National Organic Standards Board Meeting

Biltmore Hotel | Providence, RI

October 15, 2012 – October 18, 2012

National Organic Standards Board Meeting
Providence, RI, October 15-18, 2012
Agenda

Schedule at a Glance

	Monday Oct 15	Tuesday Oct 16	Wednesday Oct 17	Thursday Oct 18
AM	- Call to Order - Secretary's Report - NOP Update - Open Public Comment	- GMO ad-hoc Subcommittee - Crops Subcommittee	- Handling Subcommittee	- Compliance, Accreditation & Certification Subcommittee - Deferred Items - Final Votes
PM	- Livestock Subcommittee	- Materials Subcommittee	- Policy Development Subcommittee	- Officer Elections - Subcommittee Work Plans - Other Business - Closing Remarks

Meeting Format

- The USDA National Organic Program (NOP) National List Manager presents an overview of petitioned substances and Technical Reports in consistent format.
- NOSB members present Subcommittee discussion documents and proposals on petitioned substances.
- Public comments are grouped to correspond with each Subcommittee's presentation.
- Each Subcommittee's proposals are discussed and may be voted on by the Board before moving to the next Subcommittee.
- If more deliberation is needed, final votes will be deferred to Thursday, October 18.
- NOTE: Agenda items may be withdrawn or votes may be postponed at the discretion of the Board.

Public Comments

- All persons wishing to comment at NOSB meetings during public comment periods should sign up in advance. Commenters can sign up in person at the meeting if the schedule allows.
- Each commenter must state their name and affiliation for the record at the beginning of his or her public comment.
- Each person may sign up for only one speaking slot. Speakers have been allotted 4 minutes to testify with 3 minutes for questions and answers from the Board.

Monday, October 15	8:00 AM	**Call to Order** ***Dr. Barry Flamm, Chairperson*** - Announcements - Introductions - NOSB Mission
	8:15 AM	**Secretary's Report** ***Dr. Wendy Fulwider, Secretary*** - Acceptance of May 2012 Meeting Transcripts and Voting Results as Official Record
	8:30 AM	**National Organic Program Update** **Miles McEvoy, Deputy Administrator, National Organic Program** **Mark Lipson, Organic and Sustainable Agriculture Policy Advisor, OSEC-MRP**
	9:30 AM	**Break**
	9:45 AM	**Open Public Comment** - Public comments that are not specific to a particular Subcommittee, or which address topics not on the agenda
	12:00 PM	**Lunch**
	1:00 PM	**Open Public Comment continued**
	2:15 PM	**Livestock Subcommittee** ***Dr. Wendy Fulwider, Chairperson*** - Present Subcommittee proposals and summarize written comments **Topics:** - Proposal: Nonanoic acid (pelargonic acid) - petitioned - Proposal: Pet Food Amino Acids - petitioned - Discussion document: Omnivore diets (methionine) - GMO Vaccines Working Group update: Dr. Jean Richardson (15 min)
	3:00 PM	**Break**
	3:15 PM	- Public comments related to Livestock Subcommittee
	4:45 PM	- Break for Subcommittee to modify proposals as needed - Board votes if ready
	5:30 PM	**Recess**

Tuesday, October 16	8:00 AM	**GMO Ad Hoc Subcommittee** **Zea Sonnabend, Chairperson** - Present Subcommittee proposal and summarize written comments **Topics:** - Discussion document: GMOs and seed purity
	8:15 AM	- Public comments related to GMO Ad Hoc Subcommittee
	9:05 AM	**Break**
	9:20 AM	**Crops Subcommittee** ***Jay Feldman, Chairperson*** - Present Subcommittee proposals and summarize written comments **Topics:** - Proposal: Ferric Phosphate - petitioned - Proposal: Oxidized lignite (humic acid) - petitioned - Proposal: Propylene glycol monolaurate (PGML)- petitioned - Proposal: Review of Inert Ingredients - Proposal: Rotenone (For 205.602) - Proposal: Sulfuric acid - petitioned - Proposal: Biodegradable Mulch Film Made From Bioplastics – petitioned
	11:00 AM	- Update from the Tree Fruit Working Group: David Granatstein - Presentation: Consumers Union: Dr. Urvashi Rangan - Presentation: Organic Seed Alliance: Kiki Hubbard
	12:15 PM	**LUNCH**
	1:15 PM	- Public comments related to Crops Subcommittee
	3:20 PM	**Break**
	3:35 PM	- Break for Subcommittee to modify proposals as needed - Board votes if ready

Tuesday, October 16	4:15 PM	**Materials Subcommittee** ***Dr. Jennifer Taylor, Chairperson*** - Present Subcommittee proposals and summarize written comments **Topics:** - Proposal: Research Priorities
	4:30 PM	- Public comments related to Materials Subcommittee
	4:45 PM	- Break for Subcommittee to modify proposals as needed - Board votes if ready
	5:00 PM	**Recess**

Wednesday, October 17	8:00 AM	**Handling Subcommittee** ***John Foster, Chairperson*** - Present Subcommittee proposals and summarize written comments - Representatives from the American Academy of Pediatrics (AAP) (Dr. Jatinder Bhatia) and the Food and Drug Administration (FDA) (Dr. Sue Anderson), invited by the NOP, will be available to respond to Board member questions. **Topics:** - Proposal: Ascorbyl palmitate - petitioned - Proposal: Beta-carotene (synthetic) - petitioned - Proposal: Lutein - petitioned - Proposal: Lycopene - petitioned - Proposal: L-Carnitine - petitioned - Proposal: L-Methionine - petitioned - Proposal: Taurine - petitioned - Proposal: Nucleotides - petitioned - Discussion document: Auxiliary/"other" ingredients
	10:00 AM	**BREAK**
	10:15 AM	- Public comments related to Handling Subcommittee
	12:30 PM	**LUNCH (until 1:45 when Handling Subcommittee returns from break)**
	1:30 PM	- Break for Subcommittee to modify proposals as needed - Board votes if ready
	3:00 PM	**BREAK**

Wednesday, October 17	3:15 PM	**Policy Development Subcommittee** ***Colehour Bondera, Chairperson*** - Present Subcommittee proposals and summarize written comments **Topics:** - Proposal: Conflict of Interest and Ethics - Proposal: Public Comment Procedures - Proposal: Public Communications
	4:00 PM	- Public comments related to Policy Development Subcommittee
	4:45 PM	- Break for Subcommittee to modify proposals as needed - Board votes if ready
	5:30 PM	**Recess**

Thursday, October 18	8:00 AM	**Compliance, Accreditation and Certification Subcommittee** ***Joe Dickson, Chairperson*** - Present Subcommittee proposals and summarize written comments **Topics:** - Discussion document: Calculating Percentage of Organic Ingredients - Discussion document: Biodiversity update
	8:30 AM	- Public comments related to CAC Subcommittee
	8:50 AM	**Deferred Proposals/Final Votes**
	10:00 AM	**BREAK**
	10:15 AM	**Deferred Proposals/Final Votes**
	12:00 PM	**LUNCH**
	1:00 PM	**Deferred Proposals/Final Votes**
	3:00 PM	**BREAK**
	3:15 PM	**NOSB Officer Elections**
	3:30 PM	**Subcommittee Workplans**
	4:45 PM	**Other Business and Closing Remarks** - Farewell/presentation of plaque to Barry Flamm
	5:00 PM	**Adjourn**

National Organic Standards Board
Livestock Subcommittee
Petitioned Material Proposal
Nonanoic acid

July 17, 2012

Summary of Proposed Action:
Nonanoic acid is a nine-carbon straight chain fatty acid which occurs at low levels in foods such as grapes, milk, oranges and apples. While there may be some non-synthetic sources of nonanoic acid, the petitioned material is a synthetic substance used as a topical insect repellent, with short term action requiring frequent treatment of livestock.

Nonanoic acid is an EPA registered fungicide and herbicide, and as such it does not appear on permitted substance lists in Canada, the European Union or Japan. There is potential for negative impact on the agro-ecosystem and soils. Further, there are a number of effective alternative treatments already available in addition to IPM and management practices. For these reasons the Livestock sub-committee is not recommending to add nonanoic acid to 205.603, insect repellent insecticide.

Evaluation Criteria

(Applicability noted for each category; Documentation attached) **(see "B" below)**	**Criteria Satisfied?**
1. Impact on Humans and Environment N/A	☐ Yes ☒ No ☐
2. Essential & Availability Criteria ☐ N/A	☐ Yes ☐☒ No
3. Compatibility & Consistency ☐ N/A	☐ Yes ☐☒ No
4. Commercial Supply is Fragile or Potentially Unavailable N/A as Organic (only for § 205.606)	☐ Yes ☐ No ☒

Substance Fails Criteria Category: [3] **Comments:**
Nonanoic acid is an EPA registered fungicide and herbicide that can be used as a weed killer and blossom thinner.
Proposed Annotation (if any):

Basis for annotation: ☐ To meet criteria above ☐ Other regulatory criteria ☐ Citation
Notes:

Recommended Committee Action & Vote, including classification recommendation (state actual motion):

Classification Motion: Nonanoic acid (CAS112-05-0) as petitioned is synthetic
Motion by: Jean Richardson Seconded by: Colehour Bondera
Yes: 7 No: 0 Absent: 1 Abstain: 0 Recuse: 0

Listing Motion: To add nonanoic acid (CAS 112-05-0) to 205.603, insect repellent, insecticide

Motion by: Jean Richardson Seconded by: Tracy Favre
Yes: 0 No: 7 Absent: 1 Abstain: 0 Recuse: 0

Crops	☐	**Agricultural**	☐	**Allowed[1]**	☐
Livestock	x☐	**Non-synthetic**	☐	**Prohibited[2]**	☐
Handling	☐	**Synthetic**	☐x	**Rejected[3]**	x☐
No restriction	☐	**Commercial unavailable as organic**	☐	**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:

Approved by Committee Chair to Transmit to NOSB

Wendy Fulwider, Committee Chair July 17, 2012

NOSB Evaluation Criteria for Substances Added To the National List

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

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]			X	
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		The TR was not clear on this issue
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]	X	X		The TR (lines 333-338) suggests that beneficial nematodes may be affected negatively by this substance
4. Does the substance contain List 1, 2 or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]		X		
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		X		
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		X		
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]	X			TR (lines 293-297) indicates potential wind drift impact on blossoms and weeds; TR (lines 333-338) concern over

				negative impact on nematodes in soil; lack of clarity on impact on beneficial nematodes and earthworms
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]		X		
10. Are there any harmful effects on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4]	X	X		TR (lines 383-385) indicates that the substance is an irritant, but was not evaluated for chronic toxicity.
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.

NOSB Evaluation Criteria for Substances Added To the National List

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

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]	X			
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]		X		
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		
4. Is there a natural source of the substance? [§205.600 b.1]			X	
5. Is there an organic substitute? [§205.600 b.1]			X	
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			X	
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X			TR (lines 398-400 and 413-414; 421-441) indicates a wide range of natural substitute products.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]		X		
9. Is there any alternative substances? [§6518 m.6]	X			
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			TR (lines 446-515) describes systems of Integrated Pest Management (IPM)

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

NOSB Evaluation Criteria for Substances Added To the National List

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

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

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

NOSB Evaluation Criteria for Substances Added To the National List

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

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			X	

production or destroy crops or supplies;				
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or			X	
e. Are there other issues which may present a challenge to a consistent supply?			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.

National Organic Standards Board
Livestock Subcommittee
Petitioned Material Proposal
Required Synthetic Amino Acids for Pet Foods

August 20, 2012

Summary of Proposed Action:
Thirteen synthetic amino acids were petitioned for use in organic pet foods. The Subcommittee evaluated the petition, TR, had discussion with State Feed Control Officials and concluded that only Taurine for cats was deemed necessary as a synthetic addative and thus allowed. It was determined that the manufacturers could meet the required levels of Arginine, DL-Methionine, Cysteine, L-Lysine, Tryptophan, Threonine, Histidine, Isoleucine, Leucine, Phenylalanine, Tyrosine, Valine to meet the criteria for "complete and balanced" as required by American Association of Feed Control Officials (AAFCO) with typical ingredients.

This petition checklist is only for Taurine for cats.

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

1. Impact on Humans and Environment ☒ Yes ☐ No ☐ N/A
2. Essential & Availability Criteria ☒ Yes ☐ No ☐ N/A
3. Compatibility & Consistency ☒ Yes ☐ No ☐ N/A
4. Commercial Supply is Fragile or Potentially Unavailable ☒ Yes ☐ No ☐ N/A
   as Organic (only for § 205.606)

Substance Fails Criteria Category: [ ] **Comments:**

Proposed Annotation (if any): 205.603(e)(4) Taurine (CAS 107-35-7) for cats

Basis for annotation: ☒ To meet criteria above ☐ Other regulatory criteria ☐ Citation
Notes: The other 12 petitioned Amino Acids failed to meet the necessity criteria

Recommended Committee Action & Vote, including classification recommendation (state actual motion):

Classification Motion: Motion to classify amino acids (Arginine, Methionine, Cystine, Lysine, Taurine, Tryptophan, Threonine, Histidine, Isoleucine, Leucine, Phenylalanine, Tyrosine, and Valine) as synthetic.
Motion by: Mac Stone Seconded by: Colehour Bondera
Yes: # 7 No: # 0 Absent: # 1 Abstain: # 0 Recuse: # 0

Listing Motion: Motion to list amino acids (Arginine, Methionine, Cystine, Lysine, Taurine, Tryptophan, Threonine, Histidine, Isoleucine, Leucine, Phenylalanine, Tyrosine, and Valine) on section 205.603 on the National List for use in organic pet food.
Motion by: Mac Stone Seconded by: Colehour Bondera
Yes: # No: # 7 Absent: # 1 Abstain: # 0 Recuse: #0

Listing Motion: Motion to list Taurine (CAS 107-35-7) on 206.603(e)(4) for cats
Motion by: Wendy Fulwider Seconded by: Calvin Walker
Yes: # 7 No: # 0 Absent: # 1 Abstain: # 0 Recuse: # 0

Crops	☐	**Agricultural**	☐	**Allowed[1]**	☒
Livestock	☒	**Non-synthetic**	☐	**Prohibited[2]**	☐
Handling	☐	**Synthetic**	☒	**Rejected[3]**	☐
No restriction	☐	**Commercial unavailable as organic**	☐	**Deferred[4]**	☐

[1]Substance voted to be added as "allowed" on National List to § 205.603 with Annotation (if any): Taurine (CAS 107-35-7) on 206.603(e)(4) for cats

[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: 12 petitioned items rejected for lack necessity to formulate complete and balanced feeds for cats and dogs

[4]Substance was recommended to be deferred because
If follow-up needed, who will follow up:

Approved by Committee Chair to Transmit to NOSB

Wendy Fulwider, Committee Chair 8/16/12

NOSB Evaluation Criteria for Substances Added To the National List

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

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]		x		
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]		x		
4. Does the substance contain List 1, 2 or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]		x		
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		x		
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		x		
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		x		
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		x		
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]		x		
10. Are there any harmful effects on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4]			x	
11. Is there an adverse effect on human health as defined by			x	

applicable Federal regulations? [205.600 b.3]				
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.

NOSB Evaluation Criteria for Substances Added To the National List

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

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			
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]		x		
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		x		
4. Is there a natural source of the substance? [§205.600 b.1]	x			
5. Is there an organic substitute? [§205.600	x			

b.1]				
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]	X Taurine	Arginine, DL-Methionine, Cysteine, L-Lysine, Tryptophan, Threonine, Histidine, Isoleucine, Leucine, Phenylalanine, Tyrosine, Valine		From the TAP and petition and discussions with Feed Control Officials, only Taurine was determined absolutely necessary for cats, for diet formulators to meet AAFCO guidelines
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X			
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]		x		
9. Is there any alternative substances? [§6518 m.6]		x		
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]		x		

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

NOSB Evaluation Criteria for Substances Added To the National List

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

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]	x			
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]	x			

3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]			x	
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]	x			
5. Is the primary use as a preservative? [§205.600 b.4]		x		
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]	x			
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: a. copper and sulfur compounds;		x		
b. toxins derived from bacteria;		x		
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?		x		
d. livestock parasiticides and medicines?		x		
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?			x	

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

NOSB Evaluation Criteria for Substances Added To the National List

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

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	

[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.

National Organic Standards Board
Livestock Subcommittee
Discussion Document:Omnivore Diets

August 21, 2012

I. Introduction

The National Organic Standards Board (NOSB) Livestock Subcommittee (LS) seeks the organic community's discussion on the framework for natural omnivore diet materials, production, manufacturing, and commercial availability. Pigs, chickens, and turkeys are omnivores. These omnivores eat primarily both plants and non-plant (meat) materials. Cattle, sheep, rabbits, and bison are herbivores. As herbivores, they eat primarily plant materials. The LS views the natural behavior of chickens, turkeys, and pigs to be omnivorous. Therefore, the LS is considering the options of providing both plants and animal materials that are compatible with organic principles, production practices, and that allow omnivores their natural diet of plant and animal materials rather than feeding an unnatural herbivore diet. The LS is seeking stakeholder input on the issue of an omnivorous diet for organically raised omnivores.

II. Background

Chickens, turkeys, and pigs are omnivores. Omnivores, by nature, eat plant and non-plant materials. Organic production practices require that poultry and pigs be reared outdoors and on the soil. Because of this requirement, poultry and pigs should already be consuming plant and animal materials. These materials may include (1) grass and other plants, (2) insects and other invertebrates, (3) carrion, (4) vegetables, (5) fish or meat materials naturally, (6) herbs, (7) fruits, and (8) berries, nuts, and whatever else they find to eat. By foraging, the animals are performing their natural behavior in consuming a diverse diet that includes non-plant life.

Practical poultry and swine diets fed for normal growth, maintenance, production, and reproduction require essential amino acids, minerals, vitamins, and possibly fatty acid supplementation. As the organic community moves toward reducing or removing synthetic supplements in omnivore diets, a real need exists for organic omnivore producers to provide or be provided options for supplying the essential nutrients to these omnivores. Essential nutrients are needed in poultry and pig diets due to their inability to manufacture certain nutrients in adequate amounts for maintenance, growth, reproduction, and production. While some organic practices, including access to bio-diverse healthy pastures may provide some of these nutrients, supplementation may still be required. A case in point is methionine, an essential amino acid for poultry and pigs. Methionine comes in natural and synthetic forms. Methionine is naturally present in all feedstuffs with protein; however, the amount of methionine present varies among the various feedstuffs. Natural sources of methionine are corn gluten meal, crab meal, fishmeal, blood meal, alfalfa meal, and sunflower meal according to the NOP, (2012), Methionine Task Force, 2011, and NOP Technical Review of Methionine, 2011. There

is at least one company that market sea kelp which is claimed to replace synthetic methionine There is an organic feed mill which manufactures a soy free feed mix using fishmeal for providing sufficient amino acids(methionine, lysine, etc.), mineral, vitamins (Favre, 2012). However, the mill manufactures medium to small formulations, primarily for small or hobby poultry producers. The cost and availability at a commercial level may be prohibitive. As it relates to fish meal, there seems to be an inadequate supply of fish meal with no synthetic preservatives added that would make fishmeal a possible 1:1 replacement for synthetic methionine. There is interest in developing a natural source for methionine through extraction, fermentation or hydrolyzing protein, but at present, none of these processes currently provide a commercially viable alternative to synthetic methionine. (Fanatico, 2010). There is a potential herbal methionine on the market in India that might have applicability in the United States. Research results are promising and mixed. (Walker, 2012). Chattopadhyay, 2006 and Halder, G., and Roy, 2007 reports a 1:1 replacement for synthetic methionine with herbal methionine in broiler rations. However, Salome, et.al. 2010 reported inferior results. The difference could be due to herbal ingredients in the natural methionine product. Salome, et. al. 2010 suggested that the methionine requirement of broilers could be met by the supplementation of DL-Methionine and the use of animal protein sources.

Synthetic methionine was first petitioned in 1995, with technical reviews in 1996, 1999, 2001, and 2011. Currently, synthetic methionine is allowed in poultry diets at a maximum level of 4 pounds per ton of feed for layers, 5 pounds for broilers, and 6 pounds for other poultry. From October 2, 2012 to October 1, 2017, the step-down rate will be 2 pounds for layers, 2 pounds for broilers, and 3 pounds for other poultry. Methionine will be up for a sunset review prior to 2017 and a new petition by the Methionine Working Group (MWG) has been submitted. Therefore, the LS is seeking to advise and assist in increasing the dialogue in the organic community on possible approaches to obtaining viable and commercially available natural methionine alternatives for poultry before the October 31, 2017 sunset date for synthetic methionine.

Meat by-products and fish meals are good natural sources of essential minerals and vitamins. LS solicits our stakeholder input on possible ways to reduce synthetic nutrients (minerals, vitamins, and amino acids, etc.) in organic livestock rations by organic omnivore producers regardless to scale and type of operation. Significant work has been done on alternatives to synthetic methionine; yet more effort is still required. Time is of the essence. We believe that the current work into researching natural forms of methionine is encouraging. However, it needs to be accelerated. It could be that not one, but multiple organic practices may be required in order to provide a viable alternative to synthetic methionine.

III. Relevant Areas of the Rule

Relevant areas of the rules are briefly stated in this section. At Section 2110(3) of the Organic Foods Production act (OFPA) it reads, "…. no use of growth promoters and hormones on such livestock, whether implanted, ingested, or injected, including antibiotics and synthetic trace elements used to stimulate growth or production of such livestock." The National Organic Program regulatory text at § 205.239 (a) states, "the producer of an organic livestock operation must establish and maintain livestock living conditions which accommodate the health and ***natural behavior of animals***." The rule at §205.239(a) (1) further asserts that "access to the outdoors, shade, shelter, exercise areas, fresh air, and the environment are required." At §205.238(a)(2), it reads, "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)" is required.

At § 205.237 Livestock feed.

(a) The producer of an organic livestock operation must provide livestock with a total feed ration composed of agricultural products, including pasture and forage, that are organically produced and, if applicable, organically handled: *Except,* That, non-synthetic substances and synthetic substances allowed under §205.603 may be used as feed additives and supplements, (b) the producer of an organic operation must not: (1) use animal drugs, including hormones, to promote growth; (2) provide feed supplements or additives in amounts above those needed for adequate nutrition and health maintenance for the species at its specific stage of life; (3) feed plastic pellets for roughage; (4) Feed formulas containing urea or manure;
(5) feed mammalian or poultry slaughter by-products to mammals or poultry; or (6) use feed, feed additives, and feed supplements in violation of the Federal Food, Drug, and Cosmetic Act.(OFPA, 2002).

IV. Discussion

Prior to the 1950's poultry and pigs were fed a plant and meat based diet without synthetic amino acids such as methionine. One former NOSB member stated, "we have seemingly made vegetarians out of poultry and pigs" in §205.237(5) (b). As the organic community moves toward reducing or removing synthetic nutrients in the diets of poultry, a heightened need exists for the organic community to rally around omnivore producers to marshal our collective efforts in finding viable alternatives to synthetic methionine, and to help find approaches for making them more commercially available. The approaches need to be compatible with (1) omnivore natural behavior and food sources, (2) organic principles, and (3) good organic omnivore management practices.

To enhance our ability to consider and incorporate public comment into our decision-making process, the LS is seeking public input on this topic as a means of addressing this important concern. In particular, the LS seeks input regarding solutions to low supply of materials, commercial availability, approaches for providing a greater opportunity for the expression of an animal's natural behavior and providing a path for nutritional management of omnivores as omnivores rather than feeding a natural omnivore as a vegetarian or herbivore.

V. Discussion Questions Request from Stakeholders

The LS is seeking the public's perspective on the questions below. (Please indicate the question number in responses provided to these questions below.)

1. Would you recommend the LS look at a possible annotation to allow 100% organic meat scraps or by-products to be used in omnivore diets (poultry and pigs), since it is natural for these omnivores to consume both plant and animals materials? Explain.
2. Natural herbal methionine, potato meal, and corn gluten meal are showing promising results. Should this type of research effort increase? Explain.
3. There is a natural herbal methionine manufacturer in India that touts their product as being a 1:1 replacement for synthetic methionine. How can this product be brought to commercial availability/viability within the next three years in the United States?
4. How can the organic community spur more production and manufacturing of natural amino acids, including methionine and lysine, vitamins, and minerals products for livestock and aquaculture rations in the next three to five years?
5. While the FDA regulates the safety of meat/slaughter by-products, what additional organic regulations or safeguards should be in place before organic livestock producers feed mammalian or avian slaughter by-products to their omnivore livestock?
6. Would the organic brand be damaged if organic livestock producers were given the choice of feeding organic animal by-products and naturally or organically harvested fish by-products? Explain.
7. Would a rule change at §205.237(5) (b) to allow the feeding of organic meat offal or by-products to omnivores be appropriate to help fulfill the essential amino acids, vitamins, and minerals requirement? If yes, state the language you would use. If no, offer viable suggestions to dealing with the absence of synthetic amino acids in omnivore rations.

VII. References

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VIII. Summary

Poultry and pigs are omnivores and naturally eat plant, animal, and non-animal materials. Yet in organic livestock production, they are fed as vegetarians and herbivores. Maybe it is time to feed organic materials that are of both plant and animal origin.

IX. Committee Vote:

Moved: Tracy Favre Second: Jean Richardson

Yes: 8 No: 0 Abstain: 0 Absent: 0 Recusals: 0

National Organic Standards Board
GMO Ad hoc Subcommittee
Discussion Document
GMOs and Seed Purity
August 17, 2012

Introduction

Organic stakeholders are concerned about keeping genetically modified organisms (GMOs) (i.e., the products of transgenic plant or animal breeding) out of organic livestock feed, crops, and food. The production and handling of organic goods prohibits the use of “excluded methods” including transgenic modification. This prohibition applies to seeds used on organic farms. The organic community continues to be proactive in developing positions, procedures, and practices to encourage GMO prevention. An important part of this is ensuring genetic purity of seed used on organic farms. Pure seed is a cornerstone of true sustainability in an organic farming system.

Policy Memo 11-13 from the National Organic Program (NOP) affirms that organic certification is process based. The public comments to National Organic Standards Board (NOSB) and NOP continue to indicate a strong concern by both producers and consumers of organic foods for stronger steps to limit the potential and/or unintended presence of GMOs.

In 2012, the NOSB established the GMO Ad hoc Subcommittee. In this discussion document, the sub-committee seeks the input from organic stakeholders on the possibly of strengthening seed purity as one step to avoid the potential contamination of crops with GMOs. Seed may be the most impactful and efficient point in the supply chain at which GMO contamination of organic feed, crops, and food could be limited and controlled. This suggestion implies that recommending standards for the genetic content of seeds used in organic production would be an appropriate point of focus for NOSB.

Background

- The NOP Organic Rule refers to Genetic Engineering (GE) as an "excluded method". “Organic” is a label that indicates that a process has been followed to exclude GMOs.

- Producing organic feed, crops, and food ‘free’ of GMOs requires starting with seed that is not contaminated by GMOs.

- Public and marketplace expectations for the absence of GMOs in organic goods call for implementing best practices on conventional and organic farms to minimize the potential for such contamination.

- We suggest that the process for ensuring genetic purity of commercial seeds in organic production must be stricter than conventional crop production. Clean seed must be planted for the farmer to harvest uncontaminated food or feed. Planting and harvesting contaminated seed can increase the likelihood of “creeping contamination” from year to year, since any additional GE drift into a field planted with partially contaminated seed would produce food, crops, or feed with a higher level of contamination than in the original seed.

- Genetic purity in seed cannot be addressed by field observations of various visual off-types as has been practiced by the seed industry in the past. Genetic purity must also now encompass the presence or absence of GE contamination, with the protocols for making such a determination structured to meet the concerns and demands in the marketplace.

Relevant Areas of the Rule

NOP standards[1] adopted by USDA in a final rule published in December 2000 and fully implemented in October 2002 prohibited the use of GMOs in the production and handling of organic products certified to national organic standards.

The terminology used for GMOs in the NOP Regulation is "excluded methods" and is specified under section 205.2 (Terms Defined) as:

> **Excluded methods**. A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Excluded methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, *in vitro* fertilization, or tissue culture.

Detection and Testing Requirements: Under the residue testing requirements of NOP, products from certified organic operations may require testing when there is reason to believe that certified products have come into contact with prohibited substances or have been produced using excluded methods.

This requirement is specified in Subpart G (Administrative) of the regulations:

> **§ 205.670 Inspection and testing of agricultural product to be sold or labeled "organic."**
>
> (b) The Administrator, applicable State organic program's governing State official, or the certifying agent may require pre-harvest or post-harvest testing of any agricultural input used or agricultural product to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" when there is reason to believe that the agricultural input or product has come into contact with a prohibited substance or has been produced using excluded methods. Such tests must be conducted by the applicable State organic program's governing State official or the certifying agent at the official's or certifying agent's own expense.

[1] Title 7 CFR Part 205 - National Organic Program

NOP Policy: The NOP finalized a Policy Memo on July 22, 2011 (Policy Memo 11-13) on GMO. This policy memo reiterates that the use of GMOs is prohibited under NOP regulations, and answer questions that have been raised concerning GMOs, organic production, and handling. The clarification provided is consistent with the explanations provided in the preamble, thus emphasizing that organic certification is a process-based standard and the presence of detectable GMO residue alone does not necessarily constitute a violation of the regulation.

Commercial Availability of Organic Seed: The NOP regulations at 7 CFR § 205.204 require that organic producers use organic seeds, annual seedlings, and planting stock. The regulations allow producers to utilize non-organic seeds and annual or perennial planting stock when organic varieties are not commercially available.

The term "commercial availability" is defined under section 205.2 (Terms Defined) as:

The ability to obtain a production input in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic production or handling, as determined by the certifying agent in the course of reviewing the organic plan.

Discussion

1. Currently the organic standards require that seed used in organic production not be produced using excluded methods; and the marketplace is increasingly sensitive to contamination of organic crops by GMOs yet no standard or system exists to determine that the foundation of the value chain – seed - is free of GMOs.

2. The private sector has a variety of requirements and standards related to quantification of genetic materials (GM) content yet most of that data is not accessible to an accredited certifying agent and, therefore, is not currently helpful in terms of oversight and compliance. If it were available, there is no protocol within the organic sector for evaluating and using the testing results.

3. Farmers growing seed are increasingly being required to test for GMOs by their buyers in an ad hoc manner. Buyers may have different test protocols and evaluation of results which makes it difficult to compare and use the information.

4. Securing a supply of GMO free seed is critical to the long-term ability of organic to meet consumers' expectation of organic vis-a-vis GMOs.

5. Current NOP policy doesn't require verification that seed is free of GMO. However, if someone desires to have as thorough a process as possible to exclude GMOs, they may want to address their seed purity to the extent possible.

6. Despite the distinction between "excluded methods are not used" and "no traces of GMOs are present," the expectations of some consumers confuse these claims (and some marketers encourage this confusion).

7. The NOSB may consider in the future a universal genetic purity standard for seed to be used in organic production systems. An example of the standard would be the presence or absence of GE content, and the standard is equally applicable to conventional and organic seed. For example- no GE seeds found in a 3,000 seed sample. “None found” in a 3,000 seed sample corresponds statistically to a 95% probability that the actual GE contamination level in the seed lot is between zero percent and 0.10%. The use of terms like “non-detect” or” none found in the sample” is consistent with this goal, and less confusing than the statistical expression summarizing what “none found” in a sample means relative to the level of certainty that the whole lot is not contaminated.

8. The need to use organically grown seed is affected by the need for commercially available GMO tested seed to satisfy buyers. Farmers are challenged to balance prevention of GMO with adherence to the guidance on organic seed.

Discussion Questions

The GMO ad-hoc subcommittee is seeking response from the organic community to several questions regarding seed purity as follow:

1. Is there a need to establish a seed purity standard or protocol to ensure that planting seed meets the requirements of the NOP rule? Explain your answer.

2. What is currently known about the level of GMO contamination of seed used by organic farmers and any associated testing of seed on the farm or in the supply chain? Comments from farmers, seed companies, or buyers describing the following would be relevant:
   • the scope of testing (e.g. frequency, methods, costs);
   • the threshold used for rejection; and
   • the outcome of seeds that are rejected.

3. What testing methods are appropriate to use in order to determine and label for seed purity and to verify compliance to a seed purity standard?

4. How would an example such as proposed in Discussion point #7 above affect your farm or business?

5. Is there a better suggestion for a seed purity standard than that proposed in Discussion point #7 above? Describe.

6. What is known about relevant sampling, testing, and detection level protocol necessary to implement such a standard?

7. What training, guidance, or resources do certifiers need to verify compliance for to a seed purity standard?

8. What approach could an organic seed producers used to safeguard against GMO contamination from an adjacent or neighboring conventional farm? Buffer zones,

distance, planting time, pollination factors, and contamination possibilities/solutions could be included in your response.

Subcommittee Vote:
Motion to adopt the proposed Discussion Document on GMOs and Seed Purity.

Moved: Zea Sonnabend Second: Calvin Walker
Yes: 6 No: 0 Abstain: 0 Absent: 1

National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal
Biodegradable Mulch Film Made from Bioplastics

August 15, 2012

Introduction

A petition was submitted requesting the addition of biodegradable biobased bioplastic mulch to section 205.601(h) of the National List. This petition involves definitions of new substances, which the subcommittee recommends be incorporated into the listing. The subcommittee explicitly seeks public comment on the definitions and possible restrictions on use.

Background

Biodegradable mulch film made from bioplastics is petitioned to section 205.601 of the National List for use in organic crop production. This is an alternative to petroleum-based plastic mulches that do not completely biodegrade. Over the past 50 years much research and development has gone into developing biodegradable mulches which are the subject of this petition. As product development has been underway, removal and disposal of polyethylene plastic mulches has become increasingly difficult because its removal is time-consuming, delays cover cropping and must largely be sent to landfills. The OFPA requires the removal of plastic mulches at the end of the growing or harvest season (7 U.S.C. 6508).

The petitioner argues that OFPA's mention of plastic was not intended to refer to biodegradable mulch film. Biodegradable mulch is intended to biodegrade by the end of the season or prior to the beginning of the following season. This distinction leads us to question whether the approval of the petition would require a rule change to allow the mulch to biodegrade in the field or whether the two substances should be treated as separate and distinct. However, bioplastics are defined in terms of "plastics," according to the petitioner, "Biodegradable Plastic Mulch is defined as plastic mulching material that meets both of the following requirements." Furthermore, bioplastics fit the definition of plastic, "Any of various organic compounds produced by polymerization, capable of being molded, extruded, cast into various shapes and films, or drawn into filaments used as textile fibers." (*American Heritage Dictionary*) The petition defines biodegradable mulch film as mulching materials that:

1) meet the requirements of ASTM International (formerly American Society for Texting and Materials) Standard D6400 or D6868 specifications, or of other international standard specifications with essentially identical criteria, i.e. EN 13432, EN 14995, ISO 17088; and

2) show at least 90% biodegradation absolute or relative to microcrystalline cellulose2 in less than two years, in soil, tested according to ISO 17556 or ASTM 5988.

Additionally, the petitioner suggests that the reference to "fully biodegradable" in section 205.206(c)(1) be defined when referencing bioplastic degradation in soil. Full biodegradation is covered under several standards which discuss the compostability of the petitioned product. These include, American Society for Testing and Materials (ASTM) Standard D5988 (biodegradability of bioplastic in soil), ASTM Standard D6400 (biodegradability of bioplastic in compost), and ASTM Standard D6868 (biodegradability of bioplastic specifications). The

ASTM definition of “biodegradable plastic” is, “a degradable plastic in which the degradation results from the action of naturally occurring microorganisms such as bacteria, fungi, and algae.”

The petition further clarifies, that according to the European Bioplastics’ definition, bioplastics are biobased, biodegradable, or both. The ASTM definition of “biobased material” is “organic material in which carbon is derived from a renewable resource via biological processes. Biobased materials include all plant and animal mass derived from carbon dioxide recently fixed via photosynthesis, per definition of a renewable resource.” Biobased materials are certified using the ASTM D6866 method, which certifies the biologically derived content of bioplastics.

The petition provides the following description: biodegradable films are produced from bioplastics that meet standards for aerobic biodegradation in soil. These bioplastics are comprised of structural units which may be easily broken down into carbon substrates by soil microorganisms. Under aerobic conditions, these microorganisms are able to utilize the carbon substrates as a food source. This metabolism of the carbon substrates ultimately results in two simple compounds – carbon dioxide and water.

Relevant areas in the Rule

OFPA §6508 (c) says

> For a farm to be certified under this chapter, producers on such farm shall not -
> …(2) use plastic mulches, unless such mulches are removed at the end of each growing or harvest season;

The regulations provide at §205.206(c) that

> Weed problems may be controlled through:
> … (6) Plastic or other synthetic mulches: *Provided,* That, they are removed from the field at the end of the growing or harvest season.

And the National List includes at §205.601(b)(2)

> Mulches.
> …(ii) Plastic mulch and covers (petroleum-based other than polyvinyl chloride (PVC)).

Discussion

Neither conventional plastic mulch nor biodegradable bioplastic mulch can perform all of the functions—particularly, feeding the soil—that organic mulches perform. However, there are times—such as when cold soil is a problem—when the qualities of plastic or bioplastic have been viewed as necessary. As always, it is our understanding that the use of synthetic mulch products will be limited to those circumstances when natural organic mulches are inappropriate or impossible to use. When this is the case, it makes sense to use a material that degrades in place rather than one that is removed and taken to a landfill. On the other hand, the subcommittee believes that it may be difficult to separate claims from truth concerning biodegradability and the source of the material. In addition, the subcommittee would like to make a robust recommendation that correctly describes biodegradable biobased bioplastic mulches that meet the three criteria above. According to the European Bioplastics definition, bioplastics are biobased, biodegradable, or both. The committee intends this recommendation to cover those bioplastics that are both biobased and biodegradable.

The subcommittee understands the importance of a definition, which it is proposing, and is particularly interested in public comment on the biobased classification and the ASTM standard. Meeting this standard, however, does not automatically ensure that the mulch will be "removed from the field at the end of each growing or harvest season." This removal may require steps like tilling the film into the ground. The subcommittee therefore proposes the annotation that growers take appropriate actions to guarantee that the mulch decomposes within the appropriate time frame.

Evaluation Criteria

(Applicability noted for each category; Documentation attached)	**Criteria Satisfied? (see "B" below)**		
1. Impact on Humans and Environment	☒ Yes	☐ No	☐ N/A
2. Essential & Availability Criteria	☒ Yes	☐ No	☐ N/A
3. Compatibility & Consistency	☒ Yes	☐ No	☐ N/A
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for § 205.606)	☐ Yes	☐ No	☒ N/A

Substance Fails Criteria Category: [ ] **Comments:**

Proposed Annotation:
List on §205.601(b)(2) Mulches: (iii) Biodegradable biobased bioplastic mulch meeting the following criteria: (A) Completely biodegradable as shown by: 1) meeting the requirements of ASTM Standard D6400 or D6868 specifications, or of other international standard specifications with essentially identical criteria, i.e. EN 13432, EN 14995, ISO 17088; and 2) showing at least 90% biodegradation absolute or relative to microcrystalline cellulose in less than two years, in soil, tested according to ISO 17556 or ASTM 5988; (B) Biobased certified using the ASTM D6866 method; (C) Must be produced without excluded methods; (D) Must be produced without engineered nanomaterials; and (E) Grower must take appropriate actions to ensure complete degradation at the end of each growing or harvest season.

Basis for annotation: ☒ To meet criteria above ☒ Other regulatory criteria ☐ Citation
Notes: Annotation is necessary to meet the requirements of OFPA §6508(c).

Recommended Subcommittee Action & Vote, including classification recommendation (state actual motion):

Classification Motion:
Biodegradable Mulch Film Made from Bioplastics is synthetic.

Motion by: Colehour Bondera Seconded by: Jay Feldman
Yes__**8**___ No__**0**__ Abstain__0__ Recuse__0__ Absent__**0**__

Listing Motion:
To list on §205.601(b)(2) Mulches: (iii) Biodegradable biobased bioplastic mulch meeting the following criteria: (A) Completely biodegradable as shown by: 1) meeting the requirements of ASTM Standard D6400 or D6868 specifications, or of other international standard specifications with essentially identical criteria, i.e. EN 13432, EN 14995, ISO 17088; and 2) showing at least 90% biodegradation absolute or relative to microcrystalline

cellulose in less than two years, in soil, tested according to ISO 17556 or ASTM 5988; (B) Biobased certified using the ASTM D6866 method; (C) Must be produced without excluded methods; (D) Must be produced without engineered nanomaterials; and (E) Grower must take appropriate actions to ensure complete degradation at the end of each growing or harvest season.

Motion by: Colehour Bondera Seconded by: Barry Flamm
Yes__**7**___ No__**0**__ Abstain__**1**__ Recuse__**0**__ Absent__**0**__

Crops	☒	**Agricultural**	☐	**Allowed**[1]	☐
Livestock	☐	**Non-synthetic**	☐	**Prohibited**[2]	☐
Handling	☐	**Synthetic**	☒	**Rejected**[3]	☐
No restriction	☐	**Commercial unavailable as organic**	☐	**Deferred**[4]	☐

[1]Substance voted to be added as "allowed" on National List to § 20 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:

Approved by Subcommittee Chair to Transmit to NOSB

Jay Feldman, Subcommittee Chair August 15, 2012

NOSB Evaluation Criteria for Substances Added To the National List

Category 1. Adverse impacts on humans or the environment? Substance: Biodegradable Mulch Film Made from Bioplastics

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		TER 525-531: The production of PLA & PHA involves fermentation processes & feedstocks derived from natural sources (with the exception of genetically-modified organisms). The potential for environmental

				contamination from these products is limited, with the exception of the metal salt catalysts used to polymerize PLA (Bastioli, 2005). No reports of tin contamination from production of bioplastics were found.
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		x		TER 533-537: Many of the feedstocks used in the production of AAC could be hazardous if they were spilled or discharged into the environment during manufacture & processing. No specific reports of environmental contamination from these compounds as a result of manufacturing bioplastics were found. Systematic reviews of the environmental impact from manufacturing of bioplastics were not found. TER 547-550: Erucamide, glycerol, & searic acid amide could be released to the environment through multiple manufacturing processes, including bioplastics production. No research reports were found that described environmental releases of these chemicals from bioplastics manufacturing.
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]		x		TER 614-621: The researchers concluded that using PE mulch may have a harmful effect on the environment due to increased runoff & is less sustainable than vegetative mulch (Rice et al., 2001). Based on their similarities in construction & intended use, bioplastic mulches would likely have similar environmental impacts to PE mulch, though their greater tendency to degrade sooner than PE mulch may decrease some of the adverse environmental impacts. TER 623-627: Anaerobic degradation of bioplastics may produce methane (greenhouse gas). Research was not found that quantified methane emissions from bioplastic mulch use. Degradation of bioplastic mulches must take place in an aerobic environment in the soil to prevent methane emissions. TER

				629-630: Adverse environmental impacts from the use of bioplastic mulches are only likely to occur if the material does not completely biodegrade in soil. TER 652-657: Some reports have shown that bioplastics containing terephthalic acid at concentrations over 50% do not completely biodegrade in soil (Bastioli, 2005).
4. Does the substance contain List 1, 2 or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]			x	
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		x		TER 566-567: The plastics are inert in the soil when they are intact, and are biodegraded by soil microorganisms.
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		x		TER 582-587: Given the complete aerobic biodegradation of bioplastic mulches, the by-products are carbon dioxide, water, & soil biomass. Soil biomass refers to the total amount of microorganisms in the soil, excluding plant roots & macrofauna (NRCS, 2012). The increase in biomass may cause a concomitant increase in the populations of microorganisms that degrade the mulches on a local basis. This could lead to changes in the population dynamics of microorganisms in the soil. TER 593-595: Complete degradation of the bioplastics depends on blending the polymers to maximize degradability & depends on the composition of soil microorganisms.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		x		TER 352-354 ASTM standard D5988 is designed to be applicable to bioplastic materials that are “not inhibitory to the bacteria & fungi present in the soil”…it could be assumed that the bioplastic does not inhibit soil bacteria or fungi by its breakdown processes. TER 357-358: Many bacteria & fungi in the soil can use bioplastics derived from starch as a carbon source (Shah et al., 2008). TER 409-410: Biochar, a method of generating carbon black for soil

				amendment, may help promote nutrient use efficiency in treated soils (Chan, 2008; Hunt, 2010).
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		x		TER 446-447: Studies were not found that specifically assessed the ecotoxicity of bioplastics following degradation in the soil, & a better understanding of bioplastic degradation & soil environmental effects is needed. TER 462-466: It seems unlikely that the source material (the bioplastic film) would interact with other organisms & cause toxicity. The material is manufactured to remain intact & inert during its intended use, then (ideally) break down at the end of the season.
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]	x	x		TER 330-333: The petitioner states that biodegradable mulch film is defined in two ways…Second, by "show[ing] at least 90% biodegradation absolute or relative to microcrystalline cellulose in less than two years, in soil, tested according to ISO 17556 or ASTM 5988." TER 347-350: ISO 17556 & ASTM 5988 are equivalent standards. They "describe the standard test method for determining aerobic biodegradation of plastic materials in soil." This standard is most applicable to the proposed use of the bioplastic mulch because the mulches will be left in the field at the end of the season to biodegrade according to their petitioned use. TER 356-357: Biodegradability is quantified by measuring the amount of carbon dioxide released from the soil over time. TER 362-370: degradation occurs quicker when chiseled or tilled into the soil during times of warm temperatures & moisture in soils with high organic matter. TER 374-375: Hydrolysis breaks PLA into lactic acid & water-soluble compounds. Once this breakdown occurs, PLA is completely mineralized to CO2, water, & biomass. TER 384-386:

				Degradation of PHA occurs by enzymatic hydrolysis at the surface of the film, which is carried out by soil microbial populations. Hydrolysis breaks the PHA polymers into oligomers & monomers which are subsequently consumed & assimilated by microbes in the soil as nutrients. TER 395-399: All of the commercially available AAC polymer materials contain terephthalic acid, which is most responsible for determining the degradation rates in AAC plastics. As the fraction of terephthalic acid increases, the degradation rate decreases. No significant biological degradation was found when the molar fraction of AAC was increased to more than 60%, which is thought to be due to the relatively low melting point of terephthalic acid (Bastioli, 2005). TER 405-410: Carbon black is elemental carbon in the form of a particulate that is manufactured from burning or partial combustion of hydrocarbons (NLM, 2011)…it is resistant to breakdown in the soil environment. TER 412-419: Titanium dioxide is found as the minerals rutile, octahedrite, brookite, ilmenite, & perovskite. Titanium dioxide may persist in soil as the by-product of titanium tetrachloride hydrolysis (ATSDR, 1997), so it may persist from use in bioplastic mulch as well. Titanium dioxide may settle out into sediments & persist for long periods of time (ATSDR, 1997). The compound is characterized by ATSDR as " a very inert compound" (ATSDR, 1997). TER 421-425: Erucamide (plasticizer) binds strongly to soil & sediments in water & is likely to bioconcentrate in aquatic organisms, meaning it will occur at higher levels up the food chain (NLM, 2011). The physical properties of erucamide suggest that the material

				will persist in the environment, and would be found in the water, soil & air if released (NLM, 2011). TER 427-431: Glycerol (plasticizer) released to the environment will be present as both a vapor & a particle in the atmosphere, but will be degraded within hours (NLM, 2011). The potential for bioconcentration in aquatic organisms is low for glycerol in aquatic environments (NLM, 2011).
10. Are there any harmful effects on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4]		x		TER 663-673: Pesticide runoff may be increased if plastic mulches are used in agricultural production due to the creation of impervious surfaces (Rice et al., 2001). The increase in pesticide loads may lead to an overall increase in the pesticide load in waterways which could potentially impact human health by causing increases in pesticide loads in downstream drinking water sources. No other reports of impacts on human health from the use of bioplastic mulches were found in the published literature.
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.

NOSB Evaluation Criteria for Substances Added To the National List

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

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]	x			TER 294-296: Bioplastic mulches are manufactured with the addition of synthetic plasticizers and colorants which are added using a synthetic process.
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]	x			TER 301-302: To develop PLA the lactic acid monomers must be polymerized. This is accomplished through the use of a chemical catalyst. TER 302-305: Fermentation is a naturally occurring process, but under laboratory conditions, the feedstocks and environmental conditions are manipulated in order to provide an environment that is most conducive to production of PLA, a process which would be unlikely to occur in nature. TER 309-310: Researchers have developed genetically-engineered bacterial strains that produce PHA more efficiently & in differing polymer amounts. TER 313-315: PHA production by fermentation is a natural process, but the conditions used in laboratories to maximize yields and polymer amounts are not naturally occurring. TER 317-319: Some feedstocks used to produce AAC are naturally occurring, but the chemical processes used to refine them for use do not occur in nature, nor do the synthetic processes that are used to create the ester linkages.
3. Is the substance created by naturally occurring biological processes? [6502 (21)]	x	x		
4. Is there a natural source of the substance? [§205.600 b.1]			x	
5. Is there an organic substitute? [§205.600 b.1]			x	
6. Is the substance essential for			x	

handling of organically produced agricultural products? [§205.600 b.6]				
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	x			TER 679-682: The petitioned substance would be an alternative to synthetic, non-degradable substance, polyethylene plastic mulch. Bioplastic mulch is produced through synthetic processes as previously described, but is created to be biodegradable, a reason for its petitioned use in organic agriculture. TER 684-690: Mulches made from biomass include bark, cocoa-bean hulls, corncobs, grass clippings, leaves, pine needles, sawdust, straw, & wood chips. Biomass mulch availability may depend on what types of plants or crops are available in the area & the type of crop they are used in.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]			x	
9. Is there any alternative substances? [§6518 m.6]	x			TER 717-721: Living mulch involves planting a low-growing cover crop that is effective at competing with weed species. The drawback is that living mulches compete for nutrients & water & reduce yields. Reports discuss the need to strike a balance between environmental impact, cost, ease of use, & crop yields to determine which alternative is most beneficial for individual farms & crops.
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.

NOSB Evaluation Criteria for Substances Added To the National List

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

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]			x	
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]	x	x		The substance is of synthetic origin but appears to completely biodegrade in a two-year timeframe. This serves as an alternative to the current practice of using synthetic, non-degradable, polyethylene plastic mulch.
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]	x			
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]			x	
5. Is the primary use as a preservative? [§205.600 b.4]			x	
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]			x	
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: a. copper and sulfur compounds;		x		
b. toxins derived from bacteria;		x		
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?		x		
d. livestock parasiticides and medicines?		x		
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?		x		TER 218- 221: Bioplastic mulch is used as a production aid, but is not technically considered a row cover because they increase soil temperature, reduce weed pressure, maintain soil moisture levels, and may

				help extend the growing season.

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

NOSB Evaluation Criteria for Substances Added To the National List

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

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. 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	

[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.

National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal
Ferric Phosphate (to Remove)

August 15, 2012

Introduction:
Ferric Phosphate has been petitioned to be removed from the National List 205.601(h). The reason given in the petition is that it cannot be used without EDTA, which according to the EPA can either be considered an active ingredient or an inert ingredient.

Background:
In 2007 the NOSB considered a petition for "Sodium Ferric Hydroxyl EDTA" aka "Ferric Sodium EDTA" and voted not to allow it, partly because of concern about the EDTA component. In 2008 and 2009 Steptoe & Johnson Law Firm submitted a petition to delist Ferric Phosphate. The main argument was that it does not work by itself and is always used with EDTA. The Technical Report (TR) requested in 2009 was received in June 2010. From 2009 to 2011 the Walter Talarek Law Firm submitted voluminous amounts of written comment in defense of keeping Ferric Phosphate listed. Much of the data submitted with this comment was not considered in the TR and needed to be reviewed objectively.

These two law firms represent competing product manufacturers and each is accusing the other of misrepresenting their data. Therefore the NOSB is having a big challenge in determining the truth among all the arguments. The Crops Subcommittee requested an unbiased review of a few specific and targeted questions of all available information, including the TR, the public comment from the last 2 years, and independent sources.

Relevant areas in the Rule:
The National List includes at:

§205.601(h)

As slug or snail bait. Ferric phosphate (CAS # 10045–86–0).

and

§205.601(m)(1)

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

Discussion:
The Supplemental TR (STR) received in July 2012 addressed the following questions and provided the following answers. At the request of the NOP, the USDA Agricultural Research Service (ARS) reviewed the STR; ARS citations follow below.

1. Is ferric phosphate alone an effective molluscicide? Can it be combined with other ingredients besides EDTA and still work, or are EDTA and related compounds the only ones that contribute to efficacy?
    - *STR 66-69: Effective bait formulations have been made by combining a metal with "an appropriate organic ligand" to form a metal chelate, [1] for example aluminum and iron chelates (Henderson and Triebskorn, 2002). The compound EDTA is one example of a chelating agent, and it appears that all of the ferric phosphate slug and snail baits currently marketed in the U.S. contain EDTA in their formulations.*

- *STR 182-187: Based on the available studies (summarized in Table 1), there is not enough evidence to definitively conclude that ferric phosphate alone is an effective molluscicide when incorporated into ingestible baits. The limited evidence does support the conclusion that iron baits that contain a chelating agent such as EDTA are typically more effective at killing snails and slugs than iron baits that lack a chelating agent (Henderson et al., 1989; Zheng et al., 2008; Whaley, 2007). However, the Whaley (2007) study demonstrated that ferric phosphate alone can have at least some molluscicidal activity against slugs.*
- *STR 192-194: Besides EDTA, at least one other chelating agent has been used in combination with ferric phosphate in order to increase its efficacy as a molluscicide. That compound is (S,S)-ethylenediaminedisuccinic acid (EDDS), a structural isomer of EDTA that is biodegradable (Tandy et al., 2006).*
- *ARS pg. 1: The report…presents convincing evidence that ferric phosphate is toxic to slugs, but that it requires a chelating agent as a synergist in order to make it an effective product. Other types of aminopolycarboxylic acid chelating agents are available and EDDS, at least, is also an effective synergist.*

2. Are there reasons for concern about EDTA beyond what information goes into a tolerance exemption, such as effects on soil organisms or contamination in groundwater?
    - *STR 273-275: there is not enough evidence to definitively conclude whether ferric phosphate molluscicides containing EDTA are toxic to earthworms following typical rates of application.*
    - *STR 282-283: No information was found linking the specific use of EDTA in pesticide formulations to groundwater pollution.*
    - *ARS pg. 2: The Technical Review might have gone into more detail on potential environmental challenges posed by EDTA and compared it to other aminopolycarboxylic acid chelating agents. On the one hand, industrial use of EDTA has resulted in detectable residues in oceans and surface water, without apparent harm. On the other hand, such wide distribution and concentration within sediments could have unforeseen effects on particular ecosystems.*

3. Does the EDTA as used with ferric phosphate pose the same concerns as the EDTA that was reviewed as part of the Sodium Ferric Hydroxyl EDTA?
    - *STR 295-296: The EDTA used with ferric phosphate poses the same concerns that were raised for EDTA as part of the review of sodium ferric hydroxyl EDTA*
    - *ARS pg. 2: The Technical Review makes the case that EDTA poses the same concerns whether used with ferric phosphate or as sodium ferric hydroxyl EDTA. Given the dynamic nature of the status of a chelated molecule of EDTA, the Technical Review's conclusion seems reasonable.*

4. Are there any unbiased studies that back up the findings of Edwards et al. (2009) as cited in the TR or with contrasting results? Does the Edwards et al. (2009) study seem biased?
    - *STR 318-319: There are three available studies that evaluate the potential toxicity of ferric phosphate molluscicides containing EDTA to earthworms: Edwards et al., 2009 (sponsored by Lonza Ltd.); Langan and Shaw, 2006 (not sponsored by Lonza Ltd., however the authors were assisted by two Lonza employees); Luhrs, 2009 (sponsored by Neudorff).*
    - *STR 411-413: Based on the available studies (summarized in Table 2), there is not enough evidence to definitively conclude whether ferric phosphate molluscicides*

containing EDTA are toxic to earthworms following typical rates of application. All of the studies have strengths and limitations.

- *ARS pg. 2: Although the Technical Review concludes that there is not enough information to conclude with certainty that ferric phosphate slug-control products are harmful to earthworms, the study by Langan and Shaw (2006) certainly seems to be independently gathered data showing that under some conditions and for some earthworm species, Sluggo-type products can be harmful. Accepting this conclusion would indicate that the Edwards study is not likely to be biased.*

STR and ARS responses have been incorporated into the Checklist. Despite the information presented in the STR, the Crops Subcommittee recommends to vote down the petition to remove Ferric Phosphate from the National List. The generic active ingredient, Ferric Phosphate, needs to be considered separately from any other ingredients, either active or inert.

The inerts in the formulated Ferric Phosphate product are allowed under section 205.601(m)(1). Because of this, the generic ferric phosphate substance should remain on the National List. The NOSB-NOP-EPA Working Group on Inerts (IWG) will address the topic of inerts in pesticide products.

Minority View

The supplemental information received by the Crops Subcommittee concludes that it is actually the combination of at least two ingredients, ferric phosphate and EDTA, that establishes the efficacy of the registered product currently allowed under the ferric phosphate listing: § 205.601 Synthetic substances allowed for use in organic crop production, (h) As slug or snail bait. Ferric phosphate (CAS # 10045–86–0).

ARS pg. 1, as cited above, states, “[The TR] presents convincing evidence that ferric phosphate is toxic to slugs, but that it requires a chelating agent as a synergist in order to make it an effective product.” The STR, line 82, states,

> “[I]n a letter to the NOSB, the technical director for OMRI comments, “Based on the evidence compliled by OMRI, ferric phosphate as currently listed at 205.601(h) is not effective as an active ingredient without an additional chelating agent, such as EDTA,” and, “chelating agents such as EDTA facilitate the absorption of the metal into the body.” (OMRI, 2010)”

STR, line 90, states, “Puritch et al. (1995) claimed that an effective mollusc bait would be composed of both a simple iron compound and a second component, such as edetic acid (EDTA), hydroxyehyl derivative of edetic acid, or a salt of these acids. It also stated that individually neither component is toxic to terrestrial molluscs, but the composition becomes toxic once it is ingested. Therefore, this patent suggests that a chelating agent such as EDTA is necessary for ferric phosphate to be an effective molluscicide.”

In the lexicon of pesticide law, a material that is incorporated into a pesticide for the purpose of killing the target pest, and therefore necessary to kill, or elevate its efficacy in killing the target pesticide, is considered an active ingredient in that product. Therefore, EDTA must be evaluated an active component of the mixture of chemicals in the current slug or snail bait allowed under section 205.601(h).While ferric phosphate or similar iron salts may express toxic

properties, as identified in several studies, STR, line 117, indicates that, “It [Henderson et al., 1989] was reported that the baits containing the chelated compound killed a greater proportion of the slugs than the baits with the simple, iron salt, but quantitative results and tests of statistical significance were not provided.” Other studies do show less efficacy associated with pure iron phosphate baits when compared to the chelated baits.

The minority view holds that the use of EDTA is integral to killing the slug and snail as the target organism with the level of efficacy to be of value in the field. Therefore, the petitioner is correct that EDTA is an active ingredient in the materials allowed under section 205.601(h) since under this provision “ferric phosphate” is not sold for slug or snail bait without EDTA for its active properties and therefore must be evaluated in reaching a determination on its acceptability for listing on the National List.

The ARS review, pg 2, and the STR, line 295, find that, “The EDTA used with ferric phosphate poses the same concerns that were raised for EDTA as part of the review of sodium ferric hydroxyl EDTA.”

> STR, line 298 states, “The NOSB Crops Committee voted to reject sodium ferric hydroxyl EDTA (SFH EDTA) for use as a slug and snail bait in 2007 (NOSB Crops Committee, 2007). The reasons cited for rejection were that ferric phosphate is already listed for that use, concerns about potential harm to humans and the environment, and inconsistency with organic farming and handling. The Crops Committee concluded that EDTA clearly has the potential to be harmful to the environment and can result in the detrimental movement of metals in soils and river sediments. Furthermore, the Crops Committee was concerned about EDTA’s slow rate of biodegradation and its persistence in the environment. The EU Commission risk assessment on EDTA (EC, 2004) was cited as the reference for this conclusion. The potential harmful effects of EDTA on human health were also a concern to the Crops Committee. In particular, the Committee concluded that “EDTA is a very strong metal chelating agent, especially for calcium. It is poorly absorbed in mammalian GI tract and concerns have been raised that excessive usage in food could deplete the body of Ca and other minerals” (NOSB Crops Committee, 2007).”

The minority view associated with these facts supports the claims of the petitioner.

Evaluation Criteria

(Applicability noted for each category; Documentation attached)	**Criteria Satisfied? (see “B” below)**		
1. Impact on Humans and Environment	☒ Yes	☐ No	☐ N/A
2. Essential & Availability Criteria	☒ Yes	☐ No	☐ N/A
3. Compatibility & Consistency	☒ Yes	☐ No	☐ N/A
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for § 205.606)	☐ Yes	☐ No	☒ N/A

Substance Fails Criteria Category: [ ] **Comments:**

Proposed Annotation (if any): N/A

Basis for annotation: ☐ To meet criteria above ☐ Other regulatory criteria ☐ Citation
Notes:

Recommended Subcommittee Action & Vote, including classification recommendation (state actual motion): Motion to remove Ferric Phosphate from section 205.601(h)

Classification Motion: N/A

Listing Motion: Motion to remove Ferric Phosphate from section 205.601(h)

Motion by: Carmela Beck Seconded by: Jay Feldman
Yes__**3**___ No__**5**__ Abstain__**0**__ Recuse__**0**__ Absent__**0**_

Crops	☒	**Agricultural**	☐	**Allowed**[1]	☐
Livestock	☐	**Non-synthetic**	☐	**Prohibited**[2]	☐
Handling	☐	**Synthetic**	☒	**Rejected**[3]	☒
No restriction	☐	**Commercial unavailable as organic**	☐	**Deferred**[4]	☐

[1]Substance voted to be added as "allowed" on National List to § 205. 601(h) 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:

Approved by Subcommittee Chair to Transmit to NOSB

Jay Feldman, Subcommittee Chair August 15, 2012

NOSB Evaluation Criteria for Substances Added To the National List

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

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other) [1],[2]
1. Are there adverse effects on environment from manufacture, use, or disposal?			X	

[1] Unidentified line numbers refer to the Ferric Phosphate TR, June 15, 2010.
[2] STR labeled line numbers refer to the Supplemental Ferric Phosphate TR, July 26, 2012.

[§205.600 b.2]				
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		The only by-products of this process are sodium sulfate and water. Sodium sulfate is precipitated with lime and used as a secondary raw material. The water is released into a wastewater clarification plant (260-261). No information was found linking the specific use of EDTA in pesticide formulations to groundwater pollution (STR 282-283). While reported as occurring naturally in soil, ferric phosphate, if combined with chelating agents such as EDTA or EDDS may cause the accumulation of larger concentrations of iron than would be expected under normal conditions (303-305). On the one hand, industrial use of EDTA has resulted in detectable residues in oceans and surface water, without apparent harm. On the other hand, such wide distribution and concentration within sediments could have unforeseen effects on particular ecosystems (ARS, pg. 2).[3] [Minority view addition: Sodium cyanide and formaldehyde are used in making EDTA.[4]]
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		Another important issue is the level of mammalian toxicity of iron phosphate-based molluscicides containing EDTA or other chelating agents, especially since if chelating agents increased the uptake of iron from soils into crops they may be fed upon by humans (342-345). The EPA (1998) states: A number of ecological effects toxicology data requirements were waived based on the known lack of toxicity of iron phosphate to birds, fish and non-target insects, its low solubility in water, conversion to less soluble form in the environment (soil), and its use pattern (soil application). (424-426). Submitted studies involving ground beetles, rove beetles and earthworms demonstrated that the product will not affect these organisms at up to two times the maximum application rate (430-432). If NOP's consultant who wrote Report had had access to Neudorff's Opinion, he would have seen that Edwards et al (2009) serves to demonstrate the harmlessness of NEU1165M Slug & Snail Bait to earthworms when it is applied at the recommended application rate (Talarek, 7)[5]. This section also states that assuming the reports of mammalian toxicity are accurate, that would demonstrate the potential for some level of persistence on the food chain. This is a non-sequitur. If one

[3] USDA Agricultural Research Service (ARS) review of the STR, June, 26, 2012.
[4] http://en.wikipedia.org/wiki/Ethylenediaminetetraacetic_acid
[5] Law Offices of Walter G. Talarek, P.C. letter to the NOP, October 7, 2011.[6] Unidentified line numbers refer to Ferric Phosphate TR, June 15, 2010.

				reads the reports of adverse incidents reported to EPA, one sees that most incidents involve minor acute effects that immediately follow oral exposure of dogs to the product; the incidents do not occur one month, two months, or a year after exposures. The environmental impact of ferric phosphate slug & snail baits is clear – there is none (Talarek, 7). [Minority view discussion: Combination toxic to earthworms, perhaps more. (409-417)[6]TR discusses Edwards et al (2009) conclusions, "Clearly, molluscicides containing iron phosphate and EDTA or EDDS chelating agents may present significant environmental hazards to earthworms, domestic animals and humans and these issues need further investigation. The registration statuses of these chemicals in USA and Europe should be reviewed in light of these new data and conclusions "(Edwards, et al. 2009). The TR says "This also illustrates a mode by which ferric phosphate could be introduced into the food chain." (347-351) Although the Technical Review concludes that there is not enough information to conclude with certainty that ferric phosphate slug-control products are harmful to earthworms, the study by Langan and Shaw (2006) certainly seems to be independently gathered data showing that under some conditions and for some earthworm species, Sluggo-type products can be harmful. Accepting this conclusion would indicate that the Edwards study is not likely to be biased. (ARS)]
4. Does the substance contain List 1, 2 or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]		X		
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		X		During the formulation process, there are no chemical reactions which form ferric EDTA or ferric phosphate EDTA as an active ingredient (Talarek, 5). [Minority view discussion: EDTA can result in the detrimental movement of metals in soils and river sediments (EU Commission Risk Assessment on EDTA)]
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		X		[Minority view discussion: Grčman et al. (2003) found that addition of 10 mmol EDTA/kg soil (2920 mg/kg) decreased the structure of the fungal community in heavy metal polluted soil compared to a control treatment on days 1 and 56 after application. Results of a different trial showed that EDTA caused stress to soil microorganisms, as indicated by a significant increase in the *trans* to *cis* phospholipid fatty acid ratio (Grčman et al., 2003). Epelde et al. (2008) studied the effects of

[6] Unidentified line numbers refer to Ferric Phosphate TR, June 15, 2010.

				EDTA (1000 mg/kg soil) on soil enzyme activities, potentially mineralizable nitrogen, soil basal microbial respiration, and substrate induced respiration (a measure of potentially active microbial biomass). In control non-polluted soils, EDTA caused a significantly negative effect on the soil microbial community activity (evidenced by a decrease in dehydrogenase activity and basal respiration). Examples of phytotoxicity observed in studies following the addition of EDTA to soil (1000-2920 mg EDTA/kg soil) include necrotic lesions on cabbage leaves/lowered yield of cabbage biomass, decrease of corn growth to 60% of control, signs of chlorosis and necrosis in white bean, and decreased biomass of cardoon plants (Grčman et al., 2003; Evangelou et al., 2007; Epelde et al., 2008). The studies demonstrating toxic effects of EDTA on soil microorganisms and plants involved EDTA soil concentrations that are much greater than the EDTA soil concentration expected from the use ferric phosphate baits, but it is not known if toxic effects on soil microorganisms and plants would occur from the use of slug and snail baits containing EDTA because no studies were found that tested relevant concentrations of EDTA in soil. (STR 237-269) Also, EDTA is not degraded rapidly in the environment and is the most abundant anthropogenic chemical in some European surface waters (SFHEDTA checklist[7])]
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		The EPA (2008) reported 5 domestic animal deaths, 8 major domestic animal incidents and 106 moderate and minor domestic animal incidents from the sue of iron phosphate slug and snail baits marketed in the USA up to May 7, 2008 (322-324). While this may be true, it is important to note that when the incident reports are reviewed carefully, in most cases, and in particular with regard to the reports of domestic animal deaths and major animal incidents, there are speculative exposures to the products, animals had preexisting conditions which were more likely to have caused the effects or there were exposures but the effects could not have been caused by the products; however, Neudorff felt that it was obligated under the law to report all incidents no matter how remote the exposure an effect relationship (Talarek, 5). EPA's August 13, 1997, Decision Memorandum on "Consideration of Registration of an end-use

[7] SFHEDTA Checklist is the checklist produced by the Crops Committee for Sodium Ferric Hydroxyl EDTA November 2007.

				product (NEU1165M Slug & Snail Bait, EPA File Symbol 67702-G)…does not indicate that there is a significant hazard to humans or domestic animals (Talarek, 6). EPA has issued tolerance exemptions for ferric phosphate & all the inert ingredients in Neudorff's slug & snail baits, thus indicating that these chemicals are safe to humans if used according to good agricultural practice (Talarek, 6). Neudorff's opinion contains documentation demonstrating that ferric phosphate slug & snail baits are not harmful to earthworms & other non-target organisms (Talarek, 6). Based on the available studies, there is not enough evidence to definitively conclude whether ferric phosphate molluscicides containing EDTA are toxic to earthworms following typical rates of application (STR 411-413). [Minority view discussion: "Clearly, molluscicides containing iron phosphate and EDTA or EDDS chelating agents may present significant environmental hazards to earthworms, domestic animals and humans and these issues need further investigation. The registration statuses of these chemicals in USA and Europe should be reviewed in light of these new data and conclusions "(Edwards, et al. 2009). (348-351)] Although the Technical Review concludes that there is not enough information to conclude with certainty that ferric phosphate slug-control products are harmful to earthworms, the study by Langan and Shaw (2006) certainly seems to be independently gathered data showing that under some conditions and for some earthworm species, Sluggo-type products can be harmful. Accepting this conclusion would indicate that the Edwards study is not likely to be biased. (ARS)]
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		The EPA describes ferric phosphate as ubiquitous in nature. It is a solid. It is not volatile and does not readily dissolve in water, which minimizes its dispersal beyond where it is applied (291-292). [Minority view:See above, 6 and 7.]
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]		X		Examples of the solubilization of phosphate from ferric phosphate by soil microorganisms such as *Penicillium radicum* & others, are common in literature. It is also reported to occur naturally in the soil as fertilizer (278-280). [Minority view discussion: Assuming the reports of mammalian toxicity are accurate, that would demonstrate the potential for some level of persistence in the food chain. (414-415)). EDTA is not degraded rapidly in the environment and is the most abundant anthropogenic chemical in some European surface waters (SFHEDTA checklist.)]

10. Are there any harmful effects on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4]		X		No unreasonable adverse effects to human health are expected from the use of iron phosphate (467). One might presume that only the reports of mammalian toxicity cited in question 9 are likely to be of potential concern. (503-504); Neudorff states that there are no reports of mammalian toxicity cited in the discussion of Evaluation Question #9. There is only the statement "[a]ssuming the reports of mammalian toxicity are accurate, that would demonstrate the potential for some level of persistence in the food chain". Not only does the discussion under Question #9 not list or discuss any such reports, but the one sentence in the section mentioning reports of mammalian toxicity is a non-sequitur (Talarek, 8).
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.

NOSB Evaluation Criteria for Substances Added To the National List

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

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			
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]	X			
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		
4. Is there a natural source of the substance? [§205.600 b.1]	X			Ferric phosphate occurs in nature but the natural source is not able to be commercially produced [Minority view discussion: It is not effective for mollusc control without EDTA. (ARS)]
5. Is there an organic substitute? [§205.600 b.1]		X		
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			X	
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X			Examples have been reported in various semi-professional literature, albeit they are intended for home and garden use rather than agricultural purposes (513-519). The "All Natural Snail & Slug Spray RTU"…is not registered with EPA…this RTU product is intended for home & garden use, which means it might be impractical for agricultural use (Talarak, 8).
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]			X	
9. Are there any alternative substances? [§6518 m.6]		X		Many of the "natural" remedies or deterrents for slugs and snails are abundant in the semi-professional literature, such as home and gardening publications and blog sites on the internet (529-537). Copper tape, diatomaceous earth.[8]The discussion lists spot treating with ammonia solutions, spraying with salt solutions, direct removal of slugs & snails observed & placement into containers of soap, water alcohol or other harsh solution to kill them, & predators, such as birds, mammal & toads. However, none of these methods are practicable for commercial agriculture (Talarek, 8).
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]		X		One last important point to mention is that no organic growers have supported Steptoe & Johnson's petition, and organic growers have

[8] Petition for sodium ferric hydroxyl EDTA, p. 20

				supported the continued listing of ferric phosphate (Talarek, 8). [Minority view discussion: The direct removal of any slugs or snails observed and placement into a container of soap [type not specified] and water, alcohol, or other harsh solution to kill them. Birds, small mammals, and especially toads, have been said to be predators on slugs and snails, but are obviously not readily controllable. (532-535) Cultivation.[9]]

[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.

[9] Petition for sodium ferric hydroxyl EDTA, p. 21

NOSB Evaluation Criteria for Substances Added To the National List

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

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			Ferric Phosphate is the only effective molluscicide available to organic growers. [Minority view discussion: It's a synthetic material that does not present a compelling need for it as well as the toxic substances necessary for its manufacture.]
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]	X			Following typical rates of application, ferric phosphate + chelator baits do not harm earthworms. No information was found linking the specific use of EDTA in pesticide formulations to groundwater pollution (273-283). [Minority view discussion: EDTA is inert under some circumstances and can build up in soil. It is the most abundant anthropomorphic chemical in some European surface waters. It can enhance the movement of metals in soil and river sediments.(EU commission risk assessment on EDTA)]
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]			X	
5. Is the primary use as a preservative? [§205.600 b.4]			X	
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]			X	
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: a. copper and sulfur compounds;		X		
b. toxins derived from bacteria;		X		
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?	X			Ferric phosphate is a mineral. [Minority view discussion: Ferric phosphate plus EDTA does not fit into any category.]
d. livestock parasiticides and medicines?		X		
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?		X		

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

NOSB Evaluation Criteria for Substances Added To the National List

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

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. 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	

[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.

National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal
Oxidized Lignite/Humic Acid

August 15, 2012

Introduction:
A petition was submitted requesting the addition of "Humic Acid Derivatives – Hydrogen Peroxide extracted", which is also known as Oxidized Lignite.

Background:
The Crops Subcommittee encountered considerable confusion over what this material actually is and whether leonardite humates subject to oxidation in the environment could also be known as oxidized lignite. A Technical Evaluation Report (TER) was commissioned to address the nature of this petitioned substance and compare it to the other humic acid derivatives that are alkali extracted as per National List section 205.601(j)(3).

Relevant Areas in the Rule:
The National List includes at §205.601(j)(3)

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

Discussion:
In reviewing the information in the TER it was apparent that a substance named oxidized lignite could occur through natural processes in the field or through using super-heated water or ozone in a lab (TER lines 258 - 263). However since the manufacturing process in this petition is redacted as Confidential Business Information, it is not clear how to propose listing this substance to distinguish it from these other methods of production. Therefore the motion that is being proposed is to add Hydrogen Peroxide extraction to the annotation for Humic Acids on the National List. Included in the motion is that this new clause will expire in 2017, to enable all the humic acids to be re-reviewed together at their normal sunset date.

The Crops Subcommittee noted in their review that leonardite materials extracted with hydrogen peroxide do not have any residual synthetic materials in the end product because the hydrogen peroxide breaks down completely into water and oxygen. Humic Acids that are alkali extracted do contain a surplus of potassium or other cations from the extractant, and it has never been clear what amount of alkali is necessary for the extraction but is not considered fortification.

Another key issue in the deliberation over this material is the fact that there are many alternative substances and practices that can be used to enhance plant uptake of nutrients, which is the primary use for this product class. The justification statement in the petition only compared hydrogen peroxide extraction with alkali extraction for humic acids, but did not address the bigger context of soil-building practices as alternatives. The TER did address the soil-building practices and alternative substances that can be used. However, the contention by the petitioner that humic acids must be deliverable in liquid form was not discussed in the TER. The Subcommittee majority does not feel that the need for nutrients in liquid form is a compelling reason to distinguish this from the alternatives.

Evaluation Criteria

(Applicability noted for each category; Documentation attached)	**Criteria Satisfied? (see "B" below)**		
1. Impact on Humans and Environment	☒ Yes	☐ No	☐ N/A
2. Essential & Availability Criteria	☐ Yes	☒ No	☐ N/A
3. Compatibility & Consistency	☐ Yes	☒ No	☐ N/A
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for § 205.606)	☐ Yes	☐ No	☒ N/A

Substance Fails Criteria Category: [2,3] **Comments:**

Proposed Annotation (if any): "Humic acids – naturally occurring deposits, water, alkali *and hydrogen peroxide* extracts only."

Basis for annotation: ☒ To meet criteria above ☐ Other regulatory criteria ☐ Citation
Notes:

Recommended Subcommittee Action & Vote, including classification recommendation (state actual motion):

Motion:
Humic Acids – Hydrogen Peroxide extracted are synthetic.

Motion by: Zea Sonnabend Seconded by: Colehour Bondera
Yes__**8**___ No__**0**__ Abstain__**0**__ Recuse__0__ Absent__**0**__

Listing Motion:
To change the listing in [7 CFR 205.601(j)(3)] to: "Humic acids – naturally occurring deposits, water, alkali *and hydrogen peroxide* extracts only, to expire in 2017."

Motion by: Zea Sonnabend Seconded by: John Foster
Yes__**3**___ No__**5**__ Abstain__**0**__ Recuse__**0**__ Absent__**0**__

Crops	☒	**Agricultural**	☐	**Allowed**[1]	☒
Livestock	☐	**Non-synthetic**	☐	**Prohibited**[2]	☐
Handling	☐	**Synthetic**	☒	**Rejected**[3]	☐
No restriction	☐	**Commercial unavailable as organic**	☐	**Deferred**[4]	☐

[1]Substance voted to be added as "allowed" on National List to § 205. 601(h) 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:

Approved by Subcommittee Chair to Transmit to NOSB

Jay Feldman, Subcommittee Chair August 15, 2012

NOSB Evaluation Criteria for Substances Added To the National List

Category 1. Adverse impacts on humans or the environment? Substance: Humic Acids – Hydrogen Peroxide extraction

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			There may be environmental contamination from coal mining (see TER 339-340) "surface mines are more likely than underground mines to result in surface water pollution." The treatment with hydrogen peroxide may release carbon dioxide into the atmosphere, but because of the CBI that cannot be determined. (TER 343-346)
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]				TR 394-396: Humic substances appear to depress some organisms in the environment while stimulating others (Peterson, 1989). There is therefore no clear-cut answer to this criteria.
4. Does the substance contain List 1, 2 or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]		X		
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		X		If anything the use of such humic substances would enhance the uptake of other fertilizer materials. (TER lines 353-354)
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]	?			There is always a potential for detrimental interactions, but in the TER lines 356-357: "However, because of their widely varying structures and functions, it is difficult to predict with certainty the effects of humic substances in the soil."
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		TER 404-412: "The impact of oxidized lignite on soil organisms is inconclusive."
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		While the TER discusses concerns over the humic substances in drinking water and in aquatic environments (TER lines 365-369 and 386 - 388), there is no reason to think the substance would end up in these places as used in organic farming.
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]		X		Lignite itself is very persistent (TER lines 279 - 280) but the reacted versions of it will break down faster. Persistence in this case is not undesirable as the unreacted humates are used in organic agriculture for their long-term

				benefits.
10. Are there any harmful effects on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4]	X	X		The TER in lines 302 - 326 gives extensive literature on the negative effects of coal and coal dust on human health. However these all stem from burning coal for fuel, hazards in mining coal, and if lignite ends up in drinking water. None of them relate to any harmful effects from using extracted humic acids as a soil amendment.
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.

NOSB Evaluation Criteria for Substances Added To the National List

Category 2. Is the Substance Essential for Organic Production? Substance: Humic Acids – Hydrogen Peroxide extraction

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)]	?			Unknown because of CBI
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]	X			
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		Oxidized lignite may be created by naturally occurring processes, but that is why this substance is referred to as hydrogen peroxide extracted Humic Acids.
4. Is there a natural source of the substance? [§205.600 b.1]			X	
5. Is there an organic substitute? [§205.600 b.1]			X	
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			X	
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X			TER 502: "Non-synthetic lignite may be used in place of the liquefied oxidized or alkali treated lignite." TER 522: "It is also possible to treat lignite coal by microbial fermentation (Catcheside and Ralph, 1999)."
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]			X	
9. Is there any alternative substances? [§6518 m.6]	X			TER 491-498: "Compost, cover crops, manure, mulch, and other natural sources of organic matter can all increase humic acid content of the soil (Magdoff and Weil, 2004). Humic acids from decaying organic matter have been empirically shown to have the same benefits as those from fossil sources, such as lignite (Weil and Magdoff, 2004)." TER 557: "Synthetic ligninsulfonates are also used as chelating agents for micronutrients [7 CFR 205.601(j)(4)]."
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			Any soil-building practice that increases the organic matter in soil will be similar in action to these substances, only they take more time. Green manures, rotation, incorporating crop residues and using compost are all equivalent to the use of these substances. (TER 569 - 581)

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

NOSB Evaluation Criteria for Substances Added To the National List

Category 3. Is the substance compatible with organic production practices? Substance: Humic Acids – Hydrogen Peroxide extraction

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		As the organic rule is written, synthetic substances for crop inputs must fall within one of the exception areas mentioned in #7 below. Since this does not, it cannot be considered consistent with the rule.
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]	X	X		While agronomically this appears to be a compatible material and humic substances are primarily beneficial to soil and plants, the concerns over coal mining to produce the starting ingredient do not contribute to the overall sustainability of this materials over other practices.
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]			X	
5. Is the primary use as a preservative? [§205.600 b.4]			X	
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]			X	
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: a. copper and sulfur compounds;		X		
b. toxins derived from bacteria;		X		
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?		X		
d. livestock parasiticides and medicines?		X		
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?		X		

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

NOSB Evaluation Criteria for Substances Added To the National List

Category 4. Is the commercial supply of an agricultural substance as organic, fragile or potentially unavailable? [§6610, 6518, 6519, 205.2, 205.105 (d), 205.600 (c) 205.2, 205.105 (d), 205.600 (c)] **Substance: Humic Acids – Hydrogen Peroxide extraction**

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	

[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.

National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal
Propylene Glycol Monolaurate (PGML)

August 7, 2012

Introduction:
PGML has been petitioned to be added to section 205.601(e) of the National List. PGML is an acaricide; a pesticide that kills members of the Acari group – ticks and mites. Stated in the petition (pg. 5), specifically PGML is seen as, "a broad spectrum antimicrobial agent to control fungi and bacteria that cause decay of post-harvest fruit and vegetables."

Relevant areas in the Rule:
The National List includes at §205.601(e)

As insecticides (including acaricides or mite control).

Discussion:
While potentially useful as an additional tool for controlling Acari pests, it is not needed as it can be substituted with alternatives including cultural practices and biological controls -- other options are available which do not have the impacts on human and environmental health. That the environmental impacts leave more damage overall than benefit, is of notable concern, when considered in regard to efficacy. As a synthetic product, this material is not consistent with either organic nor sustainable production systems. As a tool made for use in conventional agricultural systems, PGML does not serve as an organic system tool.

Those who supported adding PGML to the National List said that while there are other organic options, they are very sporadic in how well they control the target pests or even under certain circumstances if they will control them at all. The impact on crop quality, and the potential environmental impact when using the alternative materials can be somewhat of a concern, as well. Giving organic farmers another tool that is better than those they currently rely upon is exactly what this process is all about if we can properly look at the risk/ benefit.

Evaluation Criteria:

(Applicability noted for each category; Documentation attached)	**Criteria Satisfied? (see "B" below)**		
1. Impact on Humans and Environment	☐ Yes	☒ No	☐ N/A
2. Essential & Availability Criteria	☐ Yes	☒ No	☐ N/A
3. Compatibility & Consistency	☐ Yes	☒ No	☐ N/A
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for § 205.606)	☐ Yes	☐ No	☒ N/A

Substance Fails Criteria Category: [1, 2, 3]

Proposed Annotation (if any):

Basis for annotation: ☐ To meet criteria above ☐ Other regulatory criteria ☐ Citation
Notes:

Recommended Subcommittee Action & Vote, including classification recommendation (state actual motion):

Classification Motion:
PGML is synthetic.

Motion by: Colehour Bondera Seconded by: Zea Sonnabend
Yes__**8**___ No__**0**__ Abstain__**0**__ Recuse__0__ Absent__**0**__

Listing Motion:
Add PGML to the National List §205.601(e) as an acaracide.

Motion by: Colehour Bondera Seconded by: John Foster
Yes__**2**___ No__**6**__ Abstain__**0**__ Recuse__0__ Absent__**0**__

Crops	☒	**Agricultural**	☐	**Allowed**[1]	☐
Livestock	☐	**Non-synthetic**	☐	**Prohibited**[2]	☐
Handling	☐	**Synthetic**	☒	**Rejected**[3]	☒
No restriction	☐	**Commercial unavailable as organic**	☐	**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(e). Describe why material was rejected:
Not needed and environmental impacts too costly.

[4]Substance was recommended to be deferred because

If follow-up needed, who will follow up:

Approved by Subcommittee Chair to Transmit to NOSB

Jay Feldman, Subcommittee Chair **August 7, 2012**

NOSB Evaluation Criteria for Substances Added To the National List

Category 1. Adverse impacts on humans or the environment? **Substance:** Propylene Glycol Monolaurate (PGML)

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			There can be with misuse or disposal since beneficials can be destroyed… Human irritation if mis-used. Feedstock for manufacture comes from petroleum, natural gas or coal. Manufacture requires burning of petroleum, thus greenhouse gas production. See TR - line 231 onward.
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]	X			Fossil fuel dependent (234-6).
4. Does the substance contain List 1, 2 or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]		X		List 4B.
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]	X			Can enhance toxicity of other 'biocides' (255).
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]	X			Both beneficial mites (soil food web & organic matter decomposers) and fungi directly impacted; limited studies (283-299 & 309-316)…
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]	X			Potential impact on soil food web mites (283-299 & 309-316).
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]				Unclear/unknown.
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]		X		
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4]	X			Minimal, but can cause short-term skin and eye reactions (328-335). PGML is a "Toxicity Category III" substance in terms of eye irritation (US EPA Fact Sheet, 2004). As listed in 40 CFR 156.62, US EPA establishes the four toxicity categories: I, II, III and IV. Toxicity category I is highly toxic and severely irritating, category II moderately toxic and moderately irritating, category III slightly toxic and slightly irritating, and category IV practically non-toxic and not an irritant. Toxicity category III substances cause eye irritation effects, but the irritation effects are reversible within seven days. Toxicity category IV substances do not cause eye irritation effects.
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			X	

to FDA's good manufacturing practices? [§205.600 b.5]				
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.

NOSB Evaluation Criteria for Substances Added To the National List

Category 2. Is the Substance Essential for Organic Production?
Substance: Propylene Glycol Monolaurate (PGML)

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			
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		Manufactured from petroleum, natural gas, or coal by a process involving chemical change.
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		Could be, however commercially it is not…
4. Is there a natural source of the substance? [§205.600 b.1]			X	
5. Is there an organic substitute? [§205.600 b.1]			X	
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			X	
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X			Non-synthetic botanical and fungal-derived acaricides (354).
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]		X		
9. Is there any alternative substances? [§6518 m.6]	X			Horticultural oils (petroleum distillates), soaps, sulfur and sucrose octanoate esters (SOE) also appear on the National List and are used to control mites in organic production (360-1).
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			Rotation, nutrient management, selection of mite-resistant varieties, and the release of predators and parasites (342), dust management, resistant varieties and biological controls (370-398). Water management is a viable practice as well.

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

NOSB Evaluation Criteria for Substances Added To the National List

Category 3. Is the substance compatible with organic production practices?
Substance: Propylene Glycol Monolaurate (PGML)

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		Toxic to aquatic life.
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]		X		No, petroleum based.
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]			X	
5. Is the primary use as a preservative? [§205.600 b.4]			X	
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]			X	
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: a. copper and sulfur compounds;		X		
b. toxins derived from bacteria;		X		
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?		X		Glycol esters do not appear in an OFPA category. In evaluating the petition for sucrose octanoate esters (SOE), the NOSB determined that esters are equivalent in their manufacture and mode of action to 'soap,' which appears as a category of synthetic authorized for use in production on the National List at 7 U.S.C. §6517(c)(1)(B)(i) (NOSB, 2005) (116-119). However, the PGML molecule does not have the hydrophilic-lipophilic structure of a soap (27-28), as also seen by its solubility in organic solvents, low water solubility, high saponification value, and low hydrophilic-lipophilic balance value, all of which indicate a substance that is lipophilic, but does not have the hydrophilic-lipophilic structure of a soap (38-44).
d. livestock parasiticides and medicines?			X	
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?			X	

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

NOSB Evaluation Criteria for Substances Added To the National List

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

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	

[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.

National Organic Standards Board
Crops Subcommittee
Policy and Procedure Proposal
Other ("Inert") Ingredients in Pesticide Formulations on the National List

August 22, 2012

Introduction

This Policy and Procedure Proposal for review of other ("inert") Ingredients in pesticide formulations on the National List addresses the many recommendations of the NOSB and concerns of the public about the crop production materials that are allowed for use in certified organic production under the National List section of OFPA (7 USC 6517).

This proposal consists of a roadmap for initiating the review of these substances in groups over a four year timespan, with the goal of completing the majority of the reviews by the end of the current sunset period for §205.601(m) and §205.603(e) (the sections in 7 CFR 205 that list inert ingredients) in October of 2017. This document contains a proposal for new regulatory language, a series of steps to use in preparing for inerts review, screening guidelines that the Technical Evaluation Reports (TERs) will address, a tentative list of the proposed groups, and a rough timeline for review and completion.

In order to initiate development of the necessary TERs by 2013, a vote on moving forward at the Fall 2012 NOSB meeting will be followed by additional details on the procedure, which will be finalized at the Spring 2013 meeting of the Board. Though it is recognized that many of these substances are not truly "inert," this proposal retains use of the word inert in the regulatory language "inert (other) ingredients," as that is the terminology used in Environmental Protection Agency (EPA) regulations and the Organic Foods Production Act of 1990 (OFPA). However, like EPA, the NOSB encourages the labeling of products permitted in certified organic production with the phrase "other ingredients" per EPA's finding, "Since neither federal law nor the regulations define the term "inert" on the basis of toxicity, hazard or risk to humans, non-target species, or the environment, it should not be assumed that all inert ingredients are non-toxic."[1]

Background

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

[1]See EPA, Inert (other) Pesticide Ingredients in Pesticide Products - Federal Register and Pesticide Registration Notices on Other (Inert) Pesticide Ingredients, "In September 1997, the Environmental Protection Agency (EPA) issued Pesticide Regulation Notice 97-6 which encourages manufacturers, formulators, producers, and registrants of pesticide products to voluntarily substitute the term "other ingredients" as a heading for the "inert" ingredients in the ingredient statement on the label of the pesticide product. EPA made this change after learning the results of a consumer survey on the use of household pesticides. Many comments from the public and the consumer interviews prompted EPA to discontinue the use of the term "inert." Many consumers are misled by the term "inert ingredient", believing it to mean "harmless." Since neither federal law nor the regulations define the term "inert" on the basis of toxicity, hazard or risk to humans, non-target species, or the environment, it should not be assumed that all inert ingredients are non-toxic."

NOP regulations concerning allowed inert ingredients are out-of-date when compared with current EPA regulations, since EPA eliminated its list categories when it completed its tolerance reassessment. The NOSB recommended in April 2010 that NOP establish a task force in collaboration with EPA and the NOSB to examine this problem and provide a recommendation to the Board for re-evaluation of former List 3 and List 4 inerts. In October 2010, the NOSB recommended the renewal until October 21, 2017 of the current exemption on the National List permitting former List 4 inerts "pending review by the program of inerts individually and as a class of materials".[2] In May 2012, the NOSB recommended an expiration date of October 21, 2017 for the current exemption that permits former List 3 inerts in passive pheromone dispensers, to coincide with the sunset date for List 4 inerts.

The NOSB-NOP-EPA working group was established in June 2010, known as the Inerts Working Group (IWG). Current members include: Jay Feldman (NOSB), Zea Sonnabend (NOSB), Chris Pfeifer (EPA Biopesticides and Pollution Prevention Division), Kerry Leifer (EPA Registration Division), Emily Brown Rosen (NOP), and Lisa Brines (NOP). The group has collected information regarding current classification of the former List 3 and 4 inerts and presented a discussion document at the November 2011 NOSB meeting.[3]

For more detail on the background of inerts discussions among the NOSB and references in OFPA and the USDA organic regulations, please see the above referenced documents.

Regulatory Language Proposal

The NOSB proposes this language to replace the current listing at section 205.601(m) and 205.603(e). The NOSB recommends that this change, including the listing of any approved (inert) ingredients, be completed prior to the October 21, 2017 sunset date for List 4 inerts:

Current language at sections 205.601(m) and 205.603(e):

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

Replace the language at sections 205.601(m) and 205.603(e) with:

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

(i) Substances permitted for use in minimal risk products exempt from pesticide registration under FIFRA section 25(b);

(ii) Reserved (for list of approved other ("inert") ingredients)

Discussion of Procedure

[2] October 28, 2010 recommendation available at http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5087999&acct=nosb

[3] Available at http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5094901&acct=nosb

The policy proposal creates a four-year timeframe for evaluation of inert ingredients currently in use in organic agriculture that are not exempt from pesticide registration under FIFRA section 25(b). This includes former EPA List 4b and List 3 inerts in pheromones that were identified through information supplied by the Material Review Organizations OMRI (Organic Materials Review Institute) and WSDA (Washington State Department of Agriculture). It also will include inert ingredients that have previously petitioned, and a call for other (inert) ingredients. This list so far is 126 individual substances.

The NOSB proposes review of inerts by classes or groups, rather than by individual substance. The NOSB believes that allowing a class of substance by group will reduce the burden of the Board to individually review each substance previously allowed under the exemption for former List 4 or former List 3 for pheromone dispensers. For the purposes of this recommendation only the group names are provided. However, the substances that are recommended by NOSB would be included by individual names and CAS numbers, entered as the class is reviewed, under 205.601(m) and 205.603(e) above. Below are the proposed groups, with approximate numbers of materials in each group:

1. Alkyl alcohols - 3
2. Alkyl alkoxylates - 4
3. Alkylphenol ethoxylates - 9
4. Dyes - 2
5. EDTA and salts - 2
6. Fatty aid ethoxylates - 4
7. Fatty acids esters and salts - 6
8. Low risk polymers, as defined under 40 CFR 180.960 - 8
9. Mineral acids, bases and their inorganic salts -22
10. Organic acids and salts - 3
11. Polyalkoxlylates and polyalkoxylated alkyl ethers - 5
12. Polysorbates - 5
13. Preservatives/antioxidants - 7
14. Tall oil and terpene derivatives - 5
15. Nonsynthetic - 14
16. Others - 27

The IWG is continuing to work in consultation with the EPA and the NOSB to categorize some of the many substances in the "other" category into additional or existing groups. The full group listing, including the list of chemicals, will be presented at the Spring 2013 NOSB meeting.

It is expected that 4-6 groups of chemicals will be evaluated every year during the four year period beginning in 2013. Should manufacturers identify ingredients in use that are not on the list for review, they will have time to come forward with a request for review. After this process is complete, manufacturers will be required to petition for the addition of new other ingredients, or “inerts,” in pesticide formulations to the National List.

Given the scope of TERs and NOSB evaluation of these materials, it is recognized that completion of this process will take substantial resources and time. The current projected timeline will involve NOSB completion of all reviews by its Spring 2015 public meeting to enable the NOP to complete rulemaking by October 2017, the sunset date for List 4 inerts.

Because of the challenge that this presents, the NOSB will assess the viability of the timeline after it completes the recommendation on the first few groups of materials.

Proposed Procedure

A. The NOSB will work with the IWG to finalize groups and screening steps.

B. The NOSB will rely on the IWG to consult with OMRI and WSDA for updated inerts lists in case there are new inerts to add to the groups.

C. The NOSB requests NOP to investigate and adopt within six months of the announcement of this proposal (Spring 2013) the appropriate mechanism for notifying manufacturers and the public regarding the inerts review process, including which inerts are under review and how to inform the IWG of inerts that are in use, but not on the list under review. .

D. The NOSB requests NOP to commission one TER per group, except where noted, and coordinate review with the Board.

E. The NOSB requests NOP to determine an appropriate format and commission a special inerts TER for each group to contain the following:
    a. a chart of all inerts in the groups by CAS number with their chemical properties, uses, types of product categories in which they occur, EPA regulatory status, including data gaps.
    b. a description of how inerts within group are related and how different, especially outliers that are significantly different from others.
    c. a chart that evaluates each inert in the group under the screening steps suggested by NOSB (Appendix 1) and any additional screening recommended by the NOSB, with input from the IWG.
    d. OFPA criteria will be addressed that are not covered in the EPA review (environment, interactions, and alternatives or essentiality)

F. Based on results of group TER, the NOSB Crops Subcommittee accepts group to move forward to NOSB agenda, or singles out one or more for individual review. The group will then move forward without the singled out one and that one will be re-reviewed in more detail if necessary.

G. The NOSB, working with the IWG, will prioritize the order of reviews so that the most potentially problematic are reviewed first. The others can be done later and some may not need full TERs. Priority also given to fully disclosed ones that have been petitioned and may fall outside one of the groups. In setting priorities, there will be consideration of the amount used in organic production if that can be determined.

H. The anticipated timeline will enable the NOSB to finalize the procedure by Spring 2013, start reviews for fall 2013 and to have as many reviews completed as possible by Spring 2015. The intention is to have an amendment to the National List in 2017, which will address the materials reviewed with an implementation period of 2 - 5 years, taking into account public comment and the need for additional reviews for reformulation and compliance.

I. By the time of the five-year sunset period, the NOSB will approach a review of those on the 25b list.

Recommended Subcommittee Action & Vote (state actual motion):

Motion:
To adopt the proposed Policy and Procedure Proposal on Other ("Inert") Ingredients in Pesticide Formulations on the National List.

Motion by: Colehour Bondera Second: Jay Feldman
Yes__**8**___ No__**0**__ Abstain__**0**__ Absent__**0**__ Recuse__**0**__

Approved by Subcommittee Chair to Transmit to NOSB

Jay Feldman, Subcommittee Chair **August 22, 2012**

Appendix A – Inerts Screen
(Modified from NOSB proposal of 2010)

(1) Toxicity Category I or II by the United States Environmental Protection Agency (EPA). These pesticides are identified by the words "DANGER" or "WARNING" on the label.

(2) A developmental or reproductive toxicant as defined by the State of California Proposition 65 Chemicals Known to Developmental or Reproductive Harm.

(3) A carcinogen, as designated by EPA's List of Chemicals Evaluated for Carcinogenic Potential (chemicals classified as a human carcinogen, likely to be carcinogenic to humans, a known/likely carcinogen, a probable human carcinogen, or a possible human carcinogen), the International Agency for Research on Cancer (IARC), U.S. National Toxicology Program (NTP), and the state of California's Proposition 65 list. Any of the following classifications shall deem the chemical a carcinogen and unacceptable:

Known to the State of California to Cause Cancer (California)
http://www.oehha.org/prop65/prop65_list/Newlist.html
Group A: Human Carcinogen (US EPA 1986 category)
http://npic.orst.edu/chemicals_evaluated.pdf :
http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1:613774867565701
Group C: Possible Human Carcinogen (US EPA 1986 category)
Known Carcinogen (US EPA 1996 category)
Likely Carcinogen (US EPA 1996 category)
Carcinogenic to Humans (US EPA 1999 category)
Likely to be Carcinogenic to Humans (US EPA 1999 category)
Suggestive Evidence of Carcinogenicity (US EPA 1999 category)
Known to be Human Carcinogens (NTP) http://ntp.niehs.nih.gov/?objectid=03C9F0A4-B1C2-31DE-ABA8508AE9949C57
Reasonably Anticipated to be Human Carcinogens (NTP)

Group 1: Carcinogenic to Humans (IARC)
http://monographs.iarc.fr/ENG/Classification/index.php
Group 2A: Probably Carcinogenic to Humans (IARC)
Group 2B: Possibly Carcinogenic to Humans (IARC)

(4) Nervous system toxicants, including chemicals such as cholinesterase inhibitors or chemicals associated with neurotoxicity by a mechanism other than cholinesterase inhibition, or listed on:

Toxics Release Inventory (TRI), EPA EPCRA Section 313 (Identified as "NEUR" on Table 1) http://www.epa.gov/tri/trichemicals/hazardinfo/hazard_chronic_non-cancer95.pdf
EPA Reregistration Eligibility Decisions (RED)
http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1:613774867565701
Insecticide Resistance Action Committee (IRAC) Mode of Action Classification:
http://www.irac-online.org/eClassification/

Acetylcholine esterase inhibitors;
GABA-gated chloride channel antagonists;
Sodium channel modulators;
Nicotinic Acetylcholine receptor agonists /antagonists;
Nicotinic Acetylcholine receptor agonists;
Chloride channel activators;
Octopaminergic agonists;
Voltage-dependent sodium channel blockers; or
Neuronal inhibitors (unknown mode of action).

California Department of Pesticide Regulation or the Materials Safety Data Sheet (MSDS) designations for cholinterase inhibitors

(5) Endocrine disruptors, which include chemicals that are known to or likely to interfere with the endocrine system in humans or wildlife, based on the European Commission (EC) List of 146 substances with endocrine disruption classifications, Annex 13 (and/or any subsequent lists issued as follow-up, revisions, or extensions).
http://ec.europa.eu/environment/docum/pdf/bkh_annex_13.pdf or
http://ec.europa.eu/environment/endocrine/strategy/substances_en.htm#report2

(6) (Regarding outdoor use) Adversely affects the environment/wildlife, based on:

1. Label precautionary statements including “toxic” or “extremely toxic” to bees, birds, fish, aquatic invertebrates, wildlife or other non-target organisms, unless these organisms are the target pest and/or environmental exposure can be virtually eliminated.
2. Pesticides with ingredients with moderate or high mobility in soil, according to the Groundwater Ubiquity Score (GUS), or with a soil half-life of 30 days or more (except for mineral products). Persistence and Soil Mobility procedures appear below.

a*)* If GUS (Groundwater Ubiquity Score) cannot be found, we search for the aerobic soil half-life and soil-binding coefficient Koc. GUS is then calculated from the formula: GUS = log10(half-life)*(4 – log10 (Koc)).

(7) Has data gap or missing information in EPA registration documents, including pesticide fact sheets, or EPA reregistration eligibility decisions, which EPA is requiring the registrant to fulfill.

(8) Contaminants and metabolites recognized by EPA that violate any of the above criteria.

(9) Known groundwater contaminants, as designated by the state of California (for actively registered pesticides) or from historic groundwater monitoring records.

National Organic Standards Board
Crops Subcommittee
Proposal to Add Rotenone to National List 205.602
as a Prohibited Natural Substance

August 7, 2012

Introduction

The NOSB Crops Subcommittee acknowledges the intent and validity of the portion of the Organic Foods Production Act (OFPA) that calls for a Special Review of Botanical Pesticides prior to the establishment of the National List [2119(k)(4)]. We wish at this time to re-review the botanical pesticide Rotenone and add it to the National List section 205.602 as a Prohibited Natural substance.

Background

The NOSB conducted its Special Review of Botanical Pesticides during their meeting that ran from October 10 to 14, 1994. As stipulated in OFPA (below) it was before the National List was established. The Rotenone portion of the minutes is quoted below (from lines 851 to 874 of the official minutes). The references used in the special review in 1994 are cited at the end of this recommendation.

> Brown reported on the low LD50 of rotenone when tested on rats, its toxicity to fish and birds and on no records of fatalities or poisonings in humans. Kinsman reported that it is used widely for lice, mange and mites in conventional production. John clarified that the Board is reviewing the natural ground root and not synthetic preparations or the synthetic extracted form of rotenone. Theuer offered that the half-life of rotenone is long and the required 24 hour withdrawal time may not be long enough and that there are many alternatives. Brian Baker stated that rotenone is restricted in its applications by private certifiers and that the California Senate repealed its registration because of incomplete information and not because of health reasons. Merrill Clark requested that the Board take actions to move production away from the use of all botanicals by considering a phase out of all botanicals. David Haehn spoke to its usefulness in livestock and aquaculture. Brian Baker informed the members that rotenone has been debated within the organic community for years and despite its shortcomings a data gaps, there are no alternatives because of the natural/synthetic rule.

Quinn moved and Kinsman seconded to place rotenone on the prohibited natural list. VOTE Yes - 1. Opposed - 8. Abstain - 4. Failed. Rotenone is kept off the list of prohibited natural substances."

The NOSB and the Secretary have the clear authority to prohibit specific natural substances (see below rule sections). Since 1994 a large amount of information has emerged from research that showed harmful effects of rotenone on the human system, leading to Parkinsons' disease and other health problems.

Rotenone Regulatory History

In March and April 2006, registrants of rotenone in the U.S. requested voluntarily cancellation from the U.S. Environmental Protection Agency (EPA) of all livestock,

residential and home owner uses, domestic pet uses, and all other uses except for piscicide uses. A data call-in was issued in 2004 requiring a sub-chronic (28-day) inhalation neurotoxicity study to further investigate the results of independent studies in animals that led to Parkinson's Disease-like symptoms. At the time the study was required, rotenone had registered uses for dust products in agricultural and residential settings which were of particular concern for inhalation exposure. However, when all agricultural and residential uses, and all food uses were voluntarily cancelled in 2006, this requirement was waived. In July 2006, EPA issued its "Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision (TRED)" in which the agency indicated its intent to revoke the three tolerance exemptions for rotenone.

The Registration Eligibility Decision (RED) was completed in 2007. The RED approved piscicidal uses granting that additional personal protective equipment (PPE) including respiratory protection will be required for all remaining uses. However, EPA states that it "cannot quantitatively asses a potentially critical effect (neurotoxicity) at doses to which rotenone users could be exposed; therefore, an additional 10x database uncertainty factor has been applied."

Remaining rotenone products are classified as Restricted Use Pesticides (RUP) due to acute inhalation, acute oral, and aquatic toxicity. According to EPA, "rotenone is applied directly to water to manage fish populations in lakes, ponds, reservoirs, rivers, streams, and in aquaculture. The chemical can be applied to an entire water body to achieve a "complete kill" or to a portion of a water body to achieve a "partial kill." Complete kills are used to eliminate all fish in the treatment area; partial kills are used to reduce or sample fish populations in the treatment area." (Source: USEPA. 2007. Reregistration Eligibility Decision (RED) Document. Office of Pesticide Programs. Washinton DC. http://www.epa.gov/oppsrrd1/reregistration/REDs/rotenone_red.pdf)

Updating the National List

While rotenone has been voluntarily cancelled by the manufacturer and its agricultural use is phasing out in the United States, a search of the internet in 2012 shows that rotenone products are still available in other countries. Because of this, and because certifiers, farmers other people involved with organic production are still getting questions from the public about rotenone, board action is needed to clarify the situation by listing rotenone as a prohibited nonsynthetic.

Therefore, the NOSB has re-reviewed this particular botanical pesticide and recommends to the Secretary that it be placed on §205.602 as a prohibited natural substance for organic agriculture. The subsequent checklist and list of references documents the basis for the recommendation.

Relevant areas in the Rule

OFPA

Sec 2118 National List (c) Guidelines for Prohibitions or Exemptions –
(2) Prohibition on the use of Specific Natural Substances
(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 be harmful to human health or the environment;

Sec 2118 National List (e) Sunset Provision –
No exemptions or prohibition contained in the National List shall be valid unless the National Organic Standards Board has reviewed such exemption or prohibition as provided in this section within 5 years of such exemption or prohibition being adopted or reviewed and the Secretary has renewed such exemption or prohibition.

Sec 2119 National Organic Standards Board (k) Responsibilities of the Board –
(4) Special Review of Botanical Pesticides. The Board shall, prior to the establishment of the National List, review all botanical pesticides used in agricultural production and consider whether any such botanical pesticides should be included in the list of prohibited natural substances."
(l) Requirements – ....the Board shall –
(1) review available information from the Environmental Protection Agency....., concerning the potential for adverse human and environmental effects of substances considered for inclusion in the proposed National List.

Discussion
The Crops Subcommittee believes that the data indicating harm to human health precipitated the removal of rotenone from the market. Therefore only the checklist for Category 1 is presented here based on the NOSB's own literature review conducted in 2012. The negative results in category 1 are sufficient for prohibition so that the other categories are not evaluated at this time.

Evaluation Criteria:

(Applicability noted for each category; Documentation attached) (see "B" below)	**Criteria Satisfied?**		
1. Impact on Humans and Environment	☐ Yes	☒ No	☐ N/A
2. Essential & Availability Criteria	☐ Yes	☒ No	☐ N/A
3. Compatibility & Consistency	☐ Yes	☒ No	☐ N/A
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for § 205.606)	☐ Yes	☐ No	☒ N/A

Substance Fails Criteria Category: [1,2,3]
Subcommittee Comments:
Adverse environmental and health impacts, lack of essentiality, and incompatibility with organic principles, as supported by the TR and checklist.

Proposed Annotation (if any):

Basis for annotation: ☐ To meet criteria above ☐ Other regulatory criteria ☐ Citation
Notes:

Recommended Subcommittee Action & Vote, including classification recommendation (state actual motion):

Classification Motion:

Rotenone is a natural substance.

Motion by: Harold Austin Second: Barry Flamm
Yes__**6**___ No__**0**__ Abstain__**0**__ Recuse__**0**__ Absent__**2**_

Listing Motion:
To add Rotenone to the National List 205.602 as a Prohibited Natural Substance.

Motion By: Harold Austin Second: Barry Flamm
Yes__**6**___ No__**0**__ Abstain__**0**__ Recuse__**0**__ Absent__**2**_

Crops	☒	**Agricultural**	☐	**Allowed**[1]	☐
Livestock	☐	**Non-synthetic**	☒	**Prohibited**[2]	☒
Handling	☐	**Synthetic**	☐	**Rejected**[3]	☐
No restriction	☐	**Commercial unavailable as organic**	☐	**Deferred**[4]	☐

[1]Substance voted to be added as "allowed" on National List to § 205. 601(h) 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:

Approved by Subcommittee Chair to Transmit to NOSB

Jay Feldman, Subcommittee Chair August 7, 2012

NOSB Evaluation Criteria for Substances Added To the National List

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

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			improper use in agriculture can cause the death of fish in nearby water.
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		

3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]			X	
4. Does the substance contain List 1, 2 or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]			X	no registered products in the U.S.
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]			X	
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]	X			see fish references and comment.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]			X	unknown for livestock or crops, but effects on humans may be transferrable to livestock.
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		
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4]	X			Rotenone inhibits mitochondrial function and has been highly correlated with Parkinsons disease (Tanner, 2011). Tanner's study is highly important because it was based on a human population from the Farming and Movement Evaluation study (FAME), nested in the Agricultural Health Study, of 84,740 private pesticide applicators (mostly farmers) (Alavanja, 1996; Blair, 2002) Rotenone has also been linked to other central nervous system pathology (Greene, 2009).
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	

2012 References Cited:

Alavanja MC, Sandler DP, McMaster SB, Zahm SH, McDonnell CJ, Lynch CF, et al. 1996. The Agricultural Health Study. *Environ Health Perspect* 104:362–369

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Beyond Pesticides 1987. Safety Source for Pest Management - Beyond Pesticides Least Toxic Service Directory – Rotenone. http://www.beyondpesticides.org/infoservices/pesticidefactsheets/toxic/ROTENONE.HTM

Blair A, Tarone R, Sandler D, Lynch CF, Rowland A, Wintersteen W, et al. 2002. Reliability of reporting on life- style and agricultural factors by a sample of participants in the Agricultural Health Study from Iowa. *Epidemiology* 13(1):94–99.

Center for Disease Control and Prevention 2010 - NIOSH Pocket Guide to Chemical Hazards Rotenone. http://www.cdc.gov/niosh/npg/npgd0548.html

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Greene JG, Noorian AR, Srinivasan S. 2009. Delayed gastric emptying and enteric nervous system dysfunction in the rotenone model of Parkinson's disease. *Exp Neurol* 218(1):154–161.

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Tamm, Dr. Lucius, et. al. 2000. *Use of Rotenone in Organic Agriculture: FiBL Statement - Noevember 2000* Research Institut of Organic Agriculture, Ackerstrasse, CH-5070 Frick. http://www.pmac.net/rotenone.pdf

Tanner CM, Kamel F, Ross GW, Hoppin JA, Goldman SM, et al. 2011. Rotenone, Paraquat, and Parkinson's Disease. *Environ Health Perspect* 119(6): doi:10.1289/ehp.1002839

US Environmental Protection Agency (EPA) 2010. EPA-HQ-OPP-2005-0494-0066 Rotenone; Notice of Receipt of Requests to Voluntarily Cancel Pesticide Registrations. *Federal Register* Vol. 75, No. 144, July 28, 2010.

US Environmental Protection Agency (EPA) 2007. EPA 738-R-07-005 Reregistration Eligibility Decision for Rotenone. http://www.epa.gov/oppsrrd1/REDs/rotenone_red.pdf

1994 References Used in NOSB Review (Selected)

EXTONET Oregon State University. 1989. Rotenone

Newsome, Wm.H, and J.B. Shields 1980. Residues of Rotenone and Rotenolone on Lettuce and Tomato Fruit after Treatment in the Field with Rotenone Formulations. American Chemical Society 0021-8561/80/1428-0722

Worthing, Charles, and R. Hance 1968. The Pesticide Manual, 9th ed. British Crop Protection Council.

NOSB (National Organic Standards Board) 1994. Papers used in the Special Review of Botanicals at the NOSB meeting in October 1994 in Rohnert Park, CA. Beyond citations here there was a TAP review from James Johnson, letter from Bart Hall-Beyer of ATTRA, an Agricola Search of citations, MSDS, and several Rotenone Fact Sheets (not well attributed).

National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal
Sulfuric Acid

August 7, 2012

Introduction:
A petition was submitted requesting the addition of sulfuric acid to the National List (7 CFR §205.601) for stabilization of digested poultry manure to a pH under 4.5 but not below 3.5.

Background:
In 2006, a similar petition was submitted for use in digested livestock manure. The Crops Committee voted unanimously to reject the petition because "Sulfuric acid, when used in livestock manure, is changed to sulfate, which is in this case a synthetically derived plant nutrient. Additionally, it is an important air pollutant, e.g. acid rain. Other wholly natural materials can be used." After some discussion by the NOSB at the October 18, 2006 meeting, and at the request of the petitioner, the vote on the petition was deferred.

Discussion:
The listing of sulfuric acid is not the only hurdle that petitioners need to clear in order to use their products. OMRI so far restricts the use of byproducts of anaerobic digestion of animal manures --used for generating methane-- to the uses allowed for raw manure. They say that these byproducts do not meet the NOP temperature and moisture criteria for processed manure. (They also do not contain the beneficial aerobic organisms that are an important benefit to the soil from composted manure.) Additional action by the NOSB and/or NOP will be needed to allow the full use of anaerobically-digested waste. (OMRI Materials Review, Summer 2012)

The Crops Subcommittee agrees with the 2006 vote and recommends denying the petition because of adverse environmental and health impacts, lack of essentiality, and incompatibility with organic principles, as supported by the checklist.

Evaluation Criteria:

(Applicability noted for each category; Documentation attached)	**Criteria Satisfied? (see "B" below)**		
1. Impact on Humans and Environment	☐ Yes	☒ No	☐ N/A
2. Essential & Availability Criteria	☐ Yes	☒ No	☐ N/A
3. Compatibility & Consistency	☐ Yes	☒ No	☐ N/A
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for § 205.606)	☐ Yes	☐ No	☒ N/A

Substance Fails Criteria Category: [1,2,3]

Subcommittee Comments:
Adverse environmental and health impacts, lack of essentiality, and incompatibility with organic principles, as supported by the TR and checklist.

Recommended Subcommittee Action & Vote, including classification recommendation (state actual motion):

Classification Motion:
Sulfuric Acid is synthetic.

Motion by: Colehour Bondera Seconded by: Nick Maravell
Yes__**6**___ No__**0**__ Abstain__**0**__ Recuse__**0**__ Absent__**2**_

Listing Motion:
To list on §205.601, sulfuric acid for stabilization of digested poultry manure to a pH under 4.5 but not below 3.5.

Motion by: Harold Austin Second: Barry Flamm
Yes__**0**___ No__**6**__ Abstain__**0**__ Recuse__**0**__ Absent__**2**_

Crops	☒	**Agricultural**	☐	**Allowed**[1]	☐
Livestock	☐	**Non-synthetic**	☐	**Prohibited**[2]	☐
Handling	☐	**Synthetic**	☒	**Rejected**[3]	☒
No restriction	☐	**Commercial unavailable as organic**	☐	**Deferred**[4]	☐

[1]Substance voted to be added as “allowed” on National List to § 205. 601(h) 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:

Approved by Subcommittee Chair to Transmit to NOSB

Jay Feldman, Subcommittee Chair August 7, 2012

NOSB Evaluation Criteria for Substances Added To the National List

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

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]			X	
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]	X			One of the primary sources of human sourced sulfuric acid in the environment is its manufacture. (TR, lines 187-191) According to the TRI, in 1996, releases of sulfuric acid to the air from 7 14 large processing facilities totaled 8,929,868 kg (19,690,359 pounds) (TR196 1998). (ATSDR, 1998. Toxicological Profile for Sulfur Trioxide and Sulfuric Acid. http://www.atsdr.cdc.gov/toxprofiles/tp117.pdf.)
3. Is the substance harmful to the environment? [§6517c(1)(A)(i);6517(c)(2)(A)i]	X			Sulfuric acid can kill organisms. Air borne sulfuric acid can cause pulmonary edema (TR lines 187-200 & lines 234-242 & lines 296-297) If sulfuric acid comes in contact with bodies of water the bioavailability of heavy metals increases. (Ostiguy). The International Agency for Cancer Research (IARC) has determined that there is sufficient evidence that occupational exposure to strong-inorganic-acid mists containing sulfuric acid is carcinogenic to humans (IARC 1992, 1997). (TR lines 313-316)
4. Does the substance contain List 1, 2, or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]		X		
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]	X			Sulfuric acid can interact with other chemicals used if it comes in contact with the other materials. (TR lines 187-191) Sulfuric acid, when used as a pH adjustor for livestock manure, is changed to sulfate, which is plant nutrient. (TR lines 226-227) Sulfuric acid is corrosive..
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		X		Sulfuric acid, when used in livestock manure, is changed to sulfate. (TR lines 226-227)..
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		Sulfuric acid is corrosive and, at high concentrations, can kill organisms. No detrimental physiological effects on soil organisms, crops or livestock are expected for this usage. Detrimental impacts from manufacture, misuse, disposal. (TR lines 178-229)
8. Is there a toxic or other adverse action of the material or its breakdown products?[§6518 m.2]	X			Sulfuric acid is corrosive; it can harm eyes, skin, and respiratory and gastrointestinal tracts. (TR lines 294-308.) . The International Agency for Cancer Research (IARC) has determined that there is sufficient evidence that occupational exposure to strong-inorganic-acid mists containing sulfuric acid is carcinogenic to humans

				(IARC 1992, 1997). (TR lines 313-316)). (ATSDR, 1998. Toxicological Profile for Sulfur Trioxide and Sulfuric Acid. http://www.atsdr.cdc.gov/toxprofiles/tp117.pdf.)
9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]	X			Sulfuric acid is not persistent. Its breakdown products are sulfate ions. It can persist in the environment if the soil is unable to neutralize it. (TR lines 330-341)..
10. Are there any harmful effects on human health? [§6517 c (1)(A)(i) ; 6517 c(2)(A)i; §6518 m.4]	X			Skin, eye respiratory and gastrointestinal tract irritation; EPA Category I toxicity; aerosol is a suspected human carcinogen (ACGIH); H_2SO_4 mist is a human carcinogen (IARC); protective clothing, eyewear & breathing protection are needed (TR lines 294-325). Sulfuric acid exposure also occurs when it is manufactured… The National Occupational Exposure Survey (NOES), conducted by NIOSH from 1981 to 1983, estimated that 56,103 and 775,348 U.S. workers may be exposed to sulfur trioxide and sulfuric acid, respectively (NOES 1990)."
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 _ Sulfuric Acid _

Question	Yes	No	N/A[1]	Documentation (TR; 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			At present, the quantity of carbon material required to induce a significant pH decline is economically prohibitive. However, if the production of acid can be optimized, possibly by using suitable lactic acid bacteria, it would offer an effective and safe means to prevent ammonia production. (TR367-369) A variety of natural absorbents can be used to reduce ammonia production; some of the most commonly employed are peat and clinoptilolite (a naturally occurring alumino-silicate mineral with high cation exchange capacities). The advantages associated with the use of either clinoptilolite or peat are that they are nonhazardous and act as good soil conditioners when spread with manure. (TR371-374)
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			Unreacted carbon, citric acid, lactic acid bacteria or materials such as clay, peat, and clinoptilote. (TR lines 356-387).
7. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			Composting animal manure can also be used. Stabilization of animal manures can also be accomplish with unreacted carbon, lactic acid bacteria or materials such as clay, peat, and clinoptilote.(TR lines 356-387) Other types of approved composted materials and dehydrated manure can be used.). Hall and Sullivan (2001) provide a review of alternative soil amendments to agricultural fertilizers and manure, including several that can be considered wholly natural, such as various plant byproducts (e.g., composted leaves), rock and mineral powders (e.g., granite dust), and seaweed products. (TR382-387) As specified under NOP §205.203(b): “The producer must manage crop nutrients and soil fertility through rotations, cover crops, and the application of plant and animal materials.” Thus, the need to use manure (whether composted, non-composted, or chemically-treated) or plant materials could be replaced through crop rotation and

				use of cover crops. (TR 409-412)

[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 __Sulfuric Acid __

Question	Yes	No	N/A[1]	Documentation (TR; 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			Sulfuric acid is the primary agent of acid rain, it is an air pollutant TR lines 46-50) Sulfuric acid, when used in livestock manure, is changed to sulfate, which is in this case a synthetically derived plant nutrient.TR lines 226-227). It has been allowed in similar uses for materials presently on the National List.
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]	X			Sulfuric acid is the primary agent of acid rain, it is an air pollutant TR lines 46-50) Sulfuric acid, when used in livestock manure, is changed to sulfate, which is in this case a synthetically derived plant nutrient. TR lines 226-227) It has been allowed in similar uses for materials presently on the National List.
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			Sulfur compounds.
b. toxins derived from bacteria;		X		
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?		X		
d. livestock parasiticides and medicines?		X		

e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?		X		

[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.

2006 recommendation: “Describe why material was rejected: Sulfuric acid, when used in animal manure, is changed to sulfate, which is in this case a synthetically derived plant nutrient. Additionally, it is an important air pollutant, e.g., acid rain. Other wholly natural materials can be used. (See Category 2, questions 4, 6, and 7.”

National Organic Standards Board
Materials Subcommittee
Proposal: Research Priorities for 2012

August 17, 2012

Introduction

A Recommendation for a Framework to Establish Research Priorities was approved at the last National Organic Standards Board (NOSB) meeting in May 2012. Part of that recommendation was that the priorities from the previous year of NOSB deliberations would be presented at each fall meeting. Therefore, we have collected suggested research topics from the NOSB subcommittees and from suggestions within the public comments and will present the top research priorities for approval this fall.

After a recommendation is finalized by the NOSB each fall the Chair of the Board will make sure it is sent to the primary organic research funders such as NIFA, ARS, NRCS, OFRF, and private foundations and other funders that may be identified. In addition all NOP staff, NOSB members and stakeholders can use the list for inspiring appropriate research.

Background

The reasons for encouraging research into organic production systems are well discussed in the previous two Materials Committee papers from fall 2011 and spring 2012.

The recommendation that was passed recommends that potential topics be prioritized. The criteria for prioritization are for those topics that the NOSB believes will have the largest long-term impact on growth and integrity of organic agriculture. These criteria are not presented in order of importance, but are evaluated by the Materials Subcommittee in selecting the top research needs.
Criteria for research topics are:

- Persistent and chronic (i.e., perennial topics of debate and need)
- Challenging
- Controversial (i.e., topics on which there are widely differing perspectives or for which there have been close NOSB votes)
- Nebulous (i.e., the research need is hard to identify but the organic agriculture need is clear). For example, improved methods of weed control.
- Lacking in primary research. That is, topics for which there is no active research being conducted, primarily relating to the criteria in OFPA for review of materials.
- Relevant to assessing the need for alternative cultural, biological, and mechanical methods to materials on the National List.

Call for Researchers
We hope that this information will be useful for researchers in many fields to defend and solicit funds for research that benefits organic production and handling. Therefore we invite the public to comment on these topics, to circulate this widely, and to recommend that funders also prioritize these topics. Please submit comment on which funding agencies should be informed of research needs for organics.

NOSB Research Priorities and issues of concern:
Several important topics have been identified and must be applied within an organic context. Research and evaluation of these and interrelated issues are urgently needed.

- **Whole Farm Systems Research**

  How can working with the natural world by including diversity of habitat, cropping systems, and biological life benefit an organic farm?
- Can crop species and varieties be specifically adapted to their site through plant breeding or cultural practices?
- How does biodiversity contribute to pest and disease resistance?
- What is the relationship between nutrient balancing fertilization practices and microbial life in the soil and susceptibility or resistance to pests?
- How can the need for a diverse ecological system be balanced with food safety concerns for a sustainable organic farming system?
- How can the complex whole environmental system inform, support and educate a farmer in developing a farming system plan?

- **Evaluation of Copper Sulfate for Rice (Sunset Review)**

  In the timeframe that $CuSO_4$ is used in the field, 5 to 15 days after planting, are there documented effects on other organisms in the rice fields (frogs, fish, insects, etc.)?
- What are the obstacles or opportunities for the use of sodium carbonate peroxyhydrate as an alternative to copper sulfate? Evaluate both agronomic and market issues.
- Can the build-up of copper in rice fields be mitigated with other minerals such as Calcium or Magnesium?
- Are there biological control alternatives for algae control in rice, such as viruses or organisms that consume algae?
- Can drill-seeding techniques be adapted so that they can be a viable alternative to product rice without copper sulfate?

- **Evaluation of Antibiotics (Tetracycline and Streptomycin alternatives)**

  What are the elements that are considered in an organic systems plan that avoids the use of antibiotics?
  (Please address any or all of the following and their relative importance: location, planting density, choice of varieties of cultivar and rootstock, diversity of cultivars in orchard and region, diversity of crops in farm and region, soil improvement practices, pruning practices and general sanitation, groundcovers or intercrops, pollinator management, other preventive or general orchard management practices, dormant copper sprays, bloom thinning/lime sulfur, early bloom sprays to prevent stigma colonization by fire blight bacteria, full and late bloom sprays to protect the floral cup, surveys for fire blight activity, computer models, others.)

- Is there any new technology that can aid organic growers in determining potential fire blight infection periods? (Detection models, in field sampling, etc)

- What are the impacts of geographic locations on the severity of fire blight and control programs?

- What materials could be potential replacements for the antibiotics as part of a comprehensive fire blight control and management component of an Organic Farm Plan? What time frame before they would be commercially available? What are the pros and cons of these materials?

- **Evaluation of Genetically Modified Vaccines (GMO)**

  GMO prevention and unintended GMO contamination are foundational to organic production and brand. It is of such importance that NOSB has a GMO Ad-Hoc Subcommittee. GMO free is a major selling point of organic commodities to consumers.

  - A need exists for research and/or outreach on easier ways to determine the types of vaccines. A better way of identifying the types of vaccines is critically important to our stakeholders, especially livestock producers. The testing of products that could be alternatives to GMO vaccines in livestock production is a top priority.

- **Organic Aquaculture**

  Organic aquaculture is on the rise. One report has shown that organic aquaculture generated over 30 billion dollars in 2006. It is said to be the fastest growing organic sector in the world according to another source. There is a great debate as to whether organic aquaculture should be approved for open, closed, or both in the United States. Therefore, research efforts pertaining to open and closed systems seem warranted in some cases.

- Research is needed or data located regarding the impact of fish waste water on the environment, and feed and other materials used (100% organic, fish by-products, synthetic nutrients, etc.). Waste management, fish health (diseases and parasites), fish escapes in open and closed systems need to be explored.

- **Methionine Alternative**

  Methionine is an essential amino acid for poultry. Prior to the 1950's poultry and pigs were fed a plant and meat based diet without synthetic amino acids such as methionine. One former NOSB member stated, in §205.237(5) (b), "We have seemingly made vegetarians out of poultry and pigs". As the organic community moves toward reducing, removing, or providing additional annotations to synthetic methionine in the diets of poultry, a heighten need exists for the organic community to rally around omnivore producers to assist in marshaling our collective efforts in finding viable alternatives to synthetic methionine and help find approaches for making them more commercially available.

- Research on alternatives such as herbal methionine, corn gluten meal, potato meal, management practices, pastures management, fish meals, animal by-products, and other non-plant materials, needs to be explored as an alternative to synthetic methionine.
- Research on the use of natural herbal methionine seemingly is showing great potential. It could possibly replace synthetic methionine at a rate of 1:1. However, more research is needed.

- **Carrageenan**

- Can Carrageenan be produced using methods that are non-synthetic and can those methods be used for all the types of carrageenan?
- Does the gel formed by carrageenan when it is used in food provoke an inflammation response? Injected or in vitro studies allegedly cannot be

compared to feeding studies because the carrageenan has formed a gel that is more resistant to degradation in food.

- Is there replicated proof that carrageenan breaks down into smaller molecular weight forms in digestion and that these forms are small enough and populous enough to pose a health concern?
- Allergic and toxicological responses to carrageenan are so far primarily anecdotal. Can there be further research done to quantify how widespread and truthful these claims are?
- Are there viable alternatives to carrageenan and if so, for what uses?

Other Topics for Future Review:

- **Parasitism**
  - The control of internal and external parasites is important to animal welfare, growth, reproduction, and production. In organic production, the control of parasites is critical. The use of antibiotics is prohibited. A limited number of substances are available to control parasites. Antibiotics are not allowed in organic livestock production for growth, reproduction, and production. Antibiotics can be used on sick animals. However, these animals cannot be sold as organic. A critical need exists to explore ways to find materials for the control of internal and external parasites in organic livestock operations.

- **Mastitis**
  - Mastitis is a disease of the mammary gland. It is an inflammation in the mammary gland. It is generally associated with dairy cattle. It can be caused by bacteria, physical injury, etc. Mastitis is one of the most common and expensive diseases of dairy cattle. It can result in reduced milk production, discarded milk, treatment, and veterinary expenses. An urgent need exists for looking at ways to reduce mastitis in dairy herds. The research needs include the areas of herbal treatment of mastitis and management practices.

- **Herd Health**
  - The assessment of preventive organic practices to improve organic livestock health is critical and of high importance. These include general animal health as it relates to diseases prevention, uterine infections in peri-parturient animals, growth, and identification of vaccine types, nutrition, and production systems.

- **Plant Extract**
    - Plant extracts that could be environmentally and economically beneficial to organically control methane producing bacteria in the animal could lead to practices that reduce methane. Reduced methane results in more energy going to the animal from a given amount of feed. This reduces total feed required to meet nutritional needs and particularly helps grazing animals that have high protein availability from pasture, but low energy. Research in this area could be economically significant.

Subcommittee Vote

Motion to adopt the proposal on NOSB Research Priorities.

Motion by: Zea Sonnabend Second: Calvin Walker
Yes: 4 No: 0 Absent: 2 Abstain: 0 Recuse: 0

National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
Ascorbyl Palmitate

August 14, 2012

Summary of Proposed Action:
Ascorbyl palmitate (AP) is a synthetic ester of ascorbic acid and palmitic acid used in infant formula as a preservative. FDA lists it as GRAS. Ascorbyl Palmitate has antioxidant properties, but, as the TR states " it remains inconclusive whether or not the body actually utilizes ascorbic acid that is metabolized from AP".

Ascorbyl palmitate has some advantages as a food preservative because it is fat soluble and very slightly water soluble. AP synergistically improves the effectiveness of other preservatives, such as tocopherols, to protect fats and oils from rancidity and prevent rancid flavor. It is used in cosmetics, animal feeds and margarine to reduce rancidity (Petition page 2). Synthetic AP is currently used in infant formula to stabilize DHA and ARA edible oils. AP, DHA, and ARA are not required by FDA to be added to infant formula.

Use of AP for stabilizing edible oils raises the issue of a lack of an established policy on "other ingredients." In December 2011 the NOSB approved use of DHA from Algal Oil and ARA from Fungal Oil, and specifically did not approve all the "other ingredients" (which included AP) for broad use in organic food. Approval was specific and explicitly not precedent setting, applying only to the petitioned formulations of DHA and ARA.

Organic alternatives to Ascorbyl palmitate exist, especially rosemary extract and tocopherols. Synthetic tocopherols are also an alternative on the National List if organic rosemary extracts are not suitable. The Petition asserts that tocopherols are currently used in infant formulas, but have limited function without AP. Another alternative is to shorten shelf life date.

Agricultural organic alternatives to AP have not been evaluated for use in infant formula. The TR states, "Other organic agricultural fat-soluble antioxidants which may be potential alternative preservatives include, but are not limited to, alpha-tocopherol (vitamin E), beta-carotene, alpha-lipoic and dihydrolipoic acids, and ubiquinone. … Like ascorbyl palmitate, ubiquinone and dihydrolipoic acid can function as synergistic antioxidants to regenerate tocopherols. No information was found to indicate whether or not these other fat-soluble antioxidants have been tested as alternatives to ascorbyl palmitate as preservatives in food or cosmetics, or are readily available for commercial use in processed foods."

According to the petitioner, certain organic alternative preservatives (carnosic acid from rosemary extract) could have effects harmful to pregnant mothers and unknown side effects in infants. No scientific data has been presented to show adverse effects or the

relative degree of efficacy of using rosemary extract in infant formula. However, the NOSB recommendation approving DHA Algal Oil and ARA Fungal Oil recognized that rosemary extract was included in both materials. It must be noted that the Petition (page 7) states “for infant formula rosemary extracts are not a suitable option” and further states that “rosemary extracts have not been tested and accepted for use in infant formula” and it is “not prudent to use these substances in food for young infants” (Petition, page 8).

As reported by the Journal of the European Food Safety Authority (June 2008), a study in rats found no effect of rosemary extract on fetus development or on the ability of the fetus to reach full term. However, this same scientific opinion states, “The toxicological data on the rosemary extracts are insufficient to establish a numerical ADI [Acceptable Daily Intake], because the toxicity data set does not provide reproductive toxicity studies or a long term study. On the other hand, the existing data, including the absence of effects in the 90-day studies on reproductive organs and lack of genotoxicity, do not give reason for concern.”

Ascorbyl palmitate, as petitioned for use in “organic” infant formula, is not used to fortify food or add nutritional value.

AP is not listed for use as a preservative in organic infant formula in European, Canadian or Japanese standards. In European standards it appears that AP as vitamin C is permitted in organic infant formula to the extent it is required by infant formula directives on vitamins (although, as noted above, data is inconclusive on actual potential absorption of ascorbic acid from AP).

According to the TR, AP does not have significant adverse impacts on the environment or on human health, although it is noted in the Petition (page 5) that high levels of ascorbic acid increase oxalic acid production and excretion with potential for oxalate bladder stones.

Evaluation Criteria

(Applicability noted for each category; Documentation attached)	**Criteria Satisfied? (see “B” below)**		
1. Impact on Humans and Environment	x☐ Yes	☐ 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 N/A as Organic (only for § 205.606)	☐ Yes	☐ No	x☐

Substance Fails Criteria Category: [2 &3] **Comments:**

Proposed Annotation (if any):

Basis for annotation: ☐ To meet criteria above ☐ Other regulatory criteria ☐ Citation
Notes:

Recommended Committee Action & Vote, including classification recommendation (state actual motion):

Classification Motion: Ascorbyl palmitate (CAS 137-66-6) is synthetic.
Motion by: Nick Maravell Seconded by: Jean Richardson
Yes: 6 No: 0 Absent: 1 Abstain: 0 Recuse: 0

Listing Motion: To add Ascorbyl palmitate (CAS 137-66-6) to the National List sec 205.605(b) for use as a preservative in infant formula.
Motion by: Nick Maravell Seconded by: Jean Richardson
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	☐	**Commercial unavailable as organic**	☐	**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: Ascorbyl palmitate (AP) is not required by FDA or other regulation to be added to infant formula. Permitted alternatives exist, including fat soluble ones, but none have been evaluated for use in infant processed foods. Objections to organic rosemary abstract are not supported by scientific data. DHA and ARA, already added to list, contain rosemary extracts. AP is a synthetic preservative and should not be added to the National List under restriction of 205.600(b)(4).
[4]Substance was recommended to be deferred because
If follow-up needed, who will follow up:

Approved by Committee Chair to Transmit to NOSB

[John Foster], Committee Chair 8/14/12

NOSB Evaluation Criteria for Substances Added To the National List

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

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]		x		TR
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		x		
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]		x		
4. Does the substance contain List 1, 2 or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]			x	
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		x		
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		x		
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]			x	
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		x		
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]		x		
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4]	x			At high doses ascorbic acid increases oxalic acid production and excretion with potential for oxalate bladder stones (Petition, page 5)
11. Is there an adverse effect on human health as defined by		x		

applicable Federal regulations? [205.600 b.3]				
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.

NOSB Evaluation Criteria for Substances Added To the National List

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

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]	x			Petition; TR lines 227-234
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		Not the petitioned material.
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		x		
4. Is there a natural source of the substance? [§205.600 b.1]		x		
5. Is there an organic substitute? [§205.600 b.1]		x		
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]		x		Shorter shelf life of product
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	x			Natural alternatives, such as rosemary oil and extracts, for addition to infant formula have not been evaluated.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]		x		
9. Is there any alternative substances? [§6518 m.6]	x			Tocopherols, derived from vegetable oils, and "only when rosemary extracts are not a suitable alternative" TR lines 124-125
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	x			Breast feeding.

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

NOSB Evaluation Criteria for Substances Added To the National List

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

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]		x		
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]		x		
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]		x		
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]		x		TR (lines 317-318) states AP "is used as a preservative, which includes the prevention of off-flavors or bad odors during shelf life of product".
5. Is the primary use as a preservative? [§205.600 b.4]	x			Petition and TR state; "The primary function of ascorbyl palmitate is as a preservative" (TR line 301)
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]	x			Primary use is to prevent "development of off-flavors or bad odors that would otherwise occur over time" (TR line 303)
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: a. copper and sulfur compounds;			x	
b. toxins derived from bacteria;			x	
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?			x	
d. livestock parasiticides and medicines?			x	

e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?			x	

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

NOSB Evaluation Criteria for Substances Added To the National List

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

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			x	

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	

[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.

National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
Synthetic Beta-Carotene

August 7, 2012

Summary of Proposed Action:

1. Petitioned for inclusion on 205.605(b) synthetic, non-agricultural addition to "organic" and "made with organic" ingredients
2. The synthetic version is what is being petitioned but there are natural versions of the ingredient on the market. Commercial availability may be a limiting factor.
3. The petition mentions for use in infant formula as a nutritional supplement and to prevent lipid components in the formula from going rancid (preservative) and as a colorant.
4. Beta-Carotene is necessary for proper development of retinas, and acts as an anti-oxidant, and in some cases as preservative.
5. Is considered GRAS as a food additive for nutrition. As a food colorant, it is exempt from certification (colors are not considered GRAS).
6. B-C can be manufactured from a variety of processes including wholly chemical, from natural sources including fungi and algae, but these methods typically use toxic solvents.
7. BASF is a key manufacturer of the ingredient
8. Commercially available manufacturing process utilizes toxic solvents and/or solvents that pose environmental risk to aquatic species if released.
9. One method of manufacture uses relatively benign solvent made from soy and corn feedstuffs.
10. Only one method from natural dehydrated carrots was discussed.
11. B-C is not required for inclusion in infant formula, therefore the committee had concerns regarding the addition of a synthetic material that is not absolutely necessary.

Evaluation Criteria

(Applicability noted for each category; Documentation attached)	**Criteria Satisfied? (see "B" below)**
1. Impact on Humans and Environment	X Yes ☐ No ☐ N/A
2. Essential & Availability Criteria	X Yes X No ☐ N/A
3. Compatibility & Consistency	X Yes ☐ No ☐ N/A
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for § 205.606)	☐ Yes X No ☐ N/A

Substance Fails Criteria Category: [ ] **Comments:**

Proposed Annotation (if any):

Basis for annotation: ☐ To meet criteria above ☐ Other regulatory criteria ☐ Citation
Notes:

Recommended Committee Action & Vote, including classification recommendation (state actual motion):

Classification Motion: Classify Beta-Carotene as petitioned as synthetic
Motion by: Tracy Favre Seconded by: Harold Austin
Yes: # 5 No: # 0 Absent: #2 Abstain: # 0 Recuse: # 0

Listing Motion: Add Beta-Carotene as petitioned to 205.605(b) for use in infant formula.
Motion by: Tracy Favre Seconded by: Joe Dickson
Yes: # 0 No: # 5 Absent: # 2 Abstain: # 0 Recuse: # 0

Crops	☐	**Agricultural**	☐	**Allowed[1]**	☐
Livestock	☐	**Non-synthetic**	☐	**Prohibited[2]**	☐
Handling	**X**	**Synthetic**	☐	**Rejected[3]**	**X**
No restriction	☐	**Commercial unavailable as organic**	☐	**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: The committee was reluctant to approve the addition of a synthetic material that was not absolutely necessary.

[4]Substance was recommended to be deferred because
If follow-up needed, who will follow up:

Approved by Committee Chair to Transmit to NOSB

John Foster, Committee Chair **August 7, 2012**

NOSB Evaluation Criteria for Substances Added To the National List

Category 1. Adverse impacts on humans or the environment?
Substance: Synthetic Beta-Carotene

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	X		Potential exists for environmental damage due to solvents used in the extraction process, which are toxic to aquatic life
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]	X	X		The solvents used in the manufacturing process are not easily biodegraded and must be properly recycled, leading to potential for improper disposal or spillage. Under proper recycling there is no environmental contamination.
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]	X	X		Could be harmful should solvents used in manufacturing be improperly disposed of
4. Does the substance contain List 1, 2 or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]			X	
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]				Information not available
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]	X	X		See comments above regarding potential for environmental contamination
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]	X	X		See comments above regarding potential for environmental contamination
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]		X		
10. Are there any harmful effects on human health? [§6517 c (1)(A)(i);	X	X		Some studies have linked beta-Carotene with increases in lung

6517 c(2)(A)i; §6518 m.4]				cancer of smokers, but generally the effects of the ingredient are considered beneficial
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]	X	X		See comments above
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]	X			When considered as a nutritional additive, when as a colorant GRAS is not applicable
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]	X	X		The FDA has established residue limits for heavy metals but there is no evidence that contamination exists in the ingredient

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

NOSB Evaluation Criteria for Substances Added To the National List

Category 2. Is the Substance Essential for Organic Production?
Substance: Synthetic Beta-Carotene

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			Per both the petition and TR, the ingredient is considered synthetically manufactured
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]	X	X		The most common formulation of the petitioned ingredient is wholly synthetic and is manufactured using a Confidential method, however there are other methods using solvent extraction from naturally occurring sources
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		The petitioned material is Synthetic Beta-Carotene
4. Is there a natural source of the substance? [§205.600 b.1]	X			Beta-Carotene is widely available in red, orange and yellow fruits and vegetables, leafy greens, some types of fungus and algae
5. Is there an organic substitute? [§205.600 b.1]	X	X		Beta-Carotene can be extracted from plants using environmentally benign solvents from fermented corn and soybean feedstocks, but it is not clear whether this process would be considered organic
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]	X	X		As a nutritional additive, Beta-Carotene has unique anti-oxidant and preservative properties, but the use as a color additive could be replaced with alternatives such as organic annatto.
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X			Naturally derived Beta-Carotene is an alternate source, although commercial viability is an issue
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]	X			Beta-Carotene may be produced by extraction from some fungi and algae using solvents
9. Is there any alternative substances? [§6518 m.6]	X	X		Organic annatto could be used as a replacement for color additive, but would not address the anti-

				oxidant and preservative properties of Beta-Carotene
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.

NOSB Evaluation Criteria for Substances Added To the National List

Category 3. Is the substance compatible with organic production practices?
Substance: Synthetic Beta-Carotene

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

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.

NOSB Evaluation Criteria for Substances Added To the National List

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

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		Neither the TR nor petition makes it clear as to why synthetic Beta-Carotene is necessary over natural
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			There is some discussion that there is only one naturally derived substitute that is commercially available.
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	X		Two suppliers are mentioned but no quantities are listed
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	X	
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or		X	X	
e. Are there other issues which may present a challenge to a consistent supply?			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.

National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
Lutein

July 17, 2012

Summary of Proposed Action:
Lutein (commonly referred to as xanthophyll) is a carotenoid, is related to beta-carotene. It is a strong antioxidant, as well as a natural pigment. Lutein is present in many vegetables such as: spinach, kale, broccoli, and green peas. The petitioned Lutein is derived from dried food grade marigolds. This is the primary source of Lutein used as a coloring agent, food and livestock feed additive, and as a nutritional supplement. Lutein comprises the macular pigment of the eye and is found in the lens. It acts as a filter to blue light and serves an important role in eye health. All Lutein must be acquired through ones diet and cannot be synthesized by the body.

The primary source of Lutein for young infants is from human breast milk. The level of Lutein in human breast milk will vary depending on the dietary intake of Lutein rich vegetables by the infant's mother. This will vary in different parts of the world due to cultural dietary eating habits. Cow milk or soy based infant formulas would need to be fortified with Lutein to equal the amounts normally found in human breast milk.

This ingredient is not required by the FDA under 21 CFR 104.20(d)(3).

The petitioner has requested their product listed **as Lutein- derived from marigold: (Tagetes erecta), and meeting the "Lutein" monograph established by the U.S. Pharmacopeia ("USP")** (when mixed with organic delivery ingredients including organic corn or safflower oil, and organic sugar and starch) as a listed substance pursuant to 7CFR 205.606, on the National List of Allowed and Prohibited Substances in the category of "Non-organically produced agricultural products allowed as ingredients in or on processed products labeled as 'organic'". They are requesting to list two specific uses of Lutein : (1) In organically labeled Infant Formula, (2) In organically labeled foods. The current petitioned source of Lutein is currently being used in organic handling. Because Lutein falls into the "*accessory nutrients"* category and was not one of the substances listed in 21CFR 104.20(d)(3) it is being petitioned for inclusion to the list of allowed substances. Because the actual method of producing Lutein is Confidential Business Information (CBI), the sub-committee could not verify that Lutein would be considered non-synthetic. Therefore the recommendation for classification of Lutein as petitioned is synthetic.

The Handling Sub-Committee was split on the listing of Lutein for use in infant formula. The basis of those voting in favor of listing it was that it currently is being used in some organic infant formulas and secondly because of the role it plays in the eye health of infants (and adults). Those on the sub-committee opposed to listing Lutein believe it is not a mandated additive by FDA for infant formula, did not have enough information in

the CBI version of the petition to determine it to be non-synthetic, it does not appear to be “essential” since it is in some brands and not in others, and there appear to be viable non-synthetic alternatives such as whey protein and microalgae sources. The rationale behind the sub-committee choosing not to include the petitioners request for the second proposed listing, for use in organically labeled foods, is based on the fact that there are currently several alternatives available as a food additive. There are also many natural and organic sources available for adults to obtain Lutein through their diet.

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

1. Impact on Humans and Environment ☒ Yes ☐ No ☐ N/A
2. Essential & Availability Criteria ☐ Yes ☒ No ☐ N/A
3. Compatibility & Consistency ☐ Yes ☒ No ☐ N/A
4. Commercial Supply is Fragile or Potentially Unavailable ☒ Yes ☐ No ☐ N/A
   as Organic (only for § 205.606)

Substance Fails Criteria Category: [2] **Comments:** This substance has not been deemed to be essential by the FDA regulations for use in fortification of infant formulas.

Proposed Annotation (if any):

Basis for annotation: ☐ To meet criteria above ☐ Other regulatory criteria ☐ Citation
Notes:

Recommended Committee Action & Vote, including classification recommendation (state actual motion):

Classification Motion: Lutein (CAS 127-40-2) as petitioned as a synthetic.
Motion by: Harold Austin Seconded by:Jean Richardson
Yes: # 7 No: # 0 Absent: # 0 Abstain: # 0 Recuse: # 0

Listing Motion: To add Lutein (CAS 127-40-2) to the National List 205.605(B) for use in infant formula only. Lutein using approved organic delivery ingredients.
Motion by: Harold Austin Seconded by: John Foster
Yes: # 3 No: # 4 Absent: # 0 Abstain: # 0 Recuse: # 0

Crops	☐	**Agricultural**	☐	**Allowed[1]**	☐
Livestock	☐	**Non-synthetic**	☐	**Prohibited[2]**	☐
Handling	☒	**Synthetic**	**x**	**Rejected[3]**	**x**
No restriction	☐	**Commercial unavailable as organic**	☐	**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: This substance has not been deemed to be essential by the FDA regulations for use in fortification of infant formulas.

[4]Substance was recommended to be deferred because
If follow-up needed, who will follow up:

Approved by Committee Chair to Transmit to NOSB

John Foster, Subcommittee Chair July 17, 2012

NOSB Evaluation Criteria for Substances Added To the National List

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

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]		X		Does require large amounts of land mass to produce. Solvents used during process of extraction could pose a potential threat to the environment. TR lines 502-512
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		Solvent storage tanks could be a potential hazard. TR lines 516-519
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		

4. Does the substance contain List 1, 2 or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]		X		
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		X		
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		X		
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]		X		
10. Are there any harmful effects on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4]		X		There is some speculation that it may play a role in Autism and ADHDD. No scientific support of these claims were found. TR lines 539-543
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			While the substance is not listed as GRAS, the petitioner has received several non-objection responses from the FDA for the use of Lutein, as petitioned. TR lines 416-433
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.

NOSB Evaluation Criteria for Substances Added To the National List

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

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]	X			Solvents (hexane, isopropyl alcohol,etc) are used during the two step extraction process. TR lines 326-329
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]	X			The petitioner claims that it uses a process similar to that used in the manufacture of Pectin or Lecithin-unbleached. TR lines 373-378 mention this claim. The TR lines 384-389
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		X		
4. Is there a natural source of the substance? [§205.600 b.1]	X			Human breast milk. Green vegetables such as spinach, kale, broccoli, and green peas.
5. Is there an organic substitute? [§205.600 b.1]	X			Powdered Lutein processed from green vegetables can be made, but the amount needed to equal the marigold source is not feasible in handling and food processing. Beta-carotene would be an alternate source as a coloring agent. Green vegetables and human breast milk.
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]		X		
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X			Human breast milk. The TR (lines 120-122) also mentions skim milk powder and whey protein.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]		X		
9. Is there any alternative substances?	X			The TR (lines 120-122) indicates that skim milk powder and whey

[§6518 m.6]				protein are possible sources of Lutein. The TR (lines 360-371) discusses obtaining lutein from microalgae, which may be a truly non-synthetic source and appears to be feasible, although not in commercial production at this time.
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			Breast feeding

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

NOSB Evaluation Criteria for Substances Added To the National List

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

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

NOSB Evaluation Criteria for Substances Added To the National List

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

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. 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			X	

regions);				
b. Number of suppliers and amount produced;			X	
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;			X	
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or			X	
e. Are there other issues which may present a challenge to a consistent supply?			X	

[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.

National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
Lycopene

July 24 2012

Summary of Proposed Action:
Synthetic lycopene is currently used in organic infant formula. Under previous NOP policy regarding nutrient vitamins and minerals, an interpretation was made that synthetic ingredients such as lycopene were allowed without being added to the National List. Current NOP policy requires a specific addition to the National List. Lycopene is neither a vitamin nor a mineral. Lycopene is a carotenoid used as a dietary antioxidant and a color. Its petitioned use is not as a preservative or a color.

In 1995, the NOSB made the following recommendation in "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 NOP did not implement accessory nutrients. Lycopene is not required by FDA or other regulation for infant formula. Neither the petition nor the Technical Review (TR) states that any independent professional association recommends it as an accessory nutrient at any specific level for enrichment or fortification. Neither the petition nor the TR presented definitive scientific information to conclude that lycopene is essential for addition to infant formula. The manufacturer notification to FDA of GRAS status (generally recognized as safe) for synthetic forms of lycopene for nutrient use does not include use in infant formula.

The human body does not produce Lycopene. However, depending on the amount of Lycopene consumed in the diet of lactating mothers, Lycopene appears in varying amounts in colostrum and breast milk. Lycopene is added to infant formula to make it more closely resemble breast milk. Levels of lycopene from natural sources in infant formulas are low. Natural and organic sources of lycopene are derived mainly from tomatoes. These sources also contain proteins from the originating plant that could be allergens. According to the petition, it is advisable to delay the introduction of potential allergens in infants less than 6 months old or even older for infants with allergy prone parents. There is no evidence that an allergy to tomatoes would produce allergic reactions to nonsynthetic lycopene, and the information in the TR hypothesized that allergic reactions to tomatoes are related to acidity and not specifically to lycopene.

The TR presented very little information on what alternatives are available in infant formula. Lycopene in breast milk is nonsynthetic. Natural and organic lycopene can be consumed in many foods, especially tomatoes, by lactating mothers. The TR states,

"The commercial use of nonsynthetic lycopene in infant formula, rather than synthetic lycopene, has not been reported, and no evidence indicating that nonsynthetic lycopene would act as a viable substitute for synthetic lycopene in infant formula has been identified." Nonorganic agricultural lycopene for use as a coloring was rejected for addition to the National List by the NOSB in 2007 for lack of justification for not producing lycopene from organic sources. There is no allowance for synthetic lycopene in organic infant formula or other organic foods in European, Canadian or Japanese organic standards.

Synthetic crystalline lycopene, the petitioned material, involves the use of synthetic solvents dichloromethane and toluene in the extraction process. The TR states, "Synthetic lycopene may also contain residues of volatile solvents. However, no information has been identified to indicate that any reported residues of heavy metals or other contaminant in excess of FDA tolerances have been identified." Information is presented on residual extracting solvents in the final product in a different form (not petitioned) of synthetic lycopene produced from *B. trispora* by the manufacturer Vitatene.

Evaluation Criteria

(Applicability noted for each category; Documentation attached) **(see "B" below)**	**Criteria Satisfied?**
1. Impact on Humans and Environment ☐ N/A	x☐ Yes ☐ No
2. Essential & Availability Criteria ☐ N/A	☐ Yes x☐ No
3. Compatibility & Consistency ☐ N/A	☐ Yes x☐ No
4. Commercial Supply is Fragile or Potentially Unavailable x as Organic (only for § 205.606)	☐ Yes ☐ No ☐

Substance Fails Criteria Category: [2 & 3] **Comments:**

Proposed Annotation (if any):

Basis for annotation: ☐ To meet criteria above ☐ Other regulatory criteria ☐ Citation
Notes:

Recommended Committee Action & Vote, including classification recommendation (state actual motion):

Classification Motion: Moved that Crystalline Lycopene be classified as a synthetic material.
Motion by: Zea Sonnabend Seconded by: Tracy Favre
Yes: 5 No: # Absent: 2 Abstain: # Recuse: #

Listing Motion: Moved that Crystalline Lycopene (CAS #502-65-8) for use in infant formula be added to the National List sec. 205.605(b).

Motion by: Jean Richardson Seconded by: Harold Austin
Yes: # No: 5 Absent: 2 Abstain: # Recuse: #

Crops	☐	**Agricultural**	☐	**Allowed[1]**	☐
Livestock	☐	**Non-synthetic**	☐	**Prohibited[2]**	☐
Handling	x☐	**Synthetic**	x☐	**Rejected[3]**	x☐
No restriction	☐	**Commercial unavailable as organic**	☐	**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: Not essential to or consistent with organic production.

[4]Substance was recommended to be deferred because
If follow-up needed, who will follow up:

Approved by Committee Chair to Transmit to NOSB

John Foster, Committee Chair July 24, 2012

NOSB Evaluation Criteria for Substances Added To the National List

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

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		No specific information found with regard to use of volatile synthetic solvents to demonstrate no adverse effects.
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		x		No specific information found with regard to use of volatile synthetic solvents to demonstrate no adverse effects.
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]		x		
4. Does the substance contain List 1, 2 or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]			x	

5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		x		
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		x		
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]			x	
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		x		
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]		x		
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4]		x		
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		x		
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]	x			Self certified as GRAS but not for infant formula.
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.

NOSB Evaluation Criteria for Substances Added To the National List

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

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]	x			Petition and TR.
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]		x		
3. Is the substance created by naturally occurring biological processes? [6502 (21)]		x		
4. Is there a natural source of the substance? [§205.600 b.1]	x			Foods high in lycopene, such as tomatoes.
5. Is there an organic substitute? [§205.600 b.1]			x	
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]		x		
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	x			Agricultural sources, such as tomatoes.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]		x		
9. Is there any alternative substances? [§6518 m.6]	x			Natural agricultural lycopenes.
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	x			Breast feeding.

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

NOSB Evaluation Criteria for Substances Added To the National List

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

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	Not a processing aid or adjuvant as referred to in 205.600(b)(2)
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]		x		
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]		x		
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]		x		
5. Is the primary use as a preservative? [§205.600 b.4]		x		
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]		x		
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:			x	
a. copper and sulfur compounds;				
b. toxins derived from bacteria;			x	
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?			x	
d. livestock parasiticides and medicines?			x	
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?			x	

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

NOSB Evaluation Criteria for Substances Added To the National List

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

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			x	

	production or destroy crops or supplies;				
d.	Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or			x	
e.	Are there other issues which may present a challenge to a consistent supply?			x	

National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
L-Carnitine

June 19, 2012

Summary of Proposed Action:
L-Carnitine is a compound that is synthesized in the body from the amino acids lysine and methionine. These amino acids are abundant in foods such as beans, avocado and red meat. The synthetic form has been petitioned for use in infant formula because soy-based formulas contain very low levels of carnitine, and infants are less able to synthesize carnitine for themselves. Cow's milk formulas also can be low in carnitine because the milk is diluted in the formula.

Unlike some other ingredients petitioned for infant formula, carnitine is not required under the FDA in 21 CFR 104.20, 107.100 or 107.10 as clarified in the NOP proposed rule on Nutrient Vitamins and Minerals. Also it appears that carnitine would be feasible to make or extract from non-synthetic sources, although that is not commercially done at this time. For these reasons the Handling Sub-committee is not recommending to add synthetic L-carnitine to the National List.

Evaluation Criteria

(Applicability noted for each category; Documentation attached)	**Criteria Satisfied? (see "B" below)**
1. Impact on Humans and Environment	X Yes ☐ 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 § 205.606)	☐ Yes ☐ No X ☐ N/A

Substance Fails Criteria Category: [2] **Comments:**
This substance is not deemed to be essential by FDA regulations for the fortification of infant formula.

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

Recommended Committee Action & Vote, including classification recommendation (state actual motion):

Classification Motion: L-Carnitine [CAS #541-15-1] as petitioned is synthetic.
Motion by: Zea Sonnebend Seconded by: Harold Austin
Yes: # 5 No: # 0 Absent: # 1 Abstain: # 0 Recuse: #0

Listing Motion: To add L-Carnitine [CAS #541-15-1] to the National List 205.605 (b)--for use in infant formula only.
Motion by: John Foster Seconded by: Harold Austin
Yes: # 2 No: # 3 Absent: # 1 Abstain: # 0 Recuse: #0

Crops	☐	**Agricultural**	☐	**Allowed[1]**	☐
Livestock	☐	**Non-synthetic**	☐	**Prohibited[2]**	☐
Handling	**x**	**Synthetic**	**x**	**Rejected[3]**	**x**
No restriction	☐	**Commercial unavailable as organic**	☐	**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: It appears that carnitine would be feasible to make or extract from non-synthetic sources, although that is not commercially done at this time.

Approved by Committee Chair to Transmit to NOSB

John Foster, Committee Chair June 19, 2012

NOSB Evaluation Criteria for Substances Added To the National List

Category 1. Adverse impacts on humans or the environment? Substance: L-Carnitine

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,		X		

	use, misuse, or disposal? [§6518 m.3]				
3.	Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		
4.	Does the substance contain List 1, 2 or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]		X		
5.	Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		X		
6.	Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		X		
7.	Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		
8.	Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		
9.	Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]		X		
10.	Are there any harmful effects on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4]		X		
11.	Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]		X		
12.	Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]	X			may be self identified. See TR Evaluation question #4 (lines 350 - 363)
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.

NOSB Evaluation Criteria for Substances Added To the National List

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

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			while there are non-synthetic ways to manufacture it, most in use for supplementation is synthesized from epichlorhydrine or trimethlamine. (TR lines 285-287)
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]		X		
3. Is the substance created by naturally occurring biological processes? [6502 (21)]	X	X		it can be produced by "biosynthetic or fermentative methods" (TR lines 294-295) but it is not clear if these would be considered non-synthetic. It appears from the TR discussion for Evaluation questions #1 and #2, that non-synthetic production would be possible but is not commercially done in the US at this time.
4. Is there a natural source of the substance? [§205.600 b.1]	X			abundant in food and human breast milk.
5. Is there an organic substitute? [§205.600 b.1]	X			organic food
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]		X		
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X			human breast milk
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]		X		
9. Is there any alternative	X			human breast milk

substances? [§6518 m.6]				
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			breast feeding

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

NOSB Evaluation Criteria for Substances Added To the National List

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

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		since the substance could be obtained from organic foods, the synthetic fortification is not compatible with organic handling.
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]		X		
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]		X		
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]	X			
5. Is the primary use as a preservative? [§205.600 b.4]		X		
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]		X		
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: a. copper and sulfur compounds;			X	
b. toxins derived from bacteria;			X	
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?			X	
d. livestock parasiticides and medicines?			X	
e. production aids including netting, tree wraps and seals,			X	

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.

NOSB Evaluation Criteria for Substances Added To the National List

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

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the comparative description provided as to why the non-organic form of the material /substance is necessary for use in organic handling?	X			provided but not convincing.
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			X	

climate and number of regions);				
b. Number of suppliers and amount produced;			X	
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;			X	
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or			X	
e. Are there other issues which may present a challenge to a consistent supply?			X	

[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.

National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
L-Methionine

July 3, 2012

Summary of Proposed Action:
The Team Leader for Infant Formula Regulation at FDA provided information about the need for L-Methionine in soy based formulas in order to meet requirements for protein quality at 21 CFR 107.100 (f) . Subcommittee members have reservations about approving synthetic L Methionine, because toxic solvents are used in extraction process. However the subcommittee recommends approval, acknowledging the fact that if L-Methionine is not added to soy formula there would be no organic soy based formula. The group discussed the fact that protein is the essential building block and there does not seem to be an alternate source of non-milk protein available in commerce for use for infant formula.

Additional comments: The Handling Subcommittee would welcome public comment about alternatives.

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	X Yes ☐ No ☐ N/A
3. Compatibility & Consistency	☐ Yes ☐ No X N/A
4. Commercial Supply is Fragile or Potentially Unavailable	X Yes ☐ No ☐ N/A
as Organic (only for § 205.606)	

Substance Fails Criteria Category: [ ] **Comments:**

Proposed Annotation (if any):

Basis for annotation: ☐ To meet criteria above ☐ Other regulatory criteria ☐ Citation
Notes:

Recommended Committee Action & Vote, including classification recommendation (state actual motion):

Classification Motion: Motion to list L-Methionine on 205.605(b) as synthetic, non-agricultural.
Motion by: TF Seconded by: HA
Yes: # 6 No: # 0 Absent: # 1 Abstain: #0 Recuse: #0

Listing Motion: Motion to list L Methionine for inclusion on 205.605(b). For use only in infant formula made with isolated soy-based protein.
Motion by: TF Seconded by: HA
Yes: # 6 No: # 0 Absent: # 1 Abstain: # 0 Recuse: #0

Crops	☐	**Agricultural**	☐	**Allowed[1]**	**X**
Livestock	☐	**Non-synthetic**	☐	**Prohibited[2]**	☐
Handling	**X**	**Synthetic**	**X**	**Rejected[3]**	☐
2No restriction	☐	**Commercial unavailable as organic**	**X**	**Deferred[4]**	☐

[1]Substance voted to be added as "allowed" on National List to § 205.605(b) with Annotation (if any): For use in or on processed infant formula labeled as "organic" or "made with organic ingredients". Annotated: For use only in formula made with isolated soy-based protein.

[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:

Approved by Committee Chair to Transmit to NOSB

John Foster, Committee Chair July 3, 2012

NOSB Evaluation Criteria for Substances Added To the National List

Category 1. Adverse impacts on humans or the environment? Substance: L-Methionine

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]	X	X		Yes, manufacture of synthetic L-Methionine typically is obtained from a precursor DL-Methionine, which uses Cyanide, considered an extremely toxic and volatile chemical. Inadvertent release of Cyanide has happened and has caused environmental damage.
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]	X	X		Yes, see above comment.
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]	X			Continued use of synthetically manufactured L-Methionine has the potential to delay the development of naturally obtained sources, including aquatic sources
4. Does the substance contain List 1, 2 or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]			X	
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]	X			Over supplementation of L-Methionine has shown to have detrimental effect on the uptake of other critical amino acids
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		X		L-Methionine breaks down fairly quickly in the environment and is therefore not considered a risk to soil or water health.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		See above comments
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		X		
9. Is there undesirable persistence or concentration of the material or breakdown products in		X		

environment? [§6518 m.2]				
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4]	X	X		Over supplementation of L-Methionine is hepatoxic, causing fatty deposits in the liver. Normal supplementation has not shown detrimental effects, and is, in fact, an essential amino acid.
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.

NOSB Evaluation Criteria for Substances Added To the National List
Category 2. Is the Substance Essential for Organic Production?
Substance: L-Methionine

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]	X	X		Both synthetic and non-synthetic methods exist, but only the synthetic method is commercially available.
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]	X	X		The manufacture of L-Methionine can be accomplished from natural materials, however, only the completely synthetic methods are commercially viable.
3. Is the substance created by naturally occurring biological processes? [6502 (21)]	X			L-Methionine is an essential amino acid that is obtained in the human diet from meat, dairy and some grains. The human body is not able to synthesize it.
4. Is there a natural source of the substance? [§205.600 b.1]	X			See above
5. Is there an organic substitute? [§205.600 b.1]	X			Yes, but not commercially viable at this time.
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]		X		
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X			It may be obtained from natural, whole food sources.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]		X		
9. Is there any alternative substances? [§6518 m.6]	X	X		Cow's milk, meat and some grains are sources, but for soy-based formulas, L-methionine is not available in sufficient amounts to meet the dietary requirements of infants.
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			Breastfeeding would eliminate the need for soy-based formulas

NOSB Evaluation Criteria for Substances Added To the National List

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

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]		X		Previous TAP and TR indicate that the synthetic manufacture of L-methionine is not considered compatible with organic handling
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]		X	X	Petitioned use is for soy-based infant formula only, but is not consistent with organic farming.
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			In fact, this is the only justification for inclusion of L-methionine in soy-based formulas
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			It is required in order to bring nutrient contents of soy-based formula up to milk-based formulas and mother's milk.
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: copper and sulfur compounds;	X			This is a sulfur-based amino acid.
a. toxins derived from bacteria;			X	
b. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?			X	
c. livestock parasiticides and medicines?			X	
d. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?			X	

NOSB Evaluation Criteria for Substances Added To the National List

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

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		Quality of the substance has not been discussed, rather the commercial availability of the organic version
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	X	Not provided but not relevant to manufacture.
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or		X	X	Same as above
e. Are there other issues which may present a challenge to a consistent supply?	X			Only as related to organic and non-synthetic versions of L-Methionine

[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.

National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
Nucleotides

August 21, 2012

Summary of Proposed Action:
Nucleotides are compounds that are made in the body from amino acids. These amino acids are abundant in whole foods with protein. The synthetic form has been petitioned for use in infant formula to increase levels of nucleotides to those in human breast milk.

Nucleotides are not mandated to be added to infant formulas under the FDA in 21 CFR 104.20, 107.100 or 107.10, as clarified in the NOP proposed rule on Nutrient Vitamins and Minerals. It may also be possible to make or extract them from non-synthetic sources, although that is not commercially done at this time. The Handling Sub-committee is recommending to add synthetic nucleotides to the National List.

Evaluation Criteria

(Applicability noted for each category; Documentation attached) **(see "B" below)**	**Criteria Satisfied?**		
1. Impact on Humans and Environment N/A	**x Yes**	☐ No	☐
2. Essential & Availability Criteria N/A	x Yes	☐ No	☐
3. Compatibility & Consistency N/A	x Yes	☐ No	☐
4. Commercial Supply is Fragile or Potentially Unavailable N/A as Organic (only for § 205.606)	☐ Yes	☐ No	x

Substance Fails Criteria Category: [ ] **Comments:**

Proposed Annotation (if any):

Nucleotides—allowed for infant formulas only in the "organic" and "made with organic categories". Nucleotides are allowed for the "made with organic claim" on all other food products.

Basis for annotation: ☐ To meet criteria above ☐ Other regulatory criteria ☐ Citation
Notes:

Recommended Committee Action & Vote, including classification recommendation (state actual motion):

Classification Motion:
Motion to classify nucleotides as synthetic.
Motion by: Tracy Favre Seconded by: Harold Austin
Yes: 7 No: 0 Absent: 0 Abstain: 0 Recuse: 0

Listing Motion:
Motion to list Nucleotides for inclusion on 205.605(b) allowed for infant formulas only in the "organic" and "made with organic categories". Nucleotides are allowed for the "made with organic claim" on all other food products.
Motion by: John Foster Seconded by: Jean Richardson
Yes: 4 No: 3 Abstain: 0 temporary Absent: Recuse: 0

Crops	☐	**Agricultural**	☐	**Allowed**[1]	X ☐
Livestock	☐	**Non-synthetic**	☐	**Prohibited**[2]	☐
Handling	x	**Synthetic**	x	**Rejected**[3]	
No restriction	☐	**Commercial unavailable as organic**	☐	**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:

Approved by Committee Chair to Transmit to NOSB

John Foster, Committee Chair August 21, 2012

NOSB Evaluation Criteria for Substances Added To the National List

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

Question	Yes	No	N/A[1]	Documentation or Justification
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]		x		
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		
4. Does the substance contain List 1, 2		X		

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

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

NOSB Evaluation Criteria for Substances Added To the National List

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

Question	Yes	No	N/A[1]	Documentation or Justification
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]	X			
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			Substances are natural, but they are synthetic when produced for commercial use
3. Is the substance created by naturally occurring biological processes? [6502 (21)]	X			They are created via natural processes, but synthetic systems are created to generate large volumes of these
4. Is there a natural source of the substance? [§205.600 b.1]	X			Yes, but not available in the quantity needed for commercial production
5. Is there an organic substitute? [§205.600 b.1]		X		
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]		X		
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X	X		Yeast may be a suitable alternative. Breast milk.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]	X			
9. Are there any alternative substances? [§6518 m.6]	X	X		See 7 above.
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X	X		See 7 above.

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

NOSB Evaluation Criteria for Substances Added To the National List

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

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			Not an essential nutrient, vitamin, or mineral.
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]			X	
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]			X	
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]	X			
5. Is the primary use as a preservative? [§205.600 b.4]		X		
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]		X		
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: a. copper and sulfur compounds;			X	
b. toxins derived from bacteria;				
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.

NOSB Evaluation Criteria for Substances Added To the National List

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

Question	Yes	No	N/A[1]	Documentation or Justification
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:Regions of production (including factors such as climate and number of regions);			x	
a. Number of suppliers and amount produced;				
b. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt				

production or destroy crops or supplies;				
c. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or				
d. Are there other issues which may present a challenge to a consistent supply?				

[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.

National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
Taurine

July 3, 2012

Summary of Proposed Action:
Taurine is a compound that is synthesized in the body from methionine and cysteine metabolism. While not technically an amino acid it is more accurately classified as a B-amino sulfone. It is found in animal protein such as seafood, beef and chicken and nearly absent from vegetarian foods. The synthetic form has been petitioned for use in infant formula because insufficient taurine could result in subpar fat digestion and absorption in infants.

Taurine is not required under the FDA in 21 CFR 104.20(d)(3), 107.100 or 107.10. Taurine can be made or extracted from non-synthetic sources, although apparently available only in small amounts at this time. Although essential for cats and thus added to cat pet food, taurine is considered a non-essential human dietary supplement.

The Handling Sub-committee is not recommending addition of Taurine to the National List.

Evaluation Criteria

(Applicability noted for each category; Documentation attached) **(see "B" below)**	**Criteria Satisfied?**
1. Impact on Humans and Environment	x☐ Yes ☐ 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 § 205.606)	☐ Yes ☐ No X N/A

Substance Fails Criteria Category: [2] **Comments:**
This substance is not deemed essential by FDA regulations for fortification of infant formula

Proposed Annotation (if any):

Basis for annotation: ☐ To meet criteria above ☐ Other regulatory criteria ☐ Citation
Notes:

Recommended Committee Action & Vote, including classification recommendation (state actual motion):

Classification Motion: Taurine (CAS# 107-35-7) as petitioned is synthetic.
Motion by: Jean Richardson Seconded by: Joe Dickson
Yes: 4 No: 0 Absent: 3 Abstain: 0 Recuse: 0

Listing Motion: To add Taurine (CAS 107-35-7) to the National List 205.605 b for use in infant formula only.

Motion by: Seconded by:
Yes: 0 No: 4 Absent: 3 Abstain: 0 Recuse: 0

Crops	☐	**Agricultural**	☐	**Allowed[1]**	☐
Livestock	☐	**Non-synthetic**	☐	**Prohibited[2]**	☐
Handling	X	**Synthetic**	X	**Rejected[3]**	X
No restriction	☐	**Commercial unavailable as organic**	☐	**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:

Approved by Committee Chair to Transmit to NOSB

John Foster, Committee Chair July 3, 2012

NOSB Evaluation Criteria for Substances Added To the National List

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

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		Inasmuch as the TR addressed this issue there does not appear to be adverse environmental effects
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		X		
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]		X		
4. Does the substance contain List 1, 2 or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]		X		
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		X		
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		X		
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		X		
8. Is there a toxic or other adverse action of the material or its breakdown products?		X		

[§6518 m.2]				
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]		X		
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4]		X		None cited in TR
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	X		TR Line 290 "taurine is not listed as GRAS.."
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.

NOSB Evaluation Criteria for Substances Added To the National List

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

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			There are non-synthetic ways to manufacture taurine (TR lines 264-268) much of the taurine used is created by commercial chemical processes (TR lines 262-263)
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]		X		
3. Is the substance created by naturally occurring biological processes? [6502 (21)]	X	X		Taurine is extracted from natural sources (TR 264-268) but only in small quantities
4. Is there a natural source of the substance? [§205.600 b.1]	X			Abundant in animal protein in food sources, and in human breast milk.
5. Is there an organic substitute? [§205.600 b.1]	X			Organic food
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]		X		
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	X			Human breast milk
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]		X		
9. Is there any alternative substances? [§6518 m.6]	X			Human breast milk
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]	X			Breast feeding

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

NOSB Evaluation Criteria for Substances Added To the National List

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

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		Because the substance could be obtained from organic foods the synthetic dietary supplement fortification is not compatible with organic handling
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]		X		
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]		X		
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]		X		Taurine is a non-essential dietary supplement (TR), lack of which "could result in subpar fat digestion and absorption by infants" (Petition, page 4, paragraph 4)
5. Is the primary use as a preservative? [§205.600 b.4]		X		
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]		X		
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: a. copper and sulfur compounds;			X	
b. toxins derived from bacteria;			X	
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?			X	
d. livestock parasiticides and medicines?			X	
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?			X	

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

NOSB Evaluation Criteria for Substances Added To the National List

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

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			Provided, but not detailed.
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **form** to fulfill an essential function in a system of organic handling?			X	
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quality** to fulfill an essential function in a system of organic handling?			X	
4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quantity** to fulfill an essential function in a system of organic handling?			X	
5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following:			X	
a. Regions of production (including factors such as climate and number of regions);				
b. Number of suppliers and amount produced;			X	
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;			X	

d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or			X	
e. Are there other issues which may present a challenge to a consistent supply?			X	

[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.

National Organic Standards Board
Handling Subcommittee
"Other Ingredients" Discussion Document
August 21, 2012

Introduction[1]

On Nov. 23, 2011, National Organic Program (NOP) Deputy Administrator Miles McEvoy sent a Memorandum to the National Organic Standards Board (NOSB) requesting clarification of "other ingredients" contained within handling materials on the National List of Allowed and Prohibited substance used in processed organic products. Since OFPA requires that each non-organic ingredient be specifically allowed, and because the National List does not specifically list "other ingredients" commonly found in formulated products, the NOP identified the need for clarity and requested that the NOSB develop a policy that specifies whether these "other ingredients" are allowed.

In the memo to NOSB, NOP requested the following:

> The NOP is requesting that the NOSB develop a policy on "other ingredients" in § 205.605 substances that is comparable to the comprehensive policy for crop and livestock materials. From this point forward, NOP is requesting that NOSB consider the presence of any "other ingredients" as part of its processes. As substances on the National List come up for sunset review, or as new petitions are considered, NOP requests that NOSB clarify whether any restrictions are warranted for "other ingredients" in § 205.605 substances. Any third-party technical report that NOP provides will include information on any "other ingredients" commonly found in the substance under review.
>
> NOP is requesting that NOSB specify any allowed "other ingredients" in the background section of its recommendations for substances recommended for listing on § 205.605, so that these allowances are clear to the organic trade, certifying agents, and NOP. Any "other ingredients" not listed on § 205.605 or not referenced in the background section of the recommendation, would not be allowed in formulations of substances on § 205.605 that are used in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

The memo continues:

> NOSB may want to address the subject further in the future with a comprehensive policy for "other ingredients" that may be included in permitted handling materials. Some questions that could be addressed in a future recommendation could include the following:
>
> 1. Should all agricultural ingredients that are "other ingredients" be organically produced?
> 2. Are synthetic preservatives allowed as "other ingredients?

In response to the memo, the NOSB Handling Sub-Committee is currently working to develop a policy for "other ingredients" that may be included in permitted handling materials. This discussion document defines "other ingredients" and the scope of their review,

[1] The NOSB Handling Subcommittee wishes to thank the members of the ad hoc Materials Working Group for providing a framework for this Discussion Document. Their names are in Appendix 3.

provides historical and regulatory background, and proposes a range of policy options for consideration along with an assessment of their impact on the organic sector.

Background

The NOP regulations require that all certified organic producers and handlers use materials that comply with the applicable parts of the Standards [7 CFR Part 205]. The Standards include Subpart G (The National List), which dictates allowed synthetic and prohibited nonsynthetic inputs for use in organic crop and livestock production and nonorganic substances allowed in organic food processing and handling.

In general, for crop and livestock production, non-synthetic materials are allowed unless prohibited. Synthetic substances may be used provided they are on the National List and used in accordance with any specified restrictions. In contrast, the handling standards require that all non-organic non-agricultural substances, whether synthetic or non-synthetic, be included on the National List. Non-organic agricultural ingredients used in the 5% of an "organic" product must also be on the National List AND commercially unavailable in organic form.

Some items on § 205.605 and on § 205.606, however, are sold as multicomponent substances or mixtures wherein the "active" or listed substance is combined with "other ingredients," (e.g. carriers, stabilizers and antioxidants) to provide a ***necessary*** technical effect on the National List substance. In certain cases, small amounts of standardizing agents may be incorporated to ensure the substance meets the specifications required by their standards of identity. Examples of § 205.605 substances that generally contain "other ingredients" include, but are not limited to, biological substances such as enzymes, dairy cultures and microorganisms; cleaners, sanitizers and disinfectants such as peracetic acid; and nutrient vitamins. Examples of § 205.606 items that generally contain "other ingredients" include, but are not limited to, casings from processed intestines, colors, fish oil, pectin, and whey protein concentrate.

The chart in Appendix 4 lists the substances currently on §205.605, the specific list of non-agricultural substances that are the subject of the NOP request; the agricultural substances currently listed at §205.606, which were not mentioned in the NOP request but some of which share the characteristic of containing "other ingredients"; and those substances recommended by NOSB but which have not yet completed the process, along with those "other ingredients" identified in the original petition, a Technical Advisory Panel (TAP) review or a Technical Report (T)R). The chart also references examples of "other ingredients" that are disclosed on specification sheets that certifiers use when determining compliance for a formulated ingredient.

Currently, the allowance of "other ingredients" in substances on the National List used in processed organic products is unclear, particularly in contrast with crop and livestock substances. For organic crop and livestock production, specific categories of "other ingredients" are allowed as inert ingredients in pesticides and excipients in animal drugs.

While inert ingredients used in pesticide products, and excipients used in animal drugs are addressed, the regulations are silent on "other ingredients" used in ***non***-pesticide and ***non***-drug products. As stated in the NOP memo of November 23, 2011, for crop and livestock

products, a synthetic “other ingredient” is prohibited unless it appears on the National List and non-synthetic “other ingredients” are allowed unless prohibited by the National List. The Handling Subcommittee believes that exceptions have been made for livestock vitamins and minerals due to the fact that they commonly contain “other ingredients” but their use is required to fulfill the nutritional needs of certified livestock.

In contrast, the National List for processed products does not include a provision that provides allowances for any “other ingredients”. Instead, certain substances on the National List, such as flavors, colors and fish oil, specify a ***restriction*** on the use of “other ingredients.” This has led some to believe that “other ingredients” used in handling materials are allowed unless specifically prohibited.

Relevant areas in OFPA and Regulations (see **Appendix 1** for full references)
OFPA prohibits a certified handler from adding “any synthetic ***ingredient*** not appearing on the National List during processing or any postharvest handling.” The National List heading in the regulations at § 205.605 and § 205.606 also specify the use of non-agricultural substances and agricultural products, respectively, referred to as ‘***ingredients.’*** While OFPA does not reference processing aids, the regulations under § 205.301(f)(4) prohibit the use of ‘***processing aids*’** during the handling of an organic product unless they are approved on the National List. Both terms are included under 205.2 (Terms Defined). Furthermore, in the final ruling on the Harvey II case the Courts determined that Congress did not distinguish between the general term “ingredients” and “processing aids,” and authorized the use of synthetic substances, whether ingredients or processing aids, for the use in handling operations so long as they appear on the National List.[2].

The Federal Rule § 205.301 determines that product composition for products labeled as "organic" must contain only ingredients that are organically produced (95%) or "be nonagricultural substances or nonorganically produced agricultural products produced consistent with the National List in subpart G of this part".

Examples of specified restrictions addressing "other ingredients" in § 205.605 include:

> Flavors, nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.
>
> Peracetic acid/Peroxyacetic acid (CAS # 79–21–0)—for use in wash and/or rinse water according to FDA limitations. For use as a sanitizer on food contact surfaces.

Examples of specified restrictions addressing "other ingredients" in § 205.606 include:

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

[2]OFPA does not refer to ‘processing aids.’ However, in the final ruling on the Harvey II case Nov. 2, 2006, the District Court of Maine ruled that the OFPA change of 2005 that allowed synthetic “ingredients” also allowed synthetic “processing aids” as long as they appear on the National List. The Court determined that Congress did not distinguish between the general term “ingredients” and “processing aids,” and authorized the use of synthetic substances, whether ingredients or processing aids, for the use in handling operations so long as they appear on the National List (Memorandum Decision on Motion to Enforce Judgment and Cross Motion for Relief from Judgment, U.S. District Court, District of Maine, Civil Docket 2:02cv216).

(f) Fish oil (Fatty acid CAS #'s: 10417–94–4, and 25167–62–8)—stabilized with organic ingredients or only with ingredients on the National List, §§205.605 and 205.606.

The inconsistent use of the term 'substance' used throughout OFPA and the regulations, and the Federal Register Notice on Procedures for Submitting National List Petitions [72 *Federal Register* 2167] has not fostered a clear and consistent approach to the issue. The Notice reads:

> Any person may submit a petition requesting a substance to be reviewed by the NOP and NOSB at any time. Each substance to be evaluated for the National List must be submitted in a separate petition. **Only single substances may be petitioned for evaluation; formulated products cannot appear on the National List.**

Discussion

Defining "other ingredients"

This discussion paper focuses on the use and allowance of "**other ingredients**" contained in § 205.605 items. The term "other ingredients," as described in the NOP Memo to NOSB, is not a recognized regulatory term with a legal definition. However since the term was used in the NOP Memo, it will be used throughout this discussion document. For this purpose, "other ingredients" will be defined as additives added during the manufacturing of a non-organic substance and ***not*** removed. They are defined as "incidental additives" by FDA.

FDA defines "incidental additives" as ingredients that are present in a food at insignificant levels and do not have any technical or functional effect in that food. An incidental additive is usually present because it is an ingredient within another ingredient used in the final product, or it is a processing aid added to a food for its technical or functional effect in the processing and present only in insignificant amounts in the final food. In such cases, per FDA labeling regulations, incidental additives and processing aids do not need to be declared on the label of the final food (certified product) (CFR Title 21 101.22(h)(3) and 101.100 (a)(3i to iii4). **See Appendix 2** for other relevant FDA Definitions.

It should be clear that "other ingredients" discussed in this paper are not the same as "ingredients" or "processing aids" used for a specific purpose ***directly*** by a certified handler in or on processed organic products. The regulations are clear that non-organic 'ingredients' or 'processing aids' used directly by a certified handler in or on a certified organic processed product must be on the National List at § 205.605 or § 205.606. "Other ingredients" are substances that are present by way of having been incorporated into an allowed substance on the National List. As such, most, if not all "other ingredients," will fall under FDA's definitions for incidental additives and, if present at only insignificant levels, are exempt from FDA's labeling requirements.

The NOP memo only requested a policy on § 205.605 listings on the National List. However non-organic ***agricultural*** ingredients or products listed on § 205.606 of the National List often contain "other ingredients" also. The Handling Sub-Committee believes it will be more efficient and result in overall better comprehension to address both sections

of the National List at the same time. Therefore, we have incorporated § 205.606 into our policy options in this discussion paper.

We have not presented policy options for synthetic solvents and processing aids used during the production of non-organic ingredients on § 205.605 and § 205.606 in this document. This topic is part of the overall 'Classification of Materials' discussion, thus we believe it is outside the scope of the "other ingredients" discussion provided the processing aids or solvents undergo a removal step.

Baseline Criteria

We believe that baseline criteria that should be used for the evaluation of "other ingredients," based on the existing requirements that are already imposed by OFPA and 7 CFR Part 205. This would parallel those identified in the NOP Memo for Inerts in crop pesticides and Excipients in Livestock drugs. These baseline criteria would apply to all policy options for review of ingredients.

The **baseline criteria** are as follows:
"Other ingredients" are those that are authorized for use in materials on the National List at § 205.605 and § 205.606 according to the following criteria:

1. The National List [7 CFR 205.605 – 606] or;
2. Mandatory federal requirements [7 U.S.C. §6519(f)] or;
3. FDA (GRAS) or otherwise [7 U.S.C. § 6517(c) and 7 U.S.C 6519(f)]; or
4. EPA [7 U.S.C. § 6517(c) and 7 U.S.C 6519(f)] or;
5. Any other federal regulatory agency with primary jurisdiction over that substance [7 U.S.C 6519(f)].

AND any component or ingredient would be disallowed if:

6. Prohibited by federal regulatory action [7 U.S.C. § 6517(d)] or;
7. Produced using excluded methods [7 CFR 205.105(e) and 7 CFR 205.2] or;
8. Contain any heavy metals or toxic residues in excess of established tolerance levels set by FDA or EPA [7 U.S.C. § 6510(a)] or;
9. It provides a technical or functional effect in the final certified organic product and therefore does not meet FDA's definition of an 'incidental additive'.

Policy Options

NOSB currently evaluates materials on a case-by-case basis without an overarching policy for "other ingredients." Additionally, ACAs and MROs have no overall guidance on other ingredients from the NOP, varying capacities for materials review and wide latitude to make decisions unless specific decisions are overruled by the NOP. While the review of materials in general for use in organic production and handling is currently quite rigorous, there is need for improvement and harmonization of the system to assure continued confidence and growth of the industry.

NOP clearly recognizes the need to improve review of non-organic ingredients as reflected by their declaration in the memo that third party technical reports will include information on "other ingredients" and their request that NOSB consider their presence as part of their review process "from this point forward." In acknowledgement of this request, the options

presented all include NOSB review of “other ingredients”. A fundamental variation between the options however is the method by which NOSB specifies the allowance of “other ingredients” after they have conducted their review.

Option A simply includes NOSB review of “other ingredients” as requested by NOP, but allows for the presence of all “other ingredients” unless they are restricted or prohibited by an annotation. Option B aligns with the request in the NOP memo, but includes suggestions to help facilitate review by certifiers and MROs and includes additional criteria that are specific to the various categories of materials on § 205.605 and § 205.606. Option C presents a blanket policy that while easy to understand would be very challenging to implement. The pros and cons of each option are described in further detail below.

Option A

For all newly petitioned non-organic ingredients, the NOSB considers "other ingredients" identified in the petition and Technical Report and documents the review in the background section of their recommendation. Items already on the National List are not subject to this provision, unless the NOSB explicitly requests a Technical Report to address the ‘other ingredient’ question of a particular item subject to Sunset Review. Unless restrictions are specified in an annotation, any “other ingredient” that meets Baseline Criteria is permitted.

Review Criteria for NOSB

Other ingredients must meet Baseline Criteria (above). NOSB will determine whether any specific prohibitions that should be specified in an annotation based on their review of “other ingredients” discussed or disclosed in the petition or Technical Report or presented in further research or public comment.

Pros:

- Processors, handlers and their suppliers have the greatest possible latitude to formulate ingredients and develop organic products.
- ACAs and MROs have a minimum amount of documentation to review.
- All products that meet the current standard and policy comply unless NOP specifies otherwise.
- Policy is the least likely to cause inconsistencies with major trading partners.
- Greater number of options for non-organic ingredients.
- Less time and energy spent on the allowed non-organic portion freeing up more time to advocate and work towards increased organic production.

Cons:

- Little incentive to source organic alternatives to ingredients on 7 CFR 205.605.
- There is no transparent way to be able to look up all of the non-organic substances that might be contained in a certified product containing non-organic ingredients.
- Potential decline in the value of the organic label due to dilution and loss of consumer confidence.

Option B

The NOSB would follow the request by NOP to consider “other ingredients” during their review as substances come up for sunset review or as new petitions are considered. The NOSB would review “other ingredients” included in the petition and Technical Report. The

NOSB recommendation includes a note that the other ingredients were reviewed and accepted. The “other ingredient” is entered into a database maintained on the NOP Website. Materials listed on § 205.605(a) and § 205.606 must not contain any "synthetic" incidental additives unless they are on the National List at § 205.605(b) or specifically allowed by NOSB. Non-synthetic incidental additives are allowed unless specifically prohibited. Synthetic incidental additives are allowed in 205.605(b) items if they are included and documented in the NOSB review. Any additional restrictions are specified in an annotation.

Other ingredients in general product categories that are currently on § 205.605 and § 205.606 and currently used in certified organic processed product will be grandfathered for one sunset period recommendations, including vitamins, minerals, enzymes, dairy cultures, yeast, microorganisms, natural flavors, and colors. NOSB can recommend exceptions for new materials that are petitioned as appropriate. The National List is restructured to create a separate category and exceptions for cleaners, sanitizers, disinfectants and other substances that are secondary direct and indirect food additives subject to a separate Baseline Criteria.

Review Criteria for NOSB:

- Other ingredients must meet Baseline Criteria (above).
- NOSB considers “other ingredients” as disclosed in the petition and Technical Report.
- If the substance is recommended for inclusion on the National List, the NOSB may specify implicit allowance of all other ingredients, deny allowance of other ingredients, or prohibit those other ingredients in the recommendation.
- NOSB may recommend “other ingredients” individually, categorically or a combination of both.
- Non-synthetic ingredients used as other ingredients in items are allowed unless specifically prohibited.
- The NOSB may stipulate in a review that any agricultural "other ingredients" must be organically produced.
- Materials listed on § 205.605(a) and 205.606 must not contain any "synthetic" incidental additives unless they are on the National List at § 205.605(b) or specifically allowed by NOSB.
- Synthetic incidental additives are allowed in 205.605(b) substances if they were reviewed, approved and documented by NOSB.
- NOSB specifies any additional restrictions or allowances in an annotation.
- As a part of the Sunset Review process, the NOSB should request Technical Reports on the following product categories currently on the National List:
    - Vitamins/Minerals
    - Enzymes (including animal enzymes)
    - Microorganisms
    - Dairy Cultures
    - Natural Flavors
    - Agricultural Colors

  The TR will help the NOSB determine whether other ingredients that are not “organic” or on the National List are currently being used in these categories and whether to recommend annotation or documentation in the database.

- "Other ingredients" contained in sanitizers or cleaners or other similar non-food inputs that are used in direct contact with certified product must be on the National List or their allowance must be specified through an annotation via a CAS number or reference to another agency's regulation, (e.g. peracetic acid), or their use must be mandated by law or specifically allowed through NOP Policy.

- Substances classed by FDA as secondary direct or indirect additives not used in direct contact with certified product are allowed provided the operator has clear intervention/contamination prevention measures detailed in their OSP.

Pros:

- Greater consistency amongst ACA's and MRO's.
- Having the NOSB provide relevant annotations for each material would enable each material to be looked at in its context.
- The NOSB assessment would be open for review and public comment, bringing greater transparency.
- Would clarify the review process for most materials that contain carriers, stabilizers, standardizing agents.
- Most likely to meet many if not most consumer advocates expectations for organic food.
- Individual ingredients would be assessed according to use and type.
- Other regulatory agencies would be referred to for legally approved formulas for cleaners, sanitizers, boiler additives.

Cons:

- Annotations can still be interpreted differently and may not always be clear.
- Annotations are verified through desk audit. Increased paperwork for verification purposes.
- This option could only work if there is a consistent policy/decision tree on how to determine nonsynthetic vs. synthetic.
- More work for the NOSB.
- More work for ACAs and MROs to collect and review the necessary information.
- Only certain specific formulas will be petitioned and receive Technical Reports. Some Branded formulations currently used in organic processed products may include other ingredients not reviewed because the manufacturer is unable or unwilling to disclose all of the ingredients.
- The NOP may not keep up the aforementioned database

Option C

All ingredients in a processed product labeled as organic must either be organically produced or on the National List. NOSB creates three new sections to the National List that are designated for incidental additives only (other ingredients). They may not be used directly by a certified handler in or on a certified product. They are allowed only by way of having been incorporated into a substance appearing on § 205.605 or § 205.606 of the National List.

Review Criteria for NOSB

- Review all petitions for other ingredients according to the Baseline Criteria, the regulations and guidance.
- Review during Sunset the “other ingredients” not previously petitioned or allowed.
- Suspend all new petitions for final ingredients until there are petitions for other ingredients. (Or: Require petitioners of final ingredients to submit petitions for other ingredients if not previously petitioned or allowed.)
- NOSB creates three new sections to the National List that are designated for incidental additives only (other ingredients). The new sections would be as follows:

    - § 205.607(a) Non-synthetic nonagricultural incidental additives allowed only in substances that appear on § 205.605(a) or § 205.605(b);
    - § 205.607(b) Synthetic nonagricultural incidental additives allowed only in substances that appear on § 205.605(b); and
    - § 205.607 (c) Non-organic agricultural incidental additives allowed only in substances that appear on § 205.605(a), § 205.605(b), or § 205.606.

- Exceptions are made for cleaners, sanitizers, disinfectants and secondary direct food additives:
    - “Other ingredients” contained in sanitizers or cleaners or other similar non-food inputs that are used in direct contact with certified product must be on the National List or their allowance must be specified through an annotation via a CAS number or reference to another agency’s regulation, (e.g. peracetic acid), or their use must be mandated by law or specifically allowed through NOP Policy.

    - Secondary direct or Indirect additives not used in direct contact with certified product are allowed provided the operator has clear intervention/contamination prevention measures detailed in their OSP.

- NOSB recommends a transition time for currently listed substances that will allow manufactures and non-organic ingredients and certified handlers adequate time to bring products into compliance. NOP will specify this transition or implementation time in their draft and final guidance.

Pros:

- More clarity about the regulation.
- Reduced number of options for non-organic ingredients and corresponding growth of organic minor ingredients that would lead to increased organic acreage and increased business opportunity.
- Customers who buy and eat organic foods can be certain that all the incidental ingredients, which by law are not required to be listed on the finished product label, in an organic product are either organic or on the National List.
- ACAs and MROs have a clear rule to make materials decisions.
- Promotes a strong incentive to use organic ingredients.
- Clear and simple process for retailers and marketers to explain to consumers.
- Most likely to meet many if not most consumer advocates expectations for organic food.

Cons:

- Most restrictive in terms of what ingredients can be used.
- All “other ingredients” (carriers, standardizing agents, stabilizers, pH adjusters, diluents, etc.) that are not on the National List or “organic” will need to be petitioned which could result in significant review and rulemaking.
- NOP and NOSB have limited time and resources and could be overly burdened by the time needed to review petitions and complete necessary rulemaking.
- Could potentially increase the number of synthetic substances on the National List, which may be misunderstood by consumers.
- Reduced number of options for non-organic ingredients and corresponding loss of products currently on the market due to limited options, especially for materials like pectin and gums.
- Would have commercial and cost implications for certified manufacturers that could lead to loss of organic products, which would lead to reduced organic acreage.
- Many products currently on the market may be non-compliant.
- Product from countries with an equivalency agreement won’t need to comply.
- Product from countries without an equivalency agreement may file a Technical Barrier to Trade complaint with the World Trade Organization.
- Would have commercial and cost implications for certified manufacturers
- Similar “cons” related to varying interpretations of annotations and the potential for the NOSB to list “other ingredients” that are petitioned by a select few.
- May result in certified organic products currently on the market becoming unavailable because a manufacturer of an ingredient chooses not to reformulate to meet these new requirements.

Other Considerations

In the course of developing policy options for this paper, several other considerations became apparent. The Handling Sub-Committee hopes to do further work on some of these subjects in the future and brings them up here because they are relevant to reviewing handling materials under any of these policy options.

- It would be helpful if the NOP creates a publicly available database that documents material review and specifies “other ingredients” that were reviewed and approved.
- If a new policy is adopted there will be need for transition time for operators to bring products into compliance. NOP will need to specify this transition or implementation time in their draft and final guidance.
- We would like to explore a recommendation to move cleaners, sanitizers, disinfectants and other non-food substances such as boiler additives to their own designated section of the National List and develop policy specific to these types of items.
- We would like to ask NOP to report on what legal and regulatory hurdles exist that prevent assigning commercial availability to all § 205.605. If no hurdles exist, we will consider drafting a recommendation that would assign commercial availability to all § 205.605 listed substances.

Increasing the use of organic ingredients and processing aids has been a very explicit goal of the organic community since early on. The key to increasing organic ingredients lies in the interpretation of the phrase, commercial availability. The NOSB has already endorsed the concept of a pro-active approach to the development and creation of organic analogs to

replace non-organic and synthetic items. Implementation of the pro-active program that would apply to both § 205.605 and § 205.606 substances would help encourage and further the development of organic minor ingredients. In turn this would likely stimulate the use of “other ingredients” in 205.605 substances that are either organic or on the National List.

Comments Requested

1. Which is your preferred option? Please answer with the following in mind:
    a. Which option best captures the intent of the law?
    b. Which option best captures the expectation of the consumer?
    c. Which option is best for the growth of the organic industry?
    d. Which option will be the most difficult to implement? Describe the obstacles.

2. Do you think that in general, ***nonsynthetic*** incidental additives should be allowed without further petitioning, review or rulemaking if they meet baseline criteria?

3. Should the use of organic substitutes be required of § 205.605 substances when they are commercially available?

4. Should organic preference (synthetic allowed when nonsynthetic is not available; nonsynthetic allowed when organic is not available) be assigned to “other ingredients”? Is this practical? How would it be enforced?

5. Is it acceptable to allow “other ingredients” as incidental components of an allowed substance on the National List? Does it make a difference knowing they are present at amounts typically below 10ppm?

6. Should sanitizers, cleaners and disinfectants be moved to their own section of the National List and dealt with separately from ingredients and processing aids?

7. Should “other ingredients” used in sanitizers, cleaners, or disinfectants be organic or on the National List?

8. How can the system of reviewing non-organic ingredients used in processed organic products be improved?

Sub-Committee Vote

Motion: The Handling Sub-Committee moves to accept this document and present it for full board discussion at the Fall 2012 NOSB meeting

Motion by: Zea Sonnabend Second: Tracy Favre
Yes: 7 No: 0 Absent: 0 Abstain: 0 Recuse: 0

Appendix 1 – Regulatory References

OFPA

SEC. 2111. [**7 U.S.C. 6510**] **HANDLING.**

(a) IN GENERAL.—For a handling operation to be certified under this title, each person on such handling operation shall not, with respect to any agricultural product covered by this title—

(1) add any synthetic ingredient not appearing on the National List during the processing or any postharvest handling

SEC. 2118. [7 U.S.C. 6517] **NATIONAL LIST.**

(a) IN GENERAL.—The Secretary shall establish a National List of approved and prohibited substances that shall be included in the standards for organic production and handling established under this title in order for such products to be sold or labeled as organically produced under this title.

(b) CONTENT OF LIST.—The list established under subsection (a) shall contain an itemization, by specific use or application, of each synthetic substance permitted under subsection (c)(1) or each natural substance prohibited under subsection (c)(2).

NOP Regulations

§ 205.2. Terms Defined.

Ingredient. Any substance used in the preparation of an agricultural product that is still present in the final commercial product as consumed.

Processing aid.

(1) Substance that is added to a food during the processing of such food but is removed in some manner from the food before it is packaged in its finished form;

(2) a substance that is added to a food during processing, is converted into constituents normally present in the food, and does not significantly increase the amount of the constituents naturally found in the food; and

(3) a substance that is added to a food for its technical or functional effect in the processing but is present in the finished food at insignificant levels and does not have any technical or functional effect in that food.

§ 205.301 Product composition.

(b) *Products sold, labeled, or represented as "organic."* A raw or processed agricultural product sold, labeled, or represented as "organic" must contain (by weight or fluid volume, excluding water and salt) not less than 95 percent organically produced raw or processed agricultural products. Any remaining product ingredients must be organically produced, unless not commercially available in organic form, or must be nonagricultural substances or nonorganically produced agricultural products produced consistent with the National List in subpart G of this part. If labeled as organically produced, such product must be labeled pursuant to §205.303.

(c) *Products sold, labeled, or represented as "made with organic (specified ingredients or food group(s)).*" Multi-ingredient agricultural product sold, labeled, or represented as "made with organic (specified ingredients or food group(s))" must contain (by weight or

fluid volume, excluding water and salt) at least 70 percent organically produced ingredients which are produced and handled pursuant to requirements in subpart C of this part. No ingredients may be produced using prohibited practices specified in paragraphs (f)(1), (2), and (3) of §205.301. Nonorganic ingredients may be produced without regard to paragraphs (f)(4), (5), (6), and (7) of §205.301. If labeled as containing organically produced ingredients or food groups, such product must be labeled pursuant to §205.304.

(f) All products labeled as “100 percent organic” or “organic” and all ingredients identified as “organic” in the ingredient statement of any product must not:

(4) Be processed using processing aids not approved on the National List of Allowed and Prohibited Substances in subpart G of this part: Except, That, products labeled as “100 percent organic,” if processed, must be processed using organically produced processing aids;

§ 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)).”

The following nonagricultural substances may be used as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” only in accordance with any restrictions specified in this section.

Examples of specified restrictions addressing “other ingredients”:

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

Peracetic acid/Peroxyacetic acid (CAS # 79–21–0)—for use in wash and/or rinse water according to FDA limitations. For use as a sanitizer on food contact surfaces.

§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”

Only the following nonorganically produced agricultural products may be used as ingredients in or on processed products labeled as “organic,” only in accordance with any restrictions specified in this section, and only when the product is not commercially available in organic form.

Examples of specified restrictions addressing “other ingredients”:

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

(f) Fish oil (Fatty acid CAS #'s: 10417–94–4, and 25167–62–8)—stabilized with organic ingredients or only with ingredients on the National List, §§205.605 and 205.606.

Appendix 2 – FDA terms

Food additive. A substance, the intended use of which results or may reasonably be expected to result, directly or indirectly, either in the substance becoming a component of food or otherwise affecting the characteristics of food. A material used in the production of containers and packages is subject to the definition if it may reasonably be expected to become a component, or to affect the characteristics, directly or indirectly, of food packed in the container. A substance that does not become a component of food, but that is used in preparing an ingredient of the food to give a different flavor, texture, or other characteristic in the food, may be a food additive. 21 CFR § 170.3.

Secondary Direct Food Additive. This term is in the title of 21 CFR 173, which was created during recodification of the food additive regulations in 1977. A secondary direct food additive has a technical effect in food during processing but not in the finished food (e.g., processing aid). Some secondary direct food additives also meet the definition of a food contact substance. For more on food contact substances, consult the Food Contact Substance Notification Program.

Indirect Food Additive - In general, these are food additives that come into contact with food as part of packaging, holding, or processing, but are not intended to be added directly to, become a component, or have a technical effect in or on the food. Indirect food additives mentioned in Title 21 of the U.S. Code of Federal Regulations (21CFR) used in food-contact articles, include adhesives and components of coatings (Part 175), paper and paperboard components (Part 176), polymers (Part 177), adjuvants and production aids and sanitizers (Part 178). Currently, additional indirect food additives are authorized through the food contact notification program. In addition, indirect food additives may be authorized through 21 CFR 170.39.

Incidental additive. 21 CFR101.100(a)(3) Incidental additives that are present in a food at insignificant levels and do not have any technical or functional effect in that food. For the purposes of this paragraph (a)(3), incidental additives are:

(i) Substances that have no technical or functional effect but are present in a food by reason of having been incorporated into the food as an ingredient of another food, in which the substance did have a functional or technical effect.

(ii) Processing aids, which are as follows:

(*a*) Substances that are added to a food during the processing of such food but are removed in some manner from the food before it is packaged in its finished form.

(*b*) Substances that are added to a food during processing, are converted into constituents normally present in the food, and do not significantly increase the amount of the constitutents naturally found in the food.

(*c*) Substances that are added to a food for their technical or functional effect in the processing but are present in the finished food at insignificant levels and do not have any technical or functional effect in that food.

(iii) Substances migrating to food from equipment or packaging or otherwise affecting food that are not food additives as defined in section 201(s) of the act; or if they are food additives as so defined, they are used in conformity with regulations established pursuant to section 4.

GRAS - "GRAS" is an acronym for the phrase Generally Recognized As Safe. Under sections 201(s) and 409 of the FD&C Act, any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive. GRAS substances are distinguished from food additives by the type of information that supports the GRAS determination, that it is publicly available and generally accepted by the scientific community, but should be the same quantity and quality of information that would support the safety of a food additive. Additional information on GRAS can be found on the GRAS Notification Program page.

Appendix 3 – Materials Working Group

The Materials Working Group is an unaffiliated ad hoc committee of volunteers with technical and regulatory background. The MWG was initiated in November, 2007 following the NOSB meeting to work on clarifying the issues surrounding the definitions of “nonagricultural,” “synthetic” and “nonsynthetic,” and to provide the NOSB with recommendations and guidance documents relating to those definitions. Participation in the group is voluntary, open and available to any interested party.

The NOSB Handling Subcommittee wishes to thank members of the Materials Working Group for their help in putting together this Discussion Document.

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Appendix 4 – Chart of § 205.605 and § 205.606 substances along with “other ingredients” identified in Technical Reviews and Petitions.

FDA Regulatory citation & Category	7 CFR 205.605	Other Ingredients (TAP, TR, Petition, NOSB Recommendation)	Comments
(a) *Nonsynthetics allowed:*			
Biological Materials			

	Animal enzymes—(Rennet—animals derived; Catalase—bovine liver; Animal lipase; Pancreatin; Pepsin; and Trypsin)	2000 TAP: Enzyme preparations usually contain diluents, preservatives (to prevent microbial growth In liquid preparations), antioxidants, and other food grade substances consistent with current good manufacturing practice. Among the substances used in commercial rennet preparations include salt (sodium chloride), propylene glycol, sodium benzoate, and sodium propionate.	
21 CFR 184.1685	Rennet		
21 CFR 184.1034	Catalase		
21 CFR 184.1415	Animal lipase		
21 CFR 184.1583	Pancreatin		
21 CFR 184.1595	Pepsin		
21 CFR 184.1914	Trypsin		
21 CFR 184.	**Dairy cultures.**	No mention of "other ingredients" (other than milk)	See specification sheets for Enzymes and Dairy Cultures
21 CFR 184.	**Enzymes—must be derived from edible, nontoxic plants, nonpathogenic fungi, or nonpathogenic bacteria.**		See specification sheets for Enzymes and Dairy Cultures
	Plant enzymes	1995 TAP: ". . . Carriers and stabilizers used to keep them mold-free and stable . . ."	
	Microbial enzymes	1995 TAP: "Preparations from microbial sources are the most important source of commercial enzymes and are produced from the fermentation of specifically selected nonpathogenic and nontoxicogenic strains of microorganisms. These microorganisms are **grown on natural food grade substances (such as starch and corn meal)**	Specification sheets lists calcium sulfate and wheat (carrier) as ingredients used in combination with enzymes. See spec sheet

		under controlled conditions which prevent the introduction of undesirable microorganisms or other substances. Enzymes are recovered from the fermentation broth under mild conditions usually by mechanical separation means, such as filtration or centrifugation and then concentrated using ultrafiltration or evaporation. **Any carriers, diluents, or processing aids used in the production of enzyme preparations are acceptable for general use in food**, and the levels used do not exceed specified limits." "**Preservatives** are almost always added during processing, and optionally in the final preparation, to prevent microbial growth and to stabilize and maintain the desired enzymic activity. Proper and appropriate use of **preservatives and stabilizers** serve to protect the consumer from unsafe or ineffective enzyme products. When the enzyme is intended for addition to food, **all such additives and diluents** must be acceptable to the FDA for use in food. They must be of food grade quality and the levels used must not exceed specified limits." 2011 Enzymes TR: "Microbial enzymes used in food processing and are typically sold as enzyme preparations, which are mixtures with the desired enzyme activity that contain preservatives (such as boric acid and natamycin), stabilizers (such as salts and aminoacetic acid), and other metabolites of the production strain." "Substances used in commercial rennet preparations include salt (sodium chloride), propylene glycol, sodium benzoate, boric acid, and sodium propionate."	for Watson Enzymes. Example spec sheet for Marzyme Enzyme lists Sodium chloride, acetic acid and sodium acetate
	Microorganisms—any food grade bacteria, fungi, and other	TAP: Only discusses enzymes, dairy cultures, and yeasts; PETITION: Miso - non-pathogenic fungi used for fermentation; Pre-gelatinized starch	

	microorganism.	added.	
21 CFR 184.	**Yeast—nonsynthetic, growth on petrochemical substrate and sulfite waste liquor is prohibited**	Yeast, Autolysate, Brewer's, Nutritional - nothing added Yeast, Bakers - Yeast cake is mixed with oils, emulsifiers and water... (From TAP 1996) Yeast, Smoked - Hickory smoke added for flavor. Spec sheet included with TAP (1996) showing only yeast and Hickory smoke flavor.	**(Autolysate; Bakers; Brewers; Nutritional; and Smoked—non-synthetic smoke flavoring process must be documented)**
Defined Substances			
	Acids (Alginic; Citric—produced by microbial fermentation of carbohydrate substances; and Lactic).	no "other ingredients"	
21 CFR 184.1011	Alginic acid	no "other ingredients"	
21 CFR 184.1033	Citric acid	1995 TAP: "pure substance"	
21 CFR 184.1061	Lactic acid	TAP: NO additives noted; MSDS Indicates impurities in mfg proess possible (10-20% Lactic Acid lactate)	
21 CFR 184.1115	Agar-agar.	1995 TAP: no "other ingredients." 2011 TR: no "other Ingredients."	
21 CFR 184.1155	Bentonite.	1995 TAP: no "other ingredients."	
21 CFR 184.1191	Calcium carbonate.	no "other ingredients"	
21 CFR 184.1193	Calcium chloride.	No TAP; no "other ingredients"	
21 CFR 184.1230	Calcium sulfate—mined.	2001 TAP: Terra Alba as mined may contain certain impurities (limestone (calcium carbonate) and various naturally occurring forms of silica). No "added ingredients."	

21 CFR 172.620	Carrageenan.	1995 TAP: Carrageenan precipitated isopropyl alcohol may contain traces of residual isopropyl alcohol (21 CFR refers only to water extraction); may contain residues of epichlorhydrin from chlorinated antimicrobials. If recovered by drum drying, may contain up to mono- and diglycerides or up to 5% polysorbate 80. Chemicals may be added when standardizing carrageenan: sugar, sodium chloride, potassium chloride, phosphate salts, other hydro-colloids. 2011 TER: No mention of "added ingredients."	Example Specification sheet: Standardized with Sucrose
21 CFR ??? GRAS	Diatomaceous earth—food filtering aid only.	Some DE is calcined in the presence of suitable flux (soda ash (sodium carbonate) or other alkaline salt)	
21 CFR ??? GRAS	Egg white lysozyme (CAS # 9001–63–2)	No specific combination products were identified for egg white lysozyme (or bromelain). Lysozyme is directly added to foods as a hydrochloride salt.	
21 CFR 184.	**Flavors, nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.**	The natural flavor does not contain propylene glycol, any artificial preservative, and is not extracted with hexane. Manufacturers must provide written documentation in their Organic Handling Plan, which shows that efforts were made toward the ultimate production of an organic natural flavor as listed in the stepwise progression below: 1. Natural flavor constituents and non-synthetic carrier base and preservative agents; 2. Organic flavor constituents, organic carrier base, and organic preservative agents; and 3. Organic flavor constituents extracted using organically produced solvent, organic carrier base, and organic preservative agents.	
21 CFR 172.665	Gellan gum (CAS # 71010–52–1)—high-acyl form only.	None shown in TAP, committee recommendation or petition	
21 CFR 184.1318	Glucono delta-lactone—	None shown inTAP. No committee recommendation. MSDS shows 99%	

	production by the oxidation of D-glucose with bromine water is prohibited.	GDL in petition.	
21 CFR 186.1256	Kaolin.	TAP MSDS shows 90-100% kaolin. No petition, or recommendations given	
21 CFR 184.1069	L-Malic acid (CAS # 97–67–6).	TAP: No other ingredients identified; must be from microbial fermentation.	
21 CFR 184.1443	Magnesium sulfate, nonsynthetic sources only.	TR: No other ingredients	
21 CFR 184.1540	Nitrogen—oil-free grades.	No other Ingredients	
21 CFR ??? GRAS	Oxygen—oil-free grades.	No other Ingredients	
21 CFR ??? GRAS	Perlite—for use only as a filter aid in food processing.	No other Ingredients	
21 CFR 184.1622	Potassium chloride.	No documents available on NOP website	
21 CFR 184.1634	Potassium iodide.	No other Ingredients	
21 CFR 184.1736	Sodium bicarbonate.	1995 TAP: No combinations listed. One reviewer states: "As with all synthetic inorganic salts, source must be food grade. In addition each lot should be analyzed for toxic element concentrations (mercury, lead, cadmium, arsenic, thallium and antimony) and a near zero tolerance adopted.	
21 CFR 184.1742	Sodium carbonate.	1995 TAP: No combinations listed. One reviewer states: "As with all synthetic inorganic salts, source must be food grade. In addition each lot should be analyzed for toxic element concentrations (mercury, lead, cadmium, arsenic, thallium and antimony) and a near zero tolerance adopted.	
21 CFR 184.1099	Tartaric acid—made from grape wine.	1995 TAP:	

	Waxes—nonsynthetic (Carnauba wax; and Wood resin).	Wax 2007 TAP: "Shellac is used as a hard protective coat, and will rapidly harden if not kept in a solvent. Aqueous lac will also be combined with various synthetic preservatives such as phenol, or the mixed methyl and propyl esters of p-hydroxybenzoic acid. It is almost always used with pure ethyl alcohol, but will occasionally isopropyl alcohol is used as a solvent. Often used with wood resins. Ammonium soap is used as a flowing and solidifying agent with wood resin and shellac."	
21 CFR 184.1978	Carnauba wax	1996 TAP ("Fruit Waxes"): No other Ingredients	
21 CFR 172.210	Wood rosin	1996 TAP ("Fruit Waxes"): No other Ingredients	
(b) *Synthetics allowed:*			
Sanitizers, other Secondary Direct Food Additives			Sanitizer examples and common "other ingredients" are not presented here.
21 CFR 186.1750	**Acidified sodium chlorite—Secondary direct antimicrobial food treatment and indirect food contact surface sanitizing. Acidified with citric acid only.**		
21 CFR 173.325	**Chlorine materials—disinfecting and sanitizing food contact surfaces, (Calcium hypochlorite;**	2006 TR: "products contain no other active ingredients and contain no inert ingredients other than water"	***Except,* That, residual chlorine levels in the water shall not exceed the maximum residual**

	Chlorine dioxide; and Sodium hypochlorite).		**disinfectant limit under the Safe Drinking Water Act**
21 CFR ???	Calcium hypochlorite		
21 CFR 186.1750	Sodium hypochlorite		
21 CFR 178.1010	Chlorine dioxide		
21 CFR 184.1366	Hydrogen peroxide.		
21 CFR 184.1563	Ozone.	Petition includes oxygen and air as potential secondary ingredients; no other ingredients noted	
21 CFR 178.1010	**Peracetic acid/Peroxyacetic acid (CAS # 79–21–0)—for use in wash and/or rinse water according to FDA limitations. For use as a sanitizer on food contact surfaces.**	Original petition unable to obtain from NOP website; TAP Crops and Livestock: Stabilizers are acknowledged to be not considered in the review; TAP Processing: HEDP, dipicolini acid (2, 6-pyridinedicarboxylic acid), sulfuric acid, octanoic acid, peroxyoctanoic acid, sodium 1-octanesulfonate - mentioned in TAP but not evaluated to OFPA and the NL; HEDP mentioned in TAP reviews Committee recommendation.	
21 CFR 173.370	Acetic acid		
21 CFR 184.1005	Hydrogen peroxide	No TAP, committee recommendation, or petition shown.	
21 CFR 184.1366	HEDP (1-hydroxyethylidene-1,1-diphosphonic acid)		
21 CFR 178.1010	Sulfuric acid		
21 CFR 184.1095	Octanoic acid		
21 CFR 184.1025			
21 CFR 182.1073	Phosphoric acid—cleaning of food-contact surfaces and	TAP: Always combined with surfactant. Naphthalenesulfonic acid, sodium dodecylbenzene sulfonic acid, carboxylic acids, citric acid, lactic acid,	

	equipment only.	isopropyl alcohol, mention of FDA approved solutions, EDTA ethylenediaminetetraacetic acid	
21 CFR 173.310	Cyclohexylamine (CAS # 108–91–8)—for use only as a boiler water additive for packaging sterilization.	No "other ingredients"	
21 CFR 173.310	Diethylaminoethanol (CAS # 100–37–8)—for use only as a boiler water additive for packaging sterilization.	No "other ingredients." Blended with sodium zeolite softened water.	
21 CFR 173.310	Octadecylamine (CAS # 124–30–1)—for use only as a boiler water additive for packaging sterilization.	No "other ingredients"	
Nutrient vitamins and minerals			
	Nutrient vitamin ingredients		
21 CFR 184.1930	**Vitamin A**	No other ingredients mentioned in TAP	
21 CFR 184.1950	**Vitamin D**	No other ingredients mentioned in TAP	
USP/FCC	Vitamin K_1 (Phylloquinone) [required per 21 CFR 107.100(c)]	No other ingredients mentioned in TAP	
	Vitamin K [Menaquinone-7]	No other ingredients mentioned in TAP	[GRN No. 245 submitted & withdrawn]
21 CFR 182.8890	Vitamin E [tocopherols]	No other ingredients mentioned in TAP	
21 CFR 182.8892	Vitamin E [alpha-tocopherol acetate]	No other ingredients mentioned in TAP	
21 CFR	Ascorbic acid	No other ingredients mentioned in	

182.8013		TAP	
21 CFR 182.3189	Calcium ascorbate	No other ingredients mentioned in TAP	
21 CFR 182.3731	Sodium ascorbate	No other ingredients mentioned in TAP	
21 CFR 184.1875	Thiamine hydrochloride	No other ingredients mentioned in TAP	
21 CFR 184.1878	Thiamine mononitrate	No other ingredients mentioned in TAP	
21 CFR 184.1695	Riboflavin	No other ingredients mentioned in TAP	
21 CFR 184.1697	Riboflavin-5'-phosphate, sodium	No other ingredients mentioned in TAP	
21 CFR 184.1676	Pyridoxine hydrochloride	No other ingredients mentioned in TAP	
21 CFR 184.1945	**Vitamin B12**	No other ingredients mentioned in TAP	
21 CFR 184.1530	Niacin	No other ingredients mentioned in TAP	
21 CFR 184.1535	Niacinamide	No other ingredients mentioned in TAP	
21 CFR 172.345	Folic acid	No other ingredients mentioned in TAP	
21 CFR 184.1212	Calcium pantothenate	No other ingredients mentioned in TAP	
21 CFR 182.8159	Biotin	No other ingredients mentioned in TAP	
21 CFR 182.8890	Tocopherols—derived from vegetable oil when rosemary extracts are not a suitable alternative.	No other ingredients mentioned in TAP	
21 CFR ??? GRAS	Activated charcoal (CAS #s 7440–44–0; 64365–11–3)—only from vegetative sources; for use only as a filtering aid.	Pure carbon; no other ingredients	
	Alginates.	Alginates are produced from alginic acid and various alkaline elements (pH control agents). The pH control agents (are) ammonia, calcium	

		hydroxide, potassium hydroxide, sodium hydroxide. No "other ingredients" mentioned.	
21 CFR 184.1133	Ammonium alginate		
21 CFR 184.1187	Calcium alginate		
21 CFR 184.1610	Potassium alginate		
21 CFR 184.1721	Sodium alginate		
21 CFR 184.1135	Ammonium bicarbonate—for use only as a leavening agent.	No TAP Review available; this substance is a single entity	
21 CFR 184.1137	Ammonium carbonate—for use only as a leavening agent.	No TAP Review available; this substance is a single entity	
21 CFR 182.8013	Ascorbic acid.	1995 TAP: no "other ingredients"	
21 CFR 184.1195	Calcium citrate.	1995 TAP: no "other ingredients"	
21 CFR 184.1205	Calcium hydroxide.	1995 TAP: no "other ingredients"	
21 CFR 182.8217	Calcium phosphates (monobasic, dibasic, and tribasic).	1995 TAP: no "other ingredients"	
21 CFR 182.6215	Monobasic calcium phosphate	1995 TAP: no "other ingredients"	
21 CFR 182.1217	Dibasic calcium phosphate	1995 TAP: no "other ingredients"	
21 CFR 182.1217	Tribasic calcium phosphate	1995 TAP: no "other ingredients"	
21 CFR 184.1240	Carbon dioxide.	1995 & 2006 Tap: No "other ingredients"	
21 CFR ??? GRAS	Cellulose—for use in regenerative casings, as an anti-caking agent (non-chlorine bleached) and filtering aid.	Petition: 100% cellulose (no "other ingredients"). 2001 TAP: "All additives must appear on the National List"	

21 CFR 184.	Ethylene—allowed for postharvest ripening of tropical fruit and degreening of citrus.	No "other ingredients"	
21 CFR 184.1307	Ferrous sulfate—for iron enrichment or fortification of foods when required by regulation or recommended (independent organization).	MSDS in TAP states composed of Iron II sulfate hydrate and sulfuric acid (2+) salt. No petition, or committee recommendation.	
21 CFR 184.1505	Glycerides (mono and di)—for use only in drum drying of food.	None listed in TAP, or petition. No committee recommendation.	
21 CFR 182.1320	Glycerin—produced by hydrolysis of fats and oils.	No TAP, committee recommendation, or petition shown.	
21 CFR 184.1425	Magnesium carbonate—	No" other ingredients" mentioned in TAP; but various grades mentioned	for use only in agricultural products labeled “made with organic (specified ingredients or food group(s))”
21 CFR 184.1426	Magnesium chloride—derived from sea water.	No" other ingredients" mentioned in TAP	
21 CFR 184.1440	Magnesium stearate—	No" other ingredients" identified in TAP, but identified as a potential "incidental" additive itself in the TAP review	for use only in agricultural products labeled “made with organic (specified ingredients or food group(s))”
21 CFR 184.1595	Pectin (low-methoxy).	No "other ingredients"	

21 CFR 184.1077	Potassium acid tartrate.	No "other ingredients"	
21 CFR 184.1619	Potassium carbonate.	No "other ingredients"	
21 CFR 184.1625	Potassium citrate.	1995 TAP: no "other ingredients"	
21 CFR 184.1631	Potassium hydroxide—prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches during the Individually Quick Frozen (IQF) production process.	No "other ingredients"	
21 CFR 184.1634	Potassium iodide—	No "other ingredients"	for use only in agricultural products labeled “made with organic (specified ingredients or food group(s))”
21 CFR 184.	Potassium phosphate—	No "other ingredients"	for use only in agricultural products labeled “made with organic (specific ingredients or food group(s))”
21 CFR 184.	Monobasic potassium phosphate	No "other ingredients"	
21 CFR 182.6285	Dibasic potassium phosphate	No "other ingredients"	
21 CFR 184.	Tribasic potassium phosphate	No "other ingredients"	
21 CFR 172.480	Silicon dioxide.	Petition: The 2010 petition to remove does not mention other ingredients. TR: The 1995 and 2010 TRs do not mention other ingredients.	

21 CFR 182.1087	Sodium acid pyro-phosphate (CAS # 7758–16–9) –for use only as a leavening agent.	Petition: The 2002 petition and 2009 petition to for expanded use do not mention other ingredients. TR: The 2002 and 2010 TRs do not mention other ingredients.	
21 CFR 184.1751	Sodium citrate.	TR: The 1995 TAP lists no other ingredients.	
21 CFR 184.1763	Sodium hydroxide—prohibited for use in lye peeling of fruits and vegetables.	1995 TAP: No combinations listed. One reviewer states: "As with all synthetic inorganic salts, source must be food grade. In addition each lot should be analyzed for toxic elemnt concentrations (mercury, lead, cadmium, arsenic, thallium and antimony) and a near zero tolerance adpted.	
21 CFR 182.8778	Sodium phosphates—for use only in dairy foods.	Petition: The 2001 petition for sodium hexametaphosphate mentions other sodium phosphates. TR: The 2001 TAP review states: Sodium phosphates are combined with calcium phosphates as leavening agents (Horsford, 1864; Ellinger, 1972; FMC, no date). Sodium orthophosphates are often combined with insoluble sodium metaphosphate (IMP) and various polyphosphates (Ellinger, 1972; FMC, no date). The addition of other salts, such as sodium chloride, can have a synergistic effect on water-holding capacity (Gordon and Klimek, 2000). Typical commercial mixtures contain 30-60% soluble orthophosphates and 40-70% IMP (Gard, 1996). Starches are often used as carriers (Ashford, 1994). Trisodium phosphate used for cleaning is often combined with sodium hypochlorite (bleach) (Ashford, 1994). Sodium aluminum phosphate and sodium acid pyrophosphates are also used as a leavening agents (Food Chemicals Codex, 1996). The sodium phosphates are often used in combination with various gels such as agar, alginates, carageenan, pectins, and various gums (Ellinger, 1972).	

		The previous sodium phosphates TAP Review (NOSB, 1995) only reviewed the forms mono-, di-, and tri-sodium phosphates. . This TAP Review does not cover other forms such as metaphosphates, pyrophosphates, polyphosphates, or combinations of sodium phosphates with any elemental constituents other than hydrogen.	
21 CFR 182.3862	Sulfur dioxide—for use only in wine labeled “made with organic grapes,”.	Petition: The 2010 petition does not mention other ingredients. TR: The 1995 TAP does not mention combinations. The 2011 TR mentions citric acid and carbon dioxide, both of which appear on 205.605.	Provided, That, total sulfite concentration does not exceed 100 ppm
21 CFR 184.1099	Tartaric acid—made from malic acid.		
21 CFR 182.6789	Tetrasodium pyrophosphate (CAS # 7722–88–5)—for use only in meat analog products.	Petition not linked on the NOP website. The 2002 TAP review states: "Tetrasodium pyrophosphate is combined with calcium phosphates as leavening agents (Ellinger, 1972; FMC, no date). TSPP has a synergistic effect on various foaming agents, such as alkyl polycarboxylates and triethyl citrate (Sutton, 1960). Other salts, such as sodium chloride, can have a synergistic effect on water-holding capacity of sodium phosphates (Gordon and Klimek, 2000)."	
21 CFR 172.695	Xanthan gum.	1995 TAP review by Steven Harper mentions that isopropyl alcohol is used to extract and purify xanthan gum and it is possible that trace amounts remain. FDA has limits for residual isopropyl.	

7 CFR 205.606	**Other Ingredients (TAP, TR, Petition, NOSB Recommendation)**
a) Casings, from processed intestines.	No technical report requested. No other ingredients mentioned in the petition.
(b) Celery powder.	The fresh celery is cleaned, concentrated by evaporation, heated and dried. There are no other chemicals or preserving agents used in the manufacture process.

(c) Chia (*Salvia hispanica L.*).	Spanish sage. Petition: No other ingredients mentioned. No TR requested.
(d) Colors derived from agricultural products.	See specific colors as follows:
(1) Annatto extract color (pigment CAS # 1393–63–1)—water and oil soluble.	NOSB recommended removal from the NL
(2) Beet juice extract color (pigment CAS # 7659–95–2).	Petition: "Specific formulation is withheld as a trade secret pursuant to 21CFR20.61. The characterizing principles and/or other components of this color blend are approved and are in compliance with 21CFR73."
(3) Beta-carotene extract color, derived from carrots or algae (CAS # 1393–63–1).	Petition: "Specific formulation is withheld as a trade secret pursuant to 21CFR20.61. The characterizing principles and/or other components of this color blend are approved and are in compliance with 21CFR73." "Beta-carotene and maltodextrin" in CWS powder. 2009 Petition: "The main articles of commerce are suspensions in food grade vegetable oil or the liquids in oil made dispersable in water using food grade emulsifiers."
(4) Black currant juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).	Petition: ". . . contains only the natural constituents of the processed black currant. Citric acid and invert sugar may be used for standardization purposes and these ingredients are GRAS."
(5) Black/Purple carrot juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).	Petitions: "Specific formulation is withheld as a trade secret pursuant to 21CFR20.61. The characterizing principles and/or other components of this color blend are approved and are in compliance with 21CFR73." pH of flavor is less than 4.0; since carrots are a low-cid food, a food grade acid is being added (presumably citric acid).
(6) Blueberry juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).	Petition: "Citric acid and invert sugar may be used for standardization purposes and these ingredients are GRAS."
(7) Carrot juice color (pigment CAS # 1393–63–1).	Petition: "Citric acid and invert sugar may be used for standardization purposes and these ingredients are GRAS."
(8) Cherry juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).	Petition: "Citric acid and invert sugar may be used for standardization purposes and these ingredients are GRAS."
(9) Chokeberry—Aronia juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and	Petitioner A: "Specific formulation is withheld as a trade secret pursuant to 21CFR20.61. The characterizing principles and/or other components of this color blend are approved and are in compliance with 21CFR73."

134–04–3).	Petitioner B: "Citric acid and invert sugar may be used for standardization purposes and these ingredients are GRAS."
(10) Elderberry juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).	Petition: "Citric acid and invert sugar may be used for standardization purposes and these ingredients are GRAS."
(11) Grape juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).	Petition: "Citric acid and invert sugar may be used for standardization purposes and these ingredients are GRAS."
(12) Grape skin extract color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).	Petition: "Specific formulation is withheld as a trade secret pursuant to 21CFR20.61. The characterizing principles and/or other components of this color blend are approved and are in compliance with 21CFR73."
(13) Paprika color (CAS # 68917–78–2)—dried, and oil extracted.	Petition: "Specific formulation is withheld as a trade secret pursuant to 21CFR20.61. The characterizing principles and/or other components of this color blend are approved and are in compliance with 21CFR73." NOSB: "Organic Oil must be used for the oil extraction."
(14) Pumpkin juice color (pigment CAS # 127–40–2).	Petition: "Citric acid and invert sugar may be used for standardization purposes and these ingredients are GRAS."
(15) Purple potato juice (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).	Petition: "Citric acid and invert sugar may be used for standardization purposes and these ingredients are GRAS."
(16) Red cabbage extract color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).	Petitioner A: "Specific formulation is withheld as a trade secret pursuant to 21CFR20.61. The characterizing principles and/or other components of this color blend are approved and are in compliance with 21CFR73." Petitioner B: "Citric acid and invert sugar may be used for standardization purposes and these ingredients are GRAS."
(17) Red radish extract color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).	Petition: "Specific formulation is withheld as a trade secret pursuant to 21CFR20.61. The characterizing principles and/or other components of this color blend are approved and are in compliance with 21CFR73."
(18) Saffron extract color (pigment CAS # 1393–63–1).	Petition: "Specific formulation is withheld as a trade secret pursuant to 21CFR20.61. The characterizing principles and/or other components of this color blend are approved and are in compliance with 21CFR73."
(19) Turmeric extract color	2007 Petition: "Specific formulation is withheld as a

(CAS # 458–37–7).	trade secret pursuant to 21CFR20.61. The characterizing principles and/or other components of this color blend are approved and are in compliance with 21CFR73."
(e) Dillweed oil (CAS # 8006–75–5).	No "other ingredients."
(f) Fish oil (Fatty acid CAS #'s: 10417–94–4, and 25167–62–8)—stabilized with organic ingredients or only with ingredients on the National List, §§205.605 and 205.606.	None of the other ingredients are disclosed in the Petition.
(g) Fortified cooking wines.	
(1) Marsala.	No sulfites; grapes and yeast fermented, salt added, bentonite filtered.
(2) Sherry.	No sulfites; grapes and yeast fermented, salt added, bentonite added, filtered with diatomaceous earth.
(h) Fructooligosaccharides (CAS # 308066–66–2).	Sucrose is converted by a fermentation reaction to short-chain molecules containing two, three, or four fructose units. No “other ingredients.”
(i) Galangal, frozen.	
(j) Gelatin (CAS # 9000–70–8).	Specifically states in TAP that it is often combined with other ingredients and each of these other ingredients would need to appear on the NL or be organic. Isinglass (made from fish bladders) can contain tartaric acid to balance pH as a preservative. Metabisulfite as a stabilizer. Bentonite for juice clarification. Sucrose added to increase set time. Capsules use hardening agents like glycerine, various alcohols, propylene glycol, sucrose and acacia. Starches for secondary as disintegrants. Formaldehyde and glutaraaldehyde used as hardening agents for encapsulation of flavors. Surfactants such as polysorbates used for increased dispersion. Substances considered GRAS for use in geletin capsules succinylated gelatin, arabinogalactan, silicon dioxide, glutataldehyde, n-Octyl alcohol, petroleum wax, polyacrylamide, and terpine resin.
(k) Gums—water extracted only (Arabic; Guar; Locust bean; and Carob bean).	None shown in TAP. No petition, or committee recommendation.
Gum Arabic	
Guar Gum	
Locust bean gum	
Carol bean gum	
(l) Hops (*Humulus luplus*).	
(m) Inulin-oligofructose enriched (CAS # 9005–80–5).	
Kafir Lime Leaves	None shown in petition, committee proposal, or formal

	recommendation. No TAP.
(n) Kelp—for use only as a thickener and dietary supplement.	None shown in TAP. No committee recomendationm, or petition.
(o) Konjac flour (CAS # 37220–17–0).	No petition, TAP, or committee recommendation.
(p) Lecithin—de-oiled.	No" other ingredients"
(q) Lemongrass—frozen.	No" other ingredients"
(r) Orange pulp, dried.	No" other ingredients"
(s) Orange shellac-unbleached (CAS # 9000–59–3).	No information available on NOP website
(t) Pectin (high-methoxy).*	TAP on NOP website is for low-methoxy pectin; No "other ingredients" mentioned
(u) Peppers (Chipotle chile).	No" other ingredients"
(v) Seaweed, Pacific kombu.	
(w) Starches.	
(1) Cornstarch (native).	No "other ingredients"
(2) Rice starch, unmodified (CAS # 977000–08–0)—for use in organic handling until June 21, 2009.	Petition: "Rice starch interacts with the other thickening agents to create a unique gelation agent. The combination of rice starch, locust bean gum, pectin, and carrageenen reinforce the gels of each component, provide an elastic texture and prevents syneresis separation of water). " No TR requested.
(c) Chia (*Salvia hispanica L.*).	Spanish sage. Petition: No other ingredients mentioned. No TR requested.
(3) Sweet potato starch—for bean thread production only.	Petition: Is not linked on the NOP's website. No TR requested.
(x) Tragacanth gum (CAS #–9000–65–1).	Petition: The 2007 petition mentions other gums on 606. TR: The 1995 TAP review lists no combinations. No TR requested for the 2007 petition.
(y) Turkish bay leaves.	Petition: The 2006 petition does not mention other ingredients. No TR requested.
(z) Wakame seaweed (*Undaria pinnatifida*).	
(aa) Whey protein concentrate.	No other ingredients mentioned in petition or recommendation

*Specification sheets often indicate pectin is standardized with sugar

National Organic Standards Board
Policy Development Subcommittee
Proposal: Conflict of Interest/Ethics
July 9, 2012

I. Introduction

The National Organic Standards Board (NOSB) Policy Development Subcommittee (PDS) proposes revising the Conflict of Interest (COI) and Ethics sections of December 2, 2011 NOSB's Policy and Procedures Manuel (PPM). The proposed changes are due to an on-going dialogue with the organic community, the general public, NOSB members, and the National Organic Program (NOP).

PDS further affirms that the proposed changes have evolved and been vetted through the public process, NOSB, and NOP on several occasions over the last year. The proposed recommendation proposal includes (1) COI definitions, (2) ethics revisions, and (3) outlined procedures for declaring, evaluating, and acting upon a COI.

PDS presented recommendations at the November, 2011 NOSB meeting in Savannah, Georgia. The need for further information and dialogue by some NOSB members resulted in the PDS chair deferring the recommendation at the spring 2012 meeting in Albuquerque, New Mexico. The tabling of the COI document has allowed for additional modifications to the COI document. Nevertheless, the proposed additions should provide greater transparency and expectations related to NOSB members' work on behalf of the organic community.

II. Background

The NOSB operates under the authority of Organic Foods Production Act (OFPA) and the Federal Advisory Committee Act (FACA). The NOSB recognizes that members have been specifically appointed to the NOSB to provide advice and counsel to the Secretary of Agriculture concerning policies related to the development of organic standards and the creation of amendments to the National Organic Program's National List. NOSB members have been appointed because they represent various interests involved in the organic community, thus enabling them to advise the Secretary of Agriculture on the implementation of the OFPA.

The statutory composition of the NOSB is 15 members. OFPA describes the required composition of the Board as follows: (1) four members who own or operate an organic farming operation, (2) three members with expertise in areas of environmental protection and resource conservation, (3) three members who represent the public interest or consumer interest groups, (4) two members who own or operate an organic handling operation, (5) one member who owns or operates a retail establishment with significant trade in organic products, (6) one member with expertise in the fields of toxicology, ecology, or biochemistry; and (7) one certifying agent. Thus, NOSB members are appointed to represent the interests of the organic community.

NOSB members – like most federal advisory board members – are chosen specifically because of their professional expertise within a given area. Since NOSB members represent sectors of the industry directly impacted by the Board's decisions, it is necessary to maintain a clear and detailed COI and Ethics policy. Therefore, PDS affirms that we seek to update the Board's policy and procedures on COI and Ethics.

III. Relevant Areas of the Rule

The OFPA establishes the NOSB at § 2119 (7 U.S.C. 6518) (a). It reads, "The Secretary shall establish a NOSB in accordance with the Federal Advisory Committee Act (5 U.S.C. App. 2 et seq.) (hereafter referred to in this section as the "Board") to assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of this title." The 2011 NOSB Revised Policy and Procedures Manual (PPM), dated December 2, 2011, on pages 5-11 sets forth the current NOSB's PPM.

IV. Discussion

COI and Ethics has been an issue since the beginning of humankind. It will probably continue in the foreseeable future. As it relates to the organic community, a periodical review and revision of NOSB's PPM helps to provide greater clarity, transparency, and confidence in the NOSB decisions.

An alternative approach for the PDS would be to keep the current COI and Ethics policy. However, an enhanced COI policy should help the Board, NOP, and USDA/Agricultural Marketing Service (AMS) in their continued responsiveness to the organic community's feedback and address a number of opportunities for enhanced clarity, particularly with regard to the specific procedures to be followed in declaring, evaluating, and acting upon COI and Ethics matters.

According to *41 CFR §*102-3.105*(a-j)*, federal advisory committees' agency heads are responsible for assuring that the interests and affiliations of advisory committee members are reviewed for conformance with applicable COI statutes, and regulations issued by the U.S. Office of Government Ethics (OGE), including any supplemental agency requirements, and other Federal ethics rules. For the NOSB, the agency is the AMS and the NOP.

The USDA Office of Ethics' AMS Representative has recently provided the opinion that representative members on the NOSB are specifically appointed to provide the points of views of non-governmental entities or of a recognizable group of persons (1) who own or operate an organic farming operation, (2) with expertise in areas of environmental protection and resource conservation, (3) who represent the public interest or consumer interest groups, (4) who own or operate an organic handling operation, (5) who owns or operates a retail establishment with significant trade in organic products, (6) with expertise in the fields of toxicology, ecology, or biochemistry; and (7) from the certifiers sector. These representative members have interests in the subject matter under NOSB charge. Representatives serve as the voice of groups or entities with a financial or other stake in a particular matter before an advisory committee or board.

Representative members are not covered by the "Standards of Ethical Conduct for Employees of the Executive Branch" or many of the Federal ethics laws and regulations that other Board member types are (i.e., Special Government Employees - SGE's).

However, this exemption for NOSB representatives does not mean that COI and Ethics should not be addressed. The Ethics Representative opinion specifically referenced § 102–3.105(h), stating that, "Therefore, AMS, and NOP managers have the authority to address potential conflicts of interest of representative members of the NOSB." (E-mail communication from Mary Royster, May 17, 2012).

Criteria for Effective COI Definitions and Procedures

The organic community has voiced great interest in transparency, clear COI definitions, and procedures for NOSB members in disclosing a COI or potential COI in order to continue the strong public support and confidence in the Board. The challenge is that Board members are appointed in part *because* of their interests. As such, the difference between an *acceptable* interest and a COI must be defined in a way that can be practically applied when Board members are faced with specific proposals at Board meetings. The NOSB's PDS has suggested that the goal for any COI policy is to: prevent overt advocacy for direct financial gain and the appearance of self-interest or the appearance of wrongful activity. An important part of this is acknowledging that COI is as much about the *appearance* of a personal conflict and loss of impartiality as it is about actual direct interest. Given this, a key criterion for an effective COI definition is that it delineates the interests carried by NOSB members *in the interest of a represented group,* from interests that will *directly and disproportionally benefit the NOSB member personally*.

A second criterion for an effective COI definition is that it must be clearly understood by Board members in a way that can be applied in considering specific proposals facing the Board and is easily understood by the public. In addition to these criteria, the procedural steps must be clear, easy to follow, and give both the Board members and NOP sufficient time to consider the presence of COI, and to determine the path forward should a COI be declared. Given this background, the NOP accepts responsibility for, in collaboration with the NOSB, reviewing, updating the definitions, outlining procedures related to COI and Ethics for the possible inclusion into the NOSB's PPM.

V. Recommendations

The proposed recommendations to NOSB's Policy and PPM dated December 2, 2011 are:

Recommendation #1

Page 2 (Table of Contents)

Change page numbers and captions based on approved changes.

Recommendation #2

Page 5(NOSB Mission Statement)
Revise the NOSB Mission Statement to read:

a. *To provide effective and constructive advice, clarification, and guidance to the Secretary of Agriculture concerning the NOP and any other aspects of the implementation of the OFPA of 1990.*

b. Add the word ***proposed*** before inclusion on line six (6) of NOSB Mission Statement thus it reads ***proposed inclusion***.

Recommendation #3

Page 7 (Under Duty and Loyalty)

Add

Balance personal perspectives and interests - Personal perspectives and interests are a vital source of knowledge to bring to the Board's deliberative process. These perspectives and interests must, however, be balanced with the perspectives and interests of the entire community/industry. Board recommendations should be based upon what is best for the entire community/industry. Recommendations should not be based on personal interests, or special interests of specific organizations, states or regions.

Exhibit commitment – Board members should represent the interests of all people served by this organization and not favor any individual's or group's particular special interest. Approach all Board issues with an open mind and be prepared to make the best decisions for everyone involved. Focus efforts on the mission of the community served and not on personal or organization's goals. Being first and foremost a voice for the community, and ensure that the Board is operating well and in the best interests of the community we serve.

Recommendation #4

Page 7 (Duty and Loyalty)
Move this section after "Maintaining Professional and Ethical Standards"

Recommendation #5

Page 8 (Duty and Loyalty)

a. Change the section title entitled "Recognize corporate opportunity" to "Disclosure of financial opportunity"
b. Thus, the section should read

Disclosure of financial opportunity - Before a Board member vote upon an issue in which they have a direct financial interest, said Board member must disclose the transaction to the NOP in sufficient detail and adequate time to enable the NOP to determine whether said Board member can discuss or vote on that particular matter.

Recommendation #6

Page 8 (Professional Conduct)
Revised line nine (9) under Professional Conduct to read

NOSB members shall act impartially and not give preferential treatment to any organization or individual. The impartiality includes representing their own organizations at Board meetings. If a Board member voices support for comments published by their own organization/employer, or an organization she/he is closely affiliated with (e.g., on the Board of Directors, conduct significant consulting for), she/he is to state that affiliation when making comments.

Recommendation #7

Page 9 (Conflict of Interest)
Revised line 14 to read

…….. NOP will determine whether it is appropriate for the member to vote RATHER than the Board may determine if it is appropriate for the member to vote.

Recommendation #8

Page 9
The definitions are proposed for page 9 of PPM.

Conflict of Interest -The term “conflict of interest” is defined as a situation in which there is an actual or potential direct financial interest of a Board member, or person or entity associated with a Board member, which could impair the individual's objectivity or which has the potential to create an unfair competitive advantage. Persons or entities associated with a Board member include: spouse; minor child; general partner; an organization or entity which the Board member serves as officer, director, trustee, general partner or employee; and a person with whom the Board member is negotiating for or has an arrangement concerning prospective employment. A financial interest by such an associated person or entity can disqualify a Board member to the same extent as if they were the Board member's own interests.

Potential Conflict of Interest - A “potential conflict of interest” is defined as the appearance of a loss of impartiality based on the relationship outlined in the proposed definition of a conflict of interest.

Recommendation #9

Delete the term “direct financial gain” since it is covered in the definition of COI when it states “direct financial interest.”

Recommendation #10

We recommend the added section below.

Procedures for Declaring and Evaluating a COI

Level #1 (Subcommittee)

1. At the subcommittee level, as topics are added to the subcommittee's work plan, each Board member is to evaluate possible COI or potential COI related to the topic. If the Board member has a COI or potential COI, the member should disclose the COI to said subcommittee and NOP. After a determination is made by NOP regarding the participation of said Board member. NOP final decision on all COI will be clearly recorded in the minutes.
2. It is primarily the Board member's responsibility to self-assess whether conflicts or potential conflicts exist. If one Board member believes that another Board member has a conflict, she/he should raise that one-on-one with the Board member involved or to the NOP's Designated Federal Officer (DFO). In this case, the NOP will work with said Board member to determine whether a COI exists and if recusal is warranted; the Board member raising the issue against another Board member will not be involved in the determination of a COI or a potential COI.
3. As soon as the final agenda and list of proposals for the Board's public meeting has been set, all Board members will re-assess possible COI because of their personal interests or organizational affiliation or relationships.

In general, COI's can lead to a recusal from the discussion and vote associated with the conflict. In the case of a *potential* COI, as defined above, the potential conflict may not be deemed significant enough to warrant recusal. If a Board member believes that she/he may have conflict(s) based on the definition above, she/he contact the DFO as soon as possible (within three working days) stating

a. the conflict(s) or potential conflict(s) that could exists and
b. the proposal (s) it relates to.

In the communication, said Board member is to state whether the she/he wants to recuse herself or himself without discussion, or, if the Board member wants the NOP's opinion on the need for recusal based on the nature of the potential COI. (Note: If said Board member chooses to recuse her/him, NOP will accept that without explanation. If the member is unsure, the NOP may ask for additional information about the conflict(s) to make a determination.

If an NOP opinion is needed, NOP will make the determination and communicate the decision back to the Board member expeditiously (generally within three working days) after consulting with the DFO and/or USDA Office of Ethics, if needed.

Level 2 (Biannual Meetings)

1. At the biannual meeting, in opening the discussion of each proposal or issue, the Subcommittee Chair will ask Board members to declare any recusal decisions related to the proposal(s) or issue(s). At this time, Board members shall share the determination made before the meeting. Immediately before the vote, the Board Chair will repeat the names of people who will not be voting on the motion(s); this will be captured in the voting record and minutes. The Board member is not required to share the nature of the COI at the meeting; it is sufficient to state that a conflict exists, and that she/he is recusing herself/himself. The only time a Board member needs to share the nature of the conflict is if she/he is seeking NOP input on whether recusal is appropriate or needed based on the nature of the conflict.
2. If a Board member fails to disclose a COI that is later revealed (anyone), it may lead to the reconsideration of the vote (depending on the closeness of the vote), so it is vital that Board members are aware of conflicts and disclose them at the meeting(s).
3. COI requirements do not extend to members of the public that come to the meeting and/or provide written views and opinions, unless they are expert witness(es) or consultant(s). As per public comment processes, all commenters are asked to state their affiliations at the start of their comments.
4. NOP final decisions should be included in the minutes.

Recommendation #11

On page 11 of the PPM, revise lines 8-12 to read,
Fully disclose any conflict of interest positions – Members having any commercial or immediate family interest that poses a potential or perceived conflict of interest must disclose that conflict to the subcommittee, Board, and NOP and abide by any decision of the NOP in dealing with the situation.

VI. Summary

NOSB members with diverse backgrounds are recruited to provide balance to the NOSB. While individual NOSB members represent the segments of the population from which they were selected, they also represent the greater good of the population as a whole. The revised COI and Ethics Policy are an attempt to address stakeholders, NOP, NOSB, and the public request for updating the Board‘s COI policy and provide for a greater level of transparency in the deliberation, discussion, and voting on matters pertaining to the Board authority for the benefit of the organic community.

VII. Subcommittee Vote:

Moved: C. Reuben Walker Second: Jean Richardson
Yes: 7 No: 0 Abstain: 0 Absent: 1 Recuse 0

National Organic Standards Board
Policy Development Subcommittee
Proposal: NOSB Meeting Public Comment Procedures
July 30, 2012

I. Introduction

Public input and transparency are central to the effective functioning of the NOSB. The proposed amendments to the Policy and Procedures Manual are intended to improve the ability of the NOSB to receive public comment.

II. Background

The six NOSB subcommittees meet using teleconference calls on a regular, typically twice a month basis, sharing information received from the public, actively seeking further information and data as they review an ever increasing range of complex substantive issues and develop recommendations. Twice a year the full NOSB physically meets together at a location within the U.S. These public meetings take place at different geographic locations in order to ensure that those who cannot travel long distances for reason of cost or time are more likely to have their voices heard, and assumes that more regional members of the public will attend in person, and also that regional differences in agriculture will thus be better understood by the Board as it develops recommendations to forward to the NOP.

For anyone involved in public policy it is well understood that input through public comment at open public meetings provides both challenges and opportunities. There is a delicate balance between letting everyone speak for as long as they want to, while allowing time for everyone present to be heard, and then time for their comments to be digested by those who listen and pose questions. In addition the public needs to feel confident that their views have been heard and taken into consideration before decisions are voted on. Well run and effective public meetings require clear rules and leadership. Over the last five years there has been an increasing interest by the public to attend the semi-annual meetings in order to provide public comment, and increasing mutual desire by the public and the Board to clarify and improve procedures for taking public comment. Thus, in October – November, 2011 the NOSB sought public input to clarify policy and procedures for receiving public comment specifically with reference to public meetings.

III. Relevant Areas of the Rule

The Organic Foods Production Act (OFPA) establishes the National Organic Standards Board at Section 2119 (7 U.S.C. 6518), “(a) The Secretary shall establish a National Organic Standards Board (in accordance with the Federal Advisory Committee Act (5 U.S.C. app. 2et seq.) [hereafter referred to as the “Board”] to assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of this title.”

The Policy Procedures Manual (PPM), Section VI “Policy for Public Comment at NOSB Meetings” lays out the process and the time designations of public comment and further provides for, “Other suggestions that would be appreciated by NOSB members”.

IV. Discussion

It is clear that many members of the public are frustrated by the procedures for public comment at the national meetings and they seek clarification and a desire for greater confidence that the Board members have heard what they have to say, and have seriously considered their input. Comments also requested flexibility with public involvement.

Following are some of the issues raised:

Length of time to speak

With an increased interest in public comment at meetings, there are typically many more speakers for the time allotted. While ten (10) minutes is too long to permit, it is clear that for many even five (5) minutes is a short time to speak given the complexity of issues and range of topics covered in one meeting. Requiring three (3) minutes as a time limit forces speakers to be concise and prioritize topics covered in verbal presentation. In addition speakers need to be reminded that they can also submit an expanded written version of their comments during the meeting.

One commenter stated, “The length of time is not as important as that the designation of a time be regarded as a commitment.”

While it may be that speakers have travelled long distances, incurring expense and taking time to speak for only three minutes, it is also true that attending the meeting allows face-to-face exchange of data, information and policy concerns throughout the week.

Several organizations requested that the length of time be set at five (5) minutes and decreased to three (3) minutes if there were too many presenters for time period allotted, with flexibility being provided by the Chair.

Time allotted on agenda for public comment

There is widespread concern that there is not sufficient time on the week’s agenda for public comment. While this is probably a normal perception by the public for any national board, it is nonetheless an important issue to address. In past years, public comment extended into evening hours and the Board may wish to seriously consider returning to this option.

One commenter suggested extending total time allotted for public comment by one hour.

Another stated, “We may reach a point when comments need to be prioritized, either on a first come first served, or randomized basis in order to ensure equity and diverse public input”.

Another comment suggested maintaining a waiting list for public comment.

Board questions to public speakers
There is a perception that Board members are not listening to the speakers because they do not ask many questions. And it is a perception that not all Board members are knowledgeable on the subject at hand because they do not ask questions. Thus it would seem counter-productive to consider “limiting Board questions” as a way to allow more public input, and none of the comments received suggested limiting Board questions.

Two organizations wanted it to be clear that Board question time was not considered part of the three (3) minutes of public comment, while being sure that Board members ask questions to clarify issues under consideration.

Board members should be encouraged by the Chair to ask questions that are relevant and required to assist the Board in reaching decisions on substantive issues, and to be active listeners. Further, there needs to be far greater public understanding of the inordinate number of hours every week that individual Board members in fact spend reviewing TRs, public input, committee meetings, e-mail exchanges and phone calls.

Public comment impact on Board decisions.
There is a perception that the Board does not take the time to adequately review and apply public input prior to making their decision. In order to address this very real concern the Board should always have time to recess following a public comment period prior to making a public decision on an agenda item.

Use of proxy speakers
There is a mix of public perception on use of proxy speakers. One organization suggested continued use of proxy presentations, but stated that the information could also be achieved through written testimony. Three other comments suggested refined limitations to monitor implementation.

There is a public perception that those who turn up and speak at the meeting will have a more direct impact on the immediate decisions of the Board. However there is the counter argument that the proxy is not in fact the originator of the input and cannot really answer any Board question, and such information could simply be provided in writing prior to the meeting. Eliminating proxy speakers will allow more time for those who are present in person.

Use of electronic participation in lieu of physical presence

This is not an easy issue to address. On the one hand, attending the meeting is expensive and time consuming, limiting those who may attend, and there are a number of electronic means for communicating, such as via skype, or conference speaker phone, constant tweet inputs or other social networking tools, or by having a room full of people at a distant location with a TV type satellite connection. Any one of these or a combination could allow for increased input during the hours allotted to public comment.

Indeed one might envisage a national meeting where committee members are scattered at various regional geographical locations nationwide using TV "classroom" connections, a teaching tool which university and other teachers have been using for years to teach at diverse locations simultaneously. All input would thus be essentially electronic. This would be an improvement over the faceless nature of the phone conference calls, but would be complex to set in place and would increase participation, which would in turn require more time allotment.

Conversely interested members of the public can submit public comment in writing, and public meetings rotate geographically around the US, allowing for greater regional participation over time. Further, there are already many people who physically attend and not enough time to allow everyone to comment on everything that they would like to comment on.

Based on comments reviewed and experience, the use of electronic communication is not recommended presently.

V. Recommendations

Amend SECTION VI of the PPM, entitled NOSB Policy for Public Comment at NOSB Meetings, as follows:

NOSB Policy for Public Comment at NOSB Meetings:

1. All persons wishing to comment at NOSB meetings during public comment periods must sign-up in advance per the instructions in the Federal Register Notice for the meeting.

2. All presenters are encouraged to submit public comment in writing according to the Federal Register Notice. Advance submissions allow NOSB members the opportunity to read comments in advance electronically, and decreases the need for paper copies to be distributed during the meeting.

3. Persons will be called upon to speak according to a posted schedule. However speakers should allow for some flexibility, and also note that persons called upon who are absent from the room could potentially miss their opportunity for public comment.

4. Time allotment for public comment per person will be four (4) minutes, with the options of reducing to a minimum of three (3) and extending to a maximum of five (5) minutes at the discretion of NOP working closely with the NOSB Chair in advance of the meeting.

5. Persons must give their names and affiliations for the record at the beginning of their public comment.

6. Proxy speakers are not permitted.

7. Public comment requests may be scheduled by major topics under consideration.

8. Individuals providing public comment will refrain from any personal attacks and from remarks that otherwise impugn the character of any individual.

9. The NOSB will attempt to accommodate all persons requesting public comment time, however, persons requesting time after the closing date in the Meeting Notice, or during last minute sign-up at the meeting, will be placed on a waiting list and will be considered at the discretion of the NOP working closely with the NOSB Chair depending on availability of time.

10. Members of the public are asked to define clearly and succinctly the issues they wish to present before the Board. This will give NOSB members a comprehensible understanding of the speaker's concerns.

VI. Subcommittee Vote

Moved: Colehour Bondera Second: C. Rueben Walker

Yes 7 No 0 Abstain 0 Absent 1 Recuse 0

National Organic Standards Board
Policy Development Subcommittee
Proposal: Public Communications
August 14, 2012

I. Introduction

A primary role of the National Organic Standards Board (NOSB) is to advise and counsel the Secretary, to represent the segments of the population from which they were selected, and to treat the business of the Board as fiduciaries for all members of the organic community and public at large (NOSB Policy and Procedures Manual, pp4-8).

The Federal Advisory Committee Act (FACA) Meeting Obligations to the Public (41 CFR 102-3.140) suggests that, "Any member of the public is permitted to file a written statement with the advisory committee during meetings."

In addition, the NOSB infrequently receives public communications outside of the designated public comment period. These communications include verbal and written information.

II. Background

The Organic Foods Production Act (OFPA), enacted under Title 21 of the 1990 Farm Bill, serves to establish uniform national standards for the production and handling of foods labeled as "organic." The Act authorized a new USDA National Organic Program (NOP) to set national standards for the production, handling, and processing of organically grown agricultural products. In addition, the Program oversees mandatory certification of organic production. The Act also established the National Organic Standards Board (NOSB), which advises the Secretary of Agriculture in setting the standards upon which the NOP is based. [Review at http://www.nal.usda.gov/afsic/pubs/ofp/ofp.shtml].

Sec.2119 [7 U.S.C. 6518] states that the NOSB consists of four individuals who own or operate an organic farming operation; two individuals who own or operate an organic handling operation, one individual who own or operates a retail establishment with significant trade in organic products; three individuals with expertise in areas of environmental protection and resource conservation; three individuals who represent public interests or consumer interest groups; one individual with expertise in the fields of toxicology, ecology or biochemistry, and one individual who is a certifying agent.

The statutory mission in OFPA states:

> "To assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of this title." (OFPA, Sec 2119 (a))

As stated in the NOSB Policy and Procedures Manual (PPM, p5),the NOSB Mission Statement is:

> "To provide effective and constructive advice, clarification and guidance to the Secretary of Agriculture concerning the National Organic Program (NOP), and the consensus of the organic community.

In carrying out the mission, key activities of the Board include:

- "Assist in the development and maintenance of organic standards and regulations;
- Review petitioned materials for inclusion on or deletion from the National List of Approved and Prohibited Substances (National List); Recommend changes to the National List;
- Communicate with the organic community, including conducting public meetings, soliciting and taking public comments, provide timely information and education on the NOP, making reasonable use of a variety of communication channels.
- Communicate, support and coordinate with the NOP staff. "
  The PPM (p8) states that NOSB members shall act impartially and not give preferential treatment to any organization or individual.

The PPM indicates (p6) that,

> "To fulfill their responsibilities, Board members agree to adhere to three duties: Duty of Care, Duty of Loyalty, and Duty of Obedience (p6).

The PPM continues,

> "The Duty of Care calls upon a member to participate in the decisions of the Board and to be informed as to the data relevant to such decisions. In essence, the Duty of Care requires that a member:
>
> Be reasonably informed—It is the duty of all Board members to seek and study the information needed to make a reasoned decision and/or recommendation on all business brought before the Board. The NOP will provide some of that information, but other information must be developed from independent sources."
>
> The National Organic Standards Board members study and evaluate all public communications, written and verbal communications, as a function of the NOSB role and duties, in order to benefit the organic community. In so doing, National Organic Standards Board members are able to provide effective and constructive advice, clarification and guidance to the Secretary of Agriculture and the NOP.

NOP said in the *National Organic Program Newsletter*, December 11, 2011:

> The members of the National Organic Standards Board (NOSB) and the National Organic Program (NOP) often receive letters and requests from people interested in our upcoming regulatory activities and meetings. In this note, we summarize the best way to direct your letters and requests.

As a Federal Advisory Committee, the NOSB has a well-defined scope of activity. If you have opinions and requests to share with the Board, please use the public comment period that is open before each NOSB meeting to submit your thoughts. Or, submit a formal National List petition for consideration using the guidelines provided in the link below.

The NOP is the best place to send your letters outside the NOSB public comment and petition process. In addition to formal public comment periods on specific regulatory actions, we are always open to comments on a variety of topics related to organic agriculture. While we cannot guarantee that every letter will receive a direct response, your letters do get an audience and help us identify and prioritize needs. We look forward to hearing from you!

This explanation by NOP describes the current official means of communication outlined in the PPM, which does not prohibit other forms of communication between the public and NOSB members. The NOP statement, however, suggests a need to clarify the ability of the public to provide public comments outside of Board meetings and the public comment periods to inform the Board's and Program's work.

III. Summary

The National Organic Standards Board through it Policy and Procedures Manual establishes procedures for its activities. The Manual "is designed to assist the Board in its responsibilities" (PPM, p4) and establish procedures for carrying out its responsibilities in accordance with its advisory mission.

Because of the opportunities that the Board has to hear from the organic community in the course of fulfilling its mission, it has both an opportunity and responsibility to bring to the Secretary of Agriculture information that it believes may impact on the implementation of OFPA. This communication may, by necessity, extend to organic standards and practices as well as related issues that may affect those standards and practices. Therefore, based on the communications and input it receives from the public. the National Organic Standards Board may provide effective and constructive advice, clarification, and written information, as it deems necessary, directly to the Secretary of Agriculture after each of its Board meetings.

Additionally, and as a part of its responsibility to communicate with the organic community pertaining to the implementation of OFPA, the Board must receive and review information from the NOP and other sources during its deliberations. As a stakeholder Board, the input from the organic community is valuable in the deliberations of the Board and the community decision making process. The procedures of the Board should facilitate public communication to inform these deliberations.

IV. Recommendations

PPM, Section VI, Miscellaneous Policies, page 26 is amended by adding a new subcategory (in italics):

NOSB Policy on Its Advisory Role and Communication with the Secretary of Agriculture

Based on the communications and input it receives from the public. the National Organic Standards Board may provide effective and constructive advice, clarification, and written information, as it deems necessary, directly to the Secretary of Agriculture after each of its Board meetings. This information is intended to facilitate public communication with the Secretary on critical issues that may emerge that it believes are important to the implementation and integrity of the organic standards and practices under the Organic Foods Production Act.

PPM, Section VI, Miscellaneous Policies (page 27), is amended by adding a new subcategory (in italics).

NOSB Policy for Public Communication Between NOSB Meetings.

The NOSB seeks public communication outside of Board meetings and public comment periods to inform Board and Program work.

PPM Section II (page 13) Role of the Executive Director is amended to include the following language (in italics):

Identify, implement, administer and maintain a year-round mechanism by which public feedback can be received, posted and archived for viewing by the NOP, the NOSB, and the public itself.

V. Subcommittee Vote

Moved: Jennifer Taylor Second: Colehour Bondera

Yes 8 No 0 Abstain 0 Absent 0 Recuse 0

National Organic Standards Board
Compliance, Accreditation and Certification Subcommittee

Discussion Document: Calculating Percentage Organic in Multi-ingredient Products

August 14, 2012

I. INTRODUCTION:

The purpose of this document is to review how accredited certifying agents (ACA's) and handlers are determining percentage organic ingredients in multi-ingredient products and develop clear policy that can assist the NOP in development of guidance for certifiers and handlers.

Consumers expect that labels on multi-ingredient products sold as "100% organic" or "organic" or "made with organic" reflect an accurate determination of percentage organic ingredients, and that all certifiers have uniformly calculated such percentages.

The integrity of USDA organic products in the USA and throughout the world depends on assurances of consistency and uniformity in interpretation and application of the law and regulation, especially when calculating percentage organic ingredients.

II. BACKGROUND:

The NOP regulation at§ 205.302(c), under "Calculating the percentage of organically produced ingredients" states:

> "The percentage must be determined by the handler who affixes the label on the consumer package and verified by the certifying agent of the handler. The handler may use information provided by the certified operation in determining the percentage".

Thus, when an ingredient has been certified to the "organic" category, the supplier of that ingredient must provide information to the handler making the finished product regarding the actual percentage of organic content of that ingredient.

Over the years this has resulted in a wide variety of mechanisms for determining percentage of organic ingredients, and a wide variety of ways of establishing systems which allow verification by auditors and inspectors.

For example, if the supplier does not provide positive information, verified by the certifier, that the organic ingredient contains more than 95% organic content, then many certifiers will only allow that ingredient to be calculated at 95% organic content, but not all certifiers do this.

Since the Rule was first put in place there have been an increasing number of certifying agents who certify multi-ingredient products and, with no clear guidance to the contrary, a lack of uniformity in procedures has developed. For example some certifiers may permit handlers to include 100% of the weight/volume of certified ingredients as organic, even if the ingredient is a formulated product and includes other permitted substances and may be in fact be anywhere from 95-100% organic. For example, chocolate chips may be certified organic, and contain 96 % organic ingredients, plus 4% permitted substances on §205.605or §205.606. A cookie manufacturer may be considering that the entire weight of the chips counts as organic in the final cookie product.

Further, some handlers, certifiers, inspectors may not be accurately examining the water and salt content for exclusion from the percentage calculation.

In addition there is a wide array of mechanisms in place amongst handlers as to how processing aids as opposed to additives are recorded or, if necessary calculated as part of the ingredient list.

Standard practice is to calculate organic ingredients as a percentage *of all ingredients,* although the relevant area of the regulation, § 205.302(a)(1-3), still states the calculation should be as a percentage *of finished product*.

In October 2001 the NOSB recommended to change to the regulations at § 205.302(a) to replace the phrase “finished product” with “of all ingredients”. The rationale was:

> “ Most products lose weight during processing. Dividing the total weight of all combined organic ingredients by the weight of the finished products could easily show that a product contains over 100% organic ingredients. Current practice is to divide the total weight of all combined organic ingredients by the total weight of all ingredients (excluding salt and water). This calculation establishes the total percentage of organic ingredients. The Rule should be changed to correctly calculate the percentage of organic ingredients.”

This regulation change has not yet taken place.

Sub-ingredients are often added to multi-ingredient products, such as spice or flavor or sauce mixes. Such sub-ingredients may be entirely or partially organic in ingredient make up, and the producer of such sub-ingredient mix may provide a specification sheet listing ingredients and their organic percentages. In other instances no details are provided on sub-ingredients.

When the percentage of organic ingredients as a percentage of all ingredients, is calculated to be close to 95% or close to 70% then the issue of correct labeling of that product becomes difficult for the handler and those who must approve or verify.

III. RELEVANT AREAS OF THE RULE:

NOP Regulation and Policy statements:

§ 205.302 Calculating the percentage of organically produced ingredients.

(a) The percentage of all organically produced ingredients in an agricultural product sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” or that include organic ingredients must be calculated by:

(1) Dividing the total net weight (excluding water and salt) of combined organic ingredients at formulation by the total weight (excluding water and salt) of the finished product.

(2) Dividing the fluid volume of all organic ingredients (excluding water and salt) by the fluid volume of the finished product (excluding water and salt) if the product and ingredients are liquid. If the liquid product is identified on the principal display panel or information panel as being reconstituted from concentrates, the calculation should be made on the basis of single-strength concentrations of the ingredients and finished product.

(3) For products containing organically produced ingredients in both solid and liquid form, dividing the combined weight of the solid ingredients and the weight of the liquid ingredients (excluding water and salt) by the total weight (excluding water and salt) of the finished product.

(b) The percentage of all organically produced ingredients in an agricultural product must be rounded down to the nearest whole number.

(c) The percentage must be determined by the handler who affixes the label on the consumer package and verified by the certifying agent of the handler. The handler may use information provided by the certified operation in determining the percentage.

IV. DISCUSSION:

1. Language change: It is assumed that all handlers are calculating percentage organic based on percent of all ingredients, not finished products, and yet the Rule does not state this.

The CACS is considering a recommendation for a Rule change at the spring 2013 meeting to replace at 205.302 (a), 1, 2, and 3, the language “finished product” with the phrase “of all ingredients”. Prior to this rulemaking action, the CACS is seeking information from ACA’s on current practices to bring efficient uniformity to the process, especially when ingredients cross certifier lines.

2. Typically a processor of a multi-ingredient product applies to an NOP accredited agent and receives the annual application forms and instructions of that specific certifier. Each certifier has their own set of forms, many of which are fillable documents such as a form for calculating organic percentage, several examples of which have been reviewed by the CACS. Such product formulation sheets list water and salt and processing aids which are not included in the self-calculation.

There is also usually a Product Profile form for every multi-ingredient product, listing all ingredients, name of supplier, certifier of each ingredient, and percentage of each ingredient relative to the total of all ingredients, EXCLUDING water and salt. Water may be in included in the calculation when it is specified as part of an FDA standard of identity, (includes single strength juices, does not include soy milk or juices for which there is no standard of identity). FDA standards of identity are found at 21 CFR 131-169.

With the growth of processed organic foods, it can be very difficult for handlers, certifiers and inspectors to consistently derive the same calculations with varied format specification sheets and calculation forms.

In order to obtain uniformity in organic claims for products, should the NOSB recommend standardized forms and/or the use of self-calculating tables for determining organic percentage, and specification sheets for all sub-ingredients?

3. In calculating the percentage organic of sub-ingredient mix either the handler assumes 95% organic content, or obtains additional verification of the actual organic content from the supplier to justify a higher claim. If no “Specification Sheets” (or equivalent information) on the sub-ingredients are available, the certifier and inspector has to assume the lowest denominator based on sub-ingredient list reviewed, so it defaults to 95% or 70%.

If sub-ingredients are included without a specification sheet and accompanying calculation, should ingredients be calculated as 70%, 95% or 100% based on stated labeling category?

4. Processing aids. We understand the variability among certifiers on how processing aids affect the 100% label claim. If a product is not allowed the 100% claim, does it fall all the way to 95%? This could automatically keep numerous products out of organic status and fall to “made with” status.

5. Salt. Does the ACA or handler consider other salts, such as potassium chloride as well as sodium chloride in determining calculation?

V. REQUEST FROM CAC Subcommittee:

The CACS is seeking input in developing upcoming recommendations if necessary. Please give us your input on these questions and other pertinent information, as you deem necessary.

1. What difficulties do you encounter when verifying percentage calculations for multi-ingredient products? Do supplier forms meet necessary expectations?

2. Is calculating the percentage organic made more complex when multiple certifier forms are being used to make calculations for multi ingredient products with sub-ingredients ?

3. Should all ACA's use a uniform calculation tool to verify percentage calculations?

4. Do all ACA's provide calculation tools to reviewers/inspectors? Do inspectors have their own tools? Are there an adequate number of qualified inspectors available perform this work?

5. How does use of processing aids affect percentage organic calculations? For example in the absence of other technical specification does the product default to the 95% category for the purpose of the calculation?

6. Would guidance from the NOP bring clarity and uniformity to the process? What features and characteristics should be incorporated into the policy?

7. Do we have in place adequate mechanisms to ensure that all agricultural products which have received no post harvest treatment can be verified to the 100% category as raw ingredients for calculating percentage organic in multi-ingredient products? Explain process used in calculation.

The CAC Subcommittee would appreciate receiving answers to the questions posed above as well as other suggestions on how best to ensure consistency and uniformity in determining percentage organic in multi-ingredient products.

Sub Committee Vote:

Moved: Jean Richardson Second: Calvin Walker

Yes- 8 No- 0 Abstain- 0 Recusal- 0 Absent- 0

National Organic Standards Board
Compliance, Accreditation and Certification

Discussion Document: Implementation of Biodiversity Conservation in Organic Agriculture Systems

July 23, 2012

I. INTRODUCTION:

The purpose of this Discussion Document is to review progress in implementing the Board's recommendations on biodiversity conservation, made on May 6, 2009, and to identify other aspects of implementation of the NOP biodiversity standards that may require attention.

Another purpose of this document is to draw attention to the value of biodiversity to organic production systems and the importance of implementing conservation practices.

The value of biodiversity for healthy agriculture and for society at large is recognized in the NOP rule in several places. In response, the NOSB issued Guidance statements in 2004, 2005 and as indicated above, again in 2009.

It is worth stating here what is encompassed in the term "biodiversity." Biological diversity is the diversity of life existing at three levels: genetic, species and ecosystem diversity. Therefore, the concept of biological diversity (biodiversity) includes all of the following:

- Variety in all forms of life, from bacteria and fungi to grasses, ferns, trees, insects, and mammals;
- The diversity found at all levels of organization, from genetic differences between individuals and populations (groups of related individuals) to the types of natural communities (groups of interacting species) found in a particular area; and
- The full range of natural processes upon which life depends, such as nutrient cycling, carbon and nitrogen fixation, predation, symbiosis and natural succession.

II. BACKGROUND:

The *Principles of Organic Farming*, as adopted by the NOSB on Oct 12, 2001, expresses the values and goals that link organic farming with protection of biodiversity. Many organic production systems recognize the value of biodiversity to a farm's long term sustainability as well as an understanding that agriculture systems function within, and interact with, the larger ecosystem.

A number of individuals and organizations interested in biodiversity conservation in organic agriculture have worked to advance these ideas. In particular, the Wild Farm Alliance (WFA) has published guides about biodiversity conservation for farmers and for certifiers, has produced a document on Biodiversity Compliance Assessment, and has contributed many valuable suggestions to the NOSB and NOP on ways to advance biodiversity conservation. The International Organic Inspectors Association (IOIA) has also played a very important role in filling the need for trainings on biodiversity for inspectors using the organization's own materials as well as the WFA guides. ATTRA has developed templates for Organic System Plans that include a section on biodiversity. This provides a mechanism for operators to document the practices they use to support biodiversity conservation and to convey that information to their certification body.

On April 29, 2004, the NOSB adopted a guidance document "*Compatibility with a System of Sustainable Agriculture and Consistency with Organic Farming and Handling,"* which included the following factor to be considered in the process of materials review: "*L) Does use of the substance have a positive impact on biodiversity?"*

The next year (August 16, 2005) the NOSB adopted an amendment to the OSP template which added a criterion on biodiversity to the form.

The discussion of biodiversity at the May 2008 NOSB meeting resulted in a plan for joint review of implementation of biodiversity standards by the CAC and Crops Committee and, as necessary, for the Joint Committee to prepare further guidance for Board consideration. The analysis by the Joint Committee determined that the biodiversity conservation requirements were not being implemented fully or consistently.

The Joint Committee produced a discussion paper in 2009, titled "*Implementation of Biodiversity Conservation in Organic Agriculture Systems*." The document received more than 60 written and oral comments—most strongly supported the need to improve and increase implementation of biodiversity conservation in organic agriculture. Many commentors expressed a sense of urgency for timely action.

Based on the findings of the Joint Committee, on May 6, 2009, NOSB sent a recommendation to NOP that addressed improvements in the implementation of biodiversity standards through two different vehicles:

1) Material Review by the NOSB—Add biodiversity considerations to the check list used for the review of materials; and

2) Development and implementation of the Organic System Plan—this included specific recommendations for actions to be taken by a) certified grower/producer, b) inspectors, c) certifiers, and d) NOP.

III. RELEVANT AREAS IN THE RULE:

1. The Preamble

The Preamble to the Rule (Federal Register/Vol. 65, 246/Thursday, December 21, 2000/pg. 80563) (4) CONSERVATION of BIODIVERSITY states in part:

> *"We agree with commenters and have amended the definition of organic production to require that a producer must conserve biodiversity on his or her operation. The use of "conserve" establishes that the producer must initiate practices to support biodiversity and avoid, to the extent practicable any activities that would diminish it. Compliance with the requirement to conserve biodiversity requires that a producer incorporate practices in his or her organic system plans that are beneficial to biodiversity on his or her operation.*

2. NOP Rule passages relevant to Biodiversity Conservation are as follows: §205.2 Terms defined:

Crop Rotation. Perennial cropping systems employ means such as alley cropping, intercropping and hedgerows to introduce biological diversity in lieu of crop rotation.

Natural Resources of the Operation. The physical, hydrological, and biological features of a production operation, including soil, water, wetlands, woodlands, and wildlife.

Organic Production. A production system that is managed in accordance with the Act and regulations in this part to respond to site-specific conditions by integrating cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity.

Organic System Plan. A plan of management of an organic production or handling operation that has…….

Pasture. Land used for livestock grazing that is managed to provide feed value and maintain or improve soil, water, and vegetative resources.

Soil and Water Quality. Observable indicators of the physical, chemical, or biological condition of soil and water, including the presence of environmental contaminants.

§205.200 General. Production practices….must maintain or improve the natural resources of the operation including soil and water quality.

3. Other sections of the Rule related to Biodiversity

- §205.203 Soil fertility
- §205.205 Crop rotation
- §205.206 Crop pest, weed, and disease management practice
- §205.707 Wild-crop harvesting
- §205.237 Livestock feed
- §205.238 Livestock health care
- §205.239 Livestock living conditions

IV. PROGRESS and DISCUSSION:

This section of this Discussion Document presents progress reports and discussions that are based on an analysis of the points in the NOSB's 2009 Recommendation, "*Implementation of Biodiversity Conservation in Organic Agriculture Systems*":

1) ***The Materials Review Process*:**

Recommendation from 2009: Add biodiversity considerations to the checklist used for review of materials as shown below for specific categories and lines:

Category 1. Adverse impacts on humans and the environment?

Line 3. Is the substance harmful to the environment and BIODIVERSITY?

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

Line 2. Is the substance consistent with organic farming and handling and BIODIVERSITY.

Progress Report & Discussion Points: These changes in the Materials Review Checklist were made and approved for addition to the PPM on November 5, 2009.

To assist in material review: Technical reports are frequently requested by the NOSB. Evaluation question 8 now directs the TR contractor to" describe any effects of the petitioned substance on biological and or chemical interactions in the agro-ecosystem, including physiological effects on soil organisms (including the salt index and solubility of the soil), crops, and livestock (7 USC 6518 (m)(5)."The following additional requirement to question 8 is being added:" In addition the response should describe the potential or actual impacts of the substances upon endangered species, populations, viability or reproduction of non-target organisms and the potential for measurable reductions in genetic, species of ecosystem biodiversity, if possible."

With regard to materials review, the following question comes to mind:

QUESTION: The check list question now asks, “Is the substance harmful to biodiversity?” The NOSB Guidance Document adopted 4/29/2004 asks another question, “Does use of the substance have a positive impact on biodiversity?” Although both of these questions address biodiversity, they do so from different reference points, creating harm vs. having a positive impact. ***Should the questions on used on the checklist for materials review focus on asking whether a material has a positive impact on biodiversity, in addition to the question about harm?***

2) ***Development and Implementation of the Organic System Plan:***

NOSB recommended that the following actions be taken with regard to the OSP:

a) Certified Grower/ Producer - Recommendation from 2009:
Producers shall incorporate biodiversity conservation into their OSPs. The questions on ATTRA’s OSP templates (Pages 7&8 on the farm template) or guidance tools such as those developed by WFA, provide detailed information and direction. The producer shall be ever vigilant to biodiversity problems and conservation opportunities. Conversion of native habitat to crop production has consequences to biodiversity that must be considered and the producer should discuss such planned conversion with his or her certifier before action is taken.

Progress Report: In the spring of 2011, the NOP published an updated version of the natural resources section of the OSP, with assistance from ATTRA.

On May 12, 2012, after extensive work, the Wild Farm Alliance and 39 signatories, submitted a Biodiversity Conservation Document to the NOP for inclusion into the National Organic Program Handbook. The Guidance is intended to assist producers and Certifiers understand how to comply with requirements related to the conservation of biodiversity in crops, livestock and handling operations.
The NOP is reviewing the document submitted by WFA for possible use as guidance document.

The NOSB 2009 guidance document raises the issue of conversion of native lands to organic production. In the Introduction it states “a particularly controversial issue is how to deal with conversion of native forests or grasslands for organic crop cultivation”. The document then under 2 (a) Certifier Grower/ Producer states that “conversion of native habitat to crop production has consequences to biodiversity that must be considered and the

producer should discuss such planned conversion with his or her Certifier before action is taken".

The WFA proposed Guidance presented to the NOP addresses conversion of "high conservation value land" as shown in this italicized text:

If an operation is considering converting high conservation value land, the benefits of more farmable acreage is weighed against the loss of habitat functions that may provide pollinator and predatory insect food and cover, and water quality protection to the farm. If the decision to proceed in converting the land is made, the following steps are taken depending on certification status:

i) When the land is certified organic:

(a) The operator submits for approval to the ACA a revision to the Organic System Plan (OSP) describing the proposed actions prior to implementing any conversion. This eliminates the possibility of loss of certification. The request includes photos and written evidence from a conservation organization such as USDA NRCS using their two pages Environmental Evaluation Worksheet CPA 52 which documents any adverse effects that will occur to threatened, endangered, and rare species, or causes soil erosion, degradation of water quality and other biological and environmental effects. If any adverse affects are noted, mitigation measures are implemented elsewhere on the property or in the region to compensate for loss to biodiversity. An agreement between the operator and the ACA will be made where the ACA monitors the mitigation measures until success is achieved, or more mitigation efforts are required.

ii) When none of the land to be converted is certified organic:

(a) The operator is treated as above, if the operator first creates an OSP describing the proposed actions prior to conversion and seeks approval by the ACA.

(b) If the operator does not first seek approval by the ACA, she/he submits photos and written evidence of any past adverse effects caused by the conversion, as mentioned above. An agreement between the operator and the ACA will be made where the ACA possibly requires mitigation measures that are monitored until success is achieved or more mitigation efforts are required.

The NOSB is interested in the community's response to this recommended guidance and other thoughts on this important topic.

The primary tool for ensuring biodiversity conservation compliance is education and the Guidance could be an important part of that.

Recent efforts by NCRS and NCAT projects are assisting farmers build a bridge with NOP resulting in improved conservation compliance. These efforts must continue and be strengthened.

b) Inspectors - Recommendation from 2009:

Inspectors shall receive training in biological diversity conservation such as is currently given by IOIA and include methods for verification of NOP biodiversity standards in all inspections of organic farms using appropriate checklists and other tools. Other issues not explored by biodiversity verification methods, but that should be evaluated by inspectors include:

- Sustainable practices for incorporating new land into agriculture
- Practices which enhance soil biodiversity

Progress Report: IOIA now emphasizes biodiversity conservation in its inspector training and has developed webinar training with a biodiversity focus.

Comments from individual inspectors support the need more training. Education and training about biodiversity is needed at all levels of the organic food production process before the full capacity of improved biodiversity will be realized. Stated by one inspector “from the farmer to the shopper, the value of improved biodiversity must be better appreciated and implemented. The opportunities are huge. We’ve only begun the process.”

c) Certifiers - Recommendation from 2009:

Certifiers shall adopt an OSP and other certification documents that address the NOP biodiversity requirements. Certifiers may devise a format and content for these documents that is suitable to their own certification system.

Certifiers shall require all production operations to address biodiversity conservation in their OSPs. Conversion of native habitat to crop production has important consequences to biodiversity and normally should be discouraged.

Certifiers shall document the degree to which producers are addressing biodiversity when performing inspections and when making certification decision. Only severe violations would lead to suspension or revocation of a producer’s certification, other violations would be cited as minor non-compliances by the certifiers and corrected by the operator within a specified timeframe.

Progress Report: Information received indicates that more certifiers are addressing biodiversity requirements in a systematic way. However, it

appears that to achieve consistently full implementation of requirements, more guidance from the NOP is needed.

An issue that has been reported is that some certifiers do not want inspectors to address §205.200 subject matter in inspection of handling operations. This needs to be clarified.

A suggestion for addressing "new land" issue is made in the above statement on Certified Grower/Producer.

The CACS would like to hear from Certifiers on what they have done since the 2009 recommendations were issued: what works and what doesn't.
Also CACS what like to learn from Certifiers (and Inspectors) what biodiversity conservation issues they have encountered with handling operations.

d) **National Organic Program -** Recommendation from 2009:

The NOP shall emphasize biodiversity in its training of NOP-accredited certification bodies. Trainings shall include such topics as indicators of compliance with biodiversity standards, differentiating major and minor non-compliances for violations of biodiversity standards, evaluating corrective actions taken to correct minor violations. The focus should be on education, teaching practices and the benefits of conservation. The NOP shall also revise the checklist used to audit certifiers so that it includes questions about NOP's biodiversity standards in every audit.

Progress Report: The NOP is addressing the 2009 recommendations and has started to make changes in the audit check list.

Wild Farm Alliance has provided the NOP suggestions for changes in the NOP's audit checklist to address biodiversity standards in every audit of ACAs.

V. REQUEST FROM THE CAC Subcommittee:

The CAC Subcommittee would appreciate receiving answers to the questions posed above as well as other suggestions on methods for strengthening biodiversity conservation within organic production systems for all scopes of accreditation, particularly handling.

Sub Committee Vote:

Moved: Richardson Second: Stone

Yes- 8 No- 0 Abstain- 0 Recusal- 0 Absent- 0