



National Organic Standards Board Meeting
Hilton Savannah DeSoto Hotel | Savannah, Georgia
November 29 – December 2, 2011

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National Organic Standards Board Meeting

Hilton Savannah DeSoto | Savannah, Georgia
November 29 – December 2, 2011

November 29, 2011 | November 30, 2011 | December 1, 2011 | December 2, 2011

Tuesday, November 29, 2011

8:00 a.m.	Call to Order <i>Tracy Miedema, Chairperson</i> <ul style="list-style-type: none"> – Approval of Agenda – Announcements – Introductions – NOSB Mission
8:15 a.m.	Secretary's Report <i>Wendy Fulwider, Secretary</i> <ul style="list-style-type: none"> – Acceptance of April 2011 Meeting Transcripts and Voting Results as Official Record
8:30 a.m.	NOSB Materials Review Process Update <i>Katrina Heinze, Materials Committee Chairperson</i>
9:00 a.m.	National Organic Program Report <i>Miles McEvoy, Deputy Administrator</i> National Organic Program
9:45 a.m.	Inert Materials Working Group Report <i>National Organic Program</i>
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



Wednesday, November 30, 2011

8:00 a.m. **NOSB Committee Presentations and Discussions**

Crops Committee

John Foster, Chairperson

Tree Fruit Fire Blight Update (15 minutes)

Petitioned Materials Recommendations

- Ammonium nonanoate
- Ferric phosphate (to remove)
- Indole-3-butyric acid
- Propane (odorized)

Sunset 2013 Recommendations on § 205.601

- Copper sulfate
- Ozone
- Peracetic acid

Sunset 2013 Recommendations on § 205.602

- Calcium chloride

EPA List 3 Inerts – Discussion Document

9:45 a.m.

Break

10:00 a.m.

Livestock Committee

Wendy Fulwider, Chairperson

Animal Husbandry Presentation (15 minutes)

Animal Welfare & Stocking Rates Regulatory Language Recommendation

Animal Welfare & Stocking Rates Guidance Recommendation

Animal Handling, Transit, and Slaughter Regulatory Language Recommendation

Animal Handling, Transit, and Slaughter Guidance Recommendation

Species-Specific Animal Welfare Scorecards Recommendation

Species-Specific Guidance Recommendation

12:30 p.m.

Lunch



Wednesday, November 30, 2011 (continued)

1:30 p.m. **NOSB Committee Presentations and Discussions (continued)**

Handling Committee

Steve DeMuri, Chairperson

Nutrient Vitamins and Minerals Presentation (15 minutes)

Petitioned Materials Recommendations

- Annatto extract
- Arachidonic acid (ARA) single-cell oil
- Beta-carotene
- Choline
- Docosahexaenoic acid (DHA) algal oil
- Potassium hydroxide
- Silicon dioxide
- Sulfur dioxide

Sunset 2013 Recommendations on § 205.605(a)

- Animal enzymes
- Tartaric acid

Sunset 2013 Recommendations on § 205.605(b)

- Tartaric acid

Chlorine Materials Annotation Recommendation

3:00 p.m. **Break**

3:15 p.m. **Materials Committee**
Katrina Heinze, Chairperson

Aquaculture Materials Review Update

Research Priorities Framework Discussion Document

3:45 p.m. **Compliance, Accreditation, and Certification Committee**
Joe Dickson, Chairperson

Evaluation of Materials Review Organizations Recommendation

Inspector Qualifications Recommendation

Unannounced Inspections Recommendation



Wednesday, November 30, 2011 (continued)

4:30 p.m. **NOSB Committee Presentations and Discussions (continued)**

Policy Development Committee

Barry Flamm, Chairperson

NOSB Policy and Procedure Manual Recommendations

- Administrative Team
- Committee Transparency
- Conflict of Interest
- NOSB Member & Leadership Transition

Public Comment Procedures Discussion Paper

5:30 p.m. **Recess**

Thursday, December 1, 2011

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**



Friday, December 2, 2011

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

Crops Committee

John Foster, Chairperson

Petitioned Materials Recommendations

- Ammonium nonanoate
- Ferric phosphate (to remove)
- Indole-3-butyric acid
- Propane (odorized)

Sunset 2013 Recommendations on § 205.601

- Copper sulfate
- Ozone
- Peracetic acid

Sunset 2013 Recommendations on § 205.602

- Calcium chloride

9:45 a.m. **Break**

10:00 a.m. **Livestock Committee**

Wendy Fulwider, Chairperson

Animal Welfare & Stocking Rates Regulatory Language Recommendation

Animal Welfare & Stocking Rates Guidance Recommendation

Animal Handling, Transit, and Slaughter Regulatory Language Recommendation

Animal Handling, Transit, and Slaughter Guidance Recommendation

Species-Specific Animal Welfare Scorecards Recommendation

Species-Specific Guidance Recommendation

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

1:00 p.m. **NOSB Consideration and Vote on Committee Action Items (continued)**

Handling Committee

Steve DeMuri, Chairperson

Petitioned Materials Recommendations

- Annatto extract
- Arachidonic acid (ARA) single-cell oil
- Beta-carotene
- Choline
- Docosahexaenoic acid (DHA) algal oil
- Potassium hydroxide
- Silicon dioxide
- Sulfur dioxide



Friday, December 2, 2011 (continued)

NOSB Consideration and Vote on Committee Action Items (continued)

Handling Committee

Steve DeMuri, Chairperson

Sunset 2013 Recommendations on § 205.605(a)

- Animal enzymes
- Tartaric acid

Sunset 2013 Recommendations on § 205.605(b)

- Tartaric acid

Chlorine Materials Annotation Recommendation

2:45 p.m.

Break

3:00 p.m.

Compliance, Accreditation, and Certification Committee

Joe Dickson, Chairperson

Evaluation of Materials Review Organizations Recommendation

Inspector Qualifications Recommendation

Unannounced Inspections Recommendation

3:45 p.m.

Break

4:00 p.m.

Policy Development Committee

Barry Flamm, Chairperson

NOSB Policy and Procedure Manual Recommendations

- Administrative Team
- Committee Transparency
- Conflict of Interest
- NOSB Member & Leadership Transition

4:30 p.m.

NOSB Officer Elections

4:45 p.m.

Committee Workplans

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: Fall, 2011

Substance: Ammonium Nonanoate

Committee: Crops Livestock Handling **Petition is for:** Ammonium nonanoate, as a synthetic substance for use in organic crop production as an herbicide 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 <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> |
| 2. Essential & Availability Criteria | Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A <input type="checkbox"/> |
| 3. Compatibility & Consistency | Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A <input type="checkbox"/> |
| 4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606) | Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input checked="" type="checkbox"/> |

Substance Fails Criteria Category: [2 & 3] **Comments:** There are numerous weed control alternatives and it was the general consensus of the committee that although this material is fairly benign in the environment (the exception being its toxicity to aquatic invertebrates), a broad spectrum synthetic herbicide is not compatible or consistent with organic agriculture

B. 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):

Classification Motion: Ammonium nonanoate The Crops Committee voted in Nov. 2008 that ammonium nonanoate is synthetic.

Classification of the material: Synthetic Non- synthetic _____ Absent: _____ Abstain _____

Motion by: _____ Seconded: _____ Yes: _____ No: _____ Absent: _____ Abstain: _____

Recommended Committee Action & Vote The motion is to add ammonium nonanoate to the National List 205.601 as a synthetic substance for use as an herbicide in organic food production.

Motion by: _____ Seconded: _____ Yes: 1 No: 4 Absent: 0 Abstain: 0

Crops	<input checked="" type="checkbox"/>	Agricultural		Allowed ¹	
Livestock		Non-Synthetic		Prohibited ²	
Handling		Synthetic	<input checked="" type="checkbox"/>	Rejected ³	<input checked="" type="checkbox"/>
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. X why material was rejected: Ammonium nonanoate was rejected because of questions of necessity as there are several alternatives pointed out in the TR, because of issues of consistency and compatibility and because of concerns about toxicity to aquatic invertebrates.

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:

John Foster
Committee Chair

Oct. 07, 2011
Date

EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

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

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			2011 TR pg. 6 “highly toxic to aquatic invertebrates”
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]				2011 TR pg. 6 Lines 300-320- product is rapidly biodegraded in the environment and it’s byproducts have value in food, pharmacy, and cosmetic applications. (paraphrased), although the TR states that “Specific information regarding the potential for environmental contamination associated with the manufacture of ammonium nonanoate was not found.(lines 300-301)
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]	X			2011 TR pg. 3, lines 130-134 It is a “nonselective, broad-spectrum, contact” (TR line 117) synthetic herbicide and also is an EPA registered insecticide and fungicide. “Pesticide products containing ammonium nonanoate as the active ingredient were first registered with EPA in 2006 and several have been registered since then (PAN, 2010). All of these products are listed as herbicides. Pesticide products containing the active ingredient ammonium salts of fatty acids were first registered with EPA in 1982 and many have been registered since that time (PAN, 2010). The use types listed for these products include herbicides, deer repellents, fungicides, and insecticides
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1) (B)(ii); 205.601(m)2]		X		2011 TR pg. 4 Lines 190-196 “B). Ammonium nonanoate is not listed by EPA as an inert ingredient of toxicological concern. Soap is included on the list of EPA inert ingredients of minimal concern for food and nonfood uses, but it is defined as “the water soluble sodium or potassium salts of fatty acids produced by either the saponification of fats and oils, or the neutralization of fatty acid” (EPA, 2010). Ammonium nonanoate does not meet this definition because it is an ammonium salt of a fatty acid and not a sodium or potassium salt. However, ammonium nonanoate when used as an active or inert ingredient in pesticide products is exempt from the requirement of a tolerance per 40 CFR 180.1284 and 180.910.” and lines 89-91 “According to 40 CFR 180.910, ammonium salts of fatty acids, including ammonium nonanoate, may be used as inert ingredients (surfactants) in pesticides applied to pre- and post-harvest crops. No further information was found on this usage.”
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]	X			2011 TR pg. 7 lines 326-337 “No information could be found on known chemical interactions between ammonium nonanoate and other substances allowed for use in organic production or handling. The RED for soap salts states that ammonium soaps of higher fatty acids are not compatible with soluble metallic salts such as zinc, manganese, and iron sulfates (EPA, 1992), but does not provide any further details regarding the likelihood for these interactions. This is a potential issue in organic crop production because soluble metallic salts are permitted for use as soil micronutrients following documentation of a

			<p>soil deficiency. Specifically, sulfates, carbonates, oxides, or silicates of zinc, copper, manganese, iron, molybdenum, selenium, and cobalt are permitted by 7 CFR 205.601(j)(6)(ii). The potential environmental or health effects resulting from the mixture of these incompatible materials in agricultural soil were not described.</p> <p>The MSDS for Racer® Concentrate (40% ammonium nonanoate) states that the product is incompatible with acids, strong bases, and any material incompatible with water (Smiley and Beste, 2009).”</p>
6. Are there adverse biological and chemical interactions in agro- ecosystem? [§6518 m.5]		X	2011 TR pg. 7-8 lines 343-379
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]			2011 TR pg. 7 lines 343-379, specifically lines 370-372 “No information could be found on the potential effects of ammonium nonanoate on soil organisms, soil temperature, water availability, pH levels, nutrient availability, salt concentration, solubility, or any other soil physicochemical and biological properties.”
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]	X	X	<p>2011 TR pg. 6 lines 293-295 no: “As stated in the response to Evaluation Question #4, ammonium nonanoate is expected to rapidly degrade following contact with the soil. The breakdown products are compounds that naturally occur in the soil; therefore, no toxic effects are expected.”</p> <p>Yes: TR lines 276-279: “Soap salts of fatty acids are considered to be slightly toxic to birds on an acute basis, practically nontoxic to birds on a dietary basis, slightly toxic to warm and cold water fish, and highly toxic to aquatic invertebrates (EPA, 1992). Toxicity data for nontarget insects are not available for any soap salt (EPA, 2008). Some soap salts (e.g., potassium salts of fatty acids) are registered for use as insecticides (NPIRS, 2011).”</p> <p>Complete TR answer to this question lines 246-295</p>
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]	X		<p>2011 TR pg. 5 lines 227-240 “Once released into the soil, ammonium salts of fatty acids, such as ammonium nonanoate, are expected to rapidly degrade primarily by microbial action (EPA, 1992). This is further supported by a draft environmental risk assessment of fatty acid salts prepared by HERA, which concludes that fatty acid salts with carbon chain lengths up to C18 can be considered readily biodegradable via aerobic metabolism (HERA, 2003). According to the RED for soap salts prepared by EPA, the half-life of the fatty acid components of ammonium soaps was demonstrated to be less than one day in soil (EPA, 1992).</p> <p>Regarding the potential degradation products of ammonium nonanoate in the environment, the RED states that microbial metabolism of fatty acids will result in the eventual formation of carbon dioxide and an ester, or that the carbon content of fatty acids will be converted into naturally-occurring organic substances normally produced by soil microorganisms (EPA, 1992). The BRAD for ammonium nonanoate concluded that this compound will not persist in the environment when used as an herbicide as directed (EPA, 2008). Environmental fate and groundwater data were waived for ammonium nonanoate due to EPA’s estimate of</p>

				minimal risk (EPA, 2008). No further information could be found on the persistence or concentration of ammonium nonanoate and/or its byproducts in the environment.”
10. Is there any harmful effect on human health? [§6517 c (1)(A) (i) ; 6517 c(2)(A)I; §6518 m.4]		X		2011 TR pg. 8 lines 405-407 “EPA’s RED for soap salts concluded that products containing ammonium salts of fatty acids are not likely to cause unreasonable adverse effects on human health (EPA, 1992). The toxicity of ammonium salts of fatty acids, including ammonium nonanoate, is generally low (E
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]			X	
12. Is the substance GRAS when used according to FDA’s good manufacturing practices? [§205.600 b.5]			X	
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]			X	

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

Category 2. Is the Substance Essential for Organic Production? Substance Ammonium nonanoate

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			2011 TR pg. 4-5 lines 203-215
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			2011 TR pg. 4-5 lines 203-215
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		2011 TR pg. 4-5 lines 203-215
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	
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			2011 TR pgs. 9-12 lines 436-602
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			2011 TR pgs. 12-13 lines 607-711

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 Ammonium nonanoate

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		Ammonium Nonanoate is a non-selective, broad-spectrum herbicide as well as being registered as an insecticide.
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]	X	X		The nature of its non-selective and broad spectrum action on green plants as well as it's insecticidal properties are not compatible with maintaining biodiversity which is integral to sustainability. It is relatively non-toxic and has low environmental impact
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]			X	
5. Is the primary use as a preservative? [§205.600 b.4]			X	
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]			X	
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:		X		
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			The ammonium nonanoate is a soap 2011 TR lines 18, 95-96,139-141, 157-159, 164-165, 171-172, 188
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 - Ammonium nonanoate

Question	Yes	No	N/A	Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown)
1. <u>Is the comparative description provided</u> as to why the non-organic form of the material /substance is necessary for use in organic handling?			X	
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate form to fulfill an essential function in a system of organic handling?			X	
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate quality to fulfill an essential function in a system of organic handling?			X	
4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate quantity to fulfill an essential function in a system of organic handling?			X	
5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following:			X	
a. Regions of production (including factors such as climate and number of regions);			X	
b. Number of suppliers and amount produced;			X	
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;			X	
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or			X	
e. Are there other issues which may present a challenge to a consistent supply?			X	

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: November, 2011

Substance: Indole-3-butyric acid (IBA) _CAS#133-32-4_

Committee: Crops Livestock Handling Petition is for: IBA as a plant growth regulator

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 <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> |
| 2. Essential & Availability Criteria | Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A <input type="checkbox"/> |
| 3. Compatibility & Consistency | Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A <input type="checkbox"/> |
| 4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606) | Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/> |

B. Substance Fails Criteria Category: 2 and 3 Comments: There has not been shown to be a demonstrated need for IBA in organic production. Synthetic materials to achieve propagation and to regulate plant growth is inconsistent with organic production. In addition, although #1 is checked yes, environmental impacts may be greater than indicated in the review depending on the raw materials used and the manufacturing process. In addition, although the most common probable use of IBA would be point application by dipping plant cuttings in powder dust or solution to promote rooting, the petition requests a broader use. Area application would present a different more complex risk.

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):

Classification of the material: Synthetic Non-synthetic _____ Absent: _____ Abstain _____

Motion by: Barry Flamm Seconded: Tina Ellor Yes: 6 No: _____ Absent: 1 Abstain: _____

Recommended Committee Action & Vote Motion to list under 205.601(k)

Motion by: Barry Flamm Seconded: Tina Ellor Yes: 1 No: 4 Absent: _____ Abstain: _____

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

1) Substance voted to be added as "allowed" on National List to § 205. _____ with Annotation (if any) _____

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

Describe why a prohibited substance: _____

3) Substance was rejected by vote for amending National List to § 205. _____ Describe why material was rejected: Failed Categories 2&3 and concerns under category 1 _____

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:

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]			N/A	
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]	X	X		Petitioner stated IBA is a technical grade synthesized substance from many sources. 186 products containing IBA are available in US. IBA is manufactured world wide. Thus, there might be different manufacturing procedures. (TR 227)
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		TR 282- IBA is biosynthesized in natural plants and produced by soil bacteria. It is non-toxic to avian wildlife, plants, but slightly toxic to fish and aquatic, and invertebrates and should not cause adverse effects to mammalian wildlife. EPA says IBA does not persist in the environment. TR 221 EPA also waved most tox requirements. TR 252-255 – IBA has typical hormonal dose-response pattern. TR 287- PAN data base shows no evidence of harmful effects to environment, except slight toxicity to fish.
4. Does the substance contain List 1, 2 or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]		X		TR 238- Indole (CAS#120-72-9) butyrolactone(CAS# 96-48-0) and Sodium Hydroxide (CAS# 1310-73-2) was on list 4B.
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]	X			TR 246- potentially reacts with strong oxidizers. TR 249- 250 synergistic with other chemicals and bacteria
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]	X	X		TR 44- There are two general groups of application methods in terms of toxic effect and environmental consequence. <ol style="list-style-type: none"> 1) point application: dipping plant cuttings in powder, dust or solution. 2) Area application/ broad cast: foliar spray, turf, and adding to springler system. The risks are greater under group 2.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		See # 3 above
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		See # 3 above
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]		X		See # 3 above

10. Is there any harmful effect on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4]	X	X		EPA says no known risks to human health and has granted an exemption for tolerance of residue. IBA is an “acute health hazard” under Section 311/312 Hazard class of SARA Title III Rules (MSDA-IBA,2007)
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]			N/A	
12. Is the substance GRAS when used according to FDA’s good manufacturing practices? [§205.600 b.5]			N/A	
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]			N/A	

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

NOSB Evaluation Criteria for Substances Added To the National List

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			Petitioner stated IBA is a technical grade synthesized substance
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			Petitioner/TR
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		However, IBA does occur naturally in a variety of plants.
4. Is there a natural source of the substance? [§205.600 b.1]			N/A	
5. Is there an organic substitute? [§205.600 b.1]			N/A	
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			N/A	
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X	X		IBA occurs naturally, but there is not any commercially available extraction process. The most commonly used auxin for inducing adventitious rooting is IAA, but the availability of natural sources is unclear.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]			N/A	
9. Is there any alternative substances? [§6518 m.6]		X		TR 392- 398 Researchers have evaluated the effects of several alternative materials containing growth hormones.(Not clear if these would provide the same response as an auxin.)
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			TR 499 Successful rooting from stem cuttings depend on many factors: timing, types of cutting, light, temperature, moisture and 10 other factors including plant hormones.(which may be produced naturally by the plant tissues- BF)

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

NOSB Evaluation Criteria for Substances Added To the National List

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

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]			N/A	
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]		X		TR 381- European and N. American regulations do not allow synthetic products to obtain organic propagation. It does not fit any of the allowed categories for approving synthetic inputs: 6517c1(B)
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]	X	X		IBA is biosynthesized in natural plants and produced by soil bacteria. There is no evidence that chemical properties of synthetic IBA are different from natural sources, but the manufactured IBA contains impurities.
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]			N/A	
5. Is the primary use as a preservative? [§205.600 b.4]			N/A	
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]			N/A	
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:		X		
a. copper and sulfur compounds;				
b. toxins derived from bacteria;		X		
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?		X		
d. livestock parasiticides and medicines?		X		
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?		X		

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

NOSB Evaluation Criteria for Substances Added To the National List

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: Name

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. <u>Is the comparative description provided</u> as to why the non-organic form of the material /substance is necessary for use in organic handling?				
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?				

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

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: Fall 2012, Savannah, GA	Substance: Odorized propane																								
Committee: Crops <input checked="" type="checkbox"/> Livestock <input type="checkbox"/> Handling <input type="checkbox"/> Petition is for: addition of odorized propane 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 <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>																								
2. Essential & Availability Criteria	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A <input type="checkbox"/>																								
3. Compatibility & Consistency	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>																								
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606)	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input checked="" type="checkbox"/>																								
B. Substance Fails Criteria Category: 2 Comments: Majority of CC members believe adequate alternatives exist and questioned the materials efficacy.																									
C. Proposed Annotation (if any): _____ Basis for annotation: To meet criteria above: _____ Other regulatory criteria: _____ Citation: _____																									
D. Recommended Committee Action & Vote (State Actual Motion): To amend the National List, Synthetic substances allowed for use in organic crop production, § 205.601(g)(3) – Rodenticides, to include odorized propane as petitioned. <i>Motion by: John Foster Seconded: Tina Ellor Yes: 3 No: 4 Absent: _____ Abstain: _____</i>																									
<table border="1" style="margin: auto; border-collapse: collapse;"> <tr> <td style="padding: 2px;">Crops</td> <td style="text-align: center; padding: 2px;"><input checked="" type="checkbox"/></td> <td style="padding: 2px;">Agricultural</td> <td style="padding: 2px;"></td> <td style="padding: 2px;">Allowed¹</td> <td style="padding: 2px;"></td> </tr> <tr> <td style="padding: 2px;">Livestock</td> <td style="padding: 2px;"></td> <td style="padding: 2px;">Non-Synthetic</td> <td style="padding: 2px;"></td> <td style="padding: 2px;">Prohibited²</td> <td style="padding: 2px;"></td> </tr> <tr> <td style="padding: 2px;">Handling</td> <td style="padding: 2px;"></td> <td style="padding: 2px;">Synthetic</td> <td style="text-align: center; padding: 2px;"><input checked="" type="checkbox"/></td> <td style="padding: 2px;">Rejected³</td> <td style="text-align: center; padding: 2px;"><input checked="" type="checkbox"/></td> </tr> <tr> <td style="padding: 2px;">No restriction</td> <td style="padding: 2px;"></td> <td style="padding: 2px;">Commercially Un-Available as Organic¹</td> <td style="padding: 2px;"></td> <td style="padding: 2px;">Deferred⁴</td> <td style="padding: 2px;"></td> </tr> </table>		Crops	<input checked="" type="checkbox"/>	Agricultural		Allowed ¹		Livestock		Non-Synthetic		Prohibited ²		Handling		Synthetic	<input checked="" type="checkbox"/>	Rejected ³	<input checked="" type="checkbox"/>	No restriction		Commercially Un-Available as Organic ¹		Deferred ⁴	
Crops	<input checked="" type="checkbox"/>	Agricultural		Allowed ¹																					
Livestock		Non-Synthetic		Prohibited ²																					
Handling		Synthetic	<input checked="" type="checkbox"/>	Rejected ³	<input checked="" type="checkbox"/>																				
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: Majority of CC members believe adequate alternatives exist and did not believe the material to be effective.																									
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: <div style="display: flex; justify-content: space-between;"> <div style="text-align: left;"> John Foster Committee Chair </div> <div style="text-align: right;"> 10/7/11 Date </div> </div>																									

EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

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

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	x		Long term no, short term yes, and then when misused or mishandled. TR 250
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		x		See #2 above.
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1) (B)(ii); 205.601(m)2]			x	Given the EPA's reclassification of inerts.
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		x		TR 265. Other than flammability with oxygen, no interactions between propane and other common substances used in agriculture were identified.
6. Are there adverse biological and chemical interactions in agro- ecosystem? [§6518 m.5]	x			TR 276. These are highly localized and not persistent.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]	x			TR 276. These are highly localized and not persistent.
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		x		TR 276. These are highly localized and not persistent.
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]		x		TR 276. These are highly localized and not persistent.
10. Is there any harmful effect on human health? [§6517 c (1)(A) (i) ; 6517 c(2)(A)]; §6518 m.4]		x		Not when used as directed. TR 276. These are highly localized and not persistent.
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 Odorized propane

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			However none of them have acceptable availability, applicability, functionality or efficacy. TR 316 Pet. pg. 7
7. Is there another practice that would make the substance unnecessary? [§6518 m.6]	x			Tillage, flooding, long-term fallow, smoke bombs, biological controls, removal of food, CO2, anticoagulants, trapping TR 312, 338
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]			x	See #5 above
9. Is there any alternative substances? [§6518 m.6]	x			See #6 above
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	x			See #7 above

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 Odorized propane

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 physical control, consistent with preferred pest control methodologies; propane is currently in use as vertebrate deterrent and fuel for thermal weed control. The material was allowed by the majority of private certification standards pre-NOP and was allowed under the NOP until 2007, when the substance was summarily prohibited pending successful petition and inclusion on the National List. (Petition+TR)
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]	x			See above.
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]			X	
5. Is the primary use as a preservative? [§205.600 b.4]			X	
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]			X	
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:		X		
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: Odorized propane

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. <u>Is the comparative description provided</u> as to why the non-organic form of the material /substance is necessary for use in organic handling?			X	
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate form to fulfill an essential function in a system of organic handling?			X	
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate quality to fulfill an essential function in a system of organic handling?			X	
4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate quantity to fulfill an essential function in a system of organic handling?			X	
5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following:			X	
a. Regions of production (including factors such as climate and number of regions);			X	
b. Number of suppliers and amount produced;			X	
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;			X	
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or			X	
e. Are there other issues which may present a challenge to a consistent supply?			X	

**National Organic Standards Board
Crops Committee
Proposed Recommendation
Odorized Propane**

October 7, 2011

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

(g) As rodenticides.

California Certified Organic Farmers, Inc. (CCOF) is petitioning to have odorized propane used in devices for control of burrowing pest animals added to the National List § 205.601, Synthetics for use in crop production.

In its pure form, (C₃H₈) propane is an odorless gas, but may also be compressed into a liquid (often called LPG). It is a constituent of natural gas and of crude petroleum, is isolated from these sources by a “stabilization process” using fractional distillation under pressure, and is highly flammable. It is readily available for home, transportation, farm, commercial, and industrial uses. Propane is not currently listed as an allowed substance for organic crop production under 7 CFR § 205.601. However, heat methods (fueled with propane) are allowed to control weeds and propane is used to create above ground explosions to deter birds and other vertebrate pests from orchards, vineyards, and berry farms previous to and through harvest. It is a physical control, consistent with preferred pest control methodologies. Prior to NOP implementation, the substance was allowed by multiple private certification standards and was allowed under the NOP until 2007, when the substance was summarily prohibited unless and until successfully petitioned and included on the National List.

The propane is mixed with oxygen and is exploded underground, causing a rapid expansion of gases that leads to concussive force that kills burrowing pest animals, with accompanying suffocation from consuming all the oxygen in the tunnel. The mixture is approximately 2% propane to 98% compressed oxygen, and the mixture is injected into the burrow for up to one minute before it is ignited. The Crops Committee has received a new Technical Report on this material and this has been posted by the Program for the Crops Committee, NOSB, and public review.

The Committee discussed the placement of this material on § 205.601, noting this is somewhat atypical given that the material’s efficacy is accomplished by physical action, either as an agent of concussive force or as an agent of oxygen displacement, either of which are physical control methods in common IPM parlance. The Committee discussed the possibility of creating a new subsection, § 205.601(o) – Pest control production aids, consistent with an option identified in the TR, line 171. The intent with that listing would be to provide a place on the National List for synthetic substances which are used up in their application and not present after the fact, somewhat analogous to processing aids used on food handling. While propane itself as applied is not a rodenticide, the Committee discussed the merits of classifying it under § 205.601(g) - Rodenticides. One Committee member felt strongly that propane should not be identified as a rodenticide *per se*, but ultimately agreed in framing the recommendation to place the material under § 205.601(g) in the interests of collaboration and consensus and

recognized that in fact the intended use was to control, in the main, rodents. Standards in Canada, EU and Japan either a) allow or b) do not prohibit the use of propane in organic production systems.

The Committee noted there are legitimate concerns over collateral damage from this method on endangered species. The Crops Committee wishes to make it clear to all concerned that use of the propane in a manner that violates the Endangered Species Act is a federal crime; the presumably provides adequate disincentive for such misuse.

In discussions, some members thought that this material was preferable to chemical controls currently allowed for use in organic production since it leaves no residue and complies with the mandates of § 205.206 which require that physical or mechanical controls be attempted prior to use of chemical controls. Other members felt that its use was unnecessary given the alternatives available for use, with discussion as to the applicability, efficacy, and functionality of those alternative methods. Allowed alternative methods discussed included flooding with water, a vacuum, CO₂, vitamin D₃ baits, smoke bombs, and several cultural practices listed under § 205.206(a). Some members also questioned the efficacy of propane for the petitioned use. There was again discussion about the utility of these practices across the wide range of crops, conditions and environments where propane had been used under pre-NOP private certification standards and under the NOP, until 2007 and whether that was an appropriate criterion on which to base a decision.

Another relevant discussion item was that propane is currently allowed in organic production as a physical control agent to kill weeds by heat and flame and is presently and widely used in many crops and conditions in that capacity. It is also used for fuel in so called “propane cannons” to generate loud explosions that deter wildlife from crops around harvest time, generally in and around perennial crops such as orchards, vineyards and cane berries. The Committee understands that both uses are allowed under the NOP as they are considered physical pest control methods.

The Committee recognized that if this material is included on the National List, an organic operator would still have to demonstrate that cultural practices (repellants, rotations, irrigation management, etc.) and non-synthetic physical practices (trapping, etc.) have been determined to be inadequate prior to using this management method on organic farms. In other words, the inclusion of propane on the National List would not affect the obligation to abide by § 205.206.

With those discussions had, the majority of the Crops Committee voted not to recommend odorized propane be included on the National List.

Committee Recommendation

The Crops Committee voted on the recommendation for propane to be added to the National List. The motion was as follows: To amend the National List, Synthetic substances allowed for use in organic crop production, § 205.601(g)(3) – Rodenticides, to include odorized propane as petitioned.

Committee Vote

Motion: John Foster
Yes: 3 No: 4

Second: Tina Ellor
Abstain: 0 Absent: 0

**National Organic Standards Board
Crops Committee
2013 Sunset Recommendation
Copper Sulfate**

October 4, 2011

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

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

(3) Copper sulfate—for use as an algicide in aquatic rice systems, is limited to one application per field during any 24-month period. Application rates are limited to those which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.

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

(4) Copper sulfate—for use as tadpole shrimp control in aquatic rice production, is limited to one application per field during any 24-month period. Application rates are limited to levels which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.

Background

History:

Copper sulfate as algicide, invertebrate pest control in rice

- Approved 10/16/01
- Allowed synthetic: vote 10-3-1
- 3 TAP reviewers: 1 in favor of approval, 2 against
- Annotation: one application per field per 24 month period, not to increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent
- 205.601(a)(3), 205.601(e)(3)
 - Approval renewed 11-30-07
 - 11-3-1 vote
 - —Material is still needed in organic aquatic rice systems. No compelling new information presented to warrant removal from the list.”

The original petition by CCOF stated, —In southeastern growing states there is a whole different set of rice pests and crop management issues and so the material is not widely used or needed.”

Summary

There have always been concerns over the use of copper, particularly in rice, because of its toxicity to aquatic organisms. Two out of three TAP reviewers opposed this use because of the toxicity to aquatic organisms and the fact that rice fields are attractive to animals like frogs. The TAP review also looked at alternatives to copper sulfate.

Now the Crops Committee has additional information on the severity of the threat to aquatic organisms. The California Rice Commission lists 230 species known to use rice fields in California. These include birds, mammals, reptiles, and amphibians.

Tadpoles—the larval form of frogs and toads, not the tadpole shrimp—eat algae, making them a candidate for controlling algae in rice paddies. But copper is highly toxic to amphibians (including mortality and sodium loss), with adverse effects in tadpoles and embryos at concentrations expected with the listed use. The California Rice Commission also points out that 95% of California's wetlands are gone, so rice fields provide important habitat for aquatic and semi-aquatic species who have been displaced.

ATSDR says that when copper sulfate is used in ponds, lakes, and reservoirs for controlling algae, the copper levels in the water column return to pretreatment levels within a few days. —The reduction in dissolved copper during this period was accompanied by an increase in particulate copper (e.g., sorption to algae or other organic matter, which settles into the sediments of these bodies of water). The copper in the settled particulates is in equilibrium with the water column, which greatly favors copper in a bound state.” They also say that copper can enter surface water in agricultural runoff. —The copper in the runoff water was found to be predominantly bound to drift material in the water (e.g., algae, vascular plants, invertebrates, vertebrates, and detrital material).”¹

Hundreds of studies document lethal and sublethal impacts of copper on aquatic food chains. These have been summarized by Carol Ann Woody as follows:²

Starting at the bottom the bottom of the food chain, at just 1.0 µg Cu/L green algae (*Chlorella* spp.) growth declined, at 5.0 µg Cu/L photosynthesis declined, and at 6.3 µg Cu/L photosynthesis was inhibited in a mixed algae culture (USEPA 1980). Zooplankton feed on algae and their growth and reproduction are affected by food availability. Declining algae production causes declining zooplankton production (Urabe 1991, Müller-Navarra and Lampert 1996), reducing food availability for species, such as sockeye salmon (*Oncorhynchus nerka*), that feed on zooplankton.

¹ ATSDR, 2004. Toxicological Profile for Copper. <http://www.atsdr.cdc.gov/toxprofiles/tp132.pdf> P. 141. Accessed 8/30/2011.

² Carol Ann Woody, 2007. Copper Effects on Freshwater Food Chains and Salmon: *A review*, Fisheries Research and Consulting. Pp 10-11.

Thus, copper used in rice fields tends to concentrate in the “particulate matter”, which is composed of remains of algae, plankton, and invertebrates, and this “particulate matter” is the food of tadpoles and forms the basis of aquatic food chains. The LC50 for tadpoles of *Bufo boreas* (one of the frogs found in California rice fields) is 47.49 parts per billion copper (0.04749 ppm).³ According to the TAP review (lines 680-683):

Typical application rates in paddies to control algae appear to range from 0.25 ppm to 2.0 ppm. For treating tadpole shrimp, application rates appear to be “less than 10 ppm”. With aquatic organisms showing detrimental effects at levels of about 0.4 ppm and above, this means that the application of CuSO₄ to rice paddies could kill mosquito fish, pond snails, and other organisms that could have beneficial properties.

In California, rice growers describe a system of drill seeding or dry planting rice that does not rely on copper. In this system, the seed drilling/dry planting, described in *Alternative Agriculture* (National Research Council, National Academy of Sciences, 1989) and currently in practice, allows the rice plant to be established to a stage that is not vulnerable to tadpole shrimp by the time the field is flooded. However, overly wet and warm weather in the spring is a factor that can prevent the use of this practice. The Washington State Department of Ecology describes below the action of an alternative material to copper sulfate for algae control, sodium carbonate peroxyhydrate products (<http://www.ecy.wa.gov/programs/wq/plants/algae/lakes/ControlOptions.html>). This alternative, which appears to make the use of copper sulfate as an algicide unnecessary, is approved under 205.601 with the following annotation: (a)(8) Sodium carbonate peroxyhydrate (CAS #—15630—89—4)—Federal law restricts the use of this substance in food crop production to approved food uses identified on the product label.

These Environmental Protection Agency (EPA)-registered sodium carbonate peroxyhydrate products are fast acting algaecides (algae killer) or algaestats. Algaestats do not kill algae outright but instead inhibit their growth, preventing bloom formation. Lake managers apply these products to the water to prevent algal blooms or to treat existing algae. Lake managers use these products as an alternative to copper-based algaecides not allowed in most Washington water bodies. In some parts of the world, there are copper-resistant algae strains and these products provide an alternative to treat copper-resistant algae.

The EPA registered sodium carbonate peroxyhydrate products for use in ponds, lakes, reservoirs, and drinking water sources. Sodium carbonate peroxyhydrate acts as an oxidizing agent to kill algae. When applied to water, these granular products break down into sodium carbonate and hydrogen peroxide. . .

Comments were submitted by Wolf, DiMatteo and Associates (WD+A) and CCOF. WD+A supports the continuation of the listings with annotation similar to the terrestrial use, but did not give any reasoning for the continuation. CCOF supports the

³ EPA, 2007. *Aquatic Life Ambient Freshwater Criteria—Copper*, Office of Water. EPA-822-R-07-001

continuation with annotation and change of —~~algae~~” to —~~scum~~” to match international usage. CCOF says most organic rice is exported, and none of the countries receiving CCOF certified exports recognize copper sulfate for shrimp control. However, since the methods for controlling shrimp without copper also seem to manage —scum”when it is at a damaging stage (i.e., when rice is below the water level), there appears to be little justification for keeping either listing.⁴

The information received by the committee concerning the hazards to aquatic ecosystems and the availability of alternative practices leads us to the conclusion that the use of copper sulfate in rice production should be restricted as much as possible. Our conversations with rice growers leads us to believe that particular weather conditions in some years rule out the use of cultural practices (drill-seeding) that would eliminate the need for copper sulfate. Therefore, we are recommending an annotation to both uses. We hope that the uses of and alternatives to copper sulfate will become a research priority.

Committee Recommendations

1. The Crops Committee recommends adding an annotation to the listing of copper sulfate as an algicide in rice. The motion was to approve the listing with the following addition (in italics):

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

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

(3) Copper sulfate—for use as an algicide in aquatic rice systems *when it is determined that weather conditions prevent the drill-seeding production practice*, is limited to one application per field during any 24-month period. Application rates are limited to those which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.

2. The Crops Committee recommends adding an annotation to the listing of copper sulfate for control of tadpole shrimp in rice. The motion was to approve the listing with the following annotation (in italics):

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

⁴ TAP lines 591-594: If pre-germinated seed were drilled and allowed to grow for a short while before flooding the fields, the rice most likely would escape the impacts of the shrimp and algae that only bother seedlings or rice that have not emerged above the water level. Lundberg website: “Our dry planting technique helps protect the rice from shrimp. The rice plant is well established by the time we apply the permanent flood, so the shrimp cannot ruin the crop.”

- (e) As insecticides (including acaricides or mite control).
- (4) Copper sulfate—for use as tadpole shrimp control in aquatic rice production *when it is determined that weather conditions prevent the drill-seeding production practice*, is limited to one application per field during any 24-month period. Application rates are limited to levels which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.

Committee Vote on Annotation Changes

Moved: Jay Feldman Second: Steve Demuri
Yes 4 No 0 Abstain 0 Absent 3

Committee Vote to Relist

§205.601 Synthetic substances allowed for use in organic crop production.
(a) As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems (3) Copper sulfate and (e) Copper sulfate.

Moved: Jay Feldman Second: Steve Demuri
Yes 4 No 0 Abstain 0 Absent 3

**National Organic Standards Board
Crops Committee
2013 Sunset Recommendation
Ozone**

October 7, 2011

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

- (a) As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems.
- (5) Ozone gas—for use as irrigation system cleaner only.

Committee Summary

There was a broad consensus in the organic community at the last round of sunset for this use of ozone that it should be kept on the list. There has been no new information since that time and it was generally agreed within the committee that it is a good alternative to chlorine for this use.

Committee Recommendation

The Crops Committee recommends relisting Ozone gas on 205.601 (a) As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems. (5) Ozone gas—for use as irrigation system cleaner only.

Committee Vote

Motion: Tina Ellor Second: John Foster
Yes: 4 No: 0 Abstain: 0 Absent: 3

**National Organic Standards Board
Crops Committee
Sunset 2013 Proposed Recommendation
Peracetic acid
October 4, 2011**

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

- (a) As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems.
 - (6) Peracetic acid – for use in disinfecting equipment, seed, and asexually propagated planting material.

- (i) As plant disease control.
 - (7) Peracetic acid – for use to control fire blight bacteria.

Committee Summary

A petition was received on 8/12/08 to remove the annotations for the use of Peracetic acid, which would expand the use. The Crops Committee reviewed the petition in 2009 and finally arrived at a recommendation, which was approved by the Board on November 5 2009 (0 yes, 13 no) to deny the petition.

At the same time, the Committee recommended a change in the annotation for both listings as follows:“Permitted in hydrogen peroxide formulations at concentrations of no more than 5%.” The crops committee did not wish to jeopardize the availability of the HP formulations currently used by many growers, knowing that these formulations all contain small, formerly allowed as inert concentrations of peracetic acid. The Board approved the recommendation on 11/5/09.

The NOP concurred with the NOSB recommendation. (4/23/10). To date the NOP has not issued a proposed rule to implement the rule change.

Comments submitted to regulations.gov are supportive of continued listing of Peracetic acid.

Recommendation

The Crops Committee recommends that the 2009 proposed annotation is adopted: §205.601(a)(6) Peracetic acid- for use in disinfecting equipment, seed, and asexually propagated planting material. Permitted in hydrogen peroxide formulations at concentration of no more than 5%.

§205.601(i)(7) Peracetic acid for use to control fireblight bacteria. Permitted in hydrogen peroxide formulations at concentration of no more than 5%.

Committee Votes

Motion to relist peracetic acid under 205.601(a)(6) and 605(i)(8).

Motion: Barry Flamm Second: Tina Ellor

Yes: 5 No: 0 Absent: 2 Abstain: 0 Recuse: 0

Motion to change annotation as written in 2009 recommendation (reaffirm 2009 rec).

Motion: Barry Flamm Second: Tina Ellor

Yes: 4 No: 1 Absent: 2 Abstain: 0 Recuse: 0

**National Organic Standards Board
Crops Committee
2013 Sunset Proposed Recommendation
Calcium chloride**

October 7, 2011

List: §205.602 Non-Synthetic substances prohibited for use in organic crop production.

(c) Calcium chloride, brine process is natural and prohibited for use except as a foliar spray to treat a physiological disorder associated with calcium uptake.

Committee Summary:

Calcium chloride is currently on the National List of non-synthetic materials prohibited for crop production with the following annotation: ...“brine process is natural and prohibited for use except as a foliar spray to treat a physiological disorder associated with calcium uptake.”

In considering crop materials as part of the sunset process, the Crops Committee reviews the previous NOSB work pertaining to the material, as well as any new information that has become available since the original board decision.

An updated Technical Report (TR) on this material was requested, but not received prior to consideration. Review was made of the 2001 TR, as well as the other steps taken, including the 2007 NOSB Sunset Recommendation (as adopted).

Brine process Calcium chloride would be classified as a mined substance of high solubility as mentioned in §205.203(d)(3), and as such its use is subject to the conditions established on the National List of non-synthetic materials prohibited for crop production.

The foundational principle for placing high solubility materials such as Calcium chloride, Potassium chloride, etc. on a prohibited non-synthetic materials list is spelled out in §205.203(d) – Soil fertility and crop nutrient management practice standard; “A producer may manage crop nutrients...in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients...” The current Crops Committee respects the intent of the earlier NOSB to annotate the prohibition on this material in such a way as to accomplish these nutrient management goals.

Public comment on the previously considered annotation for Calcium chloride expressed concerns regarding;

- 1) application rates applied with the proper methods in irrigation water which can supply calcium nutrient without significant soil or water contamination and with less salt burn to the crop foliage, particularly in sensitive vegetable and greenhouse crops,
- 2) the fact that chloride is an essential plant nutrient and can be deficient in some situations. In addition, some irrigation waters have almost no dissolved minerals (including chlorides and calcium), which can cause poor soil infiltration rates. Small amounts of calcium chloride added to irrigation water would be a very appropriate management choice to provide nutrients and improve the infiltration rate, and,

3) limitations on calcium chloride use are much more restrictive than the other mined natural chloride materials allowed in organic farming. The Potassium chloride annotation reads, “unless derived from a mined source and applied in a manner that minimizes chloride accumulation in the soil”. Magnesium and Sodium chloride, although high solubility mined substances, are not on the prohibited non-synthetic list at all. Some consistency is needed in how these materials are listed. Public comment suggested capturing the intent of the regulation in §205.203(d), and bringing consistency within §205.602 with the following annotation language:

Generic chloride – unless derived from a non-synthetic mined and/or brined source, and applied in a manner that minimizes chloride accumulation in soils, sub-soils, surface waters or groundwater.

It is worth recognizing that these comments still have merit, and that petitions are a viable strategy for change. Yet, the Crops Committee acknowledges that annotations cannot be changed during the sunset review process, and can only be changed through the petition process.

Committee Recommendation

Considering the fact that potential overuse of this natural substance, as well as resultant subsoil, surface water and ground water contamination warrant continued limitation of use, the recommendation is:

To retain calcium chloride on §205.602(c) Non-synthetic substances prohibited for use in organic crop production, with (c) Calcium chloride, brine process is natural and prohibited for use except as a foliar spray to treat a physiological disorder associated with calcium uptake.

Committee Vote

Motion: Colehour Bondera Second: Barry Flamm

Yes: 6 No: 0 Absent: 1 Abstain: 0 Recuse: 0

NOTE

This Discussion Document is presented by the **National Organic Standards Board Crops Committee** on behalf of the **NOSB-NOP-EPA Working Group on Inert Ingredients**. This document has not been approved by the Crops Committee, but comments on this document are welcomed, and will be supplied to the Working Group as they develop a final recommendation. The Crops Committee also seeks comments in particular on the status of former List 3 inert ingredients, which are currently permitted only in passive pheromone dispensers (§ 205.601(m)(2)). The allowance for former List 3 inert ingredients is scheduled to sunset on November 3, 2013; a vote to determine renewal is scheduled for the May 21-24, 2012 NOSB Meeting.

Inert Ingredients Discussion Document October 11, 2011

Background

Inert ingredients are defined in the National Organic Program (NOP) regulations, with reference to the Environmental Protection Agency (EPA) definition, to include any ingredient other than active ingredients used in pesticide products. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides that inert ingredients used in pesticides do not need to be disclosed on product labels.

NOP 7 CFR §205.2 Terms Defined

Inert ingredient. Any substance (or group of substances with similar chemical structures if designated by the Environmental Protection Agency) other than an active ingredient which is intentionally included in any pesticide product (40 CFR 152.3(m)).

EPA 40 CFR 152.3 Definitions

Active ingredient means any substance (or group of structurally similar substances if specified by the Agency) that will prevent, destroy, repel or mitigate any pest, or that functions as a plant regulator, desiccant, or defoliant within the meaning of FIFRA sec. 2(a), except as provided in §174.3 of this chapter

Section 6517(c)(1)(B)(ii) of the Organic Foods Production Act of 1990 (OFPA) authorizes the National Organic Standards Board (NOSB) to establish a National List of approved and prohibited substances that may include synthetic inert ingredients that are not classified by the Administrator of the EPA as “hazards of toxicological concern.”

OFPA

7 USC 6517(c)(1) Exemption for Prohibited Substances.

The National List may provide for the use of substances in an organic farming or handling operation that are otherwise prohibited under this chapter only if
...(B) the substance

... (ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern;

The NOSB, in conjunction with USDA, consulted with EPA during the development and subsequent amendments of the National List. The NOSB recommended in 1999 prohibiting List 1 and 2 inerts, and List 3 inerts that are not specifically approved by the NOSB. In 1999, the NOSB recommended that inerts on List 4 generally be allowed unless explicitly recommended for prohibition.¹ In spite of the fact that the EPA had by that time distinguished Lists 4A and 4B as those ingredients that were not of toxicological concern (4A), and those regarded as not causing adverse effects based on their use patterns (4B)². In 2002, the NOSB recommended that the Secretary of Agriculture allow the use of certain EPA List 3 inert pesticide ingredients in certain pheromone products.³ The Secretary accepted and codified the NOSB recommendations accordingly.

NOP regulation

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

In accordance with restrictions specified in this section, the following synthetic substances may be used in organic crop production...:

(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.

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

(2) EPA List 3—Inerts of unknown toxicity—for use only in passive pheromone dispensers.

In 2006, EPA reassessed all inert ingredients used in pesticide formulations allowed on food crops, including former Lists 3, 4A, and 4B inerts, to ensure that they met the requirements of the Food Quality Protection Act. Inerts allowed for use in EPA registered pesticides applied to food now must either have a residue tolerance level or an exemption from tolerance level codified at 40 CFR Part 180. As a result of this

¹ 1999 NOSB Recommendation available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=stelprdc5058968>

² In the notice 54 FR 48314 (11/22/89), EPA said (emphasis added),
“To accommodate revision of the lists, EPA has decided to subdivide List 4 into two parts. The previous list 4, representing inerts generally recorded as safe, has become List 4A, and a new List 4B has been created. List 4B is composed of inerts for which EPA has sufficient information to reasonably conclude that *the current use patterns* in pesticide products will not adversely affect public health and the environment. List 4B inerts in formulations proposed for new use patterns which cause significant increases in exposure will receive further scrutiny.” In notice 59 FR 49400 (6/28/94), EPA said, “In reviewing List 4 inert ingredients for the proposed section 25(b) rule, many inerts on the original List 4 were moved from List 4A to List 4B. In particular, acutely toxic inerts were moved to 4B because, although the testing of products for acute toxicity ensures low concern for these inerts in registered products, without such regulatory oversight there may be unacceptable acute risks.”

³ October 19–20, 2002 NOSB Meeting minutes available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5057498>

reclassification, the NOP regulations concerning allowed inert ingredients are out of date when compared with current EPA regulations. The NOSB recommended in April 2010 that NOP establish a task force in collaboration with EPA to examine this problem and provide a recommendation to the board for re-evaluation of former List 3 and List 4 inerts. In October 2010, the NOSB recommended that the current exemption on the National List that permits former List 4 inerts through October 2012 should be renewed —pending review by the program of inerts individually and as a class of materials”.⁴ The current exemption that permits former List 3 inerts in passive pheromone dispensers only is scheduled to sunset November 3, 2013 and will be voted on at the May 21-24, 2012 NOSB meeting.

A NOSB-NOP-EPA working group was established in June 2010. Members include: Jay Feldman (NOSB), Tracy Miedema (NOSB), Jeff Moyers (former NOSB), Chris Pfeifer (EPA Biopesticides and Pollution Prevention Division), Kerry Leifer (EPA Registration Division), Emily Brown Rosen (NOP), Lisa Brines (NOP), and John Punzi (NOP, on detail from AMS Pesticide Data Program). The group has collected information regarding current classification of the former List 3 and 4 inerts and gave a brief presentation at the April 2011 NOSB meeting.⁵

At this point, the Working Group has developed a few options for consideration and is requesting public comment.

I. Some initial considerations for review of inert ingredients

- a. NOSB must be able to review any substance recommended for the National List according to OFPA criteria, section 6518 (m):

–Evaluation. In evaluating substances considered for inclusion in the proposed National List or proposed amendment to the National List, the Board shall consider:

1. The potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;
2. The toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment;
3. The probability of environmental contamination during manufacture, use, misuse or disposal of such substance;
4. The effect of the substance on human health;
5. The effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock;
6. The alternatives to using the substance in terms of practices or other available materials; and
7. Its compatibility with a system of sustainable agriculture.”

⁴ October 28, 2010 recommendation available at

<http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5087999&acct=nosb>

⁵ Available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5090591&acct=nosb>

- b. This means that any EPA permitted category of “inerts” used in organic formulations would need to be reviewed. The OFPA criteria include need for use (i.e. the absence of natural alternatives) and cradle-to-grave considerations, which are not FIFRA criteria, so no list adopted under FIFRA would be satisfactory without additional consideration.
- c. In the interim, the NOSB could accept an EPA list (or lists) aligned with some of the OFPA criteria related to the potential for hazardous effects associated with use. The working group notes that the EPA’s criteria do not include need, manufacture, misuse, or disposal issues.
- d. If a baseline EPA category is accepted, the NOSB will need to provide other options for substances not covered by this list (e.g., applying OFPA criteria for review of petitioned inert ingredients).
- e. The NOSB may need to separately consider the few former List 3 chemicals that are currently in use.
- f. The WG on Inerts believes there are at least 120 substances in current use in organic production as inert ingredients that are not included in EPA’s current 25(b) list (Inerts of Minimal Concern). Most of these substances would be classified as synthetic and appear on the former EPA List 4B.

II. Proposals Under Consideration by WG-Inerts

1. Relist the allowance for former List 3 inerts “as is” for use in passive pheromone dispensers only during the 2013 Sunset review

The NOSB could renew the current exemption for former List 3 inerts for the next sunset period (i.e. through 2018). In the interim, the Working Group will continue to determine how to apply the OFPA criteria for evaluation of individual inert ingredients or categories of inerts, and provide a recommendation to NOSB for implementation by 2017, when the exemption (allowance) for former List 4 inert ingredients expires.

2. Allow the List 3 listing to sunset; former List 3 inert ingredients would need to be individually petitioned to be allowed for continued use

Guidelines for applying OFPA criteria for review of inert ingredients are still in development within the working group.

The WGI is unclear of essentiality of the approximately four former List 3 materials known to be in use. There may be alternatives to the use of these substances. This option would mean that manufacturers would need to bring forward information on lack of alternatives, safety, and environmental impacts.

The working group notes that it would be difficult for the board to review petitions in time for them to be reviewed before the November 3, 2013 sunset date for List 3 inerts. At a minimum, the NOSB may need to extend expiration date to allow

additional time for petitions and rulemaking. A channel of trade provision would also be needed.

3. Replace/amend the current listing for former List 3 inert ingredients, limiting to pheromone products.

Replacement options under consideration include the following:

- a) Inert ingredients of semiochemical dispenser products that are exempt from the requirement of a tolerance under 40 CFR 180.1122.⁶
- b) Inert ingredients for use in retrievable polymeric pheromone dispensers:⁷
 - a. Butylated hydroxytoluene (CAS # 128-37-0)
 - b. 2-Hydroxy-4-n-octyloxybenzophenone (CAS # 1843-05-6)
 - c. 2-(2-Hydroxy-3-tert-butyl-5-methylphenyl)-chlorobenzotriazole (CAS #3896-11-5)
- c) Inert ingredients for use in passive pheromone dispensers
- d) Inert ingredients for use in retrievable polymeric pheromone dispensers⁸.

4. Replace both former List 4 and List 3 references:⁹

- a) Inert ingredients eligible for FIFRA 25(b) Pesticide Products.^{10,11}

⁶ eCFR available at <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=8e1e539122b1034803f22bdbdc391ecc&rgn=div8&view=text&node=40:24.0.1.1.28.4.19.70&idno=40>

⁷ Or, alternatively, “Inert ingredients for use in for use in passive pheromone dispensers.”

⁸ Defined as a “solid matrix dispenser” delivering pheromones “at rates less than or equal to 150 grams active ingredient (AI)/acre/year” that is “placed by hand in the field and is of such size and construction that it is readily recognized and retrievable.” 59 FR 7368, March 30, 1994. (<http://frwebgate2.access.gpo.gov/cgi-bin/TEXTgate.cgi?WAISdocID=9xi50t/3/1/0&WAIAction=retrieve>) The notice says, “First, the proposal incorporates features that would limit the direct dietary exposure to the arthropod pheromones used as pesticides by requiring the formulation to be restricted to larger dispensers. This formulation restriction will limit exposure to an active ingredient resulting from the small amount that volatilizes from the dispenser and subsequently may deposit on food crops. Due to its size, the dispenser itself, with or without any remaining active ingredient, is not likely to become incorporated into food. Second, the Agency believes that an annual rate limitation of 150 grams AI/acre and a restriction to retrievably sized dispensers are likely to limit the dietary exposure to what is no greater than that found naturally in food as a result of heavy infestations of the pest arthropods. An arthropod species becomes a pest only if its populations reach levels that impede economic returns. The Agency believes there already has been dietary exposure to the arthropod pheromones deposited after volatilization from natural heavy pest infestations that could be shown to control such pest species.”

⁹ Inert ingredients not included would need to be individual petitioned, pending additional criteria adopted by NOSB.

¹⁰ http://www.epa.gov/opprd001/inerts/section25b_inerts.pdf

¹¹ Does not include synthetic former List 3 inerts known to be in use in pheromone products.

- b) Inert ingredients exempt from the requirement of a tolerance under 40 CFR 180.910, 180.920, 180.930, 180.940, 180.950, 180.960 and/or 180.1122.¹²
- c) Individual listings of inerts.
- d) Inert ingredients as permitted by the Environmental Protection Agency.¹³
- e) Hybrid approach – Class(es) of inerts plus individual listings.
- f) Classes of inerts, minus specific ones.

III. Issues and Discussion

1. Consider inert ingredients eligible for use in minimal risk pesticide products under FIFRA Section 25(b)

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) 25(b)(2), EPA may exempt from the requirements of FIFRA any pesticide that is “of a character unnecessary to be subject to [FIFRA]”. Regulations at §152.25(f) implement 25(b).

Restrictions on which ingredients may be used in minimum risk pesticide products are key aspects of the exemption, since the properties of these specific ingredients are the reason EPA exempted minimum risk pesticide products from FIFRA regulatory requirements.

The federal register notice establishing this list (61 FR 8876; Mar. 6, 1996) also noted the following:

In developing its list of exempted substances, EPA applied certain factors. Consideration was given to such factors as, (1) whether the pesticidal substance is widely available to the general public for other uses; (2) if it is a common food or constituent of a common food; (3) if it has a nontoxic mode of action; (4) if it is recognized by the Food and Drug Administration (FDA) as safe; (5) if there is no information showing significant adverse effects; (6) if its use pattern will result in significant exposure, and (7) if it is likely to be persistent in the environment.

In 2006, EPA classified 13 additional substances having tolerance exemptions under 40 CFR 180.910 and/or 180.920 as minimal risk under 40 CFR 180.950(e). The proposed rule also clarified that EPA was shifting existing tolerance exemptions for the “inert” ingredients that appear on former List 4A

¹² Includes all inert ingredients allowed for food use which are exempt from tolerance by EPA.

¹³ Would include inert ingredients for both food use and non-food use.

from that list to 40 CFR 180.950(e). 40 CFR 180.950 also includes exemptions from tolerance for certain foods, animal foods, and edible fats and oils. The current compiled list of all inerts that qualify for 25(b) exemption may be found at: http://www.epa.gov/opprd001/inerts/section25b_inerts.pdf.

The working group is aware of at least 120 inerts allowed for use in organic products that are former EPA List 4B substances that are currently in use and are not included on the 25(b) list. The majority of these substances would be classified as synthetic. If the baseline for allowance in organic products is limited to 25(b) substances, there will need to be development of an approach to apply the OFPA criteria to inert ingredients, and a phase in time to allow for reformulation and for review of petitions for substances currently allowed under the exemption for former EPA List 3 and List 4 inert ingredients.

2. Other lists of substances exempt from tolerance have been considered.

- a. EPA residue tolerance exemptions under 40 CFR 180.910 and 180.920 are established for "inert" ingredients used pre-harvest or post-harvest on crops. Exemptions under 180.930 are established for inert ingredients applied to animals. Exemptions provided under 180.940 are established for active and inert ingredients used in food-contact surface sanitizing for processing equipment solutions.
- b. 40 CFR 180.950 lists the pesticide chemicals that are exempted from the requirement of a tolerance based on the Agency's determination that these chemicals are of "minimal risk." The pesticide chemicals listed include both active and inert ingredients.
- c. 40 CFR 180.960 lists the pesticide chemicals that are exempt from the requirement of a tolerance because they meet the criteria established by the Agency to identify certain polymers that are of low risk. This section contains those polymers whose tolerance exemptions were established post-Food Quality Protection Act (FQPA) of 1996 and are based on the polymer's meeting the criteria described in 40 CFR 723.250. These compounds have been determined to present little risk to the environment because of their size, they are too large to be active in biological systems.
- d. Inerts used in Pheromones – 40 CFR 180.1122 indicates the following:
 - i. All inert ingredients of semiochemical dispenser products formulated with, and/or contained in, dispensers made of polymeric matrix materials (the monomers, plasticizers, dispersing agents, antioxidants, UV protectants, stabilizers, and other inert ingredients) are exempted from the requirement of a tolerance when used as carriers in pesticide formulations for application to growing crops only.

3. List 3 Inerts permitted for use in passive pheromone products.

NOP regulation:

§ 205.601(m)(2) EPA List 3—Inerts of unknown toxicity—for use only in passive pheromone dispensers.

The NOSB received petitions for several List 3 specific inerts for use in pheromones and voted in 2002 to add a general allowance for List 3 substances, only in passive dispensers, rather than add these specific chemicals to the National List. At this time the Working Group (including EPA) is only aware of 4 List inerts that are currently in use in pheromone dispensers used in organic production, three of them have been disclosed via petition to the NOSB:

- 2-(2-Hydroxy-3-tert-butyl-5-methylphenyl)-5-chlorobenzotriazole¹⁴ (CAS # 3896-11-5)
- 2, 2-Hydroxy-4-n-octyloxybenzophenone (CAS # 1843-05-6)
- Butylated hydroxytoluene (BHT)¹⁵ (CAS # 128-37-0)
- one other surfactant

At this time the Working Group invites manufacturers to provide information on additional substances that may be used in passive pheromone dispensers, particularly any inert ingredients that are not specifically listed above, or that are not included on the EPA 25(b) list for inerts of minimal risk.

IV. Comments Requested

The NOSB Crops Committee and NOSB-NOP-EPA Working Group on Inerts specifically invite comments on the following topics at this time:

- What are the preferred options for replacing / amending the current allowance for List 3 inert ingredients in pheromone products?
- Is the list of former List 3 inert ingredients that are currently used in NOP-compliant pheromone products accurate, or are there others in use?
- The NOP regulation uses the term —passive pheromone dispensers.” Has this terminology been problematic? Is the term —retrievable polymeric pheromone dispensers” a better fit?
- Provide suggestions regarding the process by which alternatives to the use of synthetic inert ingredients may be considered and implemented.
- What are the barriers to the development or use of alternative natural inert ingredients for use in pesticide formulations?
- What timelines for implementation are appropriate?
- What are preferred replacement options for both List 3 and List 4 references? Include any that may not have been discussed above.

¹⁴ TAP review available at <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5094039>

¹⁵ TAP review available at <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5057586>

**National Organic Standards Board
Livestock Committee
Proposed Regulatory Recommendation
Animal Welfare and Stocking Rates**

October 14, 2011

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. It is important to consider the social and ethical implications as well as scientific research with regard to animal welfare. This proposal involves the following sections:

Language changes to existing sections:

- **§ 205.2: Terms defined**
- **§ 205.238: Livestock health care practice standard**
- **§ 205.239: Livestock living conditions**

This proposal is intended to refine—not replace— previous NOSB Animal Welfare Recommendations. The combination of the 2009, 2010 and this recommendation aim to more clearly identify the parameters that define animal welfare on certified organic operations. As requested by the National Organic Program, it is our intention to create a comprehensive animal welfare program that benefits both livestock and farmers. Except for the specific sections whose proposed changes or additions are detailed in this recommendation, the November 2009 recommendation is still current.

Background

At the May 2009 NOSB meeting, the Livestock Committee presented a Discussion Document on Animal Health and Living Conditions. This document proposed that numerical scoring be used to assess body condition, lameness, coat/feather conditions and cleanliness. Please note that, as described in the discussion section, the Committee has begun and will continue to work on assessment measures that will be outlined in species-specific Guidance Documents for each species addressed in the livestock charts.

At the November 2009 NOSB meeting, the NOSB approved an Animal Welfare recommendation that proposed changes to **§205.238 Livestock health care practice standard** and **§205.239 Livestock living conditions** (including the separation into mammalian and avian sections) to give more detail to requirements to ensure animal welfare. This 2009 recommendation also noted the need for the establishment of indoor and outdoor space provision minimums.

At the fall 2010 NOSB meeting, the Livestock Committee presented Discussion Documents on Stocking Density and Handling, Transport and Slaughter, receiving public comment on both documents. This recommendation aims to refine the 2009 recommendation and consolidate it with the Livestock Committee's current recommendations on animal welfare and handling, transport and slaughter. In completing the current proposal, the Livestock Committee considered public comment and existing animal welfare standards, reviewed studies presented on animal welfare, and considered existing legislation from other countries and input from the Livestock Issues Working Group.

Relevant Areas in the Rule

The areas of the Rule currently addressing animal welfare include **205.2. Terms defined, §205.237 Livestock feed, §205.238 Livestock health care practice standard, §205.239 Livestock living conditions, and §205.240 Pasture practice standard**. This recommendation includes and builds upon changes recommended by the NOSB in November of 2009.

Discussion

The Livestock Committee has proposed a number of additions to **§ 205.2: Terms defined**. Several of these are physical alterations that are prohibited or allowed within limits. Soil, outdoor access, perches, and roosts are defined as they relate to **§ 205.238 (a) (5) Livestock Health Care Practice Standard**.

Market considerations. Increasingly, consumers are demanding that livestock be treated with respect. This market trend has led to several different product labels with animal welfare certification; this standard details specific quantitative requirements for animal stocking rates,. This recommendation intends to match the numbers currently used by the various animal welfare certification labels. Ultimately, the Livestock Committee would like the organic seal to continue to be the gold standard, indicating the most nutritious food produced in the safest and most respectful manner.

Physical alterations. A major concern when managing and working with livestock is the health and safety of animals and the people who come in contact with them. Alterations performed at the recommended age with appropriate equipment are beneficial and allowed. Dehorning may prevent serious injuries and fatalities. Castration allows males and females to be housed together with no worry of females being impregnated when they are too small or young. When teeth or hooves are injured or not wearing evenly or properly, filing or trimming is indicated. Beak trimming or toe trimming performed at the hatchery on the first day of life ensures best practices for poultry when deemed necessary.

The alterations defined are prohibited or allowed with specific limits.

Effective pain relief for dehorning or disbudding is readily available, inexpensive, and has been well-documented in University studies. Species specific guidance documents will address alterations and best practices. Pain relief for dairy and other species continues to be the subject of research since practical methods for on farm use are not yet available in many instances.

Ammonia levels in housing must be monitored as high levels may be damaging to eyes and lungs of livestock and human caretakers. Diet composition, manure management, and ventilation must be managed in a manner that maintains ammonia at a level that will not cause injury or discomfort.

Outdoor access. This is a basic tenet of organic production. Livestock must have access to fresh air and sunshine whenever possible. Exceptions may be necessary for environmental concerns or disease prevention. Concrete outdoor areas should be scraped daily or as necessary to prevent slurry accumulation. The area must be bedded if necessary to keep animals clean and dry. Housing with or without curtains does not count as outdoor access. Access to the soil should be provided when the land or pasture is dry enough that vegetation will not be destroyed if present and animals will not be in mud.

Dairy cattle housing. Tie-stalls are a traditional housing system used on family farms in many areas of the country. Larger farms may have free-stalls. Farms with bedded packs, compost packs, or no barn at all are less common. These different types of facilities all work well when managed properly. This is where outcome based standards are important to monitor the general health, cleanliness, and well-being of livestock.

Cattle require a clean dry place to lie down. There must be adequate space for all animals to lie down at the same time whether it is a pack area or a stall barn. In loose housing confinement there must be adequate space for all dairy cows to eat at the same time. If not, submissive animals tend to lose body condition and may need to be placed in a separate pen for feeding.

Bulls are commonly found on dairy farms and require special attention. For human safety reasons it is acceptable to maintain a bull in a pen or paddock separate from the milking herd. Bull calves should always be raised by their dam, or with a group of animals whether that is steers, older heifers, or dry cows so that they are less inclined to identify with humans.

Outcome-based standards. Scorecards and documents will be designed for each species to address hygiene, locomotion, body condition, lesions and injury, and anything else pertinent to a particular species. The Livestock Committee will continue to work on these documents with the organic community to develop a system that is reasonable, accurate, and enforceable. These guidance documents are intended to both provide producers with information on best management practices for proper animal care and to provide inspectors with assessment tools and the means to

consistently apply them. A farm plan approach with agreed upon corrective actions will be utilized to document improvement when problems are identified. The guidance documents will help the program, the certifiers, and producers to understand and meet the regulations. These documents will enhance the regulations and we recommend the NOP move forward with these completed recommendations for animal welfare.

Bison. Bison are not domesticated animals and therefore indoor bedded space would be an added stressor. Bison should not be confined indoors except for medical treatment.

Swine. During periods of temporary confinement provision of deep rooting materials such as straw is required to allow natural behaviors and prevent boredom. Outdoor space must allow all animals to lie down and apart from one another simultaneously.

Poultry. Poultry must be provided with the amount of space listed in the chart at the end of this document at minimum. Laying hens must be provided at least one and a half square feet inside the house as indicated in the Avian Minimum Space Requirements Chart at the end of this document. Poultry house areas with floors and solid roofs will count toward indoor space if birds have unlimited access to that space. A combination of perches and flat roosts must be in the house to encourage natural behaviors, strengthen bones via exercise, allow submissive birds to escape, reduce aggression and mortality rates. Perches allow for maximum use of vertical space within the house. Houses must provide both flat roost space and perches to allow all birds to get up off the floor at any given time. Exit areas should be large enough to allow more than one bird to go out at the same time.

Poultry outdoor areas must be managed in a manner that allows birds to perform natural behaviors which minimize stress and aggressive acts. It is the intent of the livestock committee that outdoor areas provide birds with access to the soil. A minimum of two square feet of outdoor space is required to protect the soil and to minimize parasite loads. Five or more feet of outdoor area would ensure that some vegetation would be available to birds during the growing season and producers are encouraged to provide a high quality outdoor area with vegetation that will be used and occupied by all birds listed in the chart. The farm plan should include detail as to how the time birds spend outdoors will be maximized. Producers who do not have two square feet per laying hen of certified land around houses may require transition time.

Pullets must be raised with perches or roosts and have outdoor access by 12 weeks of age. It is well documented that birds instinctively use when they are young. This practice should result in less stress and an easier transition to the layer house. Nest training may require a few weeks but shall be limited to no more than five. Broilers must have outdoor access by 4 weeks of age.

Recommendation

The language shown in the following pages is recommended for rulemaking.

§ 205.2 Terms defined.

Caponization. Castration of chickens, turkeys, pheasants, etc.

De-snooding. The removal of the turkey snood.

Toe clipping. The removal of the nail and distal joint of the back two toes of a male bird.

Dubbing. The removal of poultry combs and wattles.

Beak trimming. The removal of the curved tip of the beak.

De-beaking. Removal of more than the beak tip.

Cattle wattles. Created for ownership identification, wattles are made by surgically separating both layers of skin from the connective tissue for 2 to 4 inches on the dewlap, neck or shoulder.

Outdoor access. Animals have contact with soil when seasonally appropriate and the sky overhead and without a solid roof or walls. Fencing that does not block sunlight may be used as necessary.

Perches. A rod or branch type structure that serves as a roost and allows birds to utilize vertical space in the house.

Roost. A flat structure over a manure pit that allows birds to grip with their toes as they would on a perch.

Soil. The outermost layer of the earth comprised of minerals, water, air, and organic matter, fungi, and bacteria in which plants may grow roots.

Mulesing. Removal of skin from the buttocks of wool sheep, approximately 5 - 7cm wide and running half way from the anus to the hock to prevent flystrike.

§ 205.238 Livestock health care practice standard.

(a) The producer must establish, maintain and describe in the organic system plan practices or procedures designed to improve health care of the livestock

operation, including:

- (5) Performance of physical alterations as needed to promote the health, welfare or hygiene of animals; identify animals; or provide increased safety to farm personnel. Allowed physical alterations must be performed at the youngest possible age by trained persons in a manner that minimizes pain and stress and shall be recorded in individual (or flock) animal health records with dates, reason needed, and methods used. The following practices are prohibited:
 - (i) De-beaking, de-snooding, caponization, dubbing and toe trimming
 - (ii) Toe trimming turkeys unless performed with infra-red at the hatchery
 - (iii) Beak trimming unless performed with infrared at the hatchery
 - (iv) Tail docking of pigs and cattle.
 - (v) Wattling of cattle.
 - (vi) Face branding cattle.
 - (vii) Tail docking of sheep shorter than the distal end of the caudal fold.
 - (viii) Mulesing of sheep.
 - (ix) Routine tooth clipping of piglets.
- (6) Effective pain relief must be provided when dehorning or disbudding livestock.
- (7) Ammonia levels should be less than 10 ppm and must be less than 25 ppm indoors.
- (d) Organic livestock producers must provide their certifier with the following lists each year:
 - (2) All animals that have left the operation during the past year due to sale or mortality, and the reason for their departure

§ 205.239 Livestock living conditions. (Mammal section)

- (a) The producer of an organic livestock operation must establish and maintain year-round livestock living conditions, which accommodate the health and natural behavior of animals, including:
 - (1) Year-round access for all animals to the outdoors, shade, shelter, exercise areas, fresh air, clean water for drinking, and direct sunlight, suitable to the species, its stage of life, the climate, and the environment: Except, that, animals may be temporarily denied access to the outdoors in accordance with §§ 205.239(b) and (c).
 - (i) Livestock must be bedded or kept clean and dry per the hygiene outcome score when animals are temporarily denied access to the outdoors.

- (ii) Yards, feeding pads, and feedlots may be used to provide ruminants with access to the outdoors during the non-grazing season and supplemental feeding during the grazing season, but shall be large enough to allow all ruminant livestock occupying these spaces to feed in a manner that maintains all animals in good body condition. (iii) Continuous total confinement of any animal indoors is prohibited.
- (4) Shelter designed to allow for:
- (iv) At least one feeding space per animal in loose housing.
- (5) During the non-grazing season or during times of temporary confinement, the following will be provided.
- (i) In confined housing (free stalls, tie-stalls, etc.) at least one stall must be provided for each animal in the facility at any given time, except that:
 - (A) The confinement of animals in cages is not permitted under any circumstance.
- (6) Deep bedded straw or rooting materials must be provided for pigs to allow them to forage, explore, and otherwise prevent behavior problems associated with the lack of natural conditions during temporary confinement.

§ 205.239 Livestock living conditions. (Avian section)

- (f) The operator of an organic poultry operation shall establish and maintain poultry living conditions that accommodate health and natural behavior including:
- (1) Access to the outdoors.
 - (i) Laying hens must be provided with no less than 2 square feet of outdoor access per bird.
 - (ii) Enclosed spaces that have solid roofs overhead do not meet the definition of outdoor access and cannot be included in the space calculation of outdoor access.
 - (iii) Pullets must be provided outdoor access by 12 weeks of age when weather permits.
 - (iv) Broilers must be provided outdoor access by 4 weeks of age, provided that they are fully feathered and weather permits.
 - (v) Once layers are accustomed to going outdoors, a brief confinement period of no more than 5 weeks to allow for nest box training is permitted.
 - (vi) Outdoor access must provide birds with the opportunity to scratch and dust bathe in soil, turn around, and perform their natural behaviors.
 - (vii) Access to outdoor areas with direct sunlight must be provided during daylight hours when temperatures exceed 50°F

- (3) Suitable Flooring
 (ii) Houses with slatted floors must have enough solid floor area available that birds may freely dust bathe without crowding
- (4) Birds must have sufficient exit areas to ensure that all birds have ready outdoor access. Exit areas must allow the passage of more than one bird at a time.
- (5) Space Allowance. Poultry housing must allow:
- (i) All birds to move freely, and engage in natural behaviors.
 - (ii) All birds to perch at one time whether on a flat roost surface or perch.
 - (iii) Flat roosting areas where birds may grip with their feet
 - (iv) A combination of flat roost and perches must be provided to allow submissive birds to escape aggressors.
 - (v) The indoor space requirement must be met by the buildings interior ground floor perimeter. Perching areas and nest boxes will not be used in the calculation of floor space.
 - (vi) Indoor space allowance will not be less than 1.5 square feet per laying hen.

Avian Minimum Space Requirements Chart

Livestock Species	Indoor Space	Outdoor Runs and Pens
Chickens		
Laying hens and breeders	1.5 sq ft / bird	2.0 sq ft / bird
Pullets	5 lbs / sq ft	5 lbs / sq ft
Broilers	5 lbs / sq ft	5 lbs / sq ft
Other poultry		
Turkeys and Geese—breeding, laying, or meat birds (pounds)	7.5 lbs / sq ft	2 lbs / sq ft
Ducks-meat	5 lbs / sq ft	2 lbs / sq ft
Ducks-laying hen	2 lbs / sq ft	1 lbs / sq ft
Ducks—breeder	3.3 lbs / sq ft	1 lbs / sq ft
Reserved for additional species		

Committee Vote

Motion: Wendy Fulwider Second: Mac Stone
 Yes: 4 No: 2 Absent: 1 Abstain: 0 Recuse: 0

Minority Opinion

Sir Albert Howard (the father of the organic movement), his wife Madam Louis E. Howard, and the Organic Foods Production Act of 1990 (OFPA) focused on the whole farm system approach to organic production. Organic livestock production must be viewed as a part of a whole farm system and not in isolation from the issue of being good stewards to the environment. The Minority Opinion is consistent with section **205.200** of the regulation as it pertains to maintaining or improving the natural resources of the operation, including soil and water quality.

The Minority Opinion is intended to help move the issue of minimum space requirements for poultry and pigs alone in conjunction with meaningful practices that address natural behavior, outdoor access, and the environmental protection. The April, 2010 NOSB Livestock Committee Minority Opinion stated that “*economic or management challenges should not be a valid argument to weaken organic standards. Organic certification is not a right; it is a privilege that must be earned by meeting strict, sustainable, humane, and enforceable standards.*” The 2011 NOSB Livestock Committee minority opinion concurs with the aforementioned statements.

During the commenting period of March and April of 2011, 337 citizens submitted written or provided oral comments on poultry and pigs. The results showed that 73.5% (83 out of 113 commenters) recommended more space for poultry. Similarly, 99.6% (223 out of 224 commenters) recommended more space for pigs. Despite the overwhelming request for more space, the poultry numbers have barely changed, while no numerical change was provided to increase the space requirements for pigs.

The Minority Opinion supports increasing the space requirement of pigs to be at least equal to the Canadian space requirements. The current use of the phrase permitting swine, “to lie down and apart from one another simultaneously” can be difficult to measure. The wording does not capture the essence of pig space requirements, outdoor access, nor does it provide a clear measure for evaluating organic pig operations. The issue of space requirements and outdoor access for pigs could soon explode like the poultry issue as it pertains to space requirements, outdoor access, and natural behavior. If one thought that poultry was tumultuous; pigs could be the same. Therefore, the Minority Opinion is that both pigs and poultry need to be included in rulemaking.

Space requirements with meaningful standards that address natural behavior, outdoor access, and the environment as necessary components of the indivisible whole. The Minority Opinion recommends that poultry and pigs be provided the minimum space as outlined in tables 1 and 2, respectively. A timeline of 36 months is recommended for producers to comply after submittal for rulemaking is recommended. In addition, a minimum range of 40-50% vegetation covers is recommended, with 75% poultry and pigs being able to be outside at one time. We suggest the addition at section **205.239 (e) (i)** of the regulation. This provision will conform to environmental protection requirements in other sections of the regulation.

Recommendations

1. Prohibit routine beak conditioning or beak tipping. Except, beak conditioning may be authorized by the certifier for safety or if they are intended to improve the health, welfare or hygiene of the livestock on a case-by-case basis.
2. Add to section **205.2 (Term defined)** the term “natural behavior.” We suggest the definition by or similar to Bracke and Hopster, (2006). They defined natural behavior as behavior that animal’s exhibit under natural conditions. The ability of livestock to express natural behavior is consistent with section **205.239 (Livestock living conditions)** of the regulation.
3. Poultry and pigs’ space requirements need to be submitted for rulemaking, NOT just poultry. If pigs are left in guidance, then measureable requirements must be included.
4. All types of forced molting must be prohibited.
5. Minimum space requirements for avian are shown in Table 1. These requirements should be viewed as minimums and producers should focus on the requirements in #7 as the best guidance for ensuring adequate living conditions for birds. A maximum 36-month transition period after submittal for rulemaking is recommended.

Table 1. Avian Minimum Space Requirements Chart

Avian Species	Indoor Space*	Outdoor Runs and Pens
Chickens		
Laying hens and breeders	2.0 square feet/bird	5.0 square feet/bird
Pullets	1.0 square feet/2.0 lbs live weight	1.0 square feet/2.0 lbs live weight
Broilers	1.0 square feet/1.0 lb live weight	1.0 square feet/2.0 lbs live weight
Other poultry		
Turkeys**	1.0 square feet/5.3 lbs live weight	1.0 square feet/3.5 lbs live weight
Geese**	1.0 square feet/5.3 lbs live weight	1.0 square feet/3.5 lbs live weight
Ducks-meat+++	1.0 square feet/5.0 lbs live weight	1.0 square feet/2.0 lbs live weight
Ducks-laying hen+++	1.0 square feet/2.0 lbs live weight	1.0 square feet/1.0 lb live weight
Ducks-breeder+++	1.0 square feet/3.3 lbs live weight	1.0 square feet/1.0 lb live weight
Mobile Units		
Same as avian species requirements above		

* Indoor space is for the “temporary” confinement as outlined in the regulation **Canadian standards

+++NOSB Fall 2011 Livestock Committee Majority Recommendation

6. The Minority Opinion recommends the minimum space requirement for porcine are shown in Table 2. These requirements should be viewed as minimums and producers should focus on the requirements in #7 as the best guidance for ensuring adequate living conditions for pigs. A maximum 36-month transition period after submittal for rulemaking is recommended.

Table 2. Porcine Minimum Space Requirements Chart

Classification	Indoor Space*	Outdoor Runs and Pens
Sows and piglets+ (up to 40 days' old)	80.7 square feet for each sow & litter	26.9 square feet for each sow and litter++
Sows in group pens+	32.3 square feet/head	32.3 square feet/head
Boars in individual pens+	96.9 square feet/head	96.9 square feet/head
Growing pigs+ <ul style="list-style-type: none"> a. Up to 66# b. 66# - 110# c. 110# - 187# d. >187# 	<ul style="list-style-type: none"> a. 6.5 square feet/head b. 8.6 square feet/head c. 11.8 square feet/head d. 14.0 square feet/head 	<ul style="list-style-type: none"> a. 4.3 square feet/head b. 6.5 square feet/head c. 8.6 square feet/head d. 10.8 square feet/head

* Indoor space is for the "temporary" housing as outlined in the regulation

+ Canadian standards

++European standards

7. The Minority Opinion recommends adding the following at **§ 205.239 Livestock living conditions** of the regulation.

(e) The producer of an organic livestock operation must manage manure in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, heavy metals, or pathogenic organisms and optimizes recycling of nutrients and must manage pastures and other outdoor access areas in a manner that does not put soil or water quality at risk.

- (1) Access to the outdoors (Avian and Porcine).The operator of an organic poultry and pigs operation shall establish and maintain living conditions that accommodate health and natural behavior including:
 - (i) Poultry and pigs space requirements as shown in Table 1 and Table 2, respectively
 - (ii) Enclosed spaces that have roofs overhead do not meet the definition of outdoor access and cannot be included in the space calculation of outdoor access.
 - (iii) Pullets must be provided outdoor access by 12 weeks of age when weather permits.
 - (iv) Broilers must be provided outdoor access by 4 weeks of age, provided that they are *sufficiently* feathered and weather permits.
 - (v) Once layers are accustomed to going outdoors, a brief confinement period of no more than 5 weeks to allow for nest box training is permitted.

- (vi) Outdoor access must include providing birds with the opportunity to scratch and dust bathe in soil, turn around, flap their wings, spread their wings, and forage, without touching another bird.
- (vii) Access to outdoor areas with direct sunlight must be provided during daylight hours when temperatures exceed 50°F.
- (viii) Poultry of all species and pigs outdoor access area must have a minimum of 40-50% vegetative cover throughout the vegetative growing season and the Organic System Plan must provide a detailed description of the management proactive designed to implement this provision.
- (ix) The outdoor access area must include providing for at least 75% of the poultry and pigs to be outside at one time; birds must have enough space to include allowing birds to stretch their wings, run, forage, and find refuge areas away from other birds or predators.
- (x) Shade and outdoor areas may be provided by brush, trees or other structures.
- (xi) For poultry, all exit doors must be 14" high and be spaced evenly throughout buildings, with a total door opening of six linear feet per 1,000 hens.
- (xii) Poultry may provide cover (a horizontal barrier) and blinds (a vertical barrier) in both indoor and outdoor areas that enables birds to hide and isolate themselves from other chickens as long as these structures do not constitute confinement.
- (xiii) Poultry and pig outdoor areas must be designed to prevent or minimize soil erosion and runoff.
- (xiv) Outdoor environments must be managed to prevent soil degradation and overgrazing.
- (xv) For pigs, the outdoor living conditions must have adequate shade, shelter, rotational pastures or paddocks with the appropriate use of portable structures. Buildings and housing structures for pigs must be designed to allow outdoor access beyond door openings.
- (xvi) Farrow crates, flat decks, cages, and trimming or clipping teeth are prohibited. Castration should be performed before the piglets reach 2 weeks of age and by trained personnel.
- (xvii) Pigs should be weaned at 7 to 8 weeks of age. All pigs aged 6 weeks and older must have access to the outdoors.
- (xviii) Nose rings and tail docking are prohibited.

The Minority Opinion is being expressed as a means for enhancing the existing animal welfare document proposed by the majority. It is our opinion that if the lines are blurred between conventional and organic practices and standards, then organic consumers and producers will lose faith in the organic label.

Nature hits back when her rule about the correct relation between the plant and the animal is disregarded. She is trying to tell us that we shall have to retrace our steps and restore the natural partnership.

Sir Albert Howard, 1947
(Father of the organic movement)

**National Organic Standards Board
Livestock Committee
Proposed Guidance Recommendation
Animal Welfare and Stocking Rates**

October 14, 2011

Introduction

Animal welfare is a fundamental principle of organic production, and consumers expect that organic certification ensures humanely treated animals allowed to fulfill natural behaviors. The Livestock Committee of the NOSB considers that a focus on animal welfare warrants appropriate and effective regulation and guidance. It is important to consider the social and ethical implications as well as scientific research with regard to animal welfare. This proposal is intended to refine—not replace—the November 2009 NOSB Animal Welfare Recommendation. The combination of the 2009 and this guidance recommendation aim to more clearly identify the parameters that define animal welfare on certified organic operations. As requested by the National Organic Program, it is our intention to create a comprehensive animal welfare program that benefits both livestock and farmers. Except for the specific sections whose proposed changes or addition is detailed in this recommendation, the November 2009 recommendation is still current. This recommendation details the specific measures which the committee feels the program should include in guidance issued to the certifiers and the organic community. We have also made a separate recommendation regarding the measures that should be implemented via changes to the regulation.

Background

At the May 2009 NOSB meeting, the Livestock Committee presented a Discussion Document on Animal Health and Living Conditions. This document proposed that numerical scoring be used to assess body condition, lameness, coat/feather conditions and cleanliness. Please note that, as described in the discussion section, these assessment measures will be outlined in species-specific Guidance Documents that will be presented at the fall 2011 NOSB meeting.

At the November 2009 NOSB meeting, the NOSB approved an Animal Welfare recommendation that proposed changes to §205.238 Livestock health care practice standard and §205.239 Livestock living conditions (including the separation into mammalian and avian sections) to give more detail to requirements to ensure animal welfare. This 2009 recommendation also noted the need for the establishment of indoor and outdoor space provision minimums.

At the fall 2010 NOSB meeting, the Livestock Committee presented Discussion Documents on Stocking Density and Handling, Transport and Slaughter, receiving public comment on both documents. This recommendation aims to refine the 2009 recommendation and consolidate it with the Livestock Committee's current

recommendations on stocking density and humane handling, transport and slaughter. In completing the current proposal, the Livestock Committee considered public comment and existing animal welfare standards, reviewed studies presented on animal welfare, and considered existing legislation from other countries.

Relevant Areas in the Rule

The areas of the Rule currently addressing animal welfare include **205.2. Terms defined, §205.237 Livestock feed, §205.238 Livestock health care practice standard, §205.239 Livestock living conditions, and §205.240 Pasture practice standard**. This recommendation includes and builds upon changes recommended by the NOSB in November of 2009.

Recommended for guidance.

Livestock living conditions

Indoor stocking density. The stocking density table lists livestock by species and weight. All livestock must be provided with bedding as needed to maintain comfort and cleanliness per outcome based standards whether they are housed with or without a roof. The indoor bedded space allowance provided in this recommendation is to be considered a minimum for housed animals during temporary confinement. (205.239(b).

All animals must be able to lie down in a clean, dry place at the same time without lying on top of one another at all times. 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 or routine occurrence. If routine hoof trimming due to lameness or overgrown hooves is required, diet or management adjustments will be necessary.

Bison. Bison are not domesticated animals and therefore indoor bedded space would be an added stressor. Bison should not be confined indoors except for medical treatment.

Dairy calf housing. When considering shelter design, it should be taken into account that calves are social animals and should ideally be housed in small groups. Calves may be housed in individual pens or hutches providing that they have enough room to turn around, lie down, stretch out while lying down, get up, rest, and groom themselves; individual calf pens shall be designed and located so that each calf can see, smell, and hear other calves present on the farm.

Calves are tied on some farms while being wintered in the dairy barn or tethered to a hutch. Tethering is less desirable than group housing but may be necessary in some systems to prevent cross-sucking. Tethering is acceptable if calves are safe and meet the requirements that will be laid out in the outcome based standards and movement is not restricted.

Dairy cow housing. Standard tie-stall and free-stall operations that have individual stalls are not included in the stocking density table. Individual stall barns must be managed to keep cows comfortable and to meet the outcome based standards that are in development. These standards will include cleanliness, body condition, injuries and lesions, lameness, etc., as relevant to dairy. This means large stalls are necessary for Holsteins and Brown Swiss, while smaller stalls are indicated for smaller breeds such as Jerseys. Copious amounts of bedding such as chopped straw increase comfort and may contribute to cleaner animals, and prevent injuries and lesions.

Broken tails.

The great majority of farms do not have livestock with broken tails. Accidents do happen and occasionally tail injuries occur. Dairy cattle may be more prone to this injury. An incidence greater than 3% may indicate a problem with housing or handling. This as well as any other issue will be addressed in the Organic System Plan.

Swine. Swine farms will establish and maintain living conditions that accommodate the health and natural behavior of all pigs. The space requirement for pigs must allow every pig to lie down, stand up, turn around freely, run, root, explore, and express other normal patterns of natural behavior. The outdoor living conditions should provide shade, shelter, rotational pastures or paddocks and portable structures as needed.

Buildings and housing structures for pigs must be designed to allow outdoor access for all when seasonally appropriate. The outdoor environment must be managed to minimize soil erosion and overgrazing. Vegetation cover provides grazing, prevention of soil erosion, and promotes soil health. This approach allows for re-growth of vegetation after moving pigs.

All pigs must have access to fresh water and a high-quality feed according to their needs. Farrow crates, flat decks, cages, tail docking, and routine trimming or clipping of teeth are prohibited. Castration should be performed before the piglets reach 2 weeks of age and by trained personnel. Indoor space for pigs must be designed to allow outdoor access on the ground. Pigs should be weaned at 7 to 8 weeks of age. The farm plan must show how the time pigs are outdoors will be maximized. All pigs aged 6 weeks and older must have access to the outdoors. Temporary confinement is only permitted as outlined in OFPA Rule.

Poultry houses. In considering shelter for avian species, dry litter must be provided and maintained. Special considerations for the areas beneath the waterers may be needed to maintain dry litter. Complete clean out of a poultry house is necessary when there have been adverse health issues with the previous flock; otherwise a clean layer of bedding should be provided between flocks to provide a sanitary environment for the new flock coming in.

Poultry houses and outdoor areas must be managed in a manner that allows birds to perform natural behaviors which minimize stress and aggressive acts. Producers should be encouraged to provide environmental enrichments in the house that will relieve

boredom and discourage aggressive acts such as pecking behaviors. It is the intent of the livestock committee that outdoor areas provide birds with access to the soil. If birds do not utilize outdoor areas it may be necessary to make these areas more attractive with environmental enrichments or larger doorways for the birds. This should be incorporated into the organic farm plan.

Outdoor stocking density. Outdoor access is important for all livestock to enhance muscle tone and relieve boredom. 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. Since piglets and chicks must be protected from freezing weather, outdoor runs are not necessary. Calves, lambs, kids, and other young animals require protection from extreme weather conditions and threat from predators.

Minimum space requirements charts. The following chart is meant to address periods of temporary confinement or during the non-grazing season for mammalian species. Tie- and free-stall barns are exempt from the space requirements in this chart and must provide one stall for every animal with access to the building. The values in this chart are MINIMUM amounts only and provision of larger areas of enriched environment appropriate to the species is strongly encouraged. Outcome-based requirements (to be developed) will be an integral part of the animal welfare standard.

Mammalian Minimum Space Requirements Charts

Livestock	Indoor Floor Space	Outdoor Runs and Pens
Bison weight (pounds)	Square feet / animal	Square feet /animal
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 / animal	Square feet /animal
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 per 220 pounds	8.0 per 220 pounds

Dairy cattle weight (pounds)	Square feet / animal	Square feet /animal
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 per 220 pounds	8.0 per 220 pounds

Mammalian Minimum Space Requirements Charts (continued)

Livestock	Indoor Floor Space	Outdoor space
Swine	Square feet / animal	Square feet / animal
Sow and piglets	48.0	40.0
Sows	30.0	30.0
Boars	64.0	85.0
Growing pigs	Square feet / animal	Square feet /animal
Up to 24	2.0	Sufficient space for animals to all lie down and apart from one another simultaneously
24—47	3.0	
47—109	6.0	
109—157	9.0	
157—225	13.0	
225 and up	16.0	

Livestock	Indoor Floor Space	Outdoor Space
Sheep and goats (pounds)	Square feet / animal	Square feet / animal
Sheep and Goats	16.0	30.0
Nursing lamb or kid	4.0	8.0
Rabbits	Square feet / animal	Square feet /animal
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

Committee Vote

Motion: Wendy Fulwider Second: Mac Stone
 Yes: 4 No: 2 Absent: 1 Abstain: 0 Recuse: 0

**National Organic Standards Board
Livestock Committee
Proposed Recommendation
Animal Handling, Transport, and Slaughter**

September 21, 2011

Introduction

Humane treatment of animals is a basic principle of organic production. The Livestock Committee of the NOSB feels that appropriate and effective expanded regulations, based on social, ethical, and scientific evidence, are necessary to ensure that animal welfare considerations are upheld. The Livestock Committee recommends the addition of **§ 205.241 Animal handling, transport and slaughter: general conditions of animal welfare in handling and slaughter** to move towards a comprehensive animal welfare program in certified organic livestock operations.

Background

The Livestock Committee has presented handling, transport, and slaughter documents at the October 2010 and April 2011 meetings. The Committee has taken public comments into consideration while crafting this recommendation. The recommended regulatory language reflects current industry standards in practice due to separate animal welfare certification programs, which are verified by third party audits. The only additional proposed regulatory language included in this recommendation is intended to guard against slaughter plant abuse of newborn calves, an issue that has recently been in the public spotlight. Transporters and slaughter plants which accept organic livestock are already meeting the listed organic requirements.

Relevant Areas in the Rule

USDA organic regulations do not currently specifically cover animal handling, transport, and slaughter. Therefore, the Livestock Committee is recommending the addition of a new section titled **§ 205.241: Animal handling, transport, and slaughter**.

Discussion

The intent of this document is to assure consumers that certified organic livestock are treated with respect and according to need. This document clearly states expectations for producers, haulers, and slaughter plant personnel. The accompanying guidance document will provide additional clarity.

To avoid mistreatment on the farm, during transport to, or at the slaughter plant, specific prohibited practices are described within the willful acts of abuse. Livestock slips, and falls are also defined.

Fitness for transport. To avoid the need to cull unfit animals at slaughter, it is essential that only fit animals be loaded for transport to slaughter. Unfit cull animals are one of the biggest problems encountered at slaughter plants. Livestock that are likely to be condemned or

become downers should not be shipped. Although this shouldn't be considered a comprehensive list, animals are unfit for transport if they are any of the following: disabled, fatigued, sick, injured, lame, weak, have unhealed wounds, are within the final 10% of their gestation, are less than 48 hours old, or completely blind. Additionally, animals that are aggressive, wild, or have had little contact with humans will require good handlers, chutes, and corrals to reduce the stress of transport and confinement. The NOSB intends to create clear and concise guidance documents to assist farmers, certifiers, and others decision-makers regarding fitness for transport.

Young calves. Language protecting young calves will be new to the animal industry. In many areas of the country, there is no market for raising dairy bull calves for beef. These calves have little value and are therefore sent to slaughter at the earliest-possible age. Bull calves should be fed and managed as heifer calves on farm and must be strong enough for transport before being shipped.

Transport conditions. To ensure continued health and comfort during transport to slaughter, all shipping containers must have seasonally-appropriate ventilation, bedding (as needed), and non-slip flooring. Roughages used as bedding must be certified organic. Bedding is needed when temperatures are below freezing and animals may be in danger of being frozen to the floor or side of the trailer. If transport time exceeds 12 hours, arrangements must be made to provide food, water and rest. Additionally, emergency plans for animal care and alternative transport must be in place to cover unforeseen circumstances, such as accidents or truck breakdown.

Animal handling. Slaughter plant staff must be available after hours if needed to receive livestock. Animals are to be treated in a calm, quiet, and humane manner, which reduces stress and incidences of bruising and injury. Additionally, lighting must be enough to read a newspaper, in order to adequately identify and/or manage ill or injured livestock.

Slaughter. The recommended language below is intended to ensure that animals are handled properly and with respect throughout the slaughter process. Electric prods and euthanasia equipment must be stored in a clean, dry location. Prods are to be used solely by trained staff for human safety or medical purposes only, typically to save down animals. If an animal does not attempt to rise after being shocked once, it is to be moved immediately and carefully to a safe resting place or euthanized; it is not to be shocked a second time. If the animal makes one or two unsuccessful attempts to rise after being shocked, a second or third shock may be applied to the animal after a rest period. Plants generally allow at least twenty minutes to two hours rest. For each attempt, human assistance must be provided to help the animal to its feet. Additionally, sand or lime should be applied to the flooring as necessary to provide increased traction. If the animal is not on its feet after a third shock, it is to be moved immediately and humanely to a safe resting place or euthanized.

Ritual slaughter. Ritual slaughter is done according to religious requirements. The animal is slaughtered, without being stunned, with a razor sharp knife. When the cut is done correctly, the animal appears not to feel it. From an animal welfare standpoint, the major concern during ritual slaughter is the method of restraint. Slaughter plants will use devices that hold the animal

in a comfortable, upright position. For both humane and safety reasons; plants that conduct ritual slaughter will use modern upright restraining equipment.

Slaughter plant audits. Audits of slaughter plants provide confirmation that animals are being treated appropriately throughout the process. Animal welfare audits are currently being done in most slaughter facilities as part of various animal welfare certifications' requirements. To comply with these new organic regulations, all slaughter facilities will need to be audited yearly. Organic certifying agents can review documentation from these third-party animal welfare audits and can do any additional auditing as necessary. In-between annual third-party audits, it is necessary for plants to do self-audits on a weekly basis. Self-audits ensure that animal welfare standards are being upheld, identify problems that may arise within the facility or with individual staff members, and identify specific farms that may be shipping problematic animals to the slaughter plant. These problems may be due to animals' genetics or handling; slaughter facilities are encouraged to contact the producers of problematic animals so that these problems can be addressed in the future.

Recommendation

The language shown in the following pages is recommended for rulemaking. The livestock committee respectfully requests that the National Organic Program places only what is necessary into rule. The livestock committee wants to assure consumers that the organic industry practices a high level of animal welfare. The livestock committee does not wish to increase the paperwork burden, certification costs, or discourage small slaughter plants from organic certification.

§ 205.2 Terms defined.

Willful acts of abuse. Includes but not limited to dragging non-ambulatory, conscious animals; intentionally applying prods to sensitive animal parts, e.g., anus, ears, eyes, or reproductive parts; malicious driving of livestock on top of one another with or without direct contact with motorized equipment; loading of non-ambulatory animals for transport is excluded; beating or hitting live animals; live animals frozen to trailer floors or sides; lifting an animal by the wool or throwing the animal; and slamming gates on animals.

Livestock slip. A knee or hock touching the floor.

Livestock fall. The body touching the floor.

§ 205.241 Animal handling, transport and slaughter: general conditions of animal welfare in handling and slaughter.

(a) Handling and Transport to slaughter: Certified organic livestock will be clearly identified as organic and transported in pens within the livestock trailer clearly labeled for organic use and be contained in those pens for the duration of the trip.

- (1) It is the responsibility of the organic producer to ensure that calves have a dry navel cord and are able to stand and walk without human assistance if they are being transported to a slaughter or auction facility.
- (2) The livestock trailer/shipping container and slaughter plant must provide season-appropriate ventilation to protect against cold and heat stresses.
- (3) Bedding must be provided on trailer floors and in holding pens as needed to keep livestock clean, dry, and comfortable during transportation and prior to slaughter. Poultry crates are exempt from the bedding requirement. When roughages are used for bedding they must be organically produced and handled by a certified organic operation.
- (4) Arrangements for water and organic feed must be made if transport time exceeds twelve hours.
- (5) Slaughter plant management shall coordinate with transporters to ensure that waiting time once the livestock trailer/shipping container arrives at the slaughter facility is no more than one hour. If this is not possible animals will be covered, sheltered, or provided comfort as needed for the species.
- (6) Emergency plans that adequately address animal welfare must be in place to cover any encountered problems during transport.
- (7) Slaughter plants and livestock trailers/shipping containers must have non-slip flooring.
- (8) Gates in the unloading area must swing freely, latch securely, and be free of sharp or otherwise injurious parts. Gates are never to be slammed on animals.
- (9) Adequate lighting must be in place to allow animals to be easily observed.
- (10) Livestock slips and falls must be scored in all parts of the facility including holding areas, chutes, stun box and the stunning area. No more than 1% of livestock that walk off the trailer may fall during the unloading process. No more than 1% of cattle, sheep, or hogs may slip during unloading.
- (11) Willful acts of abuse, as defined in § 205.2, are prohibited.
- (12) Humane treatment procedures for handling immobile and fatigued animals upon arrival at the slaughter plant are in place. Handlers may use sleds and place livestock in the bucket, but may not push them up against a wall, gate, or any other object.
- (13) Electric prods are available if needed for human safety or for medical use, i.e., in an effort to save down animals. Prod use must stop after three shocks interspersed with rest periods or if the animal does not attempt to rise. Prods may never be

applied to sensitive parts of the animal: eyes, nose, ears, rectum, or reproductive organs. Prods may not be used on animals less than twelve months of age.

- (14) Euthanasia must only be performed by trained personnel.
 - (15) Euthanasia equipment must be properly stored at slaughter plants and maintenance records must be available.
- (b) Slaughter Plants must meet all FSIS requirements including Humane Slaughter Act.
- (1) No more than 3% of cattle vocalize as they move through the restrainer, stunning box and stunning area. No more than 5% of hogs squeal in the restrainer due to human provocation. No more than 5% of livestock vocalize when a head holder is used during stunning or slaughter.
 - (2) Conscious, sensible mammals must never be restrained by suspending them by their limbs.
 - (3) No more than 1% of animals slip at the stun box or in the stunning area. No more than 1% of animals' fall entering the stun box or in the stun box area.
 - (4) One hundred percent of animals are insensible prior to being hung on the bleed rail.
 - (5) 95% of cattle and sheep are effectively stunned with one shot via captive bolt or gunshot. 99% of electrodes are placed correctly when livestock are stunned with electricity.
 - (6) No more than 1% of hogs vocalize due to hot wandling. Electrodes must not be energized before they are in firm contact with the animal.
 - (7) When carbon dioxide (CO₂) or other controlled atmosphere stunning systems, including gondolas or other conveyances for holding a group of animals, are used, animals must be able to lie down or stand without being on top of one another. When head to tail conveyor systems are used, this score may be omitted.

Committee Vote

Move to accept the Livestock Committee recommendation on animal handling, transit, and slaughter proposal with discussed changes.

Motion by: Wendy Fulwider Second: Joe Dickson

Yes: 5 No: 1 Absent: 0 Abstain: 0 Recuse: 0

**National Organic Standards Board
Livestock Committee
Proposed Guidance Recommendation
Animal Handling, Transport, and Slaughter**

October 14, 2011

Introduction

Humane and respectful treatment of animals is a basic principle of organic production. The Livestock Committee of the NOSB submits this recommendation to the National Organic program and requests they issue formal guidance to assist producers, harvest facility personnel, and certifiers in developing systems that provide care and respect for the animals during this aspect of the organic food production system.

Background

Harvesting animals for meat is conducted in a countless number of types of systems as designed by individual companies or operators. These facilities must adhere to numerous food safety, worker safety, and animal welfare state or federal regulations. Many also extend religious ritual standards to the process, for clientele that demand further requirements for the process. This guidance will allow the organic food production system suppliers to verify for their customers that the harvest process is conducted in a manner consistent with the Organic Food Production Act.

Relevant Areas in the Rule

USDA organic regulations do not currently explicitly cover animal handling, transport, and slaughter. Therefore, the Livestock Committee is recommending the addition of a new section titled **§ 205.241: Humane handling, transport, and slaughter**. The protection of organic integrity of the products from commingling and contamination in the harvesting process are currently in place for operations that are certified to meet all processing facility regulations and be labeled as organic under **§205.272 :Commingling and contact with prohibited substance prevention practice standard**.

Committee Recommendation for Guidance

On Farm Handling and Facilities

Handling of livestock is necessary for proper health administration, care of newborns, aiding those with special needs, weaning, and preparation for transport. Handling of animals for transport is a stressful time for livestock. Often it is the only time they have ever been handled in such a deliberate fashion. Livestock are very aware of their surroundings and sense when operations are secure and peaceful in nature.

- a. Operations should have appropriate scale physical restraint mechanisms in place so that animals feel secure in the space confined.
- b. Even when a facility is temporarily modified to corral, sort, and load livestock, the equipment should always be adequate to keep animals from triggering their fight or flight response mechanisms.
- c. Structures, fencing, gates, and catching mechanisms must be sound and adequately designed to perform the required tasks and keep the animals calm.
- d. Facilities should be constructed and maintained to prevent injury due to sharp edges, obstruction to movement, and weak latching mechanisms.
- e. Holding facilities should be designed to allow ease of entry, ability to sort larger animals from smaller ones, and adjacent lots for weak or injured ones.
- f. Lighting, non-slip footing, and sufficient personnel are also necessary to keep animals calm and safe at this time.
- g. Young stock should not be transported until navels are dry or at least 48 hours of age.
- h. Reduced crowding for weak or lame animals, improved lighting for those with poor vision may be necessary.
- i. Excessive use of force, electric prods, lifting or restraining techniques that could further harm the animal are not permitted.
- j. Animals should be euthanized by trained personnel in a manner that minimizes suffering.

Transportation of Animals

- a. Loading of animals should be performed in a quiet, deliberate, and respectful manner.
- b. Ramp inclines should be gradual to discourage balking, likewise stepping up and down should be appropriate for the size of stock being loaded.
- c. Footing should be secure to reduce or eliminate slipping.
- d. Shipping containers should provide adequate footing, be structurally sound, and provide seasonally appropriate environmental conditions.

- e. Animals should have enough room to move within the container and be able to regain a standing position in the event of falling.
- f. Bedding may be necessary for extended duration, which if considered roughage, must be certified organic.
- g. Trips in duration longer than 12 hours may require animals have access to feed and/or water as environmental conditions dictate for animal health considerations.
- h. Poultry crates should be packed at a rate that allows sufficient space for all to lie down and maintain appropriate temperature regulation. Crates should be stacked in a manner to allow sufficient ventilation for respiration and temperature regulation. Protection from the elements may also be necessary.
- i. Poultry should not be frightened into an area which causes piling while being handled for crating or loading. Broilers should not be held by their neck or wings alone.

Slaughter Facilities

- a. Receiving pens at the plant must be sized appropriately for the class of animal being handled and designed to reduce balking.
- b. Stepping up or down should not be difficult for the animal. Ramps should also be gentle enough to encourage movement.
- c. Gaps between the shipping container and flooring of the facility must be minimal to prevent injury and provide safe and secure footing.
- d. Lighting, gates, pens, and latches should be adequate for the animals being handled and provide staff the ability to move and sort the animals in an orderly manner.
- e. Slaughter facilities are required to meet numerous local, state, and/or federal food safety regulations. Organic inspectors should have access to and the ability to review all relevant Federal or State inspection reports. These reports will show if the facility is already under the purview of an animal welfare inspection system.
- f. Inspectors and reviewers can be aided in assessing welfare in plants that are not animal welfare certified by using the species specific criteria outlined in the guidance documents also being developed by the NOSB Livestock committee. These “core” criteria will not attempt to replicate a complete

welfare audit, but will ensure that the most crucial aspects of animal welfare in handling for slaughter are defined in a way that can be objectively observed and assessed.

- g. Slaughter facilities exempt from State or Federal inspection are least likely to be animal welfare certified. Slaughter in these plants usually involves a small number of animals slaughtered at a time, and the process is slower and less mechanized than in larger plants. These conditions make it feasible for organic inspectors to observe slaughter handling and assess whether these core welfare criteria are met.
- h. Animals that arrive in a compromised physical condition must be handled in a respectful manner without the use of excessive human intervention.
- i. The use of electric prods is prohibited, except where animal and human safety is in jeopardy and is a means of last resort.
- j. Euthanasia must only be performed by trained personnel.
- k. Plants offer humane ritual slaughter, which is an indicator of respect for animal welfare.
- l. Slaughter plants may be certified by one or more animal welfare programs. Inspectors may make note of these as they may show intent of the operator to perform their duties in a respectful manner. These do not supersede the organic regulations like state or federal regulations do.

Committee Vote

Motion: Wendy Fulwider Second: Mac Stone
Yes: 4 No: 0 Absent: 3 Abstain: 0 Recuse: 0

**National Organic Standards Board
Livestock Committee
Proposed Recommendation
Species-Specific Animal Welfare Scorecards**

October 14, 2011

Introduction

Animal welfare is a basic principle of organic production. As the number of farmers in the United States decline, consumer concerns for farm animal care have increased. There are numerous animal welfare organizations and methods to verify animal welfare. The Livestock Committee believes that outcome based scores are the best measure of farm animal welfare.

Background

The United States Congress anticipated the need to elaborate livestock standards in 1990 when the Organic Foods Production Act was passed. The Humane Society of the United States played a central role in advocating for the passage of OFPA. It was understood at that time that animal welfare standards would eventually be developed. Several animal health and welfare practices were described in the Preamble accompanying the NOP Final Rule that organic livestock farmers must adhere to.

Discussion

The Livestock Committee feels that outcome based standards are the best measure for assessing the health and well-being of livestock. The four major concerns for dairy cattle are:

- Body condition
- Locomotion
- Cleanliness
- Injury and lesions

These measures are currently in use and have been well documented as welfare indicators in the livestock industry. Body condition is affected by stage of lactation and diet. Cows generally score less than 2 only if they are ill. Locomotion score may be 2 or greater if there is an injury. When cattle have a clean, dry place to lie down the majority of the herd will be clean. Grazing cattle generally have safe and spacious environments which minimize injuries and lesions. The Livestock Committee will discuss what is considered normal and acceptable for each of these measures in the future. Other welfare measures on the tally sheet include:

- Cattle affected with mange or lice
- Cattle with broken tails
- Ammonia concentration in buildings

- Other items that may need attention

Cattle may be affected with mange and lice during the winter months. This is an uncomfortable condition and requires immediate treatment. Broken tails are uncommon and are generally the result of an accident. High numbers indicate a problem with animal handling or the farm environment. Ammonia smell in buildings may indicate a lack of ventilation.

The photographs and descriptions on the dairy score card clearly show the difference between scores and have a corresponding spot on the tally sheet. The shaded boxes on the tally sheet represent areas of concern. Inspectors should view all of the cows and young stock but tally only the animals that would score in a shaded box. This identifies any issues that may need to be addressed and minimizes the amount of additional inspection time.

Committee Recommendations

- I. Dairy Auditor Tally Sheet**
- II. Dairy Scorecard**

Committee Vote

Motion: Wendy Fulwider Second: Mac Stone
Yes: 6 No: 0 Absent:1 Abstain: 0 Recuse: 0

Dairy Auditor Score Sheet

Date Producer Number of milk cows: Dry cows:	Bred heifers: 6-12 months 0-6 months
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Overview of livestock health and conditions:

Extremely thin 1	Frame obvious 2	Body condition 3 Good fat cover	Well covered 4	Obese 5
Very clean 1	Hygiene 2 Manure stains	Wet or dry manure 3 On legs udder	Extremely dirty 4	
Normal 1	Locomotion 2 Slightly affected	Cannot keep up with herd 3	Limping 4	Can't bear weight 5
Hock condition 1 May have hair loss		Swelling 2		
Number of cows missing patches of hair due to mange or lice	Number of cows with broken tails	Ammonia odor present		

Housing type: Milking herd _____ Dry cows _____
 Heifers _____ Calves _____

Three items done well at this farm:

Three items that may need attention at this farm:

Tally the number of cows that score in the appropriate shaded box.

Locomotion Scoring



Score 1 Normal Stands and walks normally. Her back is level. She makes long confident strides.



Score 2 Slightly affected - Stands with flat back and arches when she walks. Gait is slightly off.



Score 3 Cannot keep up with the grazing herd. Stands and walks with an arched back. Makes short strides and favors one or more legs.



Score 4 Lame - Arched back standing and walking. Favoring one or more limbs but can bear some weight on affected limb(s).



Score 5 Severely Lame - Pronounced arching of the back. Reluctant to move, with almost complete weight transfer off the affected limb.

Body Condition Scoring



Score 1 Extremely thin



Score 2 Frame obvious



Score 3 Frame and covering well balanced



Score 4 Frame not as visible as covering



Score 5 Obese

Hock Lesions



Score 1 No damage or may have patches of hair loss on the hock

Score 2 Swellings at the hock may be extensive, bleeding, or draining

Cow Cleanliness



Score 1 No manure stains or dried manure attached to cow.

Score 2 Manure stains but no dried manure attached to cow.

Score 3 Dried or wet manure on legs or udder.

Score 4 Cows with wet or dried manure on legs, udder, and ventral abdomen.

**National Organic Standards Board
Livestock Committee
Proposed Recommendation
Species-Specific Guidance**

October 14, 2011

Introduction

Animal welfare is a basic principle of organic production. As the number of farmers in the United States decline, consumer concerns for farm animal care have increased. There are numerous animal welfare organizations and methods to verify animal welfare. The Livestock Committee wishes to provide guidance that will assist producers and certifiers to improve and assess welfare on farm and assure consumers that animals are well cared for and that the organic community is leading with a focus on continuous improvement.

Background

The United States Congress anticipated the need to elaborate livestock standards in 1990 when the Organic Foods Production Act was passed. The Humane Society of the United States played a central role in advocating for the passage of OFPA. It was understood at that time that animal welfare standards would eventually be developed. Several animal health and welfare practices were described in the Preamble accompanying the NOP Final Rule. An organic livestock farmer must conform to the following list according to the Description of Regulations:

- 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

The NOSB was further tasked in the Preamble with creating species specific guidelines. These were to include specifics on temporary confinement, space requirements, and management guidance. The current Livestock Committee has worked with Temple Grandin, the Livestock Issues Working Group, and other individuals with specific areas of expertise toward completing this task. The Livestock Committee feels that outcome based standards best measure the health and well-being of livestock and will continue to work on those documents. The guidance documents are intended to help the program, certifiers and producers to understand and meet the regulations. These documents were written to enhance the regulations, clarify the expectation for animal welfare on organic farms and minimize the need for increased regulations.

Committee Recommendation

The Livestock Committee intends to develop species specific guidance for all species. To date, the Livestock Committee has worked with members of the organic community, certifiers, animal welfare specialists, and previous NOSB members to develop the following three species specific guidance pieces:

- I. Guidance for Assessing Animal Welfare on Organic Bison**
- II. Guidance for Assessing Animal Welfare on Organic Poultry Operations**
- III. Guidance for Assessing Animal Welfare on Organic Sheep Operations**

Committee Vote

Motion: Wendy Fulwider Second: Mac Stone
Yes: 4 No: 2 Absent: 1 Abstain: 0 Recuse: 0

Guidance for Assessing Animal Welfare on Organic Bison

Introduction

The North American Bison has undergone little modification through domestication or selective breeding. Consequently, it is still possible to compare the characteristics of today's bison to what was historically roaming the North American continent to identify the similarities to what is called typical for this animal.

Because bison remain largely undomesticated, the optimal nutritional requirements, and body conditioning will vary significantly on a seasonal basis. In addition, humane handling procedures are crucial to minimizing stress on the animals. We attempt to address those factors in this guidance document.

Bison Nutrition

General Guidance

Because bison are grazing ruminants with a four chambered stomach for feed digestion, it is easy to assume that the feed requirements for bison are similar to cattle. However, there are some significant differences in the species that require an understanding of the nutritional needs of bison.

A bison's rumen is very structured, ensuring that forage based feeds are retained for long periods of time. Bison retain feed in their digestive system longer than cattle.

Longer feed retention

means that bison have more time to digest the fiber in feeds such as sedges and grasses.

However, when

consuming alfalfa or alfalfa brome hay, there is virtually no difference in digestibility between

bison and cattle because the fiber level in alfalfa based forages is typically lower than in grasses and sedges. Forages with lower fiber levels do not need to stay in the digestive tract as long to be fully digested as compared to forages with higher fiber levels.

Bison seem to naturally self-limit intake with less dry matter consumed per unit body weight than bovines. Bison also consume feed in several small meals throughout the day vs. fewer large meals observed in bovines. This habit maintains a more uniform ruminal environment and may contribute to more complete nutrient extraction by bison vs. bovines.

Protein needs to be treated entirely different in bison diets than bovines. Bison recycle nitrogen efficiently, an evolutionary response to very low protein diets from mature

Comparison of total tract retention time and dry matter digestibility of forages between bison and cattle

	Bison	Cattle
Total Tract Retention Time (h)	78.8	68.7
Dry Matter Digestibility (%)		
Sedge hay	64	58
Grass hay	74	62

grasses during several months of the year. This recycling may cause high blood urea nitrogen levels from modestly high protein levels in the diet. In some areas, many feeds contain protein levels higher than many bison producers consider optimum making it difficult to formulate diets. Eleven or 12% protein is considered the maximum from anecdotal experience.

Animals given too high protein and feed have produced rapid growth and resulted in horn, hoof and kidney problems that lead to other problems. The over-feeding of high-nutrient feed may lead to lethargic animals that have trouble moving about, and could lead to calving problems. A cow needs nine percent protein just to maintain her condition over winter and try to develop her calf. Less than that amount of protein or severe winter could result in pulling her down physically, and thus would take more time to bring her back into condition prior to breeding. The result is a late calf or no calf the following year.

Forage samples alone would indicate that the forage or feed is sufficient for the bison's need, but examining the water could show that a critical element like copper is tied up by iron and manganese and thus causes a deficiency. Molybdenum, sulfate, nitrate, calcium and sodium can also cause mineral deficiencies due to interference. Many producers experiencing cold winter climates realize that they need to supplement with more of an energy supplement to insure that their animals have the energy to eat and be active.

Seasonal Considerations

Bison have a strong anabolic/catabolic cycle based on day length (anabolic means build up – catabolic means to tear down). All wildlife species in the northern hemispheres require this cycle for survival. It relies on the animal's ability to have a strong anabolic cycle in spring, summer, and early fall and survive nutritional deficiencies in the winter with the nutrients they stored during the anabolic cycle.

Summer grazing usually meets most bison nutrient requirements so long as carrying capacity is not exceeded and minerals are supplemented. If pasture quality and quantity is low, supplementation with hay or grains may be necessary.

It is not uncommon for bison older than 18 months of age to lose 10 to 15% of pre-winter body weight from December to April. Dry matter intake during the winter period tends to range from 1.4 to 1.8% of body weight depending on forage quality, fiber levels, metabolism and total tract retention time. In the spring to autumn, dry matter intake can be expected to range from 2.0 to 3.0% of body weight.

Nutrition and Bison Reproduction

Heifers/Cows

Bison typically mature at two years of age for both male and females. Some yearling females will breed at one year of age and give birth to a calf as they turn two years of age, but this is an exception. The nutrient intake during the pregnancy of first and second calf heifers is significantly higher than a mature cow, especially during the third

trimester. These young females must have sufficient nutrient intake to finish growing their own body in addition to finish growing a calf.

This nutrient demand will continue after the calf is born and taper off some as the calf forages on grass. Her ability to seek sufficient nutrition to grow and come into cycle during the normal breeding period is dependent on the quality of food available to her. The result is that calves are then born 45 days following the spring equinox. Normal practice is to breed females at age two with bulls that are two years or older. If a heifer does not attain sufficient size, it may be difficult for her to stand up under the weight of large mature bulls. A key concern for first and second calf heifers is to grow them to sufficient size prior to being bred to insure pregnancy each year of their lives.

A critical issue affecting pregnancy is the ability of a female to flush on highly nutrient forage or feed. Spring time usually brings forth lush vegetation that is high in nutrients. Having this available to females that have recovered from previous pregnancies will help insure a high calving percentage the following year.

Drought and high temperatures prior to and during the normal rut (breeding) period can have a negative effect on pregnancy rate. Often times, a fall green up will cause a flush in the cows that did not breed or take during the normal rut period, and the result is a late calf the next year.

Bulls

A bison male at 18 months of age will begin a lifetime cycle of winter weight loss followed by spring/summer weight gain. Mature bulls will also lose weight during the breeding season, followed by a final period in the fall to allow for weight gain.

Much like mature females, bison bulls can lose 10 to 15% of their pre-winter body weight from December to April due to a slower metabolism. During this winter period, dry matter intake will range from 1.4 to 1.8% of body weight. If grass hay diets are supplemented with grain, winter weight loss will be minimized, but compensatory gains in the spring and summer will not be as great.

During the breeding season, bulls can potentially lose 10 to 15% of body weight again. Therefore, it may be necessary to provide extra energy through supplementation to prevent too much loss of body condition. Excessive loss of body weight during breeding makes it more difficult for the bulls to regain a proper weight status prior to the start of the wintering period. It is important to ensure the bulls are of adequate body condition prior to the winter and breeding seasons. Much like the cows, thin or poorly conditioned bulls entering the winter will still lose weight and be more expensive to feed.

Body Condition and Scoring

As mentioned above, the idea body condition for bison is based upon the attributes that the animal carries in nature. Survivability and low management requirements are important characteristics.

Even though bison in commercial organic operations are selected for the meat marketplace, it is important that the commercial characteristics (size, yield, etc.) are not accomplished at the expense of sacrificing the unique genetic characteristics that allow bison to survive in a wide variety of conditions, and to calve easily. In other words, bison producers must avoid an attitude of —saw the hump, and build the rump.”

Bison characteristics are usually developed and identifiable by the time they mature at two years of age. The characteristics become more pronounced with age such as the horn growth and overall size. Calves start exhibiting typical bison characteristics late in their first year of life. The more angular and triangle shaped heads, greater horn bases and growth are found on the males, while the females have smaller horns both in diameter and length.

Female bison heads are longer and narrower than the male. Female horns are typically more curved and possess less circumference and more curvature, with the horn tips curved up and inward and often times pointing at each other.

Typical bison characteristics of the Plains bison, (*Bison, bison, bison*), include long hair under the chin forming a large rounded beard, long hair on the front legs forming leggings, and a raised pelage of usually longer and lighter colored hair located over the front shoulder. The pelage extends along the back to just behind the front shoulders. The raised hump is a distinguishing characteristic as well. Calves should exhibit the development of the hump as they approach one year of age.

Wood bison, normally associated with the Canadian provinces, (*Bison, bison athabascae*) tend to have less developed beard, leggings, and an incomplete pelage. The structure of the Wood bison is taller, more moose-like in form. The incomplete development of the beard, leggings and raised pelage, and the body higher off the ground is an advantage for Wood bison, who have to endure the deep snow and ice conditions found in Canada.

The head and neck projection of the Plains bison favored grazing of the plains in more mild climates. The Plains bison's highest point is typically found by extending a line straight up the center of the leg to a point on the back. The highest point on a Wood bison is also the hump, but it is typically projected as much as one foot forward from a line extending up the middle of the front leg to a point on the back.

Bulls that have to compete within a herd for breeding rights need to have size, muscling and strength less they be overpowered by a bull having more strength. Bison strength is a result of a wide and deep body conformation. The lack of muscle development may be attributed in part to nutrition and exercise.

Female bison need to have sufficient —spring of rib” (width and depth to provide for room for an unborn calf to grow, develop and be born). Pelvic structure is important. Females possessing a narrow pelvis or a serious drop in the top line in the last foot before the tail could very easily develop calving problems due to restriction of the birthing canal. A high tail head can also produce a problem, due to narrowing of the birthing canal to compensate for the projected high tail head.

Bison are seldom caught in a squeeze to allow a —hands on” body condition scoring system so most of the criteria used to assess the animal are visual clues. A body condition score (BCS) of 1 indicates that the animal is very thin. A BCS of 5 indicates that it is very fat. Alberta Agriculture has developed a comprehensive guide for body conditioning scoring for bison. The table below is excerpted from that guide. The entire guide is available at: [http://www1.agric.gov.ab.ca/\\$department/deptdocs.nsf/all/agdex9622/\\$FILE/bcs-bison.pdf](http://www1.agric.gov.ab.ca/$department/deptdocs.nsf/all/agdex9622/$FILE/bcs-bison.pdf). The guide can also be obtained through the National Bison Association at www.bisoncentral.com.

BODY CONDITION SCORING GUIDE FOR BISON

This table can be used to score bison in the field.

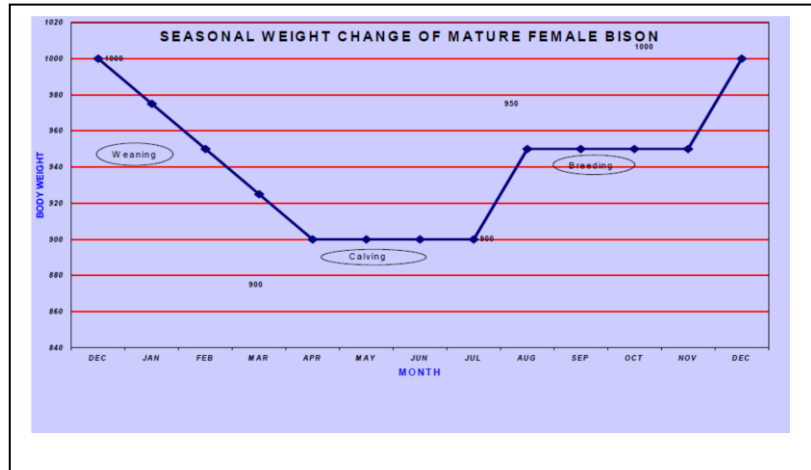
BCS	RIBS	SPINE (backbone)	HIP BONE	TAIL HEAD	HUMP
1 very thin	prominent in summer; many ribs visible; in winter, visible but less distinct	very sharp; angle of muscle is steep	prominent and edges are very sharp; rump muscles are caved in	devoid of fat; deep sunken depressions on either side of the tailhead; no fat palpable if bison is in a squeeze	sharp topline; narrow with flat sides when viewed from the front; sharp contrast between the hump and shoulder when viewed from the side
2 moderately thin	some ribs visible in summer and winter	evident but not sharp; angle of muscle is steep	readily seen and edges are sharp; rump muscles caved in slightly	sunken depressions on both sides of the tailhead; small amount of fat palpable if bison is in a squeeze	hump is narrow but not sharp; sides are flat when viewed from the front; distinct contrast between the hump and the shoulder
3 moderate	may be visible in summer but not sharp or distinct; edges round and covered in flesh; not visible in winter	not prominent but can be seen; angle of the muscle has a moderate slope similar to the roof of a tent	visible but not sharp; rump muscles are flat and angular	slight hollowing on either side of the tailhead; some fat palpable if bison is in a squeeze	well developed but not bulging; noticeable distinction between the hump and shoulder
4 moderately fat	may be visible in summer but not sharp or distinct; edges round and covered in flesh; not visible in winter	not readily seen; angle of the muscle has a gentle slope	barely visible; muscles are full but not bulging	slight depression in bulls and no depression in cows	full hump when viewed from the front but not round and bulging; little distinction between the hump and shoulder when viewed from the side.
5 very fat	not visible in winter or summer; covered in fat	not visible and is buried in fat; angle of muscle has little slope and is flat	covered in fat and is not seen; rump is rounded out and full	no depression (bulls) or bulging with fat (cows) on both sides of the tailhead	thick with rounded top when viewed from the front; blends into the shoulder when viewed from the side

Source: Alberta Agriculture, "What's the Score; Bison"

[http://www1.agric.gov.ab.ca/\\$department/deptdocs.nsf/all/agdex9622/\\$FILE/bcs-bison.pdf](http://www1.agric.gov.ab.ca/$department/deptdocs.nsf/all/agdex9622/$FILE/bcs-bison.pdf)

Optimal body condition for bison varies with the seasonal weight fluctuations of the animals.

For example, the weight of mature females will vary up to 15% throughout the year. The animals' typically achieve top weight in the late fall as they graze to store fat to provide energy for both mother and unborn calf to overwinter. The females will lose up to 100 lbs. from December to April, when calving season typically begins.



The chart at right illustrates a typical weight change for mature female bison.

Most people aim to have their bison fat in the fall so that they do not require as much feed over the winter. Most experienced producers aim to have their bison lean in the spring because excess fat may lead to calving problems.

By the beginning of breeding season, the cows should be back to a moderate to good body condition to ensure optimal conceptions rates.

The best indication of overall bison health and condition throughout the season is the hair. Healthy animals have a good hair coat that is full of life that may give a producer an indication of proper nutrition.

TIME OF YEAR	IDEAL SCORE	RANGE
November	4	3-4+
April	2+	2-3
July	3+	3-3+

Bison Health

Bison are not cattle. Differences include the age to breeding (2.5 years), nutritional requirements over winter, nutrition for slaughter animals, social structure, and longevity. Bison have a relatively good resistance to many pathogens that affect cattle.

The two primary factors affecting the health of bison are environmental/nutritional considerations, and chronic stress. Paying attention to these two areas is critical

because typical livestock therapeutic drugs are not as effective in bison as in cattle. In fact, one saying in the bison business is: —A sk bison is a dead bison.” Because bison still carry the prey/predator instinct, they will mask a sickness until seriously ill (why let the predators know your sick?). At that point, antibiotics and other therapeutic remedies will have only limited efficacy. In addition, the added stress induced to administer the treatment is so great that it often pushes the animal over the edge. This stress can be effectively eliminated by using one of the modern air-powered dart guns.

Poor environmental and feed conditions will weaken the animal’s natural immune system, and increase susceptibility for disease. A successful organic systems plan for bison must focus heavily on the ecosystem and developing systems that will provide optimal nourishment for the bison while sustaining the natural environment.

Chronic stress will have the same effect as more environmental and nutritional conditions. Bison can readily handle the acute stress that comes from a short-term perceived threat. That is the “fight or flight” response to a stimulus. They can fight or run from grizzlies or humans and when all threats are passed, go back to grazing and the adrenalin and steroid levels return to normal. However, they react poorly to extended or continuous (chronic) stress. That stress can be minimized through humane handling procedures (discussed later).

Pathogens

Bison have a strong resistance to many pathogens prevalent in other livestock. Much of this resistance is the result of the —bottleneck” that the species passed through roughly 110 years ago.

In the 1850’s, the bison population was estimated to be somewhere between 30 and 60 million animals. The domesticated livestock species introduced to the West allowed the pathogens these species carried to adapt to these new and different species. BVD, IBR, PI3, BRSV, TB, Johne’s, mycoplasma, leptospirosis, clostridia, Staph, Strep, internal and external parasites and probably pasteurella found a plethora of new ways to reproduce and spread their DNA (genes) to the demise of these native ungulates.

In the late 1800’s, bison were driven to the brink of extinction because of market hunting, war tactics against the Native Americans, and because of the introduced pathogens. Fewer than 1,000 bison survived this onslaught. The surviving animals were those bison that had a genetic resistance to these new pathogens. Testing of wild ungulate species has been undertaken for the past several decades across the western states. All wild populations show exposure to these introduced pathogens without large detrimental effects - yet these same pathogens remain of utmost importance to the livestock industry.

Today, the primary diseases affecting bison are bovine TB, brucellosis, Bovine Virus Diarrhea (BVD) and Malignant Catarrhal Fever (MCF).

Bovine Tuberculosis (TB)

Bovine Tuberculosis (TB) is a slow, progressive bacterial disease that is difficult to diagnose in the early stages. As the disease progresses, animals may exhibit emaciation, lethargy, weakness, anorexia, low-grade fever, and pneumonia with a chronic, moist cough. It usually is transmitted through contact with respiratory secretions from an infected animal. TB is a zoonotic disease meaning it can be transferred to other species, including man.

Free-ranging and privately owned bison in the U.S. have been free of TB for several decades. TB testing in bison has proven to be effective in diagnosing infected animals. If you are buying animals to start or augment your herd, have the bison over 12 months old tested. Many states are TB free and testing is not required, but as a precautionary measure require TB testing before purchasing.

Brucellosis

Brucellosis is a disease that has strong regulatory and economic guidelines for all states. A majority of states have been brucellosis free in livestock for many years.

The notable exceptions are the states that border Yellowstone National Park. State and federal regulatory agencies consider the Greater Yellowstone Area (GYA) an area of interaction with these wildlife species the last nidus of infection in the U.S. Brucellosis was introduced into bison and elk in the early 20th century. Once the organism was in these wildlife populations it became problematic to control. To this day 20 to 40 percent of the bison and elk in the GYA have been proven to harbor titers from exposure or infection.

Abortion is the most obvious indication of the disease in a herd. Brucellosis is a disease not spread from cow to cow, but from a birthing or abortive event where the abortive event including the aborted, stillborn, newborn calf and afterbirth are exposed to other animals. There are several tests to determine if bison are infected or exposed. These tests are, for the most part, accurate. There are cross-reactions with other organisms that can create suspects in your bison. Regulators are working on being able to identify these other organisms and incorporate them in the battery of tests for brucellosis —suspect” bison.

Calfhood vaccination for brucellosis (Bang’s vaccinations) is not mandatory in many states. The vaccine (RB51) is safe for use in bison. It is not as protective against abortion or infection as in cattle, but does offer limited protection. Brucellosis is also a zoonotic disease and can be transmitted to other species including man.

Bovine Virus Diarrhea (BVD)

Anywhere in the world there are cattle, there is Bovine Virus Diarrhea (BVD). This worldwide distribution makes this disease important to cattle producers. BVD is a complicated disease to discuss as it can result in a wide variety of disease problems from very mild to very severe. BVD can be one of the most devastating diseases cattle encounter and one of the hardest to get rid of when it attacks a herd. The viruses that

cause BVD have been grouped into two genotypes, Type I and Type II. The disease syndrome caused by the two genotypes is basically the same. However, disease caused by Type II infection is often more severe in cattle. The various disease syndromes noted in cattle infected with BVD virus are mainly attributed to the age of the animal when it became infected and to certain characteristics of the virus involved.

As mentioned earlier, bison appear to be resistant to clinical manifestations from exposure. BVD has been incriminated in losses of bison placed in feedlots in conjunction with cattle. Vaccinations for BVD Type I and Type II are effective in preventing the disease in bison. I have never seen the disease in free-ranging or any captive herd.

Malignant Catarrhal Fever (MCF)

Malignant Catarrhal Fever (MCF) is a generally fatal disease of cattle, bison, true buffalo species, and deer. It is caused by viruses belonging to the Herpesvirus family. MCF occurs worldwide and is a serious problem, particularly for bison in the United States and Canada.

MCF in bison is caused by a virus called ovine herpesvirus-2 (OvHV-2). Most infections are characterized by depression, separation from the rest of the herd, loss of appetite, and in many bloody diarrhea. Unlike MCF in cattle, discharge from the eyes and nasal passages of affected bison is minimal. Animals develop a fever and may pass bloody urine. The clinical course is generally 1-7 days. Most animals die within three days of developing clinical signs. There is no effective treatment for MCF in bison. Bison older than six months, particularly if stressed by bad weather, transportation and handling are the most susceptible to infection. Large outbreaks occur in feedlots, where stress due to crowding is likely.

Studies of field outbreaks strongly suggest that sheep infected with OvHV-2 are the principal source of MCF outbreaks in bison. A strong association between outbreaks in bison and recent exposure to sheep has been documented repeatedly since 1929. In some outbreaks, however, no sheep were in the vicinity immediately prior to the first case being identified. There is no evidence that transmission occurs horizontally from one bison to another. Currently there is a study supported in part by the National Bison Association to establish whether bison-to-bison transmission is a factor in natural outbreaks.

Internal parasites

It is necessary for special attention to be given to managing internal parasites on organic bison operations. Each parasite's life cycle is different and many cycles can be interrupted by changes in management. Sometimes small changes in the way the producer pastures or feed bison may slow or stop the future spread of the parasite based on the available facilities.

If breed selection, pasture management, supplements and allowed treatments are not successful in keeping sheep parasite loads from impacting well-being, individual animals need to be given conventional treatments.

External Parasites

Ticks and lice have been identified on bison and could potentially be detrimental. Bison have a thicker hair coat and identification of lice in bison is rare. Ticks have been found on bison around the tail head. In many areas where elk and deer are infested with ticks, bison sharing the same habitat are tick free.

Physical Alterations

Consistent with the low-management approach to bison, bulls are not castrated. Nor is there any need to dehorn bison.

Bison Handling

The primary objective of any handling program is to reduce stress on the animals while assuring the safety of handlers. A bison organic systems plan must discuss how the producer will handle or move bison; how they manage them on range; how they confine and feed them; as well as how they are worked in the corral.

It is important to recognize that bison are an extremely social animal with strong matriarchal divisions. Establishing a herd with the correct social balance, and the ability for animals to express their natural behavior, is the first step in reducing stress.

Bison have a very intact social structure that has definite spacing requirements between individuals and family groups. This spacing requirement may be different for different sexes and ages of animals throughout various times of the year. Herds that generate their own replacements from offspring will develop family groups between related individuals.

The pasture environment includes the size and shape of the pastures, forage quantities and qualities available, watering sources, spatial requirements for individuals and/or family groups as well as a myriad of other considerations. Social stress will become a factor if pasture size is too small to give adequate spatial requirements for individuals or family groups for large herds. This causes discontent and disharmony within the herd, causing animals to breach fences and become difficult to handle.

Bulls will separate from the herds after breeding and only young bulls are allowed to stay with the cows and calves. Post-breeding, the bulls have been nutritionally and physically stressed and should be checked for wounds or other forms of trauma.

Corrals

Corrals and working facilities should be designed to minimize the stress on animals, and to facilitate the ability of handlers to gently apply and release pressure. The amount of space allowed for each individual animal depends upon the amount of time that the animal will be maintained in the corral. When animals are introduced into a new herd, it is advisable to house those animals in the corral for several days so that the animals can adjust to their new environment. The producer should allow a minimum of 250 sq. /ft. (preferably 400 sq. ft.) per adult animal in this type of confined situation.

Never place just one bison in a corral or pasture for extended periods. Because they are extremely social, they will experience chronic stress when isolated from the herd.

When handling bison, the producer should strive for a gentle “dance” of applying pressure, the animal moving away from the pressure and then releasing the pressure. The fact that we move into an animal’s flight zone giving it pressure and when it moves away from us, we release the pressure by either not moving with them in the same direction (by stopping) or we move in a different direction. This sets up a positive cause and effect relationship – that is we get into their flight zone putting pressure on them, and they, by moving away from us get released from the pressure.

The National Bison Association—in cooperation with Dr. Temple Grandin of Colorado State University—developed has developed a bison welfare audit form to measure several areas of working bison in the corral. That audit form is included as an attachment at the end of the Guidance Document.

Inside housing is rarely used for bison. These animals are adapted for extreme weather conditions in the outdoors. Bringing the animals inside actually increases stress.

Calving

Human interaction with calving bison should be held to a minimum. Because bison have not been bred to produce calves larger than nature intended, cows rarely need assistance in calving.

One of the most important things a bison cow needs at calving time is peace. There is no fixed rule regarding amount of space a calving bison cow needs. However, the producer can judge that space by monitoring the cow’s behavior: If she changes her behavior with the producer’s presence (such as standing up, running off or her labor arrests) she needs more space. If the other bison pester her and she cannot get away, then she needs more room.

Nature also needs the cow to be leaner to give birth effectively. A fat bison cow will have trouble giving birth, and the calf from such a cow will likely be too big and too hard to birth.

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Guidance for Assessing Animal Welfare on Organic Poultry Operations

Introduction

The following is provided to aid in assessment of whether or not the requirements of § 205.238-241 are being met sufficiently to demonstrate adequate animal welfare conditions on organic poultry operations. In addition, this document provides further guidance to producers for improving poultry welfare. The internationally recognized “five freedoms” (freedom from hunger, thirst and malnutrition; freedom from fear and distress; freedom from physical and thermal discomfort; freedom from pain, injury and disease; and freedom to express normal patterns of behavior) promulgated by the Farm Animal Welfare Council are a useful framework for considering animal welfare.

Nutritional requirements

Poultry must be fed a wholesome diet that meets their nutritional needs and promotes optimal health. Feed should be formulated to meet or exceed the National Research Council's *Nutrient Requirements of Poultry*, and adjusted with bird age and stage of production. Feed and water should be palatable and free from contaminants. Unless using a commercially prepared complete feed, laying hens must have access to a coarse calcium source, such as ground limestone. Water should be fresh, potable, and clean. Feed and water delivery systems should be checked daily and kept clean and in good working order. Birds must be provided with feed on a daily basis and water should be available continuously, with the rare exception of withholding for medical treatment under the advice of a veterinarian.

There should be enough feed and water space to prevent competition between birds. In double sided liner feed track, there should be at least 2 inches of feed space per bird, and 4 inches per bird for single sided feed track. Circular feeders should provide at least 1.5 inches of feeding space per bird.

Adjust the height of drinkers for easy access at each bird age and so that droppings do not fall into the water supply. There should be at least 1 bell-type drinker for every 100 hens and 1 nipple drinker per 12 hens. In small flocks, there should be a minimum of two drinkers.

Physical Alterations

Management methods should be implemented to reduce feather pecking and cannibalism (see “preventing injurious pecking” below). If these management strategies fail, therapeutic beak trimming using the infrared laser method should be considered for subsequent flocks. This amputation must be performed on chicks no later than 10 days of age, and is commonly carried out at the hatchery.

While not pain-free, infrared laser beak trimming is superior to the conventional hot blade trimming in that open wounds are eliminated and the method is more precise,

minimizing error and inconsistency. It also leaves a greater proportion of the beak intact.ⁱ

With the exception of toe trimming of turkey poults at the hatchery using infrared laser, other alterations including de-snooding, caponization, dubbing and toe clipping of birds are not permitted.

Force Molting

Forced molting by feed withdrawal is not permitted under the National Organic Program, as it causes hunger and distress. If force molting is practiced, a molt ration should be supplied that is palatable and acceptable to the birds. A molt diet is acceptable to the birds if, on average, the total amount of feed consumed per day does not differ during the molting and non-molting period. Flocks should be carefully monitored during a molt, and individual hens that are not faring well should be separated into a designated sick pen and provided with a non-molt diet. Water should never be withheld for molting purposes.

Poultry health

Poultry should be monitored for signs of stress and disease. Birds should have a healthy body condition, have good feather cover for their stage of life, and no more than 2% should have poor hygiene, lesions or other injuries. Sick or injured birds must be treated without delay or, if suffering and unlikely to recover, euthanized humanely. Producers must not withhold medical treatment from a sick animal in an effort to preserve its organic status.

Animal health plan

All poultry farms should draft and follow an animal health plan that covers the specific circumstances unique to each farm. The plan should include, at a minimum, the disease prevention strategy (such as vaccination schedules and biosecurity protocols), contingency plans for emergency situations (including failure of the power or water supply), predator exclusion steps, veterinary contacts and emergency euthanasia procedures.

Sick pens

A designated area for the treatment of injured or moribund birds should be prepared to aid recovery, by preventing competition between birds and allowing a greater level of individual care. Sick pens should be arranged for the comfort and safety of the birds during convalescence. Feed and water must be provided, with the rare exception of withholding for medical treatment under the advice of a veterinarian.

Lameness

Broiler chickens, turkeys and ducks are prone to leg problems, including angular deformities, tibial dyschondroplasia (TD), and in severe cases, ruptured tendons. These may manifest as lameness or more severe mobility impairment.

Gait scoring is a tool that can be used to assess the degree of lameness in a broiler chicken flock.^{ii,iii,iv} Randomly score 100 birds individually by viewing their walking ability using the following scale:

Score 0. No detectable gait impairment

Score 1. Slight gait defect. Wobbling or uneven gait.

Score 2. Gait abnormality. Bird has impairment, but will move away from handler when approached.

Score 3. Gait abnormality that impairs function. Bird has a limp, jerky or unsteady gait and moves away from the observer when approached, but squats again within 15 seconds. Bird prefers to squat when not coerced by handler.

Score 4. Severe gait defect. Bird remains sitting when approached or nudged, but can stand or walk when placed in a standing position by a handler.

Score 5. The bird is completely lame and cannot walk. The bird may shuffle along on its hocks.

Gait score tends to worsen as birds age.^v Birds that are suffering or are too crippled to reach feed and water should be humanely euthanized. Birds at gait score 3 and above are probably experiencing pain,^{vi,vii} so ideally no birds should reach this level. However, a reasonable place to set the target for lameness is that 95% of the birds should be gait score 2 or less at seven weeks of age or older.

Broiler chickens, turkeys and ducks are also prone to contact dermatitis. When heavy birds spend excessive time lying down in wet or soiled litter, they are prone to skin lesions on the feet, legs and breast.^{viii, ix,x} Focal ulcerative dermatitis is small skin lesions (commonly called —~~breast~~ breast buttons”) that develop on the keel bone of turkeys.^{xi} A reasonable place to set target levels is that no more than 5% of birds should show hock burn, breast blisters or foot pad dermatitis.

Additional producer guidance on preventing leg problems

While dietary deficiencies are one factor that can lead to skeletal deformities,^{xii} genetic selection for rapid early growth rate is the major contributing factor. Rapid growth is also implicated in metabolic disorders, including ascites and Sudden Death Syndrome.^{xiii} Some commercial broiler crosses are more susceptible to leg problems than others,^{xiv} but slow growing broiler strains are generally less prone to these weaknesses. They are also less prone to heart and circulatory problems.^{xv} The use of slow growing breeds is therefore recommended. Broiler growth should be limited to no more than 45g per day and should be achieved without feed restriction.

Other factors that can improve gait score include: increasing the daily period of darkness, lowering the stocking density, and adding whole wheat to an otherwise balanced diet. Increasing the daily period of darkness allows chickens more time to rest and less time to feed. Feeding whole wheat is thought to be effective though slowing the rate of digestion. Both of these interventions work through reducing growth rate.^{xvi} The reason that higher stocking densities can lead to lameness is more complex,

involving both lack of room available for exercise and movement, as well as factors such as additional ammonia and litter moisture.^{xvii,xviii,xix}

Additional producer guidance on preventing dermatitis

Dermatitis lesions are painful and create a gateway for bacterial infection. Avoid them by preventing wet, sticky, or compact litter. Use bedding with good moisture holding capacity, such as wood shavings, and keep litter dry (but not dusty), with good ventilation. Drinkers should be monitored to ensure they are not spilling over and causing wet areas in the litter. Water nipples with drip cups can reduce water spillage.^{xx} Moisture and temperature of the litter increase with stocking density, so if these variables become problematic, it may be necessary to raise fewer birds in the allotted space.^{xxi} Manually turning the litter can help. Floor heating systems have also been found to improve litter quality.^{xxii}

Conversely, well-managed litter is a soft substrate, while outdoor environments can cause abrasion and foot-pad dermatitis if not carefully managed.^{xxiii} Birds should be kept on cushioned, dry, clean surfaces outdoors. Rotate or move birds onto fresh pasture often enough to prevent the build-up of droppings and damage to the protective vegetative cover.

Feed composition affects the consistency and composition of bird droppings, and is therefore a factor influencing irritant qualities of litter. Protein, fat and salt content can all affect the levels of contact dermatitis, as can the source and type of raw ingredients. Within the limits of meeting nutritional requirements, adjustments to the diet may help improve litter quality.^{xxiv}

For ducks, bell-type drinkers and open water troughs have been correlated with low levels of foot pad dermatitis. Conversely, foot pad dermatitis tends to worsen in houses with nipple drinkers. There is also evidence that increasing relative humidity and ammonia levels are associated with foot pad dermatitis of ducks.^{xxv}

The health status of the flock will also affect the prevalence of contact dermatitis. Intestinal parasites, infectious disease, and poor feed quality can cause diarrhea, which will negatively impact litter friability (looseness and dryness). Prevent coccidiosis and other enteric diseases and feed good quality feed. Also strive to reduce leg problems, as lame birds will sit for longer periods of time in contact with litter.^{xxvi}



Varying degrees of foot pad dermatitis on the feet of turkeys



Foot pad dermatitis and hock burns on a broiler chicken

Disease

Disease incidence is a welfare indicator. Respiratory disease may indicate poor air quality. Incidence of internal parasites can indicate management issues such as lack of sanitation and failure to rotate outdoor areas often enough.

Poultry houses must be cleaned out completely between flocks if there have been adverse health issues with the previous flock; in other cases, the addition of a clean layer of litter will help maintain a sanitary environment.

If there is a documented occurrence of a disease outbreak in the region or relevant migratory pathway, or state or federal advisory order to confine birds, then poultry must be kept indoors to reduce the likelihood of pathogen transmission.

Any dead birds must be removed daily and disposed of in accordance with state and local laws.

Additional producer guidance on management of disease risk

Disease risk should be managed by using multiple approaches, including attention to outdoor range area, good litter management indoors, adherence to an effective biosecurity plan and ensuring clean, hygienic facilities.

Overcrowded and unsanitary outdoor environments are a disease hazard. Providing a rest period in-between flocks reduces the buildup of infectious organisms and allows the regeneration of vegetation and soil. Where stocking density is high, the environmental pathogen load may be correspondingly heavy, and bird-to-bird contact will be more frequent. Providing as much space as possible is therefore important, and the stocking density guidelines set out in the organic rule are minimum space allowances—where conditions permit, the aim should be to lower stocking densities and provide as much space as possible, while balancing freedom of movement with safety of the flock, including protection from predators.

Disease risk can be reduced in barn housing by removing droppings (e.g., via a belt in aviary systems, for example) or by preventing birds from accessing heavily soiled areas (e.g., by placing drinkers on a raised, slatted platform above a manure pit). Contact with droppings—exacerbated by high stocking density and wet, cool conditions—is a risk factor for enteric disease.^{xxvii} Litter that “isn't working”, leaking drinkers, and an inadequate ventilation system (to remove water vapor) may all increase disease risk.^{xxviii,xxix} Maintain litter in friable condition.^{xxx,xxxi} Introduce only healthy young birds from genetic lines resistant to intestinal parasites.^{xxxii}

The build-up of parasites around the barn can be avoided with the use of mobile housing,^{xxxiii} pasture rotation, reduced stocking density, and by using land with good drainage.^{xxxiv,xxxv} Other methods that are helpful include regularly mowing or grazing to keep vegetation short on pasture, and removing heavily contaminated soil around the barn before introducing a new flock.^{xxxvi} Gravel around the outside of permanent housing structures, by the exits where birds tend to congregate, can prevent muddy conditions in wet weather and provide additional drainage.

Biosecurity is a strategic plan to prevent the introduction of harmful pathogens. A good biosecurity plan will minimize disease risks and protect flocks. To prevent the spread of disease, limit movement between flocks and outside visitors. Always start with the youngest birds on the farm when doing daily chores and inspections to avoid carrying pathogens from older flocks to younger flocks. Microorganisms, such as coccidiosis for example, can be spread on vehicles and equipment, so designate specific tools and equipment for each poultry house or farm area. Transport crates should be cleaned between uses. Visitors should not enter a poultry farm if they have recently visited other flocks, unless they wear protective, disposable outerwear at both locations and ideally change clothes and shoes and shower between farms.

Mortality rates (deaths, culls)

Mortality rate is a key indicator of poultry welfare. Low mortality is also important for the economic viability of a poultry or egg production enterprise. A reasonable place to set the target for mortality is 3-5%. Birds must be protected from predators.

Additional producer guidance on lowering mortality rates

A low mortality rate is the hallmark of a well-managed poultry farm. Mortality spikes can be caused by a number of different problems, including disease outbreaks, cannibalism, and excessive losses due to predation. It is vital that producers take steps to prevent each of these outcomes, as they are all serious welfare and economic problems.

When poultry are given outdoor access, they become targets for many types of predators including coyotes, opossums, hawks, owls, and domestic dogs, to name a few. Predation is a welfare issue, as birds may suffer when attacked, are not necessarily killed quickly, and flocks can become fearful and reluctant to use outdoor areas if they are threatened by repeated attacks. To protect free-range flocks from nocturnal predators, birds must be secured in a fully enclosed coop, barn, mobile chicken house or other safe facility at night, *without fail*. Depending on the predator pressure at individual farm sites, further steps may be necessary; perimeter fences can be dug deep in the ground to prevent predators from digging underneath, and an overhang at the top of the fence will help prevent animals from climbing over. Electric fencing can further discourage ground predators, and overhead netting may be necessary to protect hens from aerial predators. Do not permit repeated heavy losses.

Preventing Injurious Pecking

Injurious pecking, including feather pecking and cannibalism should be managed so that severe outbreaks do not occur.

Additional producer guidance on management of injurious pecking

Feather pecking and cannibalism are common behavioral abnormalities of poultry, usually most problematic in large flocks of laying hens, but also sometimes seen in other poultry such as turkeys, ducks and pheasants. Severe feather pecking can lead to denuded plumage and eventually to cannibalism.^{xxxvii,xxxviii} Outbreaks of cannibalism are unpredictable, and once they begin, are very difficult to stop. Prevention is the best approach.

Beak trimming is commonly used as a prophylactic measure to prevent feather pecking and cannibalism. Beak trimming is usually effective in significantly reducing cannibalism and subsequent mortality,^{xxix,xi} although occasional outbreaks do occur in beak trimmed flocks. Beak trimming as a solution is not ideal though, as it is a painful procedure. Further, the beak tip is highly innervated and contains abundant sensory receptors;^{xli,xlii} cutting off the beak tip thus impairs sensory function. Welfare can be improved by controlling cannibalism using alternative means.

Dietary deficiencies have been linked to increased incidence of pecking damage,^{xliii} especially protein deficiencies,^{xliv,xlv} so the first step in preventing injurious pecking is to ensure that the feed is nutritionally complete. However, outbreaks of feather pecking still often occur in flocks that are fed to their nutritional requirements. There are a variety of other factors involved.

Successful control of feather pecking and cannibalism requires an integrated approach that includes consideration of three main factors: early-life experiences, the environment and genetics.^{xlvi}

Feather pecking and cannibalism are not aggressive acts—rather, science demonstrates that these are foraging pecks that have been re-directed toward feathers.^{xlvii,xlviii,xlix} In natural conditions, domestic fowl spend over 50% of their active time in foraging related activity.^{i,li} Studies have shown that hens will choose to forage for feed on the ground in loose substrate rather than eat identical food freely available from a feeder.^{lii,liii} Thus, the natural urge to forage remains strong, even when full feed is provided. The acquisition process itself—including seeking, investigating, and manipulating feed items—is nearly as important as the act of consuming the feed itself.^{liv}

Pecking preferences are formed early in life, and these are learned through experience.^{lv} Therefore, providing appropriate pecking and foraging substrate from day one^{lvi,lvii} is a critical factor shaping adult pecking preferences. Scientific research has demonstrated that early access to loose litter—such as wood shavings, sand and straw—is an important first step in reducing feather pecking, cannibalism and subsequent mortality.^{lviii,lix,lx,lxi,lxii,lxiii} Conversely, studies also show that the absence of loose-litter^{lxiv} and poor litter quality are risk factors for plumage deterioration due to feather pecking.^{lxv} Scattering grain or feed into loose litter for young chicks can also be beneficial.^{lxvi}

Lack of perches during early rearing is another important risk factor for feather pecking on organic farms.^{lxvii} Early access to perches can decrease cloacal cannibalism by giving potential victims a safe place to avoid hens who would peck them from the floor.^{lxviii,lxix,lxx} Young birds must learn how to successfully navigate perches by gaining experience with them from a young age, which shapes their cognitive spatial abilities.^{lxxi} Pullets should have access to perches elevated above 35 centimeters at no later than four weeks of age.^{lxxii,lxxiii} Higher perches are generally better,^{lxxiv} although they must be constructed and arranged in a way that allows easy access, or else hens can miss a landing, fall and become injured (see section on providing perches for laying hens in indoor housing below).

Feather pecking often begins to appear in affected flocks shortly after moving pullets from the rearing to the laying house. When transferring pullets, there are many potential stressors including changes in light intensity, diet, house layout and access to the outdoors. Stress can be partially alleviated by matching the rearing and laying

environments as closely as possible.^{lxxv} Do not change the feed or lighting program at the same time pullets are moved into the laying house.

Since cannibalism is thought to have a hormonal basis, the risk of cannibalism may be reduced by using lighting programs that delay the age at which hens first begin to lay eggs to after 20 weeks of age.^{lxxvi} Flocks that begin laying eggs before 20 weeks of age have approximately four times the risk for vent pecking as compared with flocks that begin laying at a later age.^{lxxvii}

When feather pecking outbreaks occur in adult hens, lowering the light level is a commonly used intervention. While somewhat effective, the problem with dimming the light is that, like beak trimming, the underlying cause of the problem is not addressed. To truly attend to the welfare issue, the natural early motivation of a hen to forage and peck should be channeled appropriately into desirable adult pecking behavior, as discussed above.

Feed form is also important for attracting and sustaining foraging related pecks and regulating appetite. Studies show that a mash diet is better than pelleted feed for reducing feather pecking and cannibalism.^{lxxviii,lxxix} The small particle form takes longer to consume, sustaining foraging related pecking behavior for a longer period of time as birds pick out individual feed particles.^{lxxx} A diet high in insoluble fiber has also been shown to help to reduce and control cannibalism,^{lxxx} and millrun, oat hulls, rice hulls, and lucerne meal are effective sources.^{lxxxii} Additional foraging enrichments such as maize, barley-pea silage, carrots,^{lxxxiii} straw^{lxxxiv,lxxxv} seeds in suet, and cabbage leaves^{lxxxvi} have been shown to attract interest and reduce the tendency to perform injurious pecking.

Most importantly, it has been repeatedly demonstrated in scientific studies that flocks making good use of an outdoor range area (where more foraging and exploring opportunities are provided for them) are significantly less likely to feather peck and cannibalize flock mates.^{lxxxvii,lxxxviii,lxxxix,xc,xci,xcii,xciii} One study found that when at least half the flock was observed outdoors during good weather, there was a five-fold decrease in the risk of feather pecking. On these farms, it is likely that hens are directing their pecking behavior at appropriate foraging substrate, rather than at each other.^{xciv} Therefore it is essential to provide attractive outdoor areas and encourage hens to go outside (see section on outdoor access below).

If possible, time the introduction of pullets into the laying house so that they will have good weather when the doors are first opened to permit outdoor access. If inclement weather prevents them from using the range area when they are young, it may be difficult to encourage them out when they grow older.^{xcv}

Other risk factors that have been associated with injurious pecking include:

- Restricting access to portions of the indoor litter area,^{xcvi}
- Restricting access to the outside range area,^{xcvii}
- Changing the diet three or more times during the laying period;^{xcviii,xcix}

- Using lights inside the nest boxes;^c
- Use of bell drinkers;^{ci,cii}
- Inadequate number of drinking places;^{ciii}
- Reduced indoor temperature (below 68° F);^{civ}
- Not keeping cockerels with the hen flock;^{cv} and
- Dietary deficiencies.^{cvi}

Feather pecking, cannibalism, and the associated mortality have genetic components, which means that these traits can be selected against in breeding programs.^{cvii,cviii,cix,cx} Different hen strains vary in their propensity to exhibit injurious pecking behavior.^{cxii} It is therefore critical to source hens that exhibit low levels of feather pecking behavior. Because breeding efforts to control cannibalism are ongoing, it is difficult to pinpoint lasting recommendations on specific genetic lines. If a severe outbreak occurs, consider using a different supplier, switch to a different hen strain, or use a different breed or hybrid altogether.

For more information on managing feather pecking without beak trimming see:

—A guide to the practical management of feather pecking & cannibalism in free range laying hens” at:

www.defra.gov.uk/publications/files/pb10596-feather-pecking-050309.pdf

Newberry RC. 2003. Cannibalism. In: Perry GC (ed.), Welfare of the Laying Hen, Poultry Science Symposium Series, 27 (Wallingford, U.K.: CABI Publishing, pp. 239-58).

Indoor Living Conditions

Housing must protect birds from the elements, maintain a comfortable temperature, provide ventilation and allow birds to exercise and conduct natural behavior. Cages are not permitted. Bedding indoors provides comfort, insulation, and pecking and scratching opportunity. However, it must be maintained in clean, dry condition. Slatted-floor systems are useful under watering areas to prevent wet litter.

The indoor climate must be modulated for light, temperature, and air quality to provide a comfortable environment for the birds. Lighting should provide for an 8 hour rest period daily. Indoor temperatures must not be so warm that birds pant or so cold that they huddle together. Ventilation must be adequate to prevent the buildup of ammonia. Ammonia levels should generally be less than 10 ppm. Ammonia level testing must be documented and ammonia levels must be at or below 25ppm. General levels can be tested using ammonia test strips and if excessive ammonia is noted a second test using passive dosimeter or gas detection tubes should be conducted. Dust should also be kept to a minimum.

Layers should be provided with nest boxes—at least one box per 5 birds is recommended. If community nest boxes are provided, there should be at least 9 square feet of nesting space for every 100 hens.

Laying hens must also be provided with perches—at least 6 inches of elevated perch space per hen is suggested. There must be enough perch and/or flat roost space for all hens to simultaneously rest off of the floor at night. Turkeys can be provided with elevated platforms and ramps in addition to or instead of perches.^{cxii}

Poultry must be provided with dustbathing areas. Preferred substrates include sand, wood shavings and peat. On outdoor range areas, chickens usually create their own preferred dustbathing locations in loose, dry dirt. Dustbathing balances oil levels in the feathers,^{cxiii,cxiv,cxv} and helps keep the plumage in good condition.

Ducks should have access to water for bathing and head dunking in addition to water for drinking. Water related activity is part of the natural behavior of waterfowl. At a minimum, ducks should be able to dip their heads and splash their feathers with water. This behavior will help keep their nostrils, eyes and feathers clean.^{cxvi,cxvii} Troughs are often used to provide an open water source and these can be situated on grids or slats over a drainage channel to prevent adjacent litter from becoming wet. Nipple drinkers do not permit ducks to wet their eyes or feathers, and can lead to poor eye and plumage cleanliness.^{cxviii} Open water sources should be cleaned daily.

Additional producer guidance on providing perches for laying hens in indoor housing
Perches are an important enrichment in indoor housing for laying hens. The foot of a hen is anatomically adapted to close around a perch,^{cxix,cxx} and this is the natural resting position for chickens. Perch use maintains bone volume and bone strength,^{cxxi,cxxii,cxxiii} and can serve as a refuge for subordinate hens to avoid aggressive interactions with more dominant hens.^{cxxiv} Research demonstrates that hens are highly motivated to perch at night.^{cxxv,cxxvi,cxxvii} When given a choice, hens often prefer to roost on higher perches as opposed to those that are closer to the floor.^{cxxviii,cxxix}

Bumblefoot is a bulbous swelling of the footpad caused by a localized infection.^{cxxx} Some hen breeds are more susceptible than others, and the condition is associated with poor hygiene and poor perch design.^{cxxxi,cxxxii} The use of plastic perches or the commonly used soft wooden perches measuring 25 mm (0.98 in) in width are thought to contribute to poor foot health, as manure and moisture are able to accumulate on the structure's top where the birds' feet rest.^{cxxxiii} Incidence of bumblefoot can be reduced by providing hens with hardwood perches that are approximately 1.5 inches in diameter with a flattened top^{cxxxiv,cxxxv} and by limiting walking exposure to mud and manure.^{cxxxvi}

Hens selected for egg production are prone to osteoporosis and subsequent bone fractures.^{cxxxvii,cxxxviii,cxxxix} These often go undetected unless hens are palpated by an experienced veterinarian. The way perches are arranged inside the poultry house can have an effect on the incidence of bone fractures. Research suggests that the upper limit on a hen's ability to jump from one perch to another is about three feet,^{cxli} and

angles greater than approximately 45° can be difficult to navigate.^{cxli} At a minimum, hens need approximately 6 inches of perch space to take-off, and 6-9 inches to land.^{cxlii} Perches should be large enough for hens to maintain stable footing, about 1.5 inches in diameter.^{cxliii,cxliiv} These general requirements may differ depending on the size and previous experience of the hen, so adjustments may be necessary for individual flocks. Injuries are more likely to occur if perch design and layout require hens to jump beyond their natural capabilities.^{cxlv}

Providing perches at a young age can also help reduce the risk of floor eggs,^{cxlvi} as pullets must be skilled at flying up and down in order to access elevated nest boxes.^{cxlvii}

Outdoor Access and Living Conditions

Outdoor access must be provided to all poultry, with the following exceptions:

- Pullets younger than 12 weeks of age.
- Broiler chickens younger than 4 weeks of age.
- Outdoor temperatures below 50°F.
- Other inclement weather such as heavy snow, sleet, rain, wind or extreme heat that would endanger the health or welfare of the animals.



Pullets must be provided outdoor access by 12 weeks of age, when weather permits. As a guide, doors for outdoor access should be at least 14 inches high, spaced uniformly and provide direct access to the outdoors. Total door opening should be at least 6 feet/1000 birds.^{cxlviii} Once layers are accustomed to going outdoors, a brief confinement period of no more than 5 weeks to allow for nest box training is permitted. Broiler chickens must be provided outdoor access by 4 weeks of age, provided that they are fully feathered and

weather permits.

Enclosed spaces that have a solid roof overhead (sometimes called “~~perches~~” or “winter gardens”) do not meet the definition of outdoor access and cannot be included in the space calculation of outdoor access.

Additional producer guidance on outdoor access

Outdoor areas for poultry should be fully vegetated, where possible. Grasses, legumes, and other forage provide interest and enrichment to poultry, who consume not only greens, but also insects, grubs, and seeds. However, high traffic areas tend to become denuded of vegetation, so steps must be taken to keep outdoor areas in good condition. Rotate the use of range areas by taking flocks off of pasture to prevent the buildup of infectious organisms and allow the re-growth of vegetation. Fields can also be rotated

between species with different parasite spectrums, such as cattle and poultry. Harvested crop fields also make good poultry runs.

Layout is important for attracting hens to use outdoor space. There should be plenty of exits from the hen house, and they should be easily accessible and large enough for several hens to pass through simultaneously. Since hens are prey animals, they are naturally wary of overhead predators, and will sometimes avoid open range if some sort of cover is not provided. Cover, either artificial or natural structures, should therefore be provided.^{cxlix} Natural cover can take many forms, including tall plantings of vegetation, bushes, and trees,^{cl} however, large swaths of thick undergrowth can actually attract ground predators if fences don't exclude them. Maize plantings and low pollard willows (*Salix*), for example, have worked on organic farms to attract hens outdoors.^{cli} In "tree range" production, the outdoor area is planted with short trees, such as orchard varieties. Flocks with canopy cover from trees are more likely to have better plumage condition at the end of lay than those without canopy cover.^{clii}



Artificial structures that provide shelter, shade, and security can also be constructed.^{cliii,cliv} Cover made from a wide variety of wood, plastic or recycled materials, in designs both low to the ground and high enough to include perches, have been innovated by producers with success. Camouflage nets are another option.^{clv} If artificial cover is portable, it can be moved to different range areas to encourage more even distribution of the flock, preventing buildup of

contamination over highly frequented areas.

For more information see: Fanatico, A. 2006. Alternative poultry production systems and outdoor access. Available through the National Sustainable Agriculture Information Service at: www.attra.ncat.org

Space Allowances

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

Livestock Species	Indoor Space	Outdoor Runs and Pens
Chickens		
Laying hens and breeders	1.5 sq ft / bird	2.0 sq ft / bird
Pullets	5 lbs / sq ft	5 lbs / sq ft
Broilers	5 lbs / sq ft	5 lbs / sq ft
Other poultry		
Turkeys and Geese—breeding, laying, or meat birds (pounds)	7.5 lbs / sq ft	2 lbs / sq ft
Ducks—meat	5 lbs / sq ft	2 lbs / sq ft
Ducks—laying hen	2 lbs / sq ft	1 lbs / sq ft
Ducks—breeder	3.3 lbs / sq ft	1 lbs / sq ft

Humane Handling of Poultry

Poultry should be handled quietly and firmly, with care taken to avoid unnecessary distress and dislocated or broken bones during catching and loading for transport. Poultry catching should be scheduled to minimize the time to slaughter as well as climatic stress during catching, transport and holding. Birds should not be picked up by the neck or wings.

Transport is a stressful experience,^{clvi,clvii} as birds are subjected to noise, vibration, motion, overcrowding, feed and water deprivation, social disruption, and potential temperature extremes.^{clviii,clix,clx} Aim to reduce these stressors and comfort the birds wherever possible. Transportation units should provide space enough that all birds can lie down at the same time and none are on top of each other. Birds must be protected from heat and cold. Delivery of poultry for slaughter should be scheduled such that they are not deprived of water for longer than 12 hours.

Birds must be fit for transport before being loaded for slaughter. Due to the stress involved, animals must be healthy enough to withstand the rigors of the journey. Birds exhibiting obvious signs of poor health, weakness or injury are not fit for transport. These birds should be euthanized using the most humane method available.

Inspectors should discuss procedures for poultry catching and loading with the producer and must observe poultry being caught and loaded for slaughter at the annual inspection and note percentage of birds with broken/dislocated legs/wings.

Additional producer guidance on humane handling of poultry

Low-stress handling is as important for poultry as it is for livestock. Although commonly carried this way, research shows that birds react with a significant stress response when picked up and held upside-down by the legs, as this is a physiologically abnormal

posture for chickens.^{clxi} Handling, crating and loading for transportation, have been identified by researchers as major sources of stress and trauma.^{clxii} Bruising and injuries are well-documented, and these are not only welfare problems, but can also result in carcass downgrading and economic loss to producers.^{clxiii, clxiv, clxv, clxvi, clxvii} Ideally, all poultry should be handled individually, upright, and carried gently using two hands.

Catching and carrying turkeys can also cause bruises and injuries. Turkeys can be driven or herded into transport crates instead, which reduces stress levels.^{clxviii}

Euthanasia and Depopulation

Individual birds who are ill or injured, are suffering, and are unlikely to recover, should be euthanized without delay. All euthanized and depopulated birds must be confirmed dead before disposal. No live birds should be found on dead piles.

Permitted methods include:

- Hand held electrical or percussive stunning using an instrument designed for the specific size/age of the species, followed by neck cutting;
- Cervical dislocation by stretching the neck to sever the spinal cord and cause extensive damage to the major blood vessels.
- Barbiturate overdose administered by a licensed veterinarian (with special considerations noted below)
- Decapitation
- Carbon dioxide or a mixture of nitrogen and argon gases, delivered in an appropriate container at acceptable concentrations.

Acceptable gas mixtures include:

- a minimum of 2 minutes exposure to any mixture of argon, nitrogen or other inert gases with atmospheric air and carbon dioxide, provided that the carbon dioxide concentration does not exceed 30 percent by volume and the residual oxygen concentration does not exceed 2 percent by volume; or
- a minimum of 2 minutes exposure to argon, nitrogen, other inert gases or any mixture of these gases in atmospheric air with a maximum of 2 percent residual oxygen by volume.

Methods that are not permitted include, but are not limited to:

- Suffocation
- Blow to the head by blunt instrument
- Equipment that crushes the neck including killing pliers or burdizzo clamps
- Carbon monoxide
- Neck wringing (holding the head while swinging the body in a circular motion)
- Maceration in a wood chipper

Additional producer guidance on euthanasia and depopulation

The term euthanasia is derived from Greek words meaning “god death” and is applied to the killing of an animal with minimal pain and distress.^{clxix} Animals that are suffering must be euthanized in a timely manner, and should not be left for extensive periods, over a weekend, for example.

Barbiturate injection or inhalant anesthetics administered by a veterinarian are the ideal methods for a limited numbers of hens, as they most closely meet the goals of killing with minimal pain and distress. However, these methods have not been widely used on farm settings due to cost and convince issues associated with culling large numbers of birds. Producers should also be aware that drug residues associated with the use of barbiturate injections will prevent the use of carcasses for human consumption, and dead birds must be disposed of carefully, because residues could also be unwittingly consumed by other animals eating the carcass or could become an environmental pollutant. Dead poultry should be disposed of in a way that does not attract wildlife.

Research demonstrates that inhalation of an inert gas (including argon and nitrogen) is probably painless, as they are colorless, odorless gases and birds do not demonstrate aversive reactions with initial exposure. In carefully controlled behavior experiments, turkeys and chickens are willing to enter a chamber filled with inert gas in order to access food.^{clxx,clxxi} Argon and nitrogen can be used to kill chickens on the farm. Containerized gas killing systems have been developed for culling large numbers of birds,^{clxxii} and these can be built on either a large or small scale, depending on the needs of individual producers. Such a system is the most humane method for killing large numbers of chickens on the farm that researchers have identified to date.

The use of CO₂ is problematic as there are both physiological and behavioral lines of scientific evidence suggesting that CO₂ may be unpleasant and possibly very distressing to inhale, as it is an acidic gas, pungent at high concentrations.^{clxxiii,clxxiv}

Exhaust fumes from an idling car engine are an unacceptable source of carbon monoxide, due to problems with production of other gases, inadequate gas concentration, and gas temperature.

While purpose-build macerators are sometimes used to kill unwanted chicks at hatcheries, using a wood chipper to dispose of a spent laying-hen flock is never acceptable.

It is extremely important to confirm that all animals are dead before disposal. When depopulation is performed on large flocks, depending on the methods used, it can be difficult to ensure that birds are actually dead and not simply lying still or unconscious. There is a very high potential for birds that are not dead, but are severely injured, to suffer greatly. Each bird must be methodically checked, and dead piles must be examined carefully for any sign of movement. A backup method of euthanasia must be in place to kill any birds that recover. Careful attention to this step in the euthanasia process is essential to ensuring a humane end for farmed poultry.

Slaughter of Poultry

All slaughter facilities must be audited yearly. Organic certifiers can use documentation from other third-party animal welfare audits that have been performed and should do additional auditing as necessary.

Slaughter establishments must also perform self-audits on a weekly basis. Self-audits ensure that animal welfare standards are being upheld, identify problems that may arise within the facility or with individual staff members, and identify specific farms that may be shipping problematic animals to the slaughter plant. These problems may be due to animals' genetics or handling; slaughter facilities are encouraged to contact the producers of problematic animals so that these problems can be addressed in the future.

In electrical water-bath stunning systems, birds must be shackled by both legs. Birds with broken or dislocated wings should be humanely killed before being shackled.

Stunning

Poultry must be rendered unconscious by stunning, or killed before being bled by simultaneous severance of both carotid arteries or by decapitation. Bleeding without stunning requires a high level of operator competency to avoid causing pain and missing cutting of both carotid arteries. A very sharp blade or knife of sufficient length is needed so that the point of the knife remains outside the incision during the cut; the point of the knife should not be used to make the incision. The incision should not close over the knife during the throat cut. Decapitation may be achieved by manual or automatic means.

Decapitation must be performed using a sharp instrument which achieves the complete severance of the head from the body by cutting all the major vessels of the neck and the spinal cord with a sharp instrument. All mechanical and automatic instruments used in this method shall be sharp and inspected frequently for sharpness. The poultry slaughter establishment shall ensure that all instruments and equipment are maintained so that they function effectively. All birds (100%) should be dead before they enter the scald tank.

For inspector assessment, 99% of the birds must be rendered insensible by the stunning method chosen. Arched neck and wings tucked in are visible signs of effective stunning.

Additional producer/processor guidance on stunning for slaughter

Electric stunning: The disadvantage of electric stunning for poultry is that birds must be shackled and hung upside-down before they enter the stunner. Care must be taken to avoid pre-stun electrical shocks. Amperage must be high enough that birds lose consciousness and are not merely paralyzed. The electric current shall be administered so as to produce effective surgical anesthesia or death with a minimum of excitement and discomfort. The current necessary to produce an effective stun changes depending

the species and electrical frequency. These are outlined in the World Organization for Animal Health, Terrestrial Animal Health Guide, Chapter 7.5, Slaughter of animals (available at: www.oie.int/index.php?id=169&L=0&htmfile=chapitre_1.7.5.htm), and the minimum currents are as follows:

- Broiler chickens and spent laying hens, 100 milliamperes per bird
- Turkeys, 150 milliamperes per bird
- Ducks and geese, 130 milliamperes per bird

For high frequency settings of 200-400 Hz, the minimum current needed to stun chickens is 150 milliamperes. For frequency settings of 400-1500 Hz, the minimum current is 200 milliamperes. For turkeys, frequency settings of 200-1500 Hz require a 400 milliamperes current setting.

These are minimal settings, and higher current levels better ensure that more birds will be effectively rendered unconscious.^{clxxv}

Gas stunning: Acceptable gas mixtures include argon, nitrogen, and low initial levels of CO₂ in one of the following combinations, as described by the World Organization for Animal Health:

- a minimum of 2 minutes exposure to 40 percent carbon dioxide, 30 percent oxygen and 30 percent nitrogen, followed by a minimum of one minute exposure to 80 percent carbon dioxide in air; or
- a minimum of 2 minutes exposure to any mixture of argon, nitrogen or other inert gases with atmospheric air and carbon dioxide, provided that the carbon dioxide concentration does not exceed 30 percent by volume and the residual oxygen concentration does not exceed 2 percent by volume; or
- a minimum of 2 minutes exposure to argon, nitrogen, other inert gases or any mixture of these gases in atmospheric air with a maximum of 2 percent residual oxygen by volume.

To avoid unnecessary stress and trauma due to handling, chickens should remain in their transport crates while being conveyed through the gas tunnels. Gas concentrations must be monitored for precision at all times. An alarm system is necessary to indicate malfunctions.

Bleeding

Once stunned, birds should be bled without delay to ensure that consciousness is not regained. Bleeding shall be accomplished by severing both carotid arteries or by decapitation. Sufficient bleeding time (at least 30 seconds, 60 seconds for gas stunning, and approximately 2 to 3 minutes for electric stunning resulting in cardiac arrest) shall be allowed to prevent the unacceptable condition known as “red skins” or “cadavers” which may occur with insufficient bleeding. For inspector assessment, 99% must be

effectively cut by hand or by the bleed machine. Remaining birds must be cut by a backup person.

The inspector will monitor condition of carcasses exiting the scald tank. Birds exiting the scald tank should not show signs that they entered it alive. —“Redskins” with uncut throats indicate that they entered the scalding water alive, and those with cut throats could possibly have entered before becoming unconscious.

For poultry, the percentage of chickens with broken or dislocated wings should not exceed 2%, with zero being the goal. No broken legs should be noted.

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Guidance for Assessing Animal Welfare on Organic Sheep Operations

Introduction

The following is provided to aid in assessment of whether or not the requirements of § 205.238-241 are being met sufficiently to demonstrate adequate animal welfare conditions on organic sheep operations.

Nutritional Requirements

Body condition scoring of sheep

Because wool covering makes visual examination of sheep body condition more difficult than with other species of livestock, body condition scoring may be helpful in determining whether the nutritional requirements of the ewe flock are being met and also in assessing the health status of sheep.

Estimated external fat cover is used as a base for estimating body condition. The fingertips are used to palpate fat cover over and around the vertebrae in the loin region. The best area to palpate is just behind the last rib. The spinal column has a vertical process at the midpoint of the back and a transverse process horizontal to the back and just below the loin. The prominence of these two points, or their lack of prominence due to fat cover, is helpful when estimating body condition. The recommended scoring system uses body condition scores ranging from 0 to 5. A condition score of 0 indicates extreme emaciation; a score of 5 represents excessive obesity. A condition score of 2.5-3 is considered as a medium fat-condition score for a healthy ewe at breeding and starting into the late gestation stage of pregnancy. If, within a “uniform” group or flock, several or more ewes differ from the majority in body condition score it may mean they are parasitized, diseased, aged (lacking teeth) or have other non-nutritional problems. As a rule, no more than 5% of the ewe flock should be below target body condition scores for the stage of production.

Scoring:

1. Feel for fullness of muscle and fat cover. (illustration)
2. Feel for the spine in the center of the sheep’s back behind the last rib and anterior to the hipbone. (illustration)
3. Feel for the tips of the transverse processes. (illustration)

Target body condition scores based on stage of production

Dry Ewe	1.5-2.0
Breeding	2.5-3.0
Early Gestation	2.0-2.5
Late Gestation*	2.5-3.0
Early Lactation*	3.0-3.5
Late Lactation, Weaning	2.0-2.5

*Add .5 to the target score for ewes expecting or nursing twins.

Body Condition Score 0: Sheep is extremely thin, unthrifty and weak. Skeletal features, such as backbone, shoulder blades and ribs, very prominent. Wasted muscle tissue evident. Eye socket is prominent and sunken. May be humped back and isolates self from flock.

Body Condition Score 1: Sheep is extremely thin, unthrifty but agile. Skeletal features are prominent with no fat cover. No apparent muscle tissue degeneration. Has strength to remain with the flock.

Body Condition Score 2: Sheep is thin but strong and thrifty with no apparent muscle structure wasting. No evident fat cover over the backbone, rum and ribs, but skeletal features do not protrude.

Body Condition Score 3: Sheep are thrifty with evidence of limited fat deposits in fore rib, over top of shoulder, backbone, and tail head. Hipbone remains visible.

Body Condition Score 4: Moderate fat deposits give the sheep a smooth external appearance over the shoulder, back, rump, and fore rib. Hipbone is not visible. Firm fat deposition becomes evident in brisket and around the tail head.

Body Condition Score 5: Sheep are extremely fat with the excess detectable over the shoulder, backbone, rump, and fore rib. Excess fat deposits in brisket, flank, and tail head regions lack firmness. Sheep appear uncomfortable and reluctant to move about. Quality fleeces are generally found.

Other areas of importance in providing adequate nutrition to sheep:

- Sheep need to be provided with enough roughage in the diet to ensure proper rumen function. After weaning, 70% of daily dry matter fed should be long fiber roughage/forage.
- There should be sufficient access to forage when fed that all sheep have sufficient access to meet their nutritional requirements within 24 hours.
- If supplementary concentrates are fed, all animals in a group should be able to eat at the same time.
- Ewe lambs should not be bred unless they have reached 70% of their mature body weight. If ewe lambs are bred to lamb before they are 18 months of age, they may need to be fed separately from the ewe flock to ensure adequate nutrition during gestation.
- Lambs should not be weaned before 5 weeks of age. Early weaned lambs need a high-protein ration and should not be put on forage only.
- If culling does not remove older sheep with damaged or missing teeth from the flock, attention should be given to providing sufficient feed of a type these sheep can eat and digest.

Sheep Health

When managed in a pasture-based or range system as required by organic production, with attention to suitability of species, and selective breeding for desirable traits, sheep can require few health inputs, require little lambing intervention, operator- or veterinary-provided health treatment and yet display optimal health.

Internal Parasites

It is necessary for special attention to be given to managing internal parasites on organic sheep operations. If breed selection, pasture management, supplements and allowed treatments are not successful in keeping sheep parasite loads from impacting well-being, individual animals need to be given conventional treatments. Lambs are more susceptible to parasites than ewes.

Lameness

Sheep hooves should be examined periodically or at least once yearly, and trimmed if necessary. 95% of the sheep should walk with no obvious limp. Animals with chronic or infrequent trimming management will be seen grazing on their knees and often will have grass stains on their knees. To simplify assessment, sheep can be classified as either lame or not lame. On a 5 point lameness scoring system, sheep that score as 3, 4, or 5 would be classified as lame.

Score 1. Completely normal walking

Score 2. No obvious limp, but may have slight gait abnormalities.

Score 3. All sheep that walk with an obvious limp. Sheep with a score 3 are able to keep up with their flock mates when the group is walking.

Score 4. All sheep that walk with an obvious limp and refuse to bear their full weight on one or more legs. Score 4 animals are not able to keep up with their flock mates when the group is walking.

Score 5. All sheep that have great difficulty walking. Score 5 sheep are barely able to walk.

Physical Alterations

Tail docking should only be done if needed for prevention of fly strike. When necessary, tail docking should be performed by suitably trained and competent individuals on lambs that are between 24 hours and 14 days old. Tails should not be docked shorter than the distal end of the caudal tail fold.

If castration is necessary to avoid breeding by ram lambs, banding should be done by suitably trained and competent individuals on lambs that are between 24 hours and no more than 30 days old.

Sheep Living Conditions

Flocks may be managed with only natural shelter, depending upon climate, breed and lambing season. If sheep are housed or fed in lots, conditions should be such to maintain a cleanliness score or 1 or 2 for 95% of the flock.

Cleanliness Scoring

Fleece maintenance is necessary to prevent manure from accumulating on the back end, rear legs and tail if present. The presence of manure in the fleece is an indicator of poor management that can lead to low conception rates and harbor external parasites. Messy rear ends may be due to washy forage growth or may be from untreated internal parasite loads. Excessive wool growth is problematic for newborn lambs to find the nipple and receive the valuable colostrum.

Score 1. The entire sheep is clean except its feet and lower half of the legs. Animals on lush green pastures may have some soiling of the rear legs..

Score 2. Both the upper and lower legs are soiled and the body/breast and sides are clean.

Score 3. Both the legs and belly are soiled.

Score 4. The legs, belly and sides of the body are soiled.

95% of the sheep should have a cleanliness score of 1 or 2.

Space Allowances

If sheep are confined in buildings or lots during the non-grazing season, the following minimum space allowances should be met. Because the standards require outdoor access for organic livestock unless weather conditions would be injurious to animal health, and because sheep tend towards respiratory difficulties when confined unless ventilation and moisture control is optimum, it is important that confinement of sheep to buildings be of a temporary nature—for treatment of illness, or shelter due to inclement weather, winter lambing or post-shearing—and that outdoor access be provided as soon as possible.

Livestock	Indoor Floor Space	Outdoor Space
Sheep and goats (pounds)	Square feet / animal	Square feet / animal
Sheep and Goats	16.0	30.0
Nursing lamb or kid	4.0	8.0

For ewes with lambs add 5 square feet for lambing percentages over 170%. Ewes lambing in confinement should be provided with a dry, bedded area for lambing and should be checked at least 3 times daily during lambing time for lambing difficulties or unclaimed lambs. Lambing jugs (pens) as small as 16 square feet in area may be used for up to three days for a ewe and her lamb(s) to separate them from the rest of the flock for a period of bonding and observation.

Pasturing Sheep

Important factors in managing sheep on pasture:

- Pastures need to be rotated and rested to minimize parasite infestation.
- Sheep need to be protected from predation.
- If electronet fencing is used, it should be kept properly energized.
- Sheep on pasture should be checked at least twice/day during lambing, once/day otherwise.

Humane Handling of Sheep

Sheep should be handled quietly and firmly, with care taken to avoid unnecessary pain or distress. Sheep should not be caught by the fleece, or lifted or dragged by fleece, limbs, ears or tail. Electric prods should not be used on sheep.

Mortality Rates in Sheep Production

In assessing the level of animal welfare that is met on an organic sheep operation, mortality rates and causes should be examined and considered. Mortality in sheep production is generally looked at in terms of lamb mortality before and after weaning and ewe mortality.

Lamb mortality rates are impacted by the prolificacy of the ewe breed (multiple births=higher mortality rate) and lambing conditions. The primary causes of neonatal lamb death are starvation and hypothermia. A lamb survival rate of 95% at weaning is considered to be a goal by many sheep producers.

Similarly, a death loss of 5% or less in weaned lambs or ewes is considered to be indicative of good management. Weaned lambs in organic systems are impacted most greatly by parasites or predation. The mortality rate of ewes is affected by culling rate; if older ewes are kept on the farm, the mortality rate could be higher.

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: <u>November 2011</u>	Substance: <u>Annatto extract color (pigment CAS # 1393-63-1)—water and oil soluble</u>
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Committee: Crops Livestock Handling Petition is for removal of Annatto extract color (pigment CAS # 1393-63-1)—water and oil soluble on the National List § 205.606

A. Evaluation Criteria (Applicability noted for each category; Documentation attached)	Criteria Satisfied? (see B below)
1. Impact on Humans and Environment	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
2. Essential & Availability Criteria	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
3. Compatibility & Consistency	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606)	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A <input type="checkbox"/>

B. Substance Fails Criteria Category: 4 Comments: At this time, the Handling Committee believes that sufficient evidence exists that both forms, liquid and powdered, of organic annatto extract color are available. We understand that there may be applications where the forms available do not perform. We ask that handlers or certifiers who are aware of these applications provide written public comment for the fall 2011 NOSB meeting so they can be considered.

C. Proposed Annotation (if any): Current annotation is "Oil and Water Extracted." Proposed annotation is "Liquid and powdered forms." See committee comments at end of document for details_____

Basis for annotation: To meet criteria above: X Other regulatory criteria: _____ Citation: The Handling Committee is recommending an annotation change to include both forms of annatto extract color so that the NOSB has the flexibility to list one or the other should public comment be received that the forms of organic extract color that are available do not perform in all applications

D. Recommended Committee Action & Vote (State Actual Motion): Recommend changing the annotation of Annatto Extract Color from "Water and Oil Soluble" to "Liquid and Powdered Forms."

Motion by: Heinze Seconded: Dickson Yes: 6 No: 0 Absent: 1 Abstain: 0
 Recommend removing Annatto color, with all annotations, from the National List §205.606
 Motion by: Heinze Seconded: Dickson Yes: 6 No: 0 Absent: 1 Abstain: 0

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

- 1) Substance voted to be REMOVED as "allowed" on National List to § 205. 606 with Annotation (if any) Liquid and Powdered Forms
- 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:

<u>Steve Demuri</u> Committee Chair	<u>September 29, 2011</u> Date
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NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? Substance – Annatto extract color (pigment CAS # 1393-63-1)—water and oil soluble

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		
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		

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

Category 2. Is the Substance Essential for Organic Production? Substance – Annatto extract color (pigment CAS # 1393-63-1)—water and oil soluble

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		Material is manufactured by extraction from the annatto seed with either oil or water combined with physical agitation.
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		
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		
4. Is there a natural source of the substance? [§205.600 b.1]	X			This is the natural source
5. Is there an organic substitute? [§205.600 b.1]	X			Organic forms of this material are available in the marketplace
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]		X		Not used for production
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X			This is the natural source
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]	X			This petition is for evaluation of commercial availability. See category 4.
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		

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

Category 3. Is the substance compatible with organic production practices? Substance – Annatto extract color (pigment CAS # 1393–63–1)—water and oil soluble

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			
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		Primary use is as a color. However use is not to recreate or improve color lost in processing but to provide consumers with a color with which they are familiar. For example, cheddar cheese is orange due to use of annatto.
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		

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

Category 4. Is the commercial supply of an agricultural substance as organic, fragile or potentially unavailable? [§6610, 6518, 6519, 205.2, 205.105 (d), 205.600 (c) 205.2, 205.105 (d), 205.600 (c)]

Substance - Annatto extract color (pigment CAS # 1393-63-1)—water and oil soluble

Question	Yes	No	N/A	Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown)
1. <u>Is the comparative description provided</u> as to why the non-organic form of the material /substance is necessary for use in organic handling?	X			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). The NOSB recommended relisting at the October 2010 NOSB meeting: http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5088016&acct=nosb
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		<p>When annatto was originally listed public comment was received saying that organic annatto seeds were not available. Today organic seeds are available. However, annatto is used in both a liquid and powdered form. During the Sunset 2012 review of this material public comment was received, and supported by an informal market review by the NOSB Handling Committee, that the liquid form was available. Mixed public comment was received about the availability of the powdered form. At the time, removing one form but not the other could not be done during the sunset review process.</p> <p>This petition is for the removal of all forms from §205.606. The petitioner states that they have provided an organic liquid form for some time and have just recently, spring 2010, introduced a powdered form. The Handling Committee has conducted a second informal market survey and found that some, but not most, products (e.g., some brands of organic mac & cheese) that would be expected to be using the powdered form have switched to using organic annatto.</p> <p>At this time, the HC believes that sufficient evidence exists that both forms, liquid and powdered, of organic annatto extract color are available. We understand that there may be applications where the forms available do not perform. We ask that handlers or certifiers who are aware of these applications provide written public comment for the fall 2011 NOSB meeting so they can be considered.</p>
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		Quality of the organic annatto extract color has not been a question. The committee has no information indicating that organic forms of the material are not commercially available.
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		The petitioner states that there is sufficient supply of organic annatto seeds and both liquid and powdered organic annatto extract color to meet demand. The committee has no information to contradict this statement.

5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following:		X		
a. Regions of production (including factors such as climate and number of regions);				
b. Number of suppliers and amount produced;	X			The petition is from the supplier of organic annatto extract color.
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: <u> Fall 2011</u>	Substance: <u> Arachidonic acid single-cell oil (ARA)</u>
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Committee: **Crops • Livestock • Handling** Petition is for: Inclusion on the National List 7CFR § 205.605(a)

A. Evaluation Criteria (Applicability noted for each category; Documentation attached)	Criteria Satisfied? (see B below)
1. Impact on Humans and Environment	Yes <input checked="" type="checkbox"/> No • N/A •
2. Essential & Availability Criteria	Yes <input checked="" type="checkbox"/> No • N/A •
3. Compatibility & Consistency	Yes <input checked="" type="checkbox"/> No • N/A •
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606)	Yes • No • N/A <input checked="" type="checkbox"/>

B. Substance Fails Criteria Category: _____ **Comments:** _____

C. Proposed Annotation (if any): _____

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

D. Recommended Committee Action & Vote (State Actual Motion): Approve as
Motion is list the material as a non-synthetic, designating the material for §205.605(a)

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

Motion is to list the petitioned material Arachidonic acid single-cell oil (ARA) on the National List 7 CFR, §205.605(a) as Arachidonic acid single-cell oil (ARA)

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

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

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:

Steve DeMuri _____
Committee Chair

October 7, 2011
Date

NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

**Category 1. Adverse impacts on humans or the environment?
(ARA)**

Substance Arachidonic acid single-cell 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? ¹ [§205.600 b.2]		x		<p>The TR concluded that the petitioned substance, ARA Single-cell Oil, is produced primarily by a “non-genetically-modified soil fungus <i>Mortierella alpina</i>,” and that the fungus is safe for consumption by humans and other life. <i>See TR at lines 204-205</i> (fungus “not believed to cause disease in humans and biota.”)</p> <p>The TR described the production, extraction and purification method of the natural oil. <i>See TR lines 212-256</i>. The TR noted that the post-extraction and purification processes “remove any extraction and purification solvents from the oil,” <i>see TR at lines 270-73</i>, and concluded that the removed solvents are typically “recycled and reused.” <i>See TR at 271-2</i> Any other impurities such as “trace metals, and oxidation products” are “removed physically through filtration or addition of adsorbents” <i>See TR at lines 249-50</i></p> <p>Lastly, the TR stated at 273: “No residual hexane from the extraction process has been detected in samples of ARA Single-cell Oil using methods with detection limits of 0.3 ppm .” The TR also cited a single Swiss study that tested more than 40 non-organic vegetable oils that used a similar extraction technology for hexane residues and concluded that less than 13% had any detectable residue and the level was “below acceptable tolerances.” <i>See TR at line 237</i></p> <p><i>See also Question 2 below</i></p>
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 (m)(3)]		x		<p>The TR concluded that the petitioned substance is produced under completely controlled conditions--“aerobic fermentation of the fungus in shake flasks containing a growth medium.” <i>See generally TR line 212; see also generally TR lines 204-256</i> (describing inputs, manufacturing process and waste byproducts) Because the fungus is grown in a controlled environment, there appear to be no environmental issues arising from the process. <i>see also lines 407-409</i> (noting FDA GRAS notice reported no heavy metals or pesticides detected in petitioned substance)</p>
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		x		<p><i>See Question 2 above, citing TR lines 204-256; see also TR at lines 204-205</i> (fungus “not believed to cause disease in humans and biota.”)</p>
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]			x	<p>This is a substance used as an ingredient in an organic processed food. It is not used in production and contains no listed inerts.</p>

¹The criteria set forth in 7 CFR §205.600(b) are applicable solely to “synthetic substances used as a processing aid or adjuvant.” The petitioned substance is not a processing aid or adjuvant. *See TR at line 90-94* The TR determined the petitioned substance be a non-synthetic. *See TR at line 286* (“ARA Single-cell Oil does not appear to be a synthetic substance.”) Accordingly, the criteria listed in §205.600(b) are inapplicable to the petitioned substance. *See e.g. 7 CFR §205.600(c)* (“Non-synthetics...will be evaluated using the criteria [in the OFPA].”) However, the TR included review of most of these questions so the results are cited out of an abundance of caution.

5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		x	The substance is used as an ingredient in an organic processed food. No detrimental interactions were noted in the TR. <i>See TR lines 123-145</i> (discussing combinations with substances in formulations); <i>see also TR at lines 204-205</i> (fungus “not believed to cause disease in humans and biota.”)
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		x	This is a substance used as an ingredient in an organic processed food. It is no longer in the agro-ecosystem. <i>See also TR at lines 204-205</i> (fungus “not believed to cause disease in humans and biota.”)
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		x	This is a substance used as an ingredient in an organic processed food. It is no longer in the agro-ecosystem. <i>See also TR at lines 204-205</i> (fungus “not believed to cause disease in humans and biota.”)
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		x	This is a substance used as an ingredient in an organic processed food. It is no longer in the agro-ecosystem. <i>See also TR at lines 204-205</i> (fungus “not believed to cause disease in humans and biota.”)
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]		x	This is a substance used as an ingredient in an organic processed food. It is no longer in the agro-ecosystem. <i>See also TR at lines 204-205</i> (fungus “not believed to cause disease in humans and biota.”)
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]	x		<p>The Safety of the Fungus: The TR concluded that the scientific literature regarding the fungus from which the oil is extracted discloses that there is no reason to believe that any harm to humans or other life will occur. <i>See TR at lines 204-205</i></p> <p>Health Benefits from Consumption: With regard to the health of those that consume the petitioned substance, the TR concluded: “Research suggests that a balance of ARA and DHA are necessary to the normal growth and development of infants.” <i>See TR at lines 126-27</i> The TR also noted that many studies have reported “statistically significant improvements to retinal maturation, visual acuity, and cognitive function” while one study cited “reported no benefit.” <i>See TR at lines 418-32</i> The TR appears to conclude the vast body of evidence of health benefits far outweighed the single study that found no measurable benefit.</p> <p>The TR also cited the World Health Organization (“WHO”) recommendation that “ARA should be supplied in the diets of infants aged 0–6 months” and noted the Institute of Medicine has established intake levels for infants aged 0–6 months and small children. <i>See TR at lines, 593-596</i></p> <p>Safety Analysis</p> <p>“ARA Single-cell Oil is generally recognized as safe for human consumption, even in vulnerable infant populations.” <i>See TR at lines, 496-97</i> The TR cited the “most recent safety assessment of ARA Single-cell Oil” in the scientific literature, <i>TR at lines 448-52</i>, and summarized its findings: “All results of the genotoxicity assays were negative” and “No adverse effects attributed to consumption of the ARA Single-cell Oil were observed even at the highest dose” which in the study was “29-times higher than the anticipated intake” for term infants. <i>See also TR at lines 459-62</i> (noting that Australia and New Zealand “reviewed the toxicological database for ARA Single-cell Oil and determined that ARA Single-cell oil did</p>

		<p>not induce any histopathological, biochemical, or hematological changes that would be indicative of toxicity” at doses far higher than allowed for infant formula.)</p> <p>With regard to the safety of the consumption of the petitioned substance by infants (the extracted ARA) the <i>TR at lines 430-32</i>, stated: “Despite mixed results on many of the purported benefits of ARA supplementation in infant formula, adverse effects in infants fed formulas enriched with ARA/DHA have not been observed in randomized trials for up to one year.”</p> <p>The TR noted that a now ten year old from 2001 study reported incidents of “flatulence, diarrhea, apnea, and jaundice in infants that were fed formulas with long-chain PUFA.” <i>TR at lines 438-9</i> However, the TR did not did attribute these common infant ailments to any particular infant formula ingredient. To the extent these common infant ailments have been reported to FDA as “adverse events” arising from infant formula consumption, FDA’s review has apparently concluded the events are <i>de minimis</i> in light of the nearly universal consumption of infant formula, and thus below the threshold of regulatory action.</p> <p>Excessive Consumption</p> <p>The TR cited one study that examined “the effect of increasing dietary ARA seven-fold” and concluded, “no effects on platelet aggregation, bleeding times, balance of vasoactive metabolites, serum lipid levels, or immune response were observed” <i>TR at lines 438-9</i> In addition, after review of a meta-analysis of 25 case-control studies evaluating a variety of effects, the TR concluded: “No effects in humans at high ARA doses were identified.” <i>See TR at lines 438-9</i></p> <p>Absence of Contaminants</p> <p>The TR accepted the data provided by Petitioner that was also provided to the FDA and concluded: “No residues of heavy metals or other contaminants have been reported in ARA Single-cell Oils at levels higher than FDA tolerances.” <i>See TR at lines 378-9</i> The TR also accepted as un rebutted by other literature the finding that no solvent used in processing the ARA oil was detectable in the final product, and that the sole study in the scientific literature that tested more than 40 conventional (non-organic) vegetable oils for residues from processing solvents found no residue at an actionable level. <i>See TR at lines 386-90</i></p> <p>Global Regulatory Treatment on Safety</p> <p>Because organic authorities do not assess food safety generally, the TR surveyed a few jurisdictions to assess the regulatory treatment by agencies charged with safety evaluations. Of course, the TR noted that the substance is recognized as GRAS in the U.S. <i>See e.g. TR at lines 90-92</i> (petitioned substance is GRAS); <i>TR, at lines 616-17</i> (noting one GRAS petition that cited 5 safety studies)</p>
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			<p>The petitioned substance has been evaluated from a safety perspective by several countries and multi-lateral institutions. <i>See e.g. TR at lines, 459</i> (citing Australia and New Zealand). In particular, the TR noted that in Canada approved the petitioned substance “after assessing the toxicology, chemistry, microbiology, and nutrition of ARASCO® as a food ingredient.” <i>See TR at lines 185-89</i> Other regulatory approvals for the petitioned substance for use in infant formula include, Australia, New Zealand, China, France, and the Netherlands—of note also, the European Union similarly allows “ARA Single-cell Oil from <i>M. alpina</i>” in infant formula. <i>See TR at lines 190-93</i> Lastly, the TR noted that the petitioned substance would fall under Codex’s general rule for food grade oils that allows their use provided they are free of prohibited additives like coloring agents etc. <i>See TR at lines 197-98</i></p> <p>In the United States, ARA Single-cell Oil is proposed for addition to infant formula and other organic food products. <i>See TR at lines 141-143</i> ARA has not currently been petitioned for GRAS designation as an addition to food items other than infant formula. <i>See TR at lines, 573-4</i></p>
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		x	<p>The TR concluded that there is no adverse human health impact under federal regulations. “ARA Single-cell Oil is considered by FDA as GRAS in infant formula when used in combination with docosahexaenoic acid (DHA).” <i>See TR at lines 90-92</i> Also, “ARA Single-cell Oil is generally recognized as safe for human consumption, even in vulnerable infant populations.” <i>See e.g. TR at lines, 496-97</i> ARA is presently allowed for use solely in infant formula and growing-up milks. <i>See TR at lines, 650-51.</i></p> <p>The TR plainly stated that the state of the science is that, “adverse effects in infants fed formulas enriched with ARA/DHA have not been observed in randomized trials for up to one year.” <i>See TR at lines, 431-32</i></p>
12. Is the substance GRAS when used according to FDA’s good manufacturing practices? [§205.600 b.5]	x		<p>The TR concluded: “ARA Single-cell Oil is characterized as GRAS under three different names submitted by four different applicants” <i>See TR at lines 332-36</i> (citing Martek Biosciences (GRN No. 41), Mead Johnson Nutritionals (GRN No. 80), Abbott Laboratories (GRN No. 94), and Cargill, Inc. (GRN No. 326)) when used in term and preterm infant formula along with GRAS concentrations of DHA.</p> <p>In addition to GRAS status, when ARA oil appears as an ingredient in infant formulas, the manufacturers submit premarket notification to FDA under section 412 of the Federal Food, Drug, and Cosmetic Act (FFDCA). Section 412 of FFDCA describes the more stringent statutory requirements that apply to infant formula as compared to the regulation of other foods (FDA, 2006)</p>
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		x	<p>The TR described the production, extraction and purification method of the natural oil. <i>See TR lines 212-256.</i> The TR noted that the post-extraction and purification processes “remove any extraction and purification solvents from the oil,” <i>see TR at lines 270-73,</i> and concluded that the removed</p>

			<p>solvents are typically “recycled and reused.” <i>See TR at 271-2</i> Any other impurities such as “trace metals, and oxidation products” are “removed physically through filtration or addition of adsorbents” <i>See TR at lines 249-50</i></p> <p>Lastly, the <i>TR</i> cited Petitioner’s evidence at <i>line 273</i>: “No residual hexane from the extraction process has been detected in samples of ARA Single-cell Oil using methods with detection limits of 0.3 ppm.” The <i>TR</i> also cited a single Swiss study that tested more than 40 non-organic vegetable oils that used a similar extraction technology for hexane residues and concluded that less than 13% had any detectable residue and the level was “below acceptable tolerances.” <i>See TR at line 237</i></p>
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¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

Category 2. Is the Substance Essential for Organic Production? Substance Arachidonic acid single-cell oil (ARA)

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			The TR concluded the fungus from which the petitioned substance is isolated is “produced naturally via fermentation” <i>line 260-63</i> , but the extraction process typically involves a “nonpolar solvent.” <i>See TR at 263</i> (“ARA Single-cell Oil is produced naturally via fermentation of <i>M. alpina</i> and some other single-celled organisms. However, to extract the ARA Single-cell Oil from the fungus, a nonpolar solvent (usually hexane) is used.”) <i>See TR at 260-63</i>
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 TR concluded that the petitioned substance is a non-synthetic. <i>See TR at line 286</i> (“ARA Single-cell Oil does not appear to be a synthetic substance.”); <i>see also TR at lines 274-78</i> (Applying National Organic Standards Board (NOSB) Joint Materials and Handling Committee draft policy: “extraction with a synthetic not on the National List would not result in a material being classified as synthetic unless either the extraction resulted in chemical change or the synthetic remained in the final material at a significant level”(NOSB, 2010).”)
3. Is the substance created by naturally occurring biological processes? [6502 (21)]	x			The TR concluded that the petitioned substance is the product of a biological process. <i>See TR lines 260-63</i>
4. Is there a natural source of the substance? [§205.600 b.1]	x			ARA is present in foods, but for use in infant formula, or as a supplemental micronutrient in adult food products, the ARA must be extracted by a chemical process. <i>See TR lines 221-240</i> (noting extraction methodologies). “Chicken and eggs are the primary sources of ARA in the U.S. diet.” <i>TR at lines, 660-61.</i>
5. Is there an organic substitute? [§205.600 b.1]				<p>There are no known certified organic sources of the extracted ARA oil. <i>See TR lines 466-80</i> (citing no certified source of ARA oil)</p> <p>The TR noted that fish oil is not an acceptable substitute because (a) “fish oil is not an organic agricultural product per se” and (b) “[f]ish oil does not contain high levels of pre-formed ARA” thus it must be “supplemented with another source of ARA (e.g., egg phospholipid or ARA Single-cell Oil) to achieve a fatty acid profile for optimal nutrition” and (c) “fish oil contains high levels of EPA, which can result in adverse effects on growth of pre-term infants even at low concentrations.” <i>See TR at lines, 475-80</i></p> <p>The TR noted that using organic eggs as an ARA source is generally not commercially feasible because achieving an egg with sufficient phospholipids requires “feeding chickens the biomass of ARA-producing fungus.” <i>See TR at lines, 468-72</i> The TR also noted this approach is generally considered “wasteful of resources because ARA contents in egg phospholipids are relatively low and most of the egg is often discarded after phospholipid extraction.” (internal citations omitted) <i>See TR at lines, 303-07.</i> Based on the TR, the necessary chicken feed would not be organic because ARA</p>

				producing fungus would have to be added to complete its nutrient profile and it is not an organic material at this time.
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]	x			The petitioned substance is unique because it is the only plant-based source of ARA currently available and is the most widely used ARA source in conventional and organic infant formulas. <i>See e.g. TR at lines, 468-69</i> (“There are three main sources of ARA ...for supplementing infant formula: ARA Single-cell Oil, fish oil, and egg phospholipids.”) Unlike animal sources, such as eggs or animal flesh, ARA from fungal oil is vegetarian, carries no risk of containing harmful environmental contaminants that an animal may ingest, <i>see TR at line 212</i> (noting fungus is grown in flasks) and there is no literature suggesting this production methodology adversely impacts biodiversity. <i>See TR at lines 394-95</i> (“No information was found on the effect of ARA Single-cell Oil on the environment or biodiversity”)
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]		x		The TR concluded that there are “Three main sources of ARA ...for supplementing infant formula: ARA Single-cell Oil, fish oil, and egg phospholipids.” <i>See TR at lines, 468-69</i> The petitioned substance is the only plant-based source of ARA. <i>Id.</i> non-synthetic, non-agricultural substance under 205.605(a). <i>See TR 286</i> (“ARA Single-cell Oil does not appear to be a synthetic substance.”) There is no plant-based agricultural substitute for the petitioned substance. <i>TR at lines, 657-665</i> (discussing common sources); <i>TR at lines, 666</i> (noting “ eggs, poultry, beef, some fish” are principle ARA sources.)
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]	x			The TR concluded the substance is a non-synthetic, non-agricultural substance. <i>See TR 286</i> (“ARA Single-cell Oil does not appear to be a synthetic substance.”)
9. Is there any alternative to using the petitioned substance in terms of practices or other available materials? [§6518(m)(6)]		x		According to the TR, there are no other plant-based sources of ARA, thus there is no vegetarian alternative to the petitioned substance. <i>TR at lines, 657-665</i> (discussing common sources); <i>TR at lines, 666</i> (noting “ eggs, poultry, beef, some fish” are principle ARA sources in adult diet.) For infants, the adult sources are not alternatives. <i>See also Question 7</i>
10. Is there an “alternative[s] to using the substance in terms of practices” that would make the substance unnecessary? [§6518 (m)(6)]		x		The petitioned substance is a food additive and there are no “practices” that substitute for its presence.

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

Category 3. Is the substance compatible with organic production practices? Substance Arachidonic acid single-cell oil (ARA)

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			The petitioned substance is not the product of an excluded method and is a non-synthetic according to the TR.
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			The petitioned use of ARA Single-cell Oil is as a nutritional food ingredient added to infant formulas. ARA Single-cell Oil is added to infant formula to increase free ARA levels in formula to those comparable to ARA levels in human breast milk. <i>TR at lines, 37-40</i>
5. Is the primary use as a preservative? [§205.600 b.4]		x		<i>TR at lines, 37-40</i>
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		<i>TR at lines, 37-40</i>
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:			x	The petitioned substance is not used in production.
a. copper and sulfur compounds;				
b. toxins derived from bacteria;			x	The petitioned substance is not used in production.
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?			x	The petitioned substance is not used in production.
d. livestock parasiticides and medicines?			x	The petitioned substance is not used in production.
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?			x	The petitioned substance is not used in production.

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

Category 4. Is the commercial supply of an agricultural substance as organic, fragile or potentially unavailable? [§6610, 6518, 6519, 205.2, 205.105 (d), 205.600 (c) 205.2, 205.105 (d), 205.600 (c)]

Substance Arachidonic acid single-cell oil (ARA)

Question	Yes	No	N/A	Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown)
1. <u>Is the comparative description provided</u> as to why the non-organic form of the material /substance is necessary for use in organic handling?			x	The substance is not petitioned for inclusion on 7 CFR §205.606
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate form to fulfill an essential function in a system of organic handling?			x	
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate quality to fulfill an essential function in a system of organic handling?			x	
4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate quantity to fulfill an essential function in a system of organic handling?			x	
5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following:			x	
a. Regions of production (including factors such as climate and number of regions);				
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	
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NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: ___ Fall 2011 _____

Substance: Color, Beta-carotene extract, derived from carrots

Committee: Crops Livestock Handling **Petitioned for** annotation change from Beta-carotene extract color, derived from carrots (CAS# 1393-63-1) to beta-carotene extract color, derived from carrots or algae (CAS#7235-40-7) **on the National List § 205.606**

A. Evaluation Criteria (Applicability noted for each category; Documentation attached)	Criteria Satisfied? (see B below)
1. Impact on Humans and Environment	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
2. Essential & Availability Criteria	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
3. Compatibility & Consistency	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
4. Not or Inconsistently Available as Organic	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>

B. Substance Fails Criteria Category: _____ **Comments:** _____

C. Proposed Annotation (if any): annotation change from Beta-carotene extract color, derived from carrots (CAS# 1393-63-1) to beta-carotene extract color, derived from carrots or algae (CAS#7235-40-7)
 Basis for annotation: To meet criteria above: _____ Other regulatory criteria: The petition is to change the annotation for the current §205.606 listing of beta-carotene extract color to add beta-carotene derived from algae (see evaluation category #4 for details) and to change the CAS# to the correct one for beta-carotene. The current CAS# is for annatto extract Citation: __

D. Recommended Committee Action & Vote (State Motion): __Recommend changing the annotation for colors derived from agricultural products (3) Beta-carotene extract color, derived from carrots (CAS# 1393-63-1) to colors derived from agricultural products (3) beta-carotene extract color, derived from carrots or algae (CAS#7235-40-7)

Motion by: Heinze Seconded: Demuri Yes: 4 No: 0 Absent: 3 Abstain: _____

Crops		Agricultural	<input checked="" type="checkbox"/>	Allowed ¹	<input checked="" type="checkbox"/>
Livestock		Non-Synthetic		Prohibited ²	
Handling	<input checked="" type="checkbox"/>	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 § 205.606 with Annotation (if any) beta-carotene extract color, derived from carrots or algae (CAS#7235-40-7) _____

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 20, 2011
Date

NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment?

Substance - Color, Beta-carotene extract,

derived from carrots

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		Technical Review lines 531-545: “Production of beta-carotene from (algae) will surpass synthetic as well as other natural sources due to microalgae sustainability of production and their renewable nature.”
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		Technical Review lines 531-545: “Production of beta-carotene from (algae) will surpass synthetic as well as other natural sources due to microalgae sustainability of production and their renewable nature.”
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		Naturally present in variety of agricultural products
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	This is an agricultural product used as an ingredient in an organic processed food. It is no longer in the agro-ecosystem.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]			X	This is an agricultural product used as an ingredient in an organic processed food. It is no longer in the agro-ecosystem.
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]			X	This is an agricultural product used as an ingredient in an organic processed food. It is no longer in the agro-ecosystem.
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]			X	This is an agricultural product used as an ingredient in an organic processed food. It is no longer in the agro-ecosystem.
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]		X		See #11 below
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		X		Technical Review lines 136-140: Recognized as GRAS by FDA. Certification of the color not needed to protect human health
12. Is the substance GRAS when used according to FDA’s good manufacturing practices? [§205.600 b.5]	X			Technical Review lines 136-140, 385-416: Recognized as GRAS by FDA.
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		X		Technical Review lines 485-492

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

Category 2. Is the Substance Essential for Organic Production? Substance - Color, Beta-carotene extract, derived from carrots

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		<p>Petition: Beta-carotene is produced from natural strains of the algae <i>D. salina</i> and is extracted from the algae using carbon dioxide, ethanol, or vegetable oil.</p> <p>Technical Report lines 243-248: Other extraction solvents that can be used to extract beta-carotene from algae are carbon dioxide, acetone, methanol, propan-2-ol, hexane, ethanol, and vegetable oil. Note that a previous NOSB recommendation (http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5088018&acct=nosb) recommended an annotation be added to the broad listing of colors, derived from agricultural products on §205.606. The added annotation change was “Must not be produced using synthetic solvents and carrier systems or any artificial preservative.”</p> <p>Full description of manufacturing, derived from algae, is listed in Technical Review lines 325-346. The TR also describes synthetic sources of beta-carotene. These are not the subject of this petition.</p>
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		Beta-carotene is extracted from the algae
3. Is the substance created by naturally occurring biological processes? [6502 (21)]	X			Beta-carotene produced by strains of algae (petition and TR)
4. Is there a natural source of the substance? [§205.600 b.1]			X	Petitioned material is from a natural source
5. Is there an organic substitute? [§205.600 b.1]		X		Beta-carotene derived from carrots was originally recommended for listing by the NOSB (see transcripts from Spring 2007 meeting) because of evidence that specific varieties of carrots/growing conditions were required to produce the color and none were available in organic form. This petition goes on (see question #1 above) to say that the color derived from carrots is not available in organic form because of the solvents that would be used for extraction.
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]	X			Petitioner states that color is used to make products meet consumer expectations.
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]			X	Petitioned material is from a natural source
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]	X			Material is being petitioned for listing on §205.606. See category 4.
9. Is there any alternative substances? [§6518 m.6]		X		Beta-carotene extract derived from carrots is currently listed on §205.606. The petition is to add an annotation to also list beta-carotene extracted from algae. The petitioner states that beta-carotene extracted from carrots is not commercially available because use of synthetic solvents is required. The Technical Review supports that statement (lines 257-262, 353-355).

				Technical Review states that annatto color may be used as an alternate in some applications.
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]		X		

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

Category 3. Is the substance compatible with organic production practices? Substance - Color, Beta-carotene extract, derived from carrots

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			Use of colors in organic handling is fairly common. There are other colors on §205.606
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. Use of colors in organic handling is fairly common
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]			X	This is an agricultural product used as an ingredient in an organic processed food. It is not used in agriculture.
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]	X			Nutritional quality of food not affected by use of color.
5. Is the primary use as a preservative? [§205.600 b.4]		X		Use is as a color in handling products
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		This material is not used to replace color lost during processing, but to enhance color of finished product to meet consumer expectations.
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:			X	Petitioned material is not for use in production
a. copper and sulfur compounds;			X	
b. toxins derived from bacteria;			X	
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?			X	
d. livestock parasiticides and medicines?			X	
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?			x	

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

Category 4. Is the agricultural substance inconsistently or not commercially available as organic?

Substance - Color, Beta-carotene extract, derived from carrots

Question	Yes	No	N/A	Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown)
1. <u>Is the comparative description provided</u> as to why the non-organic form of the material /substance is necessary for use in organic handling?	X			The petitioner states that beta-carotene extracted from carrots is not commercially available because use of synthetic solvents is required. The Technical Review supports that statement (lines 257-262, 353-355).
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate form to fulfill an essential function in a system of organic handling?			X	
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate quality to fulfill an essential function in a system of organic handling?			X	
4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate quantity to fulfill an essential function in a system of organic handling?			X	
5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following:			X	
a. Regions of production (including factors such as climate and number of regions);			X	
b. Number of suppliers and amount produced;			X	
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;			X	
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or			X	
e. Are there other issues which may present a challenge to a consistent supply?	X			See response to question #1.

NOSB COMMITTEE RECOMMENDATION
Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: Fall 2011	Substance: DHA from Algal Oil																								
Committee: Crops • Livestock • Handling X Petition is for: inclusion on the National List 7 CFR, §205.605																									
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: _____ _____ _____																									
C. Proposed Annotation (if any): _____ _____ Basis for annotation: To meet criteria above: _____ Other regulatory criteria: _____ Citation: _____																									
D. Recommended Committee Action & Vote (State Actual Motion): _ Motion is list the material as a non-synthetic, designating the material for §205.605(a) Motion by: <u>Tracy Mledema</u> Seconded: <u>Katrina Heinze</u> Yes: <u>7</u> No: <u>0</u> Absent: _____ Abstain: _____ Motion is to list the petitioned material, "DHA Algal Oil" on the National List 7 CFR, §205.605(a) as "DHA from Algal Oil" Motion by: <u>Tracy Mledema</u> Seconded: <u>Katrina Heinze</u> Yes: <u>7</u> No: <u>0</u> Absent: _____ Abstain: _____																									
<table border="1" style="margin: auto; border-collapse: collapse;"> <tr> <td style="padding: 2px;">Crops</td> <td style="padding: 2px;"></td> <td style="padding: 2px;">Agricultural</td> <td style="padding: 2px;"></td> <td style="padding: 2px;">Allowed¹</td> <td style="padding: 2px; text-align: center;">x</td> </tr> <tr> <td style="padding: 2px;">Livestock</td> <td style="padding: 2px;"></td> <td style="padding: 2px;">Non-Synthetic</td> <td style="padding: 2px; text-align: center;">x</td> <td style="padding: 2px;">Prohibited²</td> <td style="padding: 2px;"></td> </tr> <tr> <td style="padding: 2px;">Handling</td> <td style="padding: 2px; text-align: center;">x</td> <td style="padding: 2px;">Synthetic</td> <td style="padding: 2px;"></td> <td style="padding: 2px;">Rejected³</td> <td style="padding: 2px;"></td> </tr> <tr> <td style="padding: 2px;">No restriction</td> <td style="padding: 2px;"></td> <td style="padding: 2px;">Commercially Un-Available as Organic¹</td> <td style="padding: 2px;"></td> <td style="padding: 2px;">Deferred⁴</td> <td style="padding: 2px;"></td> </tr> </table>		Crops		Agricultural		Allowed ¹	x	Livestock		Non-Synthetic	x	Prohibited ²		Handling	x	Synthetic		Rejected ³		No restriction		Commercially Un-Available as Organic ¹		Deferred ⁴	
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E. Approved by Committee Chair to transmit to NOSB:

**Steve Demuri
Committee Chair**

**October 7, 2011
Date**

NOSB EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment?

Substance - _ DHA from Algal Oil

Question	Yes	No	N/A¹	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? ¹ [§205.600 b.2]			x	The TR evaluated the petitioned substance and concluded that there are no adverse effects under this criterion. <i>See TR lines 409-407 and 430-455; see also</i> Question 2 below (statutory form of criterion)
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		x		The TR concluded that there are no adverse environmental impacts, noting that the sole solvent used is “recycled.” <i>See generally TR lines 430-455</i> (describing inputs, manufacturing process and waste byproducts); (disposal method for biomass substrate for algal growth “eliminates” any possibility of adverse environmental impact); (noting that algae are grown and not wild-harvested so possibility of “excessive harvesting” is inapplicable); (no information that algal oil production has “adverse impact on biodiversity”); <i>see also lines 407-409</i> (noting FDA GRAS notice reported no heavy metals or pesticides detected in petitioned substance)
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		x		<i>See</i> Question 2 above, citing <i>TR lines 407-409 and 430-455</i>
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]			x	This is a substance used as an ingredient in an organic processed food. It is not used in production and contains no listed inerts.
5. Is there potential for detrimental chemical interaction with other materials used? ² [§6518 m.1]		x		No detrimental interactions were noted in the TR. <i>See TR lines 123-151</i> (discussing combinations with substances)
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]			x	This is a substance used as an ingredient in an organic processed food. It is no longer in the agro-ecosystem.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]			x	This is a substance used as an ingredient in an organic processed food. It is no longer in the agro-ecosystem.
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]			x	This is a substance used as an ingredient in an organic processed food. It is no longer in the agro-ecosystem.
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]			x	This is a substance used as an ingredient in an organic processed food. It is no longer in the agro-ecosystem.
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i;		x		The substance is widely added to food products, including infant formulas, for its healthful benefits. <i>See TR at lines 496-524</i> The TR contains a chart at lines 775-776 that lists more

¹ The criteria set forth in 7 CFR §205.600(b) are applicable solely to “synthetic substances used as a processing aid or adjuvant.” The petitioned substance is not a processing aid or adjuvant. *See TR at lines 49-50* The TR determined the petitioned substance be a “nonsynthetic.” *See TR at line 298* (“the substance should be considered non-synthetic.”) Accordingly, the criteria listed in §205.600(b) are inapplicable to the petitioned substance. *See e.g.* 7 CFR §205.600(c) (“Nonsynthetics...will be evaluated using the criteria [in the OFPA].”) However, the TR included review of most of these questions so the results are cited out of an abundance of caution.

² The criterion appearing at 7 U.S.C. §6518(m)(1), applies only to “interactions with other materials used in organic farming systems.” Because this substance is petitioned as a handling material, this criterion appears inapplicable.

§6518 m.4]			<p>than 10 countries, including the U.S., E.U., Canada, Japan, France, Belgium, U.K. etc. that have set reference intake levels of DHA for optimal health. The chart includes intake levels from leading organizations, such as the World Health Organization, World Association of Perinatal Medicine, Early Nutrition Academy and the Child Health Foundation.</p> <p>With regard to harmful effects, the TR reported that the scientific literature revealed no harmful effects for adults except those associated with “Consumption of high levels of DHA (in the form of fish oil)...” <i>See TR at lines 463-494</i></p> <p>With regard to infant formula, no studies were cited that found adverse events reported to FDA have been treated as <i>de minimis</i> and below the threshold of regulatory significance by FDA. <i>See TR at lines 463-494; See also #11 below</i></p>
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		x	<p>The petitioned substance is recognized as GRAS, and thus is considered safe under federal law, and is defined as a food additive that is properly used in foods, beverages and infant formula. It has no adverse impact on human health when used under normal conditions. The TR notes that specific GRAS notices were submitted by Petitioner that described DHA use levels for certain products, including infant formula and that “The notices were reviewed by FDA and at the time of submission, FDA had no questions about the proposed supplementation levels of DHA or the rationale behind adding DHA to the specific food products.” <i>See TR at lines 804-06</i></p> <p>The TR cites reports of adverse events for adults based on excessive consumption via fish oil sources. <i>See TR at lines 457-524.</i> The safety of the substance is also evident in that adverse events reported to FDA regarding infant formula that contains DHA have been treated as <i>de minimis</i> and below the threshold of regulatory significance by the FDA <i>See also #12 below.</i></p>
12. Is the substance GRAS when used according to FDA’s good manufacturing practices? [§205.600 b.5]	x		<p><i>See e.g. TR Line 670</i> (“DHA Algal Oil is a substance which is considered GRAS (FDA, 2001)”; <i>TR lines 75-85</i> (citing FDA GRAS Notices No. GRN 000041 and No. GRN 000137) The GRAS notices establish that FDA has no objection to the use of DHA Algal Oil under the conditions of use. (FDA, 2001).</p> <p>In addition to GRAS status, when DHA Algal Oil appears as an ingredient in infant formulas, the manufacturers submit premarket notification to FDA under section 412 of the Federal Food, Drug, and Cosmetic Act (FFDCA). Section 412 of FFDCA describes the more stringent statutory requirements that apply to infant formula as compared to the regulation of other foods (FDA, 2006).</p>
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		x	<p>The TR concluded the available literature demonstrates no heavy metal or other harmful residues have been detected in the petitioned product. <i>See TR lines 403-424</i></p>

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

Category 2. Is the Substance Essential for Organic Production? Substance - DHA from Algal 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			The TR concluded the algal oil is the product of a “naturally occurring biological process,” <i>line 278</i> , but the DHA extraction process is a “chemical process.” <i>See TR at 279</i>
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		<i>See TR line 298</i> (“the substance should be considered non-synthetic.”); <i>see also TR lines 288-292</i> (Applying National Organic Standards Board (NOSB) Joint Materials and Handling Committee draft policy: “extraction with a synthetic not on the National List would not result in a material being classified as synthetic unless either the extraction resulted in chemical change or the synthetic remained in the final material at a significant level.”)
3. Is the substance created by naturally occurring biological processes? [6502 (21)]	x			The TR concluded that the petitioned substance is the product a biological process. <i>See TR lines 278-279</i>
4. Is there a natural source of the substance? [§205.600 b.1]		x		DHA is found in fish flesh, eggs and marine algae. <i>See TR lines 327-341</i> (noting fish, shellfish and egg sources). However, DHA must be extracted from the natural materials using extraction technologies. <i>See TR lines 330-338</i> (noting extraction methodologies). For example, while fish oil appears on 7 CFR §205.606, it is not known if the processing necessary to obtain or isolate the DHA from fish oil renders the final food additive a synthetic or non-agricultural, non-synthetic under 7 CFR §205.605. <i>See e.g. TR at line 685</i> (“DHA and EPA are <i>components</i> of fish oil but are not specifically regulated” by the GRAS specifications for fish oil)(italics in TR)
5. Is there an organic substitute? [§205.600 b.1]		x		There are no known certified organic sources of algal oil, nor certified organic sources of algal oil DHA. There are no certified organic sources of fish oil or DHA obtained from fish oil.
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			x	DHA Algal Oil is the most widely used source of DHA in infant formula. Unlike fish oil sources of DHA, DHA from algal oil is vegetarian, carries no risk of containing harmful environmental contaminants like mercury and does not deplete wild fish or algae stocks. <i>See TR at lines 399-419</i> In addition, DHA is currently widely used in organic foods. Consumers, seeing products labeled as both Organic and containing DHA have chosen to purchase these products. DHA is essential for consumers to continue to have access to these organic products.
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]		x		The petitioned substance is plant based non-synthetic, non-agricultural substance. There is no plant-based agricultural substitute for the petitioned substance..
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]	x			The TR concluded the substance is a non-synthetic, non-agricultural substance. <i>See TR line 298</i> (“the substance should be considered non-synthetic.”).
9. Are there “alternatives to using the substance in terms of practices or other available materials”?		x		According to the TR, there are no other plant-based sources of DHA. <i>See TR lines 327-341</i> (noting fish, shellfish and egg sources). Fish sources of DHA require the animals be

[§6518(m)(6)]			<p>“cooked, then strained and pressed to extract the oil and other liquids.” <i>TR at line 331</i> The TR noted that several factors can cause fish oil additives to “increase fishy off-flavors in milk,” <i>see TR at lines 905-907</i>, and that the various types of fish oil each behave differently in formulation and several types of antioxidants to “prevent oxidation and development of off-flavors” have been studied. <i>TR at lines 910-917</i> Lastly, unlike animal-based DHA sources that require the animal be slaughtered, the TR notes the absence of any findings in the scientific literature that the algal source lessens biodiversity. <i>See TR at line 455</i></p> <p>The breadth of uses for the petitioned substance also suggests that another material is unlikely to always be an acceptable substitute—“DHA Algal Oil is as an ingredient as a source of DHA in foods, beverages, infant formulas, and as a dietary supplement. Some of the foods and products the petitioner lists as intended or current foods to supplement with DHA Algal Oil include: cookies and crackers, breads and rolls, meat products, condiments, beverages (including flavored milk and milk products, soy milk, other dairy products, and juices), pasta, dietary supplements, and infant formula.” <i>See TR at lines 49-54.</i></p>
10. Is there an “alternative[s] to using the substance in terms of practices” that would make the substance unnecessary? [§6518 (m)(6)]		x	The petitioned substance is a food additive and there are no “practices” that substitute for its presence.

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

Category 3. Is the substance compatible with organic production practices? Substance - DHA from Algal 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			As noted earlier, the criteria set forth in 7 CFR §205.600(b) are applicable solely to “synthetic substances used as a processing aid or adjuvant.” The petitioned substance is not a processing aid or adjuvant. <i>See TR at lines 49-50</i> The TR determined the petitioned substance be a “nonsynthetic.” <i>For a lengthy description of the manufacturing process of this substance, please See TR lines 225-272</i>
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			<i>See TR line 49.</i> (“The petitioned use of DHA Algal Oil is as an ingredient as a source of DHA in foods, beverages, infant formulas, and as a dietary supplement.”)
5. Is the primary use as a preservative? [§205.600 b.4]		x		<i>See TR line 49.</i> (“The petitioned use of DHA Algal Oil is as an ingredient as a source of DHA in foods, beverages, infant formulas, and as a dietary supplement.”)
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		<i>See TR line 49.</i> (“The petitioned use of DHA Algal Oil is as an ingredient as a source of DHA in foods, beverages, infant formulas, and as a dietary supplement.”)
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:			x	The substance is not used in production.
a. copper and sulfur compounds;			x	The substance is not used in production.
b. toxins derived from bacteria;			x	The substance is not used in production.
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?			x	The substance is not used in production.
d. livestock parasiticides and medicines?			x	The substance is not used in production.
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?			x	The substance is not used in production.

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

Category 4. Is the commercial supply of an agricultural substance as organic, fragile or potentially unavailable? [§6610, 6518, 6519, 205.2, 205.105 (d), 205.600 (c) 205.2, 205.105 (d), 205.600 (c)]

Substance DHA from Algal Oil

Question	Yes	No	N/A	Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown)
1. <u>Is the comparative description provided</u> as to why the non-organic form of the material /substance is necessary for use in organic handling?			x	The substance is not petitioned for inclusion on 7 CFR §205.606
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate form to fulfill an essential function in a system of organic handling?			x	
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate quality to fulfill an essential function in a system of organic handling?			x	
4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate quantity to fulfill an essential function in a system of organic handling?			x	
5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following:			x	
a. Regions of production (including factors such as climate and number of regions);				
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			x	

temporarily restrict supplies; or				
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: November 2011

Substance: Potassium Hydroxide

Committee: Crops Livestock Handling **Petitioned for** annotation change from -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” to -Potassium hydroxide—prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches” **on the National List § 205.605(b)**

A. Evaluation Criteria (Applicability noted for each category; Documentation attached)	Criteria Satisfied? (see B below)
1. Impact on Humans and Environment	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
2. Essential & Availability Criteria	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
3. Compatibility & Consistency	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
4. Not or Inconsistently Available as Organic	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>

B. Substance Fails Criteria Category: _____ **Comments:** _____

C. Proposed Annotation (if any): annotation change from -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” to -Potassium hydroxide—prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches during the canning or Individually Quick Frozen (IQF) production process”

Basis for annotation: To meet criteria above: _____ Other regulatory criteria: The petition is to change the annotation for the current §205.605 (b) listing of potassium hydroxide to add the allowed use of lye peeling of peaches for canning, in addition to peaches for freezing. Citation: _____

D. Recommended Committee Action & Vote (State Motion): ___Recommend changing the annotation for potassium hydroxide from -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” – to -Potassium hydroxide—prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches during the canning or Individually Quick Frozen (IQF) production process” on the National List § 205.605(b)

Motion by: DICKSON Secounded: MIEDEMA Yes: 6 No: 0 Absent: 1 Abstain: 0

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

1) Substance voted to be added as -allowed” on National List to § 205. with Annotation (if any) prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches

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 – Potassium Hydroxide

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		TAP lines 163-186: “Peach processing plants using lye peeling are generally restricted by state and local waste water treatment requirements, which has resulted in a limited number of plants and sites in operation (O’Bara, 2001). Data supplied by the petitioner indicates that alkalinity of waste is not a factor, due to the natural acidity of the fruit, which must be additionally buffered during on-site treatment (Finn, 2001).”
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		See #1 above.
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		See #1 above.
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	This is an agricultural product used as an ingredient in an organic processed food. It is no longer in the agro-ecosystem.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]			X	This is an agricultural product used as an ingredient in an organic processed food. It is no longer in the agro-ecosystem.
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]			X	This is an agricultural product used as an ingredient in an organic processed food. It is no longer in the agro-ecosystem.
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]			X	This is an agricultural product used as an ingredient in an organic processed food. It is no longer in the agro-ecosystem.
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 193-194: “The petitioner has submitted experimental data showing no increase in potassium content of the fruit due to 193 the use of potassium hydroxide.”
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		X		See #10 above.
12. Is the substance GRAS when used according to FDA’s good manufacturing practices? [§205.600 b.5]	X			TAP lines 216-237: “Potassium Hydroxide is Generally Recognized As Safe under 21 CFR 184.1631. Federally approved food uses are 218 summarized in Table 1.” Referenced table includes used in peeling of fruits and vegetables, allowed under 21 CFR 173.315(a)(1)
13. Does the substance contain		X		TAP lines 229-236

residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]				
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¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

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

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			The petition and the TAP describe the production method in detail. TAP lines 48-51: Food grade potassium hydroxide is obtained commercially from the electrolysis of potassium chloride solution in the presence of a porous diaphragm [21 CFR 184.1631(a)]. The reaction can be characterized as follows: $KCl + H_2O \rightarrow HCl + KOH$
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			According to the TAP, the source potassium chloride is natural, but the process renders the resultant potassium hydroxide synthetic (lines 138-139). Potassium chloride occurs naturally as sylvite, and it can be extracted from sylvite or from salt water. Potassium hydroxide is also a by-product of the synthesis of nitric acid from potassium nitrate and hydrochloric acid.
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		See #2.
4. Is there a natural source of the substance? [§205.600 b.1]	X			Potassium hydroxide can be obtained naturally by the leaching of wood ash, but this method is not commercially practiced (TAP lines 136-140).
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			Petitioner states that this substance is the only viable method of commercial peach peeling, and as such, is used to make products meet consumer expectations.
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X			TAP lines 141-143: Solutions of some natural acids such as citric and tartaric have been used to peel peaches. This works by disintegrating the peel and requires large volumes of water. It also prevents browning. However, this is not apparently used due to the corrosive effect of the solutions on metal equipment (Woodruff, 1986).
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]		X		Substance is synthetic.
9. Is there any alternative substances? [§6518 m.6]		X		See #7. The only natural alternative is not commercially viable.
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]		X		

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

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

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			
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]			X	This substance is used as an ingredient in an organic processed food. It is not used in agriculture.
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]	X			Nutritional quality of food is not degraded, and is in some cases improved over other processing methods.
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:				Petitioned material is not for use in production
a. copper and sulfur compounds;				
b. toxins derived from bacteria;			X	
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?			X	
d. livestock parasiticides and medicines?			X	
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?			x	

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

Category 4. Is the agricultural substance inconsistently or not commercially available as organic?

Substance - Color, Beta-carotene extract, derived from carrots

Question	Yes	No	N/A	Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown)
1. <u>Is the comparative description provided</u> as to why the non-organic form of the material /substance is necessary for use in organic handling?			X	This is not an agricultural substance.
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate form to fulfill an essential function in a system of organic handling?			X	
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate quality to fulfill an essential function in a system of organic handling?			X	
4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate quantity to fulfill an essential function in a system of organic handling?			X	
5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following:			X	
a. Regions of production (including factors such as climate and number of regions);			X	
b. Number of suppliers and amount produced;			X	
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;			X	
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or			X	
e. Are there other issues which may present a challenge to a consistent supply?			X	

Additional Background

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--Potassium hydroxide—prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches.

Committee Summary

Potassium hydroxide is a synthetic, inorganic compound produced by the electrolysis of potassium chloride. Also known as potash, it is a strong base and alkaline in solution. Much of its utility in food processing is based on its function as a caustic strong base. Potassium hydroxide is widely used in food processing as a pH adjuster, cleaning agent, stabilizer, thickener and poultry scald agent. It is also used in the lye peeling of fruits and vegetables. The FDA lists potassium hydroxide as GRAS for humans (21 CFR 184.1631), which are allowed under 21CFR 173.315(a)(1) - Chemicals used in washing or to assist in the peeling of fruits and vegetables. In fruit and vegetable peeling, potassium hydroxide serves to weaken the glycolytic bonds of pectin, which is responsible for skin adhesion. Weakening these bonds allows the peeling of fruit and vegetable skins by water spray or other mechanical methods.

In 1995, the NOSB approved the addition of potassium hydroxide to 205.605(b), with an annotation prohibiting its use in the lye peeling of fruits and vegetables. This restriction was based on concerns about the environmental effects of the waste products of the lye peeling process, and the fact that mechanical and non-chemical alternatives were available for most fruits and vegetables.

In 2001, a petitioner sought to expand the use of potassium hydroxide by amending the annotation to read ~~“prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches during the Individually Quick Frozen (IQF) production process.”~~ The 2001 TAP review for that expansion noted that ~~“The stone fruit (peaches, nectarines, and apricots) do not appear to currently have alternative methods available on a commercial scale to achieve peeling without the use of caustic substances.”~~ The 2001 TAP review also noted that the environmental effects which had originally resulted in the restrictive annotation could be mitigated with the use of good wastewater management practices. Peach processing plants are generally restricted by state and local wastewater treatment requirements, and the natural acidity of the fruit and additional pH adjustments buffer the alkalinity of the wastewater. Because no commercially viable alternatives are available, and processing practice mitigates the potential environmental effects, the NOSB approved the expanded annotation.

A new petition from the same petitioner was filed in 2011, seeking to expand the annotation again to allow the use of potassium hydroxide for the peeling of fresh peaches to be canned. The petition confirms the lack of commercially viable alternatives for this use, and the mitigation of potential environmental impact. The processing of peaches for canning and freezing is identical up until the freezing or canning step.

Based on the petition, the 2001 TAP review, and the rationale of the 2001 NOSB, the Handling Committee supports the expansion of this annotation to allow potassium hydroxide to be used in the peeling of both IQF and canned peaches. Accordingly, since

canning and freezing are the primary commercially processing methods used for peaches, we favor removing the language regarding IQF methods so that the exception to the prohibition on lye peeling applies to all peach peeling.

Committee Recommendation(s)

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

§ 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—Potassium hydroxide—prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches.

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: <u>Fall 2011-Savannah, GA</u>	Substance: <u>Silicon Dioxide</u>																								
Committee: Crops <input type="checkbox"/> Livestock <input type="checkbox"/> Handling <input checked="" type="checkbox"/> Petition is for: Removal of Silicon Dioxide from the National List § 205.605(b)																									
A. Evaluation Criteria (Applicability noted for each category; Documentation attached) Criteria Satisfied? (see B below)																									
1. Impact on Humans and Environment	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>																								
2. Essential & Availability Criteria	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A <input type="checkbox"/>																								
3. Compatibility & Consistency	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A <input type="checkbox"/>																								
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606)	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input checked="" type="checkbox"/>																								
B. Substance Fails Criteria Category: <u>2, 3</u> Comments: Silicon Dioxide (synthetic) no longer meets criteria 2, 3 because a natural, certified organic alternative is available for organic processors for certain applications. _____																									
C. Proposed Annotation (if any): <u>205.605(b) Synthetics allowed—Silicon Dioxide—providing sufficient evidence showing natural alternatives are not commercially available for a specific produce/process is presented.</u> Basis for annotation: To meet criteria above: <u>2</u> Other regulatory criteria: _____ Citation: <u>205.600(b)(1)</u>																									
D. Recommended Committee Action & Vote, including classification recommendation (State Actual Motion): _____ Classification of the material: Synthetic _____ Non-synthetic _____ Absent: _____ Abstain _____ Motion by: _____ Secinded: _____ Yes: _____ No: _____ Absent: _____ Abstain: _____ Recommended Committee Action & Vote <u>Change annotation—see Committee Recommendation</u> _____ Motion by: <u>John Foster</u> Secinded: <u>Steve DeMuri</u> Yes: <u>5</u> No: <u>1</u> Absent: <u>1</u> Abstain: <u>0</u>																									
<table border="1" style="margin: auto; border-collapse: collapse;"> <tr> <td style="padding: 5px;">Crops</td> <td style="width: 20px;"></td> <td style="padding: 5px;">Agricultural</td> <td style="width: 20px;"></td> <td style="padding: 5px;">Allowed¹</td> <td style="text-align: center; width: 20px;">x</td> </tr> <tr> <td style="padding: 5px;">Livestock</td> <td></td> <td style="padding: 5px;">Non-Synthetic</td> <td></td> <td style="padding: 5px;">Prohibited²</td> <td></td> </tr> <tr> <td style="padding: 5px;">Handling</td> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td style="padding: 5px;">Synthetic</td> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td style="padding: 5px;">Rejected³</td> <td></td> </tr> <tr> <td style="padding: 5px;">No restriction</td> <td></td> <td style="padding: 5px;">Commercially Un-Available as Organic¹</td> <td></td> <td style="padding: 5px;">Deferred⁴</td> <td></td> </tr> </table>		Crops		Agricultural		Allowed ¹	x	Livestock		Non-Synthetic		Prohibited ²		Handling	<input checked="" type="checkbox"/>	Synthetic	<input checked="" type="checkbox"/>	Rejected ³		No restriction		Commercially Un-Available as Organic ¹		Deferred ⁴	
Crops		Agricultural		Allowed ¹	x																				
Livestock		Non-Synthetic		Prohibited ²																					
Handling	<input checked="" type="checkbox"/>	Synthetic	<input checked="" type="checkbox"/>	Rejected ³																					
No restriction		Commercially Un-Available as Organic ¹		Deferred ⁴																					
1) Substance voted to be added as “allowed” on National List to § 205. _____ with Annotation (if any) (b) Synthetics allowed—Silicon Dioxide—providing sufficient evidence showing natural alternatives are not commercially available for a specific product/process is presented.																									
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: <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="text-align: center;"> <u>Steve Demuri</u> Committee Chair </div> <div style="text-align: center;"> <u>October 4, 2011</u> Date </div> </div>																									

EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment?

 Substance Silicon Dioxide

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			7/29/10 Petition pg. 3 1996 TAP questions. 1, 3
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		1996 TAP (Montecalvo, Jefferey) reviews questions. 2, 3
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		CP Kelco 2005 Petition to keep SiO ₂ on list, pg 1 1996 TAP questions 1, 2,3, 5 (Montecalvo, Jefferey, Zimmer)
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1) (B)(ii); 205.601(m)2]		X		The petition and TAP do not note any
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		X		1996 TAP (Jefferey, Montecalvo) 7/29/10 Petition to remove, pg. 3
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		X		1996 TAP (TR (Jefferey, Montecalvo) questions 2, 5
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]			X	This is a handling material
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		1996 TAP 7/29/10 Petition to remove, pg. 3
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]		X		1996 TAP questions: 2, 3, 5, 7 7/29/10 Petition to remove, pg. 3 CP Kelco 2005 Petition to keep SiO ₂ on list, pg 1
10. Is there any harmful effect on human health? [§6517 c (1)(A) (i) ; 6517 c(2)(A)I; §6518 m.4]	X			Only with improper use/handling. MSDS 1996 TAP, question 4 7/29/10 Petition to remove, pg 3
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]	X			NOSB materials database information 7/29/10 Petition to remove, pg 3
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]	X			NOSB materials database information
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		X		Petition and TAP do not mention any.

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 Silicon Dioxide

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			7/29/10 petition to remove, pg 2 1996 TAP 1/20/10 pg 1 Ribus Letter to Miles McEvoy
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		7/29/10 petition to remove, pg 2 1996 TAP NOSB Materials Database
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		7/29/10 petition to remove, pg 2 1996 TAP NOSB Materials Database
4. Is there a natural source of the substance? [§205.600 b.1]	X			Yes, but not in functional amounts 1996 TAP
5. Is there an organic substitute? [§205.600 b.1]	X			7/29/10 Ribus petition to remove, pg 11
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]		X		The function it performs is essential; not the substance 7/29/10 petition to remove, pg 11
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X			7/29/10 petition to remove, pg 11
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]		X		1996 TAP NOSB materials database 7/29/10 petition to remove, pg 1-11
9. Is there any alternative substances? [§6518 m.6]	X			1996 TAP 7/29/10 petition to remove, pg 1-11 1/20/10 pg 1 Ribus Letter to Miles McEvoy
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			Using an alternate compound only. 7/29/10 petition to remove, pg 1-11 1996 TAP 1/20/10 pg 1 Ribus Letter to Miles McEvoy

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 ___ Silicon Dioxide

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		Synthetic substance and only needed if no alt. substances are avail. 1996 TAP review (Montecalvo)
2. Is the substance consistent with organic farming and handling, and biodiversity? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]		X		Synthetic substance and only needed if no alt. substances are avail. 1996 TAP review (Montecalvo)
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]			x	This is a handling input. No negative impact on environment following use. 7/29/10 Petition pg. 3 1996 TAP questions. 1, 3
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]		X		TAP and petition do not note any.
5. Is the primary use as a preservative? [§205.600 b.4]		X		7/29/10 petition to remove, pg 1 NOSB materials database 1996 TAP review
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		7/29/10 petition to remove, pg 1 NOSB materials database 1996 TAP review
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:		X		
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: _ Silicon Dioxide _**

Question	Yes	No	N/A	Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown)
1. <u>Is the comparative description provided</u> as to why the non-organic form of the material /substance is necessary for use in organic handling?			X	The petition is for removal of SiO2 from 205.605 7/29/10 Petition to remove proposes use of organic alternative to SiO2
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	The petition is for removal of SiO2 from 205.605 7/29/10 Petition to remove proposes use of organic alternative to SiO2
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	The petition is for removal of SiO2 from 205.605 7/29/10 Petition to remove proposes use of organic alternative to SiO2
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	The petition is for removal of SiO2 from 205.605 7/29/10 Petition to remove proposes use of organic alternative to SiO2
5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following:			X	The petition is for removal of SiO2 from 205.605 7/29/10 Petition to remove proposes use of organic alternative to SiO2
a. Regions of production (including factors such as climate and number of regions);			X	The petition is for removal of SiO2 from 205.605 The petition is for removal of SiO2 from 205.605 7/29/10 Petition to remove proposes use of organic alternative to SiO2
b. Number of suppliers and amount produced;			X	The petition is for removal of SiO2 from 205.605 7/29/10 Petition to remove proposes use of organic alternative to SiO2
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	The petition is for removal of SiO2 from 205.605 7/29/10 Petition to remove proposes use of organic alternative to SiO2
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or			X	The petition is for removal of SiO2 from 205.605 7/29/10 Petition to remove proposes use of organic alternative to SiO2
e. Are there other issues which may present a challenge to a consistent supply?			X	The petition is for removal of SiO2 from 205.605 7/29/10 Petition to remove proposes use of organic alternative to SiO2

**National Organic Standards Board
Handling Committee
Proposed Recommendation
Silicon Dioxide**

October 14, 2011

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 a naturally occurring substance that is generated following oxidation reactions involving silicon in the Earth's crust. Silicon dioxide is a major component in sand, quartz, diatomaceous materials, and is found as biogenic silica in organisms. Silicon dioxide's (chemical formula is SiO₂) exists both as an amorphous and crystalline structures and is frequently found in a three-dimensional polytetrahedral structure where the two oxygen atoms of one SiO₂ molecule are associated with a silicon atom of another SiO₂ molecule. This molecular association generates structures exhibiting unique properties such as immiscibility in both water and oil and an extremely large surface area. These characteristics have been capitalized upon for their functionality in a diverse set of applications and industries including (but not limited to): glass production, ceramics, optical cable fiber production, food processing, food packaging, pharmaceutical production/packaging, soil amendments, and as inert compounds/carrier systems within pesticides. While silicon dioxide is found in natural sources, most industrial applications use silicon dioxide generated from synthetic sources/processes.

The food industry frequently uses a silicon dioxide as its properties allow for enhanced process-ability and functionality in food products and manufacturing practices. Some common applications of silicon dioxide in the food industry are: as an anti-caking agent (most common application), an anti-foam agent, a stabilizer in beer production, an adsorbent in foods prepared as tablets for special dietary use, as carriers (such as a component of microcapsules for flavoring oils), and for various other uses allowed under jurisdiction of the FDA. Silicon dioxide is also allowed internationally for various uses in food products (in both conventional and organic foods) by the European Union, Codex, Canada, Japan, and by IFOAM for organic processing.

In 2010 the NOSB voted to relist silicon dioxide despite knowing that an application to remove silicon dioxide was at the NOP. During the relisting process, the Handling Committee produced the following concerns based upon debate and information presented during the sunset review process:

1. The Handling Committee has discussed and collectively agrees that there is the need to encourage the growth of agricultural--and preferably organic--alternatives to nonagricultural substances presently allowed on the National List for use in organic handling operations, and considers this to be just such an opportunity.

2. Public comment indicates that while organic alternatives exist that may replace silicon dioxide as currently listed, the Handling Committee is concerned that *applicable* alternatives do not exist for sufficient uses and applications of silicon dioxide in organic handling.

Given the above concerns, the NOSB voted to relist silicon dioxide and publically note that additional information, data, and clarification of processors' needs regarding silicon dioxide would be needed for future deliberation during the upcoming discussion on silicon dioxide's removal from § 205.605(b).

As such, § 205.605(b) today allows silicon dioxide to be utilized in organic foods labeled in the "organic" and "made with organic" categories. The petition currently under consideration is to remove its listing on § 205.605(b), stating there now exists a viable, non-synthetic, certified organic substitute to silicon dioxide available from a rice-hull based material. This alternative substance exhibits similar functional properties as silicon dioxide since it is produced from rice hulls which naturally contain a high concentration of silica. In addition, the current petition claims that the rice-hull product's applicability should not be in question as:

"The proposed rice concentrate has been produced and sold in commercial quantities (domestically and internationally) to organic and natural food / feed producers for many of the exact same uses as SiO₂."

While an extensive review has been completed by the Handling Committee concerning the environmental, health, and applicability concerns of synthetic dioxide from the TAP reviews, previous petitions, prior NOSB discussions; the primary consideration/debate for whether or not synthetic silicon dioxide should remain on § 205.605(b) is rooted in consideration of § 205.600(b)(1) which states:

The following criteria will be utilized in the evaluation of substances or ingredients for the organic production and handling sections of the National List:

(b) In addition to the criteria set forth in the Act, any synthetic substance used as a processing aid or adjuvant will be evaluated against the following criteria:

(1) The substance cannot be produced from a natural source and there are no organic substitutes

Given this section of the regulation, and the charge of the NOSB to make decisions consistent with the overall intent of the regulation, the NOSB has considered the current petition to remove silicon dioxide by analyzing the previous information as to why synthetic silicon dioxide was originally listed on § 205.605(b). Resultant of this analysis, it has been concluded that silicon dioxide was previously listed due its unique properties and its overall safety and limited environmental concerns. However, since the initial listing, the following new information regarding a new agricultural substitute has been presented:

Table 1. Use Rates of Organic Rice Concentrate vs. SiO₂

	<u>2007-2008*</u>	<u>2009-Present*</u>
Spice Blends	1:1 or 1.2:1	1:1
Dry Beverages	Did not work	1:1
Dried Fruit	Did not work	1:1
Tablets	1.1 or 1.2:1	1:1
Sauce Mixes	1.1 or 1.2:1	1:1
Flavor Carrier (oil & water)	1.2:1	0.8:1 or 1:1

*Ratios are expressed as rice concentrate: SiO₂

The above table from the petition attempts to demonstrate that the rice-hull based alternative described in the 2010 petition to remove silicon dioxide has been available since 2007 and has undergone reformulation in 2009 such that it now can be substituted for silicon dioxide nearly 1:1 ratios. Given this new information, the NOSB must determine whether sufficient evidence has been presented by the petitioner as to whether this natural organic alternative is sufficient in all applications to remove silicon dioxide from § 205.605(b).

While the new data does address concerns noted by the Handling Committee during the Sunset review process; the Handling Committee feels that it is still limited, not published from a third party source, and does not conclusively demonstrate its applicability in all products and processes. However, while the data presented in this petition is not sufficient to completely remove silicon dioxide, the Handling Committee feels that the availability of a natural alternative must be acknowledged.

Therefore, with respect to the change in NOSB Policy and Procedures Manual, the Handling Committee did not vote to remove silicon dioxide in its entirety but recommends a change to the annotation to silicon dioxide as noted below to be consistent with the intent of § 205.600(b)(1).

Committee Recommendations

1. Motion to remove the following substance:

§ 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 Vote

Motion: John Foster Second: Steve DeMuri
Yes: 0 No: 5 Abstain: 0 Absent: 2

2. Motion to amend the annotation of the following substance:

§ 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—providing sufficient evidence showing natural alternatives are not commercially available for a specific product/process is presented.

Committee Vote

Motion: John Foster Second: Steve DeMuri
Yes: 5 No: 1 Abstain: 0 Absent: 1

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: Fall 2011 Savannah, GA	Substance: Sulfur dioxide																								
Committee: Crops <input type="checkbox"/> Livestock <input checked="" type="checkbox"/> Handling <input type="checkbox"/> Petition is for: Amendment of Sulfur dioxide annotation from the National List § 205.605(b)																									
A. Evaluation Criteria (Applicability noted for each category; Documentation attached) Criteria Satisfied? (see B below)																									
1. Impact on Humans and Environment	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A <input type="checkbox"/>																								
2. Essential & Availability Criteria	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>																								
3. Compatibility & Consistency	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>																								
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606)	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input checked="" type="checkbox"/>																								
Substance Fails Criteria Category: Comments: Annotation provides adequate mitigating conditions.																									
Proposed Annotation (if any): § 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, provided that total sulfite concentration does not exceed 100 ppm.																									
Basis for annotation: To meet criteria above: <u> 1 </u> Other regulatory criteria: _____ Citation: _____																									
D. Recommended Committee Action & Vote, including classification recommendation (State Actual Motion): _____ Classification of the material: Synthetic _____ Non- synthetic _____ Absent: _____ Abstain _____ Motion by: _____ Seconded: _____ Yes: _____ No: _____ Absent: _____ Abstain: _____																									
Recommended Committee Action & Vote § 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, provided that total sulfite concentration does not exceed 100 ppm.																									
Motion by: <u> John Foster </u> Seconded: <u> Steve DeMuri </u> Yes: <u> 5 </u> No: <u> 0 </u> Absent: <u> 2 </u> Abstain: <u> 0 </u>																									
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25%;">Crops</td> <td style="width: 25%;"></td> <td style="width: 25%;">Agricultural</td> <td style="width: 25%;"></td> <td style="width: 25%;">Allowed¹</td> <td style="width: 25%; text-align: center;">x</td> </tr> <tr> <td>Livestock</td> <td></td> <td>Non-Synthetic</td> <td></td> <td>Prohibited²</td> <td></td> </tr> <tr> <td>Handling</td> <td style="text-align: center;">X</td> <td>Synthetic</td> <td style="text-align: center;">X</td> <td>Rejected³</td> <td></td> </tr> <tr> <td>No restriction</td> <td></td> <td>Commercially Un- Available as Organic¹</td> <td></td> <td>Deferred⁴</td> <td></td> </tr> </table>	Crops		Agricultural		Allowed ¹	x	Livestock		Non-Synthetic		Prohibited ²		Handling	X	Synthetic	X	Rejected ³		No restriction		Commercially Un- Available as Organic ¹		Deferred ⁴		
Crops		Agricultural		Allowed ¹	x																				
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 § 205.605 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, provided that total sulfite concentration does not exceed 100 ppm.																									
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:																									
<i>Steve DeMuri</i> Committee Chair	10-14-10 Date																								

EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment?

Substance: sulfur dioxide

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			Yes, but not at levels used TAP 9-26-11 Draft ln 422-424. TAP 9-26-11 Draft ln 84-89
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]	X			Yes, but not at levels used TAP 9-26-11 Draft ln 422-424. TAP 1-14-11 ln 68-73, 270-275, 277-281; TAP 9-26-11 Draft ln 84-89, ln 406-414.
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)j]			X	N/A-for handling purposes
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1) (B)(ii); 205.601(m)2]			X	N/A-for handling purposes
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	N/A-for handling purposes
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]			X	N/A-for handling purposes
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]	X			Yes, but not at levels used TAP 9-26-11 Draft ln 422-424. TAP 9-26-11 Draft ln 84-89
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]	X			Yes, but not at levels used TAP 9-26-11 Draft ln 422-424. TAP 9-26-11 Draft ln 84-89. TAP 1-14-11 422-434;
10. Is there any harmful effect on human health? [§6517 c (1)(A) (i) ; 6517 c(2)(A)I; §6518 m.4]	X			TAP 1-14-11 ln; TAP 9-26-11 Draft ln 434-459, 461-462;
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]	X			TAP 1-14-11 ln 440-445, 447-477; 21 CFR 182.3762; TAP 9-26-11 Draft ln 430-432. 1995 TAP Bob Durst.
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]	X			TAP 9-26-11 Draft ln 338-347; 21 CFR 182.3762
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		X		TAP 9-26-11 Draft ln 395-396;

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 sulfur dioxide

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			TAP 1-14-11 ln 258-265.
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			Possible: TAP 9-26-11 Draft ln 402-403; 1995 TAP R.C. Theuer.
3. Is the substance created by naturally occurring biological processes? [6502 (21)]	X			TAP 1-14-11 ln 258; TAP 9-26-11 Draft ln
4. Is there a natural source of the substance? [§205.600 b.1]	X			TAP 1-14-11 ln 258-260. TAP 9-26-11 Draft 322-331; 1995 TAP R.C. Theuer.
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			TAP 9-26-11 Draft 327-328. 1995 TAP Bob Durst. TAP 9-26-11 Draft ln 172-176.
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]		X		TAP 9-26-11 Draft ln 467-478. 1995 TAP R.C. Theuer.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]			X	N/A- Synthetic
9. Is there any alternative substances? [§6518 m.6]		X		TAP 9-26-11 Draft ln 467-478. 1995 TAP Bob Durst
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]		X		TAP 9-26-11 Draft ln 467-478

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; sulfur dioxide

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	N/A-for handling purposes
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]			X	N/A-for handling purposes
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]	X			TAP 9-26-11 Draft ln 387-389.
5. Is the primary use as a preservative? [§205.600 b.4]	X			TAP 9-26-11 Draft ln 377. 1995 TAP R.C. Theuer
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		TAP 9-26-11 Draft ln 377
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:		X		N/A-for handling purposes
a. Copper and sulfur compounds;			X	N/A-for handling purposes
b. Toxins derived from bacteria;			X	N/A-for handling purposes
c. Pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?			X	N/A-for handling purposes
d. Livestock parasiticides and medicines?			X	N/A-for handling purposes
e. Production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?			X	N/A-for handling purposes

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: sulfur dioxide

Question	Yes	No	N/A	Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown)
1. <u>Is the comparative description provided</u> as to why the non-organic form of the material /substance is necessary for use in organic handling?			X	Petition is to amend annotation of an all ready allowed synthetic.
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	N/A.
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	N/A.
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	N/A.
5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following:			X	
a. Regions of production (including factors such as climate and number of regions);			X	
b. Number of suppliers and amount produced;			X	
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;			X	
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or			X	
e. Are there other issues which may present a challenge to a consistent supply?			X	

**National Organic Standards Board
Handling Committee
Sunset 2013 Proposed Recommendation
Animal Enzymes on §205.605(a)**

August 16, 2011

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 Vote:

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

Animal enzymes—(Rennet—animals derived; Catalase—bovine liver; Animal lipase; Pancreatin; Pepsin; and Trypsin).

Moved: Steve DeMuri

Second: Katrina Heinze

Yes: 5

No: 0

Abstain: 0

Absent: 2

**National Organic Standards Board
Handling Committee
Sunset 2013 Proposed Recommendation
Tartaric acid on §205.605(a) and §205.605(b)**

October 4, 2011

List: National Organic Program Subpart G: The National List of Allowed and Prohibited Substances. §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* AND
(b) *Synthetics allowed***

Committee Summary:

Tartaric acid is currently included on the National 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)).” This material is listed both as a Nonsynthetic allowed with an annotation of “made from grape wine” (§205.605 (a)) and a Synthetic allowed with an annotation of “made from malic acid” (§205.605 (b)).

Tartaric acid was added in both locations through a Federal Register notice on October 31, 2003 (61988 Federal Register, Volume 68, No. 211, #61988) resulting from a October 31, 1995 NOSB recommendation. Transcripts from that meeting are included below:

“Tartaric Acid (Made from grape wine)

Determined to be non-synthetic; Vote – Unanimous (1 absent).

The NOSB’s decision is to allow this material for use in organic food processing;

Vote – Unanimous (1 absent).

“Tartaric Acid (Made from malic acid)

Determined to be synthetic; Vote – Unanimous (1 absent).

The NOSB’s decision is to allow this material for use in organic food processing;

Vote: 10 aye / 4 opposed.

Both listings of tartaric acid were recommended by the NOSB for relisting as part of the sunset process at the May 2008 meeting. The non-synthetic listing, “made from grape wine,” was recommended for relisting by a vote of 13 yes, 1 abstention and 1 absent. The synthetic listing, “made from malic acid,” was recommended for relisting by a vote of 10 yes, 3 no, 1 abstention and 1 absent. At the meeting public comment was received saying that the two sources of tartaric acid result in materials

with different properties that are used in different applications but that the predominant form of tartaric acid on the market is made from grape(s) or grape wine. No public comment was received at that meeting indicating that tartaric acid made from malic acid and listed on §205.605(b) was no longer necessary. The board recommendation from the May 2008 meeting said, “A petition to remove tartaric acid made from malic acid from 205.605 b) would allow for the fuller reconsideration of the listing of material as well at a future date.”

The listings of tartaric acid on both sections of §205.605 are due for a sunset review by 2013 (Federal Register Vol. 76, No. 105: AMS–NOP–11–0003). In response to this Federal Register notice, six public comments have been received with all supporting the relisting of tartaric acid. Specifically to the §205.605a non-synthetic listing, four public comments supported the relisting and one supported relisting or moving to §205.606 if there was sufficient evidence to demonstrate that it could be produced organically in appropriate form, quality and quantity. For the §205.605b synthetic listing, four public comments supported the relisting. One public comment supported relisting tartaric acid but did not indicate whether that support was for one or both listings.

In early September 2011 the NOSB received a petition for removal of tartaric acid from §205.605b. The petition indicates that there are no functional differences between the tartaric acid sourced from grape wine or from malic acid and that there is sufficient tartaric acid sourced from grape wine. Additionally, the petition goes on to say that tartaric acid is not sourced from malic acid but rather maleic anhydride. A Technical Review has been requested from the National Organic Program. It is expected to be completed by the end of October to allow for public comment. Should it not be received, the Handling Committee intends to defer a vote on this material until the spring 2012 meeting.

At this time however, we believe that there is insufficient evidence to support the need for both listings of tartaric acid. In two sunset reviews, we have received little public comment providing technical reasons why a synthetic source and form is needed when the non-synthetic source/form is the predominant version available.

Committee Vote

The Handling Committee recommends renewal of Tartaric Acid, made from grape wine on the National List section §205.605(a)

Moved: Katrina Heinze Second: Steve Demuri
Yes: 6 No: 0 Absent: 1 Abstain: 0 Recuse: 0

The Handling Committee recommends renewal of Tartaric Acid, made from malic acid on the National List section §205.605(b)

Moved: Katrina Heinze Second: Steve Demuri
Yes: 1 No: 5 Absent: 0 Abstain: 0 Recuse: 0

**National Organic Standards Board
Handling Committee
Proposed Recommendation
Chlorine Materials**

October 5, 2011

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

Chlorine is a member of the salt-forming halogen series, combines readily with many other elements, 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 and is not infrequently found in higher natural concentrations as well. 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.

The annotations limiting the use of chlorine in §205.601(a) (2), §205.603(a)(7), and §205.605(b), do not align with a November 1995 NOSB recommendation on chlorine materials. This recommendation stated that chlorine materials should be allowed for use in organic crop production, organic food processing, and organic livestock production with the following annotation:

“Allowed for disinfecting and sanitizing food contact surfaces. Residual chlorine levels for wash water in direct crop or food contact and in flush water from cleaning irrigation systems that is applied to crops or fields cannot exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (currently 4mg/L expressed as Cl_2).”

This annotation was crafted to acknowledge that levels of chlorine permitted in municipal drinking water were considered acceptable for organic food production and handling. The language used in the proposed NOP rule published in March 2000 did not include the terms “in direct crop or food contact” and “in flush water ... that is applied to crops or fields.” The language used under §205.605 (handling uses) only mentions use in disinfecting food contact surfaces, leading some handlers to question whether chlorine could be used in direct food contact. The NOP responded in the preamble of the final rule (65 FR 80548, 80616, December 21, 2000) which stated that the use of the term “residual chlorine” referred to the chlorine that was present in water when it exited the facility as effluent.

The NOSB revisited the issue through a May 2003 recommendation. At that time, the NOSB noted that “residual chlorine” is a scientific term used when measuring chlorine. Residual chlorine (also called free or available chlorine) is the chlorine that remains available in solution after the disinfection step is complete, when the initial added chlorine material has been reduced by reaction, bound to the organic matter, or evaporated. The residual chlorine is what is still available to oxidize other substances. Residual chlorine is the fraction of available chlorine in solution derived from the disinfectant source. When calcium hypochlorite or sodium hypochlorite is used, the proper measure for residual chlorine is the sum of the concentrations of hypochlorous acid (HOCl) and hypochlorite ion (OCl⁻). For chlorine dioxide (ClO₂), all unreacted chlorine is considered to be free chlorine. Another frequently used term is total chlorine, which is a measurement of the free plus inactive forms.

In 2003, the NOSB stated: “The Organic Foods Production Act is not designed to function as a waste water regulation. Instead, it is a regulation designed to protect organic integrity. As such, processing operations must demonstrate compliance with the chlorine annotation by monitoring the chlorine content of the water which is in direct contact with organic products, not the wash water which is discharged from the facility.”

In December 2010, the NOP issued draft guidance clarifying the use restrictions of chlorine materials in organic production and handling (the background of which is provided again within this recommendation). On review and consideration of this draft guidance, informed by public comment and review of a new TR provided by the NOP (supplied for Crops Committee sunset review), and with respect to the change in NOSB Policy and Procedures Manual, the Handling Committee wishes to recommend a change to the annotation to chlorine materials as noted below.

Additionally, the Handling Committee would like to note that other chlorine compounds, such as hypochlorous acid, may be appropriate materials to add to the annotation upon appropriate review, recommendation and Board vote.

Committee Recommendation

The Handling Committee recommends the annotation of the following substance as follows:

§ 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

Chlorine materials (calcium hypochlorite, chlorine dioxide, and sodium hypochlorite) for disinfecting and sanitizing food contact surfaces, equipment and facilities may be used up to maximum labeled rates.

Chlorine materials in water used in direct crop or food contact is permitted at levels approved by the FDA or EPA for such purpose, provided the use is followed by a rinse with potable water at or below the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act or followed by other effective intervention or testing steps that would reduce and verify the residual chlorine levels to be 4mg/L or less on the product.

Chlorine in water used as an ingredient in organic food handling must not exceed the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act.

Committee Vote

Motion: John Foster

Second: Tracy Miedema

Yes: 6 No: 0

Abstain: 0 Absent: 1

**National Organic Standards Board
Materials Committee
Proposed Discussion Document
Aquaculture Materials Review Update**

September 27, 2011

Background

Based on work of the Aquaculture Task Force over the period of several years, the NOSB has adopted some recommendations regarding aquaculture:

[Aquaculture Standards](#)

(<http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5056878>)

3/29/07

[Aquatic Plants](#)

(<http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5070396&acct=nosb>) 5/22/08

[Net Pens and Related Issues](#)

(<http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5074509&acct=nosb>) 11/19/08

[Fish Feed – Fish Oil and Fish Meal & Related Issues](#)

(<http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5074508&acct=nosb>) 11/19/08

[Bivalves](#)

(<http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5081491&acct=nosb>) 11/5/09

None of these have been implemented as regulations. If they were to become regulations, they would establish new sections of the National List:

§ 205.609 Synthetic substances allowed for use in organic aquatic plant production.

§ 205.610 Nonsynthetic substances prohibited for use in organic aquatic plant production.

§ 205.611 – Synthetic substances allowed for use in organic aquatic animal production.

§ 205.612 Nonsynthetic substances prohibited for use in organic aquatic animal production.

In order to determine what changes might need to be made to the materials evaluation process, the Aquaculture Task Force submitted two —tail balloon” petitions, for carbon dioxide and vitamins. The Materials Committee has drawn some conclusions from the process of considering those petitions and formulated some questions for discussion.

What we learned from the trial balloons

- We need different criteria for open systems as opposed to closed systems. We don't know what those criteria will be, but we can't even start to think about them without knowing whether the substance will be contained in a land-based pond or tank, or will be used in net pens in open water.
- Petitions need to include:
 - The use pattern of the material—quantity, how it is added to the system, etc.
 - Aquaculture-specific information—for example, on environmental fate, interactions with other substances and organisms.
 - References to applicable laws and regulations that are aquaculture-specific.
- Petitions should not only cite petitions and TRs for crops and livestock, but also cite references that are relevant to the use of the material in an aquatic system. Some issues will carry over, but others will not.
- We need to deal with specific materials, not categories, at least until we get our material evaluation process worked out.

Further Committee Thoughts on Development of an Aquaculture Review Process

- The review of aquaculture materials needs to align with NOP's drafting of proposed aquaculture standards. Petitioners may submit petitions to the NOP for review of aquaculture materials by the NOSB. However, the NOSB will defer requests for technical review until the program publishes proposed aquaculture standards, or until the NOP otherwise notifies the NOSB to take up these petitions to coordinate with rulemaking.
- The Materials committee will continue to develop the process of evaluating aquaculture materials through the review of the two —trial balloons” submitted by the Aquaculture Working Group.
- The Materials Committee proposes that a separate Aquaculture Committee, overlapping in membership with Crops and Livestock, be established to evaluate materials.

Questions about the Development Process for Board Discussion and Public Comment

1. Are there international bodies or organizations with a good material review process? If so, who? How could we interact with these entities to address material evaluation issues that we have?
2. How do we ensure that our organic aquaculture material review process is viewed from an aquaculture lens rather than a crop or livestock lens, while not compromising organic farming and environmental principles? In other words, how do we maintain the level of review of materials consistent with crops and livestock uses, while viewing materials in their unique application to aquaculture systems?

3. How can the review of aquaculture materials proceed cautiously while not compromising consumer expectation of the organic label? What do consumers expect from organically produced aquaculture products, and how does that translate into specific requirements concerning materials, e.g., environmental impacts, hormones, organic feed, etc.?

Questions Concerning the Material Evaluation Process:

1. What criteria are specific to open systems? Closed systems?
2. Which evaluation questions in current crops/livestock evaluations are relevant to aquaculture materials?
3. Which evaluation questions do not apply, or need to be modified?
4. What new questions need to be asked about aquaculture materials?
5. What information needs to be considered in assessing the essentiality of a material in the context of cultural practices as they apply to water instead of soil ecosystems?
6. Do different questions need to be asked about carnivorous and herbivorous fish? Carnivorous fish pose additional problems, as has been pointed out by commenters. Because of the bioaccumulation of toxic chemicals, it is difficult to find clean natural foods for carnivorous fish.

Committee Vote

Moved: Katina Heinze Second: Tina Ellor
Yes: 7 No: 0 Abstain: 0 Absent: 0

**National Organic Standards Board
Materials Committee
Proposed Discussion Document
Research Priorities Framework**

September 27, 2011

Introduction

At the April 2011 National Organic Standards Board (NOSB) meeting, public comment was received, and supported by discussion among NOSB members, asking the NOSB to create a process to collect, prioritize and advocate for research related to use of materials in organic production or handling. The Materials Committee accepted the request as a workplan item. This document shares the committee's current thinking on a process to collect, prioritize, and maintain research needs related to organic production methods and materials on the National List of Allowed and Prohibited Substances, or being petitioned for listing on, the National List. The committee has posed questions at the end of the document on which we seek the input of the full NOSB, the USDA National Organic Program (NOP) and the public so that we can continue our work.

Background

The discussion of whether a material should be listed on the National List is sometimes a balance of the benefits that use of the material brings balanced against concerns with the use of the material—that is, we are concerned about both whether the use of the material is consistent with a system of organic and sustainable agriculture and whether effective and efficient alternatives exist. Over the past several years the NOSB has been faced with extending use of several materials (e.g., methionine and tetracycline) concerning which we heard public comment that the public wished that better alternatives had been identified. The NOSB has heard evidence that alternatives exist, but has found the evidence insufficient in some way, such as the lack of „hard“ science to support their viability or an inadequate consideration of the variation in production conditions.

The discussion and public comment at the April 2011 NOSB meeting related to the use of tetracycline and streptomycin for use in fire blight control on apple and pear trees highlighted the need for research into alternatives for some materials on the National List. Several public comments talked about the lack of funding for these topics or the need for adequate justification that research was necessary. As a result of those discussions, the NOP issued letters to the USDA National Institute for Food and Agriculture (NIFA) and the USDA Agricultural Research Service (ARS) to request their assistance in prioritizing research on alternatives to tetracycline and streptomycin for fire blight control in apples.

Subsequent to NOSB debate on tetracycline, the NOSB heard public comment asking the NOSB to be more proactive in advocating for research related to

materials use in organic production. It was clear at the meeting that a more formalized approach to advocating for research was needed. Hence, the Materials Committee accepted the workplan item to develop a framework for doing so.

In developing this framework, the committee asked what problems such a framework was intended to address. As we reviewed the past several years of board discussion on materials we saw that:

- The NOSB continues to receive petitions to extend the listing date of materials for which the NOSB has recommended an “expiration” date (e.g., methionine). A lack of research on alternatives means that these extensions continue to be requested and recommended by the board without NOSB consensus.
- We want to see more resources invested into priority areas of need related to materials and organic production practices.
- Some materials being reviewed by the Board come with widely differing perspectives related to benefits and risks, and the NOSB has no opportunity to be proactive about getting research into alternatives.
- There is no public forum for publishing a list of research needs and priorities. As a consequence, there is little incentive to research those areas because there is no public acknowledgment that funding is needed.

The primary goal of this framework is to gain NOSB alignment on criteria for prioritizing research needs and a process for collecting and communicating research needs. Additional benefits could include:

- Influencing where research dollars are directed
- Allowing the NOSB to be more proactive with regards to problematic or controversial National List substances by creating a mechanism to advocate for primary research ahead of material review dates
- Highlighting research results that will satisfy many different stakeholders and align the various stakeholders on research conclusions
- Reducing disagreement within the organic community by increasing the amount of primary research on which decisions could be based
- Increasing the amount of research being done related to organic agriculture. Today, the research community may not always be aware of the research needs of organic producers and handlers. Awareness could allow for USDA funding of primary research in these top priority areas and provide support for researchers submitting grants requests these research areas.
- Encouraging publication of field-level work. We know that organic farmers are continually „researching” new production methods at the farm level but often these ideas are discussed at farm conferences and not further disseminated. Our hope is that a list of „top needs” could encourage certifiers, regulators and other stakeholders to support farmers in their research and publication of their research.

Process Framework

In the Materials committee discussions the following process framework was developed:

1. The Materials Committee will collect research topics from public comment, NOP and NOSB committees on an on-going basis. Specifically, the Materials committee should review research topic needs after every NOSB meeting to ensure that public comment and NOSB discussion on new research needs are added to a „running“ list.
2. Research topics will be kept by the committee on an all-inclusive „running“ list. The list would include a description of the research and how the research needs to apply in an organic context.
3. On an annual basis, the committee will review the list and based on the criteria discussed below recommend the top research priorities for NOSB review, discussion, change and approval. We envision that the top priorities will be about five topics but discussed that a „hard“ number was not needed or even desirable. Additionally, we do not envision ranking the top priorities. Our goal would be to have a short list of the „select few“ research topics for which the NOSB believes research would have the largest long-term impact on growth and integrity of organic agriculture.
4. On an annual basis, the NOSB will review the list and make any needed additions, amendments and deletions from the top priorities list. The list will be published as an NOSB recommendation that the items on it be a focus for research needs. It is not our intention that the NOP would have to take action on the list beyond making it available for public awareness.

The criteria for prioritization are focused on selecting the few „big ideas“ that the NOSB believes will have the largest long-term impact on growth and integrity of organic agriculture. The criteria would be research topics that are:

- Persistent and chronic (i.e., perennial topics of debate and need)
- Challenging
- Controversial (i.e., topics on which there are widely differing perspectives or for which there have been close NOSB votes)
- Nebulous (i.e., the research need is hard to identify but the organic agriculture need is clear). For example, improved methods of weed control.
- Lacking in primary research. That is, topics for which there is no active research being conducted.

Although we hope that the research will eventually address the problems on the list, we also realize that solutions will not be found immediately. If properly used, the „select few“ research topics should not change drastically from year to year but should reflect long-standing, difficult to address needs within the industry. Over a longer timeframe, topics will drop off and be replaced with others. The committee notes that while the „running“ list of research needs may be long, the goal of

prioritization will be to select only a few „big ideas“ that will have the largest impact for the industry. Therefore, many worthwhile research needs will not be prioritized.

As the committee discussed this framework there was some discussion on how these research needs worked with material Technical Reviews. It was clear to the committee that duplicating or replicating Technical Reviews was not the intention. Rather, the Technical Reviews can highlight areas where primary research is lacking--for example, research into eliminating barriers to commercial availability (e.g., alternatives to de-oil soy lecithin) or research into viable, available alternatives for current materials or methods. No topic on the list should be a review of existing research. For that, Technical Reviews are the best course.

Requested Input from NOSB, NOP and Public Comment

1. What additions or changes would you make to the process for collecting and maintaining the list of research needs?
2. Are there other criteria that you would want the board to consider when prioritizing research topics? What research needs would our proposed criteria have „missed“ without the addition of additional criteria?
3. The committee proposes that the top priorities be reviewed on an annual basis. What benefits or drawbacks exist for extending or shortening this review time? Specifically with respect to research, funding and topic awareness time frames?
4. Is the collection, prioritization and publication of research needs an topic in which the NOSB should engage?

Committee Vote:

The Materials Committee moves to accept this document and present it for full board discussion at the fall 2011 NOSB meeting:

Moved: Katrina Heinze Second: Tina Ellor

Yes: 6 No: 0 Abstain: 0 Absent: 0 Recuse: 0

**National Organic Standards Board
Compliance, Accreditation and Certification Committee
Proposed Recommendation
Evaluation of Materials Review Organizations**

October 1, 2011

Introduction

The assessment of specific substances for compliance with the National Organic Standards – known as “Materials Review” – is a foundational element in the organic supply chain. Certifiers and other materials review organizations regularly review materials as a service to their clients, and these decisions directly impact the organic integrity of growing, livestock and handling operations and ultimately the integrity of the USDA Organic label. The uniformity, consistency and integrity of materials review decisions is of paramount importance to the integrity of the entire organic supply chain, and the National Organic Program must play a primary role in supervising and monitoring these activities.

Following the NOP’s request for NOSB advice on this issue, the CACC prepared a discussion document for the April, 2010 NOSB meeting in Seattle. This document summarized the issue and the NOP request, and posed a number of specific questions about specific facets of this complex subject. The board received written and oral public comment from numerous stakeholders, including certifiers, materials review organizations, input manufacturers and others. The CACC has evaluated these comments and has carefully considered them in making the current recommendation.

Background

On January 18, 2011, the NOP Deputy Administrator requested the participation of the NOSB in developing a clearer NOP policy on the oversight of materials review organizations:

The NOP is interested in developing a more uniform and consistent procedure for evaluating the competency and quality of material evaluation programs, as approved by accredited certification agencies or by other third party organizations.

The NOP is requesting that the National Organic Standards Board (NOSB) develop a recommendation that delineates the criteria that should be used by certifying agents and third party organizations to evaluate materials used in organic production and handling. The recommendation should include the criteria and process that should be used to determine the approval of input substances used in crop production (e.g. fertilizers, pest control materials, soil amendments, crop production aids), livestock production (e.g. feed supplements, feed

additives, medications and livestock production aids), post-harvest handling and food processing (e.g. processing aids, sanitizers, facility pest control materials).

A number of organizations currently provide materials review services to producers and certifiers. At least one of those organizations is an independent organization that is not an Accredited Certifying Agent or under any NOP oversight. At least one other materials review organization is a formal subdivision of an ACA, and many ACAs provide some material review services to clients on a formal or informal basis. The CACC agrees with the NOP that there is a clear need for more uniform and consistent policies governing material review services, and we believe that all organic stakeholders would benefit from a clearly defined NOP guidance around the qualification and activities of these organizations.

Challenges

1. All certifying agents review input materials for compliance with the NOP regulations. Most certifying agents do not publish their list of approved inputs. This leads to a lack of transparency of what materials have been approved for use in organic production and handling.
2. There are numerous organizations reviewing materials for compliance with the NOP regulations. On numerous occasions a material that is allowed by one certifying agent is prohibited by another. This lack of consistency in what materials are approved creates an uneven regulatory landscape, is unfair to organic producers and handlers, and leads to certifier shopping to find the certifying agent that allows more materials.
3. There have been situations where the NOP has disallowed the continued use of materials and material review organizations continue to list/register these materials as approved for use in organic production/handling.
4. A universal list of approved substances is not currently available to organic producers and handlers. It is difficult for many organic producers and handlers to understand what materials are allowed and which materials are prohibited. This regulatory uncertainty causes reluctance by many potential organic producers and handlers to enter the organic trade.
5. OMRI and WSDA maintain a publically available list of approved materials. The process for removing substances from these approved lists is not consistent. There is not a consistent process for material input manufacturers to appeal decisions made by OMRI, WSDA or certifying agents.
6. The NOP does not have direct regulatory authority over material manufacturers. If material manufacturers violate the organic standards or fraudulently represent their product as approved for organic use the NOP does not have authority to issue civil penalties or propose adverse actions. Currently organic producers and handlers bear the risk of using substances that may not comply with the NOP regulations.

Relevant Areas in the Rule

While both OFPA and the Rule deal extensively with the review of materials as performed by NOSB, NOP and ACAs, neither provides any language that relates directly the work or oversight of materials review organizations.

Discussion

Based on the challenges presented above, the committee's March discussion document solicited feedback from impacted stakeholders on a number of specific questions. Those specific questions are attached to this document as Appendix A.

The committee spent several meetings carefully weighing and discussing each of the stakeholder responses to the various discussion questions. This analysis yielded the following recommendation.

Recommendation

The NOSB recommends that the National Organic Program actively regulate materials evaluation programs, in order to facilitate consistent and uniform materials review decisions.

Materials Review Organization (MRO) Qualification

In order to facilitate adequate oversight and enforcement of the activities of MROs, the National Organic Program should require that MROs become Accredited Certifying Agents (ACAs). MROs that only perform material review services should be certified under a new accreditation scope which restricts certification activities to materials review. ACAs who perform other certification types would simply add the materials review scope to their existing accreditation. Furthermore, the NOSB feels that materials review activities (providing a public "list" of approved NOP compliant inputs) should ultimately only be allowed by NOP accredited entities.

The NOSB acknowledges that the creation of a new accreditation scope is a complicated and potentially long-term undertaking. In the shorter term, we encourage the NOP to provide detailed guidance on the material review process in order to promote consistency and uniformity among currently operating MROs while longer term regulatory changes are undertaken. At minimum, such guidance should cover personnel training and qualification, audit standards, input disclosure, and other factors necessary for evaluating materials with regard to NOP compliance.

MRO operation and review criteria

MROs should use OFPA, the USDA National Organic Standards, NOP guidance and the National List as the base standards for their operations and activities. MROs should not make synthetic vs. non-synthetic determinations except as

guided by NOP materials classification guidelines. MROs should be compliant with ISO 65 standards, which require the development of detailed review protocols and policies.

MROs must make their review process -- including organizational hierarchies, procedures and governance structures related to materials decisions -- transparent to all stakeholders. While the creation of such review criteria and procedures by the NOP should necessarily be done in partnership with certifiers, MROs and other stakeholders, we do not believe that the creation of a formal Task Force is necessary to accomplish this goal. The NOSB functions as an advisory body which represents diverse factions of the organic community, and has carefully considered rich stakeholder feedback in creating this recommendation.

Structure and Consistency of a Materials List

We believe that the most effective way to ensure consistency among MROs is to ensure that all such organizations are operating by a consistent set of review protocols and procedures. NOP oversight and accreditation will promote consistency both by requiring a uniform set of procedures and by allowing NOP to monitor materials review decisions made by accredited MROs.

While a generic materials list is an extremely valuable guidance tool to the organic producers and input manufacturers who rely on MRO services, we do not believe it is the interest of the organic community to require producers to *only* use inputs on any materials list. Many local products and custom mixes are provided on a regional basis, and such materials are reviewed by ACAs as part of the certification process. Membership on a list should never be a requirement for use of an input on an organic operation.

The NOP should work closely with certifiers and existing MROs to determine a set of subcategories and list structure which reflects the review criteria to be used for each category. Such structure should at minimum reflect the National List Categories reflected in 205.601-201.606, and potentially include sub-types of National List categories. For example, OMRI's generic materials list currently divides the "Crops" category into the classes Crop Fertilizers and Soil Amendments (CF), Crop Pest, Weed and Disease Control (CP), and Crop Management Tools and Production Aids (CT). We also note that the effective use of such a list is contingent on guidance as to the point at which an agricultural product ceases to be a crop and becomes the subject of processing/handling. The current National List contains several post-harvest handling substances in both 206.601 and 605.605, and the precise contour of the line between crops and handling should be resolved prior to the design of such a list.

We believe that the NOP should maintain a single, national Generic Materials List along with a Brand Name Materials List. The generic materials list would serve as guidance to ACAs and the industry on specific substances' consistency with the rule, and as a record of NOP decisions on such materials (including synthetic vs. non-synthetic and agricultural vs. non-agricultural determinations). A

brand name list would serve as an aggregation of ACA/MRO decisions which had been reported the NOP. Such a list would drive inter-ACA/MRO consistency and provide a valuable service to the organic community. Both lists should be available to the public via the NOP website, and updated in real time. Such lists will only be possible once consistent and transparent review criteria and oversight mechanisms are established. Regular communication of materials review decisions by MROs to the NOP would also facilitate NOP monitoring of MRO decisions.

Finance and Oversight

We believe that the MRO program should at least be financed in part by those input producers seeking review. Under a model which follows the existing ACA structure, entities seeking certification (or review) would pay certification costs directly to the ACA/MRO. Accreditation would managed financed through the existing NOP accreditation structures.

Similarly, programmatic oversight and appeals would also be handled by the same set of structures which currently govern the oversight of ACAs. MROs would be different from other ACAs only in terms of the scope of their certification activities. As with existing ACAs, the NOP should provide clear and uniform guidance, training, oversight, audits and enforcement over MROs. NOP should review their existing appeals process to ensure that input manufacturers have the same ability to appeal and MRO decision as producers currently have to appeal ACA decisions.

Enforcement and Fraud

The NOP MRO process should clearly hold the MRO accountable for mistakes and prescribe penalties, just as is currently the case for ACA certification decisions. NOP should pursue legal action against fraudulent manufacturers. We believe that NOP oversight of MROs as ACAs is the most effective way to ensure consistency and integrity in the organic input material supply chain, and provides the most powerful set of tools to prevent fraud, monitor compliance, and enforce the National Organic Standards.

Committee Vote

Motion by: Joe Dickson Second: John Foster
Yes: 5 No: 0 Absent: 1 Abstain: 0 Recuse: 0

**National Organic Standards Board
Certification, Accreditation and Compliance Committee
Proposed Recommendation
Inspector Qualifications**

September 14, 2011

Background

On June 23, 2011, the Deputy Administrator of the National Organic Program (NOP) issued a memorandum to the chair of the National Organic Standards Board (NOSB) requesting a proposal outlining the criteria that inspectors should be required to meet prior to conducting inspections of organic production and handling operations. The Certification, Accreditation and Compliance Committee (CACC) has reviewed this request and, in consultation with representatives from the organic community, developed this proposal. We believe that it would be appropriate, and in the best interest of the organic community, for the NOP to issue guidance to Accredited Certification Agencies (ACAs) on this subject and respectfully submit our recommendations below.

Relevant Regulatory Text

The NOP regulations require that certifiers use employees and contractors with sufficient expertise in organic production. The following passages represent all of the rule language directly addressing or related to inspector qualifications:

205.501 General requirements for accreditation.

(a) A private or governmental entity accredited as a certifying agent under this subpart must:

- (1) Have sufficient expertise in organic production or handling techniques to fully comply with and implement the terms and conditions of the organic certification program established under the Act and the regulations in this part;
- (2) Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart; ...
- (4) Use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part;
- (5) Ensure that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned.

(6) Conduct an annual performance evaluation of all persons who...perform on-site inspections...

§ 205.504 Evidence of expertise and ability.

A private or governmental entity seeking accreditation as a certifying agent must submit the following documents and information to demonstrate its expertise in organic production or handling techniques...:

(a) *Personnel.*

(1) A copy of the applicant's policies and procedures for training, evaluating, and supervising personnel;

(2) The name and position description of all personnel to be used in the certification operation, including ... certification inspectors, ...;

(3) A description of the qualifications, including experience, training, and education in agriculture, organic production, and organic handling, for:

(i) Each inspector to be used by the applicant and...

(4) A description of any training that the applicant has provided or intends to provide to personnel to ensure that they comply with and implement the requirements of the Act and the regulations in this part.

Discussion

Organic inspectors perform a critical function in the ongoing fulfillment the Organic Foods Production Act and the NOP regulations. What professional and technical skills, knowledge and training are necessary to conduct effective inspections? There are currently no specific qualification criteria or standards for what constitutes the "sufficient expertise" called for by the section 205.501(a)(1) of the regulations. This discussion seeks to clarify issues related to defining standard inspector qualifications for all ACAs, and offers a proposal for baseline levels of:

- a) pre-requisite experience, training and knowledge,
- b) continuing education and training, and
- c) performance oversight and assessment .

Because there are a number of different scenarios under which ACAs employ inspectors-including full time employees, part time employees, regular contractors, one-off contractors, etc- we must consider a system that allows for a wide variety of ACA- inspector relationships while ensuring that the inspectors are doing their part to uphold the high levels of integrity expected by the organic community.

In the absence of specific regulatory requirements for the qualifications of organic inspectors, ACAs have instituted a wide range of requirements and criteria in their hiring process, training, and performance monitoring. While the CACC is aware of the requirements of a few ACAs in particular, the actual extent and range of these specific requirements among the 100 worldwide NOP approved ACAs is not fully known.

The International Organic Inspectors Association (IOIA), formed in 1991, offers an organic inspector training program which is broadly recognized among ACAs. The IOIA training is currently the only training of which we are aware that is targeted at organic inspectors. Most ACAs include IOIA training certificate among their baseline inspector qualification criteria. Some ACAs require additional training beyond the IOIA certificate. These commonly include apprentice inspections and/or annual inspector trainings. Some ACAs, especially those located outside the United States, do not require IOIA training.

The CACC believes that targeted training, such as that provided by IOIA, should be strongly encouraged. We suggest that the NOP consider entering in to a Memorandum of Understanding or other recognition agreement or subcontract with IOIA so that IOIA can be formally recognized and authorized by the NOP. This could allow IOIA to create a formal inspector approval for inspectors who have successfully passed their training course and participate in continuing education. While IOIA currently offers an “accredited inspector” status, it is the understanding of the CACC that this designation is not particularly meaningful to ACAs during their hiring process, and that relatively few qualified inspectors seek “accreditation”. We believe that having a pool of inspectors which are formally approved by IOIA under the auspices of the NOP would be extremely beneficial to the entire organic community.

It is essential that during the accreditation process, ACAs are verified as hiring only competent, trained inspectors. Anecdotal evidence suggests that while the qualifications of certification personnel are evaluated during current NOP audits, those of contract or part-time inspectors are not often reviewed. The CACC is particularly concerned about situations where an ACA may rely on only one inspector, or a small handful of inspectors, to perform all of the inspections for an ACA. In particular, it is essential that the ACA has sufficient criteria for assigning different types of operations to that inspector.

At minimum, all ACA’s should be required to attend annual NOP trainings and those trainings must include clear direction as to inspector qualification and continuing education. We find arguments that such trainings are cost prohibitive unconvincing. The NOP has been offering these trainings in many locations in the US and abroad for many years and has been clear of their intention to continue to do so. Those ACAs who need to adjust fees or adjust budgets accordingly need to do so. This is essential in

assuring their clients—and thereby the general public—that they are operating on a level playing field in the national and international arena. This is critical to prevent responsible ACAs from falling victim to certifier shopping based on costs which have been subsidized by systematic use of under qualified inspectors who charge less for their services. The training of ACAs is essential to ensuring that they have the opportunity to make judgments about the qualifications of the inspectors they use.

We recognize that there is not absolutely uniform need for training, experience or education for inspector qualifications across all types of inspections. Distinctions are needed according to the types of operations that are being inspected. These can be defined in different layers and to different degrees. The first and broadest categorization is by scope: Crops, Handling, or Livestock. Wild crop harvesting, the fourth scope under the NOP, should be considered a subtype of crop production, as it is of minor prevalence, and an experienced organic crops auditor can effectively perform these inspections after a focused briefing on specific issues and standards related to wild crop harvesting practices.

Within those three major lenses of the scope of production there are then a range of specialties and levels of complexity. Because of the significant diversity of crops and operation types, we cannot reasonably set the same requirements for inspectors of all the possible different crops, processes, products, animals and livestock rearing methods. While a good inspector should be capable of inspecting any operation under the general scope to which they are qualified, some types of production are particularly complicated and may require additional training. Dairy is one sub-category of livestock that arguably calls for a separate qualifications category. Dairy operations often involve unique practices and standards from other livestock production that require special training and experience for the inspector.

An additional challenge posed in appropriately assigning inspectors to operations is balancing the need for familiarity with the production system and ensuring a lack of conflict of interest. Operations being inspected rightfully expect that the inspector understand the fundamentals of the product being produced or handled. For example, an otherwise qualified inspector who is also growing strawberries or has grown strawberries might likely be a qualified inspector to inspect another strawberry farm. However, the strawberry farm being inspected may object to an inspector who currently or previously worked for a business that is in direct market competition. We recognize that this may be less of an issue for ACAs where inspectors are full time employees.

While familiarity of the inspector with the type of operation being inspected is necessary, what is more critical is the type of general auditing skills that are not easily taught. To a large extent, a typical organic inspector is a “general practitioner”. Many of the general auditing skills are applicable across the entire range of organic inspections. Expertise in

one of the three general areas makes it easier for an inspector to increase their scope to include additional types of inspections. We believe that a successful crop inspector can be more quickly trained to also do handling inspections than someone who has no inspection experience. Therefore, we believe that the specific-scope qualification criteria should be more flexible for an experienced inspector who is extending the scope of their existing qualifications.

We believe that ongoing continuing education is essential for organic inspectors. Like many other professions, we believe that organic inspectors should stay up to date on the emerging issues in the field through attending conferences, advanced trainings, or other educational events where either specific or general knowledge can be acquired. While most, if not all, ACAs do not currently require this of their inspectors, we assert that they can, and indeed should.

We recognize that we must be careful to implement requirements that are fair to all ACAs, regardless of size, but also seek to provide a meaningful baseline for hiring inspectors to assure to the greatest degree possible consistency the organic production marketplace and the consumer marketplace. At this time, we suggest that standardized inspector qualifications requirements should remain somewhat broadly defined. The organic inspector profession is not large or deep enough presently to accommodate many narrowly define scopes of qualifications. There is a need for definitions and requirements for baseline qualifications that will meet the needs of having capable knowledgeable inspectors but that are practical and achievable by inspectors and the ACAs.

Beyond the required NOP annual performance evaluation for all inspectors, it is unknown to what extent ACAs monitor inspector performance, provide constructive feedback, and require corrective action when correctable performance issues are detected. Some ACAs provide an evaluation of every inspection report. Some ACAs may require periodic witness audits of their inspectors, however this is currently unusual, perhaps due to limited administrative and over-sight resources within the ACAs. We believe that more rigorous oversight of the inspectors by ACAs would provide value to the organic community. Organic inspectors, especially those that work on contract for a number of ACAs, would likely welcome more feedback about their performance.

It is essential that ACAs are capable of ensuring that only qualified inspectors perform their inspections and assert that annual NOP training is essential for ACAs just as annual inspection training is for inspectors. While some ACAs use complex database systems to match inspector qualifications with the operation type, this can also be accomplished using simpler methods not requiring computerized systems. However it is done, we believe that each ACA must be able to justify why the specific inspector has

been assigned to a particular operation and why they are qualified to perform the inspection.

Proposed Guidance

Baseline Qualification Criteria for Organic Inspectors

A. As fundamental initial “organic inspector” criteria:

1. Baseline pre-requisite knowledge and expertise for initial „organic inspector” status.
 - a. Minimum two years of combined work experience, education, and training in organic production, applicable to the scope of inspections to be initially performed: crops, handling, or livestock.
 - b. Must include at least two of the three different criteria: *experience* with the scope of operations to be inspected, *education* relevant to the scope of operations to be inspected, or specific *training* within the scope of operations to be inspected.
 - c. Training equivalent to the Independent Organic Inspectors Association (IOIA) basic training, i.e. four days of concentrated training culminating in a qualifying exam.
 - d. Apprenticeship consisting of a minimum of three shadow inspections, accompanied by an experienced organic inspector and followed by witness inspections where the apprentice is observed and deemed competent by the experienced inspector or certifying agent.
 - e. Must have a good evaluations and recommendations by an experienced organic inspector or certifying agent assessing the inspector understanding of inspection protocols and applicable organic standards.
 - f. Once an individual has established themselves as a competent organic inspector in any one of the three general areas, addition of a new scope does not require an additional two years of focused experience and training in that area. General organic inspecting skills are applicable to all areas and can therefore greatly assist the inspector in expanding their scope, while seeking whatever specific additional knowledge is required to sufficiently understand the new area.

B. As continuing organic inspector criteria:

1. Continuing Education
 - a. Annual training by Accredited Certifiers Association (ACA) to update on specific procedures of the ACA as well as National Organic Program (NOP) standards updates and guidelines.
 - b. Minimum 8 hours annual continuing education related to the type of inspection work performed. Each hour of curriculum time (e.g. class time,

coursework, field study, testing), equals one hour of continuing education hours. Trainings conducted by ACAs and closed to the general inspection community do not apply toward continuing education hours given their tendency to focus on certifier procedures, rather than broad knowledge such as agronomic and food industry practices, and general auditing skills.

- c. In-depth training on the topic of recordkeeping and/or accounting must be included as part of continuing education, and IOIA is encouraged to develop a training to fulfill this need.
- d. Continuing education credits include webinars, seminars, workshops, and colleges and university extension programs related to the type of inspection work performed or new scope of inspection interest.

C. ACA accreditation criteria to ensure adequate monitoring and oversight of inspector qualifications:

1. Annual attendance of NOP trainings.
2. Documented inspector qualification monitoring program that readily provides verification that all inspectors employed or contracted in the service of the ACAs are qualified according to these criteria.
3. Provide programmatic and consistent annual training to inspectors regarding processes, policies and procedures specific to the ACA. Training materials used must be available for review during accreditation audits and included in annual ACA updates to the NOP.
4. Provide all inspectors with performance assessment and oversight accordingly:
 - a. Witness audits by ACA to be conducted at a minimum every 300 inspections or 3 years, whichever is less. Results must be documented. Witness audits may be conducted by certification management, senior inspectors or senior reviewers.
 - b. Evaluation of every inspection provided to the inspector.
 - c. Annual performance evaluation provided to the inspector.
 - d. All serious or persistent performance issues that arise during any of the above assessments must be documented by the ACA, and must include documented corrective action and improvement measures as deemed necessary by the ACA.

Committee Vote

Motion: John Foster Second: Barry Flamm
Yes: 6 No: 0 Abstain: 0 Absent: 0 Recuse: 0

**National Organic Standards Board
Certification, Accreditation and Compliance Committee
Proposed Recommendation
Unannounced Inspections**

September 14, 2011

Background

On June 23, 2011, the Deputy Administrator of the National Organic Program (NOP) issued a memorandum to the chair of the National Organic Standards Board (NOSB) requesting a proposal on best practices for unannounced inspection. The Certification, Accreditation and Compliance Committee (CACC) has reviewed this request and, in consultation with representatives from the organic community, developed this proposal.

Currently, unannounced inspections are allowed, but not required, under the NOP regulations. Some Accredited Certification Agencies (ACA's) conduct many unannounced inspections, often to fulfill international requirements, while others may conduct none. We believe that it would be appropriate for the NOP to issue guidance to ACA's on this subject and respectfully submit our recommendations below.

Relevant Regulatory Text

7 CFR § 205.403 On-site inspections.

(a) *On-site inspections.*

- (1) A certifying agent must conduct an initial on-site inspection of each production unit, facility, and site that produces or handles organic products and that is included in an operation for which certification is requested. An on-site inspection shall be conducted annually thereafter for each certified operation that produces or handles organic products for the purpose of determining whether to approve the request for certification or whether the certification of the operation should continue.
- (2)
 - (i) A certifying agent may conduct additional on-site inspections of applicants for certification and certified operations to determine compliance with the Act and the regulations in this part.
 - (ii) The Administrator or State organic program's governing State official may require that additional inspections be performed by the certifying agent for the purpose of determining compliance with the Act and the regulations in this part.
 - (iii) Additional inspections may be announced or unannounced at the discretion of the certifying agent or as required by the Administrator or State organic program's governing State official.

(b) *Scheduling.*

- (1) The initial on-site inspection must be conducted within a reasonable time following a determination that the applicant appears to comply or may be able to comply with the requirements of subpart C of this part: *Except*, That, the initial inspection may be delayed for up to 6 months to comply with the requirement that the inspection be conducted when the land, facilities, and activities that demonstrate compliance or capacity to comply can be observed.
- (2) All on-site inspections must be conducted when an authorized representative of the operation who is knowledgeable about the operation is present and at a time when land, facilities, and activities that demonstrate the operation's compliance with or capability to comply with the applicable provisions of subpart C of this part can be observed, except that this requirement does not apply to unannounced on-site inspections.

(c) *Verification of information.* The on-site inspection of an operation must verify:

- (1) The operation's compliance or capability to comply with the Act and the regulations in this part;
- (2) That the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation;
- (3) That prohibited substances have not been and are not being applied to the operation through means which, at the discretion of the certifying agent, may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples.

(d) *Exit interview.* The inspector must conduct an exit interview with an authorized representative of the operation who is knowledgeable about the inspected operation to confirm the accuracy and completeness of inspection observations and information gathered during the on-site inspection. The inspector must also address the need for any additional information as well as any issues of concern.

(e) *Documents to the inspected operation.*

- (1) At the time of the inspection, the inspector shall provide the operation's authorized representative with a receipt for any samples taken by the inspector. There shall be no charge to the inspector for the samples taken.
- (2) A copy of the on-site inspection report and any test results will be sent to the inspected operation by the certifying agent.

Discussion

The CACC believes that unannounced inspections are one of the most powerful and useful tools in the NOP regulations to ensure compliance across certified operations and give consumers additional reasons to trust the organic label. We believe that all ACA's should be conducting unannounced inspections of a significant portion of their clients every year.

Unannounced inspections serve the dual purpose of giving the ACA the opportunity to observe the activities of a specific operation without the advance notice provided in the annual monitoring inspections, but also acts as a deterrent factor to other operations who may consider acting in noncompliance with the NOP. ACA's who already conduct significant unannounced inspections report that word of unannounced inspections tends to spread among groups of organic operations. A consistent approach to unannounced inspections is essential in order to ensure organic integrity, reinforce the public trust in the organic label and create an even playing field for certifiers and certified operations alike.

We strongly recommend that the NOP provide guidance that includes a specific percentage of operations which must have unannounced inspections every year. We are proposing a five percent requirement across the board for all ACA's. This will ensure fair and equitable application of unannounced inspections by certifiers of all sizes and will not unfairly impact small or large ACA's. Because ACA's have the option of charging certified operations for unannounced inspections (either on a per inspection basis or as part of their overall fee structure), we do not believe that requiring ACA's to conduct unannounced inspections will have a negative financial impact on ACA's. The proposal for five percent of operations per year is in line with IFOAM and COR. As these international organic standards already require unannounced inspections, a number of NOP ACA's have experience in conducting these types of inspections and are already performing at least the 5% proposed.

ACA's may be disinclined to conduct unannounced inspections in remote geographic areas or areas where they do not have regular inspection services or inspectors. While we understand the financial and operational considerations, we believe that an ACA should and must be able to conduct an unannounced inspection in any area they offer certification services or they are failing to maintain adequate resources to effectively and equally apply this oversight. At this time, we are not proposing that the ACA be required to conduct annual unannounced inspections in each country, of each product type, or each certification scope. Such requirements could result in a single operation having an unannounced inspection every year, while the majority of a certifier's operations would not receive an unannounced inspection in any year, which predictably leads to absurd outcomes. Instead, we recommend that ACA's have a systematic plan for equitably distributing unannounced inspections across their clients to ensure a reasonable representation of certified operators.

We believe that ACA's can appropriately use unannounced inspections either for targeted, risk based investigation purposes or simply randomly. We do not believe that ACA's should be limited to performing either one type of unannounced inspection or the other, and will be able to determine the appropriate balance of the two types. We

recommend that ACA's develop risk assessment systems to document the operations who they have determined to be most at risk for noncompliance, and therefore a higher priority for an unannounced inspection. While we have provided some elements of a risk assessment guide, we believe that this is not comprehensive, and that ACA's will be able to use other criteria for determining whether an operation is a good candidate for an unannounced inspection. ACA's are encouraged to share their risk assessment criteria among themselves to facilitate this process.

Some ACA's may use unannounced inspections in conjunction with sampling visits. Collecting samples during the course in order to fulfill the (currently draft) requirements for pesticide residue testing can be an efficient use of ACA and inspector resources. While we do not discourage this practice, we want to be clear that a sample collection alone is not sufficient to fulfill an unannounced inspection requirement. The inspector must also observe some aspects of an operation's activities or fields, facilities or products. An unannounced inspection must include the creation of an inspection report by the inspector and review by the ACA, even though the inspection may be limited in scope. Especially if the operator's representative was not present at the inspection, it is important that the ACA document the visit and the observations of the inspector and supply a copy of this report to the inspected operation.

While operations are required by the NOP to make all documents relevant to certification available during normal business hours, in practice, many operations (particularly small farmers) may not be able to make all records available during an unannounced inspection. When an operation is able to make all records available, and the operator's representative is able to spend the necessary time with the inspector, there is no reason why an unannounced inspection cannot fulfill the annual on-site monitoring requirements of NOP 205.403. If the ACA conducts unannounced inspections at their own expenses, as some do, it may even be preferred by the operation to have the unannounced inspection be a full annual inspection. While we think it is reasonable for inspectors to show up unannounced and require some time from the operation, we expect that ACA's respect the business realities of the certified operations. Inspectors should not make unreasonable demands on their time, such as expecting an operation to stop all activity and spend an entire day with the inspector. Especially in cases where the unannounced inspection is being conducted randomly, as opposed to based on risk factors, or in the case of small businesses and sole proprietorships, unannounced inspections can be done relatively quickly and without too much interruption in daily activities. We discourage ACA's, inspectors or certified operations from expecting all or most unannounced inspections from fulfilling the annual inspection requirements.

The issues of trespassing and property access can be controversial. ACA's must provide specific, written guidance to their inspectors and their clients describing their policies on having inspectors access certified operations when a representative of the operation is not present. While laws may vary from state to state (and country to country), we strongly recommend that ACA's instruct inspectors never to enter on to private land or roadways without permission. Even if an operation has signed a certification contract stating that they allow access at any time, we are concerned that inspectors could be in violation of trespassing laws if they do so. At many operations, there are observations that can be made by an inspector from public property, such as roadways and parking lots.

At some operations, such as closed facilities or biosecure chicken houses, it may be absolutely essential that a representative be present to allow access to the facilities in order for an unannounced inspection to provide any kind of meaningful observation by the inspector. In these cases, we believe that it may be useful to provide some advance notice to the operation so that they can ensure a representative is present. ACA's currently have a number of different approaches to pre-inspection notification. Some ACA's may provide as long as 48 hours advance notice before an "unannounced" inspection. We believe that the latter is excessive notice and could allow a fraudulent operation sufficient time and warning to clean or obscure elements of their facilities, storage areas, ledgers, and so on. We suggest that a limit of no more than four hours pre-inspection notice provides reasonable time for an operation to make a representative available, while limiting the amount of pre-inspection preparation that can occur. We recognize that this is a somewhat arbitrary time limit, and we suggest feedback from ACA's on this requirement. In any event, The ACA must include notice to applicants of their policies regarding notice and expectations for compliance.

Proposed Guidance

1. ACA's are required to conduct periodic unannounced inspections at minimum of five percent (5%) of their total certified operations per year. For calculation purposes, the number of operations will be counted as the number reported by the ACA to the NOP during the annual update each January. For ACA's with less than 20 certified operations, they are required to conduct one (1) unannounced inspection each year.
2. The ACA should strive to conduct unannounced inspections broadly across all certified operations, including a broad spectrum of production types, products and locations. ACA's should not limit unannounced inspections to nearby operations or certain production types. ACA's should have a long term plan for conducting unannounced inspections across their client base, including geographic location and certification scope. ACA's shall not accept applications

for certification from locations where they are unable or unwilling to conduct unannounced inspections.

3. ACA's may choose operations for periodic unannounced inspections may be random, risk based, or the result of a complaint or investigation. The ACA is not required to disclose to the operation the reason for the unannounced inspection.
 - a. Risk factors for conducting an unannounced inspection of an operation may include, but are not limited to:
 - i. Previous noncompliance issues
 - ii. Complaints
 - iii. Organic and non-organic production, especially of visually indistinguishable varieties
 - iv. Likelihood of drift or contamination potential
 - v. Product market value or prevalence
4. Unannounced inspections may fulfill the requirements for annual on-site monitoring inspections required by section 205.403 only if the inspector is able to conduct a full inspection of the operation as required by this section. Unannounced inspections may be limited in scope, depth and breadth, and may cover only certain aspects of the operation such as parcels, facilities, products, etc. ACA's may direct the inspector to a portion of the operation to review during an unannounced inspection.
5. An inspection report must be written by the inspector, sent to the client and reviewed by the ACA and a decision communicated to the client as per NOP 205.403 and the ACA's internal protocols.
6. Inspectors may conduct sampling during an unannounced inspection. Such an inspection may count towards both the number of samples and towards the number of unannounced inspections an ACA is required to take annually. However, if a visit of the operation is to count as both an instance of sample collection and an unannounced inspection, the inspector must review some aspects of the operation besides simply collecting a sample.
7. An unannounced inspection may occur even if no representative of the operation is present.
 - a. Wherever possible, an unannounced inspection should include no prior notification of the operation to be inspected before the inspector arrives on site. In special cases or where extenuating circumstances make it impossible to conduct any type of observation of the operation without prior notification (such as biosecurity issues), the ACA may notify the operation up to four (4) hours prior to the inspector arriving on site to ensure that appropriate representatives are present.
 - b. If a representative of the operation is not present, observations of the operation including, but not limited to, the following may be observed:
 - i. Condition of soil fertility
 - ii. Health of the plants
 - iii. Condition of soil and water

- iv. Erosion issues
 - v. Evidence of, or lack of, herbicide, fungicide or pesticide use
 - vi. Condition of facilities, including pest control and contamination risks
 - vii. Condition of pastures and indicators of grazing
8. ACA's are responsible for providing adequate training to their inspectors to ensure that inspectors do not trespass or break any other laws during unannounced inspections. Inspectors should not enter private property without explicit permission of the operation. Inspectors must have adequate identification, such as a business card and/or explanatory letter from the ACA, to demonstrate that they are acting on behalf of the ACA. ACA's must have a written policy on unannounced inspections and inspector access to certified facilities that is provided to all clients and to inspectors.
9. If an operation refuses to allow an inspector access to any part of an operation, including the non-organic portions of the operation, during normal business hours, the operation shall be considered non-compliant with NOP section 205.403 and the ACA should promptly issue a Notice of Noncompliance to the operation.
10. ACA's must clearly disclose to their clients their protocols for unannounced inspections. ACA's may charge their clients fees for unannounced inspections as long as these fees are clearly disclosed to all clients preemptively.

Committee Vote

Motion by: John Foster

Second: Barry Flamm

Yes: 6

No: 0

Absent: 0

Abstain: 0

Recuse: 0

**National Organic Standards Board
Policy Development Committee
Proposed Recommendation
Administrative Team**

July 12, 2011

Introduction and Background

The Policy and Procedures Manual (PPM) of the NOSB represents the board policies on committee responsibilities, board procedures, and other matters of board operational policy. It was noted at the Spring 2011 NOSB meeting that there is no description in the PPM of the Administrative Team, an informal group consisting of the Chair, Vice Chair, Secretary and Executive Director which has traditionally convened on a regular basis to coordinate the operations and logistics of the board's work. This recommendation updates the PPM to add a description of this group.

Relevant Areas in the Rule

The Organic Foods Production Act of 1990, 7 USC 6518 (a), directed the Secretary of Agriculture to establish the National Organic Standards Board and described its composition, authority and duties.

Discussion

As noted, the Administrative Team has met on a regular basis (generally weekly) as a forum for the Officers of the board and the Executive Director to plan, coordinate and administer the board's operations. This team does not deal directly with the substance of the board's work but rather with the administrative and operational details of the NOSB's meetings and overall work. While this is not an official committee of the NOSB, the PDC recommends that a brief description of the Administrative Team be included in the PPM since this team is often referenced in board and committee meetings.

Recommendation

The PDC recommends that Section IV of the NOSB Policy and Procedures Manual be amended by insertion of the following description, in the section entitled "Officer Responsibilities," immediately following the "Secretary" description:

Administration Team

The term "Administrative Team" describes a group consisting of the Chair, Vice Chair, Secretary and Executive Director. This group may meet on a weekly basis or as needed by teleconference or correspond by email in order to coordinate the overall logistics and operations of the board, the officer responsibilities noted above, and the overall support provided to the Board by the Executive Director.

Committee Vote

Motion: to accept the proposed amendment to the Policy and Procedures Manual described above.

Motion by: Joe Dickson Second: Calvin Walker

Yes: 6 No: 0 Abstain: 0 Absent: 0 Recuse: 0

**National Organic Standards Board
Policy Development Committee
Proposed Recommendation
Committee Transparency**

October 03, 2011

Introduction:

A number of stakeholders in the organic community have recently requested more visibility and transparency of National Organic Program (NOP), National Organic Standards Board (NOSB) meetings and actions. We recognize that the public availability of these records is critical to the meaningful engagement of the full organic community in public decision-making. The purpose of transparency is to create accessibility to organic program records and materials- including minutes of committee meetings associated with the NOP and NOSB activities. Enhanced public awareness of how NOSB decisions are made would enhance collaboration between the organic community and the Board.

Transparency should be a relevant concept throughout the NOP and NOSB. According to OGC opinion the NOSB committee meetings are subject to Freedom of Information Act (FOIA) and the Federal Advisory Committee Act (FACA).

Background:

The 1967 Freedom of Information Act (FOIA) establishes the public's right to obtain information from federal government agencies and allows for openness and disclosure of information to the public. The FOIA requires that the activities of government be accountable and transparent.

A foundational role for transparency has been recognized by the NOSB and NOP.

The Executive Director is obligated to, "Record and maintain records of Board and committee meetings, this includes maintaining all board archives and records in a manner that provides for easy access to all public information in cooperation with the Board Secretary" .

In regard to formal collaboration procedures between the NOSB and NOP, the PPM indicates that,

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)", (PPM, pg23).

Therefore, the NOSB and NOP are encouraged to act in a manner that will support visibility, openness, and transparency in all business operations with easy access to all public information.

As per a July 25, 2011 communication with USDA/OGC Attorney Advisor, Karen Carrington:

The Section 10(b) of the Federal Advisory Committee Act (FACA), as, (Public Law 92-463, 5 U.S.C. App.) provides that,

"Subject to section 552 of title 5, United States Code, the records, reports, transcripts, minutes, appendixes, working papers, drafts, studies, agenda, or other documents which were made available to or prepared for or by each advisory committee shall be available for public inspection and copying at a single location in the offices of the advisory committee or the agency to which the advisory committee reports until the advisory committee ceases to exist.

The purpose of section 10(b) is to provide for the contemporaneous availability of advisory committee records that, when taken in conjunction with the ability to attend committee meetings, provide a meaningful opportunity to fully comprehend the work undertaken by the committee. "

Attorney Carrington further indicated that before materials are given public access, the agency would conduct a review of them under the Freedom of Information Act to ensure that personal information is not revealed. Nevertheless, deliberative information that goes to the essence of duties as a board member will most likely be disclosed publicly under the FOIA process.

Recommendations

Section III (pg 12) Role of the Executive Director is amended to include the following language:

Arrange, facilitate, and record the NOSB Committee conference calls necessary to achieve the most efficient workings of the Board. Minutes are distributed to committees for confirmation of accuracy and approval. Committee minutes must fully capture the discussion, reflect the diversity of opinions expressed during meetings, and provide context for those opinions by identifying their source (name or position) i.e. farmer/grower, environmentalist/resource conservationist, consumer/public interest advocate, handler/processor, retailer, scientist, USDA accredited certifying agent, NOP, etc - in order that transparency exist and content remain

useful for committee members, board members and our stakeholder public.

Section III (pg 13) Role of the Executive Director is amended to include the following language:

Maintain executive committee meeting minutes and committee meeting minutes, committee records, reports, transcripts, appendices, working papers, drafts, studies, agendas and other documents which were made available to or prepared for or by the NOSB or its committees, and make such documents available for public inspection and copying at the Agency, electronically via the World Wide Web; and/or, upon written request in printed form.

Committee Vote:

Moved: Jennifer Taylor Second: Calvin Walker
Yes: 6 No: 0 Abstain: 0 Absent: 0

**National Organic Standards Board
Policy Development Committee
Proposed Recommendation
Conflict of Interest**

August 28, 2011

Introduction

The National Organic Standards Board (NOSB) seeks to update the Board's conflict of interest (COI) policy. The major issue for the NOSB's Policy Development Committee (PDC) is to strengthen the NOSB's policy on COI. The goals for updating the existing NOSB's COI policy are (1) to update the COI policy and (2) outline general procedures for dealing with a real, apparent, and potential COI by NOSB members, if it arises. The proposed recommendations are part of a continued quest by NOSB members in being responsive to requests by stakeholders. The proposed policy additions should provide for greater transparency of NOSB members' work for the greater good of the organic community.

Background

The NOSB recognizes that members have been specifically appointed to the NOSB to provide advice and counsel to the Secretary of Agriculture concerning policies related to the development of organic standards and the creation of amendments to the National Organic Program's National List. NOSB members have been appointed because they have professional expertise that enables them to advise the Secretary of Agriculture. The statutory composition of NOSB is composed of 15 members. The federal statutory composition of the NOSB provides for:

- four (4) members who own or operate an organic farming operation;
- three (3) members with expertise in areas of environmental protection and resource conservation;
- three (3) members who represent the public interest or consumer interest groups;
- two (2) members who own or operate an organic handling operation;
- one (1) member who owns or operates a retail establishment with significant trade in organic products;
- one (1) member with expertise in the fields of toxicology, ecology, or biochemistry; and
- one (1) member who is a certifying agent.

Within this statutory framework, the professional expertise may, at times, present an inherent COI. To prevent overt advocacy for direct financial gain and the appearance of self-interest or the appearance of wrongful activity, the NOSB has adopted a COI policy (NOSB, Policy & Procedure Manual, 2010, pg. 9). At this time, the PDC of the NOSB seeks to update the Board's policy and procedures on COI. The updates are

stakeholder driven. Some of the stakeholder advocates, who have expressed a need to update the NOSB's COI policy, include (1) the National Organic Coalition, (2) Center for Food Safety, (3) Cornucopia, (4) Food and Water Watch, and (5) former NOSB Chair Jim Riddle.

The proposed COI policy will enhance and build upon the existing NOSB's COI policy. The recommendations include providing a definition for (1) COI (real), (2) apparent COI, (3) potential COI, (4) immediate family member, and (5) financial interest. A listing of procedural steps is outlined.

Relevant Areas of the Rule

The *Organic Foods Production Act* (OFPA) establishes the National Organic Standards Board at §2119 (7 U.S.C. 6518) (a). It reads, "The Secretary shall establish a National Organic Standards Board (in accordance with the Federal Advisory Committee Act (5 U.S.C. App. 2 et seq.) (hereafter referred to in this section as the "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 this title." The 2010 NOSB Revised Policy and Procedures Manual (PPM) dated October 28, 2010, on page 9 sets forth the current NOSB's COI policy. The professional conduct of NOSB members are alluded to in the PPM on page 8. Therefore, action and activities of the NOSB members on matters pertaining to organic should be in the best interest of the organic community as a whole.

Discussion

The benefits of the proposed recommendations are (1) to define terms such as COI (real), apparent COI, potential COI, immediate family members, and financial interest, and (2) suggest procedures for managing COI in the conduct of business by the Board. The fruition of an updated COI policy should help provide greater transparency and confidence in Board decisions by the organic community. The lack of an updated COI policy can give a negative connotation of the Board responsiveness to many constituent groups' request.

An alternative approach would be to keep the current COI policy. However, a revised Board COI will enhance the Board's continued responsiveness to the organic community's request, in addition to maintaining high professional and ethical standards. Previously, the June, 1999 NOSB Procedures Taskforce Report to the Board on COI was approved. Ultimately, the Board's COI policy was updated to read:

"Members of the Board shall refrain from taking any official Board action from which that Board member is or would derive direct financial gain. Board members shall disclose their interest to the Board and the public, when they or their affiliated business stand to gain from a vote, which they cast in the course of Board business. Under certain

circumstances, the Board may determine whether it is appropriate for the member to vote.

That members of the Board shall refrain from promoting for consideration any material, process or practice for which the member is or would derive direct financial gain arising out of such Board action. The act of promoting such material, process or practice shall include private discussion with members of the Board advocating the value of the material, public discussion and/or written advocacy.

A "direct financial gain" is defined as monetary consideration, contractual benefit or the expectation of future monetary gain to a Board member, including but not limited to, financial gain from a party who manufactures, distributes or holds exclusive title to a formula for a material or product, process or practice." [NOSB's PPM, 2010, page 9.]

The current document seeks to enhance the existing COI policy. It attempts to do so by, (1) proposing definitions for COI (real), apparent COI, potential COI, immediate family member, and financial interest, (2) suggesting procedures for dealing with a given COI, and (3) developing a Declaration of Interest Form.

Recommendations

Recommendation #1

The first three paragraphs shown below are on page 9 of the 2010 PPM and will remain the same.

The NOSB recognizes that members have been specifically appointed to the NOSB to provide advice and counsel to the Secretary concerning policies related to the development of organic standards and the creation and amendment of the National List. NOSB members have been appointed because they have professional expertise which enables them to advise the Secretary. This professional expertise may, at times, present an inherent conflict of interest (COI). To prevent overt advocacy for direct financial gain and the appearance of self-interest or the appearance of wrongful activity, the NOSB has adopted an updated COI policy.

Members of the Board shall refrain from taking any official Board action from which that Board member is or would derive direct financial gain. Board members shall disclose their interest to the Board and the public, when they or their affiliated business stand to gain from a vote, which they cast in the course of Board business. Under certain circumstances, the Board may determine whether it is appropriate for the member to vote.

That members of the Board shall refrain from promoting for consideration any material, process or practice for which the member is or would derive direct financial gain arising out of such Board action. The act of promoting such material, process or practice shall

include private discussion with members of the Board advocating the value of the material, public discussion and/or written advocacy.

Recommendation #2

The definitions below are to be inserted before paragraph #4 on page 9 of the 2010 PPM.

A “conflict of interest (real)” is defined as a financial or non-financial interest that could cause or influence a Board member decision directly or indirectly as it relates to matters that are before the Board as a whole or as part of a committee, task force, advisory group, public hearing, etc.

An “apparent conflict of interest” is defined as a financial or other interest that would not necessarily influence a Board member, but could result in one’s objectivity and independence being questioned by others.

A “potential conflict of interest” is defined as a financial or other interest that a reasonable person could be uncertain as to whether or not it should be reported.

An “immediate family member” includes a Board member’s spouse, children, parents, brother, sister, or spouse of a brother or sister.

A “financial interest” is defined as any kind of financial interest. No specific dollar amount of the financial interest needs to be disclosed. Some of the examples of financial interest include (1) employment, (2) shares, (3) contract, (4) stocks, (5) consultancy, (6) paid work, etc.

A “direct financial gain” is define as monetary consideration, contractual benefit or the expectation of future monetary gain to a Board member, including but not limited to, financial gain from a party who manufacture distributes or holds exclusive title to a formula for a material or product, process or practice.

Conflicts can be real, perceived, and numerous. Below are two examples

Example #1

What is the situation? Board member Z’s spouse works in sales of Company A. She stands to gain a cash bonus if Company A is successful in getting the approval of a certain product by the Board.

Why could this be perceived as a conflict of interest? Board member Z has an immediate family member who stands to gain financially by Company A lobbying the Board for the approval of a certain product.

What should be done? Board member Z should abstain from voting due to an immediate family member who stands to gain financially from a Board action.

Example #2

What is the situation? Board member X frequently plays golf with representatives of Company A over the last year. Company A is lobbying the Board for the approval of a certain material.

Why could this be perceived to be a conflict of interest? The frequent golfing connection with Company A could create a perceived conflict of interest.

What should be done? Board member X should decide if he/she can be objective and if he/she has a COI. If no COI, is determined, said Board member can participate in the discussion and vote. If not sure, said Board and/or committee should determine if Board member X can participate in the discussion and vote on said matter. The final decision must be clearly recorded in the minutes.

Recommendation #3

Add the section below:

Procedural Steps for Conflict of Interest Determination and Resolution

Step 1. Annually, each Board member must complete a Declaration of Interest Form (DIF). The DIF should show all interests (businesses, investments, and agricultural endeavors) of their own, those of immediate family members, and those of the companies and/or organizations they have represented over the last 12 months. All conflicts regarding substances and practices being considered by the NOSB should be declared on the DIF. Each member is responsible for the timely revision of their annual DIF, if warranted.

Step 2. The DIF will be compiled annually and given to the Board Chair or Secretary so it can be easily referenced during the Board's and/or a particular committee discussion and voting sessions.

Step #3. Each Board member is mainly responsible for declaring his/her conflict of interest (COI) prior to any specific discussion during any committee meeting, public hearing, etc.

Step #4: Prior to each vote, the chair will ask all Board members, if anyone has a COI in that particular matter.

Step #5. Upon such declaration, the member can either voluntarily refrain from voting, or can request that the Board decide if the conflict warrants said member abstaining from voting.

Step #6. The ability to participate in a particular discussion and vote must be by a majority vote.

Step #7: The Board's or committee's final decision must be clearly recorded in the minutes.

Summary

NOSB members with diverse backgrounds are recruited to provide balance to the NOSB. While individual NOSB members represent the segments of the population from which they were selected, they also represent the greater good of the population as a whole. The revised COI policy and procedures are an attempt to address several stakeholders' request for updating the Board's COI policy and provide for a greater level of transparency in the deliberation, discussion, and voting on matters pertaining to the Board authority for the benefit of the organic community.

DECLARATION OF INTEREST FORM

Directions: The declaration of interest form must be completed each year. If additional space is needed, please continue on a separate sheet of paper.

Name: _____ Period(MM/DD/YYYY): _____

A. Interest (I and or an immediate family member)

1. _____ works for an organization that uses, sells, reviews, or otherwise involves a number of substances or topics related to organic production or processing. I do not think that my involvement with any of these substances or issues would constitute a conflict of interest and/or preclude my ability to vote on recommendations that may be on the National Organic Standards Board (NOSB) or committee work plans.

2. _____ works for an organization with a vested interest in a specific substances or topic related to organic production or processing. If this substance or issue were to be voted on by NOSB, I will declare a conflict of interest and ask the NOSB for an opinion, or recuse myself due to a conflict of interest.

B. Affiliations/organizations (last 12 months)

1. Provide a listing of affiliations/organizations

I hereby declare that the disclosed information is correct. I will inform the Board Chair or designee of any change in these circumstances in a timely manner.

Signature Date

Committee Vote:

Moved: C. Reuben Walker Second: Colehour J. Bondera
Yes: 7 No: 0 Abstain: 0 Absent: 0

**National Organic Standards Board
Policy Development Committee
Proposed Recommendation
NOSB Member and Leadership Transition**

July 26, 2011

Introduction

Critical to the effective functioning of the committees of the NOSB is the smooth transition between and during terms of the Board. The proposed addition to the Policy and Procedures Manual is intended to clarify the transition process to enable continuity and effective participation.

Background

While the NOSB Board Chair, elected by the members at the Fall meeting, has typically appointed committee Chairs and members to take their positions at the start of the new year-long term, the manual is not clear on the timing of the transition, except to say, “The outgoing committee chair should work as mentor for the new committee chair and vice-chair for a period of at least two months after transition.” (p20) This transition could most effectively be achieved by appointments taking effect after an orientation and mentorship period, with the incoming Chairs, Vice-Chairs, and members being seated at the beginning of the new term.

The manual does not specifically set a timeframe for the effective date of committee appointments with the new committee composition, but implies that terms of committee membership are to be concurrent with the yearly Board term. The manual only refers to officers in indicating that they “will assume their positions at the conclusion of the Fall Board meeting pursuant to the election.” (p14)

The manual is silent on the issue of transitioning board members between committees during a Board term, leaving the issue of committee assignments to the discretion of the Board Chair. (p11)

Relevant Areas of the Rule

The *Organic Foods Production Act* (OFPA) establishes the National Organic Standards Board at §2119 (7 U.S.C. 6518) “(a) The Secretary shall establish a National Organic Standards Board (in accordance with the Federal Advisory Committee Act (5 U.S.C. app. 2 et seq.) (hereafter referred to in this section as the “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 this title.” The Policy and Procedures Manual sets forth procedures (p20) for the transition of Committee Chairs, “In order to avoid disruption in the quality and volume of work produced by the NOSB...” At the same time, the

section of the manual entitled Board Member Standards reads, “Each [NOSB] member must be willing to serve on committees as assigned by the Chair...” (p11)

Discussion

Committee transitions after the Fall Board meeting.

To effect a smooth and seamless transition between Board member terms, it is believed by the Policy and Development Committee that committee Chair, Vice-Chair, and member terms on their respective committees should run concurrent with Board terms, providing for orientation and mentorship periods, as outgoing Chairs, Vice-Chairs and members help train those incoming. In terms of Chairs, it is particularly helpful for continuity that the followup to the Fall board meeting be conducted with the committee leadership during that term. To the extent that additional work must be completed relative to Fall Board meeting decisions, clarifications issued, follow through on public comments presented at the meeting, and new assignments for moving forward, new committee leadership and membership during the period after the election of new officers could be disruptive.

In addition, with the Board composition changing after the Fall appointment of new NOSB members by the Secretary and until an assessment can be made of new member expertise and background, the reconfiguration of committee assignments is premature and can be disruptive to the ongoing committee process. Therefore, the Committee believes that changes to committee composition should generally not be made between the Fall Board meeting and the seating of the new Board in January.

In an effort to ensure full and active participation of new committee members and newly appointed NOSB members, the transition period after the Fall Board meeting should be used as an orientation and mentorship period. In that regard, new NOSB members should be notified that it is expected that they take their committee assignments in observer status directly after their appointment to the Board to the extent feasible. This will require the Chair to speak with newly appointed and existing Board members within two weeks of the appointment of new NOSB members and announce committee assignments within a two-week period after that. New Board members should be encouraged to attend the Fall Board meeting after their appointment. It is the committee’s belief that the travel costs associated with their participation should be reimbursed by NOP if necessary to facilitate their participation.

Committee transitions after the Spring Board meeting.

If after the Spring Board meeting a Board member would like to change committees, either adding to or stepping down from his/her assignments, a request should be made to the Board Chair. If the request does not alter the preferred number of committee members in the range of five to seven, the expectation is that the request will be approved, unless the Board Chair states in writing that such change will

interfere with the functioning of the committee.

Establishing a mentorship system.

The committee believes that the Board should formally institute a mentorship system to ensure effective participation by new Board members in committee and Board deliberations. To accomplish this, the committee believes that new Board members should be asked by the Board Chair to identify a mentor from existing Board members as soon after their appointment as possible, but no later than two weeks, or if the Board member prefers the Board Chair shall assign a buddy in the same time frame.

A section in the Policy and Procedures Manual must be amended to provide clarification and guidance regarding the transition of committee Chairs, Vice-Chairs, as well as existing and newly appointed members.

Filling Officer Vacancies

Language is needed to clarify the process for replacing the Chair of the Board, should there be a resignation. The current process of filling vacancies in the positions of Vice-Chair and Secretary clearly states that, "Should the Vice-Chair or Secretary resign or fail to serve the full term, the Executive Committee shall appoint an interim officer." (p14) However, under the responsibilities of the Vice-Chair, there is only a reference to an "absence" of the Chair with the language, "The Vice Chair shall act in the absence of the Chair." (p13) To clarify the process for replacing the Chair in the case of a resignation, the committee proposes to use the same process that is used in the case of the resignation of the Vice-Chair and Secretary by having the Executive Committee appoint an interim Chair "until the next regularly scheduled meeting of the Board, during which an election will be held to fill the remainder of the term." (p14)

Recommendations

I. Amend Section V to read (*changes are in italics*):

Section V

This section starts by defining the responsibilities of the different Committee Chairs and respective Vice-Chairs, *and includes guidance on procedures for transition of Committee Chairs, Vice-Chairs, and existing and newly appointed members.* In addition, this section covers the general and specific collaboration procedures between NOSB and NOP. [p20]

The Section "PROCEDURES FOR THE TRANSITION OF COMMITTEE CHAIRS" is amended as follows:

PROCEDURES FOR THE TRANSITION OF COMMITTEE CHAIRS, VICE-CHAIRS, AND MEMBERS

Committee Chairs, Vice-Chairs and members shall be appointed to serve annually by the Chair of the Board. The annual committee term shall be concurrent with the one-year term established by the Secretary (beginning on January 24 and ending on the following January 23). Newly appointed Chairs, Vice-Chairs and committee members will assume their positions at the beginning of the new term, after a period of orientation and mentorship provided by the outgoing Chair, Vice-Chair, and members.

In order to avoid disruption in the quality and volume of work produced by the NOSB, the appointment of Committee Chairs, Vice-Chairs, and members will follow these procedures:

After Election of NOSB Officers at Fall NOSB Meeting

1. Appointment of Committee Chairs

The Board Chair should appoint Committee Chairs from members with at least one year of NOSB experience, ideally. It is recommended that a new Committee Chair should have experience as Committee Vice-Chair.

2. Appointment of Committee Vice-Chairs

A Committee Vice-Chair shall be appointed by the Committee Chair and should be someone who has expressed to the Chair of the Committee interest in eventually serving as Committee Chair.

3. Time Frame for Appointments

Committee Chairs shall be appointed as Incoming Chairs in not more than 30 days after the newly elected NOSB Chair takes office (or continues in office), and incoming Vice-Chairs shall be appointed by Committee Chairs in no more than two weeks after that.

4. Exchange of Committee Files

Upon appointment, new and outgoing Committee Chairs should have a formal meeting to exchange all files related to the committee's work and to complete the first committee work plan under the new committee leadership.

5. Review of Committee Files

New Committee Chairs should review all work plan items and active files involving committee work.

6. Mentorship Period

The Incoming Chair and Vice-Chair of each committee shall participate in an orientation and mentorship period with the outgoing Chair and Vice-Chair of their committee until being seated in their positions at the beginning of the new term on January 24.

After the Appointment of the New NOSB Members, Prior to January 24

7. New Committee Member Appointments

New incoming committee members shall be appointed by the Board Chair, in consultation with the outgoing and incoming committee Chairs, no more than two weeks after the appointment of the new NOSB members by the

Secretary, with the Chair seeking and taking into account the expressed member interest, expertise, background, as well as new board composition.

8. Communication with Newly Appointed Members

Once appointed, incoming committee members shall be included in all emails pertaining to the committee assignments.

9. Attendance at Committee Meetings and Fall NOSB Meeting

New incoming members of the committee should participate in observer status in committee meetings upon their appointment, and should be encouraged to attend the Fall Board meeting.

10. New Member Mentorship.

The Board Chair, to facilitate an effective transition for new members of the Board and ensure effective participation in committee and board deliberations, shall ask incoming Board members to identify a mentor from existing Board members as soon after their appointment as possible, but no later than two weeks, or, if the Board member prefers or the Board member takes no action, the Board Chair shall assign a mentor in same time frame.

Between Board Appointments and Fall Board Meeting

11. Changing Committee Appointments

If a Board member would like to change committees, either adding to or stepping down from his/her assignments, a request shall be made to the Board Chair. If the request does not alter the preferred number of committee members in the range of five to seven, the expectation is that the request will be approved, unless the Board Chair states in writing that such change will interfere with the functioning of the committee. The Chair's determination should be made in consultation with Committee Chairs and the Executive Committee.

12. Filling Vacancy of Committee Chair and/or Vice-Chair

In the case of a vacancy in the positions of Committee Chair, the Committee Vice-Chair shall assume the Committee Chair position and the new Committee Chair shall appoint a new Vice-Chair in accordance with the consultation procedures cited above.

II. Amend Section III (**ELECTION OF OFFICERS. A. NOMINATION**, p14) to read as follows:

“Should the *Chair*, Vice Chair, or Secretary resign or fail to serve the full term, the Executive Committee shall appoint an interim officer.”

Committee Vote:

Moved: Jay Feldman Second: Barry Flamm

Yes: 5 No: 0 Abstain: 0 Absent: 1 Recuse: 0

**National Organic Standards Board
Policy Development Committee
Proposed Discussion Document
Public Comment Procedures**

October 4, 2011

Introduction

With the goal of involvement from all parts of the organic community, the National Organic Standards Board (NOSB) has historically sought to ensure that public input is central to its decision making process. The Policy Development Committee (PDC) seeks to collect public input on its miscellaneous policy on this subject, in an effort to assess the effectiveness of its public hearing process and its perceived utility in assisting the Board to make decisions that build public support for and trust in the standard. In order to do this, the PDC seeks public input regarding the establishment of a policy that clearly defines an effective public comment process in NOSB deliberations.

Background

Activities of the NOSB include, “conducting public meetings, soliciting and taking public comments” (NOSB Policy Procedure Manual [PPM] p5), in order to carry out the NOSB mission.

As discussed in the PPM (p27 - Miscellaneous Policies), several items stand out as vital for public comment at NOSB meetings. Specifically, it is stated that people who wish to comment at NOSB meetings during public comment periods can do so by following the rules in place, as well as using suggestions to better ensure that they are well-received.

Further, current policy states, “Each person will be given 5 minutes to speak, unless otherwise indicated by the Chair,” (p27) and continues, “No person will be allowed to speak during the public comment period for more than 10 minutes, unless otherwise indicated by the Chair.” (p27)

Finally, it is put forth that written proxies can be submitted to allow another person to speak on behalf of a member of the public, and that, “Individuals providing public comment will refrain from any personal attacks and from remarks that otherwise impugn the character of any individual.” (p27)

The policy gives the NOSB Chair discretionary authority in determining time allotments for public commenters within the established parameters. The PDC is seeking public input on issues that may require additional clarity, including, but not limited to, the following:

- How the NOSB informs the public of time allotments for public commenters during NOSB meetings;

- How the NOSB publicly acknowledges public comment;
- How the NOSB responds to popular or pressing issues raised in numerous public statements, but not included in the meeting agenda;
- Whether the time designated refers to presentation time, or to question and discussion time by NOSB members, or a combination of both; and,
- Whether comments from those who cannot be present can only take either the form of submitted written comment, or of proxy-delivered live comment, or whether, in addition, other options with modern media tools might allow live- or pseudo-live input from public members who are not present. (Along these lines, although Skype may not be an appropriate method, should the public input process make available by electronic or real-time technology a means for fostering broader public access to the public comment process?)

This document presents a set of questions and seeks public input. In addition, there may be additional questions and issues raised by the public that merit responses and the PDC encourages those being brought to this process.

Relevant Areas of the Rule

The *Organic Foods Production Act* (OFPA) establishes the National Organic Standards Board at §2119 (7 U.S.C. 6518), “(a) The Secretary shall establish a National Organic Standards Board (in accordance with the Federal Advisory Committee Act (5 U.S.C. app. 2 et seq.) [hereafter referred to in this section as the “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 this title.” The PPM [<http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELDEV3013893>] (Section VI, Miscellaneous Policies) includes (p27), “Policy for Public Comment at NOSB Meetings.” This lays out the process and the time designations of public comments, including that, “Each person will be given 5 minutes to speak,” and, “No person will be allowed to speak during the public comment period for more than 10 minutes.” Both of these statements are followed by the caveat, “unless otherwise indicated by the Chair.” Furthermore, process and time designation points are made in a subsequent section entitled, “Other suggestions that would be appreciated by NOSB members,” which provides additional direction to the public comment process

Discussion

In both policy and practice, the NOSB has traditionally put great value in comments delivered in person. The NOSB moves meetings around the country to allow easier access by a broad group of people and organizations, that otherwise would not have access, during each meeting. The Board sets aside a large proportion of the meeting time for public comment. And, the Board has adopted policy that guarantees those who have pre-registered and attend meetings at least a minimum amount of time in which to deliver their message.

A modification to the basic structure that the Policy provides for public comment is being

considered. The Committee seeks input and discussion from all interested parties that will assist in clarifying and addressing public needs, and ensuring the effectiveness and efficiency of the process. Public comment is sought to address questions included within the discussion points that follow.

Time limits and adequate representation

In the Federal Register notice announcing an NOSB meeting, the public is informed about the public comment period and the time restrictions. As increased numbers of people seek to participate in this process, time limitations become a factor in scheduling time allotments for individual participants.

There may be several ways to handle a large number of requests for public comments.

1. A special announcement could be posted in the Federal Register subsequent to the initial announcement indicating that a time reduction is being put in place for public comments. This was done for the Spring 2011 NOSB meeting, reducing the time allotment from 5 to 3 minutes.
2. A need to condense public statements could be announced at the beginning of the NOSB meeting, indicating that there are many who wish to make comments and requesting that comments be kept as brief as possible. In addition, NOSB members could be asked to keep their questions limited. This voluntary time reduction approach may achieve the time savings needed.
3. An assessment of those signed up and those actually present at the meeting could be made at the beginning of the meeting (or at the beginning of each day of the meeting), and a determination made as to whether time reductions are necessary.
4. The Board could decide to extend public comment into the evening hours to accommodate more people.

Given that the public comment period cannot be unlimited, should the requests to make public comment be prioritized? Should the total number of public comment slots be limited by category/topic or by some other means? Should more time be allocated for public comments (including going into the evening/night as necessary)? Should the published announcement indicating time periods for public comment be eliminated and full authority be given to the NOSB Chair or designated Board committee to determine how the issue can best be decided?

Another component regarding public comment at NOSB meetings pertains to whether the allocated time refers to „presentation“ time, „question and discussion“ time from NOSB members, or a combination. Should the policy be clarified to state a fixed presentation time, as well as a maximum question and discussion time? Should NOSB member questions be limited? Who should allow the variation or combine the time into some clear total? Or, is this best done by the Board Chair during the meeting, subject to the circumstances at hand? Also, should the time allocated be flexible or related to the number of requests? Or should it remain as it is now in the PPM? Is some other designation of time(s) more appropriate?

Hearing from those who cannot attend

Comments from those who cannot be present be present during public comment could be submitted in written form, through a live proxy, or by electronic means with modern media tools that allow for live- or pseudo-live input. (Along these lines, while Skype may not be the appropriate method, it may be necessary to identify and maintain an electronic or real-time means of fostering public comment access.) Should public comment through live/"remote" means be allowed and/or encouraged? Furthermore, given the limits of time, should the recent revisions to the PPM to clarify proxy procedures (p27) continue, or should the proxy practice be abolished¹?

Responding to public comment and serving the advisory role

It can further be posited that the NOSB should respond to overarching issues, which are repeatedly raised by the public at the meeting, *even if those issues were not on the agenda*. Some stakeholder groups have suggested that at the end of each Board meeting a communication from the NOSB be sent to the Secretary of Agriculture to convey issues that have come up during public comment and to fulfill the Board's statutory responsibility in its advisory capacity. According to some stakeholders, both those within and outside the NOSB, it is a responsibility of the Board that public comment is publicly acknowledged in this and possibly other ways. How should this be handled: prior to, during, or after public comment has occurred? Furthermore, what type of response or action should the public expect from the NOSB when issues not on the agenda are raised repeatedly in public comment? Should communications to the Secretary on issues raised in public comment be formalized? Does this communication and advisory function serve as an important public-private partnership that is responsive to the concerns raised by the broader organic community?

Conclusion

In order to best meet the goals of the NOSB and incorporate public comment into its decision making, the PDC is seeking public input on the Board's decision making process and efforts that may better ensure that the public feels welcome and is heard through its participation. Time for clarification and discussion has been viewed as helpful to both NOSB members and the public. How can this be balanced with the number of interested public commenters vis-à-vis the time available on the schedule?

The PDC is seeking the public's perspective on the questions below. (Please indicate the question number in responses provided on this topic.)

¹ The PPM (p27) on this point reads, "The NOSB will attempt to accommodate all persons requesting public comment time, however, persons requesting time after the closing date in the Meeting Notice, or during last minute sign-up at the meeting, will be placed on a waiting list and will be considered at the discretion of the NOSB Chair depending on availability of time. Similarly, persons who have signed up to address the NOSB for their 5-minute slot and have also served as a proxy for another person will be placed on a waiting list if they wish to speak for a third time on the same topic, and will be considered at the discretion of the NOSB Chair depending on availability of time. This should allow more members of the public time to present."

- 1) Given that the public comment period cannot be unlimited, how should the requests to make public comment be prioritized?
- 2) Should the policy be clarified to state a fixed presentation time for public comment?
- 3) Should policy also define a maximum question and discussion time once public comment is received?
- 4) Who should allow the variation or combine the time(s) into a defined total in #3 above?
- 5) Is time setting best done by the Board Chair, at the time of the meeting, depending upon the circumstances at hand?
- 6) Should the time allocated be flexible or related to the number of requests?
- 7) Should the public comment time allowed remain as it is now in the PPM?
- 8) Is some other designation of time(s) more appropriate?
- 9) Should public comment through live/"remote" means be allowed and/or encouraged?
- 10) Given the limits of time, should the recent revisions to the PPM to clarify proxy procedures (p27) continue? Or, should the proxy practice be abolished?
- 11) How can this function (NOSB serving as an advisory role) best serve as a public-private partnership that is responsive to the concerns raised by the broader organic community?

The public is encouraged to provide any additional questions and thoughts regarding the most effective and efficient approach for the NOSB to manage the public comment process associated with its Board meetings.

Committee Vote

Moved: Colehour Bondera

Second: Barry Flamm

Yes 6

No 0

Abstain 0

Absent 0