance:** Formic Acid

Committee: Crops ☐ Livestock X Handling ☐ Petition is for: adding Fomic Acid, CAS # 164-18-6, on the National List § 205.603 for use as a pesticide solely within honeybee hives.

A. Evaluation Criteria (Applicability noted for each category; Documentation attached)

		Criteria Satisfied? (see B below)
1.	Impact on Humans and Environment	Yes **X** No ☐ N/A ☐
2.	Essential & Availability Criteria	Yes **X** No ☐ N/A ☐
3.	Compatibility & Consistency	Yes **X** No ☐ N/A ☐
4.	Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606)	Yes ☐ No ☐ N/A **X**

B. Substance Fails Criteria Category: _____ Comments: With the annotation, Formic Acid does not fail any category, based on information contained in the petition, which was the only source of information provided. Even though the Livestock Committee conducted additional research, the Committee has requested a Technical Review of Formic Acid, and will reevaluate the recommendation when the TR becomes available. Given the current situation in apiculture with regard to mites, the recommendation of the 2001 NOSB, the position of the Apiculture Working Group, and the fact that with the annotation Formic Acid meets all the Evaluation Criteria, the Livestock Committee firmly believes that Formic Acid warrants being added to the National List § 205.603

C. Proposed Annotation (if any): for use as a pesticide solely within honeybee hives

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

D. Committee Recommendation Regarding Synthetic / Non-synthetic: Motion that Formic Acid be considered a synthetic substance.

Motion by: Kevin Engelbert *Seconded:* Tina Ellor *Yes:* 6 *No:* 0 *Absent:* 2 *Abstain:* 0

E. Recommended Committee Action & Vote (State Actual Motion): Motion to add Formic Acid, CAS # 164-18-6, to the National List § 205.603 for use as a pesticide solely within honeybee hives.

Motion by: Daniel G. Giacomini *Seconded:* Jennifer Hall *Yes:* 5 *No:* 0 *Absent:* 3 *Abstain:* 0

Crops		Agricultural		Allowed[1]	**X**
Livestock	**X**	Non-Synthetic		Prohibited[2]	
Handling		Synthetic	**X**	Rejected[3]	
No restriction		Commercially Un-Available as Organic[1]		Deferred[4]	

1) Substance voted to be added as "allowed" on National List to § 205.603 with Annotation (if any) for use solely as a pesticide within honeybee hives.

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: _____

4) Substance was recommended to be deferred because _____ If follow-up needed, who will follow up _____

F. Approved by Committee Chair to transmit to NOSB:

Kevin K. Engelbert — **Committee Chair**

August 3, 2010 — **Date**

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

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		No references found stating that the production and transporting of formic acid cause environmental contamination. Petition pg. 13
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		Because formic acid is used only in the hive, no environmental residues are expected to occur outside the hive. Petition pg. 11; No references found stating that the use of formic acid in honey production poses an environmental risk. Petition pg. 13
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			Formic acid is a strong acid, and as such the potential for chemical interaction does exist, but on the Material Safety Data Sheet (MSDS) the substance is rated 0 (stable) for Reactivity Petition pg. 48 & 51
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 with regard to soil interactions. Formic acid is used in conventional livestock agriculture as a preservative and antibacterial agent in livestock feed, and sometimes added to poultry feed to kill salmonella bacteria. Petition pg. 4
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		No known ecotoxicity data, but the breakdown products are less toxic than formic acid itself. Petition pg. 52, 53
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]	X			Short term degradation products are not likely, but long term degradation products may arise. Petition pg. 53 Although, no references found stating that the use of formic acid poses an environmental risk. Petition pg. 13
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]	X			If mishandled there are potential acute and chronic health effects involving skin and mucous membrane contact, along with inhalation and ingestion The substance may also be toxic to organs with repeated or prolonged exposure. Petition pg. 48 If handled properly and used according to label instructions, no harm to human health can be expected, and formic acid is a natural constituent of many foods. Petition pg. 15 & 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	

[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 - Formic Acid

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			Petition pgs. 6 & 7
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		Petition pgs. 6 & 7
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		Petition pgs. 6 & 7
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		The use of powdered sugar or Sucrose Octanoate Ester results in a short term increase in mortality rates of mites outside the hive, but no impact inside the hive. Petition pg. 16
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. above
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]		X		Drone comb removal helps control mites by removing a large portion of the mites, but does not remove them all, especially if the hive produces a small number of drones.. Petition pg. 29

[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 - Formic Acid

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			Formic acid is produced by bees and other insects as a venom, but in tropical regions the mites reproduce year round and consequently the mite populations can increase too rapidly for the honey bees to contend with. Petition pgs. 4 & 24 Formic Acid allowed in Canada & Europe. Canadian General Standards Board, Organic Production Systems Permitted Substances List, pg. 16 & EU-Regulation2092/91, 1804/1999 Annex C: Beekeeping and Beekeeping Products; Paragraph 6.3(e) Petition pgs. 9 & 10
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]	X			Honey bees produce minute levels of formic acid, which is found naturally in honey , and no increase in the levels of formic acid in honey are expected. Petition pgs. 10 & 17 Formic Acid allowed in Canada & Europe. Canadian General Standards Board, Organic Production Systems Permitted Substances List, pg. 16 & EU-Regulation2092/91, 1804/1999 Annex C: Beekeeping and Beekeeping Products; Paragraph 6.3(e) Petition pgs. 9 & 10
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: 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		

[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 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 - Formic Acid

Question	Yes	No	N/A	Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown)
1. Is the comparative description provided 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	

National Organic Standards Board
Livestock Committee
Reaffirmation of Spring 2010 Meeting Votes on
Sunset 2012 Recommendation

July 13, 2010

Committee Summary

At the Spring 2010 NOSB Meeting, the Livestock Committee recommended, and the NOSB passed, a recommendation involving twenty five (25) Sunset materials on §205.603 (included below). The public comment period for the Spring recommendations did not close until after the meeting was completed; therefore, the Livestock Committee agreed to determine of any of those comments warranted a change in our recommendation. We received two (2) comments on §205.603 materials: one commentator stated that Oxytocin and Ivermectin should be removed from the National List, and another stated that all materials should remain on the National List. No evidence was presented to justify removing those two (2) materials, and therefore, in accordance with the current Sunset process rules, the Livestock Committee recommends the vote stands.

With regard to §205.604 (also included below), no additional comments were received, and the Livestock Committee recommends the vote stands.

Committee Recommendations

The Livestock Committee recommends that the votes at the Spring 2010 Meeting on Sunset Recommendations – 2012 stand as recorded.

Committee Vote:

Motion: Dan Giacomini Second: Jeff Moyer
Yes: 7 No: 0 Abstain: 0 Absent: 1

Kevin K. Engelbert, Chair

NOSB Final Vote:

Motion: Second:
Yes: No: Abstain: Absent:

NOSB Livestock Committee – Sunset Recommendation – 2012

I. List: 205.603 Synthetic substances allowed for use in organic livestock production

II. Category Uses
(a) As disinfectants, sanitizers, and medical treatments as applicable
(b) As topical treatment, external parasiticide or local anesthetic as applicable
(c) As feed supplements
(d) As feed additives
(e) As synthetic inert ingredients
(f) As excipients

III. Committee Summary: To abide the current rules for the Sunset process, for the Livestock Committee to put forth a recommendation that would allow a material on the National List to expire, significant evidence must be found by the Committee or presented by the public that there is no further need for the substance, because naturals exist that can supplant their use. Or, evidence must exist that a substance fails the criteria by which it was originally put on the National List. Public comment against a material on the National List is not sufficient to recommend removal. Also, clarification of or changes to the annotation of a material cannot be dealt with during the Sunset process; a new petition would need to be submitted and handled through the regular petition process.

Given the constraints of the current Sunset Review process, the Livestock Committee determined which of the materials on 205.603 had enough current information to recommend re-listing, and which materials needed further technical information (TRs). The committee received no evidence from the public that would indicate an individual material should be allowed to sunset, either because a natural now exists that would supplant its use, or because there is new evidence that it now fails the criteria for listing. The materials presently recommended for re-listing include their current annotation.

DL-Methionine does not appear in this Sunset Review because it was re-petitioned on July 31, 2009 with a different annotation and, therefore, will be handled through the regular petition process.

IV. Committee Recommendations:

The Livestock Committee recommends the renewal of the following substances in the use category 205.603.

(a) As disinfectants, sanitizer, and medical treatments as applicable:

(3) Atropine (CAS #–51–55–8)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires:

(i) Use by or on the lawful written order of a licensed veterinarian; and
(ii) A meat withdrawal period of at least 56 days after administering to livestock intended for slaughter; and a milk discard period of at least 12 days after administering to dairy animals.

(4) Biologics—Vaccines.

(5) Butorphanol (CAS #–42408–82–2)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR Part 205, the NOP requires:

(i) Use by or on the lawful written order of a licensed veterinarian; and
(ii) A meat withdrawal period of at least 42 days after administering to livestock intended for slaughter; and a milk discard period of at least 8 days after administering to dairy animals.

(6) Chlorhexidine—Allowed for surgical procedures conducted by a veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.

(8) Electrolytes—without antibiotics.

(9) Flunixin (CAS #–38677–85–9)—in accordance with approved labeling; except that for use under 7 CFR part 205, the NOP requires a withdrawal period of at least two-times that required by the FDA.

(13) Hydrogen peroxide.

(14) Iodine.

(15) Magnesium hydroxide (CAS #–1309–42–8)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires use by or on the lawful written order of a licensed veterinarian.

(17) Oxytocin—use in postparturition therapeutic applications.

(18) Paraciticides. Ivermectin—prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock.

(19) Peroxyacetic/peracetic acid (CAS #–79–21–0)—for sanitizing facility and processing equipment.

(20) Phosphoric acid—allowed as an equipment cleaner, *Provided* , That, no direct contact with organically managed livestock or land occurs.

(21) Poloxalene (CAS #–9003–11–6)—for use under 7 CFR part 205, the NOP requires that poloxalene only be used for the emergency treatment of bloat.

(22) Tolazoline (CAS #–59–98–3)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires:

(i) Use by or on the lawful written order of a licensed veterinarian;
(ii) Use only to reverse the effects of sedation and analgesia caused by Xylazine; and
(iii) A meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals.

(23) Xylazine (CAS #–7361–61–7)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires:

(i) Use by or on the lawful written order of a licensed veterinarian;
(ii) The existence of an emergency; and
(iii) A meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals.

The Livestock Committee recommends deferral of the vote on the following materials in this use category until further technical information is obtained:

(1) Alcohols.

(i) Ethanol-disinfectant and sanitizer only, prohibited as a feed additive.
(ii) Isopropanol-disinfectant only.

(2) Aspirin-approved for health care use to reduce inflammation.

(7) Chlorine materials—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

(i) Calcium hypochlorite.
(ii) Chlorine dioxide.
(iii) Sodium hypochlorite.

(10) Furosemide (CAS #–54–31–9)—in accordance with approved labeling; except that for use under 7 CFR part 205, the NOP requires a withdrawal period of at least two-times that required that required by the FDA.

(11) Glucose.

(12) Glycerine—Allowed as a livestock teat dip, must be produced through the hydrolysis of fats or oils.

(16) Magnesium sulfate.

The Livestock Committee recommends not renewing the following substances in this use category:

None

The Livestock Committee recommends the renewal of the following substances in the use category 205.603.

(b) As topical treatment, external parasiticide or local anesthetic as applicable:

(2) Iodine.

(3) Lidocaine—as a local anesthetic. Use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals.

(4) Lime, hydrated—as an external pest control, not permitted to cauterize physical alterations or deodorize animal wastes.

(5) Mineral oil—for topical use and as a lubricant.

(6) Procaine—as a local anesthetic, use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals.

(7) Sucrose octanoate esters (CAS #s–42922–74–7; 58064–47–4)—in accordance with approved labeling.

The Livestock Committee recommends deferral of the vote on the following materials in this use category until further technical information obtained:

(1) Copper sulfate

The Livestock Committee recommends not renewing the following substances in this use category:

None

The Livestock Committee recommends the renewal of the following substances in the use category 205.603.

(c) As feed supplements:

None

The Livestock Committee recommends deferral of the vote on the following materials in this use category until further technical information is obtained:

None

The Livestock Committee recommends not renewing the following substances in this use category:

None

The Livestock Committee recommends the renewal of the following substances in the use category 205.603.

(d) As feed additives:

(2) Trace minerals, used for enrichment or fortification when FDA approved.

(3) Vitamins, used for enrichment or fortification when FDA approved.

The Livestock Committee recommends deferral of the vote on the following materials in this use category until further technical information is obtained:

None

The Livestock Committee recommends not renewing the following substances in this use category:

None

The Livestock Committee recommends the renewal of the following substances in the use category 205.603.

(e) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

None

The Livestock Committee recommends deferral of the vote on the following materials in this use category until further technical information is obtained:

(1) EPA List 4—Inerts of Minimal Concern.

The Livestock Committee recommends not renewing the following substances in this use category:

None

The Livestock Committee recommends the renewal of the following substance in the use category 205.603.

(f) Excipients, only for use in the manufacture of drugs used to treat organic livestock when the excipient is: Identified by the FDA as Generally Recognized As Safe; Approved by the FDA as a food additive; or Included in the FDA review and approval of a New Animal Drug Appliction or New Drug Appliction.

The Livestock Committee recommends deferral of the vote on the following materials in this use category until further technical information is obtained:

None

The Livestock Committee recommends not renewing the following substances in this use category:

None

Committee Vote:

Motion: Dan Giacomini Second: Wendy Fulwider
Yes: 6 No: 0 Abstain: 0 Absent: 2
NOSB Final Vote:

Motion: Jeff Moyer Second: Tina Ellor
Yes: 14 No: 0 Abstain: 0 Absent: 1

NOSB Livestock Committee – Sunset Recommendation – 2012

I. List: 205.604 Nonsynthetic substances prohibited for use in organic livestock production

II. Category Use

(a) Strychnine

III. Committee Summary: Some commentors specifically mentioned that strychnine should remain as a prohibited substance on the National List. The Livestock Committee agrees with the commentors that strychnine should remain as a prohibited substance on the National List because its use negatively impacts humans and the environment, is not considered essential for organic production and is not compatible with organic production practices. While the committee did receive some comments that some forms of strychnine may be beneficial as animal health care products, the committee did not agree that this reason justified removal of strychnine from §205.604. Interested parties should proceed with the petition process for amending annotations to allow specific uses of strychnine.

IV. Committee Recommendation(s):

The Livestock Committee recommends the renewal of the following substances in this use category:

(a) Strychnine

Committee Vote:

Motion: Dan Giacomini Second: Wendy Fulwider
Yes: 5 No: 0 Abstain: 0 Absent: 3

National Organic Standards Board
Livestock Committee
Section 205.603
2012 Sunset Recommendation

July 27, 2010

List: §205.603 Synthetic substances allowed for use in organic livestock production

Category Uses
(a) As disinfectants, sanitizers, and medical treatments as applicable
(b) As topical treatment, external parasiticide or local anesthetic as applicable
(e) As synthetic inert ingredients

Committee Summary

To abide the current rules for the Sunset process, for the Livestock Committee to put forth a recommendation that would allow a material on the National List to expire, significant evidence must be found by the Committee or presented by the public that there is no further need for the substance, because naturals exist that can supplant their use. Or, evidence must exist that a substance fails the criteria by which it was originally put on the National List. Public comment against a material on the National List is not sufficient to recommend removal. Also, clarification of or changes to the annotation of a material cannot be dealt with during the Sunset process; a new petition would need to be submitted and handled through the regular petition process.

Given the constraints of the current Sunset Review process, the Livestock Committee determined which of the materials on §205.603 had enough current information to recommend re-listing, and which materials needed further technical information (TRs). The committee received no evidence from the public that would indicate an individual material should be allowed to sunset, either because a natural now exists that would supplant its use, or because there is new evidence that it now fails the criteria for listing. The materials presently recommended for re-listing include their current annotation.

There were eleven (11) materials deferred at the Spring 2010 NOSB Meeting pending new Technical Reviews (TRs), and one (1) material deferred pending the outcome of the collaborative effort between the NOSB Crops Committee and the Environmental Protection Agency (EPA) regarding List 4 Inerts. For further clarification on List 4 Inerts, please reference the NOSB final recommendation from the April 26-29, 2010 meeting. The TRs in question will not be available for review by the Livestock Committee until early 2011. Even though List 4 Inerts not longer technically exist, they are still recognized by the general public, and will be until a new list, appropriately labeled, becomes available.

Rather than defer these votes again, until the Spring 2011 meeting, a majority of the Livestock Committee believes, given the current Sunset process rules, that the deferred materials should remain on the National List.

Committee Recommendations:

The Livestock Committee recommends the renewal of the following substances in the use category §205.603.

(a) As disinfectants, sanitizer, and medical treatments as applicable:

(1) Alcohols.

(i) Ethanol-disinfectant and sanitizer only, prohibited as a feed additive.
(ii) Isopropanol-disinfectant only.

(2) Aspirin-approved for health care use to reduce inflammation.

(7) Chlorine materials—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

(i) Calcium hypochlorite.
(ii) Chlorine dioxide.
(iii) Sodium hypochlorite.

(10) Furosemide (CAS #–54–31–9)—in accordance with approved labeling; except that for use under 7 CFR part 205, the NOP requires a withdrawal period of at least two-times that required that required by the FDA.

(11) Glucose.

(12) Glycerine—Allowed as a livestock teat dip, must be produced through the hydrolysis of fats or oils.

(16) Magnesium sulfate.

The Livestock Committee recommends deferral of the vote on the following materials in this use category until further technical information is obtained:

None

The Livestock Committee recommends not renewing the following substances in this use category:

None

The Livestock Committee recommends the renewal of the following substances in the use category §205.603.

(b) As topical treatment, external parasiticide or local anesthetic as applicable:

(1) Copper Sulfate

The Livestock Committee recommends deferral of the vote on the following materials in this use category until further technical information obtained:

None

The Livestock Committee recommends not renewing the following substances in this use category:

None

The Livestock Committee recommends the renewal of the following substances in the use category §205.603.

(e) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

(1) EPA List 4---Inerts of Minimal Concern.

The Livestock Committee recommends deferral of the vote on the following materials in this use category until further technical information is obtained:

None

The Livestock Committee recommends not renewing the following substances in this use category:

None

Committee Vote:

Motion: Daniel Giacomini Second: Jennifer Hall
Yes: 6 No: 1 Abstain: 0 Absent: 1
Kevin K. Engelbert, Chair

National Organic Standards Board
Livestock Committee
Organic Apiculture Recommendation

August 17, 2010

Introduction

Honey, and its associated products are valued in the organic food industry. A key alternative to refined sugars and a respected contributor to managing allergies and abrasions, honey represents an iconic product, one that consumers assume is one of the purest and simplest ways to eat as close to nature's intent. Since honeybees are animals, the Livestock Committee of the National Organic Standards Board takes responsibility for developing a recommendation for USDA standards to govern the production of organic honey and honey-related products, such as pollen, propolis, royal jelly, beeswax, and bee venom. Because the biology and behavior of honeybees is so markedly different from other types of organic livestock, and because they fly and forage a wide area, specific standards are required to ensure consistency between organic certifiers and to ensure that organic honey meets consumers' expectations for organic products.

Honey is the end result of an intricate process of Nature, performed by honey bees, which also serves as a critical input in successful agriculture and food for other species of animals and birds. At least 30% of agriculture relies directly on pollination, a job that bees perform with pure enjoyment. As the bee retrieves the nectar it needs to eat, it also collects pollen. As it travels from flower to flower on a variety of different plants to satisfy its hunger, it carries the pollen with it, thereby 'pollinating' other plants and crops, a necessary jump-start to crop maturity. While not only a functional requirement for some crops, and definitely honey production, in the true spirit of organic, the honey bee promotes biodiversity. That these bees and their forage be managed organically has a significant impact. At the near bottom of the food chain, and responsible through forage for their own contribution to 'drift,' it is important to create reliable, rigorous standards that ensure the quality and organic integrity of the food supply.

In the past decade, several issues have arisen to pose real threats to the health and survival of all honey bees. Tracheal mites, Varroa mites and Colony Collapse Disorder have all been identified as reasons for significant declines in healthy bee colonies, in fact colonies that are able to survive at all.

The commercial organic honey industry is well in place, despite the lack of organic standards specific to organic apiculture. Refined standards, which provide much needed clarification on practices specific to honeybee product production, will ensure the continued success and growth of the U.S. organic honey market. While the many certified producers have honored all the requirements of the existing regulation, there has been some variation in certifier expectations and interpretation. Finally, the EU and Canada have detailed apiculture requirements as part of their organic standards. In order to facilitate effective trade with other countries, and to effectively compete in the international market, it is important that a U.S. organic apiculture standard be implemented.

Background

As the original organic standards were being developed, an NOSB Apiculture Task Force was charged with development of organic apiculture standards. In September 2001, they issued a report and Draft Organic Apiculture Standards. The draft organic apiculture standard established allowed and prohibited production practices for organic apiculture operations based on the requirements of the Organic Foods Production Act (OFPA). It was consistent with the National Organic Program Final Rule, published December 21, 2000, and cross-references applicable sections of the rule.

The OFPA-based livestock certification requirements include provisions for the origin of livestock, the feed ration, living conditions, health care management practices, and the record keeping arrangements necessary for identification and audit trail purposes. All livestock certification requirements were addressed in the draft organic apiculture standard.

During the same time period as the release of this recommendation, the first Organic Rule was being prepared for implementation as of October 2002. The competition for priorities to address left organic apiculture on the list of items requiring attention in the future improvement and embellishment of the law.

In the interim, certifiers have used the existing Livestock Standards as a baseline for certifying organic apiculture operations, 205.236 – 205.239, and the related sections of the National List, 205.603 and 205.604. The fact that apiculture varies considerably from other livestock operations has lead to a great deal of variability in the requirements of certification. Growing pressure from the apiculture industry, the certifier community and the movement toward equivalency agreements spawned a renewed effort to develop apiculture specific organic standards.

At the Fall 2009 NOSB Meeting, the Accredited Certifiers Association Apiculture Working Group presented a document which suggested updates to the 2001 NOSB Apiculture Recommendation. The Livestock Committee's current recommendation incorporates many of the ACA Apiculture Working Group's recommendations, and also attempts to harmonize certain requirements - such as the forage zone, surveillance zone, and transition period - with EU and Canadian organic apiculture standards.

Much has changed in the intervening years. The largest organic apiculture community, in the state of Hawaii, had long been free of the Varroa mite, one of the most dangerous bee pests. In recent years, the mites reached Hawaii, and its organic honey producers struggle for survival. The feral hives are nearly extinct and the commercial hives fight for another season without the same tools as their international organic competitors from Canada and the EU, whose standards allow the use of formic acid for mite control.

Amendments to the National List

The ACA Working Group discussed materials specific to beekeeping, and noted that some which are specific to beekeeping will be required to be petitioned for inclusion on the National

List. The following are materials the Working Group believes must be reviewed for appropriate status and petitioned for addition to the National List if necessary.

Formic acid
Thymol
Carbon Dioxide

The Group does not believe that oxytetracline or terramycin should be approved for use in organic beekeeping. Antibiotics are not permitted for any other type of livestock. Synthetic miticides are also not permitted.

The Group also believes that organic formulations of feed supplements are now available, thus non-organic feed supplements do not need to be added to the National List. This includes vegetable shortening and confectionary sugar. These products are produced organically at this time.

The Group also discussed materials used in the smokers. The Group agreed that synthetic materials in bee smokers are prohibited unless listed on the National List. The Group also recommends that tobacco be added to §205.604, Nonsynthetic substances prohibited for use in organic livestock production.

The Group states that there are several materials that are not recognized by the EPA for use in bees including Folic acid, Lactic acid and Oxalic acid for mite control. If these materials do receive EPA registration, the Group recommends they be petitioned for inclusion on the National List. The group recommends that Folic acid and Lactic acid should have the following annotations:

Folic Acid – for use as a pesticide to control varroa mites solely within honeybee hives, after last honey harvest; discontinue 30 days prior to addition of bee product harvest equipment.

Lactic acid – after last honey harvest; discontinue 30 days prior to addition of bee product harvest equipment. The need must be documented and approved prior to use.

The National Organic Standards Board will consider substances related to organic honey bee production for inclusion on the National List as they are petitioned.

Recommendation

The Livestock Committee recommends that the following apiculture standards be added to the organic regulations:

Organic Apiculture Standard

§ 205.2 Terms Defined

Apiary or bee yard. An area of a collection of hives or colonies of bees kept for their bee products.

Apiculture. The management and production of honey bees, queens and bee products.

Bee products. Honey, wax, propolis, royal jelly, beeswax, pollenand bee venom or any other product from bees intended for human use or consumption.

Colony. Queen bee with its attendant worker bees and drone bees used to produce bee products.

Forage zone. Land or bodies of water, within a 1.8 mile (3 km) radius of the edge of the apiary/bee yard which provides bees with water, nectar, honeydew, pollen and propolis.

Harvest Equipment. Equipment used to collect bee products for sale as organic, including honey supers, frames from which royal jelly will be harvested, and any other equipment in contact with organic bee products.

Hive. Equipment used in the production of bee products to include hive boxes, bottom boards, covers, frames, comb.

Nucleus colony or nuc. A smaller sized hive box with reduced numbers of bees and brood, usually containing a queen; used for expansion of the apiary operation.

Replacement bees. Bees introduced into an existing organic apiary operation to replenish established colonies which have been lost to overwintering, predators or other catastrophic loss.

Surveillance zone. Land area of a 2.2 mile radius (3.4 km) beyond the forage zone which may not contain high risk activities.

§ 205.240 Apiculture practice standard.

The application of this practice standard is to regulate the production of bee products, not to require the use of organic bees for organic crop pollination.

(a) Origin of bees

(1) Transition
Bee products from an apiculture operation that are to be sold, labeled, or represented as organic must be from colonies and hives which have been under continuous organic management for no less than one year prior to the removal of the bee products from the hive.

At the beginning of the one year transition, foundation wax must be replaced and all brood comb must be new and produced by bees under organic management.

Foundation may be sourced from:
(i) Organic foundation
(ii) Plastic foundation dipped in organic or conventional wax
(iii) Organic or conventional wax

Once an entire apiary has been converted to organic production, all plastic foundation must be dipped in organic wax. Queen bees are not required to undergo transition.

(2) Replacement Bees
The introduction of bees from organic sources or from non-organic sources (i.e. packaged bees), is permitted for replacement purposes *Provided,* That the bees from non-organic sources are limited to 25% of colonies present in the previous honey flow, are managed organically for at least 60 days , and harvest equipment is removed from the hive during the 60 days.

(i) 25% count is based on the total number of colonies going into winter

(3) Expansion of the apiculture operation may be done by
(i) Purchase of organic hives and bees
(ii) Splitting of existing organic colony to form nucleus colony
(iii) Purchase of nonorganic bees, providing that they undergo a one year transition as per requirements in §205.240(a)(1).

(b) A producer of organic apiculture products must develop an organic apiculture plan in accordance with the provisions in § 205.201. In addition, the organic apiculture plan must:

(1) Contain a map of the apiary which shows the location of the hives, the forage zone, including the location of organic and wild land, and the surveillance zone, including the location of all non-organic areas and human housing;

(2) Forage Zone: Provide a description of all crops grown, the quantity of organic and/or wild forage to be provided per colony, including the type or types of forage, approximate bloom period, forage density, competing species density, honeybee colony density, colony health, colony strength, topography, and climatic conditions; and any sources of potential contamination located within the 1.8 mile (3 km) forage zone.

(3) Surveillance Zone: Provide a description of crops grown and high risk activities such as sanitary landfills, incinerators, sewage treatment facilities, power plants, golf courses, human housing, towns or cities, land to which prohibited materials are applied, and all other sources of potential contamination located in the surveillance zone of 2.2 miles (3.4 km) beyond the forage zone. GMO crops, deemed by the accredited certifying agent to be attractive to bees, are not permitted on land within the surveillance zone.

(4) Describe the water sources available in the forage zone;

(5) For split operations, list and describe the management practices used to prevent commingling and contamination, including measures to prevent commingling resulting from bee drift and robbing.

(c) A producer of organic apiculture products must maintain records in accordance with § 205.103 and § 205.236(c). Split operations are required to identify hives that have been treated with materials not permitted under §205.603 or materials prohibited under §205.604. Records must include:

(1) map of the forage zone, the surveillance zone, and the flowering times of the various plants in those zones for all bee yards
(2) affidavits verifying the 3 year land management history for the certified forage zones
(3) sources of foundation and whether foundation is organic
(4) date of last use of prohibited substances
(5) identification system for hives and bee yards
(6) verification that all comb has been drawn out under organic management
(7) the season these “clean” frames had been used for the production of organic honey
(8) a system of tracking hives, queens introduced or raised, monitoring through the season
(9) a list of inputs used and labels of inputs
(10) records of feeding including materials and dates
(11) source of any organic sugar, organic honey, organic pollen and/or organic pollen substitutes fed to colonies; certification documentation for materials fed
(12) estimated yields of all bee products per hive
(13) dates of harvest of bee products
(14) sales records of bee products
(15) packaging and labeling for bee products sold

(d) The producer must maintain colonies on land that is managed in accordance with the provisions in § 205.202 through § 205.207. All apiaries and transportation activities must be included in the OSP and approved prior to movement.

(e) The producer must provide bees with water and organic feed by:

(1) managing the forage zone as certified organic (either as crops or wild harvest) under the provisions of 205.202 through 205.207

(2) recognizing that bees from the operation may occasionally and minimally forage on non-organic land in the surveillance zone. The Organic System Plan must demonstrate that sufficient organic forage is available within the forage zone throughout the year. Given that even in well-managed operations with sufficient forage in the forage zone, a small number of bees will travel out of the forage zone to forage, the OSP must also demonstrate the crops in surveillance zone offer minimal risk to organic integrity.

(f) The producer of an organic apiculture operation may:

(1) provide supplemental feed from organic honey, organic sugar syrup, and/or pollen substitutes and supplements that are allowed under 205.603, *Except*, That, the producer must not provide organic sugar syrup less than 15 days prior to placement of bee product collection equipment.

(g) The producer of an organic apiculture operation must not:

(1) Maintain colonies during the forage season in an area where a significant risk of contamination by prohibited materials exists within a 1.8 mile (3 kilometers) radius of the apiary, as described in the operation's organic apiculture plan.

(h) Approved hive construction materials include:

(1) Hives must be made of non-synthetic materials, including wood and metal, not treated with prohibited substances.

(2) Outside hive surfaces may be painted with non-lead based paints.

(3) Plastic foundation may be used if dipped in organic beeswax

(i) The producer must establish and maintain preventive health care practices, including:

(1) Selection of bee stocks, hive densities, and colony locations appropriate to site-specific conditions and resistant to prevalent diseases and pests;

(2) Maintenance of adequate supplies of honey and pollen in the hive, including leaving hives with reserves of honey and pollen sufficient for the colony to survive the dormancy period;

(3) Use of foundation wax not contaminated with diseases or pests;

(4) Destruction of equipment and bees contaminated with disease or pests;

(5) Use of management methods or modified equipment to control pests and diseases;

(6) Use of therapeutic applications of non-synthetic materials to control pests, parasites, and diseases, *Provided*, That such materials are not prohibited under § 205.604; and

(7) Use of therapeutic applications of synthetic materials, *Provided*, That such materials are allowed under § 205.603.

(j) The producer must not:

(1) Accept the presence of pests, parasites, or disease without initiating efforts to restore the health of the colony;

(2) Use synthetic materials not listed as allowed under § 205.603;

(3) Use non-synthetic materials prohibited under § 205.604;

(4) Use lumber treated with synthetic materials not listed as allowed under § 205.603 or non-synthetic materials prohibited under § 205.604 for hive construction materials;

(5) Use synthetic materials or non-synthetic materials prohibited under § 205.604 in bee smokers;

(6) Use synthetic bee repellants to remove bees from their honey;

(7) Annually destroy bee colonies following honey flows;

(8) Rotate hives between organic and non-organic management; or

(9) Sell apiculture products as organic if they contain a residue of a prohibited material greater than 5 percent of the Environmental Protection Agency's tolerance for the specific material, pursuant to § 205.671.

Committee Vote:

Motion: Kevin Engelbert Second: Jeff Moyer
Yes: 6 No: 0 Abstain: 0 Absent: 2
Kevin K. Engelbert, Chair

National Organic Standards Board
Livestock Committee
Recommendation to Change §205.238(c)(2) in Conjunction with Scientifically Acceptable Animal Welfare Practices Regarding the Care of Organic Livestock

August 17, 2010

Introduction

Acceptable animal welfare practices include the treatment of livestock in such a way as to prevent disease and alleviate suffering in the animal. Strict reading and full enforcement of §205.238(c)(2) could make many common and acceptable best-management practices utilized by organic livestock producers to manage their livestock in such a way as to meet those two basic requirements not only discouraged but illegal. This recommendation is to help clarify the current language in the regulation and the Organic Food Production Act (OFPA) in this regard.

Background

The situation where the National List of Allowed and Prohibited Substances (NL) is a listing of specific substances allowed in organic production or processing, and in many cases those substances are rarely used as pure substances in actual production situations, created a conflict between producers and certifiers almost from the day the NOP Organic Rule went into effect.

The National Organic Standards Board (NOSB) attempted to deal with this problem by passing a recommendation to add “excipients” to §205.603 of the NL so that the drug of concern and the legal excipient carriers present in the commercial form of the drug as it was actually administered to the animal were legal in organic livestock production.

Excipients (§205.603(f)) was added to the NL in FR notice TM-07-0123 on December 13, 2007 with a fairly extensive annotation that partly included “Identified by the FDA as Generally Recognized As Safe; Approved by the FDA as a food additive; or Included in the FDA review and approval of a New Animal Drug Application or New Drug Application”.

Over time, it was determined that many substances that qualified as animal drugs, and contained excipients, were not reviewed by FDA. In November 2009, the NOSB passed a recommendation for a technical correction to the annotation for excipients to add “or approved by APHIS” to make the annotation more fully encompassing and complete.

At the same time, public comment was received that appeared to address a problem with another portion of the annotation regarding the use of the term “drugs” in the definition. The problem seemed to be that the excipients were used in many more products than simply “drugs”. The Livestock Committee (LC) recommended, and the full board passed, an amendment to add the term “animal health care products” to the definition to include a wide-range of substances. The LC stated at the time that they would put creating a definition for the term “animal health care products” to the committee’s workplan for the following meeting.

In preparing a recommendation to define the term “animal health care products”, the regulatory language guiding the current definition of “animal drug” was reviewed more completely. The list of substances included in the definition of “animal drug” is so broad that the LC felt it was not possible to parse a definition for the new term that would help alleviate the problem it was trying to correct. In all options considered “animal health care products” remained a subset of the term “animal drug” and bound to its restrictions.

At this point, the LC further reviewed the public comment presented on this topic at the November 2009 meeting. Upon further study including a review of OFPA and the National Organic Program (NOP) Final Rule, it became apparent that the larger problem was not with the use of the term “drug” in the annotation for “Excipients” on the NL but in the problematic nature of §205.238(c)(2) that animal drugs could not be administered in the absence of illness.

The LC was concerned that full and complete enforcement of the regulation, and the intent that it appears to show, would prohibit the use of many substances allowed on the NL. Full enforcement of the section could result in the prohibition of such commonly accepted preventive practices as the use of teat dip at milking time to help prevent the incidence of mastitis, and welfare practices such as the use of pain relief medication during castration, dehorning and surgery not related to illness. These restrictions would completely contradict sound animal welfare practices that many constituents from all sectors of the organic industry believe not only should be allowed in organic livestock production, but at least encouraged if not actually required.

In an effort to more clearly understand the intent of Congress regarding this particular language in OFPA and the NOP regarding the language in the Final Rule, the LC reviewed testimony provided to the NOSB at a public meeting on November 28, 2007, by current Deputy Secretary of Agriculture, Dr. Kathleen A. Merrigan and the Preamble of the Final Rule.

Sec. Merrigan stated that at the time of the passage of OFPA, which was developed in the late 1980s and passed in 1990, it was understood that organic livestock production would eventually include standards for animal health and welfare. Merrigan acknowledged that “rulemaking is a dynamic process and standards may be amended as science emerges to suggest alternative strategies”.

The Preamble accompanying the National Organic Program (NOP) Final Rule also anticipated further animal health and welfare standards stating that an organic livestock producer must establish “practices to minimize the occurrence and spread of disease and parasites” and “conduct all physical alterations to promote the animals’ welfare and in a manner than minimizes stress and pain”.

In a peer-reviewed article published in the Journal of Dairy Science (LeBlanc, et al. 2006. J. Dairy Sci. 89:1267), the authors describe some of the major areas of development in the field of animal health care over the previous 25 years. The greatest scientific advancement noted was the shift from disease treatment to disease prevention. From the mid-1960s to the late 1980s, when OFPA was developed, a major thrust of animal health care was a proactive intervention of both clinical and subclinical disease. The term illness was typically referred to infectious disease and as a stand-alone occurrence. It was during this phase that “pre-treating” in the absence of either clinical or subclinical illness became common.

In the late 1980s until today, current developments in animal health care and welfare call for more systematic and holistic management programs to maintain the health and welfare of animals. Modern scientific-based herd management incorporates an integration of many disciplines from nutrition, environment, vaccination protocols, and improved monitoring in an effort to prevent clinical disease from manifesting itself and requiring more invasive treatment.

One peer-reviewed scientific article (Erb, et al. 1985. J. Dairy Sci. 68:3337) showing the value of this recent development in animal health care examined the direct and indirect relationship between diseases on dairy farms. After studying the records of nearly 3000 dairy animals, the authors found that females suffering from dystocia (more commonly called a difficult or assisted calving) were at increased risk to suffer from other disorders such as retained placenta, metritis, mastitis, poor reproductive performance and earlier culling. Prophylactic action to prevent the animal from suffering from a difficult calving decreased the chance of all those other disorders occurring. Many other disease paths were also identified in this study. The path outlined here is only used as an example and is not intended as the breadth that this recommendation is intending to cover.

To further make the point of the change in definition of the term “illness”, only metritis and mastitis would have been described as an illness by many animal health care professionals at the time OFPA was being developed. Today, all of these disorders are considered an illness, disease, or disorder and great effort should be practiced in all livestock operations to prevent this downward cascade from beginning.

Another aspect of critical animal health care which some individuals do not believe is covered in the current language of the Final Rule is the use of pain relief medication. The Preamble clearly states that the intention of animal health care regulations is to minimize stress and pain in the animal. To say that this is the goal but that the use of allowed pain relief medications is prohibited in organic livestock production would be considered cruel by most if not all individuals concerned with the animal health and welfare.

Relevant areas in the Rule

25. ORGANIC FOODS PRODUCION ACT OF 1990
Title XXI of the Food, Agriculture, Conservation, and Trade Act of 1990
(Public Law 101-624)
SEC. 2110. [7 U.S.C. 6509] ANIMAL PRODUCTION PRACTICES AND MATERIALS.

(d) HEALTH CARE.

(1) PROHIBITED PRACTICES.—For a farm to be certified under this title as an organic farm with respect to the livestock produced by such farm, producers on such farm shall not use subtherapeutic doses of antibiotics; use synthetic internal parasiticides on a routine basis; or

(c) administer medication, other than vaccinations, in the absence of illness.

(2) STANDARDS.—The National Organic Standards Board shall recommend to the Secretary standards in addition to those in paragraph (1) for the care of livestock to ensure that such livestock is organically produced.

PART 205—NATIONAL ORGANIC PROGRAM
Animal drug. Any drug as defined in section 201 of the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 321), that is intended for use in livestock, including any drug intended for use in livestock feed but not including such livestock feed.

FDCA. SEC. 201. [21 U.S.C. 321] Definitions; generally
For the purposes of this Act—
(g)(1) The term "drug" means
(A) Articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and
(B) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and
(C) Articles (other than food) intended to affect the structure or any function of the body of man or other animals; and
(D) Articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) or sections 403(r)(1)(B) and 403(r)(5)(D), is made in accordance with the requirements of section 403(r) is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) is not a drug under clause (C) solely because the label or the labeling contains such a statement.

PART 205—NATIONAL ORGANIC PROGRAM
§ 205.238 Livestock health care practice standard.

(c) The producer of an organic livestock operation must not:

(2) Administer any animal drug, other than vaccinations, in the absence of illness;

Discussion:

In organic livestock production, scientifically advanced substances and practices help prevent the occurrence of many clinical diseases and disorders. The use of these preventives is not the same as treatment in the absence of an illness. As the definition of illness itself has expanded from infectious disease to all aspect that impair the health and welfare of the animal, the recognition of a new phase in animal health care and welfare is necessary. These substances and practices are encouraged in all areas of animal welfare and they should not only be allowed in organic livestock production, they should be encouraged. Without a proper understanding of the evolution of animal health care and of the definition of the term “illness”, a strict interpretation of the regulation as it is currently written, such practices would not only not be encouraged but they could be prohibited.

The LC is concerned that a strict reading of the current language in the Rule could result in an over-zealous enforcement where accepted animal health care substances and techniques would be prohibited including, but not limited to, the use of injectables for improved immunological, physiological and reproductive response, the use of teat dips during milking to minimize the exposure to mastitis-causing bacteria, supportive therapy during periods of stress, and pain relief medication during practices such as the removal of horns or non-injury related surgery and other veterinary practices.

As the definition of illness has evolved, without clarity of allowed animal health care practices that should not only be not be prohibited but should be encouraged, the LC recommends additional language to §205.238(c)(2) to clarify OFPA to accommodate a more complete understanding of modern health care practices and use of the term "illness". The LC is not recommending that a definition to the term "illness" be added to the NOP Final Rule. The Committee felt greater clarity would be achieved with a modification of the restrictive language in §205.238(c)(2).

Recommendation:

The Livestock Committee recommends the following change be made to §205.238(c)(2), with the additional language shown in italics.

PART 205—NATIONAL ORGANIC PROGRAM
§ 205.238 Livestock health care practice standard.

(c) The producer of an organic livestock operation must not:

(2) Administer any animal drug, other than vaccinations, *preventives, and pain relief medications,* in the absence of illness;

Committee Vote

Motion: Daniel Giacomini Second: Tina Ellor
Yes: 6 No: 0 Abstain: 0 Absent: 2
Kevin K. Engelbert, Chair

National Organic Standards Board
Livestock Committee
Animal Welfare Discussion Document
Stocking Density

September 9, 2010

Introduction

Animal welfare is a basic principle of organic production. The Livestock Committee of the NOSB considers that a focus on animal welfare warrants appropriate and effective regulation. Good animal welfare requires that animals be able to perform species specific behaviors and enjoy as natural and normal a life as possible.

From its conception, regulation in organic agriculture was intended to provide conditions that foster the natural behavior of livestock. Since research in organic animal production has increased considerably, it is now possible to obtain science-based evidence for justifying and supporting expanded regulation for improved animal management practices.

With this proposal, which involves several terms defined and added language to **§205.239 Livestock living conditions**, the Livestock Committee intends to move closer to the goal of providing stricter definitions for animal welfare in certified organic operations.

Background

The need for specificity regarding animal welfare has been considered by the Livestock Committee for many years. Consumers have become increasingly concerned about the welfare of farm animals. Organic farmers have led the way in animal welfare, and continuous improvement and clarification of the Standards are a major part of that. Stocking density, outdoor access, pasture, and outcome based standards are important components.

Livestock Committee members wish to provide specifics that will reduce confusion between producers, inspectors and certifiers. Further, the Livestock Committee determined that the imprecise language had created unintended production practices which could allow the welfare of some animals to be compromised.

The following document is a continuation of the fall 2009 NOSB animal welfare recommendation; the intention of this document is to refine, not replace, topics related to animal stocking rates. The National Organic Standards Board is presenting a framework to include the topic of stocking rates in the regulation and to invite additional discussion. In presenting the current proposal for discussion, the Livestock Committee carefully reviewed studies presented on animal welfare, considered existing legislation from other countries, and weighed comment from the organic community. Some of the major documents reviewed were:

- American Humane
- Animal Welfare Approved
- Global Animal Partnership
- Humane Farm Animal Care
- Department for Environment, Food and Rural Affairs (UK)
- Organic Production Systems, General Principles, and Management Standards (Canada)

Relevant Areas in the Rule

Those areas of the Rule which impact animal welfare include **§205.237 Livestock feed**, **§205.238 Livestock health care practice standard** and **§205.239 Livestock living conditions**. However, historical context relating to animal welfare and the intent of the Rule is best found in the testimony provided to the NOSB on November 28, 2007, by Kathleen Merrigan and William Lokeretz, both of Tufts University at that time. Dr. Merrigan reflected upon the time she had spent in helping write the Organic Foods Production Act as staff of the US Senate Committee on Agriculture, Nutrition and Forestry. The introduction to their presentation is reproduced here:

"The United States Congress foresaw the need to elaborate livestock standards in 1990 when it passed the Organic Foods Production Act. The report accompanying the Senate bill included the following statements anticipating additional standards and directing the NOSB to recommend additional standards to the Secretary.

> More detailed standards are enumerated for crop production than for livestock production. This reflects the extent of knowledge and consensus on appropriate organic crop production methods and materials. With additional research and as more producers enter into organic livestock production, the Committee expects that USDA, with the assistance of the National Organic Standards Board will elaborate on livestock criteria. (Report, 292)
>
> There are not many organic livestock producers at this time, perhaps as few as one hundred. A major reason is that few producers are willing to invest in raising animals organically since USDA explicitly prohibits meat and poultry from being labeled as organically produced. There is also little consensus on appropriate livestock standards and thus State and private programs vary widely. (Report, 302)
>
> The Board shall recommend livestock standards, in addition to those specified in this bill, to the Secretary. (Report, 303)2

These passages do not explicitly discuss health and welfare, but the general consensus of the organic community is that animal health and welfare would be encompassed whenever such standards were developed. Also, records show the central role played by The Humane Society of the United States in advocating for passage of OFPA, and it was widely understood at the time that organic livestock production would eventually include specific standards requiring superior welfare for animals.

Animal health and welfare standards were also anticipated by USDA when it promulgated the National Organic Program Final Rule. The Preamble accompanying the NOP Final Rule describes several animal health and welfare practices, most of which have yet to be fully articulated by the program. According to the Description of Regulations, an organic livestock producer ***must***:

- Select species and types of livestock with regard to suitability for site-specific conditions and resistance to prevalent diseases and parasites

- Provide a feed ration including vitamins, minerals, protein, and/or amino acids, energy sources, and, for ruminants, fiber.
- Establish appropriate housing, pasture conditions and sanitation practices to minimize the occurrence and spread of diseases and parasites.
- Maintain animals under conditions which provide for exercise, freedom of movement, and reduction of stress appropriate to the species.
- Conduct all physical alterations to promote the animals' welfare and in a manner that minimizes stress and pain.
- Establish and maintain livestock living conditions which accommodate the health and natural behavior of the livestock.
- Provide access to the outdoors, shade, shelter, exercise areas, fresh air, and direct sunlight suitable to the species, its stage of production, the climate, and the environment.
- Provide shelter designed to allow for the natural maintenance, comfort level, and opportunity to exercise appropriate to the species.

Furthermore, in sections relating to comments, the Preamble describes several issues that the Secretary understood would require elaboration in the short-term, but for which he had insufficient expertise to prescribe. In these cases, a central role for the NOSB is established, with the Board soliciting public comment, building consensus, and providing expert recommendations to USDA on animal health and welfare standards.

- (Confinement) species-specific guidelines would be developed in conjunction with future NOSB recommendations and public comment.
- We will seek additional input from the NOSB and public comment before developing such standards (on a specific length of time that cattle or other species may be confined prior to slaughter).
- We anticipate that additional NOSB recommendations and public comment will be necessary for the development of space requirements.
- The NOP will work with the NOSB to develop additional guidance for managing ruminant production operations.
- We will continue to explore with the NOSB specific conditions under which certain species could be temporarily confined to enhance their well-being."

Discussion

The tables below list livestock by species and weight. The indoor bedded space allowance is to be considered a minimum for housed animals. Outdoor runs for cattle are to be considered a minimum during the non-grazing season when weather allows animals to leave the indoor bedded area. Cattle pastured during the non-grazing season may not require an indoor bedded area. Piglets and chicks must be protected from freezing weather, so outdoor runs would not be necessary. Calves, lambs, kids, and other young animals require protection from frostbite.

Basic outcome standards for hygiene, locomotion, body condition, lesions and injury would be expected in addition to the minimum space requirements. No more than 5% of ruminant animals should have an extremely low body condition score, be obviously lame, or have lesions or injuries. No more than 2% of non-ruminant animals should have an extremely low body condition score, be obviously lame, or have lesions or injuries. No animals should have broken tails. There are many welfare groups writing standards with numbers and consumers are demanding animal welfare certification. Ultimately, the Livestock Committee will need to include numbers with the outcome based standards.

The less space provided per animal the more labor intensive it may be to keep them clean and in good health. Bedding keeps animals warm, clean, and dry and also protects animals from developing lesions due to abrasion on rough surfaces. Animals must be managed in a manner that lameness does not become a common and routine occurrence as a result of diet or housing. If routine hoof trimming due to lameness is required adjustments to diet or environment are indicated. Outdoor access allows exercise to enhance muscle tone and relieve boredom.

Bison are not domesticated animals and therefore indoor bedded space would be an added stressor.

Poultry houses and outdoor areas are to be managed in a manner that allows birds to perform natural behaviors which minimize stress and aggressive acts. Poultry mortality lessens when perches are provided because they encourage natural behaviors; strengthen bones via exercise, reduce aggression, and mortalities. Perches also allow for maximum use of vertical space within the house. Two square feet of outdoor space is required because paddocks need to be rotated to minimize parasite load for the birds and to protect the soil.

Outcome based standards require that birds be in good body condition, have good feather cover for stage of life, no more than 2% with impaired gait, poor hygiene, lesions or other injuries. Like ruminants, poultry would not need to be scored unless a problem is obvious.

Mobile poultry units require the same amount of indoor space per bird but allow the house to be moved so birds always have access to fresh vegetation.

§ 205.239 Livestock living conditions. (Mammalian section)

(c) The producer of an organic livestock operation may provide temporary confinement for an animal for the following reasons. If only one animal requires treatment another animal of the same species should be within visual proximity as a lone animal experiences increased stress. Temporary confinement may last no longer than necessary to safely perform the procedure, or address the condition:

(5)(iii) Ventilation in confined housing must be adequate to prevent buildup of ammonia. Ammonia level testing must be documented and ammonia levels must be at or below 25ppm.

Livestock	Indoor Bedded Space / Animal	Outdoor Runs and Pens
The space allowances listed below are to be considered minimums when animals cannot be provided pasture access. Young may be kept indoors when there is danger of frostbite.		
Bison weight (pounds)	NA	Square feet
Up to 220	NA	70.0
220-440	NA	120.0
440-770	NA	190.0
Over 770	NA	400 .0

Beef cattle weight (pounds)	Square feet	Square feet
Up to 220	15.0	10.0
220-440	25.0	20.0
440-770	40.0	30.0
770-1100	50.0	40.0
over 1100	10.0 sq. ft per 220 pounds	8.0 sq. ft per 220 pounds live weight

Dairy cattle weight (pounds)	Square feet	Square feet
Up to 220	15.0	10.0
220-440	25.0	20.0
440-770	40.0	30.0
770-1100	50.0	40.0
over 1100	10.0 sq. ft per 220 pounds	8.0 sq. ft per 220 pounds live weight

Sheep and goats (pounds)	Square feet	Square feet
Adults up to 230	16.0	10.0
Doe with one kid	22.0	12.0
Kid: up to 75	4.0	2.0

Swine	Square feet	Square feet
Sows and piglets	48.0	40.0
Sows	30.0	30.0
Boars	64.0	85.0
Growing pigs (pounds)	Square feet	Square feet
Up to 22	1.0	0.5
22--44	2.0	1.0
44--110	3.0	1.0
110--154	4.0	2.0
154--220	5.0	2.5
220--265	6.0	3.0

Rabbits	**Square feet**	**Square feet**
Adult rabbits	3.0	20.0
Pregnant does	5.0	20.0
Doe and litter	8.0	20.0
Young rabbits 5-12 weeks	1.0	N/A
Reserved for additional species		

§ 205.239 Livestock living conditions. (Avian section)

(1)(iv) Outdoor access should be provided at the rate of 2 square feet per bird. This would allow for rotation of paddock, re-growth of any vegetation, and reduced parasite load.

(3) Ventilation must be adequate to prevent buildup of ammonia. Ammonia level testing must be documented and ammonia levels must be at or below 25ppm.

(h) Space Allowance

Poultry housing must be sufficiently spacious to allow all birds to move freely, stretch their wings and engage in natural behaviors. Perching areas and nest boxes may not be used in the calculation of floor space. Slatted/grated floors may be considered floor space.

(i) Birds in mobile poultry units are subject to the same minimum space requirement as housed birds.

Poultry	**Indoor Bedded Space / Animal**	**Outdoor Runs and Pens**
	Square feet	Square feet
Laying hens	1.5 1.2 / bird with 6 inches perch space / bird	2.0
Pullets	1.0 / bird with 4 inches perch space / bird	2.0
Breeders	1.5 / bird 1.2 / bird with 6 inches perch space / bird	2.0
Broilers	1 sq. ft. / 6 lbs.	1 sq. ft. / 3 lbs.
Turkeys and Geese—breeding, laying, or meat birds (pounds)	1 sq, ft. / 7 lbs.	1 sq. ft. / 7 lbs.
Ducks-meat	1.0	3.0
Ducks-laying hen	2.5	6.0
Ducks—breeder	1.5	6.0

Mobile poultry units	Square feet	Maximum number of birds / acre
Laying hens Broilers Turkeys Geese	1.5 / bird 1.0 / bird 7 pounds / square foot 7 pounds / square foot	Laying hens: 800/acre Broilers:1000 /acre Turkeys:540/acre Geese:540/acre

Reserved for additional species		

(i) Access to Outdoors

(1) Doors should be spaced uniformly over the length of the poultry house. There must be direct access to outdoor areas. These should be at least 14 inches high and spaced evenly about the building. The total door opening available must be 6 feet per 1,000 hens.

Committee Vote

Motion: Jeff Moyer Second: Kevin Engelbert
Yes: 7 No: 0 Abstain: 0 Absent: 1

National Organic Standards Board
Livestock Committee
Animal Welfare Discussion Document
Animal Handling, Transport, and Slaughter

September 9, 2010

Introduction

Animal welfare is a basic principle of organic production. The Livestock Committee of the NOSB considers that a focus on animal welfare warrants appropriate and effective regulation. Good animal welfare requires that animals be able to perform species specific behaviors and enjoy as natural and normal a life as possible.

From its conception, regulation in organic agriculture was intended to provide conditions that foster the natural behavior of livestock. Since research in organic animal production has increased considerably, it is now possible to obtain science-based evidence for justifying and supporting expanded regulation for improved animal management practices.

With this proposal, which involves several terms defined and added language related to animal handling, transport and slaughter, the Livestock Committee intends to move closer to the goal of providing stricter parameters for animal welfare in certified organic operations.

Background

The need for specificity regarding animal welfare has been considered by the Livestock Committee for many years Consumers have become increasingly concerned about the welfare of farm animals. Organic farmers have led the way in animal welfare, and continuous improvement and clarification of the Standards are a major part of that. Stocking density, outdoor access, pasture, and outcome based standards are important components.

Livestock Committee members wish to provide specifics that will reduce confusion between producers, inspectors and certifiers. Further, the Livestock Committee determined that the imprecise language had created unintended production practices which could allow the welfare of some animals to be compromised.

The following document is a continuation of the fall 2009 NOSB animal welfare recommendation; the intention of this document is to refine, not replace, topics related to animal handling, transport, and slaughter. The National Organic Standards Board is presenting a framework to include the topic of animal handling, transport, and slaughter in the regulation and to invite additional discussion on the topic. In presenting the current proposal for discussion, the Livestock Committee carefully reviewed studies presented on animal welfare, considered existing legislation from other countries, and weighed comment from the organic community. Some of the major documents reviewed were:

American Humane	Humane Farm Animal Care
Animal Welfare Approved	Department for Environment, Food and Rural Affairs (UK)
Global Animal Partnership	Organic Production Systems, General Principles, and Management Standards (Canada)

Relevant Areas in the Rule

Those areas of the Rule which impact animal welfare include **§205.237 Livestock feed**, **§205.238 Livestock health care practice standard** and **§205.239 Livestock living conditions**. However, historical context relating to animal welfare and the intent of the Rule is best found in the testimony provided to the NOSB on November 28, 2007, by Kathleen Merrigan and William Lokeretz, both of Tufts University at that time. Dr. Merrigan reflected upon the time she had spent in helping write the Organic Foods Production Act as staff of the US Senate Committee on Agriculture, Nutrition and Forestry. The introduction to their presentation is reproduced here:

"The United States Congress foresaw the need to elaborate livestock standards in 1990 when it passed the Organic Foods Production Act. The report accompanying the Senate bill included the following statements anticipating additional standards and directing the NOSB to recommend additional standards to the Secretary.

> More detailed standards are enumerated for crop production than for livestock production. This reflects the extent of knowledge and consensus on appropriate organic crop production methods and materials. With additional research and as more producers enter into organic livestock production, the Committee expects that USDA, with the assistance of the National Organic Standards Board will elaborate on livestock criteria. (Report, 292)
>
> There are not many organic livestock producers at this time, perhaps as few as one hundred. A major reason is that few producers are willing to invest in raising animals organically since USDA explicitly prohibits meat and poultry from being labeled as organically produced. There is also little consensus on appropriate livestock standards and thus State and private programs vary widely. (Report, 302)
>
> The Board shall recommend livestock standards, in addition to those specified in this bill, to the Secretary. (Report, 303)2

These passages do not explicitly discuss health and welfare, but the general consensus of the organic community is that animal health and welfare would be encompassed whenever such standards were developed. Also, records show the central role played by The Humane Society of the United States in advocating for passage of OFPA, and it was widely understood at the time that organic livestock production would eventually include specific standards requiring superior welfare for animals.

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which have yet to be fully articulated by the program. According to the Description of Regulations, an organic livestock producer ***must***:

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- Conduct all physical alterations to promote the animals' welfare and in a manner that minimizes stress and pain.
- Establish and maintain livestock living conditions which accommodate the health and natural behavior of the livestock.
- Provide access to the outdoors, shade, shelter, exercise areas, fresh air, and direct sunlight suitable to the species, its stage of production, the climate, and the environment.
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Furthermore, in sections relating to comments, the Preamble describes several issues that the Secretary understood would require elaboration in the short-term, but for which he had insufficient expertise to prescribe. In these cases, a central role for the NOSB is established, with the Board soliciting public comment, building consensus, and providing expert recommendations to USDA on animal health and welfare standards.

- (Confinement) species-specific guidelines would be developed in conjunction with future NOSB recommendations and public comment.
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Discussion

Handling

Mammalian

It is important to keep animals calm. They are all herd animals and will become agitated if one is separated from the group. When moving a group of animals it is important to understand the flight zone and point of balance. If the handler is too close animals will become upset. If animals are moving and become hesitant, do not rush, touch, or strike them. Once the lead animal decides it is safe to cross a shadow or other object of intimidation the herd will follow.

The point of balance is an animal's shoulder. When handlers are in front of the point of balance animals will not move forward. When handlers are behind the point of balance animals move forward. Groups will often move quietly through a well designed chute with no problems. A light tap on the back behind the shoulder is often all that is required to get an animal to move forward.

Calm animals are the easiest to move. Livestock have different vision and hearing systems than humans which must be considered. Yelling and loud noise is very upsetting to livestock as is any change in flooring that must be crossed. Flapping objects, drafts, hissing air, and water sprayed on the face will cause animals to balk. Once animals become excited it will take 20-30 minutes for them to calm down. Electric prods should not be required or allowed to move animals through a chute or onto a trailer. Once people learn how to properly handle animals and remove objects from the environment that livestock find frightening, the prod becomes unnecessary. Flags, sorting boards, and rattle paddles may be used to encourage animals to move without touching the animal. Light can also be used to encourage animal movement as animals will move toward the light.

Non-slip flooring is a must whether it is grooved or textured concrete, or rubber matting. Walkways must be free of ice. Gates must be in good repair such that animals are not cut or bruised.

Avian

Birds should be caught for loading after they have settled in for the night and before they become active in the morning. Birds should be handled carefully and with respect to prevent injury. Ideally birds should be carried upright or held by both legs if they are inverted.

Rabbit

Rabbits must be handled carefully in order to prevent back injuries. One hand should be placed under the chest and one under the rump.

Transport

Mammalian

Animals that may be at risk for being a down animal should be slaughtered on farm or sent to the nearest local processing plant. At risk animals should not ever be loaded for long distance transport. Bulls and boars may need to be penned separately to prevent injury to other animals.
During temperature extremes measures must be taken to keep animals comfortable. During periods of extreme heat animals should be loaded and hauled during the night. Sand is a

cooling bedding material and prevents slipping. Misters or sprinklers should be used during rest stops if animals are open-mouth panting. Panels can be removed from trailers to improve air movement through the trailer. If animals must be hauled more than ten hours a rest stop with feed and water is necessary. Injuries and mortalities at delivery points must be documented to determine if any changes need to be made at the farm or by the transporter. Healthy organic animals do not have the health and mortality issues during transport that other animals may incur.

Straw bedding should be used in trailers during periods of extreme cold to prevent slipping and maintain warmth. Trailers are closed up, minimizing air movement through the trailer. Mature animals generally tolerate cold weather much better than extreme heat. Calves less than one week old should not be transported long distance.

When an immobile or fatigued animal does arrive at a plant there must be accommodations allowing the animal to rest and recover. Stretchers, sleds, hand carts, or other mechanized equipment may be used to humanely move the animal.

Avian
Birds must have adequate space to lie without being on top of one another during transport. Care must be taken to maintain comfortable environmental conditions for birds during transport.

Rabbit
Long transport times add stress which results in negative effects on meat quality. Rabbits should have enough space in transport to lie down comfortably and without being on top of one another. Care must be taken to maintain comfortable environmental conditions during transport.

Slaughter

Minimum acceptable scores
Mammalian

Stunning
Any of the following procedures renders an animal unconscious which is necessary before slaughter may begin.

1. Captive bolt stun or firearm. Captive bolt stun is safer than a firearm as there is no danger to people or other animals from a free bullet. Captive bolt is used where animals can be easily restrained or with animals unable to stand or walk.

Abattoirs must achieve 95% effective stunning with a single shot.

2. Electric stunning. The animal feels nothing when this procedure is done correctly. There are two types of electric stunning: head only and head to back. With head only the animal must be bled immediately. Head to back stunning stops heart function.

Abattoirs must achieve 99% effective stunning with a single application of the stunner.

3. Gas stunning or other chamber method—Hogs, sheep.
   Plants must achieve 100% on a 100 animal audit. A window or an internal video camera must be installed so that the animal's behavior before loss of posture can be viewed. There must be no attempts to escape from the container or struggling before the animal loses posture or the ability to stand. Vigorous movement after the animal falls over (has lost consciousness) should be ignored.

4. Halal and kosher slaughter methods are allowed. Animals must be insensible before hoisting.

Insensibility
It is important for an animal to be insensible as a result of stunning to ensure that the animal does not experience pain or fear. When viewed from a distance, the most important signs to look for in a properly stunned (insensible) animal are:

1. A floppy head
2. Tongue hangs straight out and is limp
3. The back and head hang straight down. There is no arched back righting reflex.

Animals that show all three of the above signs will be insensible and blinking and other eye reflexes will be absent.

The score must be 100% on a 100 animal audit. Animals must be rendered insensible before hoisting to the rail or starting dressing procedure.

Vocalization
Vocalization (squeal or moo) by hogs or cattle in the stun box may indicate something frightening or painful which should be corrected immediately. This measure is used in the stun box or restrainer for cattle and pigs and must not exceed 5%. This includes driving the animals into the stun box or restrainer. This measure is not used for sheep because they tend to communicate vocally on a more constant basis.

Falling
Only 1% or less may fall on a 100 head audit. Falling is defined as any part of the body touching the floor.

Electric prods may not be used.

Small plant scoring
With a sample size of less than 20 animals a single error in stunning, falling, or vocalization is allowed. This data may be aggregated over time to achieve the larger sample. Insensibility before hoisting must be 100%.

Avian

1. Electric stun. The disadvantage for poultry with electric stunning is that they must be shackled and hung upside down before they enter the stunner.

    - 99% of the birds must be rendered insensible by the stunner. Applies to both electric and controlled atmosphere.
    - 99% must be effectively cut by the bleed machine.
    - Live birds must not enter the scalder.
    - Broken and dislocated wings--there may be no more than 3% on a per bird basis fails regardless of bird weight. One percent is excellent for light weight birds.

2. Gas stunning or other chamber method. Plants must achieve 100% on a 100 animal audit. A window or an internal video camera must be installed so that the animal's behavior before loss of posture can be viewed. There must be no attempts to escape from the container, vigorous wing flapping or struggling before the animal loses posture or the ability to stand. Vigorous movement after the animal falls over (has lost consciousness) should be ignored.

Poultry would gain the greatest humane benefit from carbon dioxide or a mixture of nitrogen and argon gases, delivered in an appropriate container at acceptable concentrations. Much research has been conducted to achieve more humane slaughter conditions for poultry. Nitrogen gas mixtures are being successfully used in some instances and should be investigated by plants seeking to upgrade or renovate their slaughter practices.

Rabbit

There are few processing plants in the U.S. for rabbits. Electric stunning is the standard while smaller producers are trained in cervical dislocation.

Committee Vote

Motion: Jeff Moyer Second: Kevin Engelbert
Yes: 7 No: 0 Abstain: 0 Absent: 1

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: October 2010	Substance: Yeast

Committee: Crops ☐ Livestock ☐ Handling √ **Petition is for moving Yeast from National List § 205.605(a) to § 205.606**

A. Evaluation Criteria (Applicability noted for each category; Documentation attached) **Criteria Satisfied? (see B below)**

1.	Impact on Humans and Environment	Yes √	No ☐	N/A ☐
2.	Essential & Availability Criteria	Yes √	No ☐	N/A ☐
3.	Compatibility & Consistency	Yes √	No ☐	N/A ☐
4.	Commercial supply is Fragile or Potentially Unavailable as Organic	Yes √	No ☐	N/A ☐

B. Substance Fails Criteria Category:
Comments: The petitioner requested that yeast be moved to 606 so that organic production methodology would be required. While this may well be suitable for human consumption it would cause hardship to livestock producers who are required to use organic agricultural materials with no commercial availability option. The question of its agricultural nature is also controversial so the Handling Committee has crafted a compromise that keeps yeast on 205.605(a) but adds an annotation that requires organic if available for human consumption.

C. Proposed Annotation (if any): Yeast – When used as food, a fermentation agent, or supplement, yeast must be organic if its end use is for human consumption; nonorganic yeast may be used when equivalent organic yeast is not commercially available. Growth on petrochemical substrate and sulfite waste liquor is prohibited.

Basis for annotation: To meet criteria above: _____ Other regulatory criteria: Livestock feed requirements

D. Recommended Committee Action & Vote (State Motion):

Classification of the material: Non- synthetic; Absent: 1; Abstain: 0

Motion by: Joe Smillie; Seconded: John Foster; Yes: 6; No: 0; Absent: 1; Abstain: 0

Recommended Committee Action & Vote
Motion by: Joe Smillie; Seconded: John Foster; Yes: 6; No: 0; Absent: 1; Abstain: 0

Crops		Agricultural		Allowed[1]	X
Livestock		Non-Synthetic	X	Prohibited[2]	
Handling		Synthetic		Rejected[3]	
No restriction		Commercially Un-Available as Organic[1]		Deferred[4]	

1) Substance voted to be added as "allowed" on National List to § 205.605 with Annotation (if any): Yeast – When used as food, a fermentation agent, or supplement, yeast must be organic if its end use is for human consumption; nonorganic yeast may be used when equivalent organic yeast is not commercially available. Growth on petrochemical substrate and sulfite waste liquor is prohibited.

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: _____

Substance was recommended to be deferred because _____ If follow-up needed, who will follow up _____

E. Approved by Committee Chair to transmit to NOSB:

Steve DeMuri **Committee Chair**

September 9, 2010 **Date**

EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

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

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			On the National List 205.605 One of the benefits of organic production is that it eliminates adverse effects on the environment
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		
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		
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		X		
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		
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 concentration of the material or breakdown products in environment?[§6518 m.2]		X		
10. Is there any harmful effect on human health? [§6517 c (1)(A) (i) ; 6517 c(2)(A)I; §6518 m.4]		X		
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		

[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: Yeast

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is there a natural source of the substance? [§205.600 b.1]	X			
2. Is there an organic substitute? [§205.600 b.1]	X			
3. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]	X			
4. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X			
5. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]	X			
6. Is there any alternative substances? [§6518 m.6]		X		
7. Is there another practice that would make the substance unnecessary? [§6518 m.6]		X		
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		
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]		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.

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

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, and biodiversity? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]	X			
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			
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: 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		

[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 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 - Yeast

Question	Yes	No	N/A	Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown)
1. Is the comparative description provided as to why the non-organic form of the material /substance is necessary for use in organic handling?	X			See Attachment
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			See Attachment
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			There may be supply eventually for all Human consumption uses and possibly feed but other livestock uses are not possible in the foreseeable future. See attachment

Committee Summary

Petition is for moving Yeast from

National List § 205.605(a) to 205.606

The petitioner requested that yeast be moved to § 205.606 so that organic production methodology would be required. There has been a long history to this petition. Clearly the petitioner has pointed out the ecological differences between organic and conventional production methodology. The issue of whether yeast production is agricultural is controversial with vocal adherents on each side. This makes its placement on § 205.606 problematic. Organic yeast is now available in many forms for human consumption so the committee wants the industry to use these organic sources. The NOP has recently allowed yeast to be certified after examining the certification of the process and the product. In discussion with members of the Livestock committee another concern became clear. Moving yeast to § 205.606 would cause hardship to livestock producers because they are required to use only organic agricultural materials with no commercial availability option. While there is a strong possibility that organic yeast may be available for feed the other uses of yeast in livestock health preparations could not comply with the organic requirement. Taking these policies, concerns, and needs into consideration, the Handling Committee has crafted a compromise that keeps yeast on § 205.605 but adds an annotation that requires organic if available for human consumption.

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: ____October 2010 _____ | **Substance: __Pectin (low-methoxy) _____**

Committee: Crops ☐ Livestock ☐ Handling X Petition is for:__ Moving Pectin (low-methoxy) from National List § 205.605 to 205.606_____

A. Evaluation Criteria (Applicability noted for each category; Documentation attached) **Criteria Satisfied? (see B below)**

1.	Impact on Humans and Environment	Yes ☐	No ☐	N/A X
2.	Essential & Availability Criteria for moving 605 to 606	Yes X	No ☐	N/A ☐
3.	Compatibility & Consistency	Yes ☐	No ☐	N/A X
4.	Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606)	Yes ☐	No ☐	N/A X

B. Substance Fails Criteria Category: ___n/a_____ Comments:

C. Proposed Annotation (if any): __n/a

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

D. Recommended Committee Action & Vote (State Actual Motion): _

- Motion: Moved that Pectin (low-methoxy, non-amidated) is non-synthetic, agricultural:

  Motion by: Smilie Seconded: Demuri Yes: 6 No: 0 Absent: 1 Abstain: 0

- Motion: Moved that the following changes be made to the NL listings for pectin:
  - Pectin (low-methoxy) be removed from listing on 205.605(b)
  - Pectin (high-methoxy) be removed from listing on 205.606
  - Pectin (non-amidated forms only) be added to 205.606

  Motion by: Smilie Seconded: Demuri Yes: 6 No: 0 Absent: 1 Abstain: 0

Crops		Agricultural	X	Allowed[1]	X
Livestock		Non-Synthetic	X	Prohibited[2]	
Handling	X	Synthetic		Rejected[3]	
No restriction		Commercially Un-Available as Organic[1]	X	Deferred[4]	

_____

1) Substance voted to be added as "allowed" on National List to § 205.606 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:_____

_____

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:

_____ _____

Committee Chair **Date**

NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? **Substance -** _Pectin (low-methoxy)___

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	Reviewed in original 1995material review; no changes
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]			X	
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]			X	
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	
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]			X	
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]			X	
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 concentration of the material or breakdown products in environment?[§6518 m.2]			X	
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]			X	
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	

[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 - Pectin (low-methoxy)

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			See attached Committee Summary included after Category 4 Checklist
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		See attached Committee Summary included after Category 4 Checklist
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		See attached Committee Summary included after Category 4 Checklist
4. Is there a natural source of the substance? [§205.600 b.1]	X			See attached Committee Summary included after Category 4 Checklist
5. Is there an organic substitute? [§205.600 b.1]		X		See attached Committee Summary included after Category 4 Checklist
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]	X			Jams & jellies cannot be made without pectin
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X			The non-amidated forms of pectin are non-synthetic
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]	X			See attached Committee Summary included after Category 4 Checklist
9. Is there any alternative substances? [§6518 m.6]		X		See attached Committee Summary included after Category 4 Checklist
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]		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.

Category 3. Is the substance compatible with organic production practices? **Substance-** Pectin (low-methoxy)

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	Reviewed in original material review; no changes
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]			X	
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	
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: 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	

[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 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 - __ Pectin (low-methoxy)

Question	Yes	No	N/A	Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown)
1. Is the comparative description provided as to why the non-organic form of the material /substance is necessary for use in organic handling?			X	Reviewed in 1995 original material review; no changes
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	

Committee Summary:

The petitioner requested that pectin (low-methoxy) be moved from 205.605 to 205.606 so that organic production methodology would be required and the material would be subject to commercial availability requirements. Pectin (high-methoxy) is already listed on 205.606. These two pectins have different food processing uses (i.e., low methoxy pectin binds with sugar at a lower brix level), but are manufactured using essentially the same process. The petitioner presented documentation that stated that the main difference between high and low methoxy is the degree of esterification that results only from a longer extraction period. This longer extraction process does not result in chemical change and hence the material is not synthetic. The origin of the raw material and the extraction process used are identical for both low and high methoxy pectins. The real difference in pectin products is whether they are amidated (chemically modified with ammonia after the extraction process) or not. In investigating the original NOSB analysis of low-methoxy pectin, it seems that they either thought it was always amidated or that it went through a second process, which may be why it was placed on 205.605(b). The EU organic regulation allows pectin, does not distinguish between high and low methoxy forms and prohibits amidated forms. The original technical review dated August 17th, 2009, and the subsequent supplemental technical review requested by the Handling Committee and dated July 30th 2010 supported the petitioners position. Therefore we think that Pectin (low-methoxy) be moved to 205.606 and combined with Pectin (high-methoxy) into one listing with a new annotation to read Pectin (non-amidated forms only).

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: _____**Oct 25-28, 2010**_____ | **Substance:** _____**Glucosamine Hydrochloride**_____

Committee: Crops ☐ **Livestock** ☐ **Handling** X **Petition is for:** ___**inclusion**_____

_____ **on the National List § 205.605b**_____

A. Evaluation Criteria (Applicability noted for each category; Documentation attached) **Criteria Satisfied? (see B below)**

1.	Impact on Humans and Environment	Yes ☐	No X	N/A ☐
2.	Essential & Availability Criteria	Yes ☐	No X	N/A ☐
3.	Compatibility & Consistency	Yes ☐	No X	N/A ☐
4.	Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606)	Yes ☐	No ☐	N/A X

B. Substance Fails Criteria Category: 1 _

Comments: At issue: Disposal of toxic substances created by manufacture, Potentially toxic "dosage"

_____

C. Proposed Annotation (if any): ____N/A_____

_____

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

D. Recommended Committee Action & Vote (State Actual Motion): _Motion is to add Glucosamine HCL to the National List, 205.605b._____

Motion by:Tracy Miedema_____Seconded:_Steve DeMuri_____ Yes: _0____ No: _5___ Absent: ___1____ Abstain: ___0__

Crops		Agricultural		Allowed[1]	
Livestock		Non-Synthetic		Prohibited[2]	
Handling	X	Synthetic	X	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:_____

_____

3) Substance was rejected by vote for amending National List to § 205. _____Describe why material was rejected:_____

_____

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:

_____ _____

Committee Chair **Date**

NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

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

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			The manufacturing process is confidential and so, little information is available. There is an acid hydrolysis step in the process and, therefore, the disposal of acidic waste may be an issue. Theoretically, the acidic waste could be neutralized, depending on the amount produced.
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]	X			There is an acid hydrolysis step in the process and, therefore, the disposal of acidic waste may be an issue
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		The substance itself is not, but acidic waste is produced during production, and disposal of that waste could be harmful to the environment
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		Non-shellfish glucosamine HCl would be used in a final product form (i.e.food supplement, functional food). No deleterious reactions are known to occur in these forms. This product would not be applicable to organic production substances applied to crops.
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]			X	
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		Glucosamine HCl is made for human consumption and is not applicable to soil organisms, crops, or livestock.
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 concentration of the material or breakdown products in environment? [§6518 m.2]			X	
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]	X			Glucosamine appears to be well-tolerated for periods up to three years. The usual dose of glucosamine in studies was 1,500 mg/day in three doses, however, up to 3,200 mg/day were well-tolerated by subject; presumably doses beyond that would be harmful to humans.
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		X		Glucosamine hydrochloride is used as a nutritional supplement to relieve joint pain and is not normally part of any other foods to enhance handling/processing.
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]		X		Glucosamine hydrochloride is not generally recognized as safe (GRAS) when used according to FDA's good manufacturing practices. The FDA ceased its evaluation of glucosamine hydrochloride for GRAS status on September 9, 2004.
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		X		Glucosamine hydrochloride supplements do not contain residues of heavy metals or other contaminants in excess of FDA tolerances.

[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 - _____

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			Glucosamine hydrochloride is produced through a proprietary process that utilizes a non-genetically modified organism, *Aspergillus niger*, in a dextrose-based fermentation. The glucosamine is then isolated from the fungal biomass via acid hydrolysis, and the glucosamine hydrochloride is filtered, crystallized, centrifuged, dried, and packaged for commercial use. More specific information is not available due to the proprietary nature of the manufacturing process.
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			The glucosamine hydrochloride manufactured by the process described in the response to Evaluation Question 1 is slightly different chemically from glucosamine extracted from natural animal sources. The HCl moiety is added onto the synthesized glucosamine, due to the acid hydrolysis.
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		See process above. However, Glucosamine is an amino monosaccharide that is an essential component of mucopolysaccharides and chitin. Glycosaminoglycans (mucopolusaccharides) are large complexes of negatively-charged carbohydrate chains that are incorporated into mucous secretions, connective tissue, skin, tendons, ligaments, and cartilage of animals and shellfish.
4. Is there a natural source of the substance? [§205.600 b.1]	X			Glucosamine can be derived from shellfish waste.
5. Is there an organic substitute? [§205.600 b.1]		X		There is not an organic agricultural product that can be substituted for glucosamine.
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		A non-synthetic form of glucosamine is not available.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]		X		A non-synthetic form of glucosamine is not available.
9. Is there any alternative substances? [§6518 m.6]		X		
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]		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.

Category 3. Is the substance compatible with organic production practices? Substance – Glucosamine Hydrochloride

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			There are some issues with the manufacture, but the substance itself is compatible with handling.
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]			X	Not used in farming
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]			X	Not used in farming practice
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]			X	Glucosamine hydrochloride is used as a nutritional supplement to relieve joint pain and is not normally part of any other foods to enhance handling/processing.
5. Is the primary use as a preservative? [§205.600 b.4]		X		Glucosamine hydrochloride is not used as a preservative.
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		Glucosamine hydrochloride is not used to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk).
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		Not used in production.
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.

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 - Glucosamine Hydrochloride

Question	Yes	No	N/A	Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown)
1. Is the comparative description provided as to why the non-organic form of the material /substance is necessary for use in organic handling?		X		A non-synthetic form of glucosamine is not available. Additionally, there are no final standards for organic shellfish production.
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	

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: October 2010 | **Substance:** Hops

Committee: Crops ☐ Livestock ☐ Handling √ **Petitioned for removal from the National List on § 205.606**

A. Evaluation Criteria (Applicability noted for each category; Documentation attached) **Criteria Satisfied? (see B below)**

1.	Impact on Humans and Environment	Yes ☐ No ☐	N/A √
2.	Essential & Availability Criteria **for Removal**	Yes ☐ No √	N/A ☐
3.	Compatibility & Consistency	Yes ☐ No ☐	N/A √
4.	Not or Inconsistently Available as Organic	Yes √ No ☐	N/A ☐

B. Substance Fails Criteria Category: **NA** Comments: **This is a petition for removal from the National List**

C. Proposed Annotation (if any): NONE

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

D. Recommended Committee Action & Vote (State Motion): **Removal from section 205.606 of the National List**

Motion by: Joe Smillie *Seconded:* Steve DeMuri *Yes:* 0 *No:* 6 *Absent:* 1 *Abstain:* 0

Crops		Agricultural	X	Allowed[1] Not removed	X
Livestock		Non-Synthetic		Prohibited[2]	
Handling	X	Synthetic		Rejected[3]	
No restriction		Commercially Un-Available as Organic[1]	X	Deferred4	

1) **Substance voted to not be removed from the National List section § 205.606**

On the basis of written and public comment in response to this petition to remove, organic hops were deemed not to be available in the form, quantity, or quality to currently justify removal from 205.606. To do so would negatively impact the organic brewing industry. Many varieties of organic hops are becoming more available however, and it is the Handling Committees intention that future boards take this into consideration for any future petitions to remove, or at the next sunset of this material. The committee also reminds the industry that as a section 205.606 listed material, hops is subject to commercial availability scrutiny when used in an organic product.

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:_____

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:

Steve DeMuri — **Committee Chair**

September 3, 2010 — **Date**

NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

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

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]			XX	This is an agricultural product.
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]			XX	
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]			XX	
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]			XX	
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]			XX	
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]			XX	
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]			XX	
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]			XX	
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]			XX	
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]			XX	
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]			XX	
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]			XX	
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]			XX	

[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 - HOPS

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)]			XX	This is an agricultural product.
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)]			XX	
3. Is the substance created by naturally occurring biological processes? [6502 (21)]			XX	
4. Is there a natural source of the substance? [§205.600 b.1]			XX	
5. Is there an organic substitute? [§205.600 b.1]			XX	
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			XX	
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]			XX	
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]			XX	
9. Is there any alternative substances? [§6518 m.6]			XX	
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]			XX	

[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 - HOPS

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]			XX	This is an agricultural product.
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]			XX	
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]			XX	
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]			XX	

5. Is the primary use as a preservative? [§205.600 b.4]			XX	
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]			XX	
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: a. copper and sulfur compounds;			XX	
b. toxins derived from bacteria;			XX	
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?			XX	
d. livestock parasiticides and medicines?			XX	
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?			XX	

[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 4. Is the agricultural substance inconsistently or not commercially available as organic?
Substance - Hops

Question	Yes	No	N/A	Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown)
1. Is the comparative description provided as to why the non-organic form of the material /substance is necessary for use in organic handling?			XX	This is a petition for **removal**. Petitioner claims adequate supply of organic hops is now available.
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?			XX	The petitioner claims that hops can now be sourced as organic, but a significant number of written and public comments at the Spring 2010 NOSB meeting contended that although some varieties of hops were available as organic, not all varieties are equal, and many varieties used for specific flavor profiles or beer types were not available.

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?		XX		See number 2 above. As 205.606 listed materials, hops are subject to commercial availability scrutiny, so varieties of hops that are available as organic must be used. The onus of proof is on the handler to prove to it's certifier that conventional forms of hops would be necessary in an organic product.
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?		XX		The petitioner describes why organic hops are now available, but credible public comment refutes that all necessary varieties are available as organic.
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);	XX			Availability information was submitted in the petition. In the United States, hops are primarily grown on family owned and operated farms in the Pacific Northwest, with the majority of hop farms located in Washington's Yakima Valley. In 2008, the State produced 30,595 acres of hops, which made up 75% of the U.S. commercial hop production. Behind Washington was Oregon with 6,370 acres (15.5%) and Idaho with 3,933 acres (9.5%)
b. Number of suppliers and amount produced;	XX			The organic hop industry has made significant advances since the NOSB recommendation to include hops on the National List in June 2007. Hop farmers in the Pacific Northwest, as well as other growing regions throughout the U.S., are now producing organic hops on at least 100 acres of farmland, resulting in tens of thousands of pounds of organic hops produced domestically in 2009. This effort has resulted in at least nine new organic hop varieties, bringing the total number of available organic hop varieties to at least thirty. Public comments indicate that although the organic hops industry has grown, there is still not the form, quantity, and quality available to serve the entire organic beer industry.
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;		XX		No information provided on this aspect of availability.
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or		XX		No information provided on this aspect of availability.
e. Are there other issues which may present a challenge to a consistent supply?	XX			New and greater amounts of organic hop varieties continue to be produced. In the not too distant future, hops could legitimately be removed or allowed to sunset from the National List.

National Organic Standards Board
Handling Committee
Sunset Recommendation – 2012
Reaffirmation of April 2010 § 205.605(a) Recommendations

September 3, 2010

List: 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

(a) Nonsynthetics allowed

Committee Summary

Federal register notice of the sunset of these materials elicited no public comments against re-listing.

Review of the original recommendations, historical documents, and public comments does not reveal unacceptable risks to the environment, human, or animal health as a result of the use or manufacture of these materials. There is no new information contradicting the original recommendation which were the basis for the previous NOSB decisions to list these materials.

Committee Recommendation(s)

The handling committee reaffirms it's recommendation for the renewal of the following substances in this use category as published in the final rule:

Acids (Alginic; Citric – produced from microbial fermentation of carbohydrate substances; and Lactic)
Bentonite
Calcium Carbonate
Calcium Chloride
Carageenan
Dairy cultures
Diatomaceous earth – food filtering aid only
Kaolin
Nitrogen – oil free grades

Oxygen – oil free grades

Perlite – for use only as a filter aid in food processing

Potassium chloride

Sodium bicarbonate

Sodium carbonate

Waxes – nonsynthetic (Carnauba wax; and Wood resin)

Committee Vote:

Motion: Steve DeMuri Second: Tracy Miedema
Yes: 6 No: 0 Abstain: 0 Absent: 1

National Organic Standards Board
Handling Committee
Sunset Recommendation – 2012
Reaffirmation of April 2010 § 205.605(b) Recommendations

August 30, 2010

List: 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

(b) Synthetics allowed

Committee Summary

Federal register notice of the sunset of these materials elicited no public comments against re-listing since the April 2010 NOSB meeting

Review of the original recommendations, historical documents, and public comments does not reveal unacceptable risks to the environment, human, or animal health as a result of the use or manufacture of these materials. There is no new information contradicting the original recommendation which were the basis for the previous NOSB decisions to list these materials.

Committee Recommendation(s)

The handling committee reaffirms it's recommendations for the renewal of the following substances in this use category as published in the final rule:

Calcium phosphates (monobasic, dibasic, and tribasic)

Carbon dioxide

Ethylene – allowed for postharvest ripening of tropical fruit and degreening of citrus.

Glycerin – produced by hydrolysis of fats and oils

Hydrogen peroxide

Magnesium carbonate – for use only in agricultural products labeled 'made with organic (specified ingredients or food group(s)),' prohibited in agricultural products labeled 'organic"

Magnesium chloride – derived from sea water

Magnesium stearate - for use only in agricultural products labeled 'made with organic (specified ingredients or food group(s)),' prohibited in agricultural products labeled 'organic"

Ozone

Potassium acid tartrate

Potassium carbonate

Potassium citrate

Potassium hydroxide – prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches during the Individually Quick Frozen (IQF) production process

Potassium phosphate - for use only in agricultural products labeled 'made with organic (specified ingredients or food group(s)),'' prohibited in agricultural products labeled 'organic''

Xanthan gum

Alginates

Ammonium bicarbonate – for use only as a leavening agent

Ammonium carbonate - for use only as a leavening agent

Ascorbic Acid

Calcium citrate

Calcium hydroxide

Committee Vote:

Motion: Steve DeMuri Second: Tracy Miedema
Yes: 6 No: 0 Abstain: 0 Absent: 1

National Organic Standards Board
Handling Committee
Sunset Recommendation – 2012
Reaffirmation of April 2010 § 205.606 Recommendations

August 30, 2010

List: 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."

Committee Summary:

Federal register notice of the sunset of these materials elicited no public comments against re-listing after the April 2010 NOSB meeting.

Review of the original recommendations, historical documents, and public comments does not reveal unacceptable risks to the environment, human or animal health as a result of the use or manufacture of these materials. There is no new information contradicting the original recommendation which were the basis for the previous NOSB decisions to list these materials. As 205.606 listed materials, all are subject to commercial availability scrutiny for use in organic products.

Committee Recommendation(s)

The handling committee reaffirms it's previous recommendation for the renewal of the following substances in this use category as published in the final rule:

Casings – from processed intestines

Celery powder

Chia (*Salvia hispanica L.*)

Dillweed Oil (CAS # 8006-75-5)

Fish Oil (fatty acid CAS #'s 10417-94-4 and 25167-62-8) stabilized with organic ingredients or only with ingredients on the National List 205.605 and 205.606

Galangal, frozen

Gelatin (CAS # 9000-70-8)

Gums – water extracted only (Arabic, Guar, Locust bean, and Carob bean)

Konjac flour (CAS # 37220-17-0)

Lemongrass – frozen

Orange shellac – unbleached (CAS # 9000-59-3)

Pepper, chipotle pepper

Kelp – for use only as a thickener and dietary supplement

Sweet potato starch – for bean thread production only

Turkish bay leaves

Wakame seaweed (*Undaria pinnatifida*)

Committee Vote:

Motion: Steve DeMuri Second: Joe Smillie
Yes: 6 No: 0 Abstain: 0 Absent: 1

National Organic Standards Board
Handling Committee
Sunset Recommendation – 2012
Glycerides (Mono and Di)

August 30, 2010

List: 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

(b) Synthetics allowed:

Glycerides (mono and di)—for use only in drum drying of food.

Committee Summary

Federal register notice of the sunset of these materials brought forth public comment against re-listing mono- and di-glycerides in favor of a certified organic alternative. This comment was provided by the manufacturer of the proposed alternative substance. At that time and since that time, no documentation has been provided (such as testimonials from food manufacturers using the proposed alternate) to demonstrate the utility of the proposed alternate in applications of mono- and di-glycerides. Several commenters supported re-listing this material during in April-May of 2010.

In an organic processing context, mono- and di-glycerides are used only in drum drying of foods.

Review of the original recommendations, historical documents, and public comments does not reveal unacceptable risks to the environment, human, or animal health as a result of the use or manufacture of these materials. There is no new information contradicting the original recommendation which were the basis for the previous NOSB decisions to list and re-list these materials.

Committee Recommendation(s)

The handling committee recommends the renewal of the following substance in this use category as published in the final rule:

Glycerides (mono and di)—for use only in drum drying of food.

Committee Vote

Motion: John Foster Second: Joe Smillie
Yes: 6 No: 0 Abstain: 0 Absent: 1

National Organic Standards Board
Handling Committee
Recommendation for Annotation Change on § 205.606
For Colors Derived From Agricultural Products

August 17, 2010

List: National Organic Program Subpart G: The National List of Allowed and Prohibited Substances. §205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic.

(d) Colors derived from agricultural products

Committee Summary

The following colors are on section §205.606 of the National List (Federal Register Vol. 72, #123, June 27, 2007):

1. Annatto extract color (pigment CAS # 1393–63–1)—water and oil soluble.
2. Beet juice extract color (pigment CAS # 7659–95–2).
3. Beta-Carotene extract color from carrots (CAS # 1393–63–1).
4. Black currant juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
5. Black/Purple carrot juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
6. Blueberry juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
7. Carrot juice color (pigment CAS # 1393–63–1).
8. Cherry juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
9. Chokeberry—Aronia juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
10. Elderberry juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
11. Grape juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
12. Grape skin extract color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
13. Paprika color—dried powder and vegetable oil extract (CAS # 68917–78–2).
14. Pumpkin juice color (pigment CAS # 127–40–2).
15. Purple potato juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).

16. Red cabbage extract color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
17. Red radish extract color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
18. Saffron extract color (pigment CAS # 1393–63–1).
19. Turmeric extract color (CAS # 458–37–7).

These nineteen colors were added to section §205.606 of the National List after the §205.605(a) listing of Colors -- nonsynthetic only was allowed to sunset off the National List. The 'sunsetting' of colors from §205.605(a) resulted in a number of petitions for listing of various colors on §205.606. The Handling Committee of the NOSB reviewed each of these petitions and made recommendations to list each on the National List. Of those petitions, these nineteen colors were recommended for listing by the NOSB at the March 2007 NOSB meeting.

Annotations for several of the colors were discussed in detail at that meeting. For each of the nineteen colors recommended for listing, either oil or water extraction plus physical processing (e.g., cutting, grinding, drying) was listed as the manufacturing process. For ten of the colors the petitioner specifically identified that 1) the extraction process was a physical process, 2) water, invert sugar and citric acid may be added during manufacturing, 3) the color was not formulated or processed with any synthetic adjuvant or aid and 4) no chemical solvents were used in processing. Additionally, this petitioner provided evidence that their manufacturing process was certified organic to the National Organic Program regulations even though the raw material color input was not. The other nine petitions did not indicate that solvents beyond water or oil were used. This was strongly supported by public comment during the March 2007 NOSB meeting.

For two colors, annatto and paprika, the Handling Committee originally recommended that oil extraction be restricted to using organic oil. In both cases, this annotation was deemed too restrictive and was not included in the final recommendation. A quote from the March 2007 meeting transcripts best captures this perspective, "Annotations restrict the use of materials that come in a variety of ways to the ones which are acceptable to be used in organic production. It is not used to designate how things get produced. Oil, organic oil crossed that line. If you wanted to say oil production as opposed to water production, both of those are available, and if you were narrowing in on one that's acceptable, that's appropriate, but this is imposing organic regulations on a nonorganic world." It was this perspective that only annotations which limited which available nonorganic materials could be used but did not impose additional organic restrictions on nonorganic materials that kept the NOSB during the March 2007 meeting from adding additional annotations restricting how the colors were extracted.

Since the March 2007 meeting, it has come to the attention of the Handling Committee that there may be confusion as to whether synthetic solvents may be used to extract some of these colors and whether use of synthetic solvents in the preparation of the colors listed on §205.606 was within the original intent of the listing. After reviewing transcripts from the March 2007 meeting, petitions, committee recommendations, the Handling Committee believes the use of

synthetic solvents for extraction did not fall within the original review of the Handling Committee or NOSB. Specifically, none of the colors that were reviewed included synthetic solvent extraction as a possible manufacturing process. The Handling Committee further believes that the use of synthetic solvents for extraction of these colors is not necessary since each of the colors was petitioned as available in the marketplace without synthetic solvent extraction.

Since there does seem to be some confusion as to the original intent of the listing, the Handling Committee is recommending that the annotation for Colors derived from agricultural products on §205.606 be changed to the following:

(d) Colors derived from agricultural products – Must not be produced using synthetic solvents and carrier systems or any artificial preservative.
This annotation is identical to the annotation for flavors listed on §205.605(a).

Committee Recommendations

The Handling Committee recommends that the annotation for Colors derived from agricultural products be changed and that the new listing on §205.606 be:

(d) Colors derived from agricultural products – Must not be produced using synthetic solvents and carrier systems or any artificial preservative.

Committee Vote

Motion: Katrina Heinze Second: Steve DeMuri
Yes: 5 No: 0 Abstain: 0 Absent: 2

National Organic Standards Board
Handling Committee
Sunset Recommendation – 2012
Flavors

September 3, 2010

List: 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

(a) Nonsynthetics allowed

Committee Summary:

Federal register notice of the sunset of these materials elicited no public comments against re-listing.

Review of the original recommendations, historical documents, and public comments does not reveal unacceptable risks to the environment, human, or animal health as a result of the use or manufacture of these materials. There is no new information contradicting the original recommendation which were the basis for the previous NOSB decisions to list these materials.

The Handling Committee recognizes that the category of flavors is broad, including everything from simple herbal extracts to complex compound flavors. As the organic industry has evolved, there has been investment in developing organic alternatives for some individual flavors, or classes of flavors, within the category. Because "Flavors" as a large category is listed on 205.605(a), commercial availability does not apply and there is no requirement that the organic alternatives that have been developed be used when available. The NOSB acknowledged this conundrum when Flavors was reviewed for sunset relisting in 2007. The complexity of the category and proprietary nature of most flavor formulas and processes was such that the board did not feel that it was practical to individually list flavors on the National List, so chose to relist the category as a single listing. That is still true today.

The Handling Committee does believe that there is a possibility of dividing the flavor category into rational subparts which could then be listed on the appropriate section of the National List. For example, herbal extracts could very well be determined to be agricultural and could be listed on §205.606. One could even envision when they would not need to be listed because they would be available as organic. The rational division of the flavor category and the appropriate way to list these flavor classes, or not list certain classes, requires specific knowledge and expertise which the Handling Committee felt went beyond the scope of a Technical Review.

In order to avoid unnecessary disruption to industry, we are recommending relisting of Flavors on §205.605(a), but we are also communicating our belief that the full category should not be relisted in five years when next reviewed for sunset. Instead, we recommending that the NOSB, in consultation with the National Organic Program, establish a Flavors Task Force. The Flavors Task Force would be asked to develop a recommendation to appropriately divide

flavors into rational subparts, or classes, composed of flavors which shared similar sources and processes. The recommendation would include whether the class was compatible with organic production, how the sub-part should be classified on the National List, and would petition for listing of the class, if necessary, on the National List. We expect that this work could be done prior to the next sunset review for flavors.

Committee Recommendation(s):

The handling committee recommends the renewal of the following substances in this use category as published in the final rule:

Flavors, non-synthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.

Committee Vote:

Motion: Katrina Heinze Second: Steve DeMuri
Yes: 6 No: 0 Abstain: 0 Absent: 1

National Organic Standards Board
Handling Committee
Sunset Recommendation – 2012
Magnesium Sulfate

August 23, 2010

List: 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

(a) Nonsynthetics allowed

Committee Summary:

Federal register notice of the sunset of these materials elicited no public comments against re-listing.

Review of the original recommendation, historical documents, and public comments does not reveal unacceptable risks to the environment, human, or animal health as a result of the use or manufacture of this material. There is no new information contradicting the original recommendation which was the basis for the previous NOSB decision to list this material.

Committee Recommendation(s)

The handling committee recommends the renewal of the following substance in this use category as published in the final rule:

Magnesium Sulfate – non-synthetic sources only

Committee Vote:

Motion: Steve DeMuri Second: Joe Smillie
Yes: 5 No: 0 Abstain: 0 Absent: 2

National Organic Standards Board
Handling Committee
Sunset Recommendation – 2012
Yeast

August 30, 2010

List: 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

(a) Nonsynthetics allowed

Yeast- nonsynthetic, growth on petrochemical substrate and sulfite waste liquor is prohibited (Autolysate; Bakers; Brewers; Nutritional; and Smoked-non-synthetic smoke flavoring process must be documented)

Committee Summary

Federal register notice of the sunset of these materials elicited a number of public comments and a detailed petition requesting that yeast be moved to 205.606.

Review of the original recommendation, historical documents, and public comments does not reveal unacceptable risks to the environment, human, or animal health as a result of the use or manufacture of this material. There is information contradicting the original technical review which was the basis for the previous NOSB decision to list this material. This information cited OFPA as a basis for recognizing yeast as agricultural. The Handling Committee has examined this and issued a recommendation.

Committee Recommendation(s)

The handling committee recommends the renewal of the following substance in this use category as published in the final rule:

Yeast- nonsynthetic, growth on petrochemical substrate and sulfite waste liquor is prohibited (Autolysate; Bakers; Brewers; Nutritional; and Smoked-non-synthetic smoke flavoring process must be documented)

Committee Vote

Motion: Joe Smillie Second: Steve DeMuri
Yes: 6 No: 0 Abstain: 0 Absent: 1

National Organic Standards Board
Handling Committee
Sunset Recommendation – 2012
Chlorine Materials

September 7, 2010

List: 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

(b) Synthetics allowed

Chlorine materials

Committee Summary

Along with fluorine, bromine, iodine, and astatine, chlorine is a member of the halogen series that forms the group 17 of the periodic table—the most reactive group of elements. It combines readily with nearly all elements. Chlorine is a member of the salt-forming halogen series and is extracted from chlorides through oxidation often by electrolysis. With metals, it forms salts called chlorides. As the chloride ion, Cl^-, it is also the most abundant dissolved ion in ocean water. In nature, chlorine is found primarily as the chloride ion, a component of the salt that is deposited in the earth or dissolved in the oceans — about 1.9% of the mass of seawater is chloride ions. Even higher concentrations of chloride are found in the Dead Sea and in underground brine deposits. In industry, elemental chlorine is usually produced by the electrolysis of sodium chloride dissolved in water.

Chlorine compounds are the most common equipment and food contact sanitizers used in the food processing and handling and are recognized by the FDA as being appropriate for their intended use. The health and environmental hazards associated with its manufacture and use are well researched and are mitigated through worker protection protocols, Good Manufacturing Practices, and oversight by local, state and federal agencies. The food processing community, pre-NOP certification programs, and past NOSB decisions have determined that—coupled with these mitigating features—the proven efficacy and reliability of these chlorine materials in support of food safety concerns outweighs the risks.

Federal register notice of the sunset of chlorine materials brought forth no public comments against re-listing. Several commenters supported re-listing this material.

Review of the original recommendations, historical documents, and public comments does not reveal unacceptable risks to the environment, human, or animal health as a result of the use or manufacture of these materials, though there are various health hazards associated with their use as noted above. There is no new information contradicting the original recommendation which were the basis for the previous NOSB decisions to list and re-list these materials.

The Handling Committee anticipates that in the near future the NOP will provide to the industry further guidance and clarification regarding the use of these materials.

Committee Recommendation(s)

The handling committee recommends the renewal of the following substance in this use category as published in the final rule:

Chlorine materials—disinfecting and sanitizing food contact surfaces, *Except,* That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (Calcium hypochlorite; Chlorine dioxide; and Sodium hypochlorite).

Committee Vote

Motion: John Foster Second: Steve DeMuri
Yes: 6 No: 0 Abstain: 0 Absent: 1

National Organic Standards Board
Handling Committee
Sunset Recommendation – 2012
Ferrous Sulfate

September 7, 2010

List: 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

(b) Synthetics allowed:

Ferrous sulfate

Committee Summary

Federal register notice of the sunset of these materials brought forth no public comments against re-listing ferrous sulfate. Several commenters supported re-listing this material.

Ferrous sulfate is used to fortify foods.

Review of the original recommendations, historical documents, and public comments does not reveal unacceptable risks to the environment, human, or animal health as a result of the use or manufacture of these materials. There is no new information contradicting the original recommendation which were the basis for the previous NOSB decisions to list and re-list these materials.

Committee Recommendation(s)

The handling committee recommends the renewal of the following substance in this use category as published in the final rule:

Ferrous sulfate—for iron enrichment or fortification of foods when required by regulation or recommended (independent organization).

Committee Vote

Motion: John Foster Second: Steve DeMuri
Yes: 6 No: 0 Abstain: 0 Absent: 1

National Organic Standards Board
Handling Committee
Sunset Recommendation – 2012
Pectin (Low-methoxy)

August 30, 2010

List: 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

(a) Nonsynthetics allowed

Pectin (low-methoxy)

Committee Summary

Federal register notice of the sunset of these materials elicited no public comments against re-listing.

Review of the original recommendation, historical documents, and public comments does not reveal unacceptable risks to the environment, human, or animal health as a result of the use or manufacture of this material. There is new information contained in the petition and technical review contradicting the original technical review which was the basis for the previous NOSB decision to list this material. The Handling committee has examined this and issued a recommendation.

Committee Recommendation(s)

The handling committee recommends the renewal of the following substance in this use category as published in the final rule:

Pectin (low-methoxy)

Committee Vote

Motion: Joe Smillie Second: Steve DeMuri
Yes: 6 No: 0 Abstain: 0 Absent: 1

National Organic Standards Board
Handling Committee
Sunset Recommendation – 2012
Phosphoric Acid

September 7, 2010

List: 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

(b) Synthetics allowed

Phosphoric acid —cleaning of food-contact surfaces and equipment only.

Committee Summary

Phosphoric acid is used in cleaning operations to remove encrusted surface matter and mineral scale found on metal equipments such as boilers and steam producing equipment. The chemical reaction of phosphoric acid with minerals found in deposits makes them water soluble and easy to remove. The original technical review found phosphoric acid to necessary for organic processing and to meet the OFPA 2119(m) criteria when used for the cleaning of food contact surfaces and equipment only.

Review of the original recommendation, historical documents, and public comments does not reveal unacceptable risks to the environment, human, or animal health as a result of the use or manufacture of this material. There is no new information contradicting the original recommendation which was the basis for the previous NOSB decision to list this material.

Committee Recommendation(s)

The handling committee recommends the renewal of the following substances in this use category as published in the final rule:

Phosphoric acid —cleaning of food-contact surfaces and equipment only.

Committee Vote

Motion: Joe Dickson Second: Steve DeMuri
Yes: 6 No: 0 Abstain: 0 Absent: 1

National Organic Standards Board
Handling Committee
Sunset Recommendation – 2012
Silicon Dioxide

September 7, 2010

List: 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

(b) Synthetics allowed

Silicon dioxide

Committee Summary

Silicon dioxide is common additive in the production of foods, where it is used primarily as a flow agent in powdered foods, to absorb water in hygroscopic applications, and in some cases used to suppress foaming in liquids under agitation. It is the primary active component of diatomaceous earth which has many uses ranging from filtration to insect control.

In 2007 (docket TM-04-07) public comment asserting that the inclusion of silicon dioxide on the National List was no longer necessary due to the availability of a certified organic alternative substance. This comment was provided by the manufacturer of the proposed alternative substance. At that time and since that time, insufficient documentation has been provided (such as testimonials from food manufacturers using the proposed alternate) to demonstrate the utility of the proposed alternate in all applications where silicon dioxide is presently used. Several commenters supported of re-listing these materials prior to the April 2010 NOSB meeting.

Review of the original recommendation, historical documents, and public comments does not reveal unacceptable risks to the environment, human, or animal health as a result of the use or manufacture of these materials. It does require special handling due to inhalation risks; limitations on its use and handling are governed by worker safety protocols and Good Manufacturing Practices. There is no new information contradicting the original recommendation which were the basis for the previous NOSB decisions to list the material.

The Handling Committee is aware that a petition to remove silicon dioxide from the National list is currently in the NOP review process; the complete petition had not reached the Handling Committee in time to review and vote at the October 2010 NOSB meeting. We intend on reviewing the petition in due course.

Committee Recommendation(s)

The handling committee recommends the renewal and inclusion of the following substance in this use category as published in the final rule:

Silicon dioxide

Committee Vote

Motion: John Foster Second: Steve DeMuri
Yes: 6 No: 0 Abstain: 0 Absent: 1

National Organic Standards Board
Handling Committee
Sunset Recommendation – 2012
Sodium Citrate

September 7, 2010

List: 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

(b) Synthetics allowed

Sodium citrate

Committee Summary

The sodium salts of citric acid – monosodium citrate, disodium citrate and tri sodium citrate – are collectively listed as "sodium citrate." These substances are used similarly as pH control/buffering agents and stabilizers in food products. The original technical review found sodium citrate to be consistent with the OFPA 2119(m) criteria.

Review of the original recommendation, historical documents, and public comments does not reveal unacceptable risks to the environment, human, or animal health as a result of the use or manufacture of this material. There is no new information contradicting the original recommendation which was the basis for the previous NOSB decision to list this material.

Committee Recommendation(s)

The handling committee recommends the renewal of the following substances in this use category as published in the final rule:

Sodium citrate

Committee Vote

Motion: Joe Dickson Second: Steve DeMuri
Yes: 6 No: 0 Abstain: 0 Absent: 1

National Organic Standards Board
Handling Committee
Sunset Recommendation – 2012
Sodium Hydroxide

September 7, 2010

List: 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

(b) Synthetics allowed

Sodium hydroxide—prohibited for use in lye peeling of fruits and vegetables.

Committee Summary

Sodium hydroxide is a strong base used as a pH adjuster. The use of a sodium hydroxide dip is the only method of producing a traditional pretzel. Other possible uses include as part of traditional olive production to remove a bitter component of the olive, and as a processing aid in cocoa manufacture. The original technical review notes that sodium hydroxide is also used in the lye peeling of fruits and vegetables; this practice presents an adverse environmental impact due to the combination of spent lye and high BOD (biological oxygen demand) from the waste vegetable matter. Accordingly, this use is not allowed in organic production.

Review of the original recommendation, historical documents, and public comments does not reveal unacceptable risks to the environment, human, or animal health as a result of the use or manufacture of this material. There is no new information contradicting the original recommendation which was the basis for the previous NOSB decision to list this material.

Committee Recommendation(s)

The handling committee recommends the renewal of the following substances in this use category as published in the final rule:

Sodium hydroxide—prohibited for use in lye peeling of fruits and vegetables.

Committee Vote

Motion: Joe Dickson Second: Steve DeMuri
Yes: 6 No: 0 Abstain: 0 Absent: 1

National Organic Standards Board
Handling Committee
Sunset Recommendation – 2012
Sodium Phosphates

September 7, 2010

List: 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

(b) Synthetics allowed

Sodium phosphates—for use only in dairy foods.

Committee Summary

Sodium phosphate is used as an emulsifier, coagulant, stabilizer, emulsifier, sequestrant and pH control/buffer in food production. It is used specifically in dairy foods as an emulsifier, to keep protein and fat from separating in products like cheese and pudding. The original technical review found sodium citrate to be consistent with the OFPA 2119(m) criteria.

Review of the original recommendation, historical documents, and public comments does not reveal unacceptable risks to the environment, human, or animal health as a result of the use or manufacture of this material. There is no new information contradicting the original recommendation which was the basis for the previous NOSB decision to list this material.

Committee Recommendation(s)

The handling committee recommends the renewal of the following substances in this use category as published in the final rule:

Sodium phosphates—for use only in dairy foods.

Committee Vote

Motion: Joe Dickson Second: Steve DeMuri
Yes: 6 No: 0 Abstain: 0 Absent: 1

National Organic Standards Board
Handling Committee
Sunset Recommendation – 2012
Sulfur Dioxide

September 7, 2010

List: 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

(b) Synthetics allowed

Sulfur dioxide—for use only in wine labeled "made with organic grapes," Provided that total sulfite concentration does not exceed 100 ppm.

Committee Summary

Sulfur dioxide is an preservative used for preventing the oxidization of wine. It has been used for centuries as part of the traditional winemaking process. Sulfur dioxide is produced naturally by the burning of elemental sulfur. The original technical review, and the NOSB which reviewed the original petition found that the traditional use of sulfur dioxide in wine would be permissible only in wines labeled "made with organic grapes," and not in wines labeled "organic."

Review of the original recommendation, historical documents, and public comments does not reveal unacceptable risks to the environment, human, or animal health as a result of the use or manufacture of this material. There is no new information contradicting the original recommendation which was the basis for the previous NOSB decision to list this material.

The committee is aware that that a petition has been submitted to alter the annotation for sulfur dioxide. This petition is currently in the NOP process and will not be voted on at the October 2010 NOSB meeting. We intend to review the petition in due course.

Committee Recommendation(s)

The handling committee recommends the renewal of the following substances in this use category as published in the final rule:

Sulfur dioxide—for use only in wine labeled "made with organic grapes," Provided that total sulfite concentration does not exceed 100 ppm.

Committee Vote

Motion: Joe Dickson Second: Steve DeMuri
Yes: 6 No: 0 Abstain: 0 Absent: 1

National Organic Standards Board
Handling Committee
Recommendation for § 205.606
Sunset Review of Colors Derived From Agricultural Products

August 17, 2010

National Organic Program Subpart G: The National List of Allowed and Prohibited Substances. §205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic.

(d) Colors derived from agricultural products

Committee Summary

The following colors were added to the National List (Federal Register Vol. 72, #123, June 27, 2007). This is the first time that these colors are being reviewed for sunset. The colors are:

1. Annatto extract color (pigment CAS # 1393–63–1)—water and oil soluble.
2. Beet juice extract color (pigment CAS # 7659–95–2).
3. Beta-Carotene extract color from carrots (CAS # 1393–63–1).
4. Black currant juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
5. Black/Purple carrot juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
6. Blueberry juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
7. Carrot juice color (pigment CAS # 1393–63–1).
8. Cherry juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
9. Chokeberry—Aronia juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
10. Elderberry juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
11. Grape juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
12. Grape skin extract color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
13. Paprika color—dried powder and vegetable oil extract (CAS # 68917–78–2).
14. Pumpkin juice color (pigment CAS # 127–40–2).
15. Purple potato juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).

16. Red cabbage extract color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
17. Red radish extract color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
18. Saffron extract color (pigment CAS # 1393–63–1).
19. Turmeric extract color (CAS # 458–37–7).

Annato extract color – water and oil soluble is considered in a separate recommendation made by the National Organic Standard Board (NOSB) Handling Committee for the Fall 2010 full NOSB meeting. This recommendation addresses the other eighteen colors. Colors are used as ingredients in foods to meet the aesthetic requirements of consumers.

A Technical Review, dated October 14, 2005, on the category of colors was prepared for the National Organic Program (NOP) and NOSB. It is titled "Overview of Food Color Additives."

These eighteen colors were added to section §205.606 of the National List after the §205.605(a) listing of Colors -- nonsynthetic only was allowed to sunset off the National List. The NOSB in their October 19, 2006 recommendation stated that:

> *"There was a comment addressing the concern that colors . . . were added to the National List without a technical review by the NOSB. The Handling Committee requested and received a technical overview of food color additives on October 14, 2005. This technical review offered no information that would suggest that non-synthetic colors are inconsistent with organic practices. There were numerous comments opposing renewing the listing of non-synthetic colors. A few commenters requested that they be moved to 205.606, an action which cannot be taken as part of Sunset. Several commenters cited that non-synthetic colors had been placed on the National List without being petitioned and without the recommendation of the NOSB. The Board finds merit in this observation. Colors, non-synthetic cannot be renewed through the Sunset process because there was never an NOSB recommendation for its placement on the National List.*

As a result petitions were received for listing a number of colors on §205.606. Of those petitions, these eighteen colors, plus annatto, were recommended for listing by the NOSB. For each of these information was received, supported by public comment, indicating that for suitability for food color:

- Very specific varieties of the particular raw material, high in color compounds, are needed. Typically eating varieties cannot be used.
- The raw material must be processed immediately after harvesting so the growing area must be within close proximity to a color manufacturing location.
- Colors are used at low percentages in the finished products. Typically less than one percent.
- In many cases, it is more lucrative for farmers to sell into the fresh market than to sell to ingredient manufacturers.

The NOSB has received nine public comments in support of, and no public comments opposed to, the relisting of these eighteen colors in response to the Federal Register notice of the sunset of these colors (AMS-TM-09-0074). In addition, six public comments were received in response to the Federal Register notice on the spring 2010 NOSB meeting (AMS-TM-10-0021) asking that all §205.606 items be relisted.

A review of the original petitions and recommendations, historical documents, and public comments does not reveal unacceptable risks to the environment, human or animal health as a result of the use or manufacture of these colors. There is no new information contradicting the original recommendation which were the basis for the previous NOSB decisions to list these colors. As §205.606 listed materials, all are subject to commercial availability scrutiny for use in organic products.

Several public comments were received asking that the CAS Numbers listed for various colors were incorrect. The Handling Committee asks that the National Organic Program review the CAS numbers listed on the National List for each of these colors for accuracy and make any technical corrections necessary.

Committee Recommendations

The Handling Committee recommends the re-listing of the following colors on §205.606:

1. Beet juice extract color (pigment CAS # 7659–95–2).
2. Beta-Carotene extract color from carrots (CAS # 1393–63–1).
3. Black currant juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
4. Black/Purple carrot juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
5. Blueberry juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
6. Carrot juice color (pigment CAS # 1393–63–1).
7. Cherry juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
8. Chokeberry—Aronia juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
9. Elderberry juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
10. Grape juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
11. Grape skin extract color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
12. Paprika color—dried powder and vegetable oil extract (CAS # 68917–78–2).
13. Pumpkin juice color (pigment CAS # 127–40–2).

14. Purple potato juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
15. Red cabbage extract color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
16. Red radish extract color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
17. Saffron extract color (pigment CAS # 1393–63–1).
18. Turmeric extract color (CAS # 458–37–7).

The Handling Committee asks that the National Organic Program review the CAS numbers listed on the National List for each of these colors for accuracy and make any technical corrections necessary.

Committee Vote

Motion: Katrina Heinze Second: Steve DeMuri
Yes: 5 No: 0 Abstain: 0 Absent: 2

National Organic Standards Board
Handling Committee
Recommendation for § 205.606
Sunset Review of Annatto Extract Color – Oil and Water Soluble

August 17, 2010

List: National Organic Program Subpart G: The National List of Allowed and Prohibited Substances. §205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic.

(d) Colors derived from agricultural products

Committee Summary

Annatto extract color (pigment CAS # 1393–63–1)—water and oil soluble was added to the National List (Federal Register Vol. 72, #123, June 27, 2007). This is the first time that annatto extract color is being reviewed for sunset. Annato extract color is used as an ingredient in foods to meet the aesthetic requirements of consumers.

A Technical Review, dated October 14, 2005, on the category of colors was prepared for the National Organic Program (NOP) and NOSB. It is titled "Overview of Food Color Additives."

Annato extract color, as well as eighteen other colors, was added to section §205.606 of the National List after the §205.605(a) listing of Colors -- nonsynthetic only was allowed to sunset off the National List. The NOSB in their October 19, 2006 recommendation stated that:

> *"There was a comment addressing the concern that colors . . . were added to the National List without a technical review by the NOSB. The Handling Committee requested and received a technical overview of food color additives on October 14, 2005. This technical review offered no information that would suggest that non-synthetic colors are inconsistent with organic practices. There were numerous comments opposing renewing the listing of non-synthetic colors. A few commenters requested that they be moved to 205.606, an action which cannot be taken as part of Sunset. Several commenters cited that non-synthetic colors had been placed on the National List without being petitioned and without the recommendation of the NOSB. The Board finds merit in this observation. Colors, non-synthetic cannot be renewed through the Sunset process because there was never an NOSB recommendation for its placement on the National List.*

As a result petitions were received for listing a number of colors on §205.606. Of those petitions, annatto extract color, as well as eighteen other colors, was recommended for listing by the NOSB. There was general agreement that annatto extract color should be listed on the National List but some debate as to the proper annotation. The Handling Committee originally recommended that the annotation include a restriction that only organic oil be used for extraction of the annatto. That annotation was viewed as being too restrictive and was not included in the final recommendation. Additionally, there was some discussion as to the two forms, liquid and powder of annatto extract color, and how to include both in the annotation. The final result was that the annotation reads "oil and water extracted."

The NOSB has received ten public comments related to the relisting of annatto extract color in response to the Federal Register notice of the sunset of annatto (AMS-TM-09-0074). In summary:

- Five supported the relisting
- One handler specifically identified that they have been unable to source, as organic, a powdered version of annatto extract color which is necessary for their product. They have found a liquid form, as organic, but it is not suitable for use in their product. They have also tested a 100% ground annatto seed powder, which is highly variable in color and thus does not meet the consumer desire for consistency. Additionally, use of this seed powder resulted in off flavors not desired by the consumer.
- Three public comments asked that annatto extract color be removed from the National List because a sufficient organic supply was now available.
- One public comment was from a supplier of organic liquid annatto extract color saying that they were able to supply the market needs of industry.

In addition, six public comments were received in response to the Federal Register notice on the spring 2010 NOSB meeting (AMS-TM-10-0021) asking that all § 205.606 items be relisted.

In response to these public comments, the NOSB Handling Committee conducted an informal market survey. It appears that products which would be expected to use a liquid annatto extract color (e.g., cheese, yogurt) are in fact using organic annatto. Conversely, products which would be expected to use a powdered annatto extract color (e.g., dry cheese powder products like macaroni and cheese) are not using organic annatto. This supports the public comments received. Additionally, the public commenter who is a supplier of organic liquid annatto extract color was contacted and confirmed that they do not have a powdered version available in organic form. A search of the internet did not find a powdered version beyond the 100% ground annatto seed referred to above.

A review of the original petitions and recommendations, historical documents, and public comments does not reveal unacceptable risks to the environment, human or animal health as a result of the use or manufacture of annatto extract color. As a §205.606 listed material, annatto extract color is subject to commercial availability scrutiny for use in organic products.

As a result of our review, the Handling Committee believes that liquid annatto extract color is now available in sufficient, form, quantity and quality and should no longer be listed on §205.606 but that the powdered form is not available in sufficient form, quantity or quality and should still be listed on §205.606.

Committee Summary

The Handling Committee recommends that the liquid form of Annatto extract color (pigment CAS # 1393–63–1)—water and oil soluble be relisted on §205.606

Committee Vote

Motion: Katrina Heinze Second: Steve DeMuri
Yes: 0 No: 5 Abstain: 0 Absent: 2

Committee Summary

The Handling Committee recommends that the powdered form of Annatto extract color (pigment CAS # 1393–63–1)—water and oil soluble be relisted on §205.606

Committee Vote

Motion: Katrina Heinze Second: Steve DeMuri
Yes: 5 No: 0 Abstain: 0 Absent: 2

National Organic Standards Board
Handling Committee
Sunset Recommendation – 2012
Fructooligosaccharides (CAS # 308066-66-2)

August 23, 2010

List: 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."

Committee Summary:

Federal register notice of the sunset of this material elicited no public comments against re-listing.

Review of the original recommendation, historical documents, and public comments does not reveal unacceptable risks to the environment, human or animal health as a result of the use or manufacture of this material. There is no new information contradicting the original recommendation which was the basis for the previous NOSB decision to list this material. As a 205.606 listed material, it is subject to commercial availability scrutiny for use in organic products.

Committee Recommendation(s):
The handling committee recommends the renewal of the following substance in this use category as published in the final rule:

Fructooligosaccharides (CAS # 308066-66-2)

Committee Vote:

Motion: Steve DeMuri Second: Tracy Miedema
Yes: 5 No: 0 Abstain: 0 Absent: 2

National Organic Standards Board
Handling Committee
Sunset Recommendation – 2012
Hops (*Humulus luplus*)

August 30, 2010

List: 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."

Hops (*Humulus luplus*)

Committee Summary

Federal register notice of the sunset of this material elicited public comments against re-listing.

Review of the original recommendation, historical documents, and public comments does not reveal unacceptable risks to the environment, human or animal health as a result of the use or manufacture of this material. There is new information contradicting the original recommendation which was the basis for the previous NOSB decision to list this material.This information contained in a petition cites the increased production of organic hops. The petition calls for the removal of Hops from 205.606 . The Handling committee has examined this and issued a recommendation.As a 205.606 listed material, it is subject to commercial availability scrutiny for use in organic products.

Committee Recommendation(s)

The handling committee recommends the renewal of the following substance in this use category as published in the final rule:

Hops (*Humulus luplus*)

Committee Vote:

Motion: Joe Smillie Second: Steve DeMuri
Yes: 6 No: 0 Abstain: 0 Absent: 1

National Organic Standards Board
Handling Committee
Sunset Recommendation – 2012
Inulin – oligofructose enriched (CAS # 9005-80-5)

August 23, 2010

List: 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."

Committee Summary:

Federal register notice of the sunset of this material elicited no public comments against re-listing.

Review of the original recommendation, historical documents, and public comments does not reveal unacceptable risks to the environment, human or animal health as a result of the use or manufacture of this material. There is no new information contradicting the original recommendation which was the basis for the previous NOSB decisions to list this material. As a 205.606 listed material, it is subject to commercial availability scrutiny for use in organic products.

Committee Recommendation(s):
The handling committee recommends the renewal of the following substance in this use category as published in the final rule:

Inulin – oligofructose enriched (CAS # 9005-80-5)

Committee Vote:

Motion: Steve DeMuri Second: Joe Smillie
Yes: 5 No: 0 Abstain: 0 Absent: 2

National Organic Standards Board
Handling Committee
Sunset Recommendation – 2012
Pectin (High-methoxy)

August 31, 2010

List: 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."

Pectin (high-methoxy)

Committee Summary

Federal register notice of the sunset of this material elicited no public comments against re-listing.

Review of the original recommendation, historical documents, and public comments does not reveal unacceptable risks to the environment, human or animal health as a result of the use or manufacture of this material. There is no new information contradicting the original recommendation which was the basis for the previous NOSB decision to list this material. As a 205.606 listed material, it is subject to commercial availability scrutiny for use in organic products.

Committee Recommendation(s)

The handling committee recommends the renewal of the following substance in this use category as published in the final rule:

Pectin (high-methoxy)

Committee Vote:

Motion: Joe Smillie Second: Steve DeMuri
Yes: 6 No: 0 Abstain: 0 Absent: 1

National Organic Standards Board
Handling Committee
Sunset Recommendation – 2012
Corn Starch

September 7, 2010

List: 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."

Corn starch (native).

Committee Summary

Federal register notice of the sunset of corn starch brought forth no public comments against re-listing; several public comments requested the re-listing of this material.

Corn starch is the starch of the corn (or maize) grain obtained from the endosperm of the corn kernel. Corn starch is often included as an anticaking agent in baking powders. It is also often used in powdered sugar (10X or confectioner's sugar). Corn starch is also used as a thickening agent in soups and liquid-based foods, such as sauces, gravies and custards.

Review of the original recommendation, historical documents, and public comments does not reveal unacceptable risks to the environment, human or animal health as a result of the use or manufacture of these materials. There is no new information contradicting the original classification as an agricultural substance; neither is there new information contradicting the recommendation which were the basis for the previous NOSB decisions to list this material. As with all materials listed on §205.606, corn starch should be subject to commercial availability determinations by Accredited Certification Agencies.

Committee Recommendation(s)

The handling committee recommends the renewal of the following substance in this use category as published in the final rule:

Corn starch (native).

Committee Vote

Motion: John Foster Second: Steve DeMuri
Yes: 6 No: 0 Abstain: 0 Absent: 1

National Organic Standards Board
Handling Committee
Sunset Recommendation – 2012
Whey Protein

August 23, 2010

List: 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."

Committee Summary:

Federal register notice of the sunset of this material elicited no public comments against re-listing.

Review of the original recommendation, historical documents, and public comments does not reveal unacceptable risks to the environment, human or animal health as a result of the use or manufacture of this material. There is no new information contradicting the original recommendation which was the basis for the previous NOSB decision to list this material. As a 205.606 listed material, it is subject to commercial availability scrutiny for use in organic products.

Committee Recommendation(s)

The handling committee recommends the renewal of the following substance in this use category as published in the final rule:

Whey protein concentrate

Committee Vote:

Motion: Steve DeMuri Second: John Foster
Yes: 5 No: 0 Abstain: 0 Absent: 2

National Organic Standards Board
Handling Committee
Discussion Document - The Use of
Nutrient Supplementation in Organic Foods

September 2, 2010

In 1995 the NOSB recommended to the Secretary of the USDA that nutrient vitamins and minerals appear on the National List as a class or category of allowed synthetic materials. The board also recommended that the class of allowed materials not be static, but be inclusive of materials that had received independent assessment and recognition as supplementing the human diet or providing support for optimal health. When the National List was proposed by the Secretary, an annotation appeared that was not part of the 1995 board recommendation.

> National List §205.605(b): Nutrient Vitamins and Minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines for Foods

That annotation limited the category of materials by adopting, by reference, an FDA guidance document that was first drafted in the 1970s. The inclusion of the annotation that adopted the FDA guidance transformed the NOSB recommendation of a non-static category of materials into fixed list of vitamins, as well as restricted even their use to situations where the supplementation was for the purpose of restoring nutrients lost during the processing of the food product.

There has been significant development in the science of human nutrition since the 1995 NOSB recommendation. There has also been considerable change in the legal framework regarding the inclusion of supplemental nutrients in food products with the passage of significant federal legislation since the 1995 NOSB Recommendation.

The NOSB seeks to update its thinking on the science of supplementation of foods that carry the organic label and seeks a better understanding of the legal framework within which the National List must take its place. We pose the following questions:

1. Have there been scientific developments in the field of human nutrition that suggest the NOSB should revisit its 1995 recommendation?

2. Have there been legal developments in the federal statutory and regulatory system that suggest the NOSB should revisit its 1995 recommendation?

3. What was the rationale for the addition of the annotation referring to 21 C.F.R. 104.20 to the NOSB's 1995 recommendation and is that rationale still applicable?

4. Should the role of nutrient supplementation, or fortification, be different for food products that carry the organic label than for conventional food products?

5. What is the role of the NOP envisioned by Congress in the OFPA regarding this topic?

6. What is the role of the NOSB envisioned by Congress in the OFPA regarding this topic?

Committee Vote:

Motion: Tracy Miedema Second: Steve DeMuri
Yes: 6 No: 0 Abstain: 0 Absent: 1

National Organic Standards Board
Materials Committee
Guidance Document -- Engineered Nanomaterials in Organic Production, Processing and Packaging

September 2, 2010

Introduction

There is overwhelming agreement within the organic industry to prohibit nanotechnology in organic production and processing at this time. However, there is confusion over the definition of what exactly should be prohibited. Additionally, there is disagreement over how to prohibit the products of this technology in the organic industry. Everyone shares a concern about the contamination by products of nanotechnology. This concern includes the ability of the regulatory agency, the National Organic Program (NOP), to fully control two of the major sources of contamination in final organic food products: food contact surfaces and primary packaging. This subject is further complicated since nanotechnology is a new and developing technology. This document offers guidance to the NOP on how the National Organic Standards Board (NOSB) believes the area of most concern about this technology can be regulated within the current rules and regulations already in place. This guidance document requests cooperation with the NOP to help the NOSB make further recommendations to more clearly regulate this developing technology within the organic industry. Finally, this document requests the NOP allow the NOSB to host a symposium at one of its upcoming meetings to better understand this technology.

Background and Discussion

The potential contamination by extremely small particles of a substance that may exhibit characteristics distinct from the bulk products is of great concern to the organic industry and consumer. As with all materials that are not naturally occurring, the Organic Foods Production Act (OFPA) requires us to question the impacts on health and safety to humans, animals, and the environment of these extremely small synthetic particles with unique properties in determining whether these substances are safe and advantageous. The determination of whether these materials should be allowed in organic production and processing should be made separately from the allowance and consideration of the same substance in its bulk form.

Defining area of concern

The NOSB received public comment via previous documents from the Materials Committee (MC) related to nanotechnology and the products of nanotechnology. Public comment overwhelmingly agrees that nanotechnology in organic production and processing be prohibited at this time. However, there is considerable debate and disagreement on what exactly nanotechnology is and what products of nanotechnology should be prohibited.

A Technical Review (TR) was requested to aid the MC, and the Board has utilized this TR, dated June 28, 2010, and other supporting materials to develop a definition of the area of concern within the larger term of nanosized materials and products of nanotechnology. The TR identifies three sources of nanosized materials: natural, incidental and engineered. Natural

nanosized products such as corrosion particles and sea spray are not practical to prohibit. Incidentally produced nanosized particles, such as those created in traditional production methods such as grain milling and milk homogenization have been present in materials utilized within the crops, livestock, and food industries for decades and are not the areas of concern.

The MC proposes a definition for Engineered Nanomaterials. The MC believes all substances that would fall under this definition are synthetic and therefore should be prohibited in organic production and processing unless specifically allowed on the National List of Allowed and Prohibited Substances (NL). Further, the MC believes that these items may have unique properties that distinguish them from their bulk-sized counterparts and that no listings on the NL were intended at the time of listing to include the engineered nanomaterial form. The MC firmly believes that nothing currently on the NL has been reviewed or a TR performed that included any aspect of the manufacture, use and disposal of that substance in a nanomaterial form, and that nothing on the list should currently be allowed in this form.

> *Engineered nanomaterials: substances deliberately designed, engineered and produced by human activity to be in the nanoscale range (approx 1-300 nm) because of very specific properties or compositions (e.g. shape, surface properties, or chemistry) that result only in that nanoscale. Incidental particles in the nanoscale range created during traditional food processing such as homogenization, milling, churning, and freezing, and naturally occurring particles in the nanoscale range are not intended to be included in this definition. All nanomaterials (without exception) containing capping reagents or other synthetic components are intended to be included in this definition.*

There was extensive debate within the MC regarding the size range included in the definition. The TR specifically states that the classic definition of nanotechnology is within the 1-100 nm range. However, the TR specifically states that size is not the best determinant for the items of concern. Better determinants would include size to mass ratio or specific reference to unique characteristics. The main concerns leading us to restrict these materials are unique properties or functions that could be harmful to the animal, human or the environment and the potential for contamination by these small particles within organic production and processing. The MC recognizes that there may be substances less than 100 nm in size that offer no unique properties or functions and offer no potential problems with their use or contamination. Conversely, it is recognized that small particles, larger than the 100 nm limit, can offer very unique properties and a great potential for contamination. Substances larger than 300 nm also could exhibit unique properties than those of their bulk counterparts as well. The main issue of concern is the potential contamination from these very small materials that are poorly studied in regard to being harmful to animals, humans and the environment. Public comment with scientific citations from consumer and environmental groups received during the November 2009 and April 2010 meetings of the NOSB requested the inclusion of a size range up to 300 nm within the definition of materials of concern. The MC has chosen to include that size range in this definition, with the qualifier that this size restriction is an approximate. The more important issue is the unique properties that occur with the small sized particle.

The MC requests the NOP to accept the definition listed above as synthetic substances, that they may have unique properties that distinguish them from all listings of these substances in a bulk form, and that they are not allowed by a listing of the bulk form of the substance on the

NL, pending a further recommendation from the NOSB, and implementation thereof by the NOP, on the use, or prohibition, of engineered nanomaterials in organic production processing and packaging. Furthermore, the Board requests the NOP work with the NOSB on the adequacy of the definition, any potential areas of concern that may not be included in this definition, parts of this definition that are not workable within enforcement, and possible adjustments to the approximate size constraints that may be needed.

Extent of enforcement

Again, the concern with these substances is not only their intentional use in organic production and processing but also the contamination from these substances during production and processing.

The MC would support the application of these restrictions to primary packaging and food contact surfaces as well as the normal management of organic crops and livestock and processing of final retail products. There is great concern for contamination that could occur from the primary packaging (i.e., packaging materials in physical contact with the certified organic product) and via food contact surfaces that the organic product comes in contact with during production and processing. The MC requests that the NOP work with the NOSB during the time this guidance document is in place to determine whether enforcement of restrictions in these two areas is possible, practical, and legal. The MC is interested in restricting as much as possible the potential for contamination by these substances, while recognizing the problems and potential harm to the NOP and the industry of requesting a level of enforcement that is not practical, possible or legal.

Additional concern exists over the inadvertent contamination that could occur out of the control of the production or processing management. Such sources could include, but certainly are not limited to, the use of a nanotechnology filter in a municipal or other water supply that contaminates the water used in the facility even at very low levels. In cases, where there is inadvertent contamination from a source out of the organic facility's control and where no alternatives exist, the MC does not believe this restriction should force the facility to move to a new location or be forced out of organic production. The MC requests the NOP work with the Board to clarify such situations.

The MC recognizes that these restrictions could not apply in cases where the use of materials covered within the definition is required by law. A potential example of this would be a requirement to place a nanosensor in contact with a perishable product, such as raw meat, that would detect bacterial growth, toxin production, or other spoilage.

Request for a Symposium

The MC requests the NOP allow the NOSB to call for a symposium on this topic. This field of science is very complex and complicated. It is a new science that is still developing rapidly. Board members have studied this science in the preparation of four related documents. There is still much confusion. The MC believes a face-to-face symposium to discuss the issues related to the human-engineered portion of this science would help to clarify these confusing issues, and serve to educate both the Board and the NOP on this topic.

The Symposium would need to be specific to the areas of concern within the science of nanotechnology in order to more clearly define the term used to enforce a prohibition. It should include the areas described above regarding the potential for contamination in areas such as primary packaging and food contact surfaces. Other areas of interest regarding this topic could be included to help educate the NOSB members. The selection of speakers for the symposium should focus on education for the members of the Board and fairness to as many sides of the debate as possible.

The NOSB recognizes that it may take some time to organize and schedule such a symposium. The NOSB requests cooperation with the NOP to work with the NOSB on this matter. The NOSB hopes that this matter will be a high enough priority to allow for some budget consideration for this topic. The NOSB recognizes that there may be budgetary matters involved in conducting such a symposium that are beyond its influence or control.

Future developments

At some point in time in the future, after working with the NOP according to the terms of this guidance document, the MC will return to this topic to propose further recommendations.

Such a recommendation could include fine-tuning and greater clarity regarding the definition of the sector of this technology being prohibited, a more definitive statement on the extent of the prohibition of the substances within the definition, potentially recommending a complete §205.105 prohibition, a §205.105 prohibition unless as provided in the NL, or a statement that these substance are synthetic and all the prohibitions regarding that policy would be in place. As a result, future Boards are requested to be very diligent and cautious in their consideration for adding annotations to substances already on the NL or to be added to the NL that would allow the engineered nanomaterial form of a substance in organic production or processing.

A future recommendation could include considerations determined after working in cooperation with the NOP on the legality and ability to restrict and enforce the use of such substances in primary packaging, food contact surfaces, or other areas of potential contamination. The Board recognizes that since contamination from these substances is a primary concern, a future Board could be influenced by a limitation of its ability to prevent contamination in final processing and how that could impact the extent of prohibition it imposes on other aspects of production and processing within the industry.

A more specific recommendation or rule change may come after the Board becomes better informed on this subject from information learned in the symposium that is being requested.

Committee Vote:

The MC moves to accept this document as a guidance recommendation specifically asking the NOP to:

- Accept as a working definition:

  Engineered nanomaterials: substances deliberately designed, engineered and produced by human activity to be in the nanoscale range (approx 1-300 nm)

because of very specific properties or compositions (e.g. shape, surface properties, or chemistry) that result only in that nanoscale. Incidental particles in the nanoscale range created during traditional food processing such as homogenization, milling, churning, and freezing, and naturally occurring particles in the nanoscale range are not intended to be included in this definition. All nanomaterials (without exception) containing capping reagents or other synthetic components are intended to be included in this definition

- Disallow the engineered nanomaterial form of substances currently on the NL since nothing on the NL has been reviewed or a TR performed that included any aspect of the manufacture, use and disposal of the listed substances in a nanomaterial form.
- Accept materials that meet the working definition of engineered nanomaterials as synthetic substances.
- Accept that engineered nanomaterials may have unique properties that distinguish them from all listings of these substances in a bulk form, and that they are not allowed by a listing of the bulk form of the substance on the NL, pending a further recommendation from the NOSB, and implementation thereof by the NOP, on the use, or prohibition, of engineered nanomaterials in organic production processing and packaging.
- Work with the NOSB to determine whether enforcement of restrictions in primary packaging and food contact surfaces is possible, practical, and legal.
- Work with the NOSB to schedule a symposium on the topic of engineered nanomaterials to aid in evaluating (i) the adequacy of the definition, (ii) any potential areas of concern that may not be included in this definition, (iii) the enforceability of the various parts of the definition, (iv)possible adjustments to the approximate size constraints that may be needed, and (v) the effect of different regulatory approaches, including, but not limited to a complete §205.105 prohibition, a §205.105 prohibition unless as provided in the NL, or a statement that these substance are synthetic and all the prohibitions regarding that policy would be in place; all for the purpose of considering the development of a rule change on their use or prohibition.

Committee Vote:

Motion: Dan Giacomini Second: Wendy Fulwider
Yes: 6 No: 0 Abstain: 0 Absent: 0

National Organic Standards Board
Certification, Accreditation and Compliance Committee
Recommendation to Allow "Certified to USDA guidelines" on
Principal Display Panel of All Organic Labeling Categories
(100% Organic, Organic and Made with Organic)

July 12, 2010

Introduction

The National Organic Program was established with three labels of organic certification and sale of products. All three are subject to the same inspection process and oversight. As such, each product category carries the same credibility for its claim, and requires equal time and resources of the USDA, the certifying community, and the multitude of organizations affiliated to the organic industry.

Of the three NOP labeling options, packages that qualify for MWO have created questions in the consumer community. Absent the ability to use the USDA Organic Seal or some other form of National verification, various labeling strategies have emerged, which have confused and at times misled the public. Adding to the lack of clarity, non-certified products with less than 70% organic have used the word "organic" outside of the ingredients statement, which is non-compliant with NOP requirements. Finally, some manufacturers even include the word "organic" in their Brand Names. This places the word "organic" on the principal display panel irrespective of whether the product complies with the handling and composition requirements of the National Organic Program 7 CFR part 205.

These marketplace conditions blur the distinct validity of the "Made with Organic" category, as created in the original legislation. The number of "made with organic" (MWO) products in the marketplace continues to increase. This is good for organic agricultural volume. It is also good for consumers to have more choices on the shelf that contain 70% or greater organic content. Evidence of the growth should be more visible in the marketplace, to add value to the products, the industry and to enhance the public understanding of the strength and growth of organic agriculture overall.

In order to communicate the merit of the MWO category of products to consumers, further the recognition of the growth of the full spectrum of USDA organic products, and strengthen the position for increased NOP funding through greater shelf presence, the CACC recommends a consistent optional label statement on MWO products certified and sold in the U.S.

Background

The regulatory requirements for the handling and composition of products eligible to display "made with organic …" on its principal display panel are found in the following sections of 7 CFR.

205.102 Use of the term, "organic."

Any agricultural product that is sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must be:

(a) Produced in accordance with the requirements specified in §205.101 (organic system plan) or §§205.202 through 205.207 (crops) or §§205.236 through 205.239 (livestock) and all other applicable requirements of part 205; and

(b) Handled in accordance with the requirements specified in §205.101 or §§205.270 through 205.272 and all other applicable requirements of this part 205.

§ 205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling.

To be sold or labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s)),," the product must be produced and handled without the use of:

(a) Synthetic substances and ingredients, except as provided in §205.601 or §205.603;

(b) Nonsynthetic substances prohibited in §205.602 or §205.604;

(c) Nonagricultural substances used in or on processed products, except as otherwise provided in §205.605;

(d) Nonorganic agricultural substances used in or on processed products, except as otherwise provided in §205.606;

(e) Excluded methods, except for vaccines: *Provided,* That, the vaccines are approved in accordance with §205.600(a);

(f) Ionizing radiation, as described in Food and Drug Administration regulation, 21 CFR 179.26; and

(g) Sewage sludge.

§ 205.270 Organic handling requirements.

(c) The handler of an organic handling operation must not use in or on agricultural products intended to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s)),," or in or on any ingredients labeled as organic:

(1) Practices prohibited under paragraphs (e) and (f) of §205.105.

(2) A volatile synthetic solvent or other synthetic processing aid not allowed under §205.605: *Except,* That, nonorganic ingredients in products labeled "made with organic (specified ingredients or food group(s))" are not subject to this requirement

§ 205.301 Product composition.

(c) Products sold, labeled, or represented as "made with organic (specified ingredients or food group(s))*."* Multi-ingredient agricultural product sold, labeled, or represented as "made with

organic (specified ingredients or food group(s))” must contain (by weight or fluid volume, excluding water and salt) at least 70 percent organically produced ingredients which are produced and handled pursuant to requirements in subpart C of this part. No ingredients may be produced using prohibited practices specified in paragraphs (f)(1), (2), and (3) of §205.301. Nonorganic ingredients may be produced without regard to paragraphs (f)(4), (5), (6), and (7) of §205.301. If labeled as containing organically produced ingredients or food groups, such product must be labeled pursuant to §205.304.

(f) All products labeled as “100 percent organic” or “organic” and all ingredients identified as “organic” in the ingredient statement of any product must not:

(1) Be produced using excluded methods, pursuant to §201.105(e) of this chapter;

(2) Be produced using sewage sludge, pursuant to §201.105(f) of this chapter;

(3) Be processed using ionizing radiation, pursuant to §201.105(g) of this chapter;

(4) Be processed using processing aids not approved on the National List of Allowed and Prohibited Substances in subpart G of this part: Except, That, products labeled as “100 percent organic,” if processed, must be processed using organically produced processing aids;

(5) Contain sulfites, nitrates, or nitrites added during the production or handling process, Except, that, wine containing added sulfites may be labeled “made with organic grapes”;

(6) Be produced using nonorganic ingredients when organic ingredients are available; or

(7) Include organic and nonorganic forms of the same ingredient.

§ 205.304 Packaged products labeled “made with organic (specified ingredients or food group(s)).”

(a) Agricultural products in packages described in §205.301(c) may display on the principal display panel, information panel, and any other panel and on any labeling or market information concerning the product:

(1) The statement:

(i) “Made with organic (specified ingredients)” ….etc.

(b) Agricultural products in packages described in § 205.301 (c) must: … etc.

(c) Agricultural products in packages described in § 205.301 (c) must not display the USDA seal.

Discussion

While the use of the USDA seal for organic products is optional, most producers of organic products have chosen to use it, and consumers have come to strongly equate the seal with organic integrity and USDA certification. The creation of a similar declaration for the “Made

with Organic" category would facilitate greater consumer confidence in these products and overall growth of the category.

Although a similar amount of work, inspections and cost are invested by organic food producers and professionals in the certification of MWO products, consumer and industry recognition of MWO products is not as high as for "organic" products in the marketplace. As a result, the actual size of the organic products market is underestimated. The total amount of organic acreage, production, processing, inspection and oversight needs to be accurately accounted for in the public and governmental sectors.

Continued growth of the organic sector and increase in organic acreage is dependent on the visibility, recognition of value (environmental protection, energy conservation, health) and affordability of organic products in the marketplace. The growth of the organic sector – and consequently, economic analysis and investment in it -- is hampered by the current confusion between certified MWO products, mislabeled products making some organic claim, and completely uncertified products. In addition, the MWO label is missing out on an opportunity to not only benefit from confidence in the minimum 70% organic content, but also the fact that these products and most ingredients undergo many more inspections than the majority of the food supply, which leads to enhanced levels of food and worker safety.

The USDA 'Organic" seal makes organic products more visible in the marketplace, but it is not available for use on products in the MWO category – they are certified, but cannot use the seal. If there were a consistent and authorized statement of credibility on MWO products, it would increase their recognition by, and subsequent value to and likely adoption by the consumer.

We believe that the use of some statement, identifying products in the MWO category as certified under the USDA NOP regulations, would provide a reliable tool to reduce the current labeling confusion and questionable practices, and legitimize the efforts of the producers of MWO products. While potentially easier to extend the use of the existing USDA seal to "made with organic" products, or creating another seal specific to this category, the CACC recognizes those options may have the potential to create more confusion as to the differences between the stricter "organic" (95+%) and 100% organic categories. We also received feedback ranging from concern to outright disapproval of our March 8, 2010 discussion document proposing this route.

Recommendation

The CACC recommends a concise and consistently worded statement that communicates the USDA certified status of "Made with organic" products. Since most shoppers make their quality judgment and purchase choices based on information on the front of the package, it is important that the verifying statement also be available for placement on the front panel, The CACC proposes the clear "Certified to USDA guidelines" be added as 205.304(a)(4), in type following the same requirement as 205.304(a)(1)(iii). The use of this statement will convey the integrity and legitimacy of the USDA certification for MWO products in the same way it has for "organic" products. This will also provide easy to access education to consumers, increasing their confidence in and awareness of the volume of organic products in the marketplace.

The addition of the "Certified to USDA guidelines." statement, as described above, does not change the certification process, production or processing practices. It does not convey that the USDA performed the certification, only that they establish the guidelines. As a result, the marketing of MWO products will be improved by employing a simple, easy to understand statement that minimizes confusion and increases the recognition and value of organic products.
To keep options on the principal display panel equal, the CACC also recommends adding the same optional language, "Certified to USDA guidelines." as section 205.303(a)(6), held to the type size, style and color limitations found in 205.303(a)(2).

These changes would appear as follows, in the regulation.

§ 205.303 Packaged products labeled "100 percent organic" or "organic."

(a) Agricultural products in packages described in §205.301(a) and (b) may display, on the principal display panel, information panel, and any other panel of the package and on any labeling or market information concerning the product, the following:

(1) The term, "100 percent organic" or "organic," as applicable, to modify the name of the product;

(2) For products labeled "organic," the percentage of organic ingredients in the product; (the size of the percentage statement must not exceed one-half the size of the largest type size on the panel on which the statement is displayed and must appear in its entirety in the same type size, style, and color without highlighting.)

(3) The term, "organic," to identify the organic… etc.

(6) NEW The statement "Certified to USDA guidelines", (subject to the same type limitations in 205.303(a)(2)).

§ 205.304 Packaged products labeled "made with organic (specified ingredients or food group(s))."

(a) Agricultural products in packages described in §205.301(c) may display on the principal display panel, information panel, and any other panel and on any labeling or market information concerning the product:

(1) The statement:

(i) "Made with organic (specified ingredients)" ….etc.

(ii) (ii) "Made with organic (specified food groups)": … etc.

(iii) Which appears in letters that do not exceed one-half the size of the largest type size on the panel and which appears in its entirety in the same type size, style, and color without highlighting.

(2) The percentage of organic ingredients… etc.

(3) The seal, logo or other identifying mark of the certifying agent that certified the handler of the finished product.

(4) NEW The statement "Certified to USDA guidelines", (subject to the same type limitations in 205.304(a)(1)(iii)).

(b) Agricultural products in packages described in § 205.301 (c) must: … etc.

(c) Agricultural products in packages described in § 205.301 (c) must not display the USDA seal.

Committee Vote

Motion: Jennifer Hall Second: Joe Smillie
Yes: 5 No: 0 Abstain: 0 Absent: 1

National Organic Standards Board
Compliance, Accreditation, and Certification Committee
Clarifying Limitations of § 205.101(b):
Recommended Guidance Toward Reducing Fraud in the Organic Marketplace

June 28, 2010

Introduction

The organic market is nearing its first decade of existence under full implementation of the National Organic Program; many positive features stand out as contributing to a more sustainable, healthy environment as a function of the legislation and regulations we as an industry operate under, being the beneficiaries of a confident consumer base who choose to support the common goals of the organic community: producers, processors, distributors, retailers, and consumers. Having said that, we recognize a gap in the long supply chain from producers to consumers providing opportunities to game the system and create an uneven playing field, providing cause for skepticism about the organic integrity of the industry at large.

Since the inception of the NOP the activities of many traders and distributors have been considered to be excluded under § 205.101(b). This was also the case in many pre-NOP private organic standards, which served to provide a starting point and inertia for the current system. That starting point was focused around the activities of distributors of packaged, finished goods.

Uncertified brokers, distributors and traders dealing in organic goods lack the regular oversight of organic certification agents and the NOP. Chief among our concerns is the misrepresentation and sale of non-organic goods sold with an organic claim, often using an otherwise valid organic producer certificates to support the sale. This is most often reported in organic commodity crops such as grains, soybeans, and hay or in livestock and not limited to a particular geographic region of the United States. This appears to be facilitated by the frequently opaque relationship between seller, transporter, and buyer where the transporter takes some form of title to the goods and sells to multiple buyers. The degree to which these business relationships are prevalent or problematic outside of the US is unknown.

While we see value and benefit in making changes in the relevant regulatory language to require certification for distributors, brokers, and traders, we recognize that this is lengthy, arduous task that will require additional development and effort to be successful. Fortunately, we find that language already exists in the regulation to provide ample oversight of many activities currently conducted without the benefit of organic certification and concomitant enforcement activity, and without even the record keeping provisions required for exempt operations under § 205.101(c).

Regulatory Citations Background

§ 205.101(b) provides for the following:

(1) A handling operation or portion of a handling operation is excluded from the requirements of this part, except for the requirements for the prevention of commingling and contact with prohibited substances as set forth in § 205.272

with respect to any organically produced products, if such operation or portion of the operation only sells organic agricultural products labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” that:

(i) Are packaged or otherwise enclosed in a container prior to being received or acquired by the operation; and

(ii) Remain in the same package or container and are not otherwise processed while in the control of the handling operation.

Discussion

While this language supports the continued allowance for exclusion of finished product brokers, traders, and distributors of finished, packaged goods—whether wholesale ingredients or retail products—***it does not support exclusion of unpackaged agricultural commodities*** such as grain, soybeans, hay, or livestock, which are not generally packaged or enclosed in a container prior to being received by the broker, trader or distributor and, if they are, generally do not stay in that container for the duration of the handler’s activities.

Hay or cattle are not packaged at all and so clearly do not meet the provisions of § 205.101(b)(1)(i). While some may argue that enclosure in a bulk container constitutes a ‘package’, we find this argument unconvincing; nonetheless, bulk soybeans, pulses and grains are typically received by truckers, traders or distributors from one container (e.g. silo, bulk trailer, rail car) and transferred to another container (e.g. rail car, bulk trailer, silo) at some point in the transaction. Accordingly, even if a truck trailer or rail car were to be considered ‘packaging’, many if not most transactions would fail to meet the provisions found in § 205.101(b)(ii). Several other commodities and goods are often sold, brokered, and traded in a similar fashion; transactions of all commodities not consistent with the provisions in § 205.101(b)(1) are not subject to the exclusion allowed under this part.

Recommendation

The CACC recommends that the National Organic Program issue guidance clearly articulating the limitations of § 205.101(b)(1) and the need for handling operations involved in the activities described above to immediately seek organic certification or be subject to appropriate enforcement activity. We see no reason to allow a grace period for such certified operators since the regulations are clear and presently in effect.

We provide the following language as an option for the Program when issuing such public notice:

“This notice is provided to inform the general public and interested parties that the National Organic Program (NOP) staff has determined that the limitations to the applicability of § 205.101(b) have not been adequately observed and that a number of uncertified handlers have been operating in a manner inconsistent with 7 CFR Part 205 and the National Organic Program.

Handling operations selling or otherwise representing commodities such as grains, soybeans, hay, or cattle and commonly referred to as brokers, traders, or distributors of those commodities, *are not excluded from the requirements of 7 CFR Part 205*, including but not limited to organic certification, *unless* such an operation only sells organic agricultural products labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" that:

(i) Are packaged or otherwise enclosed in a container prior to being received or acquired by the operation; and

(ii) Remain in the same package or container and are not otherwise processed while in the control of the handling operation.

Hay is typically sold or transported in bales of various sizes and configurations on trailers without packaging; cattle are sold on the hoof in trailers. These activities are inconsistent with § 205.101(b)(1)(i). Brokers, traders or distributors of such organic goods are therefore required to be certified organic operators, maintaining product segregation and records sufficient to verify compliance with OFPA 1990 and 7 CFR part 205, the National Organic Program.

Commodities such as grains and soybeans are typically not packaged and are received from one container or vessel and transported in another container or vessel; this is inconsistent with § 205.101(b)(1)(ii). Brokers, traders or distributors of such organic commodities are therefore required to be certified organic operations, maintaining product segregation and records sufficient to verify compliance with OFPA 1990 and 7 CFR part 205, the National Organic Program.

Handlers currently engaged in brokering, trading or distribution activities in a manner inconsistent with § 205.101(b) are not in compliance and may be subject to penalties and fines as per § 205.100(c)(1)."

Committee Vote

Motion: John Foster Second: Barry Flamm
Yes: 4 No: 0 Abstain: 0 Absent: 1

National Organic Standards Board
Policy Development Committee
Ad Hoc Committees

July 22, 2010

Introduction

This recommendation allows for the formation of Ad Hoc Committees comprised of NOSB members when deemed necessary to carry out critical work.

Background

The National Organic Standards Board is comprised of six standing committees: Crops (CC), Livestock (LC), Handling (HC), Policy Development (PDC), Certification, Accreditation, and Compliance (CACC), and Materials (MC), and an Executive Committee (EC) comprised of the NOSB officers and the chair of each of the standing committees. At times, policy or guidance development cuts across multiple committee jurisdictions and requires the expertise of, and input from, members of several standing committees to be completed. In these cases, it would be beneficial for a provision in the NOSB Policy and Procedures Manual (PPM) allowing for the formation of Ad Hoc committees to effectively carry out NOSB work.

Relevant Areas in the Rule

Sections §205.600, §205.607.

Discussion

Currently, although they have been formed in the past, there are no provisions in the NOSB Policy Manual for commissioning Ad Hoc committees when policy or guidance development would clearly benefit from the experience and input of members from various standing committees, or from the combination of two or more standing committees. A recent example of this arrangement is the Joint Handling and Materials Committee that was formed to collaborate on and develop recommended policy regarding classification of materials for the National List. Additionally, at times, excessive workload could require formation of an ad hoc or joint committee to tackle large NOSB mandated tasks, such as sunset material reviews or evaluation of large numbers of concurrently submitted petitions to add materials to the National List. With input from standing committee chairs, the NOSB Chairperson should monitor committee work plans and workload, and determine when and if the formation of an ad hoc committee would benefit the effectiveness of the NOSB. Once a determination is made by the NOSB chair that an ad hoc committee should be formed, that decision would be brought to the Executive Committee for discussion and approval.

Recommendation

The Policy Development Committee recommends that the formation of ad hoc committees be allowed when required, and that procedures for doing so be described in Section IV of the NOSB Policy Manual, as attached.

Committee Vote:

Motion: Steve DeMuri Second: Jay Feldman
Yes: 4 No: 0 Abstain: 0 Absent: 1

SECTION IV

Board Committees

Committees play an important role in administering the Board's responsibilities. Committees exist to provide greater depth and clarity in the Board's responsibility to make informed decisions. For example, at the request of the Secretary seeking advice on a matter related to the NOP, the full Board may request that a committee conduct research and analysis or draft proposed recommendations to be considered by the full Board. Except for the Executive Committee, no committees are authorized to act in place of the Board. Committees are empowered to analyze information and bring draft recommendations to the Board for action.

Committee chairs are appointed by the Board Chair. The current standing committees are:

- Certification, Accreditation, and Compliance
- Crops
- Handling
- Livestock
- Materials
- Policy Development

The Livestock Committee, the Crops Committee and the Handling Committee will each have co-chairs. One co-chair will guide all committee discussion and will oversee the committee's work plan. The other co-chair will be responsible for the committee's consideration of materials and will serve as the liaison to the Materials Committee.

1. Committee recommendations are finalized by the NOSB according to the following process:
2. Committee drafts the recommendation.
3. Draft recommendation is posted for public comment.
4. Public comments are considered by committee when making recommendation to the Board.
5. Board takes action on the recommendation

Board actions may include adoption of the recommendation as presented by the committee, amending and then adopting the recommendation, rejecting the recommendation, or referring the recommendation back to committee for further development.

Committee Meetings

Committees may hold meetings via telephone conference calls. Two weeks' notice should be provided in scheduling such calls. The date and time set for the call is a product of committee dialog regarding the most conducive schedule. This dialog may occur on a previous conference call or through E-mail. All E-mail requests for meeting times should allow 48 hours to respond.

Emergency calls may be scheduled with less notice only after each member is contacted to reach a consensus on time and date of the meeting. If the members do not respond to E-mail requests, the chair or their designee must contact the member by phone.

Standing Committees

Certification, Accreditation, and Compliance Committee (CACC) The Certification, Accreditation, and Compliance Committee drafts recommendations for consideration by the Board to provide guidance, clarification or proposed standards of certification, accreditation and compliance sections of the organic regulations [7CFR Part 205] and OFPA. The CACC occasionally works with other committees to develop joint recommendations where certification and compliance issues are involved.

Crops Committee (CC) The Crops Committee drafts recommendations for consideration by the Board to provide guidance, clarification or proposed standards of the crop production section of the organic regulations as contained in [7CFR Part 205] and OFPA. The CC reviews petitions, substances scheduled to sunset, technical advisory panel reports, and public comments concerning materials used for crop production which have been requested for addition to or removal from the National List. The CC occasionally works with other committees to develop joint recommendations where crop issues are involved.

Handling Committee (HC) The Handling Committee makes draft recommendations for consideration by the Board to provide guidance, clarification or proposed standards of the handling and labeling sections of the organic regulations as contained in [7CFR Part 205] and OFPA. The HC reviews petitions, substances scheduled to sunset, technical advisory panel reports and public comments concerning materials used for processing and handling which have been requested for addition to or removal from the National List. The HC occasionally works with other committees to develop joint recommendations where handling issues are involved.

Livestock Committee (LC) The Livestock Committee drafts recommendations for consideration by the Board to provide guidance, clarification or proposed standards of the livestock and livestock feed sections of the organic regulations as contained in [7CFR Part 205] and OFPA. The LC reviews petitions, substances scheduled to sunset, technical advisory panel reports and public comments concerning materials used for livestock production which have been requested for addition to or removal from the National List. The LC occasionally works with other committees to develop joint recommendations where livestock issues are involved.

Materials Committee (MC) The Materials Committee drafts recommendations for consideration by the Board to provide guidance, clarification or proposed standards of the National List section of the organic regulations as contained in [7CFR Part 205] and OFPA. The MC works with the NOP, NOSB Committees and TAP Contractors in managing the Materials Review Process including tracking petitions, sufficiency reports, materials scheduled to sunset and sunset review process In addition to a chair appointed by the Board Chair, the MC shall include in its membership one of the co-chairs from each of the Livestock, Crops, and Handling committees. Other members may be appointed as needed. The MC occasionally

works with other committees to develop joint recommendations where materials are involved.

Policy Development Committee (PDC) The Policy Development Committee makes draft recommendations for consideration by the Board to provide guidance, clarification or proposed standards of Board operations, policies and procedures. The PDC maintains the content and updates to the NOSB Policy and Procedures Manual and New Member Guide. The PDC occasionally works with other committees to develop joint recommendations where policy issues are involved.

Task Forces

As determined by the Board or Executive Committee, task forces shall be appointed to explore specific issues and present draft recommendations to the Board or to a committee. Task forces may include non-Board members of the public. Each task force shall include at least one member of the NOSB. Minutes shall be taken of task force meetings. Each task force shall submit a final report to the Board. Each task force shall be disbanded when its work has concluded or when the Board determines the task force is no longer necessary.

Ad Hoc Committees

At the discretion of the NOSB Chairperson, with approval of the Executive Committee, an ad hoc NOSB committee may be formed to develop policy and guidance on specific issues that involve multiple standing committee jurisdictions, or for issues or tasks that are very large and require additional resources to complete. Ad hoc committees may be comprised only of current NOSB members, and could either be a combination of two or more standing committees to form a “joint” committee, or could be a totally new committee comprised of selected NOSB members from various standing committees. Commissioned ad hoc committees will disband when the assigned task(s) is complete, at the discretion of the NOSB chairperson.

National Organic Standards Board
Policy Development Committee
Clarification and Updating Section V Direction on
NOSB / NOP Collaboration Process

July 27, 2010

Introduction

The Policy Development Committee (PDC) continues its efforts to improve the Board's Policy and Procedures Manual (PPM).This recommendation presents suggested changes to the National Organic Standards Board (NOSB) / National Organic Program (NOP) collaboration guidance in Section V of the PPM.

Background

The PDC has been systematically reviewing the NOSB Policy and Procedures Manual to improve and update directions for the Board. Section V was reviewed and revisions approved at the November 2009 Board Meeting. However, the part in Section V addressing NOSB/NOP collaboration was deferred for further consideration due to the organizational changes then occurring in the NOP. The NOP has new leadership, changed reporting structure and position in AMS, and increased staffing and funding. This calls for reexamination of how the parties work together in the interest of the organic community and the public at large.

The effective operation of the NOSB requires close coordination with the staff of the NOP in accordance with the transparency requirements of the FACA guidelines and OFPA statute and regulations. In this spirit, the mission of the NOSB and the intent of the Organic Foods Production Act (OFPA) are best fulfilled if both the board and the NOP staff work together closely. To ensure NOSB effectiveness, NOP resources are committed to ensuring that the Board effectively carries out its responsibility to determine acceptable practices and materials in accordance with OFPA standards. The functions of the NOSB, including its committee's decisions making process and their effectiveness, are central to the success of the NOP, organic integrity, protection of health and the environment, and sustained growth of the organic sector.

Relevant Areas in the Rule

The Organic Foods Production Act of 1990, 6518 (a) directed the Secretary of Agriculture to establish the National Organic Standards Board and prescribed its duties.
The Act, 6503 (a), also directed the Secretary to establish an organic certification program.
The NOP became the executive agency administering the program.

Discussion

The initial work of the PDC last year focused on streamlining the directions now in PPM

Section V. Subsequently, as discussed above, it was determined that the changes at NOP required a more comprehensive revision resulting from NOP and public discourse. A discussion document was developed for the April 2010 Board meeting asking questions about the present collaboration process and proposing changes to current directives. A limited number of public comments were received. One commenter emphasized that, "We would not like to see the Board meeting without the Public or meeting with the NOP without Federal Register Notice and the opportunity for public comment." The Board has and will continue to strictly follow FACA rules, which address this issue. This commenter also said, "It seems that regardless of leadership, funding or staffing that the collaboration process overall should not change." The PDC believes these changes at NOP merit consideration of various means to improve collaboration. Another commenter "suggest(s) that NOSB focus its role on justifying standards modifications and prioritising standards development." The Committee has weighed all comments in developing the proposed revision to Section V of the PPM which follows:

NOSB-NOP COLLABORATION

The Organic Foods Production Act (6518 (a)) directed the Secretary of Agriculture to establish a National Organic Standards Board to assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of the Act. In 6503 (a) of the Act, the Secretary was directed to establish an organic certification program. The National Organic Program (NOP) has become the governmental institution to accomplish this and is the means through which the NOSB provides advice and assistance to the Secretary of Agriculture.

The mutual goals to advance the integrity of organic products, principles and products can best be accomplished through team work and cooperation between the NOSB and the NOP and is implemented regularly through two-way feedback by the NOSB Executive Director and periodically at the Executive Committee's monthly calls. Especially at these calls, NOSB committee work plans and priorities are discussed and NOP requests and opinions are aired.

An effective collaboration process between the NOP and the NOSB should ensure that NOP receives NOSB input and feedback, and vice versa. The process can be complicated due to several factors like the following:

- The NOSB is a FACA advisory committee, and as such, must conduct business in the open, under the requirements of P.L. 94-409, also known as "Government in the Sunshine Act" (5 U.S.C.552b).
- The USDA cannot delegate its authority as a regulatory body to private citizens, even when those private citizens are appointed by the Secretary to provide advice. However, the NOSB has unique statutory authority related to the determination of materials as approved or prohibited substances for inclusion on the National List.
- The NOSB cannot direct USDA or bind the Secretary through its actions; for example, it cannot obligate funds, contract, or initiate policies on its own accord.

Several collaboration approaches may be required depending on the type of issue faced by the Board. Below are descriptions of the most common situations faced by the NOSB. In all cases, the end product should be a recommendation by the Board to the NOP and each recommendation should be accompanied by a cover sheet illustrated in figure 1.

1. **Materials proposed to be added to or removed from the National List.**
   The NOSB has the statutory authority to consider and recommend materials for addition to, or deletion from, the National List of Approved and Prohibited Substances, or to add, remove, or modify annotations restricting the use of such listed materials.

2. **Recommendation for modification of existing standards or new standards.**
   The NOSB will use the decision making procedures outlined in Section VIII to justify modifying existing standards or proposing new standards. The NOP may request that the NOSB develop recommendations for new or existing standards. The request should be in writing and should include a statement of the problem to be addressed, background, including the current policy or situation, statuatory/ regulatory authority, legal situation, and desired timeframe for receiving the recommendation. The request will be posted on the NOP web site.

3. **Providing advice on NOP policy and interpretation of standards.**
   An examples are: NOSB providing comments on specific actions by the NOP, such as the yeast and compost policies.

4. **Compliance and Enforcement**.
   The NOP is responsible for compliance and enforcement. The NOP welcomes NOSB input on standards, but NOSB involvement in active investigations or enforcement actions is not appropriate. As timely and appropriate, the NOP reports to NOSB on the status of enforcement actions and also posts the status on the NOP web site.

5. **Management Review.**

NOSB may review the quality management system and internal audits to ensure that the NOP is managed effectively and efficiently. For example, the NOSB has a role to play in terms of seeing that corrective actions with OIG are completed.

In all the above situations, FACA procedures must be carefully followed to provide transparency and necessary public input.

The primary means of collaboration will be through NOP participation in Executive Committee (EC) and Standing Committee calls. The NOP Deputy Administrator or designee will participate in all EC calls. The NOSB Executive Director (ED) will participate in all NOSB calls as described in the ED duties in the PPM. Upon request and mutual agreement, the Deputy Administrator will participate in Standing Committee calls. In addition, each Standing Committee will be assigned an NOP staff person to provide additional technical, legal, and logistical support.

Work plans for action items are developed for each upcoming public board meeting. This is the

mode for developing recommendations and discussion documents. Work plan procedures are described in detail in Section VIII, page 32. The proposed work plans are presented and discussed at each public board meeting, but may be revised based on comments and Board priorities and resources.

NOP publicly made requests at board meetings are important considerations in the development of Committee work plan. These NOP requests to NOSB will be followed up in writing stating the problem to be addressed, background, statutory authority and the time frame for response. The proposed Committee Work plans will be reviewed at the next EC call following the Board meeting, with participation by the NOP Deputy Administrator. This participation in the development of work plans is vital for effective NOSB/NOP collaboration. Due to change in circumstances, these work plans may need to be revised prior to the posting of the final agenda of the upcoming Board meeting. Committee work plan changes will be done in consultation and full knowledge of the EC and NOP.

Committee Vote:

Motion: Barry Flamm Second: Steve DeMuri
Yes: 4 No: 0 Abstain: 0 Absent: 1

Figure 1: Form Used to Submit NOSB Final Recommendations to the NOP
(Non Materials Recommendations)

Formal Recommendation by the
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 the Recommendation (Including Recount of Vote):

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

Committee Vote:

Moved: _____ **Second:** _____

Yes: __ **No:** __ **Abstain:** __ **Absent:** __ **Recusal:** __

National Organic Standards Board
Policy Development Committee
Sunset Review Process – Policy Proposal

August 28, 2010

Introduction

This document discusses the Policy Development Committee's proposed policy on Sunset Review, regarding the need for clarification and adjustment to the process of review by the NOSB. The proposed policy will be presented at the Fall 2010 Board meeting for a vote.

Background

The current process for Sunset Review is guided by statutory language in the Organic Foods Production Act, Sec. 2118(e),[1] the NOSB Policy and Procedures Manual (PPM),[2] and several Federal Register[3] notices that describe the process.

While the statute does not define the process for validating an exemption or prohibition, it requires the NOSB to review "as provided in" Section 2118 of the act. In the strict sense of the law, this language would seem to require that the National List to be reevaluated to ensure that the list is in conformance with the standards as spelled out in Section 2118; "that the use of such substances – (i) would not be harmful to human health or the environment; (ii) is necessary to the production or handling of the agricultural product because of the unavailability of wholly natural substitute products; and, (iii) is consistent with organic farming and handling." This reasoning would extend to the other provisions of this section as it applies to prohibitions and exemptions reviewed in the sunset process.

The Federal Register notices reinforce the notion that the sunset process is a complete review that assesses those materials on the list in accordance with the standards of Section 2118. As a result, the notices seek public input in three categories: "Category 1. Adverse impacts on humans or the environment?; Category 2. Is the substance essential for organic production?, and; Category 3. Is the substance compatible with organic production practices?"[4]

---

[1] §**2118 [7 U.S.C. 6517] NATIONAL LIST.** (e) SUNSET PROVISION.-No exemption or prohibition contained in the National List shall be valid unless the National Organic Standards Board has reviewed such exemption or prohibition as provided in this section within 5 years of such exemption or prohibition being adopted or reviewed and the Secretary has renewed such exemption or prohibition.

[2] NOSB: Policy and Procedures Manual (Revised May, 2006), pp.56-59.

[3] 70FR35177 (2005), 72FR73668 (2008).

[4] See Evaluation Criteria for Substances Added to the National List, 72FR73670 (Dec. 28, 2007)

The document entitled “Sunset and the National List of Allowed and Prohibited Substances” (NOSB Materials Committee Draft) includes in its section on background the following: “We consider the Congressionally-mandated sunset of exemptions and prohibitions contained in the National List to be a similar review and renewal process – that of the conditions that justified the exemption or prohibition in the first instance.”
The NOP has previously taken the position that the Board has narrow authority under the sunset process. As such, the PPM establishes limitations on the sunset process not found in the other documents. The PPM clearly states the following:

> Sunset is a regulatory process for determining the continued listing of a material already approved or prohibited on the National List for use in organic agriculture production and handling. It is not used to petition to add a new substance nor is it used to change an existing annotation. If the review and renewal process is not concluded by the expiration date, the use of the material will become prohibited.
>
> Since sunset is defined as the reviewing of regulations to ensure the continued relevance and not the creation of new regulation, all substance [sic] must be renewed as listed. If there is a need to consider changing an annotation or moving a material from one list to another, this may be accomplished through the existing procedures for petition.
>
> In a February 16, 2010 document entitled “Sunset Review Under the National Organic Program (NOP),” the program has provided an interpretation of OFPA that enables broader Board authority to modify and amend annotations, and a shifting of the burden of proof to the public to retain exempted materials. With respect to burden of proof, NOP states that, “During the sunset review process, the NOSB may: . . .3) Recommend the removal of an exempted material from the National List due to a lack of public comment substantiating the importance of a continued listing.” NOP cites that public comments should demonstrate that the renewal of removal of a substance on the National List meets the standards of Section 2118, OFPA. In addition, most importantly, NOP concurs with those who have interpreted a broad authority for the Board under the sunset process. NOP says,
>
> There is nothing in OFPA to prohibit the NOSB from making a recommendation to modify or amend an annotation during the sunset review process. However the NOSB Policy Manual states in the sunset review procedures that amending or creating new annotations is not part of the sunset review process. The NOSB would need to amend their sunset review policy in order to recommend amending annotations during the sunset review process. No annotation can be changed without going through the rulemaking process.

There is general agreement that the sunset review process must be informed a the outset by input from the public.

The proposed sunset policy seeks to clarify the authority and procedures of the NOSB in the sunset review of materials to include (i) a thorough review of the previous and updated scientific assessments and essentiality determination, and (ii) modifications or amendments to annotations, to the extent necessary to meet the statutory standards.

Relevant Areas in NOSB Policy and Procedures Manual and OFPA

Sunset Review Process (pp56-59, PPM), 7 U.S.C. 6517, NATIONAL LIST. (e) Sunset Provision. §**2118 [7 U.S.C. 6517] NATIONAL LIST.** (e) SUNSET PROVISION.-No exemption or prohibition contained in the National List shall be valid unless the National Organic Standards Board has reviewed such exemption or prohibition as provided in this section within 5 years of such exemption or prohibition being adopted or reviewed and the Secretary has renewed such exemption or prohibition.

Discussion

There is agreement that the sunset process should not be disruptive to the organic market. In this context, there are two key factors that drive the analysis under the sunset review process, the burden of materials review and the limitations on material use. First, should those in the organic market (users) be required to justify (or defend) current materials on the list (burden of proof)? Second, to what extent can the limitations on the use of the listed materials be changed to reflect current information (revised annotations)?

The statute embraces the idea that if the system of organic farming and handling is based on risk or hazard avoidance, then it should avoid reliance on synthetic inputs to the greatest extent possible. It is in this spirit that the law mandates a periodic sunset review that consistently updates the analysis that supports the listing. So, the review should not allow the use of a material just because it meets a prescribed health and environmental standard, as is the case with environmental or health laws. Rather, OFPA requires an assessment of essentiality. As a result, the evaluation criteria ask, “Is there another practice that would make the substance unnecessary,” and other questions of compatibility. This process should be constantly asking how or if the reliance on listed materials can be reduced. Those requiring the use of the inputs on the list should supply the NOSB with a specific justification for why continued use of the listed material is essential. At the same time, to the extent that the previous Board decisions do not have a complete record of review, clarity is needed on an appropriate process to fill the documented gaps in knowledge.

Once a material is defended or data is received that questions the listing, the process should allow for the amending of annotations. Since the statute subjects the sunset process to the same review standards as the original National List process, it follows that the same tools for restricting the use of those materials should be available to the Board. In an attempt to best protect against disruption in the organic market, annotations rather than complete prohibitions are called for in the face of available data.

In its Federal Register notices on sunset, the NOP stated at the outset, “Because these substances may be critical to the production and handling of a wide array of raw and processed organic agricultural products, their expiration could cause disruption of well-established and accepted organic production, handling, and processing systems.” The sunset process is the statutory mandate to periodically question what is established and accepted and reaffirm or alter previous decisions as needed.

The sunset process to be optimally effective requires close collaboration with and resources of the NOP. Ultimately, the effectiveness of this process reflects on the credibility, integrity, and growth of the organic market. Organic agriculture represents a dramatic difference from conventionally produced food, both because of the organic systems plan and the strict limitation on allowable synthetic materials. The Committee notes that the statute holds that synthetics should not be easy to get on the National List, nor should they be easy to keep on the National List. To be truly responsive and to truly fulfill the mission of protecting consumers and ultimately farmers, the NOSB should be able to regulate the use of a material with annotations during the sunset process.

The recommendation addresses three areas of attention that are central to a comprehensive sunset review.

1. **Thorough and comprehensive review.**
   Sunset review must be a rigorous and comprehensive review process that is supported by a technical review document and public input that reevaluates and updates previous findings to ensure that a decision to renew or restrict a currently listed material is fully informed and in compliance with the statutory standards.

2. **Listed materials subject to sunset review.**
   Allowed materials under §205.601 and §205.603, §205.605, and §205.606 are sunsetted or removed from the National List unless the Board takes affirmative action to retain their uses. Similarly, prohibited uses under sections §205.602 and §205.604 will sunset unless the the Board takes action to relist.

3. **Annotations.**
   The ability to add or change annotations (restrictions) on applicable National List materials may be important to the Board's sunset decision, given changes in the use patterns of allowed materials and scientific understanding. Sunset decisions by the Board are arrived at through a two-step consecutive process that separates the decision on annotations from the final sunset decision. Under this process, first the assigned committee and then the Board reviews the technical review document(s) and public input to determine whether the material continues to comply with the statutory standards. If the committee identifies the need for a use restriction or clarification, it may propose the annotation in the form of an amendment to a motion to renew. The committee and subsequently the Board will first take up the annotation amendment and then vote on the material's renewal. The public will have an opportunity to comment on the proposed final sunset decision. An annotation to expand the use of a substance cannot be done through the sunset review process.

Recommendation

The Policy Development Committee recommends that the section entitled "SUNSET REVIEW PROCESS" (NOSB Policy and Procedures Manual, pages 56-57) be amended as follows (text in italics indicates proposed new language, and text in parenthesis indicates language to be deleted).

SUNSET REVIEW PROCESS

Background

Sunset is a regulatory process for determining the continued listing of a material already approved or prohibited on the National List for use in organic agriculture production and handling. It is not used to petition to add a new substance (nor is it used to change an existing annotation) *or new uses of a listed substance*. If the review and renewal process is not concluded by the expiration date, the use of the material will become prohibited. (Since sunset is defined as the reviewing of regulations to ensure the continued relevance and not the creation of new regulation, all substance must be renewed as listed. If there is a need to consider changing an annotation or moving a material from one list to another, this may be accomplished through the existing procedures for petition.)

Since the sunset review process is an assessment of National List substances to ensure their continued compliance with regulatory standards, the NOSB may determine that new restrictions in the form of annotations are necessary given changes in use patterns and scientific understanding. An annotation to expand the use of a substance does not fall within the purview of the sunset process and must only be considered through the petition process.

The Organic Foods Production Act of 1990 (OFPA) authorized a National List of Allowed and Prohibited Substances (Section 6517). Sections 6517 (e) mandates a Sunset Provision as follows:

“No exception or prohibition in the National list shall be valid unless the National Organic Standards Board has reviewed such exemption or prohibition as provided in this section within 5 years of such exemption or prohibition being adopted and the Secretary has reviewed such exemption or prohibition.”

The National List that was implemented in October 21, 2002 contained over 200 substances. The first sunset review of listed materials was completed in October, 2007. Decisions made through the Sunset review must be transparent, non-arbitrary, based on the best current information and in the interest of the organic community and public at large.

Steps followed in Sunset Process

Not all listed materials reach sunset status at the same time, but the review process includes these steps:

1. A public notice is placed in the Federal register (Advance Notice of Proposed Rule Making or ANPR of the pending sunset of the listed materials. The public has 60 days after the publication date to provide written comment (see Chart 1 below). The committee may request a third party technical review in anticipation of scientific evidence and claims likely to be made during public comment to the ANPR.
2. Public comments are collected and forward to the NOSB (see Chart 2).
3. The appropriate NOSB committee begins review of the material with the intent of providing a recommendation to the entire Board for the material’s removal, renewal,

or renewal with the addition of an annotation. The review is conducted based on "Force of Evidence" as presented by Board members, public comments, and scientific data from other sources (see Chart 3). This includes the original recommendation from the Board to list. The committee may request a third party technical review, if needed, to verify scientific evidence and claims made during public comment to the ANPR.

4. The reviewing NOSB committee provides its recommendation to the full Board 60 days prior to the Board Meeting. At the same time, the committee recommendations are posted on the NOSB website and open to public comments. *The recommendation may consist of a (i) simple motion to remove or renew the listing of the substance or (ii) motion to renew accompanied by an amendment containing the addition of an annotation to the listing. Regarding the addition of an annotation, the committee will, in a two-step process, first vote on the amendment with the annotation, then on the motion to renew. Should the amendment prevail in committee, the Board in its consideration will also vote first on the amendment to annotate, then the motion to renew. If the amendment to annotate does not advance out of committee, the Board will vote on the motion to renew and, per its normal process, entertain amendments from the Board.*
5. At the public NOSB business meeting, the NOSB hears additional public comment, discusses the force of evidence, and votes on the committee's recommendation.
6. The NOP reviews the NOSB recommendation and accompanying documentation and publishes a proposed rule to review the National List. The public has 90 days after the publication date to comment. All comments are made available on the NOP website.

   The NOP will review public comment and draft the final rule. The final rule will proceed through interagency (i.e. OGC , OMB, and departmental) and congressional review, and upon receiving clearance from the appropriate parties, the NOP will publish the final rule in the Federal Register. The final rule process is illustrated in Chart 4.
7. *If the clearance process required for an annotation during sunset is not able to be completed prior to the substance's expiration under the sunset process, the Board has the authority to revisit the question of the substance's removal or renewal prior to its expiration*.

Committee Vote:

Motion: Jay Feldman Second: Barry Flamm
Yes: 5 No: 0 Abstain: 0 Absent: 0

National Organic Standards Board

New Member Guide

2 0 1 0

Adopted: March 29, 2007 | Updated November 30, 2007 | Updated: May 22, 2008
Updated: November 19, 2008 | Updated: May 6, 2009 | Updated: August 20, 2010

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Welcome New NOSB Members

Congratulations and welcome to the National Organic Standards Board (NOSB)! We look forward to working with you over the next five years to advance organic regulations as defined by the Organic Food Production Act and the USDA National Organic Program. This guide is intended to provide guidance and resources to new members and to ease their transition to the NOSB.

Before your first NOSB meeting, you need to read and be familiar with the following materials:

- **Organic Food Production Act of 1990 (OFPA)**
- **Federal Register Final Rule**
- **NOSB Policy and Procedure Manual (PPM)**
- **NOP FACA Training Power Point** (to be received via email)

The first three documents listed are available at **http://www.ams.usda.gov/NOP** in the Resource Center section; brief summaries are provided below. The NOP FACA Training Power Point will be sent to all NOSB members as reference following the annual January FACA training session for NOSB members.

Questions?

Count on it. You will be assigned an NOSB mentor prior to your first official meeting to help you transition onto the Board. Your NOSB mentor will be available to you by phone or email to answer your questions as they arise. The NOSB Chair or the Executive Director can also be reached at any point to assist you. Contact information can be found at the end of this document or by contacting Lisa Ahramjian at **Lisa.Ahramjian@ams.usda.gov**.

Federal Organic Regulations & Entities: A Primer

Organic Food Production Act (OFPA)

Title XXI of the 1990 Farm Bill, known as the Organic Foods Production Act, established the National Organic Program within the Agriculture Marketing Service (AMS) of the USDA. It also established the National Organic Standards Board (NOSB), an advisory body to the NOP.

Federal Register Final Rule Establishes the National Organic Program

The December 21, 2000 final rule established the National Organic Program (NOP) within the Agricultural Marketing Service (AMS), an arm of the U.S. Department of Agriculture (USDA). NOP facilitates domestic and international marketing of fresh and processed food that is organically produced and assures consumers that such products meet consistent, uniform standards. NOP is required to establish national standards for the production and handling of organically produced products, including a National List of substances approved for and prohibited from use in organic production and handling. The final rule also established a national-level accreditation program, labeling requirements, and foreign organic program equivalency requirements.

National Organic Standards Board (NOSB)

OFPA authorized the Secretary of Agriculture to appoint a 15-member National Organic Standards Board (NOSB). The NOSB has the sole authority granted through OFPA to recommend additions to the National List of Allowed and Prohibited Substances. Further, the NOSB drafts recommendations based on needs of the industry with public and industry input. The Board's main mission is to make recommendations about whether a substance should be allowed or prohibited in organic production or handling, to assist in the development of standards for substances to be used in organic production, and to advise the Secretary on other aspects of OFPA implementation. Members come from all four U.S. regions.

The first NOSB was appointed by then Secretary Edward Madigan in January, 1992. Members of the initial board served staggered terms of 3, 4, or 5 years; all subsequent board appointees serve 5-year terms. Per OFPA, the board must consist of 15 members:

- Four farmers/growers
- Two handlers/processors
- One retailer
- Three environmentalists / resource conservationists
- Three consumer/public interest advocates
- One scientist (toxicology, ecology, or biochemistry)
- One USDA accredited certifying agent.

National List of Allowed and Prohibited Substances

Through OFPA, the NOSB has the sole authority to recommend adding materials to or removing materials from the National List. The Secretary of Agriculture has limited authority with regards to NOSB recommendation for additions to the National List; the Secretary may deny the listing of a material, but may not add a material that was not previously recommended by the board.

Technical Information

To help NOSB members assess whether materials should be added or removed from the National List, the NOSB is authorized to request technical information from internal and external sources on materials. See The Final Rule Subpart G 205.600 and the NOSB Policy and Procedures Manual Section IV for additional information.

NOSB Policy and Procedure Manual (PPM)

The PPM outlines all general procedures followed by members of the NOSB. The manual is designed to assist the Board in its responsibilities and is considered mandatory reading for all members. The PPM covers many important issues such as the NOSB Vision Statement, Duties of the Board and Officers, NOSB job descriptions, NOSB Principals to Production and Handling, Materials Review Process, TAP Contract Procedures, Sunset Review Process and other critical information that is important for you to understand. Policies and revisions are incorporated periodically, and since the manual guides you on how to craft your documents and recommendations, it is essential to refer to the manual and make sure you are following the process.

Additional Helpful Reading

NOSB Website | **www.ams.usda.gov/nosb**
Access NOSB meeting transcripts, NOSB executive committee minutes, and previous NOSB recommendations

NOP Website | **www.ams.usda.gov/nop**
Access NOP Newsroom, organic regulations, and resources for various stakeholder groups

From the Margins to the Mainstream, Advancing Organic Agriculture in the United States: National Organic Action Plan | **http://www.rafiusa.org/docs/noap.pdf**

Selecting NOSB Committees

You will work with the NOSB chair to select 2-3 standing committees from the following:

- Compliance, Accreditation, & Certification Committee
- Crops Committee
- Handling Committee
- Livestock Committee
- Materials Committee
- Policy Development Committee

New members may also have the option to join a currently-existing ad-hoc committee. Additional information on the different committees is available on page 15 of the Policy and Procedure Manual. Generally, it is best to select a committee in which you have experience. New members are also encouraged to seek guidance from the NOSB Chair or the Executive Director to best utilize your skills and experience. Committee chairs can update you on current topics under consideration and provide you with recent meeting minutes.

Demystifying the Federal Register

The Federal Register is the official daily publication for rules, proposed rules, and notices of Federal agencies and organizations, as well as executive orders and other presidential documents. The Federal Register has format and public notice rules that have to be followed. Public comment periods are generally for a minimum of 30 days, but since the organic community believes strongly in collaboration and public comment, NOP strives to allow 45 days for public comment on their notices. "If you intend to bind the public, you have to provide actual and timely notice." Several types of Federal Register notices are used at different rulemaking stages:

Advanced Notice of Proposed Rule (ANPR)

Optional – Involves proposing an idea and formally asking for public comment ***before*** you draft the proposed rule. This is strictly an idea and data collecting process that discourages back-room idea and data collection.

Notice of Proposed Rule (NPR)

Required – Provides background, Intent, and Objectives via the Preamble, Proposes specific rule language, and is Open to Public Comment.

Interim Final Rule (IFR)

Optional – Very similar to the Final Rule – still open to some public comment, used primarily when issues are controversial and some tweaking of the final rule language may be required.

Supplemental Notice of Proposed Rule (SNPR)

Optional – open to public comment on an newly proposed areas that came up during NPR that were not foreseen, but also includes some areas that are more decided and not as open to comment.

Direct Final Rule (DFR)

Special Circumstances – usually not a controversial issue and requires immediate action (good cause criteria have to be met), risky because if one commenter objects, then they have to resubmit as an NPR which costs money – and allow public comment. i.e. the banning of dangerous toys for small children.

Final Rule: 30 days before effective date

Required – Provides Background, Intent, and Objectives via the Preamble, Proposes specific rule language, and is not open to Public Comment as all public commenting time periods have either been met through the above required and optional steps, *with the exception of rules being modified to respond to court actions and deadlines*.

Any further changes to these regulations would be made through petition: "Petition for Reconsideration", and would essentially be re-run through the Federal Register process as described above.

Rulemaking 101

Commonly, laws do not contain level of detail for their practical implementation. Rather, agencies of the Executive branch have to establish rules, or regulations, to serve as guides in the implementation of laws. The rule development process can be described in five steps:

1. **Establish grant rulemaking authority**
   In NOSB's case, per OFPA
2. **Publish proposed rule with request for public comments**
   Rule is subject to Office of Management and Budget review
3. **Publish final rule addressing public comments; set effective date**
   Rule is subject to Office of Management and Budget review
4. **Congressional review**
   Congress or the Government Accountability Office has the ability to nullify rules
5. **Effective Date**
   Rules go into effect after a 30-day minimum; 60-day for major rules
   Agencies may delay or withdraw rules before they become effective

The diagram below provides additional details on the rulemaking process; this resource is also available at http://www.reginfo.gov/public/reginfo/Regmap/index.jsp.

The Reg Map

Informal Rulemaking

Step One
Initiating Events

Agency Initiatives
Agency initiatives for rulemaking originate from such things as:
- Agency priorities and plans
- New scientific data
- New technologies
- Accidents

Required Reviews

Statutory Mandates

Recommendations from Other Agencies/External Groups/States/Federal Advisory Committees

Lawsuits

Petitions

OMB Prompt Letters

Step Two
Determination Whether a Rule Is Needed

Administrative Procedure Act Provisions
Under the Administrative Procedure Act provisions that are included as part of the Freedom of Information Act at 5 U.S.C. 552, agencies are required to publish in the *Federal Register*:
- Substantive rules of general applicability
- Interpretive rules
- Statements of general policy
- Rules of procedure
- Information about forms
- Information concerning agency organization and methods of operation

Step Three
Preparation of Proposed Rule

Proposed Rule
A notice of proposed rulemaking proposes to add, change, or delete regulatory text and contains a request for public comments.

Administrative Procedure Act Provisions
Under the Administrative Procedure Act provisions at 5 U.S.C. 553, rules may be established only after proposed rulemaking procedures (steps three through six) have been followed, unless an exemption applies. The following are exempted:
- Rules concerning military or foreign affairs functions
- Rules concerning agency management or personnel
- Rules concerning public property, loans, grants, benefits, or contracts
- Interpretive rules
- General statements of policy
- Rules of agency organization, procedure, or practice
- Nonsignificant rules for which the agency determines that public input is not warranted
- Rules published on an emergency basis

Note: Even if an exemption applies under the Administrative Procedure Act provisions, other statutory authority or agency policy may require that proposed rulemaking procedures be followed.

Optional Supplementary Procedures to Help Prepare a Proposed Rule

Advance Notice of Proposed Rulemaking
An advance notice of proposed rulemaking requests information needed for developing a proposed rule.

Negotiated Rulemaking
Negotiated rulemaking is a mechanism under the Negotiated Rulemaking Act (5 U.S.C. 561-570) for bringing together representatives of an agency and the various interests to negotiate the text of a proposed rule.

Step Four
OMB Review of Proposed Rule

OMB Review Under Executive Order 12866
OMB reviews only those rulemaking actions determined to be "significant."

Independent agencies are exempt from OMB review.

Step Five
Publication of Proposed Rule

Administrative Procedure Act Provisions
The Administrative Procedure Act provisions at 5 U.S.C. 553 require proposed rules to be published in the *Federal Register*.

Step Six
Public Comments

Comments
Under the Administrative Procedure Act provisions of 5 U.S.C. 553, an agency must provide the public the opportunity to submit written comments for consideration by the agency.

As required by Public Law No. 107-347, agencies must provide for submission of comments by electronic means and must make available online the comments and other materials included in the rulemaking docket under 5 U.S.C. 553 (c).

Executive Order 12866 established 60 days as the standard for the comment period.

The holding of a public hearing is discretionary unless required by statute or agency policy.

Step Seven
Preparation of Final Rule, Interim Final Rule, or Direct Final Rule

Final Rule
A final rule adds, changes, deletes, or affirms regulatory text.

Special Types of Final Rules

Interim Final Rule
An interim final rule adds, changes, or deletes regulatory text and contains a request for comments. The subsequent final rule may make changes to the text of the interim final rule.

Direct Final Rule
A direct final rule adds, changes, or deletes regulatory text at a specified future time, with a duty to withdraw the rule if the agency receives adverse comments within the period specified by the agency.

Step Eight
OMB Review of Final Rule, Interim Final Rule, or Direct Final Rule

OMB Review Under Executive Order 12866
OMB reviews only those rulemaking actions determined to be "significant."

Independent agencies are exempt from OMB review.

Step Nine
Publication of Final Rule, Interim Final Rule, or Direct Final Rule

Congressional Review Act (5 U.S.C. 801-808)
An agency must submit most final rules, interim final rules, and direct final rules, along with supporting information, to both houses of Congress and the General Accounting Office before they can take effect.

Major rules are subject to a delayed effective date (with certain exceptions).

Action by Congress and the President could have an impact on the rule.

Administrative Procedure Act Provisions
Under the Administrative Procedure Act provisions that are included as part of the Freedom of Information Act at 5 U.S.C. 552, agencies are required to publish final rules, interim final rules, and direct final rules in the *Federal Register*.

Federal Register Act (44 U.S.C. 1501-1511)
The Federal Register Act at 44 U.S.C. 1510 (implemented at 1 CFR 8.1) requires rules that have general applicability and legal effect to be published in the *Code of Federal Regulations*.

Specific Analyses for Steps Three and Seven

Regulatory Planning and Review (E.O. 12866)
Would the rule have a $100 million annual impact, raise novel issues, and/or have other significant impacts? → **If yes** — Prepare economic impact analysis.

Regulatory Flexibility Act (5 U.S.C. 601–612)
Is a notice of proposed rulemaking required by law? → **If yes**
Would the rule "have a significant economic impact on a substantial number of small entities"? → **and yes** — Prepare regulatory flexibility analysis.
Note: Under limited circumstances analyses also are required for certain interpretive rules involving internal revenue laws (5 U.S.C. 603, 604).

Paperwork Reduction Act (44 U.S.C. 3501–3520)
Does the rule contain a "collection of information" (reporting, disclosure, or recordkeeping)? → **If yes** — Prepare information collection clearance package for OMB review and approval, and prepare request for public comments.

Unfunded Mandates Reform Act (2 U.S.C. Chs. 17A, 25)
Does the rulemaking process include a proposed rule? → **If yes**
Does the rule include any Federal mandate that may result in the expenditure (direct costs minus direct savings) by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually)? → **and yes** — Prepare unfunded mandates analysis (unless an exclusion applies).

Federalism (E.O. 13132)
Is the rule a discretionary rule that has federalism implications and imposes substantial unreimbursed direct compliance costs on State and local governments? → **If yes** — Prepare federalism summary impact statement.
Does the rule have federalism implications and preempt State law? → **If yes** — Prepare federalism summary impact statement.

Indian Tribal Governments (E.O. 13175)
Is the rule a discretionary rule that has tribal implications and imposes substantial unreimbursed direct compliance costs on Indian tribal governments? → **If yes** — Prepare tribal summary impact statement.
Does the rule have tribal implications and preempt tribal law? → **If yes** — Prepare tribal summary impact statement.

National Environmental Policy Act (42 U.S.C. 4321–4347)
Is the rule categorically excluded from review? → **If no**
Does the rule constitute a major Federal action that could significantly affect the quality of the human environment? → **and yes** — Prepare environmental assessment or environmental impact statement, as appropriate.

National Technology Transfer and Advancement Act (15 U.S.C. 272 note)
Does the rule contain provisions for which the use of voluntary standards is applicable? → **If yes** — Adopt voluntary consensus standards or explain why not.

Governmental Actions and Interference with Constitutionally Protected Property Rights (E.O. 12630)
Does the rule regulate private property use for the protection of public health or safety? → **If yes** — Prepare takings analysis.
Is rulemaking a proposed regulatory action that has takings implications (other than regulating private property for the protection of public health and safety)? → **If yes** — Prepare takings analysis.

Protection of Children from Environmental Health Risks and Safety Risks (E.O. 13045)
Is the rulemaking a "covered regulatory action"? → **If yes** — Prepare analysis of the environmental health or safety effects on children.

Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (E.O. 13211)
Is the rulemaking action a "significant energy action"? → **If yes** — Prepare statement of energy effects.

Using The Reg Map

The Reg Map is based on general requirements. In some cases, more stringent or less stringent requirements are imposed by statutory provisions that are agency specific or subject matter specific. Also, in some cases more stringent requirements are imposed by agency policy.

In a typical case, a rulemaking action would proceed from step one through step nine with a proposed rule and a final rule.

However, if a rulemaking action is exempt from the proposed rulemaking procedures under the Administrative Procedure Act provisions (explained under step three) or under other statutory authority, an agency may:

- promulgate a final rule omitting steps three through six, or
- promulgate an interim final rule omitting steps three through six, but providing a comment period and a final rule after step nine.

Also, if an agency determines that a rule likely would not generate adverse comment, the agency may promulgate a direct final rule, omitting steps three through six, but with a duty to withdraw the rule if the agency receives adverse comments within the period specified by the agency.

Drafting Requirements for Rulemaking Documents

Regulatory Planning and Review (E.O. 12866)
Rulemaking documents must comply with the specified regulatory philosophy and principles of regulation.

Civil Justice Reform (E.O. 12988)
Rulemaking documents must be written in clear language designed to help reduce litigation.

Presidential Memorandum on Plain Language (63 FR 31885)
Rulemaking documents must comply with plain language principles.

Federal Register Publications
Rulemaking documents must comply with the Federal Register regulations (1 CFR). Additional guidance and requirements are contained in the Federal Register's *Document Drafting Handbook*.

Agendas for Rules Under Development or Review

Unified Regulatory Agenda
The Unified Regulatory Agenda provides information concerning agency rules under development or review.

The Unified Regulatory Agenda is published in the *Federal Register* in the spring and fall of each year.

Regulatory Plan
The Regulatory Plan provides information concerning the most important significant regulatory actions that the agency is planning to take.

The Regulatory Plan is published in the Unified Regulatory Agenda in the fall of each year.

Regulatory Flexibility Agenda
The Regulatory Flexibility Agenda provides information concerning any rule that an agency expects to prepare or promulgate that is likely to have a significant economic impact on a substantial number of small entities.

Agency regulatory flexibility agendas are published as part of the Unified Regulatory Agenda in the spring and fall of each year.

Public Comment

Refer to the PPM for the detailed policy & procedures on the public comment process.

NOSB's Unique Role

Organic stakeholders are extremely engaged in the activities of both the NOP and the NOSB. Both groups receive an unprecedented amount of public input from farmers, businesses and consumers during every step of their decision-making process—from draft NOSB recommendation to final rule. After considering the recommendations of the NOSB, the NOP reviews public comments and industry analysis before proposing a final recommendation. However, the Secretary of Agriculture has final authority in determining all regulations.

NOSB members are in the unique position of not only representing their sector, but also representing the USDA and the public. It is therefore especially important for NOSB member to weigh public comments to help guide us towards what the public wants to see in organic regulations. The public comment process is in place to insure timely notice and to avoid back room decision-making; NOSB process must be transparent per the Sunshine Act. The following activities require public comment:

- Approving / removing materials for use in the organic industry
- Evaluating a specific Rule
- Providing clarifications

Comment Mechanisms

NOP is responsible for receiving and posting all petitions and public input directed at the NOSB. On an informal level, NOSB members are encouraged to maintain and expand their contacts base in order to maintain an open line with the needs of the organic community. On a formal level, NOSB members request input from the public in the main ways: during formal NOSB meetings and electronically or via mail in response to Federal Register notices.

During Formal NOSB Meetings

The public is invited to sign up on a first-come, first-served basis to address the Board on identified topics during ample public comment sessions. Commenters typically have 5-10 minutes, not including questions from Board members (NOSB members are encouraged to ask questions at the end). Please remember listen, let the speaker finish, make eye contact as much as possible. The public deserves our respect and attentive listening; they rely on NOSB members to consider their comments. When commenting during meetings remember to be respectful, professional, patient, informed, and concise. The PPM allows speakers to extend their allotted time with a maximum of one proxy per speaker. The public is encouraged to provide written testimony to facilitate NOSB's consideration.

In Response to Federal Register Notices

The NOP is responsible for publishing Federal Register notices, including those that identify the NOSB's draft recommendations in advance of NOSB meetings. In these notices, the public is directed on how to submit public comments: either electronically (preferred) or via mail. NOP is responsible for reviewing and posting these comments for NOSB's (and the public's) review.

Incorporating Public Comments

The review and implementation of public input takes place at the committee level. Committee members are expected to review all petitions or comments from the public before providing a recommendation to the Chair and members of the Board. Currently, a committee member is assigned to review, classify and summarize all data received by NOP, but all committee members are expected to review the data individually before making a final recommendation.

Separation of Powers

As a member of the NOSB, you are working within the Executive Branch of government. In this capacity, you are not permitted to work in the other branches while on the NOSB because of the required separation of powers.

Confidentiality

The information that is discussed in NOSB conference calls, through email, official meetings or work sessions is confidential until it is made public. It is your duty to respect and follow this level of trust and not share information until it is officially made public. As mentioned in the Policy and Procedures Manual, a Board member's loyalty is to the organic community and the public at large; however the information should be accurate and agreed upon before being shared with the public. Conference calls are confidential and are for NOSB members and NOP staff only.

Best Practices to Optimize Productivity

Staying Organized

NOSB members receive a lot of materials, both electronically and in hard copy ; staying organized can be a challenge. Members may want to create a file cabinet specifically for the NOSB, with files created yearly for each committee. Committee Chairs and Vice Chairs should save all versions and file them, committee members can just save the final copy. Public comments that you receive in the meetings can be filed, or you can find them archived on the NOP web site.

Optimizing Conference Calls and Meetings

Because members are based in all regions of the country, a great deal of the work of the NOSB involves telephone conversations. Committees are encouraged to develop the agenda together with key committee members, provide ample notice of the date and time of the meeting/conference calls, review the agenda and all documents related to agenda items, start and finish on time, and review action items. The Executive Director will take minutes at all conference calls and will send out periodic updates to a master calendar of the scheduled committee conference calls with phone-in numbers and pass codes (required to access calls). Executive committee calls are scheduled the second Friday of each month and consist of only the NOSB officers, committee chairs, and NOP personnel. NOSB members are welcome to listen in, but are not permitted to vote. All Executive Committee meeting minutes are posted on the NOP website for public access.

Organizing Email

To help optimize NOSB productivity, it is important to consistently organize and respond to emails. You are encouraged to create specific folders for each committee and utilize a filing system that works for you, keeping in mind that you don't need to save every email you receive from NOP or NOSB members.

To add a folder in Outlook:

- Click on File
- Select New and Folder
- Name folder (i.e. Crops or Handling)

Tips for Success:

- Check your inbox on a daily basis.
- Be concise and answer all questions in your responses within 24-48 hours.
- Do not attach unnecessary files.
- Do not overuse Reply to All.
- Try not to write with abbreviations.

Tracking Changes in Word Documents

Drafting and revising NOSB recommendations requires combining feedback from multiple people at multiple steps. The Microsoft Word track changes feature can help facilitate this, allowing you to merge all versions and view all edits at once. You are then able to accept or reject edits, resulting in a final version. A few tips are included below; a full demo is found in http://office.microsoft.com/training.

Turning on Track Changes

After opening your document:

Word 1997-2003:

- Go to Tools, select Track Changes.
- The review toolbar will appear at the top "TRK" will show on the status bar (bottom of the screen)

Word 2007:

- Select the Review tab
- Click Track Changes

All edits will be shown in the document in colored font. If you find it distracting to view the edits, you can select to view "Final" instead of "Final Showing Markup". If you no longer need to track changes, you can click on Track Changes to turn it off.

Reviewing Documents with Track Changes

To determine who proposed a given change, hold your curser over the change. The review toolbars allow you to approve, or reject, edits in two simple steps. First, place your cursor over the edited text. Second, click the  button to accept the edit. This will delete the track change and restore your document without showing edits. To reject the change, click the  button. This will reject the suggested edit and return your document to its original state. The **Next**  and **Previous**  buttons allow you to navigate through the document quickly. Using the drop down list on the  and  buttons, allows you to accept or reject all changes in the document at once.

There are two features in TRK that help in the review process, the **Reviewing** and **Show** toolbars. The drop-down arrow in the **Reviewing** toolbar, allows you to view the document at different stages of editing. For example, the **Original Showing Markup** selection displays all edits from all contributors highlighted in different colors. The **Original** selection presents the document prior to any edits. The **Show** toolbar allows you to select edits by type such as comments, insertions and formats. This toolbar also allows you to isolate edits by reviewer name. To print a list of changes made in a document, select Print (Word 1997-2003: File, Print; Word 2007: Microsoft Office button (top left), Print); in the Print what box, click "List of markup."

Traveling to NOSB Meetings

Airline Reservations

USDA is responsible for paying all airline costs. However, members are responsible for arranging their own airline reservations. E-tickets are issued 3 days prior to date of travel. Upon approval of all documentations, your travel coordinator will provide each person with an approved authorization number that must be provided to USDA's travel service: Lisa or Kim, Boersman Travel 888-291-6705, and identify yourself as USDA/Agricultural Marketing Service (AMS). The travel service is aware that they should obtain the best Federal government rate when possible; however, if your airline rate is over $800, please contact Katherine Benham, Travel Coordinator, National Organic Program (NOP), Katherine.benham@usda.gov via email for approval. Boersman emergency assistance is provided outside of normal business hours; please call 866-648-7861.

After scheduling your airline reservations with Boersman service and within one week of travel, you will receive an email acknowledgement from Virtually There at www.virtuallythere.com detailing your reservations and flight information. Reminder: When traveling to attend an NOSB meeting, members are not authorized to use personal credit cards to pay for airline tickets or utilize another travel service on behalf of USDA/AMS. You will not be reimbursed.

It is important to notify your travel coordinator that you plan to arrive or depart outside of the intended travel dates authorized. Also, provide notification if you plan to combine personal or business travel to attend the NOSB meeting.

Personal Owned Vehicles (POV)

If you need to travel using your own POV, please notify the travel coordinator via email, and provide mileage to/from the meeting, and dates of arrival and departure to/from residence.

Rental Car and Train Reservations

Members are not allowed to use a rental car for travel to/from hotel to obtain dinner. You will not be reimbursed. However, in the event there are no other flights to/from an airport or other modes of transportation available, and your only option is to use a rental car or train to/from a meeting, you must state why it would be advantageous to the Federal government. If the

rental car cost + gas or train is less than airline cost this would be advantageous to the Federal government. USDA will reimburse you. However, if the rental car or train cost is more than the airline, then you are responsible for paying the difference.

To reserve a rental car or train, you must obtain prior approval two weeks before a meeting. Submit to the travel coordinator a written justification stating your need, and include a cost comparison for the rental car , train and airline outlay. You can either locate a local rental car or train service and make your own reservation or submit your request to Boersman Travel service.

Meeting Space and Lodging Accommodations

USDA/NOP is responsible for reserving and paying all expenses for the meeting space and lodging. Members are not allowed to make hotel reservations within the authorized travel dates. However, if you plan to modify your arrival/departure travel dates for personal reasons, please contact the hotel and travel coordinator. To avoid "no show" charges, it's important that the hotel is aware of travel dates modification. Personal travel is non-reimbursable.

Post-Travel Document

After each meeting, the travel coordinator will forward to all members a post-travel document that should be completed and signed as soon as possible. Submit all applicable receipts (with the exception of meals) to the travel coordinator for processing for reimbursement. Travel documentation can be fax, email or mail to the attention of Travel Coordinator.

Travel reimbursement will include the following

- Rental Car or Train Expense (if applicable)
- Location per diem (meals)
- POV mileage to/from airport or meeting at .5 cents per mileage
- Roundtrip tolls fares
- Airport parking
- Local Transportation: Taxi cab fares to/from airport to hotel, or residence; tips not to exceed
- 15% of the fare; Shuttle services to/from airport to hotel, or residence
- Airline baggage

Submit your travel voucher information to:

Katherine Benham, NOSB Travel Coordinator
USDA/National Organic Program/Office of Deputy Administrator
1400 Independence Avenue, SW, Room 2646, Stop Code 0268
Washington, D.C. 20250
(202) 205-7806, Fax No.: (202) 205-7808
Katherine.Benham@usda.gov

What to Pack?

Dress code at NOSB meetings is business casual. It's suggested to bring some casual attire and moderately formal attire, for a possible formal get together, or the occasional casual dinner. Most of the hotels also have work-out rooms and pools. For the most part, dress is not too important as long as you are representing the NOSB professionally.

You might also wonder if you should pack all your papers that reference work you have done on your committees. Agenda, and agenda content, are available prior to meetings at **www.ams.usda.gov/nosb/meetings/meetings.html**. Plus, materials will be provided to you at the meetings in a book including copies of public comments, however, it is not a bad idea to bring hard copies of specific recommendations that your committee will be presenting. Also, it is always wise to bring a copy of OFPA and the Federal Register Regulation. We often refer to these documents during the meetings and they may or may not be provided. Always bring some cash for your taxi or shuttle to the hotel and from the hotel back to the airport. Extra cash for food is also recommended. Remember to save all your receipts.

List of Common Technical Sources Used by NOSB Members

Very often during the review process and discussions, NOSB members need to consult various sources of information. The following is a general list of common technical sources.

Accredited Certification Agencies

The function of the Accredited Certification Agencies (ACAs) is to certify, on behalf of USDA, that producers and handlers comply with approved organic practices. An ACA is accredited by the NOP. They operate in all regions of the United States and selected countries, and include private companies, not-for-profit organizations and several state government agencies.

Comprehensive list of ACAs: **http://www.ams.usda.gov/NOPACAs**

Federal Agencies

U.S. Department of Agriculture National Organic Program
http://www.ams.usda.gov/nop

U.S. Department of Agriculture Agricultural Research Service
http://www.ars.usda.gov

U.S. Department of Agriculture National Institute of Food and Agriculture
http://www.csrees.usda.gov

U.S. Department of Agriculture Food and Nutrition Service
http://www.fns.usda.gov/fns/

U.S. Department of Agriculture Food Safety and Inspection Service
http://www.fsis.usda.gov

U.S. Department of Agriculture National Agricultural Library Alternative Farming Systems Information Center
http://www.nalusda.gov/afsic/ofp/susagrsch.htm

U.S. Department of Agriculture Sustainable Agriculture Research and Education Program
http://www.sare.org/index.htm

U.S. Environmental Protection Agency Integrated Risk Information System
http://www.epa.gov/iris

U.S. Environmental Protection Agency Water
http://www.epa.gov/ow/

U.S. Environmental Protection Agency Water Science
http://www.epa.gov/waterscience/

U.S. Environmental Protection Agency Organic Agriculture Page
http://www.epa.gov/oecaagct/torg.html#National%20Organic%20Standards

U.S. Environmental Protection Agency Inert Ingredients Permitted in Pesticide Products
http://www.epa.gov/opprd001/inerts/lists.html

U.S. Department of Health and Human Services Agency for Toxic Substances and Disease Registry
http://www.atsdr.cdc.gov/atsdrhome.html

U.S. Food and Drug Administration's Center for Food Safety and Applied Nutrition
http://www.cfsan.fda.gov/list.html

U.S. Food and Drug Administration's Center for Food Safety and Applied Nutrition - Food Ingredients and Packaging Terms
http://www.cfsan.fda.gov/~dms/opa-def.html

U.S. Food and Drug Administration's Center for Food Safety and Applied Nutrition Inventory of Effective Food Contact Substance (FCS) Notifications
http://www.cfsan.fda.gov/~dms/opa-fcn.html

U.S. Food and Drug Administration's Center for Food Safety and Applied Nutrition Indirect" Additives Used in Food Contact Substances
http://www.cfsan.fda.gov/~dms/opa-indt.html

U.S. Food and Drug Administration's Center for Veterinary Medicine
http://www.fda.gov/cvm

U.S. Food and Drug Administration's Food Safety Risk Analysis Clearinghouse
http://www.foodriskclearinghouse.umd.edu/

U.S. Food and Drug Administration's Numerical Listing of GRAS Notices
http://www.cfsan.fda.gov/~rdb/opa-gras.html

U.S. National Institute of Health's National Institute of Environmental Health Sciences
http://www.niehs.nih.gov/centers/res-core/iowares2.htm.

U.S. Occupational Health and Safety Administration
http://www.osha.gov

Other Sources

Harvard School of Public Health, Department of Nutrition
http://www.hsph.harvard.edu/nutritionsource/index.html

Tufts' University Friedman School of Nutrition Science and Policy
http://nutrition.tufts.edu/

American Dietetic Association
http://www.eatright.org

Appropriate Technology Transfer to Rural Areas
http://www.attra.org

CABI Publishing (organic research abstracts)
http://www.organic-research.com/

Codex Alimentarius Commission
http://www.codexalimentarius.net

European Union (organic regulation)
http://www.organic-europe.net/europe_eu/default.asp#2092

Food and Agriculture Organization of the United Nations
http://www.fao.org/organicag/default.htm

Joint FAO/WHO Expert Committee on Food Additives (JECFA)
http://www.fao.org/es/esn/jecfa/database/cover.htm

International Federation of Organic Agriculture Movements
http://www.ifoam.org

International Food Information Council Foundation
http://www.ific.org

Institute of Food Science and Technology
http://www.ifst.org

Organic Farming Research Foundation
http://www.ofrf.org

Organic Materials Review Institute
http://www.omri.org

Organic Trade Association
http://www.ota.com

Research Institute of Organic Agriculture (FIBL)
http://www.organic-europe.net

Rodale Institute
www.rodaleinstitute.org

The National Sustainable Agriculture Information Service
http://www.attra.org

The Merck Index
http://www.merckbooks.com/

PubMed
http://www.ncbi.nlm.nih.gov/PubMed/

Scirus
http://www.scirus.com/

Food Ingredients
http://www.food-ingredients.com/

American Association of Bovine Practitioners
www.aabp.org

Veterinary Botanical Medical Association
www.vbma.org

American Veterinary Medical Association
www.avma.org

American Holistic Veterinary Medical Association
www.ahvma.org

Glossary of Acronyms

AAPFCO	Association of American Plant Food Control Officials
ACA	Accredited Certification Agency, also
ACA	Accredited Certifiers Association
AFBA	American Farm Bureau Federation
AFT	American Farmland Trust
AMS	Agricultural Marketing Service (home of NOP)
ANPR	Advance Notice of Proposed Rulemaking
ANSI	American National Standards Institute (private, non profit)
AOS	American Organic Standards (OTA industry guidelines)
APHIS	Animal and Plant Health Inspection Service (USDA)
ARC	Audit, Review and Certification (USDA)
ARCD	Audit Review and Compliance Division, AMS, (USDA)
ARS	Agricultural Research Service (USDA)
ATO	All Things Organic, OTA's trade show
ATTRA	Appropriate Technology Transfer for Rural Areas (within NCAT)
CAS	Chemical Abstract Service
CBI	Confidential business information
CEQ	Council on Environmental Quality
CODEX	Internationally recognized standards for foods.
CRP	Conservation Reserve Program
CSREES	Cooperative State Research, Education and Extension Service (USDA)
EPA	Environmental Protection Agency
EQIP	Environmental Quality Incentives Program
ERS	Economic Research Service (USDA)

FACA	Federal Advisory Committee Act
FAO	Food and Agriculture Organization (UN)
FAS	Foreign Agriculture Service (USDA)
FCIC	Federal Crop Insurance Corporation
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FMNP	Farmers' Market Nutrition Program
FNS	Food and Nutrition Service (USDA)
FSIS	Food Safety and Inspection Service (USDA)
GAO	General Accounting Office (investigative arm of Congress)
GIPSA	Grain Inspection, Packers and Stockyards Administration (USDA)
GMO (GEO)	Genetically Modified (Engineered) Organism
GRAS	Generally regarded as safe, used by FDA
HACCP	Hazard Analysis and Critical Control Point
IFOAM	International Federation of Organic Agriculture Movements
IOIA	Independent Organic Inspectors Association
IUCLID	International Uniform Chemical Information Database
IOAS	International Organic Accreditation Service
IQF	Individual quick frozen
ISO	International Organization for Standardization
ISO 17011	Standards for Certification Agencies (used to be ISO Guide 65)
ISO Guide 61	Guide for Accreditation Agencies
ISO Guide 65	Guide for Certification Agencies (see ISO 17011)
NAL	National Agricultural Library (USDA)
NASDA	National Association of State Departments of Agriculture
NASOP	National Association of State Organic Programs (now within NASDA)
NASS	National Agricultural Statistics Service (USDA)
NCAT	National Center for Appropriate Technology (private non-profit)
NSAC	National Sustainable Agriculture Coalition
NCGA	National Cooperative Grocers Association
NFFC	National Family Farm Coalition
NFU	National Farmers Union
NGO	Non Governmental Organization, or Civil Society Organization
NIST	National Institute of Standards and Technology
NOC	National Organic Coalition (RAFI, Center for Food Safety, NOFA, NCGA
NOP	National Organic Program (USDA)
NPDES	National pollution discharge elimination system (Clean Water Act provision)
NRCS	Natural Resource Conservation Service (USDA)
OCA	Organic Consumers Association
OFARM	Organic Farmers Association for Relationship Marketing
OFPA	Organic Foods Production Act of 1990 (Title XXI of the 1990 Farm Bill)
OFRF	Organic Farming Research Foundation
OMRI	Organic Materials Review Institute

OTA	Organic Trade Association
PR	Proposed Rule
RAFI	Rural Advancement Foundation International (now the ETC Group)
RMA	Risk Management Agency
SAN, SANET	Sustainable Agriculture Network (USDA)
SARE	Sustainable Agriculture Research and Education (grant program of USDA)
SAWG	Sustainable Agriculture Working Group (SARE-funded; national & regional)
TAP	Technical Advisory Panel
TMD	Transportation and Marketing Division of USDA (contains NOP)
TTB	Alcohol Tobacco Tax & Trade Bureau (formally Bureau of Alcohol Tobacco and Firearms (BATF))
USDA	United States Department of Agriculture
WHIP	Wildlife Habitat Incentives Program
WHO	World Health Organization
WRP	Wetland Reserve Program
WTO	World Trade Organization

National Organic Standards Board Committees

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Dan Giacomini	Chairperson
Tracy Miedema	Vice-Chairperson
Tina Ellor	Secretary

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Joe Smillie, Chairperson	Compliance, Accreditation & Certification
Steve DeMuri, Chairperson	Handling
Kevin Engelbert, Chairperson	Livestock
Katrina Heinze, Chairperson	Materials
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National Organic Standards Board
Policy Development Committee
NOSB New Member Guide
Updates

August 10, 2010

Committee Vote

Motion: To accept the recommended edits to the New Member Guide

Motion: Barry Flamm Second: Kevin Engelbert
Yes: 3 No: 0 Abstain: 0 Absent: 2