National Organic Standards Board Meeting

Red Lion on Fifth Avenue | Seattle, Washington

April 26 – 29, 2011

Title	Page
Agenda	3
Crops Committee | John Foster, Chairperson	
Petitioned Materials Recommendations	
Tetracycline	9
Nickel	15
Sunset 2012 Recommendations on § 205.601	
Chlorine materials (calcium hypochlorite, chlorine dioxide, sodium hypochlorite)	25
Copper materials (copper sulfate and fixed coppers (3 varieties))	28
Alcohols (ethanol and isopropanol)	30
Newspapers and other recycled paper and plastic mulch covers	31
Pheromones	33
Sulfur dioxide	35
Vitamin D_3	36
Streptomycin	37
Lignin sulfonate	40
Magnesium sulfate	41
Ethylene gas	42
Sodium silicate	43
Sunset 2012 Recommendations on § 205.602	
Sodium nitrate	44
Corn Steep Liquor Recommendation	47
Livestock Committee | Wendy Fulwider, Chairperson	
Stocking Rates Recommendation	55
2011 Proposal Combined with 2009 Animal Welfare Recommendation	64
Animal Handling, Transit, and Slaughter Recommendation	75

Handling Committee | Steve DeMuri, Chairperson

Petitioned Materials Recommendations

Attapulgite 80
Calcium acid pyrophosphate 85
Silicon dioxide 91
Sodium acid pyrophosphate 93

Sunset 2012 Recommendations on § 205.605(a)

Enzymes 100
Potassium iodide 101

Sunset 2012 Recommendations on § 205.605(b)

Nutrient vitamins and minerals 103
Potassium iodide 104
Tocopherols 106

Nutrient Vitamins and Minerals Recommendation 107

Chlorine Materials Annotation Recommendation 110

Materials Committee | Katrina Heinze, Chairperson

Update and Proposed Guidance Document 113

Compliance, Accreditation, and Certification Committee | Joe Dickson, Chairperson

Evaluation of Material Review Organizations Discussion Document 118

Policy Development Committee | Barry Flamm, Chairperson

NOSB Policy and Procedure Manual Recommendations

Section III & IV: Review of Vice Chair & Policy Development Committee Roles 122
Section IV: Clarification of Committee Purview 125

National Organic Standards Board Meeting

Red Lion Hotel on Fifth Avenue | Seattle, Washington

April 26 – 29, 2011

April 26, 2011 | April 27, 2011 | April 28, 2011 | April 29, 2011

Tuesday, April 26, 2011

8:00 a.m.	**Call to Order** **Tracy Miedema, Chairperson** – Approval of Agenda – Announcements – Introductions – NOSB Mission
8:15 a.m.	**Secretary's Report** **Wendy Fulwider, Secretary** – Acceptance of October 2010 Meeting Transcripts and Voting Results as Official Record
8:30 a.m.	**NOSB Materials Review Process Update** **Katrina Heinze, Materials Committee Chairperson**
9:00 a.m.	**National Organic Program Report** ***Miles McEvoy, Deputy Administrator*** **National Organic Program**
9:45 a.m.	**Inert Materials Working Group Report** ***National Organic Program***
10:00 a.m.	**Break**
10:15 a.m.	**Welcome Comments** ***Dan Newhouse, Director*** **Washington State Department of Agriculture**
10:30 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, April 27, 2011

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

Crops Committee
John Foster, Chairperson

Petitioned Materials Recommendations

- Tetracycline
- Nickel

Sunset 2012 Recommendations on § 205.601

- Chlorine materials (calcium hypochlorite, chlorine dioxide, sodium hypochlorite)
- Copper materials (copper sulfate and fixed coppers (3 varieties))
- Alcohols (isopropanol and ethanol)
- Newspapers or other recycled paper, without glossy or colored inks (2 listings)
- Plastic mulch covers
- Pheromones
- Sulfur dioxide
- Vitamin D_3
- Streptomycin
- Lignin sulfonate (2 listings)
- Magnesium sulfate
- Ethylene gas
- Sodium silicate

Sunset 2012 Recommendations on § 205.602

- Sodium nitrate

Sodium Nitrate Recommendation

Corn Steep Liquor Recommendation

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

10:15 a.m. **Livestock Committee**
Wendy Fulwider, Chairperson

Stocking Rates Recommendation

Animal Handling, Transit, and Slaughter Recommendation

Omnivore Diets for Poultry Discussion Document

11:45 p.m. **Lunch**

Wednesday, April 27, 2011 (continued)

12:45 p.m. **NOSB Committee Presentations and Discussions (continued)**

Handling Committee
Steve DeMuri, Chairperson

Petitioned Materials Recommendations

- Attapulgite
- Calcium Acid Pyrophosphate
- Silicon Dioxide
- Sodium Acid Pyrophosphate

Sunset 2012 Recommendations on § 205.605(a)

- Enzymes
- Potassium iodide

Sunset 2012 Recommendations on § 205.605(b)

- Nutrient vitamins and nutrient minerals
- Potassium iodide
- Tocopherols

Nutrient Vitamins and Minerals Recommendation

Chlorine Materials Annotation Recommendation

2:30 p.m. **Break**

2:45 p.m. **Materials Committee**
Katrina Heinze, Chairperson

Materials Classification Guidance Document Recommendation

3:30 p.m. **Compliance, Accreditation, and Certification Committee**
Joe Dickson, Chairperson

Evaluation of Materials Review Organizations Discussion Document

4:15 p.m. **Policy Development Committee**
Barry Flamm, Chairperson

NOSB Policy and Procedure Manual Recommendations

- Sections III & IV: Review of Vice Chair & Policy Development Committee Roles
- Section IV: Clarification of Committee Purview
- Section V: NOSB Member and Leadership Transition

5:00 p.m. **Recess**

Thursday, April 28, 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, April 29, 2011

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

Crops Committee
John Foster, Chairperson

Petitioned Materials Recommendations

- Tetracycline
- Nickel

Sunset 2012 Recommendations on § 205.601

- Chlorine materials (calcium hypochlorite, chlorine dioxide, sodium hypochlorite
- Copper materials (copper sulfate and fixed coppers (3 varieties))
- Alcohols (isopropanol and ethanol)
- Newspapers or other recycled paper, without glossy or colored inks (2 listings)
- Plastic mulch covers
- Pheromones
- Sulfur dioxide
- Vitamin D_3
- Streptomycin
- Lignin sulfonate (2 listings)

Sunset 2012 Recommendations on § 205.601

- Magnesium sulfate
- Ethylene gas
- Sodium silicate

Sunset 2012 Recommendations on § 205.602

- Sodium nitrate

Sodium Nitrate Recommendation

Corn Steep Liquor Recommendation

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

9:30 a.m. **Livestock Committee**
Wendy Fulwider, Chairperson

Stocking Rates Recommendation

Animal Handling, Transit, and Slaughter Recommendation

10:30 a.m. **Break**

10:45 a.m. **NOSB Consideration and Vote on Committee Action Items (continued)**

Handling Committee
Steve DeMuri, Chairperson

Petitioned Materials Recommendations

- Attapulgite
- Calcium Acid Pyrophosphate
- Silicon Dioxide
- Sodium Acid Pyrophosphate

Sunset 2012 Recommendations on § 205.605(a)

- Enzymes
- Potassium iodide

Sunset 2012 Recommendations on § 205.605(b)

- Nutrient vitamins and nutrient minerals
- Potassium iodide
- Tocopherols

Nutrient Vitamins and Minerals Recommendation

Chlorine Materials Annotation Recommendation

12:15 p.m. **Lunch**

1:15 p.m. **Materials Committee**
Katrina Heinze, Chairperson

Materials Classification Guidance Document Recommendation

2:15 p.m. **Break**

2:30 p.m. **Policy Development Committee**
Barry Flamm, Chairperson

NOSB Policy and Procedure Manual Recommendations

- Sections III & IV: Review of Vice Chair & Policy Development Committee Roles
- Section IV: Clarification of Committee Purview
- Section V: NOSB Member and Leadership Transition

3:15 p.m. **Committee Workplans**

4:15 p.m. **Other Business and Closing Remarks**

4:45 p.m. **Adjourn**

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: April 2011 | **Substance:** Tetracycline

Committee: Crops X Livestock ☐ Handling ☐ Petition is for: __

on the National List § 205.601_____

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

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

B. Substance Fails Criteria Category: __ Comments:

C. Codex._____See following evaluation._____

D. 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: _____ *Seconded:*_____ *Yes:* _____ *No:* _____ *Absent:* _____ *Abstain:* _____

Recommended Committee Action & Vote The majority of the Crops Committee recommends against the adoption of the petition to amend the listing for tetracycline by removing the expiration date on tetracycline so that the listing would state "tetracycline, for fire blight control only," thus allowing tetracycline's use to expire on October 21, 2012.

Motion by: Jay Feldman *Seconded:* Tina Ellor *Yes:* 0 *No:* 5 *Absent:* 2 *Abstain:* 0

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

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

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

Describe why a prohibited substance:_____

3) Substance was rejected by vote for amending National List to § 205. _____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**

EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

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

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			TR1[1] 149-164 Daniels, 1982.[2] Manufacture results in discharges of solvents, detergents, disinfectants. Treated plants exude tetracycline.
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]	X			Thiele-Bruhn and Beck, 2005.[3] See #6 below.
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1) (B)(ii); 205.601(m)2]	?			
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]	X			Burgos et al, 2003.[4] Bacteria with multiple resistance.
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]	X			Thiele-Bruhn and Beck, 2005 Shifts fungal-bacterial balance at environmentally relevant concentrations.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]	X			Xiujie Xie et al, 2010.[5] Tetracycline may be genotoxic to plant cells.
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]	X			See #10 below.
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]	X			Daniels, 1982. Chander et al, 2005.[6] Halling-Sørensen et al, 2002.[7] Tetracycline is taken up by plants and appears in all tissues and in exudates. Soil-bound tetracycline maintains biological activity.

[1] TR1 is TR dated January 27, 2006.
[2] MJ Daniels, 1982. Editorial: Possible effects of antibiotic therapy in plants. Reviews of Infectious Diseases 4 (Supp): 167-170.
[3] Sören Thiele-Bruhn and Iris-Constanze Beck, 2005. Effects of sulfonamide and tetracycline antibiotics on soil microbial activity and microbial biomass. **Chemosphere**, Volume 59, Issue 4, April 2005, Pages 457-465
[4] Burgos JM, Ellington BA, Varela MF., 2005. Presence of multidrug-resistant enteric bacteria in dairy farm topsoil. J Dairy Sci. 2005 Apr;88(4):1391-8.
[5] Xie, X., Zhou, Q., Bao, Q., He, Z. and Bao, Y. , Genotoxicity of tetracycline as an emerging pollutant on root meristem cells of wheat (*Triticum aestivum* L.). Environmental Toxicology, n/a. doi: 10.1002/tox.20567
[6] Chander Y, Kumar K, Goyal SM, Gupta SC, 2005. Antibacterial activity of soil-bound antibiotics. J Environ Qual. 2005 Oct 12;34(6):1952-7. Print 2005 Nov-Dec.
[7] Halling-Sørensen B; Sengeløv G; Tjørnelund J, 2002. Toxicity of tetracyclines and tetracycline degradation products to environmentally relevant bacteria, including selected tetracycline-resistant bacteria. Archives of environmental contamination and toxicology 2002;42(3):263-71.

				Degradation products have same activity as parent.
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)I; §6518 m.4]	X			TR163-71, 279-293 Lugo-Melchor et al, 2010.[8] Levy et al, 1976.[9] http://en.wikipedia.org/wiki/Tetracycline_antibiotics "Prop 65 list" http://www.oehha.org/prop65/prop65_list/files/P65single3405.pdf Workers are at risk of contracting tetracycline-resistant disease and suffering from allergic reactions. As a consequence of the widespread use of tetracyclines, the emergence and spread of tetracycline-resistant bacterial pathogens, among them the foodborne pathogen Salmonella enterica, has become a serious health hazard worldwide. Workers who handle feed with tetracycline have tetracycline-resistant flora in their intestines. Tetracyclines remain the treatment of choice for infections caused by chlamydia (trachoma, psittacosis, salpingitis, urethritis, and *L. venereum* infection), Rickettsia (typhus, Rocky Mountain spotted fever), brucellosis, and spirochetal infections (borreliosis, syphilis, and Lyme disease). In addition, they may be used to treat anthrax, plague, tularemia, and Legionnaires' disease. They may have a role in reducing the duration and severity of cholera, although drug-resistance is occurring, and their effects on overall mortality is questioned. Developmental toxin listed by the state of California.
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.

[8] Lugo-Melchor, Y., Quinones, B., Amezquita-Lopez, B.A., Leon-Felix, J., Garcia-Estrada, R., Chaidez, C. 2010. Characterization of tetracycline resistance in Salmonella enterica strains recovered from irrigation water in the Culiacan Valley, Mexico. Microbial Drug Resistance. 6(3):185-190.

[9] Stuart B. Levy, M.D., George B. FitzGerald, Ph.D., and Ann B. Macone, B.S., 1976. Changes in Intestinal Flora of Farm Personnel after Introduction of a Tetracycline-Supplemented Feed on a Farm. N Engl J Med 1976; 295:583-588.

Category 2. Is the Substance Essential for Organic Production? Substance:

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			TR1 304-312. Stockwell and Stack, 2007[10]
5. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]			X	
6. Are there any alternative substances? [§6518 m.6]	X			TR1 317-330
7. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			TR1 297-302, 335-343. Aldwinckle et al, 1998[11]. "Fireblight Management in the Pacific Northwest USA" (http://www.ncw.wsu.edu/treefruit/fireblight/principles.htm)

[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.

[10] Stockwell, V. O., and Stack, J. P. 2007. Using *Pseudomonas* spp. for integrated biological control. Phytopathology 97:244-249.

[11] H. Aldwinckle, J Norelli, and MT Momol, 1998. Fire blight: the search for better control. IDFTA Compact Fruit Tree, Vol. 31, No. 4

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

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]			X	
2. Is the substance consistent with organic farming and handling, and biodiversity? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]				
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]				
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]			X	
5. Is the primary use as a preservative? [§205.600 b.4]			X	
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]			X	
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: a. copper and sulfur compounds;				
b. toxins derived from bacteria;			X	
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?				
d. livestock parasiticides and medicines?				
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?				

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

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

Substance - _____

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

NOSB COMMITTEE PROPOSED RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: Spring 2011—Seattle, WA	Substance: Nickel as a micronutrient, added to 205.601(j)(6)(ii)

Committee: Crops X Livestock ☐ Handling ☐ Petition is for: Adding nickel to the list of micronutrients found on the National List, 205.601(j)(6)(ii)

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

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

Substance Fails Criteria Category: 1, 2, 3 Comments: Fails categories.. Annotation in place for other micronutrients already on the list and--under which nickel would also be limited--is intended to mitigate effects of micronutrient use.

Proposed Annotation:
§ 205.601 Synthetic substances allowed for use in organic crop production.
(j) As plant or soil amendments.
(6) Micronutrients—not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Soil deficiency must be documented by testing.
(i) Soluble boron products.
(ii) Sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, nickel, selenium, and cobalt.

Basis for annotation:
To meet criteria above: 1, 2, 3. Criterion: Compatibility & consistency—to minimize the likelihood to overdependence on supplemental synthetic crop fertility practices in lieu of soil building practices as mandated in § 205.203.

B. Recommended Committee Action & Vote, including classification recommendation (State Actual Motion): Classify nickel micronutrients as synthetic.

C. Classification of the material: Synthetic 5 Non- synthetic 0 Absent 2 Abstain 0

Motion by: John Foster Seconded Jay Feldman Yes: 5 No: 0 Absent 2 Abstain: 0

Recommended Committee Action & Vote List nickel as micronutrient on § 205.601(j)(6)(ii)

Motion by: John Foster Seconded: Tina Ellor Yes: 2 No: 3 Absent: 2 Abstain: 0

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

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

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

Describe why a prohibited substance:_____

3) Substance was rejected by vote for amending National List to § 205 601(j)(6)(ii) Describe why material was rejected:

Concerns over toxicity, carcinogenicity, essentiality, and use pattern (spray into tall canopy) by those voting in the majority..

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**

March 7, 2011 — **Date**

EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment?
Substance: Nickel (added to list of other micronutrients currently included on the National List)
(RPet=Revised Petition; TR=Technical Review)

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			The precise amount of nickel destined for agricultural use is unknown, but is known to be a fraction of 7% of nickel smelted and manufactured. 'Agricultural use' did not register as a subcategory within the use category "chemicals and chemical use", suggesting that nickel for micronutrient use is an exceedingly small fraction of the total in play. RPet 9c. TR lines 459+, 671+ Surface mining involves large disturbance by earth-moving equipment. Nickel is no longer produced in US, so must be imported. Refining is very energy intensive. People around refineries are exposed to toxic nickel dust and sulfur dioxide.TR 422-457
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]	x			When used as intended in this context, possibly but apparently not likely; the TR identifies certain harmful environmental effects outside of the use of nickel as a micronutrient in organic production systems. RPet 9c, 9e. TR lines 474, 484, 489+. Listed as a Hazardous Constituent of Waste (nickel, nickel compounds, nickel carbonyl, nickel cyanide) (305-306) On the other hand, these components, such as Cu, Zn, Ni, Co, Mo, Fe, and Mn, are also termed as "heavy metals". The contamination of these heavy metals to the environment is well documented. It is a situation of case by case analysis, but the contamination problem such as the contamination of nickel in old orchard where fertilizers have been used extensively might be more general than the deficiency problem (e.g. U.S. EPA's Background report on fertilizer use, contaminants and regulations; U.S. EPA's Nutrient Management and Fertilizer; and USDA's Heavy Metal Soil Contamination). (489-495) The toxicity effect of one component could be enhanced by another component. For example, scots pine (*Pinus sylvestris* L.) saplings did not survive when individually treated with 150 mg L^{-1} of copper or 150 mg L^{-1} of nickel. The lethal concentration substantially reduced to 15 mg L^{-1} each when these two components were applied simultaneously (Nieminen, 1998). (521-524)

				"Although Ni is a recognized essential mineral nutrient element for higher plants, its agricultural and biological significance is poorly understood. This is largely because of the low levels thought to be needed by plants (about 1–100 ng g^{-1} dry weight) in relation to the relative abundance of Ni in essentially all soils (> 5 kg ha^{-1})," (Bai et al., 2006 and additional references cited therein). (584-587)
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1) (B)(ii); 205.601(m)2]	**?**			Unknown Some micronutrients are chelated compounds such as chelates of citric acid, lignosulfonic acid, various amino acids, HEDTA (hydroxyethylenediaminetriaacetic acid), EDTA (ethylenediaminetetraacetic acid), and DTPA (diethylenetriaminepentaacetic acid). (97-99) Check to see if any are List 1,2, 3. Some are 4B, which likely will not be allowed in the future.
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]	**x**			If misused, excessive nickel application could result in detrimental effects, particularly by causing imbalances with other micronutrients. RPet 9a. TR lines 513
6. Are there adverse biological and chemical interactions in agro- ecosystem? [§6518 m.5]	**x**			If misused, levels above those required for plant growth and crop production can cause problems. Toxicity can occur when micronutrients are applied in excess. RPet 9. TR lines 534, 545+ When micronutrients are applied as chelates, some chelating agents such as ETDA are synthetic but do not naturally exist in soil. Potentially, these chelating agents may cause the loss of other components in soil by complexing those components and making those components soluble in water. (484-487)
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]	**x**			The TR does not note such effects when nickel is used appropriately as a micronutrient, though does suggests that possibility when misused, that is provided in excess of need. RPet 9. TR lines 560-651. The TR does not address impacts on the soil foodweb, but numerous studies show negative impacts on soil respiration and the growth of soil fungi, including mycorrhizal fungi. (Addendum)
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]	**x**			See #7 above. Nickel is active in the Ni cation and does not break down further. TR lines 661+. RPet 9, 10. Nickel is toxic and carcinogenic, it can be phytotoxic TR 489-495, 513-524, 545-555, 608-612
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]	**x**			When used correctly, the TR notes no such effects. The TR does reference a line from ATSDR-Ni in line 705 stating that, "…it is impossible to predict nickel's environmental behavior on a general basis." Nickel is a heavy metal. Contamination can be a problem, worse than deficiency, and interact

				with other metals. TR 489-495, 513-524
10. Is there any harmful effect on human health? [§6517 c (1)(A) (i) ; 6517 c(2)(A)I; §6518 m.4]	**x**			Human health effects were addressed in the TR in general terms, but not in the context of nickel used as a micronutrient. Occupational hazards and exposures of the general public to nickel did not include mention of nickel as a micronutrient. For example, "The general population is exposed to low levels of nickel because it is widely present in air, water, food, and consumer products." TR lines 816-817. RPet 9d, 10 Nickel compounds are known to be human carcinogens (ATSDR-Ni, 2005; 11th Report on Carcinogens – Nickel Compounds and Metallic Nickel). (782-783) The effect of nickel on human health is extensively discussed in ATSDR-Ni (2005). Nickel compounds "can be grouped according to their solubility in water: soluble compounds include nickel chloride, nickel sulfate, and nickel nitrate, and less-soluble compounds include nickel oxide and nickel subsulfide. Both the soluble and less-soluble nickel compounds are important with regard to all relevant routes of exposure. Generally, the soluble compounds are considered more toxic than the less-soluble compounds, although the less-soluble compounds are more likely to be carcinogenic at the site of deposition." (785-791)
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: Nickel (added to list of other micronutrients currently included on the National List)

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			None are available for rapid correction of micronutrient deficiencies or in soluble form. TR 867-882 Alyssum extracts are as efficacious as nickel sulfate in correcting or preventing Ni deficiency. Wood et al, 2006.
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			There are some plants that tend to accumulate nickel and other micronutrients when grown in appropriate conditions. TR 887-912 pH adjustment might be more important than applying "required" micronutrients for correcting "deficiency" problems. "If the deficiency is due to pH imbalance, the approach is to modify the pH of the mix. In this case, adding micronutrients can make matters worse because the level of individual micronutrients may affect the level in the plant of other micronutrients through a process called antagonism. For example, too much iron may produce manganese and zinc deficiencies, while high levels of manganese may result in iron and zinc deficiencies. Copper and zinc are also antagonistic: too much of one may produce deficiency of the other," (Ohio State University). Heavy metals such as Cu, Zn and Ni are strongly retained in soil. Excessively applied micronutrients remain in soil for a long time and may cause toxic effects to subsequent plants. (948-957
7. Is there another practice that would make the substance unnecessary? [§6518 m.6]	x			Subject to the Law of the Minimum and in the some cases, yes. A healthy soil can provide sufficient micronutrients to some crops in some cases, although the dynamics of soil properties are such that micronutrient deficiencies can be found in crops even though soil micronutrient levels appear to be adequate. TR 584+, 594+. RPet 1, 4, 12. "Although Ni is a recognized essential mineral nutrient element for higher plants, its agricultural and biological significance is poorly understood. This is largely because of the low levels thought to be needed by plants (about 1–100 ng g^{-1} dry weight) in relation to

				the relative abundance of Ni in essentially all soils (> 5 kg ha^{-1})," (Bai et al., 2006 and additional references cited therein). (584-587) The nickel deficiency was especially evident in ureide-transporting woody perennials such as pecan tree (Wood et al., 2006; Bai et al., 2006). One cause of nickel deficiency is the suppressed nickel uptake by the excessive presence of zinc (University of Georgia). The metabolic consequence of nickel deficiency was the accumulation of urea, disrupted metabolism of amino acids, and reduced urease activity. The morphological symptoms of nickel deficiency in a woody perennial were dwarfing of leaves and leaflets with respect to healthy leaves, i.e. so called mouse ear in pecan (Wood et al., 2004; Bai et al., 2006; University of Georgia). (594-600)

[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: Nickel (added to list of other micronutrients currently included on the National List)

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		Applications of synthetic micronutrients have been consistent with organic farming practices for over 30 years. Nickel is now recognized as an essential micronutrient. TR 54+, 101+, 184+, 228+, revised petition part 6, AAPFCO, professional knowledge, pre-NOP private standards, and 7 CFR 205. RPet 12 Negative impact on soil organisms. (See citations in addendum.)
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]		x		See #2 above. In the long run (and that's what "sustainable" means), it doesn't work to mine metals and add them to soils to grow crops that could be grown in other places.
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]			x	
5. Is the primary use as a preservative? [§205.600 b.4]			x	
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]			x	
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: a. copper and sulfur compounds;	x			In the nickel sulfate (most common) form.
b. toxins derived from bacteria;		x		
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?	x			Minerals.
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: Nickel (added to list of other micronutrients currently included on the National List)

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

Addendum
Some Studies of the Impacts of Nickel on Aspects of the Soil Food Web

1. Inhibition of growth of nine ectomycorrhizal fungi by cadmium, lead, and nickel *in vitro* ☆

J.D. McCreight[†, a] and D.B. Schroeder[a]
[a]Department of Natural Resources Conservation University of Connecticut, Storrs, CT 06268, U.S.A.
Received 18 February 1979;
revised 7 January 1980;
accepted 24 April 1980.
Available online 26 June 2003.

Abstract
Growth of *Amanita muscaria, Cenococcum graniforme, Laccaria laccata, Pisolithus tinctorius, Rhizopogon roseolus, Suillus brevipes, S. grevellei, S. luteus*, and *Thelephora terrestris* on Hagem Nutrient Agar as modified by Modess at 20°C for 28 days was inhibited by cadmium, lead, and nickel. All fungi were arrested by 350 µg cadmium per ml (ppm) or less. Lead arrested five species at 200 ppm or less; *Cenococcum graniforme, L. laccata*, and *S. luteus* were arrested at 2,000 ppm lead. Nickel arrested growth of six fungi at 20 ppm or less. *Amanita muscaria, S. luteus*, and *L. laccata* were arrested at 40, 175 and 225 ppm nickel, respectively. Metal concentrations that did not arrest delayed growth for 7–21 days after which the growth rate was comparable to the control.
☆Scientific Contribution No. 791, Agricultural Experiment Station, University of Connecticut, Storrs, CT 06268, U.S.A.

[†] Present address: USDA, SEA-AR, U.S. Agricultural Research Station, P.O. Box 5098, Salinas, CA 93915, U.S.A.

Environmental and Experimental Botany
Volume 22, Issue 1, February 1982, Pages 1-7

2. Nickel toxicity to fungi: Influence of environmental factors

H. Babich and G. Stotzky
Laboratory of Microbial Ecology, Department of Biology, New York University, 952 Brown Building, Washington Square, New York, New York 10003, USA
Received 13 May 1982.
Available online 16 December 2004.

Abstract
The toxicity of nickel (Ni) to the mycelial growth rates of filamentous fungi was influenced by environmental abiotic factors. Increasing the pH from acidic to alkaline levels completely eliminated the toxicity of Ni to *Achyla* sp. and *Saprolegnia* sp. Magnesium or zinc, but not potassium, sodium, calcium, or ferric, ions reduced the toxicity of Ni to *Achyla* sp. An antagonistic interaction between a combination of Ni + Pb was noted toward growth of *Achyla* sp. and *Saprolegnia* sp.; the interactions between combinations of Ni + Cd or Ni + Hg were less well defined. Chlorophyll, at 1%, reduced the toxicity of Ni toward *Saprolegnia* sp. and *Cunninghamella blakesleeana*, and increasing the chlorophyll concentration from 0.2 to 1% progressively reduced the toxicity of Ni to *Aspergillus clavatus*. The addition of 1% humic acid reduced the toxicity of Ni to *Saprolegnia* sp. and *C. blakesleeana*, and increasing the humic acid concentration from 0.2 to 1% progressively reduced the toxicity of Ni toward *Aspergillus flavus*. *A. flavus* was more resistant to Ni at 33 than at 23°C.

3. Short-term and long-term effects of cadmium, chromium, copper, nickel, lead and zinc on soil microbial respiration in relation to abiotic soil factors

P. Doelman and L. Haanstra

Abstract

The inhibition of the respiration rate by the heavy metals, Cd, Cr, Cu, Pb, Ni and Zn was investigated in five Dutch soil types in relation to the length of time these heavy metals were present in the soil. The amounts of heavy metal added as chloride salts to the soils were 0, 55, 150, 400, 1000, 3000 and 8000 $\mu g \cdot g^{-1}$, respectively. The measurements were carried out both immediately after the addition of the heavy metals and approximately 18 months later. The inhibition during the first two to eight weeks was not obscured by an extra nutrient flush to drying. During the 18 months, the toxicity decreased but was still significant. Inhibition was greatest in the sandy soil and least in the clay soil. In a loam soil and in a sandy peat soil, the inhibiting effects were intermediate, but distinct. The main abiotic factors responsible for these different degrees of inhibition were the clay fraction for Cd, the Fe content for Cu, Pb and Zn and the pH for Ni. Although clay, Fe, and Mn together with the organic matter fraction, determine the total cation exchange capacity of soil, their contribution to the toxicity of heavy metals may be antagonistic. The latter may increase the mobility due to chelation and therefore possibly increase the toxicity, while the other factors may bind the heavy metals and therefore decrease the toxicity.

Key words Cd - CEC - Clay - Cr - Cu - Fe - Long-term - Mn - Ni - Organic matter - Pb - pH - Short-term - Soil microbial respiration – Zn

Use of Alyssum extracts to correct Nickel Deficiency

B.W. Wood, R. Chaney, and M. Crawford, 2006. Correcting Micronutrient Deficiency Using Metal Hyperaccumulators:*Alyssum* Biomass as a Natural Product for Nickel Deficiency Correction. HORTSCIENCE 41(5):1231-1234. 2006.

Abstract:

The existence of nickel (Ni) **deficiency in certain horticultural crops meritsdevelopment of fertilizer products suitable for specific niche uses and for correcting orpreventing deficiency problems before marketability**, **and yields are affected. The efficacyof satisfying plant nutritional needs for Ni using biomass of Ni hyperaccumulator specieswas assessed. Aqueous extraction of *Alyssum murale* (Waldst.** & **Kit.) biomass yieldeda Ni-enriched extract that, upon spray application, corrects and prevents Ni deficiency inpecan** ICaiya *illinoinensis* **(Wangenh.)** K. **Kochi. The *Ni-Alyssum* biomass extract** was aseffective at correcting or preventing Ni deficiency as was a **commercial Ni-sulfate salt.Foliar treatment of pecan with either source at -10 mg-L` Ni, regardless of source,prevented deficiency symptoms whereas treatment at less than 10 mg-L` Ni was onlypartially effective. Autumn application of Ni to foliage at 100 mg-L-' Ni during leafsenescence resulted in enough remobilized Ni to prevent expression of morphologicallybased Ni deficiency symptoms the following spring. The study demonstrates that micro-nutrient deficiencies are potentially correctable using extracts of metal-accumulatingplants.**

National Organic Standards Board
Crops Committee
Sunset Recommendation
Chlorine Materials

March 7, 2011

Current National List Citation

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

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

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

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. They are also common disinfecting agents for farm equipment and tools. 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 organic farming 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.

Having said that, the annotation limiting the use of chlorine presently noted in §205.601(a) (2) 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 Cl2)."

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 Crops Committee wishes to recommend a change to the annotation to chlorine materials as noted below. This change of language is intended only to clarify the use allowances for chlorine compounds and bring them into alignment with NOP's intended guidance and provide a regulatory basis for ACA's to ensure compliance with historic and appropriate uses of the materials in organic farming operations.

Additionally, the Crops 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(s)

The Crops Committee recommends relisting chlorine compounds with a change to the annotation of the following substance in this use category as published in the final rule:

Chlorine materials (calcium hypochlorite; chlorine dioxide: and sodium hypochlorite)--Residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil should not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act. Chlorine products may be used up to maximum labeled rates for disinfecting and sanitizing equipment or tools.

Committee Vote

Motion: John Foster Second: Tina Ellor
Yes: 5 No: 0 Abstain: 0 Recuse: 0 Absent: 2

National Organic Standards Board
Crops Committee
2012 Sunset Recommendation
Copper Materials

March 4, 2011

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

(i) As plant disease control

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

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

Summary

The Crops Committee recognizes, as have all the technical reviews going back to 1995, that, while effective in management plant diseases, the accumulation of copper in the soil is detrimental to the environment and therefore must be monitored and carefully managed. The buildup of copper in the soil can be toxic to earthworms, fungi (including mycorrhizae), bacteria, and most soil animal life. Because copper is highly toxic to most aquatic species, runoff into waterways must be avoided. Good management practices require close monitoring to ensure that there is no accumulation in the soil.

Workers on the farm are exposed to copper pesticides through mixing, loading and/or applying the pesticide (handlers) or re-entering treated sites. It is recognized that allowed copper compounds and formulations cause dermal or eye irritation and can cause other health problems. While the labels on products contain precautionary language, the committee understands that appropriate Personal Protective Equipment (PPE) must be utilized and compliance with EPA's Worker Protection Standard, including adherence to reentry intervals, is absolutely critical when these products are used. The Committee will work with the National Organic Program to advance guidance that ensures that organic operations are strictly meeting, and to the extent possible, exceeding the standards established by the product label in meeting principles of sustainability and a sustainable work environment for all those who work in organic production.

Committee Recommendation

The Crops Committee recommends the continued listing of coppers (fixed) and copper sulfate with the addition of language that requires periodic testing of the soil for copper levels. The motion was to amend the current listing of coppers (fixed) and copper sulfate to read:

(i) As plant disease control.

(2) Coppers, fixed—copper hydroxide, copper oxide, copper oxychloride, includes products exempted from EPA tolerance, Provided, That, copper-based materials

must be used in a manner that minimizes accumulation in the soil and documented through periodic testing and shall not be used as herbicides"

(3) Copper sulfate—Substance must be used in a manner that minimizes accumulation of copper in the soil and documented through periodic testing."

Committee Vote

Motion: Jay Feldman Second: Barry Flamm
Yes: 6 No: 0 Absent: 0 Abstain: 0 Recuse: 0

National Organic Standards Board
Crops Committee
2012 Sunset Proposed Recommendation
Ethanol and Isopropanol on §205.601

March 2, 2010

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

(a) As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems.
  (1) Alcohols.
    (i) Ethanol
    (ii) Isopropanol

Committee Summary

These materials are used widely as sanitizers, extractants, inerts, and also are taxable as liquor. They can be made naturally or synthetically and were listed originally so it was clear that either form could be used. All comments specific to these materials during the last round of sunset were all in favor of relisting.

Committee Recommendations

The Crops Committee recommends the continued listing of Ethanol and Isopropanol on 205.601 Synthetics substances allowed for use in organic crop production as algicide, disinfectants, and sanitizers including irrigation system cleaning systems.

Committee Vote

Motion: To relist ethanol and isopropanol on § 205.601.
Motion by: Tina Ellor Second: Colehour Bondera
Yes: 6 No: 0 Absent: 1 Abstain: 0 Recuse: 0

National Organic Standards Board
Crops Committee
Sunset 2012 Proposed Recommendations
Mulches and Compost Feedstocks

March 3, 2011

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

(b) As herbicides, weed barriers, as applicable
(2) mulches
(i) Newspaper or other recycled paper, without glossy or colored inks

Committee summary

Although there are many alternatives to the use of newspapers as mulch, they are relatively cheap, biodegradable, and effective and the known adverse effects are minimal. When the requested technical report is received, the Crops Committee may reconsider its decision.

Committee Recommendation

Relist newspaper or other recycled paper, without glossy or colored inks on § 205.601(b).

Committee Vote

Motion by: Barry Flamm Second: Tina Ellor
Yes: 6 No: 0 Absent: 1 Abstain: 0 Recuse: 0

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

(b) As herbicides, weed barriers, as applicable
(2) Mulches
(ii) Plastic mulch and covers (petroleum based other than PVC)

Committee Summary

OFPA Section 6508 prohibits the “use plastics mulches, unless such mulches are removed at the end of each growing or harvest season ..” The Crops Committee requested a technical report for this use and thus new information might result in the revision of this recommendation. Biodegradable plastic is apparently available and might be an alternative for some applications. Because of the long use as a substitute for herbicides and other benefits to

growers and the belief that adverse effects are minimal, the CC believes continued use is acceptable.

Committee Recommendation

Relist plastic mulches and covers on § 205.601(b)(2)(ii).

Committee Vote

Motion by: Barry Flamm Second: John Foster
Yes: 6 No: 0 Absent: 1 Abstain: 0 Recuse: 0

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

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

Committee Summary

The record lacks technical information on the listing and relisting of this use. CC has not received the requested TR and subsequent to reviewing it, may wish to revise this recommendation. It appears from committee discussion newspaper feedstock use is incidental mixture with other compostable material such as livestock bedding. The Crops Committee has no basis for not allowing the continued use at this time.

Committee Recommendation

Relist on § 205.601(c)

Committee Vote

Motion by: Barry Flamm Second: Tina Ellor
Yes: 6 No: 0 Absent: 1 Abstain: 0 Recuse: 0

National Organic Standards Board
Crops Committee
2012 Sunset Recommendation
Pheromones

March 4, 2011

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

(f) As insect management. Pheromones.

Summary

Pheromones were approved for listing in 1995. In 2002, the board voted to allow List 3 inerts used in passive pheromone dispensers, through approval of the following annotation:

> Pheromones -includes only EPA-exempt pheromone products, EPA-registered pheromone products with no additional synthetic toxicants unless listed in this section, and any inert ingredients used in such pheromone formulations that are not on EPA List 1 (Inerts of toxicological concern) or EPA List 2 (Potentially toxic inerts), *Provided* the pheromone products are limited to passive dispensers. Pheromone products containing only pheromones, active ingredients listed in this section, and List 4 inerts may be applied without restriction.

The Crops Committee requested, but did not receive, a Technical Review (TR) for pheromones at the time the committee formulated its recommendation. Although the committee is concerned about making a decision about a diverse class of materials without adequate technical information, especially knowing that there have been problems with pheromone product ingredients —such as those used for the light brown apple moth— the committee wants to preserve the use of these products, which have become essential to organic fruit growing. There was discomfort around the issue of List 3 inerts being allowed ingredients in a permitted substance, but the committee trusts that the Inerts task force will be able to update and clarify the limitation on inerts in National List substances, and the board will be able to address this issue when inerts come up for review. When the committee receives the requested TR, it may reconsider this decision.

The Crops Committee does think it is necessary to clarify that it is approving pheromone products that are in passive dispensers, that have no added toxicants, and that have inerts approved by this board. Passive dispensers are those which emit pheromones by volatilization rather than by spray and produce a concentration of pheromones in a limited area.

Committee Recommendation

The Crops Committee recommends the continued listing of pheromones for insect management with the addition of an annotation that limits their use to passive dispensers, without added toxicants, and with only approved inert ingredients. The motion was to amend

the current listing of pheromones to read: “(f) As insect management. Pheromones, provided that they are in passive dispensers, without added toxicants, and with only approved inert ingredients.”

Committee Vote

Motion: Barry Flamm, Second: Nick Maravell
Yes: 5 No: 0 Absent: 2 Abstain: 0 Recuse: 0

National Organic Standards Board
Crops Committee
2012 Sunset Proposed Recommendation
Sulfur Dioxide

March 2, 2010

List: §205.601 Synthetic substances allowed for use in organic crop production.
(g) As rodenticides
(1) Sulfur dioxide—underground rodent control only (smoke bombs)

Committee Summary

The Crops Committee requested a new TR for sulfur dioxide used in this application specifically—as rodent control in smoke bomb. The new TR pointed out "The U.S. EPA has not registered sulfur dioxide for use as a rodenticide. However, U.S. EPA has registered rodent control smoke bombs with the active ingredients sulfur, charcoal carbon, and sodium nitrate or potassium nitrate (saltpeter)." (TR Sulfur Dioxide January 14, 2011 lines 139-141). The TR also states "Ignition of the smoke bomb generates a mixture of gases that may include sulfur dioxide" (ibid, line 148). Sulfur dioxide does not appear to exist as the only active ingredient in commercially produced smoke bombs used as rodenticides. The crops committee concluded that it is possible that the wrong active ingredient for smoke bombs used as rodenticides was listed historically and is recommending that sulfur dioxide for use in smoke bombs for underground control of rodents be taken off the list.

Committee Recommendations

Motion was to relist sulfur dioxide—underground rodent control only (smoke bombs) on § 205.601(g)(1)

Committee Vote

Motion: To relist sulfur dioxide—underground rodent control only (smoke bombs) on § 205.601(g)(1)
Motion: Tina Ellor Second: Barry Flamm
Yes: 0 No: 6 Absent: 1 Abstain: 0 Recuse: 0

National Organic Standards Board
Crops Committee
2012 Sunset Proposed Recommendation
Vitamin D_3

March 2, 2011

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

(g) As rodenticides
(2) Vitamin D_3

Committee Summary

The Crops Committee requested a new Technical Report for this material for this round of sunset. Following a discussion of the new TR and concerns about whether current regulation sufficiently prevents inadvertent harm to non-target species, the Crops Committee is recommending that Vitamin D_3 remain on the National List §205.601 as a rodenticide as there are very few alternative materials allowed for this use in organic crop production.

Committee Recommendations

The Crops Committee recommends the continued listing Vitamin D_3 on the National List §205.601 (g) As rodenticides.

Committee Vote

Motion: to relist vitamin D_3 on § 205.601.
Motion: Tina Ellor Second: Colehour Bondera
Yes: 5 No: 0 Absent: 2 Abstain: 0 Recuse: 0

National Organic Standards Board
Crops Committee
2012 Sunset Recommendation
Streptomycin

March 3, 2011

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

(i) As plant disease control.

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

Summary

The Crops Committee requested, but did not receive, prior to adopting its recommendation on streptomycin, an updated Technical Review (TR), noting deficiencies in the previous reviews. The committee has a 2006 TR and a1995 Technical Advisory Panel (TAP) for streptomycin. The committee proceeded based on its own research, pending the receipt of the new TR, which will be reviewed when it is received.

The antibiotic streptomycin was first approved in November 1995. Streptomycin and another antibiotic, tetracycline, were each listed with a split vote. The issue of engendering antibiotic resistance in human pathogens and in workers was raised in the 1995 TAP review. The annotation that permitted use for “fire blight control in apples and pears only” was adopted. Streptomycin antibiotics were to be reviewed again in two years, and there was to be a task force to further explore antibiotic use in fruit production.

The 1998 proposed rule would have allowed “antibiotics as pesticides.” There was public opposition to the use of antibiotics as pesticides. When the USDA published the next draft rule in early 2000, it removed the NOSB recommendations allowing streptomycin and tetracycline in order to be consistent with the prohibition of antibiotics in livestock. The two antibiotics were reinstated in the December 2000 final rule in response to comments from growers.

Thus, from the very beginning, there has been controversy over allowing these chemicals to be used in organic agriculture. The board discussion regarding the 2006 sunset included concerns about:

- Promotion of resistance in human pathogens
- Natural substitutes
- Inconsistency with the prohibition of antibiotics in livestock
- Inconsistency with organic principles
- Disagreement with the prophylactic use of antibiotics
- The Centers for Disease Control and Prevention (CDC) opposition to the use of streptomycin and tetracycline in crop production
- Failing to give an incentive for alternatives
- Reaction against organic fruit by consumers
- Possibility that antibiotics might be taken up by fruit trees

- Need for more research
- Restrictions on sales of fruit in Europe
- Disruption of the organic system.

And on the other hand,

- Lack of data showing impact on resistance in human pathogens
- Dependency of growers on the materials

Ultimately, after expressing concern and the wish that someone might petition to remove them sooner than the next sunset, the two antibiotics were renewed with a vote of 7 yes, 4 no, 1 abstention, and 2 absent.

Now, the two antibiotics have come to board again—streptomycin as a sunset 2012 material and tetracycline as a petition to remove the annotation (the 2012 expiration date). Although the committee does not have an updated TR on streptomycin, it has found that the case against streptomycin has grown stronger and that removal from 601 should be delayed no longer.

The Crops Committee was presented with evidence that streptomycin can contribute to antibiotic resistance in human pathogens when used as pesticides on plants. At the same time, additional products are available for use against fire blight. Serenade Max, Bloomtime Biological FD, BlightBan C9-1 and Blightban A506 are relatively new biological controls. Surround is a kaolin clay product that has had some success in controlling fire blight.

However, most importantly, the majority of the committee believes that the first line of defense is the choice of resistant varieties and rootstocks, a concept that the committee majority believes is a critical organic principle, essential to disease or pest prevention in organic systems. Despite this, the pattern of growth in organic apple and pear varieties in certain areas of the country has been skewed toward those varieties most susceptible to fire blight. In 2010, the leading organic apple varieties grown in Washington state were Fuji, Gala, and Granny Smith and accounted for approximately 54% of organic apple acreage —all highly susceptible to fire blight. (Some other widely-planted varieties are also highly susceptible.) The leading varieties in organic pear production were Bartlett, D'Anjou, and Bosc —80% of organic pear acreage— again among the most susceptible to fire blight. On the other hand, there are numerous apple and pear varieties that are not susceptible to fire blight.

Given the public health threat associated with antibiotic resistant, the committee majority believes that organic production should not contribute in a small or large way to antibiotic resistance. The options for new antibiotics with efficacy are eluding us as resistance continues to increase.

Similarly, the committee has been told that fire blight resistance to streptomycin in some apple production is found widely. Therefore, streptomycin's efficacy and, as a result, essentiality cannot be established.

Committee Recommendation

The majority of the Crops Committee recommends against the continued listing of streptomycin, for fire blight control in apples and pears only. The motion was to continue the listing of streptomycin, for fire blight control in apples and pears only.

Committee Vote

Motion: To relist streptomycin on § 205.601, for fire blight control in apples and pears only.
Motion: Jay Feldman Second: Tina Ellor
Yes: 0 No: 5 Absent: 2 Abstain: 0 Recuse: 0

National Organic Standards Board
Crops Committee
2012 Sunset Proposed Recommendation
Lignin sulfonate

February 15, 2011

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

(j) As plant or soil amendments.
(4)Lignin sulfonate—chelating agent, dust suppressant, flotation agent.

(l) As floating agents in postharvest handling.
(1) Lignin sulfonate.

Committee Summary

There were concerns during the last round of sunset for this material about its fate in waste water when it is used as a flotation agent. The Crops Committee addressed this concern with an annotation to relist lignin sulfonate on 205.601 (l) with the amended annotation: As floating agents in postharvest handling, subject to wastewater disposal documentation in the Organic Systems Plan to prevent adverse impact to aquatic life. It was also noted that there is a duplicate listing as a flotation agent in (j) As plant or soil amendments, so the Crops Committee is recommending relisting lignin sulfonate as plant or soil amendments with the annotation change: chelating agent, dust suppressant.

Committee Recommendation

1. Relist lignin sulfonate on § 205.601 (l) with the amended annotation: As floating agents in postharvest handling, subject to wastewater disposal documentation in the Organic Systems Plan to prevent adverse impact to aquatic life.

2. Relist lignin sulfonate on § 205.601(j)(4) with the amended annotation: chelating agent, dust suppressant.

Committee Vote

1. Motion: Tina Ellor Second: John Foster
   Yes: 5 No: 0 Absent: 2 Abstain: 0 Recuse: 0

2. Motion: Tina Ellor Second: Nick Maravell
   Yes: 5 No: 0 Absent: 2 Abstain: 0 Recuse: 0

National Organic Standards Board
Crops Committee
2012 Sunset Proposed Recommendation
Magnesium Sulfate

March 2, 2011

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

(j) As plant or soil amendments.
(5) Magnesium sulfate—allowed with a documented soil deficiency.

Committee Summary

The Crops Committee requested and received a new Technical Report on this material. The CC did not find the TR to be sufficient and has sent it back with questions addressing the differences in natural and synthetic magnesium sulfate, availability of both, and both form's functionality as soil amendments and foliar sprays. The majority of the CC felt that having the synthetic form of magnesium sulfate on the National list was inconsistent with organic crop production. The minority voted to keep this material on the list pending further technical review because of its long use and historic acceptance for use in organic crop production.

Committee Recommendations

The Crops Committee recommends against the continued listing of Magnesium sulfate—allowed with a documented soil deficiency as a soil amendment. The motion was to continue the listing of Magnesium sulfate—allowed with a documented soil deficiency as a plant or soil amendment.

Committee Vote

Motion: To relist magnesium sulfate on § 205.601
Motion by: Tina Ellor Second: Nick Maravell
Yes: 2 No: 3 Absent: 2 Abstain: 0 Recuse: 0

National Organic Standards Board
Crops Committee
2012 Sunset Proposed Recommendation
Ethylene Gas

March 2, 2011

List: §205.601 Synthetic substances allowed for use in organic crop production.
(k) As plant growth regulators. Ethylene gas—for regulation of pineapple flowering.

Committee Summary

The Crops Committee (CC) requested and received a new Supplemental Information Report on the use of Ethylene gas as a plant growth regulator, for the induction of pineapple flowering. Reference was made to the current scales of production in the US (which are in Hawaii and California) and do not amount to a large ratio of global production. The CC found the report to be sufficient, while seeking information regarding large-scale pineapple operations outside of US borders (specific reference was made to Eco-LOGICA in Costa Rica for more information). The scale of operation and the impacts on others was discussed in order to ensure that varied sizes operations were referenced. Alternatives were mentioned, including African cases with individuals carrying applicators (ensuring that small-scale operators could use products thus applied) as well as regarding research in Taiwan which showed that cold water applied three to four times at the correct time and right time intervals (24 hours) yielded production results similar to both Ethylene gas and calcium carbide options, though slightly (3-4 weeks) delayed. In addition to operation size and location concerns, the CC discussed that the subject of un-natural pineapple flower induction, facilitated using synthetic-sourced (petroleum) Ethylene gas, is inconsistent in multiple ways with overall organic standards.

Committee Recommendations

The motion was to continue the listing of ethylene gas as a plant growth regulator, for the induction of pineapple flowering. The CC recommends against the continued listing of Ethylene gas.

Committee Vote

Motion: To relist Ethylene gas—for regulation of pineapple flowering, on § 205.601(k)
Motion: Colehour Bondera Second: Tina Ellor
Yes: 0 No: 5 Absent: 2 Abstain: 0 Recuse: 0

National Organic Standards Board
Crops Committee
2012 Sunset Recommendation
Sodium Silicate

March 3, 2011

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

(l) As floating agents in postharvest handling.
(2) Sodium silicate—for tree fruit and fiber processing.

Committee Summary

The Crops Committee requested but did not receive a Technical Report (TR) on this material prior to its consideration and recommendation on sodium silicate. Without the benefit of the TR and given limited information on the use and essentiality of sodium silicate, as well as the availability of another 601-allowed floating agent for the same purpose, the committee voted unanimously against the continued listing of this chemical, pending receipt of the TR and further technical review.

Committee Recommendations

The Crops Committee recommends against the continued listing of sodium silicate —allowed for tree fruit and fiber processing as a floating agent and postharvest handling. The motion was to continue the listing of sodium silicate —allowed for tree fruit and fiber processing as a floating agent and postharvest handling.

Committee Vote

Motion: To relist sodium silicate—for tree fruit and fiber processing, on § 205.601.
Motion: Jay Feldman Second: Colehour Bondera
Yes: 0 No: 5 Absent: 2 Abstain: 0 Recuse: 0

National Organic Standards Board
Crops Committee
Sunset 2012 Proposed Recommendation
Sodium Nitrate

March 7, 2011

Current listing

§ 205.602 (g): Sodium nitrate—unless use is restricted to no more than 20% of the crop's total nitrogen requirement.

Committee Summary

Sodium nitrate was originally reviewed by Johnson, Spencer, Sachs, and Jeffrey, in 1994/5. The Crops Committee (CC) at that time determined it to be non-synthetic. The NOSB then determined that this material is unacceptable for use in organic crop production; voting it down 4-9-1 on April 27, 2005. Subsequent NOSB vote on November 1, 1995 prohibited sodium nitrate with exception as specified in annotation--Prohibited unless use is restricted to no more than 20% of crop's total nitrogen requirement. This percentage was a common restriction found in CCOF and other private party standards prior to the implementation of the NOP. In the previous sunset vote on November 17, 2005, the CC voted 5-0 to relist and the NOSB voted 14-0 to relist.

Production needs have been reportedly variously for some crops needing nitrogen for growth in cold or cool conditions, typically ascribed as necessary for leafy greens or cruciferous crops early in the season. However, use has in fact not been limited to these crops and is often found used in onions, carrots, potatoes, and other crops, but is, generally speaking, used in cooler conditions.

Human health concerns have generally been considered as minimal. Environmental/Ecological concerns focus on it being a mined, non-renewable resource and that it contributes sodium to soil. Being a foliar feed, it also does not support soil fertility through other tactics, such as additions of compost or the use of cover crops. Disposal concerns have generally been considered as minimal.

The Crops Committee discussed the Action Memorandum from the National Organic Program regarding sodium nitrate of September 21, 2010 at their regularly scheduled weekly crops committee meeting on September 27, 2010. The discussion was full and extensive, noting that the crops committee had already requested a TR for this material in the context of Sunset 2012. At that time, annotation change within sunset review was not an accepted policy of the

NOSB. Additionally, the Committee wanted to use information the TR would presumably provide and full input from the organic community regarding this material and its use.

The Committee noted that there were no existing NOSB policies or precedents for changing annotations or prohibiting a material without a petition from the organic community and that equivalency agreements or ease of trade were not included among the NOSB's review criteria. The Committee felt that all work should be done within our established process with full input from the public considered and did not feel that it would be appropriate to treat the memo as a petition without an established protocol for doing so. Since sodium nitrate was already being considered as part of the 2012 sunset process, the Committee decided to deal with this issue within that context. The Committee agreed that it is appropriate to consider during our regular sunset deliberations the principles that underlie the impediments to equivalency and did so. By virtue of the summary above and the discussion below, it is the Committee's intention for this sunset review to also serve as the response to the request from the NOP for review of sodium nitrate through its Action Memorandum of September 21, 2010.

Based on the controversial nature of sodium nitrate and the lack of international harmonization of standards regarding this material, the Crops Committee deferred the sunset deliberations and vote pending more up to date technical information and allowance for additional public comment. In reviewing this material, the Committee considered information from technical sources, past committee and board recommendations, public and comment, transcripts of past NOSB board meetings, and prior Committee and Board deliberations.

Sodium nitrate is highly soluble, generally having an analysis of around 16-0-0, and it tends to be used in support of crop production is cool conditions and in crops needing a quick boost of nitrogen, whether that be leafy greens or to promote leaf growth that will later support fruit, stem, tuber or root growth. It is used alone and also compounded in commercial fertilizer product formulations. The 2002 TAP indicates that it leaches into groundwater, is regulated as a contaminant, and has contributed to the decreased earthworm populations.

Use and dependence on sodium nitrate also can tend to producers to put off the need for strong soil-building practices, consistent with §205.203, since it behaves similarly to conventional synthetic nitrogen fertilizers. Organic producers that want to use highly soluble products do have alternatives in the form of agricultural byproducts and food processing derivatives, which are in far greater supply than when the material was first placed on the National List and are in forms more comparable and effective to use than in years past. The Committee noted that while producers ***may*** use of mined substances as per §205.203(d)(3), producers ***must*** manage crop nutrients and soil fertility through rotations, cover crops, and the application of plant and animal materials, as per §205.203(b) and the Committee wished to remind the NOSB as a whole and organic community of that distinction.

In general, there appears to be a common perception that the material is used primarily in the western US and not in the eastern US; however there are some notable and documentable

exceptions in both cases. Public comment has been mixed and more is anticipated at the April 2011 NOSB meeting, but there was consensus among the Committee that there is significant industry support to remove the existing annotation and the Committee concurred with those rationales.

Current listing:

§ 205.602 (g): Sodium nitrate—unless use is restricted to no more than 20% of the crop's total nitrogen requirement.

With no action, the material would sunset from § 205.602, which would result in unrestricted use. Removal of the annotation would result in prohibition of the material. Relisting as is would result in maintaining the status quo.

Two proposed recommendations are provided, consistent with other sunset recommendations, in the event that there is an unforeseen impediment to implementing the first recommendation, there is a default recommendation to rely on.

Committee Recommendation

Relist sodium nitrate § 205.602(g) without annotation.

Committee Vote

Motion: Jeff Moyer Second: Tina Ellor
Yes: 7 No: 0 Abstain: 0 Absent: 0

Committee Recommendation

Relist sodium nitrate § 205.602(g) with annotation: “—unless use is restricted to no more than 20% of the crop's total nitrogen requirement.”

Committee Vote

Motion: Barry Flamm Second: Tina Ellor
Yes: 7 No: 0 Abstain: 0 Absent: 0

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

March 9, 2011

Introduction

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

Background

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

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

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

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

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

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

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

Relevant areas in the Rule

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

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

Discussion

The Crops Committee determined that the status of Corn Steep Liquor (CSL) should remain non-synthetic. Last fall, the Crops Committee voted to classify CSL as synthetic based primarily on findings in the Technical Review (TR) (29-30), which states that, "The major objectives for corn steeping are to induce chemical and physical changes in the kernel by leaching the soluble components from the corn. " It goes on to say that "sulfur dioxide is added at rates of 0.1 to 0.2 percent and is used to cleave disulfide linkages, resulting in the degradation of the corn protein that encapsulates the starch granules. " (TR 99-102) The cleavage process breaks chemical bonds, thus releasing amino acids from the protein matrix into the CSL liquid The committee was also concerned that the term "corn steep liquor" may be applied to products of different processes, and that some of these products may have unknown characteristics. This recommendation was forwarded to the USDA NOP and posted

for public comment at the Fall 2010 NOSB meeting; however, the CC at that time also withdrew that recommendation from consideration by the full Board immediately prior to the Fall 2010 meeting. Regardless, the Board received 8 public comments in writing and 10 comments in person for and at the Fall 2010 meeting. While all the public comments were given full attention and consideration one commenter, Dragan Macura from Agro-Thrive, gave an excellent presentation to the board on the process of making corn steep liquor via the traditional countercurrent wet milling process. Throughout the detailed discussion it became clear that the sulfur dioxide was added at the end of the process to stop the fermentation process (a biological process) and prevent putrefaction.

Since the Fall 2010 NOSB meeting and a full board discussion of the information and the input from the general public, the CC has voted on January 24, 2011 to classify CSL as non-synthetic when created as a food processing waste from the traditional countercurrent corn wet milling process, based on a through review of all the information, documents, and public comments presented to the committee. The majority of the CC determined that the sulfur dioxide's utility in this process is in holding back a biological process (fermentation) and to prevent putrefaction and does not change the identity of CSL. The consensus of the majority is that this material when created in the manner described should continue to be considered nonsynthetic and appropriate for use in organic crop production. The majority considered that agricultural by products, food waste and products from food waste processing should not be considered as a synthetic ingredient for the purposes of organic crop production or the making of compost.

Corn starch has previously been determined to be nonsynthetic and agricultural by NOSB, and is made using the exact same steeping process as CSL. It is common usage in the organic food system as are other derivatives of this process. In the 1995 TAP Review for native cornstarch, reviewer Richard Theuer stated that "sulfur dioxide is used as a 'temporary' preservative to avoid purification of soaked corn. Later, fermentation inhibits putrefactive organisms." Dr. Theuer's recommendation was that cornstarch be classified as nonsynthetic. That same year, the NOSB determined that the SO2 used in corn starch production was a processing aid.

CSL has a long history of safe use as an added source of nutrition in animal feed, in fermentation processes, and in antibiotic production. It is not a significant source of water or air pollution. Due to the fact that CSL is composed of proteins, amino acids, carbohydrates, organic acids (such as lactic acid), vitamins, minerals and water, no environmental contamination would be expected. These components are all readily utilized by animals and microorganisms. In fact, CSL is a nutrient rich product that has been safely used as a component in livestock feed, fertilizers, and soil conditioners for many years. CSL and other nonsynthetic agricultural by products have historically provided and continue to provide a valuable source of nutrients for both soil microbial communities and organic crops. Historically, synthetic processing aids used in food have not been determined to render agricultural products synthetic; precedents are numerous and well established, with the end result providing organic producers with much needed agricultural by-products for use in composting and as soil amendments, and fertilizers.

Furthermore, the proposal that CSL should be considered to be non-synthetic is attributed to the fact that the SO2 action occurs in the endosperm protein matrix of the corn kernel, not in the steep water. There is compelling evidence that the proteins that the SO2 may alter are insoluble, thus are not a part of the CSL. General analysis of corn steep liquor reports the SO2 in CSL from 0.0009 – 0.015 (Liggett and Koffler, 1948). For use in organic crop production, the CSL is typically blended with other approved materials or used as a compost feedstock, which would further reduce the already insignificant levels of SO2 to be non-detectable.

The action of the SO2 in the countercurrent (traditional) corn wet milling process does not render CSL synthetic; the SO2 provides a buffering action to allow lactic acid fermentation to dominate over putrefaction. There is no evidence indicating that that the identity—that which makes the subject in question unique in its behavior, character, or function—of corn steep liquor as used is any different with or without SO2 as a processing aid. The behavior, character and function of the two are indistinguishable and on that basis alone, CSL remains non-synthetic.

Recommendation

The Crops Committee recommends that Corn Steep Liquor produced via the traditional countercurrent corn wet milling process be considered as non-synthetic and allowed for use in organic crop production.

Committee Vote

Motion: Consider CSL to be non-synthetic when produced via the traditional countercurrent corn wet milling process only.

Motion: Jeff Moyer Second: Tina Ellor
Yes: 4 No: 3 Abstain: 0 Absent: 0

Minority Opinion

The issue we are considering, in determining whether CSL is synthetic or non-synthetic, is a foundational issue in the determination of allowable inputs in organic production. The determination itself of whether an input is synthetic does not always determine whether that input is allowable in organic. It simply ensures that the NOSB carries out its responsibility to review and evaluate whether the use of that synthetic material meets the law's standards of sustainability. Organic integrity is built on the principle of objective review and transparency to ensure that the organic consumers' expectations are being met and that there is a level playing field for all those engaged in organic production.

The minority's position that CSL must be defined as a synthetic product is actually very straightforward and follows the policies and history of longstanding positions of the NOSB. Simply put, the process of making CSL --the wet milling countercurrent process-- is different than the natural practices that are defined in our standards, expressly because the process requires adding a synthetic chemical to an otherwise natural steeping/lactic acid fermentation process to effect a chemical change, necessary for the end product to be created. So, even though this process involves corn and a steeping process, the end result would not get that product to where its manufacturer wants without the introduction of a synthetic chemical that breaks chemical bonds and manipulates corn to turn it into something else with distinct functionality. And USDA researchers at the Agricultural Research Service (who do not have a financial interest in this discussion) have confirmed to the Crops Committee that CSL could not be created naturally with biological activity alone or as is allowed in what we have until now understood to be the nonchemical processes, as stated in the organic Rule: "cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, extracting, slaughtering, cutting, fermenting, distilling, eviscerating, preserving, freezing, chilling, or otherwise manufacturing and includes the packaging, canning, jarring, or otherwise enclosing food in a container."

The question is not whether CSL is a good product.

The question before us is whether CSL is synthetic since it is created through chemical change which requires the introduction of a synthetic chemical ingredient. We have been told that CSL is composed of proteins, amino acids, carbohydrates, organic acids (such as lactic acid), vitamins, minerals and water. All this is true. We are told that these components are all readily utilized by animals and microorganisms. And, we're told that CSL is a nutrient rich product that has been safely used as a component in livestock feed, fertilizers, and soil conditioners for many years.

The minority does not dispute this. However, all these valuable assets do not make CSL nonsynthetic. The minority believes that this is really all you need to know: a synthetic chemical introduced into a mixture with an agricultural material forces a change in the chemistry of that agricultural material in a way that would not occur through natural means. You don't really need to go further than that. However, we can shift to the underlying policy of the NOSB that establishes CSL as a synthetic product and all future products that we should review to ensure that the standards of the statute and National List are met. What follows are the policies as they apply to CSL.

We come to the minority opinion by following the NOSB's process

The minority opinion is based on the policies of the NOSB and the standards that have been developed over time. Here is our thinking, as it relates to the policies and definitions of the type of chemical change (brought on by the introduction of a chemical substance, or not occurring as a result of some natural process).

The classification of materials recommendation adopted by the board in November 2009 established three guiding principles for determining whether a substance is synthetic or non-synthetic:

- The classification of a material is determined by both the source of the inputs and the process used to make the material.
- The same material can be agricultural, non-synthetic or synthetic depending on source and process.
- If a material is processed such that it is classified as synthetic then the material is classified as synthetic regardless of source. A material of this type would most correctly be referred to as an "agriculturally sourced material which has been processed in such a way as to classify the material synthetic." Materials that are manufactured in full compliance with the final rule are outside the scope of this principle; their status with regards to use in organic is not affected by this recommendation.

These guiding principles are central to the classification of corn steep liquor. We have a material whose source is nonsynthetic, however, the source is only the first issue of concern under current standards. The process adopted by the board requires us to look at the processing applied to the source material as well. In this case, corn is an agricultural material (nonsynthetic), and the standard requires an assessment of the wet milling process to which the corn is subjected to determine whether it should be classified as synthetic.

The NOSB's classification of materials recommendation also stated:

> It is our intent through this recommendation that a material would be classified as synthetic when:
>
> - The source of the material is not "from mineral, plant, or animal matter" (from the definition of nonsynthetic) and is not a "substance created by naturally occurring biological processes" (from the definition of synthetic) or;
> - The process used to manufacture the material is synthetic (per the definition of synthetic and clarifying definitions in our recommendation) or;
> - The material contains, at a significant level, a synthetic substance not on the National List of allowed synthetics. (p.5 of 13, Nov. 2009)

In April 2010, the board adopted an addendum to the classification of materials recommendation that sought to clarify the application of the guiding principles. It said, in part:

> It is our belief that chemical changes that occur when an agricultural material is processed by itself, or in combination with other agricultural materials, the resulting material should

continue to be classified as agricultural. Clearly chemical change happens in these cases, if looked at from a purely chemistry perspective, but from a consumer perspective these materials are agricultural. The committee differentiates between these cases and those when an agricultural material is processed with a non-agricultural material, whether synthetic or non-synthetic. In these latter cases, if chemical change occurs, the resulting material would be classified as synthetic. (p.1 of 19, April 2010)

OFPA defines synthetic:

> **Synthetic** is defined as "*a substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from a naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes*" (§2103 (21)).

And chemical change is defined,

> *Chemical Change* An occurrence whereby the identity of a substance is modified, such that the resulting substance possesses a different distinct identity (see related definition of "substance") *Processing, as defined in §205.2, of agricultural products using materials allowed on the applicable section of the National List (i.e., §205.601 for crops, §205.603 for livestock and §205.605 / §205.606 for handling), does not result in chemical change as it applies to classification of materials.* (April 2010, underlined rejected by NOP)

And substance,

> *Substance* An element, molecular species, or chemical compound that possesses a distinct identity (For example, a distinct identity may be demonstrated through the material having a separate Chemical Abstract Service (CAS) number (in some cases the same material may have multiple CAS numbers), Codex International Numbering System (INS) number, or FDA or other agency standard of identity). (p.10 of 19, April 2010)

All of this is background to the following questions:

1. Is corn steep liquor a different substance from corn, or anything contained in corn? (If yes, chemical change has occurred.)
2. Is breaking disulfide bonds of the corn protein matrix a necessary part of the countercurrent wet milling process that results in corn steep liquor as a by-product?
3. Does the sulfur dioxide (a synthetic substance) that is added to the wet milling process break the disulfide bonds in creating the by-product (CSL)?

If the answer to all these questions is "yes," the classification of materials policy defines CSL as synthetic.

And, to follow our policy through to its conclusion, regardless of any of the above questions, the policy requires the following assessment:

4. As a result of added sulfur dioxide to the manufacturing process, are there significant residues of sulfur dioxide in corn steep liquor?

If the answer is “yes,” then CSL is synthetic. If it were the case that no chemical change to the source material had occurred as a result of the use of sulfur dioxide, yet if the process of producing CSL results in significant (Nov. 2009) residues of sulfur dioxide, then the policy requires a determination that the CSL is synthetic.

National Organic Standards Board
Livestock Committee
Proposed Recommendation
Animal Welfare

March 1, 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—the November 2009 NOSB Animal Welfare Recommendation. The combination of the 2009 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 addition is 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, 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 **§205.237 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

Terms defined. The Livestock Committee has proposed a number of additions to **§ 205.2: Terms defined**. Most of these are found in **§ 205.238 (a) (5) Livestock Health Care Practice Standard** and include various physical alterations, outdoor access, soil, and willful acts of abuse. Since they cause unnecessary pain and distress, often resulting in chronic pain and frustration for the animal, most physical alterations are not allowed. The outdoor access definition seeks to provide clarification for farmers and certifiers. It is our intention that livestock have contact with the soil and exposure to the sky overhead. Therefore, structures with floors and solid roofs overhead, such as enclosures typically described as “porches”, would not be included in outdoor access calculations. To avoid mistreatment on the farm, during transport, or at the slaughter plant, specific prohibited practices are described within the willful acts of abuse definition.

Indoor stocking density. The stocking density table lists livestock by species and weight. All livestock must be provided with bedding to maintain comfort and cleanliness 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. All animals must be provided with a clean, dry place to lie down. 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 is required, diet or management adjustments will be necessary.

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 frostbite.

Market considerations. Increasingly, consumers are demanding that livestock be treated humanely and 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, handling, transit, and slaughter. 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 be the gold standard, indicating the most nutritious food produced in the safest and most humane manner.

Outcome-based standards. At the fall 2011 NOSB meeting, the Livestock Committee intends to present basic outcome-based scorecards and guidance documents for each species to address hygiene, locomotion, body condition, lesions and injury. The Committee will work 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 humane animal care and to provide inspectors with assessment tools and the means to consistently apply them.

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.

Poultry. Poultry houses and outdoor areas must be managed in a manner that allows birds to perform natural behaviors which minimize stress and aggressive acts. A minimum of two square feet of outdoor space is required to protect the soil and to minimize parasite loads via paddock rotation. It is the intent of the livestock committee that outdoor areas provide birds with access to the soil. Porches or other areas with floors and solid roofs would count toward indoor space. Poultry mortality lessens when perches are provided because they encourage natural behaviors, strengthen bones via exercise, allow submissive birds to escape and reduce aggression. Perches allow for maximum use of vertical space within the house. 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.

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 two inside toes.

Dubbing. The removal of combs and wattles.

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

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.

Access to the outdoors. See Outdoor access.

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

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

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.

§ 205.238 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:

(6) Physical alterations, absolutely necessary to improve the health, welfare or hygiene of animals; identify animals; or provide increased safety to farm personnel. Physical alterations must be performed at the youngest possible age by competent 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 <u>prohibited</u>:

(i) Beak removal, castration, dubbing and detoeing of birds.
(ii) Tail docking of pigs and cattle, except when necessary for treatment of injury.
(iii) Wattling cattle .
(iv) Face branding cattle.
(v) Tail docking of sheep shorter than the caudal fold.
(vi) Mulesing of sheep.

§ 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). If animals are temporarily denied access to the outdoors, the indoor space provided shall meet the minimum indoor space requirements of the chart at the end of this document. Space is calculated by floor space on the inside of the animal's living space. 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 simultaneously without crowding and without competition for food. Continuous total confinement of any animal indoors, in yards, on feeding pads, and feedlots is prohibited. If yards, feeding pads, and feedlots are used, the outdoor space provided shall meet the minimum outdoor space requirements of the chart at the end of this section. All areas contributing to outdoor access must allow contact with the soil during the grazing season.

(2) For all ruminants, management on pasture and daily grazing throughout the grazing season(s) to meet the requirements of § 205.237, except as provided for in paragraphs (b), (c), and (d) of this section.

(3) Appropriate clean, dry bedding, sufficient to keep animals reasonably clean, comfortable and free from lesions. When roughages are used as bedding, they shall have been organically produced in accordance with this part by an operation certified under this part, except as provided in § 205.236(a)(2)(i), and, if applicable, organically handled by certified organic operations.

(6) Calves may be housed in individual pens under the following conditions:

(i) Until weaning, providing that they have enough room to turn around, lie down, stretch out when 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.

(ii) Calves shall be group-housed after weaning during the non-grazing season, and on pasture after six months of age during the grazing season.

(iii) Calves over six months of age shall have access to the outdoors at all times, except as allowed under § 205.239(c).

§ 205.239 Livestock living conditions. (Avian section)

(d) The operator of an organic poultry operation shall establish and maintain poultry living conditions that accommodate health and natural behavior:

(1) Access to:

(iv) the outdoors, at the rate of 2 square feet per bird. Enclosed spaces that have solid roofs overhead, such as those typically described as "porches", do not

meet the definition of outdoor access and cannot be included in the calculation of outdoor access. Pullets will be provided outdoor access at 12 weeks. Broilers will be provided outside access from 4 weeks of age providing they are fully feathered and weather permits. Once layers are accustomed to going outdoors, a brief confinement period to allow for nest box training is permitted. Direct access to outdoor areas will be provided when temperatures are above 50ºF.

(e) Suitable Flooring

(1) Mesh or slatted flooring under drinking areas to provide drainage;

(2) Houses with slatted floors must have 30% minimum of solid floor area available with sufficient litter available for dust baths;

(3) Litter must be provided and maintained in a dry manner.

(f) Birds must have sufficient exit areas, appropriately distributed around the building, to ensure that all birds have ready access to the outdoors. Exit areas must allow the passage of more than one bird at a time.

(g) Complete clean out of a poultry house is required if there have been adverse health issues with the previous flock; otherwise litter should be refurbished between flocks to maintain a sanitary environment.

(h) Space Allowance. Poultry housing must be sufficiently spacious to allow all birds to move freely, stretch their wings and engage in natural behaviors. Perching areas and nest boxes may not be used in the calculation of floor space. The following are required:

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

(2) Minimum total door opening length is 5 feet per 1,000 laying hens. Minimum door opening height is fourteen inches.

Mammalian Stocking Rate Charts

Livestock	**Indoor Bedded 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)		
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)		
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 Stocking Rate Charts (continued)

Livestock	**Indoor Bedded Space**	**Outdoor Runs and Pens**
Sheep and goats (pounds)	Square feet / animal	Square feet /animal
Adults up to 225	20.0	30.0
Adults over 225	25.0	40.0
Nursing lamb or kid	4.0	20.0
Weaned kid or lamb	10.0	30.0
Swine		
Sow and piglets	48.0	40.0
Sows	30.0	30.0
Boars	64.0	85.0
Growing pigs (pounds)		
Up to 24	1.0	0.5
24—47	2.0	1.0
47—109	3.0	1.5
109—157	4.0	2.0
157—225	5.0	2.5
225—255	6.0	3.0
Rabbits		
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

Avian Stocking Rate Charts

Livestock	**Indoor Bedded Space**	**Outdoor Runs and Pens**
Chickens	Square feet / animal	Square feet /animal
Laying hens and breeders	*With perch space for 20% of birds:* 1.5 *With 6 inches perch space per bird:* 1.2	2.0
Pullets	*With 3 inches perch space per bird:* 1.0	1.0
Broilers	1.0	1.0
Other poultry		
Turkeys and Geese—breeding, laying, or meat birds (pounds)	1.0 per 7.5 lbs.	1.0 per 7.5 lbs.
Ducks-meat	1.0	3.0
Ducks-laying hen	2.5	6.0
Ducks—breeder	1.5	6.0
Mobile poultry units	**Square feet per bird in mobile unit**	**Maximum number of birds per acre**
Laying hens and breeders	1.5	800
Broilers	1.0	1,000
Turkeys	1.0 per 7.5 pounds	540
Geese	1.0 per 7.5 pounds	540
Reserved for additional species		

Committee Vote

Motion: Approve the animal welfare proposal with discussed changes.
Motion by: CB Second: CW
Yes: 5 No: 0 Absent: 0 Abstain: 0 Recuse: 0

National Organic Standards Board
Livestock Committee
2011 Proposal Combined with 2009 Recommendation
Animal Welfare

March 10, 2011

Please note that text enclosed by brackets ("[ ]") and in teal text indicates animal welfare language previously recommended by the NOSB in 2009. This language is being included in this document to illustrate the combined proposed language and to provide clarity to the organic community. However, the bracketed text is not being reconsidered by the NOSB.

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

§ 205.2 Terms defined.

[*Stock density.* The number of animals on a given unit of land at any one time. This is traditionally a short-term measurement. This is very different from stocking rate which is a long term measurement of the whole pasture.]

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

De-snooding. The removal of the turkey snood.

*Toe clipping***.** The removal of the two inside toes.

Dubbing. The removal of combs and wattles.

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

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.

Access to the outdoors. See Outdoor access.

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

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

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.

§ 205.238 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:

[(1) Selection of species and types of livestock with regard to suitability for site-specific conditions and resistance to prevalent diseases and parasites;

(2) Provision of a feed ration sufficient to meet nutritional requirements, including vitamins, minerals, protein and/or amino acids, fatty acids, energy sources, and fiber (ruminants), resulting in appropriate body condition;

(3) Establishment of appropriate housing, pasture conditions, and sanitation practices to minimize indoor crowding and the occurrence and spread of diseases and parasites;

(4) Provision of conditions which allow for exercise, freedom of movement, and reduction of stress appropriate to the species;

(5) All surgical procedures shall be undertaken in a manner that employs best management practices in order to minimizes pain, stress and suffering, with the use of anesthetics, analgesics and sedatives;]

(6) Physical alterations, absolutely necessary to improve the health, welfare or hygiene of animals; identify animals; or provide increased safety to farm personnel. Physical alterations must be performed at the youngest possible age by competent 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 <u>prohibited</u>:

(i) Beak removal, castration, dubbing and detoeing of birds.
(ii) Tail docking of pigs and cattle, except when necessary for treatment of injury.
(iii) Wattling cattle .
(iv) Face branding cattle.
(v) Tail docking of sheep shorter than the caudal fold.
(vi) Mulesing of sheep.

[(7)Administration of vaccines and other veterinary biologics.

(8) Monitoring of lameness and keeping records of the percent of the herd or flock suffering from lameness and the causes.

(b) When preventive practices and veterinary biologics are inadequate to prevent sickness, the provision of prompt treatment for animals with detectable disease, lesions, lameness, injury and other physical ailments shall be instituted.

(1) Phytotherapeutic (i.e. herbal or botanical substances), homeopathic or similar products are encouraged to be used in preference to chemical allopathic veterinary drugs, provided that their therapeutic effect, for the condition which the treatment is intended, is improving.

(2) If the use of phytotherapeutic, homeopathic or similar products are not promptly alleviating illness or injury, synthetic medications may be administered: Provided, That, such medications are allowed under §205.603.

(3) Organic livestock operations shall have a comprehensive plan to minimize internal parasite problems in livestock. The plan will include preventive measures such as pasture management, fecal monitoring, and emergency measures in the event of a parasite outbreak. Parasite control plans shall be approved by the certification body. Parasiticides allowed under §205.603 may be used on:

(i) Breeder stock, when used prior to the last third of gestation but not during lactation for progeny that are to be sold, labeled, or represented as organically produced; and
(ii) Dairy stock, when used a minimum of 90 days prior to the production of milk or milk products that are to be sold, labeled, or represented as organic.

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

(1) Sell, label, or represent as organic any animal or edible product derived from any animal treated with antibiotics, any substance that contains a synthetic substance not allowed under §205.603, or any substance that contains a nonsynthetic substance prohibited in §205.604. Milk from animals undergoing treatment with prohibited substances cannot be sold as organic or fed to organic livestock. Milk from animals undergoing treatment with substances having withholding time cannot be sold as organic or fed to organic livestock during the withholding time.

(2) Administer any animal drug in the absence of illness; with the exception of vaccinations and other veterinary biologics, and anesthetics, analgesics and sedatives used in surgical procedures;

(3) Administer hormones to for growth promotion or production;

(4) Administer synthetic parasiticides on a routine basis;

(5) Administer synthetic parasiticides to slaughter stock;

(6) Administer animal drugs in violation of the Federal Food, Drug, and Cosmetic Act; or

(7) Withhold medical treatment from a sick animal in an effort to preserve its organic status. All appropriate medications must be used to restore an animal to health when methods acceptable to organic production fail. Livestock treated with a prohibited substance must be clearly identified and shall not be sold, labeled, or represented as organically produced.

(8) Withhold individual treatment designed to minimize pain and suffering for injured, diseased or sick animals, which may include forms of euthanasia as recommended by the American Veterinary Medical Association.

(9) Neglect to identify and record treatment of sick and injured animals in animal health records.

(10) Practice forced molting or withdrawal of feed to induce molting.

(d) Organic livestock producers must provide their certifier with the following lists each year:

(1) All animals on the operation during the current year, including a separate list of all purchased animals

(2) All animals that have left the operation during the past year, and the reason for their departure

(3) All animals that have had a health issue, including hoof care, and the treatment(s) the animal received.]

§ 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). If animals are temporarily denied access to the outdoors, the indoor space provided shall meet the minimum indoor space requirements of the chart at the end of this document. Space is calculated by floor space on the inside of the animal's living space. 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 simultaneously without crowding and without

competition for food. Continuous total confinement of any animal indoors, in yards, on feeding pads, and feedlots is prohibited. If yards, feeding pads, and feedlots are used, the outdoor space provided shall meet the minimum outdoor space requirements of the chart at the end of this section. All areas contributing to outdoor access must allow contact with the soil during the grazing season.

(2) For all ruminants, management on pasture and daily grazing throughout the grazing season(s) to meet the requirements of § 205.237, except as provided for in paragraphs (b), (c), and (d) of this section.

(3) Appropriate clean, dry bedding, sufficient to keep animals reasonably clean, comfortable and free from lesions. When roughages are used as bedding, they shall have been organically produced in accordance with this part by an operation certified under this part, except as provided in § 205.236(a)(2)(i), and, if applicable, organically handled by certified organic operations.

[(4) Shelter designed to allow for:

(i) Natural maintenance, comfort behaviors, and opportunity to exercise;
(ii) Temperature level, ventilation, and air circulation suitable to the species; and
(iii) Reduction of potential for livestock injury.
(iv) At least one stall per animal in the facility at any given time
(v) The confinement of animals in cages is not permitted under any circumstance.

(5) Housing, pens, runs, equipment and utensils shall be properly cleaned and disinfected as needed with approved materials in accordance with § 205.603 and § 205.604 to prevent cross infection and build-up of disease-carrying organisms.]

(6) Calves may be housed in individual pens under the following conditions:

(i) Until weaning, providing that they have enough room to turn around, lie down, stretch out when 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.

(ii) Calves shall be group-housed after weaning during the non-grazing season, and on pasture after six months of age during the grazing season.

(iii) Calves over six months of age shall have access to the outdoors at all times, except as allowed under § 205.239(c).

[(7) Swine must be housed in groups, except:
(i) Sows may be housed individually at farrowing and during the suckling period;
(ii) Boars.

(8) Piglets shall not be kept on flat decks or in piglet cages.

(b) The producer of an organic livestock operation may provide temporary confinement for an animal for the following reasons. Temporary confinement may last no longer than necessary to safely perform the procedure or address the condition:

(1) Milking, shearing, breeding, hoof trimming, birthing, health care procedures and recuperation from illness;

(2) Dangerous weather;

(3) Conditions under which the health, safety, or wellbeing of the animal could be jeopardized;

(4) Risk to soil, water, or plants.

(5) During the non-grazing season or during times of temporary confinement:

(i), the stocking rates listed in the chart in this document shall be provided.

§ 205.239 Livestock living conditions. (Avian section)

(c) The operator of an organic poultry operation shall establish and maintain poultry living conditions that accommodate health and natural behavior:

(1) Access to:

[(i) Materials for dust bathing
(ii) Adequate floor space areas, and outdoor run areas to escape from predators and aggressive behavior
(iii) Perches must be provided for all laying hens at not less than 6” per hen. Perch area can include the alighting rail immediately in front of next boxes. Multi-tier operations are required to provide perch space for 55% of birds at one time.]
(iv) the outdoors, at the rate of 2 square feet per bird. Enclosed spaces that have solid roofs overhead, such as those typically described as “porches”, do not meet the definition of outdoor access and cannot be included in the calculation of outdoor access. Pullets will be provided outdoor access at 12 weeks. Broilers will be provided outside access from 4 weeks of age providing they are fully feathered and weather permits. Once layers are accustomed to going outdoors, a brief confinement period to allow for nest box training is permitted. Direct access to outdoor areas will be provided when temperatures are above 50ºF.

[(2) Access to the outdoors, shade, shelter, exercise areas, fresh air and direct sunlight suitable to the age of the poultry, climate and the environment.

(3) Ventilation must be adequate to prevent buildup of ammonia. Ammonia levels of 10 ppm are considered acceptable while 25 ppm is considered to be high.

(4) For layers and mature birds, artificial light may be used to prolong the day length up to 16 hours. Light intensity should be lowered gradually to encourage hens to move to perches or settle for the night. Natural light should be sufficient indoors on sunny days so that inspector can read/write when lights are turned off.

(5) Birds may not be confined to the house due to a “threat” of an outbreak of disease. There must be a documented occurrence of an outbreak in the region or relevant migratory pathway, or state or federal advisory in order to confine birds.

(6) Producers must maintain records documenting periods of confinement. Producers must identify in the OSP how they plan to protect birds from disease and predators.

(7) For pasture based systems birds must be provided with access to a variety of vegetation. Management of pasture areas must be in compliance with § 205.203 – § 205.206. Birds must be protected from natural predators.

(d) Suitable Flooring

(1) Mesh or slatted flooring under drinking areas to provide drainage;
(2) Houses with slatted floors must have 30% minimum of solid floor area available with sufficient litter available for dust baths;

(3) Litter must be provided and maintained in a dry manner.

(e) Birds must have sufficient exit areas, appropriately distributed around the building, to ensure that all birds have ready access to the outdoors. Exit areas must allow the passage of more than one bird at a time.

(f) Complete clean out of a poultry house is required if there have been adverse health issues with the previous flock; otherwise litter should be refurbished between flocks to maintain a sanitary environment.]

(g) Space Allowance. Poultry housing must be sufficiently spacious to allow all birds to move freely, stretch their wings and engage in natural behaviors. Perching areas and nest boxes may not be used in the calculation of floor space. The following are required:

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

(2) Minimum total door opening length is 5 feet per 1,000 laying hens. Minimum door opening height is fourteen inches.

[(h) Health Care – specific to avian species

(1) All requirements of the National Organic Program §205.238 Livestock health care practices must be met.

(2) Withdrawal of feed to induce molting is prohibited.

(i) Euthanasia

(1) Producers must have plan for prompt humane euthanasia for sick or injured birds.

(2)The following methods of euthanasia are permitted[1]:

(i) Hand held electrical or percussive stunning followed by neck cutting;
(ii) Cervical dislocation must involve stretching the neck to sever the spinal cord and cause extensive damage to the major blood vessels.
(iii) Carbon dioxide or a mixture of nitrogen and argon gases, delivered in an appropriate container at acceptable concentrations.
(iv) Decapitation

(j) The following methods of euthanasia are not permitted[2]:

(1) Suffocation
(2) Blow to the head by blunt instrument
(3) Equipment that crushes the neck including killing pliers or burdizzo clamps[3]

[1] Based on American Veterinary Medical Association guidelines.
[2] Animal Welfare Approved, 3.2
[3] Humane Farm Animal, H. 13.c

(k) Carcass Disposal

Carcass disposal, whether from daily mortality or emergency euthanasia, must be promptly addressed, both to reduce the incidence of disease transmission, and to avoid degradation of soil and water. Following a euthanasia procedure, birds must be carefully examined to ensure that they are dead. Producers must maintain carcass disposal records to include flock identification, type of euthanasia, where disposed of. Carcass disposal can be either on or off the farm, but must be in accordance with state and local laws. If disposed of on farm, process must not degrade soil and water quality. On farm composting of carcasses is permitted. Incineration of carcasses is permitted.

(l) 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.]

Mammalian Stocking Rate Charts

Livestock	**Indoor Bedded 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)		
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)		
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 Stocking Rate Charts (continued)

Livestock	**Indoor Bedded Space**	**Outdoor Runs and Pens**
Sheep and goats (pounds)	Square feet / animal	Square feet /animal
Adults up to 225	20.0	30.0
Adults over 225	25.0	40.0
Nursing lamb or kid	4.0	20.0
Weaned kid or lamb	10.0	30.0
Swine		
Sow and piglets	48.0	40.0
Sows	30.0	30.0
Boars	64.0	85.0
Growing pigs (pounds)		
Up to 24	1.0	0.5
24—47	2.0	1.0
47—109	3.0	1.5
109—157	4.0	2.0
157—225	5.0	2.5
225—255	6.0	3.0
Rabbits		
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

Avian Stocking Rate Charts

Livestock	**Indoor Bedded Space**	**Outdoor Runs and Pens**
Chickens	Square feet / animal	Square feet /animal
Laying hens and breeders	*With perch space for 20% of birds:* 1.5 *With 6 inches perch space per bird:* 1.2	2.0
Pullets	*With 3 inches perch space per bird:* 1.0	1.0
Broilers	1.0	1.0
Other poultry		
Turkeys and Geese—breeding, laying, or meat birds (pounds)	1.0 per 7.5 lbs.	1.0 per 7.5 lbs.
Ducks-meat	1.0	3.0
Ducks-laying hen	2.5	6.0
Ducks—breeder	1.5	6.0
Mobile poultry units	**Square feet per bird in mobile unit**	**Maximum number of birds per acre**
Laying hens and breeders	1.5	800
Broilers	1.0	1,000
Turkeys	1.0 per 7.5 pounds	540
Geese	1.0 per 7.5 pounds	540
Reserved for additional species		

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

March 1, 2011

Introduction

Humane and respectful 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 Humane handling, transport and slaughter: general conditions of animal welfare in handling and slaughter** to move towards a comprehensive animal welfare program in certified organic operations.

Background

The Livestock Committee presented a discussion document on handling, transport, and slaughter was presented at the October 2010 meeting. The Committee took the 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 their 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: Humane handling, transport, and slaughter**.

Discussion

Fitness for transport. To avoid the need to cull unfit animals at slaughter, it is essential that only fit animals be loaded for transport. Unfit cull animals are one of the biggest problems encountered at slaughter plants. Although this shouldn't be considered a comprehensive list, animals are unfit for transport if they are any of the following: blind, disabled, fatigued, sick, injured, lame, weak, have unhealed wounds, are within the final 10% of their gestation, or are less than 48 hours old. 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, all shipping containers must have seasonally-appropriate ventilation, bedding (as needed), and non-slip flooring. All consumable bedding must be certified organic. 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.

Certification of transporters. At the October 2010 meeting, the NOSB passed a recommendation to clarify the limitations of § 205.101(b), which states that handling operations must be certified unless they are enclosed in a container prior to being received by the operation and that they remain in the same container and are not otherwise processed while in control of the handling operation. Since these conditions are not met for the transportation of livestock, it is the NOSB's intention that these operations would need to be certified in order to transport livestock.

Animal handling. Slaughter plant staff must be available after hours as 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 adequate in order to identify and/or mange ill or injured livestock.

Slaughter. The recommended language below is intended to ensure that animals are handled humanely 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 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 humanely 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. 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.

Slaughter plant audits. Audits of slaughter plants provide confirmation that animals are being treated humanely 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 humane treatment 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

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

(a) Handling and Transport

(1) Calves must have a dry navel cord and be able to stand and walk without human assistance if they are being transported to a slaughter or auction facility.

(2) Transporters and slaughter plants must provide season-appropriate ventilation to protect against cold and heat stresses.

(3) Bedding as appropriate must be provided to livestock during transportation and prior to slaughter. Consumable bedding in shipping containers and at plants must be certified organic.

(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 on the shipping container is no more than one hour.

(6) Emergency plans that adequately address animal welfare must be in place to cover any encountered problems during transport.

(7) Slaughter plants and 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 must be in place. Handlers may use sleds and place livestock in the bucket, may not push them up against a wall, gate, or any other object.

(13) Electric prods are available for medical use only, 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.

(14) Euthanasia must only be performed by trained personnel.

(15) Euthanasia equipment must be properly stored and maintenance records must be available.

(b) Slaughter

(1) As part of their organic certification, slaughter plants must be audited annually to meet the following criteria for animal welfare:

(a) 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.

(b) Conscious, sensible mammals must never be restrained by suspending them by their limbs.

(c) 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.

(d) One hundred percent of animals are insensible on the bleed rail.

(e) 95% of cattle and sheep are effectively stunned via captive bolt or gunshot. 99% of electrodes are placed correctly when livestock are stunned with electricity.

(f) No more than 1% of hogs vocalize due to hot wanding. Electrodes must not be energized before they are in firm contact with the animal.

(g) When carbon dioxide (CO_2) 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

Motion: Accept the Livestock Committee recommendation on animal handling, transit, and slaughter proposal with discussed changes.
Motion by: TE Second: CB
Yes: 5 No: 0 Absent: 0 Abstain: 0 Recuse: 0

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: Spring 2011—Seattle, Washington	Substance: Attapulgite

Committee: Crops ☐ Livestock ☐ Handling X Petition is for: Addition of Attapulgite on the National List § 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 **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): Attapulgite--allowed as a processing aid in the handling of plant and animal oils.

Basis for annotation: Unrestricted use would include industrial applications not appropriate to food processing.

D. Recommended Committee Action & Vote, including classification recommendation (State Actual Motion):

To consider non-chemically processed attapulgite a non-synthetic substance.

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

Motion by: ***John Foster*** *Seconded:* ***Joe Dickson*** *Yes: 6 No: 0 Absent: 1 Abstain: 0 Recuse: 0*

Recommended Committee Action & Vote : Add attapulgite to the National List, 7 CFR § 205.605(a) with annotation as noted: Attapulgite--allowed as a processing aid in the handling of plant and animal oils.

Motion by: ***John Foster*** *Seconded:* ***Joe Dickson*** *Yes: 5 No: 1 Absent: 1 Abstain: 0 Recuse: 0*

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]	

1) Substance voted to be added as "allowed" on National List to § 205.605(a) with Annotation: Allowed as a processing aid in the handling of plant and animal oils.

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

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 **Date: March 5, 2011**

EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

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

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			Those effects on environment typically encountered with open pit mining activities, and environmental protection practices are in place to remediate or mitigate earth moving and removal. (Pet page 5, TR line 142+, 232+) Mining of attapulgite does not include any chemical adjuvants or catalysts (Pet page 5, TR line 142+, 232+)
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		x		See above.
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]		x		Temporary dust hazard during mining. (TR line 232+)
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1) (B)(ii); 205.601(m)2]		x		Attapulgite is not a formulated product and has nothing added to it when used as a food processing aid.
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		x		Neither petition nor TR note any.
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		x		Neither petition nor TR note any.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]			x	Petitioned as a handling material.
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		x		Neither petition nor TR note any.
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]		x		Neither petition nor TR note any.
10. Is there any harmful effect on human health? [§6517 c (1)(A) (i) ; 6517 c(2)(A)I; §6518 m.4]	x			If handled without the mandated personal protection equipment (PPE) then inhalation hazards are noted (TR line 276+)
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]	x			See above.
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]				Included in FDA's EAFUS, and considered GRAS under EPA (TR line 340+)
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		x		No information found via TR for attapulgite, but for Fuller's Earth from China, some trace heavy metals have been found. (TR line 349+)

[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: Attapulgite

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		Formed through geologic processes, mined, then physically pulverized, screened, and packaged. (Pet page 5, TR line 142+, 232+)
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]		x		See above.
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		x		Formed through geologic processes, mined, then physically pulverized, screened, and packaged. (Pet page 5, TR line 142+, 232+)
4. Is there a natural source of the substance? [§205.600 b.1]			x	This is the natural form of the substance
5. Is there an organic substitute? [§205.600 b.1]		x		TR line 214+
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]	x			In order to bring the oils to marketable condition, some clarifying processing aid is needed.
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]			x	This is a wholly natural product.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]	x			Formed through geologic processes, mined, then physically pulverized, screened, and packaged. (Pet page 5, TR line 142+, 232+)
9. Is there any alternative substances? [§6518 m.6]		x		TR line 214+
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]		x		

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

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

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			This is a natural substance used to bring oils to a marketable condition through removal of impurities such as undesirable odors, colors, trace metals, etc.
2. Is the substance consistent with organic farming and handling, and biodiversity? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]	x			See above.
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			TR line 312+
5. Is the primary use as a preservative? [§205.600 b.4]		x		TR line 319+
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		TR 330+
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: Attapulgite

Question	Yes	No	N/A	Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown)
1. Is the comparative description provided as to why the non-organic form of the material /substance is necessary for use in organic handling?			x	
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **form** to fulfill an essential function in a system of organic handling?			x	
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quality** to fulfill an essential function in a system of organic handling?			x	
4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quantity** to fulfill an essential function in a system of organic handling?			x	
5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following:			x	
a. Regions of production (including factors such as climate and number of regions);			x	
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;			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: April 2011	Substance: Calcium Acid Pyrophosphate

Committee: Crops ☐ Livestock ☐ Handling X Petition is for the addition of Calcium Acid Pyrophosphate to the National List § 205.605(b) "for use as a leavening agent" in baked goods.

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

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

Substance Fails Criteria Category: 1and 2. Comments: The manufacture of Calcium acid pyrophosphate (CAPP) involves the reaction of phosphoric acid produced from phosphate rock with Calcium oxide . Heavy metal contamination from mining operations is a concern, as is the environmental effect of the phosphoric acid component of the manufacture. The petition does not provide compelling evidence that the material is essential for organic production, even for its petitioned use as a leavening agent for organic baked products. Sodium acid pyrophosphate (SAPP) is already listed for use for this purpose, and although there is mention of the fact that this material could be substituted for SAPP to reduce sodium content of organic baked items, there is no comparative discussion in the petition of what the actual sodium reduction would be, whether it would be significant enough to justify adding another synthetic material to the National List, or even if organic consumers desire lower sodium content in their baked goods. The TR states potential sodium reduction of up to 26%, but it is formula dependent. Calcium phosphates, also already listed materials, are also used in the leavening of bread and bakery products and do not contain sodium. There is no explanation as to the reasons for preference of CAPP over these materials, if one exists.

Proposed Annotation (if any): N/A

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

B. Recommended Committee Action & Vote, including classification recommendation (State Actual Motion):
To classify Calcium Acid Pyrophosphate as a synthetic

Classification of the material: Synthetic: X Non- synthetic_____

Motion by: Steve DeMuri Seconded: Tracy Miedema Yes: 5 No: 0 Absent: 2 Abstain: 0

Recommended Committee Action & Vote: To add Calcium Acid Pyrophosphate to section 205.605(b) of the National List

Motion by: Steve DeMuri Seconded: Tracy Miedema Yes: 0 No: 5 Absent: 2 Abstain: 0

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

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

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

Describe why a prohibited substance:_____

3) Substance was rejected by vote for amending National List to § 205. 605(b) Describe why material was rejected:
Fails Categories 1 and 2 of the National List petitioned material evaluation criteria. See above

4) Substance was recommended to be deferred because _____

If follow-up needed, who will follow up: **N/A**

C. Approved by Committee Chair to transmit to NOSB:

Steve DeMuri **February 24, 2011**
Committee Chair **Date**

EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? **Substance: Calcium Acid Pyrophosphate**

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]	X			The TR, page 7, describes environmental concerns with the phosphoric acid used to produce the CAPP, and heavy metal contamination from phosphate rock mining, another input to the CAPP manufacturing process.
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]	X			Heavy metal contamination of groundwater and estuaries possible during manufacture if not mitigated. These metals can be taken up by plants and marine life leading to concentration of heavy metals in food products. TR page 7
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		No evidence the substance itself is harmful.
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1) (B)(ii); 205.601(m)2]		X		No evidence it contains these inerts.
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		X		None identified in the TR.
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]			X	The substance is added to food as a leavening agent, not to soil or crops.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]	X			There can be an uptake of heavy metals from the phosphate rock component of the manufacturing process, but no evidence to suggest the material itself has detrimental physiological effects on soil organisms, crops, or livestock.
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		None mentioned in the TR.
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]		X		No evidence of this in the TR.
10. Is there any harmful effect on human health? [§6517 c (1)(A) (i) ; 6517 c(2)(A)I; §6518 m.4]	X			According to the MSDS and TR, the substance may cause skin, eye, and respiratory tract irritation. Can be harmful if ingested in large quantities. TR page 8.

11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		X		No evidence of such in the TR.
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]	X			The substance is isn't listed as GRAS by the FDA, but was affirmed as GRAS by the SCOGS with no limitations other than Good Manufacturing Processes. TR page 5.
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		X		There is no evidence that the substance contains heavy metals in excess of FDA tolerances. TR page 7.

[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: Calcium Acid Pyrophosphate

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 typical manufacturing method described by the petitioner states that food grade phosphoric acid produced from phosphate rock is reacted with calcium oxide (lime) to precipitate calcium dihydrogen phosphate. The calcium dihydrogen phosphate is filtered and undergoes calcinations at 270°C to form CAPP. The material is then milled to a powder and packaged. TR page 4.
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]	X			See above
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		See # 1 above.
4. Is there a natural source of the substance? [§205.600 b.1]		X		Components of some of the manufacturing inputs are natural, but some are synthetic, rendering it a synthetic (not natural) substance.
5. Is there an organic substitute? [§205.600 b.1]		X		According to the petition and the TR, page 5, there are no organic substitutes known.
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]		X		May be useful as a reduced sodium leavening agent, but no compelling evidence is provided that it meets essentiality criteria, since other listed materials serve the same function.
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]		X		There is no evidence a natural substitute product exists. TR page 5.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]		X		Used in handling, but IS synthetic and not organically produced.
9. Is there any alternative substances? [§6518 m.6]	X			SAPP is currently listed and used for the same purpose, but petitioner states CAPP would be a low sodium option. Calcium phosphates are already listed and used for the same purpose as well. No compelling rationalization provided, other than the sodium claim, as to why SAPP or Calcium phosphates don't suffice for the petitioned application.
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			Unleavened organic bakery products could be produced, by acceptability by organic consumers is unknown.

[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: Calcium Acid Pyrophosphate

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		X	Consistent with Handling, but not applicable to farming and biodiversity, since it is not applied to soil or crops..
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]			X	Petitioned for use in a Handling application.
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]	X			Nutritional quality is not negatively affected by it's use, per the TR, page 6. It can have the benefit, however, of providing a low sodium leavening agent alternative for organic processors.
5. Is the primary use as a preservative? [§205.600 b.4]		X		Primary use would be as a leavening agent for organic baked goods, not preserving. TR page 6.
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 substance, for the purpose petitioned, would act as a leavening agent, not to recreate or improve quality attributes lost in processing. However, there is an indirect impact on the texture of baked goods as CAPP neutralizes baking soda and CO_2 expands in the product during the baking process. TR page 6. The texture change is a result of processing, not a replacement function.
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:			X	Not petitioned to this committee for use in organic production, just handling.
a. Copper and sulfur compounds;			X	See above
b. Toxins derived from bacteria;			X	See above
c. Pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?			X	See above
d. Livestock parasiticides and medicines?			X	See above
e. Production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?			X	See 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 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: Calcium Acid Pyrophosphate

Question	Yes	No	N/A	Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown)
1. Is the comparative description provided as to why the non-organic form of the material /substance is necessary for use in organic handling?			X	This category pertains only to substances petitioned for addition to section 205.606. All questions in this category (4) not applicable.
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
Handling Committee
Proposed Discussion Document
Petition to Remove Silicon Dioxide from National List

March 8, 2011

Committee Summary

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

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 silicon dioxide, though it does require special handling due to inhalation risks; limitations on its use and handling are governed by worker safety protocols and Good Manufacturing Practices.

Silicon dioxide was voted by the NOSB at the fall 2010 meeting to be re-listed under the sunset review process, with the knowledge that a petition to remove silicon dioxide was in process of NOP review at that time.

In 2007 (docket TM-04-07) public comment asserting that the inclusion of silicon dioxide on the National List was no longer necessary due to the availability of a certified organic alternative substance. This comment was provided by the manufacturer of the proposed alternative substance and since has been amended twice with additional information, all of which has been provided via written and oral public comment. At that time and since that time, some evidence has been provided to demonstrate the utility of an alternate in some applications where silicon dioxide is presently used. Several public comments supported re-listing silicon dioxide prior to the April 2010 NOSB meeting as part of the sunset review process.

Two key features emerged from the discussions among the Handling committee:

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 alternatives do not exist for all uses and applications of silicon dioxide.

The Handling Committee wants to elicit public comment to identify where alternatives to silicon dioxide are or may be used effectively and appropriately. Specifically, what alternatives to silicon dioxide are available and effective for use as:

- An anti-caking agent in foods and animal feeds
- A stabilizer in beer production
- An adsorbent in tableted foods for special dietary use.
- A carrier, such as a component of microcapsules for flavoring oils.
- A defoaming agent.
- Other uses allowed under FDA

Comments from food manufacturers are particularly needed in order for the Handling Committee to assess the conditions under which silicon dioxide may be removed from the National List to promote the use of agricultural and organic alternatives and without causing undue burdens to manufacturers and consumers.

Committee Vote

Motion: To accept the discussion document
Motion by: Katrina Heinze Second: John Foster
Yes: 7 No: 0 Absent: 0 Abstain: 0 Recuse: 0

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: April 2011	Substance: Sodium Acid Pyrophosphate

Committee: Crops ☐ Livestock ☐ Handling X Petition is to expand the allowed use of Sodium Acid Pyrophosphate on the National List § 205.605(b) to include it's use as a sequestrant on cooked and uncooked produce. It is currently listed "for use only as a leavening agent".

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

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

Substance Fails Criteria Category: 1 and 3. The TR mentions no data was found on the material itself that indicated it posed potential negative impact on human health or the environment, but it did discuss that one of the primary inputs in the manufacture of SAPP, Phosphoric acid, does pose a threat if waste is not carefully managed. The petitioner did not provide compelling evidence that SAPP is necessary or essential to organic handling, and as a matter of fact, a survey of organic handlers who could potentially use this material did not reveal any who actually would if it was listed.

Proposed Annotation (if any): N/A

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

B. Recommended Committee Action & Vote, including classification recommendation (State Actual Motion):
To classify Sodium Acid Pyrophosphate as a synthetic material.

Classification of the material: Synthetic: _____ Non- synthetic_____

Motion by: Steve DeMuri Seconded: Katrina Heinze Yes: 6 No: 0 Absent: 1 Abstain: 0 Recuse: 0

Recommended Committee Action & Vote To expand the listing of Sodium Acid Pyrophosphate on 205.605(b) to include use as a sequestrant on cooked and uncooked produce.

Motion by: Steve DeMuri Seconded: Katrina Heinze Yes: 0 No: 6 Absent: 1 Abstain: 0 Recuse: 0

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

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

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

Describe why a prohibited substance:_____

3) Substance was rejected by vote for amending National List to § 205. 605(b) Describe why material was rejected:
For the reasons described in the Criteria Category discussion in Section A above.

4) Substance was recommended to be deferred because _____

If follow-up needed, who will follow up: **N/A**

C. Approved by Committee Chair to transmit to NOSB:

_____ _____

Committee Chair **Date**

EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? **Substance: Sodium Acid Pyrophosphate**

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]	X			The TR, page 9, describes environmental concerns with the phosphoric acid used to produce the SAPP, and potential heavy metal contamination from phosphate rock mining, used to produce the phosphoric acid..
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]	X			Heavy metal contamination of groundwater and estuaries possible during manufacture if not mitigated. These metals can be taken up by plants and marine life leading to concentration of heavy metals in food products. TR page 9
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		No evidence the substance itself is harmful. TR page 9.
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1) (B)(ii); 205.601(m)2]		X		No evidence it contains these inerts.
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		X		None identified in the TR.
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]			X	The substance is added to food as a leavening agent now, and has been petitioned to allow use as a sequestrant for vegetables. It is not applied to soil or crops.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]	X			There can be an uptake of heavy metals from the phosphate rock component of the manufacturing process, but no evidence to suggest the material itself has detrimental physiological effects on soil organisms, crops, or livestock. TR page 9.
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		None mentioned in the TR.
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]		X		No evidence of this in the TR.
10. Is there any harmful effect on human health? [§6517 c (1)(A) (i) ; 6517 c(2)(A)I; §6518 m.4]		X		According to the MSDS and TR, SAPP may cause body irritation in some individuals, but no evidence of it being acutely hazardous to human health.

11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		X		No evidence of such in the TR.
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]	X			TR page 6.
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]		X		There is no evidence that the substance contains heavy metals in excess of FDA tolerances.

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

Category 2. Is the Substance Essential for Organic Production? Substance: Sodium Acid Pyrophosphate

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			SAPP is manufactured by (1) partial neutralization of phosphoric acid (H_3PO_4) with sodium hydroxide (NaOH) or sodium carbonate (Na_2CO_3) to form monosodium phosphate (NaH_2PO_4) and then (2) dehydration of monosodium phosphate at approximately 250° C to form SAPP ($Na_2H_2P_2O_7$). Phosphoric acid and sodium carbonate are the feedstock for producing SAPP.
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]	X			See above
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		See # 1 above.
4. Is there a natural source of the substance? [§205.600 b.1]		X		Components of some of the manufacturing inputs are natural, but some are synthetic, rendering it a synthetic (not natural) substance.
5. Is there an organic substitute? [§205.600 b.1]		X		According to the petition and the TR, page 6, there are no organic substitutes known.
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]		X		May be useful as a reduced sodium leavening agent, but no compelling evidence is provided that it meets essentiality criteria, since other listed materials serve the same function.
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]		X		There is no evidence a natural substitute product exists. TR page 5.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]		X		Used in handling, but IS synthetic and not organically produced.
9. Is there any alternative substances? [§6518 m.6]	X			Citric acid is used currently by some manufacturers to reduce oxidation on cut fruits and vegetables. There was no explanation in the petition as to why citric acid couldn't be used.
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			A primary purpose for the material stated in the petition was for cut potatoes. An HC survey of major organic potato producers revealed that prompt production of manufactured potato products from raw potatoes greatly reduced the oxidation occurrence

				on cut or peeled surfaces of the vegetables. Stored potatoes tend to oxidize more easily the longer they are held post harvest prior to further manufacturing. All organic potato handlers contacted stated they would not use the material even if listed, and would instead continue managing harvest and storage to reduce browning.

[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: Sodium Acid Pyrophosphate

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		X	Consistent with Handling, but not applicable to farming and biodiversity, since it is not applied to soil or crops..
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]			X	Petitioned for use in a Handling application.
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]	X			Nutritional quality is not negatively affected by it's use, per the TR, page 6.
5. Is the primary use as a preservative? [§205.600 b.4]		X		Primary use would be as an anti-oxidant to reduce browning in cut cooked or uncooked produce, not to limit microbial growth.
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 substance, for the purpose petitioned, would act as an anti-oxidant on cut cooked or uncooked produce, not to recreate or improve factors lost during processing.
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:			X	Not petitioned to this committee for use in organic production, just handling.
a. Copper and sulfur compounds;			X	See above
b. Toxins derived from bacteria;			X	See above
c. Pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?			X	See above
d. Livestock parasiticides and medicines?			X	See above
e. Production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?			X	See 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 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: Sodium Acid Pyrophosphate

Question	Yes	No	N/A	Comments on Information Provided (sufficient, plausible, reasonable, thorough, complete, unknown)
1. Is the comparative description provided as to why the non-organic form of the material /substance is necessary for use in organic handling?			X	This category pertains only to substances petitioned for addition to section 205.606. All questions in this category (4) not applicable.
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
Handling Committee
Proposed Sunset 2012 Recommendation
Enzymes

February 24, 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 Recommendation(s)

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

Enzymes

Committee Vote

Motion: To relist enzymes on § 205.605(a).
Motion by: Steve DeMuri Second: Mac Stone
Yes: 5 No: 0 Absent: 2 Abstain: 0 Recuse: 0

National Organic Standards Board
Handling Committee
Sunset 2012 Proposed Recommendation
Potassium Iodide on § 205.605(a)

March 3, 2012

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

Potassium Iodide

Committee Summary

According to FDA, potassium iodide may be used as food additive and can serve the following functions:

- A nutrient in table salt as a source of iodine.
- A dietary supplement for human consumption and in animal feeds.
- A sanitizing agent for food processing equipment.

Potassium iodide is listed on the National List of Allowed and Prohibited Substance in both §205.605 (a) Nonsynthetics allowed and (b) Synthetics allowed (including nutrient vitamins and minerals, in accordance with 21CFR 104.20, Nutritional Quality Guidelines for Foods). In addition, KI may be allowed under §205.603 (d) (2), as feed additives (trace minerals, used for enrichment or fortification when FDA approved). This sunset recommendation only relates to the 605(a) listing of this substance.

KI can be both extracted from seaweeds or brines (nonsynthetic) and created through a number of chemical processes (synthetic). The 1995 technical review for this substance notes that KI extracted from brines is not commonly commercially available, but may be used in some applications. This assessment is confirmed by the 2011 technical report on KI. Accordingly, the substance is listed on both 605(a) and (b), with use of the synthetic version (on 605(b)) restricted to "Made with organic" products.

Review of the original recommendation, a 2011 technical report, historical documents, and public comments does not reveal unacceptable risks to the environment, human, or animal health as a result of the use or manufacture of this material. There is no new information contradicting the original recommendation which was the basis for the previous NOSB decision to list this material.

Committee Recommendation(s)

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

Potassium Iodide

Committee Vote

Motion by: Joe Dickson Second: Katrina Heinze
Yes: 6 No: 0 Absent: 1 Abstain: 0 Recuse: 0

National Organic Standards Board
Handling Committee
Sunset 2012 Proposed Recommendation
Nutrient Vitamins and Minerals

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

(b) Synthetics allowed

Committee Summary

Federal register notice of the sunset of these materials elicited many public comments, see attached spreadsheet NVM Public Comments Fall 2010.

Review of the original recommendations, historical documents, and public comments does not reveal unacceptable risks to the environment, human, or animal health as a result of the use or manufacture of these materials. The intent of this recommendation is to restore the 1995 NOSB Recommendation.

Committee Recommendation

The Handling Committee recommends the renewal and annotation change for the following substance:

§205.605(b): Nutrient Vitamins and Minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines for Foods

To be renewed as:

§205.605(b): Nutrient Vitamins and Minerals, restricted to materials required or allowed by law for the purpose of enrichment, supplementation or fortification of foods including infant formula, and materials the use of which is supported by the FDA or the Institute of Medicine of the National Academies

Committee Vote

Motion by: Tracy Miedema Second: Joe Dickson
Yes: 4 No: 3 Absent: 0 Abstain: 0 Recuse: 0

National Organic Standards Board
Handling Committee
Sunset 2012 Proposed Recommendation
Potassium Iodide on § 205.605(b)

March 3, 2012

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 iodide—for use only in agricultural products labeled "made with organic (specified ingredients or food group(s)),"** prohibited in agricultural products labeled "organic."

Committee Summary

According to FDA, potassium iodide may be used as food additive and can serve the following functions:

- A nutrient in table salt as a source of iodine.
- A dietary supplement for human consumption and in animal feeds.
- A sanitizing agent for food processing equipment.

Potassium iodide is listed on the National List of Allowed and Prohibited Substance in both §205.605 (a) Nonsynthetics allowed and (b) Synthetics allowed, with an annotation restricting its use to Made With Organic Products. Additionally, its use is also allowed under the 205.605(b) listing for Nutrient Vitamins and Minerals. In addition, KI may be allowed under §205.603 (d) (2), as feed additives (trace minerals, used for enrichment or fortification when FDA approved). This sunset recommendation only relates to the 605(b) listing of this substance.

KI can be both extracted from seaweeds or brines (nonsynthetic) and created through a number of chemical processes (synthetic). The 1995 technical review for this substance notes that KI extracted from brines is not commonly commercially available, but may be used in some applications. This assessment is confirmed by the 2011 technical report on KI. Accordingly, the substance is listed on both 605(a) and (b), with use of the synthetic version (on 605(b)) restricted to "Made with organic" products.

The committee believes that the currently listing of Potassium Iodide on 205.605(b) is unnecessary given its inclusion under Nutrient Vitamins and Minerals. Accordingly, we recommend that this substance be removed from 205.605(b).

Committee Recommendation(s)

The handling committee recommends the removal of this substance from section 205.605(b) of the National List:

> Potassium iodide—for use only in agricultural products labeled “made with organic (specified ingredients or food group(s)),” prohibited in agricultural products labeled “organic.”

Committee Vote

Motion by: Joe Dickson Second: Katrina Heinze
Yes: 0 No: 6 Absent: 1 Abstain: 0 Recuse: 0

National Organic Standards Board
Handling Committee
Sunset 2012 Proposed Recommendation
Tocopherols

February 24, 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

Committee Summary

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

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

Committee Recommendation(s)

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

Tocopherols – derived from vegetable oil when rosemary extracts are not a suitable alternative.

Committee Vote

Motion: To relist tocopherols on § 205.605(b).
Motion by: Steve DeMuri Second: Mac Stone
Yes: 5 No: 0 Absent: 2 Abstain: 0 Recuse: 0

National Organic Standards Board
Handling Committee
Proposed Recommendation
The Use of Nutrient Supplementation in Organic Foods

March 7, 2011

In 1995 the NOSB made a recommendation to the Secretary of the USDA on "The Use of Nutrient Supplementation in Organic Foods."

> Upon implementation of the National Organic Program, the use of synthetic vitamins, minerals, and/or accessory nutrients in products labeled as organic must be limited to that which is required by regulation or recommended for enrichment and fortification by independent professional associations.

The recommendation said, "the term 'accessory nutrients' means nutrients not specifically classified as a vitamin or a mineral but found to promote optimum health." The purpose of the "accessory nutrient" reference was given: "without this inclusion, we believe we may be limiting ourselves given future nutritional discoveries."

The recommendation thus authorized a category or class of approved materials on the National List comprised of vitamins, minerals and/or accessory nutrients. Consistent with the direction from Congress that the National List be updated and refreshed by new information, the recommendation proposed that the boundaries of the category be maintained by the state of current scientific literature and expert opinion. The reliance on current scientific literature and expert opinion properly limited the class of materials to those having received independent assessment and recognition as supplementing the human diet or providing support for optimal health.

When the National List was finally proposed by the Secretary, an annotation appeared that was not part of the authorizing NOSB recommendation.

> National List §205.605(b): Nutrient Vitamins and Minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines for Foods

The text of this listing failed to track the Recommendation. We believe the Recommendation expressly distinguished nutrients from vitamins for the purpose of including micronutrients that may be essential or that have been generally accepted as promoting optimal health. Based on the foregoing, the committee believes that the National List should be clarified by changing the listing to read: "Nutrients, Vitamins and Minerals."[1]

[1] The Committee recognizes that amendment of the actual listing, as distinguished from the annotation, will require a separate action. To that end, a separate proposal from the Handling Committee will be presented at the NOSB Spring 2011 meeting that recommends the relisting of the material with an amended annotation. Amendment of the listing itself will be the subject of a Petition that the Handling Committee intends to produce before the Fall 2011 meeting.

Also, the addition of the reference to 21 CFR **§**104.20 through an annotation altered the scope and meaning of the authorization intended by the 1995 recommendation and created significant confusion and conflict. Fortunately, the annotation was interpreted by the NOP in subsequent years in a manner that circumvented its more confusing and inappropriately restrictive aspects. Organic certifiers and businesses relied in good faith on these interpretations. Over the years innovative products have been developed that include the nutrient materials authorized by the NOP's determinations, and that are highly valued by organic consumers. Based on these facts, the record demonstrates that support for retaining the current annotation has completely dissolved and strong support for clarifying the authorization for this class of material has emerged.

The Handling Committee believes that the National List authorization intended by the 1995 NOSB Recommendation--a category of vitamin, mineral and nutrient materials for fortifying multi-ingredient organic foods in a manner consistent with existing applicable federal regulation and current scientific understanding--aligns neatly with the existing, updated record, and the demonstrated needs of the organic food industry and its consumers' expectations. Accordingly, the committee recommends that the existing National List authorization for §205.605(b) should be clarified in the following manner.

> **Proposed Amended Annotation**: "Materials required or allowed by law for the purpose of enrichment, supplementation or fortification of foods, including infant formula, and materials the use of which is supported by the FDA or the Institute of Medicine of the National Academies."

This approach, changing both the text of the listing and the annotation, comports with the OFPA and would achieve four key purposes:

- First, it would honor and implement the authorization proposed by the NOSB in 1995 by restoring the meaning of the listing and eliminating the annotation erroneously added during rulemaking.
- Second, it would annotate the listing during the sunset process in a manner that recognizes and embraces both the development of the organic marketplace since the time of the adoption of the original National List and the NOP rulings and Guidance issued since the inception of the National List by the NOP.
- Third, it would harmonize the rules on fortification, supplementation and enrichment of organic food products with the rules governing other foods in a manner that avoids unnecessary conflict with other statutes and governmental agencies.
- Lastly, it ensures the maximum freedom of choice for organic consumers.

For the purpose of the 2012 Sunset consideration to relist Nutrient Vitamins and Minerals to National List §205.605(b), the NOSB is authorized to recommend annotation changes for the purpose of limiting or clarifying the annotation. We believe amending the annotation as proposed above clarifies the listing and the annotation.

NOP Guidance

The committee sees great value in the FDA's expenditure of resources implementing its role in regulating the safety and efficacy of nutrients, vitamins and minerals and little value in a separate nutrient supplementation regime for food products that contain organic agricultural ingredients.

We respectfully request that the NOP delay publishing any Guidance regarding this listing, or materials currently in use pursuant to this listing, until after the publication of the proposed amended annotation in the Federal Register and receipt by the NOP and NOSB of comments by the public and any references or comments from the FDA and/or the Institute of Medicine.

Committee Vote

Motion by: Tracy Miedema Second: Joe Dickson
Yes: 4 No: 3 Absent: 0 Abstain: 0 Recuse: 0

National Organic Standards Board
Handling Committee
Proposed Annotation Recommendation
Chlorine Materials

March 7, 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 Cl2)."

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(s)

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

Chlorine materials (calcium hypochlorite; chlorine dioxide: and sodium hypochlorite) may be used up to maximum labeled rates for disinfecting and sanitizing food contact surfaces. Chlorine materials in water used in direct crop or food contact is permitted at levels approved by FDA or EPA for such purpose, provided the use is followed by rinse with potable water that does not exceed the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act.

Chlorine in water used as an ingredient in organic food handling should 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
Update and Proposed Guidance Document
Classification of Materials

March 4, 2011

At the November 2009 National Organic Standards Board (NOSB) meeting, the NOSB passed a recommendation on Classification of Materials. The recommendation included several "Next Steps," that the NOSB felt were required in order for the recommendation to be implemented. The primary further work required of the NOSB was development of a Guidance Document that the various stakeholders (e.g., Accredited Certifying Agents, committees of the NOSB, National Organic Program personnel) could use when classifying materials.

At the April 2010 NOSB meeting, the Joint Materials and Handling Committee presented a draft Guidance Document for public input. It was clear from that public input that the guidance document needed more work. Key points from public comment were:

- The draft guidance document accurately reflected the November 2009 NOSB recommendation
- Separate guidance documents for crops, livestock and handling inputs are needed
- Examples of crops and livestock material and how they would be evaluated need to be included
- Agreement with the committee that further clarification was needed in determining whether materials contain a "significant" amount of a synthetic input in the final material.

At the same April 2010 NOSB meeting, the NOSB passed an addendum to the definition of chemical change that the NOSB had recommended at the November 2009 NOSB meeting.

In September 2010, the National Organic Program (NOP) responded to the NOSB recommendations of November 2009 and April 2010. In general, the NOP's comments aligned with those received in public comment at the April 2010 meeting. Additionally, the NOP did not support the addendum to the definition of chemical change.

The Materials Committee has been working in response to these comments to develop a final proposed guidance document. Unfortunately, we have not made as much progress as we would have liked and do not have a complete proposed guidance document available for public review and comment at this time. Key topics that we have discussed have been the format of a guidance document, clarification of significant level of synthetic input remaining in a material, definition of chemical change and scope of classification. The purpose of this document is to provide an update to the full NOSB, the NOP and the public.

Proposed Action -- Definition of Chemical Change

The definition of chemical change approved by the NOSB in November 2009 is:

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

The April 2010 addendum approved by the NOSB is (shown as the underlined sentence):

> *Chemical Change* An occurrence whereby the identity of a substance is modified, such that the resulting substance possesses a different distinct identity (see related definition of "substance"). <u>Processing, as defined in §205.2, of agricultural products using materials allowed on the applicable section of the National List (i.e., §205.601 for crops, §205.603 for livestock and §205.605 / §205.606 for handling), does not result in chemical change as it applies to classification of materials.</u>

We appreciate the NOP's perspective on this second sentence. This recommended second sentence was the focus of much public comment at the April 2010 NOSB meeting and was edited several times by the committee during the meeting in response to public comment. After reviewing the topic and the original intent of the addendum, the Materials Committee is recommending that the NOSB rescind their April 2010 recommendation adding the second sentence to the definition of chemical change. We believe that we can address the concerns that prompted the addition of the second sentence, discussed below, through a guidance document.

The intent of the addendum was to address "whether chemical changes generated during processing methods specifically allowed in the Organic Foods Production Act (OFPA) and/or allowed National List materials, would render an otherwise agricultural product "synthetic." Public comment received at the November 2009 meeting showed a consistent concern that the recommended definition of chemical change, and its associated definition for substance, went too far and would result in a number of agricultural materials being classified as synthetic. A simple example to illustrate this point is toasted wheat kernels. Wheat kernels are clearly agricultural. When exposed to heat, the kernels toast resulting in chemical change. Public comment clearly indicated that classifying something like a toasted wheat kernel as synthetic was not the intent of OFPA.

The Materials committee agrees and will work with the original November 2009 NOSB recommended definition of chemical change within our guidance document to show that chemical changes generated during processing methods allowed in OFPA or with National List materials, where appropriate, do not result in a material being classified as synthetic.

Proposed Guidance -- Significant Amount/Level of Synthetic Input Remaining in the Material to be Classified

A key topic left unresolved in the April 2010 Draft Guidance Document was the question, "What is a significant amount/level of a synthetic input to the process remaining in the final material?" The Materials Committee spent the majority of our time on this topic evaluating two different approaches.

One approach we considered would be evaluate any known level of a synthetic substance in the final material or in the environment, as a result of the substance's manufacture, use and disposal would be a significant level. In March 2006, in a response to NOSB, the National Organic Program wrote, "One of the primary determinants of whether a food can be considered 'organic' is whether it contains or was produced with 'synthetic' substances."

Proponents of this approach suggest that consumer trust is paramount for long-term organic viability, requiring an assurance that organically labeled products meet a consistent standard in compliance with the OFPA statutory standard on synthetic agents and their allowance. OFPA states, "The National List may provide for the use of substances in an organic farming or handling operation that are otherwise prohibited under this title only if (A) the Secretary determines, in consultation with the Secretary of Health and Human Services and the Administrator of the Environmental Protection Agency, that the use of such substances (i) would not be harmful to human health or the environment…" (Sec. 2118 [7 U.S.C. 6517]). While the law does not envision the use of purposefully added synthetic materials not on the National List, the list provides the mechanism for evaluating harm. This statutory intent is captured in the "Evaluation Criteria for Substances Added to the National List" with the questions, "Is there any harmful effect on human health? [§6517 c (1)(A) (i) ; 6517 c(2)(A)I; §6518 m.4]?" and, "Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]?" Proponents believe this standard of review requires a determination as to whether there is harm associated with the use of the synthetic substance, and therefore subject to the National List review process. Under this approach, all synthetic inputs or residues must be examined to determine their associated health and environmental impacts.

The second approach we considered, and which ultimately received the support of the majority of the committee, was that a significant level of a synthetic substance in the final material means a level exceeding any applicable regulatory limits, where in effect for the material being classified, and a level without any technical and functional effects in the final material. Proponents of this approach believe this approach is more consistent with past NOSB practice and precedent, is consistent with the recommendation of the Material Working Group and reflects the bulk of the public comment we've received on this topic. Additionally, the majority of the Materials Committee was concerned with using an approach of "any known level" knowing that technology allows the detection of ever decreasing amounts of material. So a material that today has no known level of synthetic input in it may very well tomorrow have a detectable level. The majority of the committee felt that using the "any known level" approach would be disruptive to the industry as it differs from past practice and precedent and would lead to an on-going reevaluation of materials on a perpetual basis as detection levels change. As we discussed this approach, we acknowledge that a given material may not have any applicable regulatory limits or may have several. In the case where no regulatory limit is available, technical and functional effects of any remaining synthetic would need to be evaluated. In the case where, multiple regulatory limits exist, the reviewer should evaluate which best applies for the classification. For example, for a synthetic solvent used to extract a natural sourced material there may exist an OSHA inhalation limit and EPA tolerance level for an inert. Since the synthetic is present in a material to be used in crops, the EPA limit is most appropriate.

As a result of our discussions, the Materials committee recommends that the NOSB adopt as guidance that a significant level of a synthetic substance in the final material means a level exceeding any applicable regulatory limits, where in effect for the material being classified, and a level without any technical and functional effects in the final material. This guidance is intended to apply only in cases where a synthetic input is removed from the

final material with the intention of fully removing the synthetic input but complete removal is not possible. For example, extraction of a natural with a synthetic solvent.

Update -- Scope of Classification

The Materials Committee spent a considerable amount of time discussing the scope of classification and whether it should include evaluation of whether a material is allowed or prohibited for use in organic production or handling. Consistent with all past NOSB thinking on this topic, we concur that classification of a material is a separate evaluation step for a material from the evaluation of whether use of the material is consistent with organic practices.

While our conclusion may seem self-evident, we affirm that this is a critical topic for all boards to discuss and understand. As an example of the criticality of this distinction, a material, manufactured with a synthetic, may be classified as non-synthetic. However, the NOSB has a further obligation to determine whether use of that material is consistent with organic practices. In their review for classification, a NOSB committee may determine that while non-synthetic the material should be prohibited for use in organic production. Similarly, an ACA or Material Evaluation Programs may when reviewing a material determine that it is non-synthetic but during review of the manufacturing process develop concerns about its compatibility with organic practices. We believe that all stakeholders in the organic industry have an obligation to bring that information to the attention of the NOSB so that the NOSB can meet our statutory responsibility to review materials to determine if their use in organic production and handling is compatible with organic practices.

References

National Organic Standards Board Recommendations & other documents:

- Materials and Handling Committee, “Classification of Materials,” May 24, 2010
- Materials and Handling Committee, “Classification of Materials,” November 6, 2009
- Materials and Handling Committees, “Discussion Document on the Definition of Materials,” October 19, 2007
- Handling Committee and Materials Committee, “Recommendations Relative to “Agricultural” and “Nonagricultural” Substances for National List Consideration,” September 15, 2006
- Handling Committee, “Recommendations Relative to “Agricultural” and “Nonagricultural” Substances,” July 14, 2005
- Materials and Handling Committee, “Clarification of the definition of Synthetic as it is applied to Substances Petitioned for Addition or Prohibition to the National List(s),” June 23, 2005

Material Working Group

- May 2008 presentation at National Organic Standards Board meeting titled “Clarification of Definitions -- Agricultural vs. Non-agricultural”

- November 2008 presentation at National Organic Standards Board meeting titled "Clarification of Definitions -- Agricultural vs. Non-agricultural"
- May 2009 presentation at National Organic Standards Board meeting titled "Clarification of Definition of Synthetic Substance"

National Organic Program

- Memorandum for the Chairman of the National Organic Standards Board, "National Organic Standards Board Recommendations (April 2010 & November 2009)," September 30, 2010
- "Evaluation of the NOSB Recommendation on the Definition of Synthetic," March 9, 2006

Committee Vote

Motion: To rescind our April 2010 recommendation adding a second sentence to the definition of chemical change
Motion: Katrina Heinze Second: Tina Ellor
Yes: 6 No: 0 Absent: 0 Abstain: 0 Recuse: 0

Motion: move to accept this update to the public and the proposed guidance that a significant level of a synthetic substance in the final material means a level exceeding any applicable regulatory limits, where in effect for the material being classified, and a level without any technical and functional effects in the final material.
Motion: Katrina Heinze Second: Tina Ellor
Yes: 4 No: 2 Absent: 0 Abstain: 0 Recuse: 0

National Organic Standards Board
Compliance, Accreditation and Certification Committee
Proposed Discussion Document
NOP Oversight of Materials Review Organizations

March 3, 2011

Introduction

The National Organic Program has requested the National Organic Standards Board's input on the regulation and oversight of materials review organizations. Such organizations generally provide guidance to ACAs and producers on the compliance of specific generic and brand name materials with the National Organic Standards. The CACC acknowledges the complexity of this issue and its potentially substantial impact on the organic certification and production community. Accordingly, the committee intends to solicit the feedback of impacted organic stakeholders through this discussion document prior to making a recommendation to the National Organic Program.

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 organizations 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

The committee has identified a number of potential models and relevant questions on this issue. We are seeking public comments from any stakeholders on the items below.

Potential Oversight Models

A number of potential approaches have emerged in the CACC's discussion of this issue. The committee notes that this is not an exhaustive list of oversight models, but is soliciting feedback on the benefits and drawbacks of each of these approaches, along with suggestions on any other relevant models:

1. The current model, with ACAs and independent organizations existing as they are, but NOSB provides guidance on what the qualifications should be for an organization to review and approve materials under the NOP and NL structure.
2. Create a separate accreditation category for Materials Review and Approval, modeled after the existing accreditation categories. Existing non-certifier review organizations would need to apply for accreditation as a certifier within the materials review category.
3. The National Organic Program adds a materials review function, under which NOP manages a single brand names list of formulated products. This may be a pay-for-use service to offset its operating costs.
4. Status quo, with no change to current practices.
5. A combination of two or more of the above.

Discussion Questions

The CACC is seeking response from the organic community to several questions as follows:

1. Is there a need to develop a more uniform and consistent procedure for evaluating the competency and quality of material evaluation programs?
2. Should NOP regulate material evaluation programs?
3. Should reviews be performed only by authorized organizations?
4. Should authorized material review organizations only be:
    a. Independent third parties?
    b. Government (NOP, other federal agency, foreign governments)?
    c. Certifying agents?
    d. A combination of above?
    e. Other?
5. What standards should be used to judge the competency of material review organizations?
6. What criteria should be used by material review organizations to evaluate materials?
7. How do you resolve differences in listed materials from different review organizations?
8. Should there be one material list? If so, who should maintain it?
9. Should only materials on the list be permitted to be used?

10. Should “product types” be broken into categories with possibly different criteria?
11. How should the material review program be financed?
12. What programmatic over sight is needed by NOP?
13. Should there be an appeals process for manufacturers of organic input materials?
14. Currently organic producers and handlers take all of the risk for using approved materials. If a material is found to not comply with the NOP regulations then the organic producer/handler could lose certification. Is there a way to protect organic producers and handlers from manufacturers that supply them with materials that are fraudulently represented as complying with the NOP regulations?

Committee Vote

Motion by: Joe Dickson Second: Barry Flamm
Yes: 5 No: 0 Absent: 1 Abstain: 0 Recuse: 0

National Organic Standards Board
Policy Development Committee
Proposed Recommendation
Review of NOSB Vice Chair and
Policy Development Committee Job Descriptions

February 15, 2011

Introduction

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. The language of PPM is currently unclear on who is responsible for the ongoing maintenance of the PPM, since the descriptions of the responsibilities of both the Policy Development Committee and the NOSB Vice Chair include direct responsibility for maintaining the PPM. This recommendation clarifies the respective roles of the PDC and NOSB Vice Chair with regard to the maintenance of the PPM.

Background

It was noted by members of the PDC and the board in Fall 2010 that the PPM is not clear as to whether the maintenance of the PPM is the ultimate responsibility of the PDC or the NOSB Vice Chair.

Section II of the PPM describes the responsibilities of the NOSB Vice Chair:

> **Vice Chair**
> The Vice Chair shall act in the absence of the Chair. The Vice Chair shall also be responsible for maintenance and upkeep of the Policy and Procedures Manual.

Section IV of the PPM describes the responsibilities of the Policy Development Committee:

> ***Policy Development Committee (PDC)***
> The Policy Development Committee makes draft recommendations for consideration by the Board to provide guidance, clarification or proposed standards of Board operations, policies and procedures. The PDC maintains the content and updates to the NOSB Policy and Procedures Manual and New Member Guide. The PDC occasionally works with other committees to develop joint recommendations where policy issues are involved.

These two sections assign responsibility for maintenance and upkeep of the PPM to both the VC and the PDC.

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

The guidelines contained in the Policy and Procedures Manual directly impact the internal operation and policies of the NOSB, and each board member has a vested interest in the PPM's content and integrity. The participation of the Vice Chair in the maintenance of the PPM serves the interests of the Executive Committee in the smooth and effective operation of the overall board. However, the PDC is charged with matters of internal board policy, and the PPM clearly also falls within this sphere. In consideration of these equally important interests in the maintenance of the PPM, the Policy Development Committee proposes that the responsibility be shared collaboratively between the PDC and the NOSB VC. It is essential that the work of the maintenance of the PPM occur within the PDC, so that proposed changes are subject to the standard procedures regarding committee recommendations, votes, and presentation to the overall board.

The Vice Chair of the NOSB typically serves as a member of the PDC, because of the shared interest in board operations between the VC and the PDC described above. The committee recommends that the VC job description be updated to reflect that she or he should serve as a member of the PDC, and should work collaboratively with the members of the PDC to facilitate the ongoing maintenance of the PPM. The PDC description should be updated to reflect this collaborative relationship with the VC on the maintenance of the PPM.

Recommendation

The PDC recommends that Section II of the NOSB Policy and Procedures Manual be amended as follows:

> **Vice Chair**
> The Vice Chair shall act in the absence of the Chair. The Vice Chair shall <u>serve as a member of the Policy Development Committee, and work collaboratively with the PDC's members on the</u> ~~also be responsible for~~ maintenance and upkeep of the Policy and Procedures Manual.

The PDC recommends that Section IV of the NOSB Policy and Procedures Manual be amended as follows:

> ***Policy Development Committee (PDC)***
> The Policy Development Committee makes draft recommendations for consideration by the Board to provide guidance, clarification or proposed standards of Board

operations, policies and procedures. The PDC maintains the content and updates to the NOSB Policy and Procedures Manual (in collaboration with the NOSB Vice Chair) and New Member Guide. The PDC occasionally works with other committees to develop joint recommendations where policy issues are involved.

Committee Vote

Motion: to accept the proposed amendment to the Policy and Procedures Manual
Motion by: Joe Dickson Second: Jay Feldman
Yes: 5 No: 0 Abstain: 0 Absent: 0 Recuse: 0

National Organic Standards Board
Policy Development Committee
Proposed Recommendation
Policy & Procedures Manual Section V:
Procedures for Completing Committee Recommendations

February 2, 2011

Introduction

The PPM is a guide to assist the Board in the conduct of its responsibilities and it is revised as necessary to improve the functioning of the Board. The development and proposed revisions are done with public input, following the same procedures used for all NOSB committee recommendations.

Most of the Board's work is done by the standing committees, constituted by members with expertise and experience in the subject area and thus should be allowed to reach an independent committee conclusion, which may include a minority opinion. The full Board has the option to arrive at different conclusion and reject the committee recommendation.

The purpose of this recommendation is to clarify committee procedures and prerogatives for completing recommendations.

Background

During the NOSB Fall 2010 Meeting, procedural questions arose over the prerogative of a Committee to withdraw a proposed recommendation. Withdrawing a recommendation is not an uncommon practice, occurring at least once during the same Board Meeting. However in this case, the majority of the Board objected to the action of the Committee. During the insuring discussions, it became obvious that the PPM needed clarification on the subject.

Relevant areas in the Rule

OFPA provides the authority for the NOSB. Operating procedures were left to Board's discretion.

Discussion

Standing Committees develop recommendations based on the best information available, including public comment and the Committees own expertise.
At the Board Meeting additional information may be presented that may cause the Committee to reconsider its recommendation. This may be done during the Board meeting. However, the new information may be so complex, technical or controversial, that the Committee needs additional time or third party evaluation of the information. In such situations, the Committee needs to be able to take back its recommendation.

Recommendation

Revision of Section V, PPM: Procedures for Completing Committee Recommendations.

Developing committee recommendations follows these broad steps:

1. The committee prepares a recommendation or discussion document as agreed to in the committee work plan (see p. 32 PPM).
2. The recommendation or discussion document is posted for public comment.
3. Public comments are considered by the committee when making recommendation to the Board.
4. Prior to an official vote at the Board meeting, the committee may withdraw its recommendation.
5. Once presented, the Board takes action on the committee recommendation.

Note: all language following #4 on p.20 remains unchanged and should be included.

Committee Vote

Motion: to accept the proposed amendment to the Policy and Procedures Manual
Motion by: Barry Flamm Second: Calvin Walker
Yes: 4 No: 0 Absent: 1 Abstain: 0 Recuse: 0