



National Organic Standards Board Meeting
Ballroom, Salons A-D, La Jolla Marriott La Jolla, CA 92037 April 27-30, 2015

Title	Page
Handling Subcommittee Harold Austin, Chairperson	
Proposal: Glycerin - petitioned for removal	1
Proposal: Whole Algal Flour - petitioned	11
Proposal: Ammonium Hydroxide - petitioned	19
Proposal: PGME - petitioned	27
Proposal: Triethyl Citrate- petitioned	35
Proposal: Ancillary Substances for Microorganisms	41
Sunset 2016 Sunset Reviews Meeting 2: Egg White Lysozyme, L-Malic Acid, Microorganisms, Activated Charcoal, Peracetic Acid, Cyclohexylamine, Diethylaminoethanol, Octadecylamine, Sodium Acid Pyrophosphate, Tetrasodium Pyrophosphate (TSPP)	43
Sunset 2017 Sunset Summaries Meeting 1	61
Crops Subcommittee Zea Sonnabend, Chairperson	
Proposal: Exhaust Gas - petitioned	119
Proposal: Calcium Sulfate - petitioned	125
Proposal: 3-decene-2-one - petitioned	129
Discussion Document: Contamination Issues in Farm Inputs	135
Sunset 2016 Reviews Meeting 2: Ferric Phosphate, Hydrogen Chloride	143
Sunset 2017 Sunset Summaries Meeting 1	147
Materials Subcommittee Dr. C. Reuben (Calvin) Walker, Chairperson	
Discussion Document: Excluded Methods Terminology	171
Discussion Document: Prevention Strategy Guidance for Excluded Methods in Crops and Handling	181

Compliance, Accreditation, and Certification Subcommittee | Carmela Beck, Chairperson

Proposal: Peer Review	189
------------------------------	------------

Livestock Subcommittee | Tracy Favre, Chairperson

Proposal: Methionine (MET) - petitioned	193
--	------------

Proposal: Acidified Sodium Chlorite (ASC) - petitioned	207
---	------------

Proposal: Zinc Sulfate - petitioned	213
--	------------

Discussion Document: Aquaculture Legacy Document	219
---	------------

Sunset 2017 Sunset Summaries Meeting 1	229
---	------------

**National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal - Glycerin
October 21, 2014**

Summary of Proposed Action:

Petitioner has requested removal of glycerin from §205.605(b) (synthetic materials for handling), stating that there is now sufficient quantity of organically produced glycerin and that synthetic glycerin is no longer required. The petitioner believes that the process of microbial fermentation – used to produce organic glycerin – is a superior method for the production of organic glycerin, because it uses only mechanical and biological processes as required in §205.270(a) without the use of allowed synthetics listed in §205.605(b). Further, they state, “An important reason that glycerin produced by hydrolysis of fats and oils should have been included at §205.606 is that items listed at §205.606 are subject to the restriction that they can be used “only when the product is not commercially available in organic form.” Certified organic glycerin is currently available, but there is no “commercial availability” requirement to incentivize processors to use it or certifiers to require it. Consequently, glycerin should be removed from the National List in order to encourage organic agricultural production.”
(<http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5101924>)

There has been a significant amount of confusion regarding the classification of glycerin as synthetic/non-synthetic because of the various methods by which it can be manufactured. In April 2013, the National Organic Program (NOP) issued draft guidance on classification of materials that should provide some clarification on the status of glycerin produced by these various methods. However, as of this date, this guidance document has not been issued in its final form. Further, the Handling subcommittee recognizes the irony that glycerin produced from organic source materials using hydrolysis could be classified as both organic and synthetic.

Additionally, public written and oral comments presented for the Spring 2014 and the Fall 2014 NOSB meetings indicated that the removal of glycerin from §205.605(b) could have significant negative impact on natural flavorings used in organic products, due to the fact that glycerin is often used as a carrier. The comments generally expressed concern regarding the commercial availability of sufficient quantities of organically produced glycerin to meet the demand. With the current listing for flavors at §205.605(a), the annotation is as follows: “non-synthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.” During the Handling subcommittee discussion, the question came up as to whether current practice is to allow glycerin – from hydrolysis of fats and oils – currently classified as synthetic, to be used as a carrier in natural flavorings.

Because of the confusion around classification of glycerin (depending upon the manufacturing methods and source material), and the concerns regarding commercial availability of organically produced glycerin, the Handling subcommittee, after significant discussion, is proposing the listing of glycerin at §205.606 and removal of glycerin from §205.605(b).

Based upon the draft classification of materials document, glycerin that would qualify for listing at §205.606 would include glycerin produced by microbial fermentation of carbohydrate substances as well as glycerin produced from hydrolysis of fats and oils using mechanical/physical methods, as long as the original source material was agricultural. It is the Handling subcommittee’s intent with this recommendation to provide an incentive to increase the amount of organic glycerin used, while also recognizing the possibility of issues around commercial availability.

Background

Glycerin is a viscous fluid that has a sweet taste. It is used in a wide variety of products including food, cosmetics, medical and industrial applications. As listed at §205.605(b), glycerin is formulated from hydrolysis of fats and oils. Per the Technical Review (line 122), there are a variety of methods for manufacture of glycerin from hydrolysis of fats and oils:

Table 2 Processes for producing glycerin by hydrolysis of fats and oils	
Lemmens Fryer's Process	Oil or fat is subjected in an autoclave to the conjoint action of heat and pressure (about 100 PSI) in the presence of an emulsifying and accelerating agent, e.g. zinc oxide or hydroxide (sodium hydroxide can be substituted) for about eight hours. The strong solution of glycerin formed is withdrawn and replaced by a quantity of hot, clean and preferably distilled water equal to about one third to one fourth of the weight of the original charge of oil or fat and treatment continued for an additional four hours. The dilute glycerin obtained from the latter part of the process is drawn off and used for the initial treatment of the further charge of oil or fat.
Budde and Robertson's Process	The oils or fats are heated and mechanically agitated with water and sulphuric acid gas, under pressure in a closed vessel or autoclave. The advantages claimed for the process are that the contents of the vessel are free from foreign matter introduced by reagents and need no purification; that the liberated glycerin is in the form of a pure and concentrated solution; that no permanent emulsion is formed and that the fatty acids are not discolored.
Ittner's Process	Coconut oil is kept in an autoclave in the presence of water at 70 atmospheres pressure and 225-245°C temperature and split into fatty acids and glycerin, both being soluble under these conditions in water. The glycerin solution separates in the bottom of the autoclave. The aqueous solution contains at the end of the splitting process more than 30 percent glycerin.
Continuous High Pressure Hydrolysis	In this process a constant flow of fat is maintained flowing upward through an autoclave column tower against a downward counter-flow of water at a pressure of 600 PSI maintained at temperature of 480-495°F. Under these conditions, the fat is almost completely miscible in water and the hydrolysis take place in a very short time. The liberated fatty acids, washed free of glycerin by the downward percolating water, leave the top of the column and pass through a flash tank while the liberated glycerin dissolves in the downward flow of water and is discharged from the bottom of the tower into the sweet-water storage tank.

Additionally, per the petitioner, "Saponification of natural fats and oils, a process of hydrolyzing the agricultural products fat or oil with water (steam) under pressure (high-pressure splitting) or with a solution of sodium carbonate, sodium hydroxide, or potassium hydroxide (traditional process) to produce synthetic glycerin and fatty acids. The steam process is described in the 1995 Technical Advisory Panel Report on glycerin. The alkali process is the traditional process used to saponify fats and oils."

Hydrolysis of fats and oils does change the chemical properties of the source material, therefore, it is considered a synthetic.

The forms identified below as agriculture would be allowed at §205.606. Synthetic forms would not be allowed unless produced organically.

Per the petition: Four general methods of commercial glycerin production are or have been used:

1. Chemical synthesis by hydrogenolysis of carbohydrates (21 CFR 178.3500; 21CFR 172.866)) or by synthesis from propylene (mentioned in the 1995 Technical Advisory Panel report on glycerin). Neither chemical synthetic process has ever been deemed worthy of serious consideration for use in organic. Per the draft classification of materials guidance document, this form would be considered synthetic.
2. Biodiesel production comprises reaction of natural fats and oils – triglycerides – with methyl alcohol or ethyl alcohol to produce the methyl or ethyl esters of fatty acids. These synthetic fatty acid esters are the diesel fuel. Glycerin is a synthetic waste byproduct of this chemical process. The commercialization of the biodiesel process in the past few years has created an enormous supply of biodiesel glycerin that has largely displaced chemical synthesis from propylene. In fact, the low cost of biodiesel glycerin has resulted in commercialization of processes to use it as a raw material to produce epichlorohydrin, acrolein, propylene glycol, and other organic chemicals. There are safety concerns with biodiesel glycerin, discussed in Section B-11. *Per the draft classification of materials guidance document, this form would be considered non-agricultural synthetic.*
3. Saponification of natural fats and oils, a process of hydrolyzing the agricultural products fat or oil with water (steam) under pressure (high-pressure splitting) or with a solution of sodium carbonate, sodium hydroxide, or potassium hydroxide (traditional process) to produce synthetic glycerin and fatty acids. The steam process is described in the 1995 Technical Advisory Panel (TAP) Report on glycerin. The alkali process is the traditional process used to saponify fats and oils. The three sources of alkali used in this process are included in the National List. Glycerin produced by saponification was recommended by the NOSB in 1995 for inclusion on the National List with the annotation “produced by hydrolysis of fats and oils.” It is currently included on the National List as a synthetic nonagricultural substance at §205.605(b) [and also for livestock use at §205.603(a)(12)]. Certified organic glycerin is being produced by saponification of organic fats and oils. *Per the draft classification of materials guidance document, glycerin produced using saponification of natural fats and oils using steam would be considered agricultural. However, the material would be considered synthetic if an alkali catalyst was used.*
4. Microbial fermentation of carbohydrate substances (analogous to citric acid currently included in the National List at §205.605(a)) to produce non-synthetic glycerin. This production method is briefly mentioned generically in the 1995 TAP Report and referred to in the Merck Index monograph on glycerol (glycerin), which cites a U.S. Patent No. 3,012,945 issued to Noda in 1961 for yeast fermentation to produce glycerin. Currently, microbial fermentation of organic cornstarch by the yeast *Candida krusei* is used commercially to produce certified organic glycerin as well as non-synthetic non-organic glycerin. *Per the draft classification of materials guidance document, this form would be considered agricultural.*

According to the Technical Report, glycerin can be produced organically by the process of microbial fermentation using only mechanical and biological processes as required in §205.270(a) without the use of allowed synthetics listed in §205.605(b). In addition, certified organic glycerin can be produced by hydrolysis of organic fats and oils using either steam splitting or traditional saponification with a catalytic amount of an alkali (sodium carbonate, sodium hydroxide, or potassium hydroxide) on the National List. Glycerin, produced organically by fermentation is an agricultural product as defined in 7 CFR 205.2, since it is a processed product produced from an agricultural commodity, e.g. cornstarch (TR lines 130 – 131). There are currently 21 USDA certified organic operations supplying glycerin for organic food or cosmetic products. Specific supplier information (TR Table Line: 674)

Evaluation Criteria (see attached checklist for criteria in each category)

	Criteria Satisfied?		
1. Impact on Humans and Environment	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2. Essential & Availability Criteria	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> N/A
3. Compatibility & Consistency	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> N/A
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for §205.606)	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> N/A

Substance Fails Criteria Category 2, 3, 4

Subcommittee Action & Vote

Classification Motion: Motion to classify glycerin as agricultural when derived from agricultural source material and processed using biological or mechanical/physical methods described under §205.270(a).

Motion by: Tracy Favre

Seconded by: Zea Sonnabend

Yes: 6 No: 0 Absent: 2 Abstain: 0 Recuse: 0

Listing Motion: Motion to list glycerin at §205.606, produced from agricultural source materials and processed using biological or mechanical/physical methods as described under §205.270(a).

Motion by: Tracy Favre

Seconded by: Zea Sonnabend

Yes: 6 No: 0 Absent: 2 Abstain: 0 Recuse: 0

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

Notes:

Listing Motion: Motion to remove glycerin - produced by hydrolysis of fats and oils – from §205.605(b)

Motion by: Tracy Favre

Seconded by: Zea Sonnabend

Yes: 6 No: 0 Absent: 2 Abstain: 0 Recuse: 0

Approved by Harold Austin, Subcommittee Chair, to transmit to NOSB December 2, 2014

NOSB Evaluation Criteria for Substances Added to the National List - Handling

Category 1. Adverse impacts on humans or the environment?

Substance: Glycerin

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Are there adverse effects on the environment, or is there a probability of environmental contamination during use or misuse of the substance? [§205.600(b)(2), [§6518(m)(3)]		X		Wide variety of uses for food and industrial applications. Long-term history of safe use, TAP indicates no incidence of industrial poisoning. Glycerin should not come into contact with a strong oxidizing agent.
2. Are there adverse effects on the environment or is there a probability of environmental contamination during manufacture or disposal of the substance? [§6518(m)(3)]		X		For current listing: Manufactured from hydrolysis of fats and/or oils using steam splitting. Theoretically possible to have spill of oils, but this is unlikely. Fermentation methods: Unlikely
3. Are there any adverse impacts on biodiversity? (§205.200)			X	However, the petitioner claims that the residue from biodiesel production is used in the manufacture of glycerin, and one could argue that growing corn for biodiesel does have an impact on biodiversity.
4. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517(c)(1)(B)(ii)]		X		
5. Is there undesirable persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		X		Per Environmental Working Group (EWG), there seems to be no persistence in the environment. TAP and other documentation have no comment.
6. Are there any harmful effects on human health from the main substance or the ancillary substances that may be added to it? [§6517(c)(1)(A)(i); 6517(c)(2)(A)(i); §6518(m)(4), 205.600(b)(3)]		X		Glycerin is considered GRAS and has a long history of safe use in a wide variety of food, cosmetic and medical applications. It is metabolized as a carbohydrate in the body.
7. Is the substance, and any ancillary substances, GRAS when used according to FDA's good manufacturing practices? [§205.600(b)(5)]	X			See above comment.
8. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600(b)(5)]		X		Manufactured from hydrolysis of fats and oils using steam splitting and then concentrated using distillation. Fermentation methods include isolation of cornstarch from organic corn.

NOSB Evaluation Criteria for Substances Added to the National List - Handling

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

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]	X	X		As currently listed it is not considered agricultural. However, the petitioner makes the argument that it should have been listed at §205.606; if it is manufactured using steam, then it should be considered agricultural. The fermentation method could be considered agricultural since it is manufactured using isolated cornstarch from organic corn.
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			<p>Per the petition: "Saponification of natural fats and oils, a process of hydrolyzing the agricultural products fat or oil with water (steam) under pressure (high-pressure splitting) or with a solution of sodium carbonate, sodium hydroxide, or potassium hydroxide (traditional process) to produce synthetic glycerin and fatty acids. The steam process is described in the 1995 Technical Advisory Panel Report on glycerin. The alkali process is the traditional process used to saponify fats and oils. The three sources of alkali used in this process are included in the National List."</p> <p>Hydrolysis of fats and oils does change the chemical properties of the source material.</p> <p>Fermentation methods: The process for producing organic glycerin by microbial fermentation from carbohydrate substrates begins with organic corn from which cornstarch is isolated. The cornstarch is treated with enzymes to hydrolyze the starch and liberate glucose. The glucose is then fermented with an appropriate microorganism to produce glycerin. The glycerin is purified by passing through ion-exchange columns to remove inorganic elements required for growth of the microorganism and through activated charcoal to remove color and impurities.</p>
3. Is the substance formulated or manufactured by a process that	X			Hydrolysis is the opposite of condensation. A large molecule is split

<p>chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]</p>			<p>into smaller sections by breaking a bond, adding -H to one section and -OH to the other. The products are simpler substances. Since it involves the addition of water, this explains why it is called hydrolysis, meaning splitting by water. A-B + H₂O --> A-H + B-OH (http://www.biotopics.co.uk/as/condensation_and_hydrolysis.html)</p> <p>For fermentation method, see above.</p>
<p>4. Is the substance created by naturally occurring biological processes? [§6502(21)]</p>		X	<p>The process of hydrolysis is a naturally occurring process, but this material is manufacturing using high heat and pressure. Incidentally, all (food) digestion reactions are examples of hydrolysis, and the involvement of water is often not appreciated. Generally these reactions are controlled by enzymes such as carbohydrases, proteases, lipases, nucleases, more specific examples of which are fairly well known. (http://www.biotopics.co.uk/as/condensation_and_hydrolysis.html)</p> <p>For fermentation, see above.</p>
<p>5. Is there a natural source of the substance? [§ 205.600(b)(1)]</p>		X	
<p>6. Is there an organic substitute? [§205.600(b)(1)]</p>	X		<p>Petitioner claims to have a fully organic version of manufacturing using a fermentation process. See glycerin petition (http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5101924)</p> <p>Per the TR: Glycerin can be produced organically by the process of microbial fermentation using only mechanical and biological processes as required in §205.270(a) without the use of allowed synthetics listed in §205.605(b). In addition, certified organic glycerin can be produced by hydrolysis of organic fats and oils using either steam splitting or traditional saponification with a catalytic amount of an alkali (sodium carbonate, sodium hydroxide, or potassium hydroxide) on the National List.</p>
<p>7. Is the substance essential for handling of organically produced agricultural products? [§205.600(b)(6)]</p>	X		<p>Glycerin is used in a wide variety of products including food, cosmetics, industrial and medical. It is a strong humectant. In organic food products it is used to improve texture, increase volume</p>

				and is a major carrier for flavorings and colorings.
8. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]				Alcohols could be used as carriers for flavorings. There are myriad of other materials that could have a similar functional use in other formulations (such as softening and mouth feel in ice cream, keeping baked items soft, etc.) but glycerin is unique in that it can serve in all these functions.
9. Are there any alternative substances? [§6518(m)(6)]	X			Glycerin manufactured from petroleum products, glycerin from saponification of fats and oils and fermentation methods.
10. Is there another practice (in farming or handling) that would make the substance unnecessary? [§6518(m)(6)]	X	X		Given the wide use of glycerin, it is likely that there are substitutes for particular uses, but it is unlikely that any one material would work in all the applications where glycerin is used.
11. Have the ancillary substances associated with the primary substance been reviewed? Describe, along with any proposed limitations.			X	

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

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]	X			TAP says consistent when used with specific food products
2. Is the manner of the substance's use, manufacture, and disposal compatible with organic handling? [§205.600(b)(2)]		X		Current version on the National List is considered a synthetic; therefore, it would not be compatible with organic handling. According to the petitioner, there is now sufficient capacity for organically produced glycerin to supply the organic market.
3. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]				
4. Are the ancillary substances reviewed compatible with organic handling? [?]			X	
5. Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]	X			
6. Is the primary use as a preservative? [§205.600(b)(4)]		X		One of the uses of glycerin is as a preservative but it has many more uses
7. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law)? [§205.600(b)(4)]	X			Glycerin is used as a flavor and/or color carrier, and it is used to improve textures.

NOSB Evaluation Criteria for Substances Added to the National List - Handling

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

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the comparative description as to why the non-organic form of the material /substance is necessary for use in organic handling provided?			X	Petition is for removal of synthetic glycerin. Petitioner claims there is sufficient quantity of organic glycerin available. Per the TR: Glycerin can be produced organically by the process of microbial fermentation using only mechanical and biological processes as required in §205.270(a) without the use of allowed synthetics listed in §205.605(b). In addition, certified organic glycerin can be produced by hydrolysis of organic fats and oils using either steam splitting or traditional saponification with a catalytic amount of an alkali (sodium carbonate, sodium hydroxide, or potassium hydroxide) on the National List.
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate form to fulfill an essential function in a system of organic handling?			X	See above. Petitioner claims there is sufficient organic glycerin available and the synthetic version is no longer necessary.
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			See petition at: http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5101924
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			When synthetic glycerin was recommended for inclusion on the National List, there was an insufficient supply of organic glycerin. According to the petitioner, that is no longer the case. Per the TR: There are currently 21 USDA certified organic operations supplying glycerin for organic food or cosmetic products.
5. Does the industry information about unavailability include (but is 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	X			There are currently 21 USDA certified

produced;				organic operations supplying glycerin for organic food or cosmetic products. Specific supplier information (TR Table Line: 674)
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. Other issues which may present a challenge to a consistent supply?	X			

**National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal - Whole Algal Flour
January 6, 2015**

Summary of Proposed Action:

The Handling Subcommittee (HS) has again reviewed the petition and additional information submitted by Solazyme, Inc. seeking permission to have Whole Algal Flour (WAF) added to the National List of Approved Materials. (This material was referred back to the Handling Subcommittee at the Louisville National Organic Standards Board (NOSB meeting). The Handling Subcommittee proposes to recommend adding WAF to the National List at §205.605(a) - Nonagricultural (non-organic) substance (non-synthetic) allowed. Originally, the Handling Subcommittee considered adding WAF to the National List under §205.606 – Nonorganic agricultural products allowed as an ingredient in or on processed product; however, our discussion and further considerations during the original proposal presentation to the full Board at the NOSB meetings (specifically, at the October 2014 NOSB Fall meeting in Louisville led us to determine §205.606 is not the appropriate place to list this material. To be consistent with other materials already listed and to follow the guidelines of the Draft Decision Tree, the Handling Subcommittee decided this material belongs on §205.605(a) rather than on §205.606.

Background: Whole Algal Flour is manufactured from, a microalgae by fermenting and harvesting cultures of a non-toxicogenic strain of *Chlorella protothecoides*. The petitioner originally proposed listing this material on §205.606 yet noted that algae is also a single-celled organism, and as such, we could place it on §205.605(a). Its primary proposed use would be: a whole food ingredient used as either a partial replacement for food ingredients that provide dietary fat and/or protein such as cream, milk, eggs/egg yolks, and/or butter or shortening in baked goods, beverages, dairy and egg products, sauces, gravies, margarines, salad dressings and soups, or as an added ingredient for texture and mouth feel enhancement.

On September 6, 2013, the National Organic Program received the original petition and forwarded it to the NOSB's Handling Subcommittee for petition review and consideration for listing. On January 14, 2014, the Handling Subcommittee received a supplement from the petitioner: a response to questions that the HS had concerning whole algal flour after our review of the original petition. Both the original petition and the supplemental information contained confidential business information, requiring redaction. The redacted information made it difficult for the Handling Subcommittee to thoroughly review this material and its ancillary substances.

During the 30day public comment period prior to the NOSB's October 2014 Fall meeting in Louisville, , the petitioner provided additional information to the Handling Subcommittee; this information clarified some points of concern. Additionally, the petitioner (and others) provided more information and questions to the NOSB during oral public presentation and questions,. There were 14 written public comments submitted for whole algal flour; While Six commenters opposed listing whole algal flour on §205.606, eight supported adding whole algal flour to that Section. Those opposed were concerned with: 1) the amount of information withheld as confidential business information; 2) the fermentation process (as a whole, not just this material); 3) excluded methods, using a synthetic material to replace already existing organic alternatives; and 4) ancillary substances. Those that supported adding whole algal flour to the National List stated that it would not replace organic substances currently being used but give

handlers an alternative – to make a finished product that can provide a healthier organic product – a nonallergenic, vegan option. Materials used currently could be partially replaced by whole algal flour; this replacement could help to reduce calories, fat, saturated fat, and cholesterol while not impacting taste, mouth feel, or end product quality.

Discussion:

The petitioner provided the Handling Subcommittee (during written public comment and their oral comments) answers to several areas of concern that they had previously had. The HS resolved the concerns related to ancillary substances, especially the Subcommittee's requirement of a due diligence review even though some of the information was redacted. The two ancillary substances used are antioxidants: tocopherols and ascorbic acid; both are currently listed on the National List at §205.605(b). Consequently, the NOSB's ancillary substance review of a petitioned material is complete.

Another concern was the manufacturing process via fermentation and the media used during the process. A detailed list of those materials used in the fermentation growth medium was provided. This list was very typical of substances normally used in the fermentation process of other materials currently allowed on the National List. The petitioner provided two examples of two materials currently on the National List at §205.605 that are also products of fermentation; these are: Gellan gum at §205.605(a) and Xanthan gum at §205.605(b)

The petitioner also assured the Subcommittee and the full Board that no excluded methods were used by them to manufacture whole algal flour. This, together with the materials used in their manufacturing process, would be subject to review by their certifier at each annual inspection, and as it reviews their Organic System Plan during certification renewal.

Then, the discussion around essentiality comes into play: Is it or is it not essential to organic handling? Part of the original discussion was based on the belief that this material would replace currently used "organic" materials (organic milk, eggs, cream, etc.) or practices. While that is partially true, it is not the petitioner's reason for seeking to add Whole Algal Flour to the National List. The primary reason is to provide handlers with an option, so that they might be able to provide those organic consumers with allergen concerns to eggs and/or dairy products, an alternative choice of a non-allergenic option to their finished goods. It would also help provide an alternative to those looking for a vegetarian or vegan alternative in organic consumer goods. Is there currently an alternative for this material based on its intended use? The answer is no. Does this material offer something to a handler currently not accessible to their manufacturing process? The answer is possibly. Could this material be considered essential to a handler to formulate a lower in calorie, low fat, vegan, or a non-allergenic alternative to what is currently being manufactured? The answer could then be considered possibly yes. While there will be differences of opinion, we must look at what this material could provide the organic community if it were listed, versus the consequences if it is not allowed.

The Handling Subcommittee has decided that Whole Algal Flour is not essential to organic handling. The Subcommittee also recognizes that this use is inconsistent with the basic fundamental principles of organics and, as such, would not meet the expectations of organic consumers, handlers, or others within the organic community.

Explanation of Motions: During the October 2014 Fall meeting in Louisville, a classification motion was not voted on by the Subcommittee due to the redacted information pertaining to the manufacturing process and ancillary substances. Once the petitioner provided additional

information 1) this issue was reconsidered and brought to a proper vote by the Subcommittee, and 2) we decided to add whole algal flour to the National List at §205.605(a) instead of at §205.606 as originally proposed in the listing motion. The motion is presented below.

Evaluation Criteria (see attached checklist for criteria in each category)

	Criteria Satisfied?		
1. Impact on Humans and Environment	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2. Essential & Availability Criteria	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> N/A
3. Compatibility & Consistency	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> N/A
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for §205.606)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> N/A

Substance Fails Criteria Category: 2, 3

Comments: The Handling Subcommittee during its discussion about whole algal flour, particularly whether or not it should be added to the National List, decided the following: hit is not essential to organic handling and it is inconsistent with basic organic principles (replacing organic materials currently being used with this product).

Subcommittee Action & Vote

Classification Motion: Move to classify Whole Algal Flour (WAF) as non synthetic.

Motion by: Harold Austin

Seconded by: Jean Richardson

Yes: 5 No: 0 Absent: 3 Abstain 0 Recuse: 0

Listing Motion: Move to add Whole Algal Flour at §205.605(a) – Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” (a) Nonsynthetics allowed

Motion by: Harold Austin

Seconded by: Jean Richardson

Yes: 0 No: 6 Absent: 2 Abstain: 0 Recuse: 0

Proposed Annotation (if any): none

Approved by Harold Austin, Handling Subcommittee Chair, to transmit to NOSB, January 6, 2015

NOSB Evaluation Criteria for Substances Added To the National List - Handling

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

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Are there adverse effects on the environment, or is there a probability of environmental contamination during use or misuse of the substance? [§205.600(b)(2), [§6518(m)(3)]		X		It would not appear that there would be any adverse effects on the environment from the use or misuse of this material.
2. Are there adverse effects on the environment or is there a probability of environmental contamination during manufacture or disposal of the substance? [§6518(m)(3)]		X		It would not appear that there would be any adverse effects to the environment from the manufacture or disposal of this substance.
3. Are there any adverse impacts on biodiversity? (§205.200)		X		
4. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517(c)(1)(B)(ii)]		X		
5. Is there undesirable persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		X		
6. Are there any harmful effects on human health from the main substance or the ancillary substances that may be added to it? [§6517(c)(1)(A)(i); 6517(c)(2)(A)(i); §6518(m)(4), 205.600(b)(3)]		X		
7. Is the substance, and any ancillary substances, GRAS when used according to FDA's good manufacturing practices? [§205.600(b)(5)]	X			Page 6 and 7 of the petition for whole algal flour states that on June 7, 2013 the FDA issued a No Questions letter (GRN 469) for whole algal flour. The petitioner has self-affirmed whole algal flour to be GRAS, page 4 of the petition. The two declared ancillary substances used in whole algal flour (as stated in the petitioner's written public comments dated October 6, 2014) were mixed tocopherol and ascorbic acid (both of these materials are currently listed on the National List at §205.605(b).
8. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600(b)(5)]		X		

Category 2. Is the Substance Essential for Organic Production?

Whole Algal Flour

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]		X		Petitioner claims that it should be classified as a microorganism and is nonagricultural.
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]		X		Made by fermentation process in a closed system.
3. 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		Goes through fermentation and has either potassium hydroxide or sodium hydroxide added to adjust the pH. (both are on the national list).
4. Is the substance created by naturally occurring biological processes? [§6502(21)]	X			Fermentation has been considered to be a natural process.
5. Is there a natural source of the substance? [§ 205.600(b)(1)]		X		
6. Is there an organic substitute? [§205.600(b)(1)]	X			Organic milk, cream, eggs/egg yolks are currently being used and others. But, these do not serve the same as the intended purpose of whole algal flour.
7. Is the substance essential for handling of organically produced agricultural products? [§205.600(b)(6)]	X	X		There currently are alternatives being used. It could be considered essential, if it were considered that it can help to provide an alternative to currently used organic materials to provide a non-allergen/vegan alternative to those organic consumers needing an alternative choice.
8. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]		X		There could be wholly natural substitutes for this product, in part. But, for the intended use of this material there would not be a wholly natural substitute product currently available.
9. Are there any alternative substances? [§6518(m)(6)]	X			There are substances currently on the National List of Approved Substances that are being used such as: starch products, some of the gums, hydrocolloids, to name just a few.
10. Is there another practice (in farming or handling) that would make the substance unnecessary? [§6518(m)(6)]		X		

11. Have the ancillary substances associated with the primary substance been reviewed? Describe, along with any proposed limitations.	X			In the petitioners written public comments (October 6, 2014) they identified two ancillary substances used in the production of whole algal flour; those were: mixed tocopherol and ascorbic acid, both are listed on the National List at §205.605(b).
---	---	--	--	---

Category 3. Is the substance compatible with organic handling practices? Whole Algal Flour

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]	X			
2. Is the manner of the substance's use, manufacture, and disposal compatible with organic handling? [§205.600(b)(2)]	X			It is consistent with other materials currently allowed in organic handling and also currently on the National List.
3. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]	X			
4. Are the ancillary substances reviewed compatible with organic handling?	X			The ancillary substances were reviewed and found to be compatible with organic handling. The two ancillary substances identified are both currently on the National List.
5. Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]	X			
6. Is the primary use as a preservative? [§205.600(b)(4)]		X		
7. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law)? [§205.600(b)(4)]		X		The primary use is to reduce and replace substances currently being used to help reduce fat content, improve texture and mouth feel in some products. The substance is used to provide a non-allergenic and vegan alternative to materials currently used in organic handling.

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

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the comparative description as to why the non-organic form of the material /substance is necessary for use in organic handling provided?	X			There currently is not an organic form of this substance available on the market for use in organic handling.
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate form to fulfill an essential function in a system of organic handling?	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 about unavailability include (but is 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	Unknown
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. Other issues which may present a challenge to a consistent supply?			X	

**National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal - Ammonium Hydroxide
November 18, 2014**

Summary of Proposed Action:

Ammonium hydroxide is petitioned to be added to the National List at §205.605 as a boiler water additive. Ammonium hydroxide is a synthetic substance manufactured from natural gas; natural gas is used to convert atmospheric nitrogen to ammonia to which, water is added. The Handling Subcommittee proposes not to add ammonium hydroxide to the National List.

Background:

Ammonium hydroxide has been on the National Organic Standards Board (NOSB) Work Agenda on and off for several years; review of this proposal should be considered in light of that history and changing trends in processing over the intervening years.

* The NOSB Organic Good Manufacturing Practices of 1995 did not include boiler additives.

* In 2001 ammonium hydroxide was petitioned for addition to the National List. The lengthy TAP Review (2/15/01) included many appendices and a Steam Paper which analyzes and compares all the boiler additives. This report included a recommendation to prohibit ammonium hydroxide. In August 2001 there was also a lengthy analysis submitted to the NOSB comparing all the boiler additives.

* NOSB Recommendation dated October 2001 was to approve limited use of three boiler additives, cyclohexylamine, diethylaminoethanol and octadecylamine, and to approve ammonium hydroxide “for use as a boiler additive only, with removal from the National List October 21, 2005. If Office of General Counsel says no to shorter sunset date, the material remains prohibited.” Vote: 10 in favor, 3 abstentions 1 no

* The Final Rule of NOP dated September 2006 (71 FR 53299) concluded that while most commenters wanted the chemical included some did not, however, the expiration date recommended by the NOSB had lapsed. Therefore, it was not added to the list.

* A new petition was submitted on 10/30/12 to add ammonium hydroxide to the National List “solely for use as a boiler water additive, to neutralize carbon dioxide in steam condensate.” Petitioner suggests that addition of ammonium hydroxide as a boiler additive would allow elimination from the National List of the three synthetic volatile amines, cyclohexylamine and diethylaminoethanol, two neutralizing amines, and octadecylamine, a filming amine – these are approved for the limited use of packaging sterilization.

* The petition was determined to be sufficient and on 2/19/13 the Handling Subcommittee voted not to add ammonium hydroxide to the National List (6:0 with two absences).. However, there was some public comment suggesting that ammonium hydroxide may be able to replace the three boiler additives scheduled for sunset discussion in October 2014, so this proposal was posted with a request for further public comment a vote by the full NOSB was deferred pending additional public comment on all boiler additives.

Discussion

Ammonium hydroxide is a powerful alkali petitioned for use as a boiler additive because it neutralizes carbonic acid in condensate to prevent corrosion, reducing pH to 8.5 or 9.0. The level of ammonium hydroxide required in steam would depend on the level of carbon dioxide in the steam. Ammonium hydroxide is produced by the addition of water to Ammonia. Ammonia is produced on a large scale worldwide. One of its largest uses by production volume is as an ingredient in conventional fertilizer (prohibited in organic agriculture).

Ammonium hydroxide is a severe irritant which must be handled properly because exposure by humans and other mammals during production or use presents a serious toxicological concern. It is toxic by all routes – inhalation, dermal and ingestion – and the toxicity is well documented. It is an air and water pollutant and contributes as a greenhouse gas. It is toxic to fish and other aquatic species. Spillage could cause considerable environmental damage.

There are a number of alternative practices that can be used instead of boiler additives. The alternatives include: replacement of steam lines with stainless steel piping, water treatment, physical or chemical deaeration, interruption of boiler water treatment prior to organic processing runs, bleed runs, dismantling and cleaning systems prior to organic food handling, steam to steam heat exchangers, a separate secondary boiler to generate steam for direct food contact applications.

The petition requests addition of ammonium hydroxide as a “boiler additive” to neutralize carbon dioxide in order to prevent acid attack in steam condensate lines. Where steam is used in or on food it is termed “culinary steam” and used in food processing for sanitation or sterilization of food contact surfaces, including packaging sterilization. Petitioner also suggested that the form of ammonium hydroxide in steam condensate is ammonium carbonate, which is on the National List at §205.605(b). However, ammonium carbonate is allowed for use “only as a leavening agent.”

Public comment was received in Fall 2013, Spring and Fall 2014 from several commenters, including the petitioner. The majority of the public comments recommended not adding ammonium hydroxide to the National List. There were no comments from any processor or handler asking for addition of this chemical. There was no evidence provided that ammonium hydroxide could replace the three other boiler chemicals under sunset discussion.

Public comment did not indicate a demand for ammonium hydroxide, and there are many alternative practices that can be used instead of ammonium hydroxide as a boiler additive.

Evaluation Criteria

(Applicability noted for each category; Documentation attached)
below)

Criteria Satisfied? (see “B”

- | | | | |
|--|------------------------------|--|---|
| 1. Impact on Humans and Environment | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No | <input type="checkbox"/> N/A |
| 2. Essential & Availability Criteria | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No | <input type="checkbox"/> N/A |
| 3. Compatibility & Consistency | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No | <input type="checkbox"/> N/A |
| 4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for § 205.606) | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input checked="" type="checkbox"/> N/A |

Substance Fails Criteria Category: 3. Comments:

Ammonium hydroxide has the potential to cause significant toxic damage to humans, mammals, aquatic systems and greenhouse gasses and is not essential or compatible with organic agriculture and handling.

Proposed Annotation (if any): none

Recommended Committee Action & Vote

Classification Motion: Ammonium hydroxide (CAS # 1336-21-6) as petitioned is synthetic

Motion by: Jean Richardson

Seconded by: Zea Sonnabend

Yes: 6 No: 0 Abstain: 0 Absent: 2 Recuse: 0

Listing Motion: To add ammonium hydroxide (CAS # 1336-21-6) to the National List Section 205.605(b)

Motion by: Jean Richardson

Seconded by: Tracy Favre

Yes: 0 No: 5 Abstain: 0 Absent: 3 Recuse: 0

Approved by Harold Austin, Subcommittee Chair, to transmit to NOSB December 16, 2015

NOSB Evaluation Criteria for Substances Added To the National List

Category 1. Adverse impacts on humans or the environment?

Substance: Ammonium hydroxide

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]	X			Toxic to environment if spilled or volatized to atmosphere (TAP 2001 and petition pages 8, 9, and 10)
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]	X			Worker injury through breathing, ingestion or dermal contact and terrestrial damage with spills during manufacture. (Petition pages 8,9, 10, and TAP 2001).
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]	X			Toxic damage will occur through spills in terrestrial or aquatic systems, and ammonia contributes to greenhouse gases. (Petition pages 8-10) Fish are particularly at risk for toxic effects.
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			Ammonium hydroxide dissolves copper and zinc (Petition page 8 and TAP 2001)
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]	X			Petitioned substance is intended for use in handling facilities, not land application, but spills would have negative impacts. Ammonia is used in conventional fertilizer but not permitted in organic agriculture.

7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]	X			Yes, (petition page 10)
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]	X			Yes if spilled, or released into air
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]	X			When released into air the gas contributes to greenhouse gases.
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4]	X			Yes, toxic if inhaled, ingested, or dermal contact
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]	X			Yes, if inhaled, ingested, or dermal contact
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		

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

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]	X			Ammonium hydroxide is manufactured from natural gas which is used to convert atmospheric nitrogen to ammonia and then water is added to produce the hydroxide form (petition page 4 and TAP 2001).
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		Processors can utilize a number of alternative practices, such as stainless steel pipelines, physical and chemical deaeration, interrupt boiler water treatment prior to organic processing etc . These alternative practices cost time and money. (petition page 11) Although, economic considerations are not one of the criteria for suitability of materials used in organic production systems. (TAP 2001, page9)
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			There are a number of alternative practices that can be used. (Petition page11) These include pre-treating water, replacing steam pipelines with stainless steel etc.

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

Substance: Ammonium hydroxide

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]		X		As a general rule ammonia products are not considered compatible with organic production or handling (TAP 2001, page 7, page 9)
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]		X		See 1 above
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]		X		See 1 above
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]		X		
5. Is the primary use as a preservative? [§205.600 b.4]		X		
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when		X		

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

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 Ammonium Hydroxide**

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. <u>Is the comparative description provided</u> as to why the non-organic form of the material /substance is necessary for use in organic handling?			X	Not an agricultural substance
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate form to fulfill an essential function in a system of organic handling?			X	
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate quality to fulfill an essential function in a system of organic handling?			X	
4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate quantity to fulfill an essential function in a system of organic handling?			X	

<p>5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following:</p> <p>a. Regions of production (including factors such as climate and number of regions);</p>			X	
<p>b. Number of suppliers and amount produced;</p>			X	
<p>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;</p>			X	
<p>d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or</p>			X	
<p>e. Are there other issues which may present a challenge to a consistent supply?</p>			X	

**National Organic Standards Board (NOSB)
Handling Subcommittee
Petitioned Material Proposal - Polyalkylene Glycol Monobutyl Ether (PGME)
February 24, 2015**

Summary of Proposed Action:

Polyalkylene Glycol Monobutyl Ether (PGME) polymeric fluid is a boiler steam additive petitioned for use in feed pellet mills. The petition is specifically for PGME with a requested restriction of a minimum molecular weight of 1500, in accordance with conditions required by 21CFR Section §173.310. The Petitioner is requesting that PGME be added to the National List of Approved Materials at §205.605. The National Organic Standards Board (NOSB) proposes not to add PGME to the National List as petitioned.

Background:

On October 9, 2012, Pellet Products, Inc. petitioned the USDA National Organic Program (NOP) to add polyalkylene glycol monobutyl ether (PGME) to the National List of Approved Materials under section §205.605. Following this, PGME was first considered by the National Organic Standards Board (NOSB) for use as a boiler water additive at the NOSB meeting in April 2013. Information provided in a Technical Report (TR) requested by the NOSB Handling subcommittee, dated June 7, 2013, indicated that PGME does not contact food. The report stated that this is because PGME is non-volatile; PGME precipitates at boiler temperatures and is not delivered with steam, but stays in the boiler as a precipitate until the boiler cools below the cloud point and it may be removed during boiler blow-down.

Based on the findings of the TR, the NOSB Handling Subcommittee developed a proposal on August 20, 2013 stating that PGME was not required to be on the National List because PGME in liquid water does not come into direct contact with organic food. However, public comment for the fall 2013 indicated that PGME may in fact come in to contact with organic product.

In the fall 2013, following the public comment period, there was no NOSB meeting due to the government shutdown. At the NOSB's next meeting on April 29, 2014, PGME was further discussed. Following review and public comment, the NOSB Handling Subcommittee requested an additional Technical Report of limited scope, as well as further information and clarification from the Petitioner. The Petitioner provided some additional information in a letter dated December 3, 2014. Meanwhile, the limited scope TR was received on January 28, 2015.

As requested by the NOSB, the limited scope TR addressed the following questions: 1) What evidence is there that there is entrainment of PGME in water droplets during normal use?; and 2) If used as petitioned, would PGME come into contact with the organic product (pelleted feed)?

Discussion:

Function of substance

PGME is added as a processing aid to water that is used to make steam for the production of pelleted livestock feeds. PGME functions to reduce foaming and also functions as a lubricant. PGME has the unique property of inverse solubility such that it dissolves easily in cold water, but at temperatures over 104F (cloud point) it is completely insoluble. (TR, 2013, lines 59-61) Thus, PGME is not delivered with the steam, but remains in the boiler as a precipitate until the

boiler cools below cloud point. The substance, therefore, has minimal contact with the pelleted feed. Precipitated PGME may also be removed during boiler blow-down (TR, 2013, lines 112-115).

Is there entrainment of PGME in water droplets during normal use?: Yes .

In a supplemental letter dated December 3, 2014, the Petitioner states the following: "PGME is introduced directly into steam lines prior to entering the conditioner whereby its nature acts as a wetting agent and lubricant for the pellet die. Due to the introduction site and the resulting increase in through-put and pellet Durability Index (PDI), it is evident that PGME is entrained in the water during normal use. It is metered based upon the through-put of the pellet mill. Under 21CFR Part 178 Subpart D Sec 178.3570, Certain Adjuvants and Production Aids, PGME can be safely used in and on machinery used for producing or processing feed. The metered amount of PGME is maintained at <3ppm, whereas the limit is not to exceed 10ppm."

However, the limited scope TR of January 28, 2015 states the following: "Thus, unlike solids that are dissolved in boiler water at steam-producing temperatures (e.g. sodium chloride), PGME is insoluble at steam production temperatures and unlikely to carryover dissolved in moisture entrained by steam." (lines 89-91). The report continues, "Entrainment traps and filtration devices incorporated in the 3-A system standard remove particulates, including PGME precipitate if it is present as a result of a boiler malfunction." (lines 107-109).

If used as petitioned, would PGME come in to contact with the organic product (pelleted livestock feed)? Yes.

The Petitioner states in his letter of December 3, 2014 that PGME "does come in to contact with the finished pelleted feed stock but well below limits set by 21 CFR...."

The limited scope TR of January 2013 provides the following: "However, steam that has entrained moisture may contain these solids as a result of carry over. Foaming is likely to enhance carryover of dissolved solids. The prevention of foaming prevents carryover. PGME prevents foaming eliminating one source of carryover. In addition, it is not soluble in water at steam-producing temperatures. Although, it does in fact come into contact with the water from which steam is produced, it does not evolve from the boiler into the steam as a particulate. PGME is not added directly to the pellet mash." (Lines 124-129)

Adverse impacts:

PGME polymers have a low degree of toxicity (TR 2013, line 80). Since they are generally non-toxic, PGME polymers have been approved for a variety of uses in which surfaces or water treated have the potential to come into contact with food. It has also been approved for a variety of foam control applications. In these applications only a potential exposure is assumed. (TR 2013, lines 86-92) Additionally, because PGME polymeric fluids are water-soluble and non-toxic at low concentrations, they are considered environmentally friendly compounds with respect to petroleum-based lubricants that are not water soluble. (TR 2013, lines 148-151). See also TR 2013 lines 494-502. There have been no reported effects of PGME on human health. (TR 2013 lines 526-et seq).

PGME presently has a range of uses approved by the FDA. However, Canadian, CODEX and Japanese standards do not address this additive. EEC standards require that processed feeds shall not have been processed with the aid of chemically synthesized solvents (TR 2013, 301-

302). Meanwhile, IFOAM requires all additives to be declared. PGME is not included in any IFOAM list, but would be considered a non-volatile water additive that is not likely to be entrained in steam (TR 2013, lines 318-320). Finally, The FDA's GRAS list does not address this material.

Manufacture:

PGME is manufactured from ethylene oxide, by chemical processes. PGME is commonly used in modern conditioning systems for pellet feed manufacturing, which includes the use of steam. In this process, steam is directly injected into the product with a tubular apparatus called a conditioner. This heat, plus water, pressure, and time to reach a physical state, facilitates compaction of the feed mash into pellets. This approach offers the manufacturer and the feeder various advantages which justify using additional energy for steam pelleting. Mainly, the process increases production capacity and positively affects the physical, nutritional, and hygienic quality of the produced feed. While dry pelleting is done at 40°C, the use of steam to raise temperatures to 65°C and 78°C results in increases in the production rate of 250% and 275%, respectively. Production rate increased only 9% when the conditioning temperature was raised from 65 to 80°C.

Steam conditioning also decreases fixed costs such as labor and maintenance of equipment. For example, die and roller replacements are another major cost in pelleting. Observing the temperature increase of mash pressed through the pellet die and the electrical energy used to pellet, it can be seen that steam conditioning decreases mechanical friction. A decrease in friction increases both die and roller life, reducing the frequency of replacement. Thus, while the main contribution of steam conditioning is improved nutrition of the pellets, its contribution to productivity and cost-savings is also significant. (TR 2013, lines 461-474)

Natural Sources and Alternatives:

There are no natural sources of PGME. Nor are there many natural antifoam chemicals for boilers, in general. Castor oil is a natural compound that has been used to prevent foam in boilers. However, if castor oil is used care must be taken to condition boiler water so that it is not alkaline. In the case of alkaline boiler water, castor oil will undergo hydrolysis to form the sodium soap of ricinoleic acid. Although not toxic, this soap may exacerbate foaming in the boiler. In addition to castor oil, and depending upon the specific boiler conditions, other natural oils such as lard, lard burning, soybean, corn, maize, cod liver, cottonseed, olive, sunflower, safflower, peanut, ground nut, grape seed, linseed, poppy seed castor and palm oil may be used. Carnauba and peat waxes also have been used as boiler antifoams. As a note, none of these natural chemicals is as effective or has the performance and characteristics provided by PGME. Extensive water treatment is also an alternative to using antifoam chemicals. Water can be treated using reverse osmosis filtration or ion exchange resins to reduce dissolved solids. (TR 2013, lines 628-638)

In considering all of the OFPA criteria, and additional criteria at 205.600 (b), it appears that PGME does come into contact with the organic product and that pelleted feed can be produced without use of PGME.

Evaluation Criteria (see attached checklist for criteria in each category)

- ✓ Impact on Humans and Environment
- N/A

Criteria Satisfied?

- Yes
- No

- ✓ Essential & Availability Criteria Yes No
 N/A
- ✓ Compatibility & Consistency Yes No
 N/A
- ✓ Commercial Supply is Fragile or Potentially Unavailable Yes No
 N/A
as Organic (only for §205.606)

**Substance Fails Criteria Category 2, 3
Subcommittee Action & Vote:**

Classification Motion: To classify Polyalkylene Glycol Monobutyl Ether (PGME) CAS 9038-95-3 as synthetic

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

Listing Motion: To list Polyalkylene Glycol Monobutyl Ether (PGME) CAS 9038-95-3 on **§205.605 (b)** of the National List with the annotation: with molecular weight greater than 1500, for use as a boiler additive in pelleted feed production

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

Proposed Annotation: with molecular weight of 1500, for use as a boiler additive in pelleted feed production

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

Approved by Harold Austin, Subcommittee Chair, to transmit to NOSB February 24, 2015

NOSB Evaluation Criteria for Substances Added To the National List - Handling

Category 1. Adverse impacts on humans or the environment? PGME

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Are there adverse effects on the environment, or is there a probability of environmental contamination during use or misuse of the substance? [§205.600(b)(2), [§6518(m)(3)]	x	x		PGME is manufactured from ethylene oxide, propylene oxide and butanol which are chemical products of the petroleum industry. Each of these chemicals is extremely toxic. (TR 2013, 519-520) Transport of PGME is unregulated. (TR 2013, 516)
2. Are there adverse effects on the environment or is there a probability of		x		See 1 above and TR 2013, 149-151

environmental contamination during manufacture or disposal of the substance? [§6518(m)(3)]				
3. Are there any adverse impacts on biodiversity? (§205.200)		x		PGME is not readily biodegradable (TR 2013, 504 and lines 513-520)
4. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517 (c)(1)(B)(ii)]		x		
5. Is there undesirable persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]	x	x		PGME is not readily biodegradable.
6. Are there any harmful effects on human health from the main substance or the ancillary substances that may be added to it? [§6517(c)(1)(A)(i); 6517 (c)(2)(A)(i); §6518(m)(4), 205.600(b)(3)]		x		There have been no reported effects of PGME on human health (TR 2013, 526) et seq)
7. Is the substance, and any ancillary substances, GRAS when used according to FDA's good manufacturing practices? [§205.600(b)(5)]				GRAS does not address PGME. Title 21 CFR 178.3570 provides that PGME polymeric fluids may be used as a lubricant with incidental food contact at a concentration of less than 10 parts per million (TR 2013, 410-412)
8. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 (b)(5)]		x		Data was not found to substantiate the presence of detectable heavy metal contamination in PGME (TR 2013 487-488) and TR 2013, 480-487

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

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]		x		
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	x			TR 2013 line 328, and lines 366-368 and line 374
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]		x		See 2 above
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		x		See 2 above
5. Is there a natural source of the		x		There are no natural sources of PGME

substance? [§ 205.600(b)(1)]				(TR 2013, 394)
6. Is there an organic substitute? [§205.600(b)(1)]	x			Yes, there are a number of oils, such as sunflower , lard, soybean, corn, safflower etc which could be used, but very little data exists as to the efficacy of such oils for the purpose petitioned herewith(TR 2013, 665-668)
7. Is the substance essential for handling of organically produced agricultural products? [§205.600(b)(6)]	x	x		Could use a mechanical piping design for the boiler, (TR 2013, 249-250) as required under Canadian standards for culinary steam. Can make pelleted feed without the use of PGME.
8. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]		x		There are a range of oils as noted in 7 above (TR 2013, 665-668)
9. Are there any alternative substances? [§6518(m)(6)]	x			As in 8 above
10. Is there another practice (in farming or handling) that would make the substance unnecessary? [§6518(m)(6)]	x			Could try to make pellets without steam (TR 2013, 655-664) Could limit livestock feed to non-pelleted feeds and forage. Could use natural anti-foaming chemicals, but limited efficacy (TR 2013, 629-638)
11. Have the ancillary substances associated with the primary substance been reviewed? Describe, along with any proposed limitations.				

Category 3. Is the substance compatible with organic handling practices? PGME

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]		x		
2. Is the manner of the substance's use, manufacture, and disposal compatible with organic handling? [§205.600(b)(2)]	x			Yes, Provided it is manufactured and used according to regulations
3. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]	x	x		
4. Are the ancillary substances reviewed compatible with organic handling [?]				
5. Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]	x			TR 2013, 463-465

6. Is the primary use as a preservative? [§205.600(b)(4)]		x		Although not intended as a preservative, PGME addition to boiler steam improves steam quality, which improves pellet hardness (TR 2013, 423)
7. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law)? [§205.600(b)(4)]		x		

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

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the comparative description as to why the non-organic form of the material /substance is necessary for use in organic handling provided?			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 about unavailability include (but is 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. Other issues which may present a challenge to a consistent supply?			x	

**National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal - Triethyl Citrate
January 6 2015**

Summary of Proposed Action:

Triethyl Citrate (TEC), CAS# 77-93-0, is a synthetic substance petitioned to be added to the National List at §205.605 as a food additive for the intended use as a whipping enhancer for egg whites during processing. TEC is an ester of citric acid, a colorless, odorless liquid used as a food additive to stabilize foams, and especially as a whipping aid for egg whites. There are alternative non-synthetic substances that can be used for this purpose. Thus, the Handling Subcommittee proposes not to recommend that this material be added to the National List of Approved Substances.

Background:

The Petition, dated 2/10/14, was received by the National Organic Standards Board (NOSB) on 3/4/14. Following initial review, the Handling Subcommittee requested a Technical Report (TR) on 4/16/14. The TR was received on 11/6/14 and Sufficiency Review completed on 1/18/14. The petition includes no confidential business information (CBI).

Discussion:

The Petitioner states that Triethyl Citrate (TEC) is a “natural, organic compliant ingredient flavor and is also used by the egg industry as a pasteurized egg white whipping enhancer in baking, such as for angel food cakes.” However, the TR indicates that TEC may not meet NOP organic requirements for use as a flavor. The Petitioner states, and the TR concurs, that “the main reason that TEC is added to egg whites is to recreate textures and related properties which are lost during pasteurization.”

The Petitioner considers TEC nonsynthetic, based on 100% natural raw materials. However, the TR indicates that “commercial sources of TEC are produced from the reaction of citric acid and ethyl alcohol (ethanol), both of which are fermentation products from the microbial digestion of a carbon substrate.”

While there are no known commercial sources of non-synthetic or natural TEC, numerous plants and animals are non-commercial sources, including brown seaweed and tobacco. There are several alternative substances which can be used, such as sugar, some gums, and cream of tartar, which is potassium acid tartrate on the National List at §205.605(b).

TEC does not appear to have adverse impacts on human health or the environment. TEC is not permitted in organic processing in Canada, the EU or by IFOAM or the CODEX, and not listed in JAS.

Evaluation Criteria (see attached checklist for criteria in each category)

	Criteria Satisfied?		
1. Impact on Humans and Environment	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2. Essential & Availability Criteria	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> N/A
3. Compatibility & Consistency	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> N/A
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for §205.606)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> N/A

Substance Fails Criteria Category: 2, 3

Subcommittee Action & Vote

Classification Motion: Move to classify Triethyl Citrate, CAS# 77-93-0, as petitioned, as synthetic.

Motion by: Jean Richardson

Seconded by: Zea Sonnabend

Yes: 7 No: 0 Absent: 1 Abstain: 0 Recuse: 0

Listing Motion: Move to list Triethyl Citrate, CAS# 77-93-0, as petitioned, at **§205.605** of the National List without annotation.

Motion by: Jean Richardson

Seconded by: Zea Sonnabend

Yes: 0 No: 7 Absent: 1 Abstain: 0 Recuse: 0

Proposed Annotation (if any): No annotation proposed

Approved by Harold Austin, Subcommittee Chair, to transmit to NOSB February 24, 2015

NOSB Evaluation Criteria for Substances Added To the National List – Handling

Category 1. Adverse Impacts on humans or the environment? Substance: Triethyl Citrate

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Are there adverse effects on the environment, or is there a probability of environmental contamination during use or misuse of the substance? [§205.600(b)(2), [§6518(m)(3)]		X		
2. Are there adverse effects on the environment or is there a probability of environmental contamination during manufacture or disposal of the substance? [§6518(m)(3)]		X		
3. Are there any adverse impacts on biodiversity? (§205.200)		X		
4. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517 (c)(1)(B)(ii)]		X		

5. Is there undesirable persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		X		
6. Are there any harmful effects on human health from the main substance or the ancillary substances that may be added to it? [§6517(c)(1)(A)(i); 6517(c)(2)(A)(i); §6518(m)(4), 205.600(b)(3)]		X		TR lines 423-441
7. Is the substance, and any ancillary substances, GRAS when used according to FDA's good manufacturing practices? [§205.600(b)(5)]		X		TR 3224-344
8. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600(b)(5)]		X		TR 325-344 TR 393-397 FDA stipulates no more than 3 ppm arsenic and 10 ppm lead. Major TEC sources meet FDA and FCC

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

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]		X		
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			TR 247-284 Esterization of citric acid and ethanol
3. 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		
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		
5. Is there a natural source of the substance? [§ 205.600(b)(1)]		X		
6. Is there an organic substitute? [§205.600(b)(1)]		X		
7. Is the substance essential for handling of organically produced agricultural products? [§205.600(b)(6)]		X		

8. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]	X			TR 318-319 – There are no known commercial sources of non-synthetic or natural TEC. Numerous plants and animals are non-commercial sources, including brown seaweed and tobacco. TR 529 and 560 et seq. suggests sugar, some gums and salt may be used.
9. Are there any alternative substances? [§6518(m)(6)]	X			TR 525-582 – the main used during the whipping stage to enhance egg white foaming characteristics is cream of tartar (potassium acid tartrate listed at 205.605(b)) Martha Stewart 2014. Could use sugar TR 560 et seq.
10. Is there another practice (in farming or handling) that would make the substance unnecessary? [§6518(m)(6)]	X			Could use non-pasteurized egg whites
11. Have the ancillary substances associated with the primary substance been reviewed? Describe, along with any proposed limitations.	X			

Category 3. Is the substance compatible with organic handling practices?

Substance: Triethyl Citrate

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]		X		
2. Is the manner of the substance's use, manufacture, and disposal compatible with organic handling? [§205.600(b)(2)]	X			
3. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]		X		
4. Are the ancillary substances reviewed compatible with organic handling [?]			X	
5. Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]		X		

6. Is the primary use as a preservative? [§205.600(b)(4)]	X	X		TR 354-357 The addition of TEC could be considered both to aid in the foaming process and help stabilize the whipped foam. Stabilization of foam could be considered a preservative function, although it prevents deterioration not of the egg itself but of the structure achieved by the whipping action.
7. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law)? [§205.600(b)(4)]	X			TR 368-369 et seq. The main reason TEC is added to egg white is to recreate textures and related properties lost during pasteurization.

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

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

<p>5. Does the industry information about unavailability include (but is not limited to) the following?:</p> <p>a. Regions of production (including factors such as climate and number of regions);</p>			X	
<p>b. Number of suppliers and amount produced;</p>			X	
<p>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;</p>			X	
<p>d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or</p>			X	
<p>e. Other issues which may present a challenge to a consistent supply?</p>			X	

**National Organic Standards Board
Handling Subcommittee Proposal
Ancillary Substances Permitted in Microorganisms
February 2, 2015**

Ancillary substances are intentionally added to a formulated generic handling substance on the National List. These substances do not have a technical or functional effect in the finished product, and are not considered part of the manufacturing process that has already been reviewed by the NOSB.

1. Identity of **Ancillary Substances Permitted for use in Microorganisms**

Functional class	Substance name
Anti-caking & anti-stick agents	magnesium stearate, calcium silicate, silicon dioxide
Carriers and fillers, agricultural or nonsynthetic	lactose, maltodextrins, sucrose, dextrose, potato starch, non-GMO soy oil, rice protein, grain (rice, wheat, corn, barley) flour, milk, autolyzed yeast, inulin, cornstarch, sucrose.
Carriers and fillers, synthetic	micro-crystalline cellulose, propylene glycol, stearic acid, dicalcium phosphate.
Preservatives	sodium benzoate, potassium sorbate, ascorbic acid
Stabilizers	maltodextrin
Cytoprotectants used to freeze-dry microorganisms	liquid nitrogen, maltodextrin, magnesium sulfate, dimethyl sulfoxide, sodium aspartate, mannitol, sorbitol
Substrate that may remain in final product	milk, lactose, grain (rice, barley, wheat) flour, brewed black tea and sugar, soy

2. Identify any ancillary substances, or categories of substances prohibited for use in Microorganisms:

None Known

3. Describe need for the ancillary substances, review of materials, discussion, and subcommittee vote.

Ancillary substances for microorganisms primarily include the growth media used to produce the microorganism and then fillers or carriers to bring the microorganisms to purchasers in a stable and predictable form. Additional preservatives or anti-caking agents are used with some species. Capsules forms may have additional cytoprotectants and excipients. (See criteria below for discussion points).

Evaluation Criteria (provide narrative responding to each question, repeat as necessary for additional ancillary substances or groups)

- Impact on Humans and Environment:** Is there any evidence the substance(s) may be harmful to human health or the environment?

"There is no literature to suggest that the manufacture or use of microbial preparations with ancillary substances is harmful to the environment or biodiversity." (2014 TR page 26). There is no literature to suggest that microbial preparations with ancillary substances have negative effects on human health. (2014 TR page 28)

2. **Essential & Availability:** Is the substance necessary to the handling of the product because of unavailability of wholly natural substitute products, or essential for the handling of an organic product?

All the substances in the chart above are necessary because they are what keep the microorganism alive, pure and able to perform its function. Formulations of the desired microorganism products are not available without some of these ancillary substances. The availability of organic carriers and substrates is sometimes possible and the NOSB encourages the use of organic ancillary substances whenever possible. Therefore a second motion is proposed below to recommend that organic sources of ancillary substances must be used when available.

3. **Compatibility & Consistency:** Is the substance's use consistent and compatible with organic handling practices?

"There is no literature to suggest preservatives used in microbial preparations as ancillary substances exert any technical or functional preservative effect in the final fermented product. Typically, Good Manufacturing Practices (GMP) dictate that preservatives are added at a maximum level of 0.1% by weight of the finished product to exert the desired effect (FDA 2013b)." (2014 TR page 23)

Subcommittee Action & Vote

Motion: Move to approve the ancillary substances in the chart above for use with Microorganisms.

Motion by: Zea Sonnabend

Seconded by: Tom Chapman

Yes: 6 No: 0 Absent: 2 Abstain: 0 Recuse: 0

Second Motion:

Motion to amend the National List at 205.605(a) to state:

Microorganisms - any food-grade bacteria, fungi, and other microorganism. Organic sources for ancillary substances must be used when available.

Motion by: Zea Sonnabend

Seconded by: Tracy Favre

Yes: 6 No: 0 Absent: 2 Abstain: 0 Recuse: 0

Approved by Harold Austin, Subcommittee Chair, to transmit to NOSB February 2, 2015



Sunset 2016 Review Summary Meeting 2 - Subcommittee Review Handling Substances February 25, 2015

As part of the National List Sunset Review process, the NOSB Handling Subcommittee has evaluated the need for the continued allowance for or prohibition of the following substances for use in organic handling.

§205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”
(a) Nonsynthetics allowed:

Egg white lysozyme

Reference: 7 CFR 205.605(a) Egg white lysozyme (CAS # 9001–63–2)

Technical Report: [2011 TR: Enzymes](#), [2003 TAP: Enzymes, Plant and Fungal](#)

Petition(s): [06/2002](#)

Past NOSB Actions: [05/2003](#) - NOSB review and recommendation for addition to the National List; [11/2009](#) - Recommendation to relist

Regulatory Background: Added to National List effective 09/12/06 [71 FR 53299](#); Sunset renewal notice published 08/03/2011 [76 FR 46595](#)

Sunset Date: 9/12/2016

Subcommittee Review

Egg White Lysozyme (EWL) is a purified enzyme preparation extracted from chicken egg whites using an inert polymer resin. Following extraction, EWL is stripped from the resin, concentrated, purified and dried. The material is commonly used as an antimicrobial in cheese and wine making. EWL has several other applications, including health and wellness products. Egg white lysozyme is an antimicrobial protein (i.e., a protein with the ability to inhibit or kill microorganisms) comprised of 129 amino acid residues.

Egg white lysozyme controls the proliferation of bacteria during fermentation or food processing and has been shown to possess antimicrobial properties especially in relation to *Clostridium tyrobutyricum* (Kewpie Corporation, 2010; FDA, 2000). Therefore, it is used to improve the shelf life of chilled foods and confectionary products and has been used to preserve fresh fruits and vegetables, tofu bean curd, seafood, meats and sausages, potato salad, cooked burdock with soy sauce, and varieties of semi-hard cheeses such as Edam, Gouda, and some Italian cheeses (Cunningham et al., 1991). Egg white lysozyme is also incorporated into casings for frankfurters and in cooked meat and poultry products that are sold as ready-to-eat (FDA, 2000). Unlike other enzymes, egg white lysozyme does not inhibit the lactic acid bacteria that are critical for cheese fermentation. (TR, lines 161-169)

All international organic standards allow the use of egg white lysozyme in organic production. (TR, lines 406-435)

To manufacture egg white lysozyme, the lysozyme is extracted from fresh egg white by mixing in an inert polymer resin that binds to the lysozyme. The resin carrying the lysozyme is separated from the egg white. The lysozyme is then removed from the resin through the addition of salts. The lysozyme is then concentrated, purified, and dried. Although the resulting purified protein, on a dry basis is almost 100 percent



lysozyme, small amounts of other egg white proteins may be present (FDA, 2000). (TR, lines 483-488)

Because egg white lysozyme does not undergo a chemical change during the manufacturing process, the material is considered non-synthetic. Egg white lysozyme was included as part of the tentative final rule (21 CFR 184) on direct food substances affirmed as GRAS in 1998. In 2000, a GRAS petition was submitted to FDA for egg white lysozyme. FDA follow up was identified; however, it is unknown if a conclusion was made on the GRAS status of egg white lysozyme (FDA, 2000). Egg white lysozyme does act as a preservative because it inhibits the growth of deleterious organisms, prolonging the shelf life of food products. Egg white lysozyme is an important preservative in cheese manufacturing and minimizes the process called 'late blowing,' which is caused by the fermentation of butyric acid.

Egg white lysozyme is commonly used in food processing to decrease the loss of nutritional quality caused by thermal processing. The enzyme acts as an antimicrobial agent and is considered to be thermally stable. The use of egg white lysozyme may reduce the amount of thermal processing (including pasteurization and heat sterilization) needed during food manufacture, which also minimizes the loss of nutritional quality (Rahman, 2007). (TR, lines 688-692)

EWL was first added to the National List in 2006 and went through its first Sunset review in 2009. A 2003 TAP review concluded the material posed no significant risk to human health or the environment during its manufacture, had been used in the organic industry since the inception of organic processed foods, and was used as an alternative to harsher preservatives.

This is the second 2016 Sunset presentation of Egg White Lysozyme for public comment. During the first round, public comments were received regarding the fact that EWL is made from conventionally raised eggs and the question was brought forward as to whether the material could be made with organic eggs. At the time of 2003 TAP review, it was possible the newly emerging organic egg market did not have sufficient capacity to allow for manufacture of EWL using organic eggs, and no mention was made of the use of organic egg whites.

Request for Public Comments

1. The NOSB Handling Subcommittee seeks input from the public and industry as to whether there currently exist EWL manufacturers using organic egg whites to make this material.
2. At present, it appears as though the material is essentially pure, without any remaining ancillary substances. The Handling Subcommittee seeks input regarding the presence of ancillary substances in EWL following the extraction, concentration and purification processes.

Motion to Remove:

This proposal to remove will be considered by the NOSB at its public meeting.

The Handling Subcommittee believes that the full board should have the opportunity to complete the review of each sunset material by voting. The NOP has stated that to do this a motion to remove should be brought from the Subcommittee for each substance. If the Subcommittee motion to remove fails to receive a majority, the motion will still be put forward to the full board for review. The motion to remove is voted by the full board and needs to receive a 2/3 majority to recommend removal.

Based on the review, the Subcommittee proposes removal of this substance from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Consistency with Organic Production.

The Handling Subcommittee found no concerns regarding the continued listing of Egg white lysozyme on the National List. The justification of this motion is that the whole NOSB needs to consider and vote on each



material, rather than just the individual Subcommittee, to fulfill its' responsibility of Sunset Review.

Motion to remove Egg white lysozyme (CAS # 9001-63-2) from 205.605(a)

Motion by: Tracy Favre

Seconded by: Jean Richardson

Yes: 0 No: 5 Abstain: 0 Recuse: 0 Absent: 3

L-Malic Acid

Reference: 7 CFR 205.605(a) L-Malic acid (CAS # 97-67-6)

Technical Report: [04/2003](#)

Petition(s): [11/2002](#)

Past NOSB Actions: [05/2003](#) - NOSB review and recommendation for addition to the National List; [11/2009](#) - Recommendation to relist

Regulatory Background: Added to National List effective 09/12/06 [71 FR 53299](#); Sunset renewal notice published 08/03/2011 [76 FR 46595](#)

Sunset Date: 9/12/16

Subcommittee Review

L-Malic acid (CAS #97-67-6) was added to the National List (Federal Register Vol. 71, No. 175) §205.605(a) on September 11, 2006. This addition was based on a review of L-malic acid by the NOSB at their May 13-14, 2003 meeting. This material underwent its first sunset review at the Fall 2009 NOSB meeting, and was relisted. L-Malic acid is used as a flavor enhancer, flavoring agent and adjuvant, and for pH control agent in a variety of foods.

In the first meeting posting, the HS requested input on the essentiality and current use patterns of L-Malic acid. We received public comment from one certifier with 7 current clients using L-Malic acid in the wine, juice and bottled tea sectors. Another large producer gave comment confirming their current use and need for this substance. Two other commenters expressed concern that the [original TAP review](#) evaluated DL-malic acid, the synthetic form, rather than L-malic acid, the non-synthetic form currently listed. However, a review of the 2003 TAP shows that the reviewers very clearly accounted for the fact that there are two forms of this substance, very clearly recommended that the synthetic form not be listed, and that L-malic acid be listed on 605(a).

This substance is used in handling, and does not include any ancillary substances.

The Subcommittee review indicated that there are no ancillary substances. There have been no ancillary substances declared by stakeholders during the public comment periods (both oral and written). Therefore, no ancillary substances will be allowed, unless otherwise petitioned and reviewed by the NOSB and the appropriate Subcommittee. This completes the ancillary substance review.

Motion to Remove:

This proposal to remove will be considered by the NOSB at its public meeting.

The Handling Subcommittee believes that the full board should have the opportunity to complete the review of each sunset material by voting. The NOP has stated that to do this a motion to remove should be brought from the Subcommittee for each substance. If the Subcommittee motion to remove fails to receive a majority, the motion will still be put forward to the full board for review. The motion to remove is voted by the full board and needs to receive a 2/3 majority to recommend removal.

Based on the review, the Subcommittee proposes removal of L-Malic Acid from the National List based on the

following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Availability of non-synthetic alternative protein sources [§ 205.600(b)(1)], alternative substances in use [§6518(m)(6)], lack of essentiality for handling organic products [§205.600(b)(6)], inconsistent with organic handling [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]

The Handling Subcommittee found no concerns regarding the continued listing of L-Malic on the National List. The justification of this motion is that the whole NOSB needs to consider and vote on each material, rather than just the individual Subcommittee, to fulfill its' responsibility of Sunset Review.

Motion to remove L-Malic acid (CAS # 97-67-6) from section 205.605(a)

Motion by Joe Dickson

Seconded Tracy Favre

Yes: 0 No: 5 Abstain: Recuse: Absent: 3

Microorganisms

Reference: **7 CFR 205.605(b)** Microorganisms - any food grade bacteria, fungi, and other microorganism.

Technical Report: [2014 TR](#), [2003 TAP](#)

Petition(s): [12/2002](#)

Past NOSB Actions: [05/2003](#) - NOSB review and recommendation for addition to the National List; [11/2009](#) - Recommendation to relist

Regulatory Background: Added to National List with annotation, effective 09/12/06 [71 FR 53299](#), Sunset renewal notice published 08/03/2011 [76 FR 46595](#)

Sunset Date: 9/12/16

Subcommittee Review

The Listing for "Microorganisms" refers to living organisms added to food. There is some overlap with other National List entries such as Dairy Cultures and Yeasts, which are also living organisms. This listing is not meant to include either dead microorganisms or substances derived or extracted from microorganisms. Each of these latter groups must have separate listings and reviews.

These living organisms consist of bacteria, bacteriophages, fungi, and viruses. The specific types within these groups are covered in the 2014 Technical Report (TR) on pages 2 through 5. Algae were not covered by the TR and are not considered to be part of this listing.

Microorganisms are used to create desired "biogenic effects" through fermentation (such as in vinegar or miso) or to have a "probiotic effect" by interacting directly with the digestive system (such as yogurt with *L. bulgaricus*). (2014 TR page 5) They may also be used to improve palatability or nutritional value of food. Bacteriophages may be used as antimicrobial agents to control bacteria during the production or processing of foods. (2014 TR pages 5 and 10) They provide a non-synthetic alternative to cleaning agents, sanitizers, and antimicrobial products that are not allowed for use in organic food processing and handling.

Evaluation Question #1 (page 17) in the TR describes the fermentation processes for probiotics, starter cultures, and bacteriophages. The Subcommittee believes this assessment of fermentation processes to be complete enough to enable Materials Review Organizations (MROs) to determine compliance with this listing as non-synthetic substances under the existing Materials Classification guidance.

Fermentation is a naturally occurring biological process and as such does not need additional criteria under the organic law. MROs can evaluate the starting feedstocks, non-GMO affidavits, ancillary substances, and purification/ media removal steps without further guidance.

At the first posting for Microorganisms there was a call made for public comment to provide input on a chart of existing ancillary substances and to identify additional ancillary substances that may be used in formulations of microorganisms. While some public comments stated the list was incomplete, the only additional ones suggested were a few mentioned in the text of the TR. No public comments were received with evidence of compatibility issues that would lead to removal of any ancillary substances. Therefore a secondary motion and review form for ancillary substances is provided as a separate proposal. It contains the same list as the first posting with the addition of 2 more substances from the text of the TR

Ancillary substances were requested to be identified and reviewed by the TR contractor. In addition, dozens of spec sheets on products that were turned in by certifiers were looked at to gather ancillary substances for the table presented. The following were reviewed:

Ancillary Substances by Food Additive Functional Class	
Anti-caking & anti-stick agents	magnesium stearate, calcium silicate, silicon dioxide
Carriers and fillers, agricultural or nonsynthetic	lactose, maltodextrins, sucrose, dextrose, potato starch, non-GMO soy oil, rice protein, grain (rice, wheat, corn, barley) flour, milk, autolyzed yeast, inulin, cornstarch, sucrose.
Carriers and fillers, synthetic	micro-crystalline cellulose, propylene glycol, stearic acid, dicalcium phosphate.
Preservatives	sodium benzoate, potassium sorbate, ascorbic acid
Stabilizers	maltodextrin
Cytoprotectants used to freeze-dry microorganisms	liquid nitrogen, maltodextrin, magnesium sulfate, dimethyl sulfoxide, sodium aspartate, mannitol, sorbitol
Substrate that may remain in final product	milk, lactose, grain (rice, barley, wheat) flour, brewed black tea and sugar, soy

The public comment came from a few companies and certifiers in favor of continued allowance and a few groups opposed to moving this forward until the list was complete and they were reviewed further. A point raised in the comments noted that the materials that are already on the National List are listed by specific use, and therefore should be listed in the table provided for this additional use. The Subcommittee agrees with this point and the National List substances are now in the table.

The review in the TR included the following statements:

"There is no literature to suggest preservatives used in microbial preparations as ancillary substances exert any technical or functional preservative effect in the final fermented product. Typically, Good Manufacturing Practices (GMP) dictate that preservatives are added at a maximum level of 0.1% by



weight of the finished product to exert the desired effect (FDA 2013b)." (2014 TR page 23)

"There is no literature to suggest that the manufacture or use of microbial preparations with ancillary substances is harmful to the environment or biodiversity." (2014 TR page 26)

There is no literature to suggest that microbial preparations with ancillary substances have negative effects on human health. (2014 TR page 28)

For microbial preparations with ancillary substances, there are alternative practices to using nonorganic carriers and/or growth substrates for cultures. Specifically, nonorganic carriers can be replaced with organic carriers and growth substrates. Certification agencies differ in whether growth substrates and carriers are required to be organic. (2014 TR page 28)

The latter statement was discussed by the Subcommittee. The NOSB has made several recommendations in the past that commercial availability of organic sources should apply to everything on the National List. The Handling Subcommittee would like to re-affirm this position in regards to the ancillary substances used for Microorganisms and is making a motion on this in conjunction with the ancillary substance proposal.

Motion to Remove:

This proposal to remove will be considered by the NOSB at its public meeting.

The Handling Subcommittee believes that the full board should have the opportunity to complete the review of each sunset material by voting. The NOP has stated that to do this a motion to remove should be brought from the Subcommittee for each substance. If the Subcommittee motion to remove fails to receive a majority, the motion will still be put forward to the full board for review. The motion to remove is voted by the full board and needs to receive a 2/3 majority to recommend removal.

Based on the review, the Subcommittee proposes removal of this substance from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable): [OFPA criteria at 7 U.S.C. 6158(m), (7) its compatibility with a system of sustainable agriculture.

The Subcommittee found no concerns regarding the continued listing of Microorganisms. The justification for this motion is that the whole NOSB needs to consider and vote on each material, rather than just a Subcommittee.

Motion to remove Microorganisms from 205.605(b)

Motion by: Zea Sonnabend

Seconded by: Jean Richardson

Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 2



§205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”
(b) Synthetics allowed:

Activated charcoal

Reference: **7 CFR 205.605(b)** Activated charcoal (CAS #s 7440 - 44 - 0; 64365 - 11 - 3) only from vegetative sources; for use only as a filtering aid.

Technical Report: [08/2002 Activated Carbon](#)

Petition(s): [05/2002 Charcoal/Activated Carbon](#)

Past NOSB Actions: [9/2002](#) - NOSB review and recommendation for addition to the National List;
[11/2009](#) - Recommendation to relist

Regulatory Background: Added to National List with annotation, effective 09/12/06 [71 FR 53299](#); Sunset renewal notice published 08/03/2011 [76 FR 46595](#)

Sunset Date: 9/12/16

Subcommittee Review

Activated charcoal is an important filtering aid used in organic handling. It is widely used to filter water and a variety of other substances that are used in organic handling such as refined oils, grape juice, clear liquid products, and used in many distilleries.

Activated charcoal (carbon) was added to the National List on September 12, 2006, with the annotation, “only from vegetative sources: for use only as a filtering aid. (It is also on the National List under: §205.603 for use in Livestock). The Handling Subcommittee has reviewed this material in accordance with the required Sunset review process as stated by the September 2013 NOP notice to the NOSB and also the required ancillary substance review as requested in the February 3, 2014 Memorandum to the National Organic Standards Board from the NOP.

The first of two required postings for public comment was done prior to the October 2014 Fall NOSB Meetings. The second and final posting for this sunset review cycle is scheduled for the April 2015 Spring NOSB meeting. During the first round of public comments there were 11 written public comments on activated charcoal. Of those comments 7 were in support of relisting, 3 were in support of relisting only with an annotation to limit use to filtering water (as suggested by one of the reviewers in the original 2002 TAP) and require steam activation as the source of the material, and 1 commenter taking a neutral position because a new TR had not been requested to provide information updates. (It should be noted that an annotation may not be made to a material that is under Sunset Review as the Rule currently is listed).

There was no new evidence provided that identified any unacceptable risks to the environment, human or animal health resulting from the use or manufacture of activated charcoal as annotated. One concern raised was pertaining to the spent material and that was answered during oral comment period that the spent material was reconditioned by the manufacturer of the material and that was subject to review as part of the annual certification renewal process. There was no new information presented to the Handling Sub-committee or the NOSB that would call this material into question and prompt a more extensive review.

Activated charcoal use has increased during this past sunset cycle, as stated from responses provided during public comment. There are advances in alternatives such as: steam activated coal, as a source (it is uncertain what the actual availability of this source of material is at this time) – which OMRI considers to be a non-synthetic. While it appears that activated charcoal as currently listed is still needed by organic handlers, progress has been made in looking for alternatives to the current listed material. The NOSB would like to encourage stakeholders to continue to pursue these organic alternatives if available and whenever possible.

This substance is used in handling, and does not include any ancillary substances. The Subcommittee review indicated that there are no ancillary substances in this material. There have been no ancillary substances declared by stakeholders during the public comment periods (both oral and written). Therefore, no ancillary substances will be allowed, unless otherwise petitioned and reviewed by the NOSB and the appropriate Subcommittee. This completes the ancillary substance review.

Motion to Remove:

This proposal to remove will be considered by the NOSB at its public meeting. The Handling Subcommittee believes that the full board should have the opportunity to complete the review of each sunset material by voting. The NOP has stated that to do this a motion to remove should be brought from the Subcommittee for each substance. If the Subcommittee motion to remove fails to receive a majority, the motion will still be put forward to the full board for review. The motion to remove is voted by the full board and needs to receive a 2/3 majority to recommend removal.

Based on the review, the Subcommittee proposes removal of this substance from the National List based on the following criteria in the Organic Foods Production Act (OFPA) criteria 7 U.S.C. 6518(m)(6) the alternatives to using the substance in terms of practices or other available materials: and (7) its compatibility with a system of sustainable agriculture.

The Handling Subcommittee found no concerns regarding the continued listing of Activated Charcoal on the National List. The justification of this motion is that the whole NOSB needs to consider and vote on each material, rather than just the individual Subcommittee, to fulfill its’ responsibility of Sunset Review.

Motion to remove activated charcoal (CAS #s 7440–44–0; 64365–11–3) from §205.605(b).

Motion by: Harold Austin

Seconded by: Tracy Favre

Yes: 0 No: 5 Abstain: 0 Absent: 3 Recuse: 0

Peracetic acid

Reference: 7 CFR 205.605(b) Peracetic acid/Peroxyacetic acid (CAS # 79 -21- 0). 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.

Technical Report: [2000 TAP \(for processing\)](#)

Petition(s): [2008 Peracetic Acid](#)

Past NOSB Actions: [11/2000](#) - NOSB review and recommendation for addition to the National List (Note: alternate name as periacetic in meeting notes). [11/5/09](#) - Recommendation to renew

Regulatory Background: Added to National List, effective 09/12/06 [71 FR 53299](#). Sunset renewal notice published 08/03/2011 [76 FR 46595](#)

Sunset Date: 9/12/16

Subcommittee Review

Peracetic acid/Peroxyacetic acid is an important sanitizer used in organic handling. It is widely used as a sanitizer on food contact surfaces and as a disinfectant for fruits and vegetables. Peracetic acid/Peroxyacetic acid was added to the National List on September 12, 2006, with the annotation, “for use in wash and/or rinse water according to FDA limitations. For use as a sanitizer on food contact surfaces.” (It is also list on the National List under: §205.601 and §205.603 for use in Crops and Livestock respectively). The Handling Subcommittee has reviewed this material in accordance with the required sunset review process as stated by the September 2013 NOP notice to the NOSB and the required ancillary substance review as requested in the February 3, 2014 Memorandum to the National Organic Standards Board from the NOP.

The first of two required postings for public comment was done prior to the October 2014 Fall NOSB Meeting. The second and final posting for this sunset review cycle is scheduled for the April 2015 Spring NOSB meeting. During the first round of public comments there were 22 written and verbal public comments on Peracetic acid/Peroxyacetic acid. Of those comments 9 were from industry, 3 from individuals, 2 from non-profit organizations, 2 from manufacturers of the substances, 2 from certifiers, 1 from a trade association, and 1 from a USDA research scientist (2 comment were redundant verbal/written). 21 commenters were in support of relisting, 1 commenter was neutral. 1 commenter noted the TR was old and should be updated but still supported relisting. Another commenter noted the need for a more robust public discussion but still supported relisting. One comment noted the potential presence of ancillary substances.

There was no new evidence provided about unacceptable adverse impacts on human health or the environment. Commenters noted Peracetic acid/Peroxyacetic acid had less adverse impact than allowed alternatives. There was no new evidence presented that refuted the substance’s essentiality for organic production. Several industry members noted the ongoing essentiality of the substance, particularly in the dairy, beverage, fresh and cut fruit/vegetable industries. Two certifiers commented on the wide use of this substance by their clients. Several commenters noted its criticality to ensuring food safety. There was no new evidence provided about the substances incompatibility with organic production practices. Several commenters noted its compatibility given the substance breaks down to relatively benign complement (acetic acid [same acid found in vinegar] and hydrogen peroxide [which in turn breakdown to water and hydrogen]). There was no new information presented to the Handling Subcommittee or the NOSB that would call this material into question and prompt a more extensive review.

This substance is used in handling, and does not include any ancillary substances.

The Subcommittee review indicated that there are no ancillary substances. There have been no ancillary substances declared by stakeholders during the public comment periods (both oral and written). Therefore, no ancillary substances will be allowed, unless otherwise petitioned and reviewed by the NOSB and the appropriate Subcommittee. This completes the ancillary substance review for peracetic acid.

The 2000 TR notes that “Stock commercial preparations usually contain a synthetic stabilizer such as 1-

hydroxyethylidene-1,1-diphosphonic acid (HEDP) or 2,6-pyridinedicarboxylic (dipicolinic) acid to slow the rate of oxidation or decomposition.” No ancillary substances were identified during public comment however one commenter noted this section of the TR. Since Peracetic acid/Peroxyacetic acid needs to be registered with the EPA when used as an antimicrobial these substances are considered inert and are not subject to review under the ancillary substance review. Furthermore, the annotation currently states “for use in wash and/or rinse water according to FDA limitation”, which define the permitted stabilizers.

Motion to Remove:

This proposal to remove will be considered by the NOSB at its public meeting.

The Handling Subcommittee believes that the full board should have the opportunity to complete the review of each sunset material by voting. The NOP has stated that to do this a motion to remove should be brought from the Subcommittee for each substance. If the Subcommittee motion to remove fails to receive a majority, the motion will still be put forward to the full board for review. The motion to remove is voted by the full board and needs to receive a 2/3 majority to recommend removal.

Based on the review, the Subcommittee proposes removal of this substance from the National List based on the following criteria in the Organic Foods Production Act (OFPA) criteria 7 U.S.C. 6518(m)(6) the alternatives to using the substance in terms of practices or other available materials: and (7) its compatibility with a system of sustainable agriculture.

The Handling Subcommittee found no concerns regarding the continued listing of Peracetic acid/Peroxyacetic acid on the National List. The justification of this motion is that the whole NOSB needs to consider and vote on each material, rather than just the individual Subcommittee, to fulfill its’ responsibility of Sunset Review.

Motion to remove Peracetic Acid (CAS # 79–21–0), from §205.605b

Motion by: Tom Chapman

Seconded by: Zea Sonnabend

Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 1

Cyclohexylamine

Reference: 7 CFR 205.605(b) Cyclohexylamine (CAS # 108 - 91 - 8) for use only as a boiler water additive for packaging sterilization.

Technical Report: [02/2001](#)

Petition(s): [11/2000 Cyclohexylamine](#)

Past NOSB Actions: [10/2001](#) - NOSB review and recommendation for addition to the National List; [11/2009](#) - Recommendation to relist

Regulatory Background: Added to National List 09/12/06 [71 FR 53299](#), Sunset renewal notice published 08/03/2011 [76 FR 46595](#)

Sunset Date: 9/12/16

Subcommittee Review

Cyclohexylamine, a volatile amine, is a boiler water additive used to prevent corrosion in boilers and boiler distribution lines.

The material can pose serious risks to human health and the environment, and is an irritant and should be handled as such. Cyclohexylamine is often used in conjunction with other volatile amines.

Volatile amines are characterized by their high solubility in water and reactivity. These very chemical properties that make them effective as boiler water additives make them extremely difficult to remove from the steam, NOSB TAP Review Compiled by OMRI, 2001. Given this characteristic, it makes it possible that Cyclohexylamine could come into contact with food items. For this reason, its use has been limited to use only for packaging sterilization.

In August 2014, the NOSB put forth a request for information regarding the continued use of this material in boiler systems and received limited information regarding its continued use in organic processing. Some information received by the NOSB suggests that most manufacturers have already begun a move away from this material. This information, in conjunction with the potential for harm to human health and the environment, is the reason the Handling Subcommittee is recommending removal from the National List.

This substance is used in handling, and does not include any ancillary substances.

Motion to Remove:

This proposal to remove will be considered by the NOSB at its public meeting.

The Handling Subcommittee believes that the full board should have the opportunity to complete the review of each sunset material by voting. The NOP has stated that to do this a motion to remove should be brought from the Subcommittee for each substance. If the Subcommittee motion to remove fails to receive a majority, the motion will still be put forward to the full board for review. The motion to remove is voted by the full board and needs to receive a 2/3 majority to recommend removal.

Based on the Subcommittee's review, the Subcommittee proposes removal of Cyclohexylamine from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): lack of essentiality for handling organic products [§205.600(b)(6)], inconsistent with organic handling [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]

Motion to remove the boiler amines, Cyclohexylamine (CAS # 108 -91-8), Diethylaminoethanol (CAS # 100-37-8), and Octadecylamine (CAS # 124-30-1), all three with the annotation "for use only as a boiler water additive for packaging sterilization", from section 205.605(b)

Motion by: Tracy Favre

Seconded: Jean Richardson

Yes: 5 No: 0 Abstain: 0 Recuse: 0 Absent: 3

Diethylaminoethanol

Reference: 7 CFR 205.605(b) Diethylaminoethanol (CAS # 100 -37- 8) for use only as a boiler water additive for packaging sterilization.

Technical Report: [2/2001 TAP](#)

Petition(s): [11/2000](#)

Past NOSB Actions: [5/2002](#) - NOSB review and recommendation for addition to the National List;



11/5/09 - Recommendation to relist

Regulatory Background: Added to National List, effective 09/12/06 71 FR 53299, Sunset renewal notice published 08/03/2011 76 FR 46595

Sunset Date: 9/12/2016

Subcommittee Review

Diethylaminoethanol (DEAE), a volatile amine, is a boiler water additive used to prevent corrosion in boilers and boiler distribution lines. It neutralizes carbonic acid the boiler lines by scavenging free oxygen.

The material can pose serious risks to human health and the environment, and is an irritant and should be handled as such. Diethylaminoethanol is poisonous when ingested. DEAE is often used in conjunction with other volatile amines.

Volatile amines are characterized by their high solubility in water and reactivity. These very chemical properties that make them effective as boiler water additives make them extremely difficult to remove from the steam, NOSB TAP Review Compiled by OMRI, 2001. Given this characteristic, it makes it possible that Diethylaminoethanol could come into contact with food items. For this reason, its used has been limited to use only for packaging sterilization.

In August 2014, the NOSB put forth a request for information regarding the continued use of this material in boiler systems and received limited information regarding its continued use in organic processing. Some information received by the NOSB suggests that most manufacturers have already begun a move away from DEAE. This information, in conjunction with the potential for harm to human health and the environment is the reason the Handling Subcommittee is recommending removal from the National List.

This substance is used in handling, and does not include any ancillary substances.

Motion to Remove:

This proposal to remove will be considered by the NOSB at its public meeting.

The Handling Subcommittee believes that the full board should have the opportunity to complete the review of each sunset material by voting. The NOP has stated that to do this a motion to remove should be brought from the Subcommittee for each substance. If the Subcommittee motion to remove fails to receive a majority, the motion will still be put forward to the full board for review. The motion to remove is voted by the full board and needs to receive a 2/3 majority to recommend removal.

Based on the review, the Subcommittee proposes removal of Diethylaminoethanol from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): lack of essentiality for handling organic products [§205.600(b)(6)], inconsistent with organic handling [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]

Motion to remove the boiler amines, Cyclohexylamine (CAS # 108 -91-8), Diethylaminoethanol (CAS # 100-37-8), and Octadecylamine (CAS # 124-30-1), all three with the annotation "for use only as a boiler water additive for packaging sterilization", from section 205.605(b)

Motion by Tracy Favre

Seconded Jean Richardson

Yes: 5 No: 0 Abstain: 0 Recuse: 0 Absent: 3

Octadecylamine

Reference: 7 CFR 205.605(b) Octadecylamine (CAS # 124–30–1) for use only as a boiler water additive for packaging sterilization.

Technical Report: [02/2001 TAP](#)

Petition(s): [11/2000](#)

Past NOSB Actions: [10/2001](#) - NOSB review and recommendation for addition to the National List [11/5/09](#) - Recommendation to renew

Regulatory Background: Added to National List, effective 09/12/06 [71 FR 53299](#), Sunset renewal notice published 08/03/2011 [76 FR 46595](#)

Sunset Date: 9/12/2016

Subcommittee Review

Octadecylamine, a volatile amine, is a boiler water additive used to prevent corrosion in boilers and boiler distribution lines. It forms a thin film on the inside of boiler water lines and prevents the formation of carboic acid from carbon dioxide contained in the boiler water.

The material can pose serious risks to human health and the environment, and is an irritant and should be handled as such. Octadecylamine is poisonous when ingested. Octadecylamine is often used in conjunction with other volatile amines.

Volatile amines are characterized by their high solubility in water and reactivity. These very chemical properties that make them effective as boiler water additives make them extremely difficult to remove from the steam, NOSB TAP Review Compiled by OMRI, 2001. Given this characteristic, it makes it possible that Octadecylamine could come into contact with food items. For this reason, its use has been limited to use only for packaging sterilization.

In August 2014, the NOSB put forth a request for information regarding the continued use of this material in boiler systems and received limited information regarding its continued use in organic processing. Some information received by the NOSB suggests that most manufacturers have already begun a move away from Octadecylamine. This information, in conjunction with the potential for harm to human health and the environment is the reason the Handling Subcommittee is recommending removal from the National List.

This substance is used in handling, and does not include any ancillary substances.

Motion to Remove:

This proposal to remove will be considered by the NOSB at its public meeting.

The Handling Subcommittee believes that the full board should have the opportunity to complete the review of each sunset material by voting. The NOP has stated that to do this a motion to remove should be brought from the Subcommittee for each substance. If the Subcommittee motion to remove fails to receive a majority, the motion will still be put forward to the full board for review. The motion to remove is voted by the full board and needs to receive a 2/3 majority to recommend removal.

Based on the review, the Subcommittee proposes removal of Octadecylamine from the National List



based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): lack of essentiality for handling organic products [§205.600(b)(6)], inconsistent with organic handling [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]

Motion to remove the boiler amines, Cyclohexylamine (CAS # 108 -91-8), Diethylaminoethanol (CAS # 100-37-8), and Octadecylamine (CAS # 124-30-1), all three with the annotation “for use only as a boiler water additive for packaging sterilization”, from section 205.605(b)

Motion by Tracy Favre

Seconded Jean Richardson

Yes: 5 No: 0 Abstain: 0 Recuse: 0 Absent: 3

Sodium acid pyrophosphate

Reference: **7 CFR 205.605(b)** Sodium acid pyrophosphate (CAS # 7758-16-9) - for use only as a leavening agent.

Technical Report: [09/2001 TAP](#) (report is for Sodium Phosphates as a group).

Petition(s): [10/2002](#); [06/2009 petition for expanded use](#)

Past NOSB Actions: [05/2003](#) - NOSB review and recommendation for addition to the National List; [11/2009](#) - recommendation to relist; [04/2011](#) - recommendation on expanded use

Regulatory Background: Added to National List, effective 09/12/06 [71 FR 53299](#), Sunset renewal notice published 08/03/2011 [76 FR 46595](#)

Sunset Date: 9/12/2016

Subcommittee Review

Sodium Acid Pyrophosphate (SAPP) was first petitioned on 10/31/02 and added to the National List §205.605(b) effective on September 12, 2006 by Final Rule TM-04-01FR based on the NOSB recommendation of May 2003. It most recently underwent sunset review at the Fall 2009 meeting, and was relisted by the NOSB.

Sodium acid pyrophosphate (CAS # 7758-16-9) was originally petitioned for use as a leavening acid in baked goods, and was given the annotation “for use only as a leavening agent” when originally recommended for listing by the NOSB. It is a relatively common food additive with USDA and FDA approval for many functions in conventional foods. In this intended use, it is used as an acid to react with sodium bicarbonate (baking soda) to produce a controlled release of the CO₂ that leavens the baked good. SAPP is prepared by partial neutralization of phosphoric acid with sodium hydroxide or sodium carbonate to form monosodium phosphate, which is followed by molecular dehydration of that substance under controlled conditions at 250 degrees C to form SAPP. Environmental impact from manufacture and use is minimal, and it is not considered toxic to humans.

In the first meeting posting, the HS requested input on the essentiality and current use patterns of SAPP. We received comment from one certifier who noted that this substance is in current use by six clients, and is used in five of the six baking powder formulas it has reviewed. A trade organization, the International Food Additives Council (IFAC), supported its continued listing, noted that it is widely used



and essential in baked good. IFAC also noted that “Delisting SAPP would significantly limit the quality, variety and availability of organic bakery products, negatively impacting organic consumers who currently purchase organic bakery items.” One large processor commented that they currently widely use SAPP in a variety of products.

Two other comments commented in opposition to relisting SAPP, on the grounds that the TAP review was focused on the use of sodium phosphates in non-dairy milk, rather than as a leavening agent. However, the HS believes that the technical information contained in the [original TAP](#), along with the additional detail contained in the SAPP [petition](#), the [2010 TR](#) prepared for the evaluation of SAPP for use in produce, independent research, public comment and the food science expertise contained within this and past Handling Subcommittees is sufficient for a thorough review of this substance and that a new TR is not needed.

This substance is used in handling, and does not include any ancillary substances.

The Subcommittee review indicated that there are no ancillary substances. There have been no ancillary substances declared by stakeholders during the public comment periods (both oral and written).

Therefore, no ancillary substances will be allowed, unless otherwise petitioned and reviewed by the NOSB and the appropriate Subcommittee. This completes the ancillary substance review for Sodium Acid Pyrophosphate (SAPP).

Motion to Remove:

This proposal to remove will be considered by the NOSB at its public meeting.

The Handling Subcommittee believes that the full board should have the opportunity to complete the review of each sunset material by voting. The NOP has stated that to do this a motion to remove should be brought from the Subcommittee for each substance. If the Subcommittee motion to remove fails to receive a majority, the motion will still be put forward to the full board for review. The motion to remove is voted by the full board and needs to receive a 2/3 majority to recommend removal.

Based on the review, the Subcommittee proposes removal of Sodium Acid pyrophosphate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) criteria 7 U.S.C. 6518(m)(6) the alternatives to using the substance in terms of practices or other available materials: and (7) its compatibility with a system of sustainable agriculture.

The Handling Subcommittee found no concerns regarding the continued listing of SAPP on the National List. The justification of this motion is that the whole NOSB needs to consider and vote on each material, rather than just the individual sub-committee, to fulfill its’ responsibility of Sunset Review.

Motion to remove Sodium acid pyrophosphate (SAPP) (CAS # 7758-16-9) -for use only as a leavening agent, from 205.605(b)

Motion by: Joe Dickson

Seconded by: Tracy Favre

Additional discussion: none

Yes: 0 No: 5 Abstain: 0 Absent: 3 Recuse: 0



Tetrasodium pyrophosphate (TSPP)

Reference: **7 CFR 205.605(b)** Tetrasodium pyrophosphate (CAS # 7722–88–5) - for use only in meat analog products.

Technical Report: [2002 TAP](#); [2014 Limited Scope TR](#)

Petition(s): [12/2001](#)

Past NOSB Actions: [9/17/2002](#) - NOSB review and recommendation for addition to the National List; [11/5/09](#) - Sunset Recommendation to relist

Regulatory Background: Added to National List with annotation, effective 09/12/06 [71 FR 53299](#), Sunset renewal notice published 08/03/2011 [76 FR 46595](#)

Sunset Date: 9/12/2016

Subcommittee Review

Tetrasodium Pyrophosphate (TSPP) is a processing aid that is used to make certain types of meat analogs. As a processing aid it does not appear on a food label and does not contain any ancillary substances.

In reviewing the historical background for Tetrasodium Pyrophosphate (TSPP), the Handling Subcommittee (HS) had concerns that this substance was put on the list by the former NOSB in spite of the fact that the majority of the 2002 TAP reviewers were against it, it was marked on the checklist as failing the criteria, and the information about which products it was used in (and therefore why it was specifically necessary for those products) was proprietary. Therefore a new TR was commissioned to try to further evaluate the alternatives.

In the first meeting posting the HS requested public comment on the specific uses of the substance and experience with alternatives, as well as the issue of whether TSPP was primarily used to restore texture after complex (and possibly excessive) processing of vegetable protein.

Very little public comment was received for this substance. No users of TSPP came forward and no certifiers stated that their clients used this material. One industry association wrote in favor of this as well as the other food additives in sunset, but gave no specifics on uses or alternatives. Several groups opposed this material along with many other synthetics on the National List, but none gave specific information that was unique to this substance.

The HS has determined from the 2014 TR and lack of clear input from the organic community that there are ample alternatives to the use of TSPP and some of the other criteria in the rule are not sufficiently met. Therefore a checklist is presented to go into some of the specific issues. A motion is being put forward to remove TSPP from the National List.

This substance is used in handling, and does not include any ancillary substances.

Supplemental Review Information

Motion to Remove:

This proposal to remove will be considered by the NOSB at its public meeting.

The Handling Subcommittee believes that the full board should have the opportunity to complete the review of each sunset material by voting. The NOP has stated that to do this a motion to remove should be brought from the Subcommittee for each substance. If the Subcommittee motion to remove fails to receive a majority, the motion will still be put forward to the full board for review. The motion to



remove is voted by the full board and needs to receive a 2/3 majority to recommend removal.

Based on the review, the Subcommittee proposes removal of Tetrasodium Pyrophosphate from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Availability of non-synthetic alternative protein sources [§ 205.600(b)(1)], alternative substances in use [§6518(m)(6)], lack of essentiality for handling organic products [§205.600(b)(6)], inconsistent with organic handling [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]

Motion to remove Tetrasodium Pyrophosphate (CAS # 7722–88–5) - for use only in meat analog products, from 205.605(b).

Motion by: Zea Sonnabend

Seconded by: Tracy Favre

Yes: 6 No: 0 Abstain: 0 Recuse: 0 Absent: 2

Approved by Harold Austin, Subcommittee Chair, to transmit to NOSB February 25, 2015



Sunset 2017 Review Summary Meeting 1 - Request for Public Comment Handling Substances §205.605(a) April 2015

Introduction

As part of the [Sunset Process](#), the National Organic Program (NOP) announces substances on the National List of Allowed and Prohibited Substances (National List) that are coming up for sunset review by the National Organic Standard Board (NOSB). The following list announces substances that are on the National List for use in organic crop production that must be reviewed by the NOSB and renewed by the USDA before their sunset dates in 2017. This list provides the substance's current status on the National List, use description, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, this is noted in this list. To see if any new technical report is available, please check for updates under the substance name in the [Petitioned Substances Database](#).

Request for Comments

While the NOSB will not complete its review and any recommendations on these substances until the fall 2015 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the spring 2015 public meeting. These comments should be provided through www.regulations.gov by April 7, 2015 as explained in the meeting notice published in the [Federal Register](#).

These comments are necessary to guide the NOSB's review of each substance against the criteria in the Organic Foods Production Act (7 U.S.C. 6518(m)) and the USDA organic regulations (7 CFR 205.600). The current substances on the National List were originally recommended by the NOSB based on evidence available to the NOSB at the time of their last review which demonstrated that the substances were found to be: (1) not harmful to human health or the environment, (2) necessary because of the unavailability of wholly nonsynthetic alternatives, and (3) consistent and compatible with organic practices.

Public comments should focus on providing new information about a substance since its last NOSB review. Such information could include research or data that may support a change in the NOSB's determination for a substance. Public comment should also address the continuing need for a substance or whether the substance is no longer needed or in demand.

Guidance on Submitting Your Comments

Comments should clearly indicate your position on the allowance or prohibition of substances on the list and explain the reasons for your position. You should include relevant information and data to support your position (e.g., scientific, environmental, manufacturing, industry impact information, etc.).

For Comments That Support Substances Under Review:

If you provide comments in support of an allowance of a substance on the National List, you should provide information demonstrating that the substance is:

- (1) not harmful to human health or the environment;
- (2) necessary to the production of the agricultural products because of the unavailability of wholly nonsynthetic substitute products; and
- (3) consistent with organic crop production.

For Comments That Do Not Support Substances Under Review:

If you provide comments that do not support a substance on the National List, you should provide reasons why the use of the substance should no longer be allowed in organic production or handling. Specifically, comments that support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:

- (1) harmful to human health or the environment;
- (2) unnecessary because of the availability of alternatives; and
- (3) inconsistent with crop production.

For Comments Addressing the Availability of Alternatives:

Comments may present information about the viability of alternatives for a substance under sunset review. Viable alternatives include, but are not limited to:

- Alternative management practices that would eliminate the need for the specific substance;
- Other currently exempted substances that are on the National List, which could eliminate the need for this specific substance; and
- Other organic or nonorganic agricultural substances.

Your comments should address whether any alternatives have a function and effect equivalent to or better than the allowed substance, and whether you want the substance to be allowed or removed from the National List. Assertions about alternative substances, except for those alternatives that already appear on the National List, should, if possible, include the name and address of the manufacturer of the alternative. Further, your comments should include a copy or the specific source of any supportive literature, which could include product or practice descriptions; performance and test data; reference standards; names and addresses of producers or handlers who have used the alternative under similar conditions and the date of use; and an itemized comparison of the function and effect of the proposed alternative(s) with substance under review. The following table can help you describe recommended alternatives in place of a current substance that you do not want to be continued.

For Comments on Nonorganic Agricultural Substances at Section 205.606.

For nonorganic agricultural substances on section 205.606, the NOSB Handling Subcommittee requests current industry information regarding availability of and history of unavailability of an organic form of the substance in the appropriate form, quality, or quantity of the substance. The NOSB Handling Subcommittee would like to know if there is a change in supply of organic forms of the substance or demand for the substance (i.e. is an allowance for the nonorganic form still needed), as well as any new information about alternative substances that the NOSB did not previously consider.

Written public comments will be accepted through April 7, 2015 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.



**Sunset 2017 Review Summary
Meeting 1 - Request for Public Comment
Handling Substances §205.605(a)
April 2015**

Reference: 7 CFR 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)).”

§205.605(a) Nonsynthetics allowed:

[Acid, Alginic](#)

[Acid, Citric](#)

[Acid, Lactic](#)

[Attapulgite](#)

[Bentonite](#)

[Calcium carbonate](#)

[Calcium chloride](#)

[Dairy cultures](#)

[Diatomaceous earth](#)

[Enzymes](#)

[Flavors](#)

[Kaolin](#)

[Magnesium sulfate](#)

[Nitrogen](#)

[Oxygen](#)

[Perlite](#)

[Potassium chloride](#)

[Potassium iodide](#)

[Sodium bicarbonate](#)

[Sodium carbonate](#)

[Waxes \(Carnauba\)](#)

[Waxes \(Wood rosin\)](#)

[Yeast](#)



Acid, Alginic

Reference: 205.605(a) Acids (Alginic; Citric – produced by microbial fermentation of carbohydrate substances; and Lactic).

Technical Report: [02/2015 TR](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Additional information requested by NOSB

1. Please bring forth any information regarding the effect of Alginic Acid and/or Alginates on human digestion.
2. Is Alginic acid in use in organic handling and should it have its own National List listing? What are the non-synthetic alternatives in specific handling uses?

Acid, Citric

Reference: 205.605(a) Acids (Alginic; Citric – produced by microbial fermentation of carbohydrate substances; and Lactic).

Technical Report: [1995 TAP](#); [2015 TR](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Additional information requested by NOSB

NONE

Acid, Lactic

Reference: 205.605(a) Acids (Alginic; Citric – produced by microbial fermentation of carbohydrate substances; and Lactic).

Technical Report: [1995 TAP](#); [2015 TR](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)



Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))
Sunset Date: 10/21/17

Additional information requested by NOSB
NONE

Attapulgit

Reference: 205.605(a) – as a processing aid in the handling of plant and animal oils.
Technical Report: [2010 TR](#)
Petition(s): [2009 Attapulgit](#)
Past NOSB Actions: [04/2011 NOSB recommendation](#)
Recent Regulatory Background: Added to National List effective 08/03/2012 [[77 FR 45903](#)]
Sunset Date: 08/03/17

Additional information requested by NOSB
NONE

Bentonite

Reference: 205.605(a)
Technical Report: [1995 Kaolin Clay and Bentonite](#)
Petition(s): N/A
Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)
Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#)),
Sunset Date: 06/27/17

Additional information requested by NOSB
Are Bentonite and Kaolin essential in organic processing?

Calcium carbonate

Reference: 205.605(a)
Technical Report: [1995 TAP](#)
Petition(s): N/A
Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)



Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))
Sunset Date: 06/27/17

Additional information requested by NOSB
NONE

Calcium chloride

Reference: 205.605(a)
Technical Report: [1995 TAP](#)
Petition(s): N/A
Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)
Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))
Sunset Date: 10/21/17

Additional information requested by NOSB
NONE

Dairy cultures

Reference: 205.605(a)
Technical Report: [1995 TAP](#); 2015 TR for Ancillary Substances in development
Petition(s): N/A
Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)
Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))
Sunset Date: 10/21/17

Additional information requested by NOSB

The NOSB is considering removing dairy cultures from the national list since the broader listing of microorganisms may cover all currently allowed dairy cultures:

1. Is a separate listing for dairy cultures necessary or is the microorganisms listing sufficient to cover all materials used under the current dairy culture listing?
2. The following ancillary substances have been identified in dairy cultures:

Ancillary substances in dairy cultures by functional class:

Functional class	Substance name
------------------	----------------



Anti-caking & anti-stick agents	magnesium stearate, calcium silicate, silicon dioxide
Carriers and fillers, agricultural or nonsynthetic	Lactose, maltodextrins, sucrose, dextrose, potato starch, non-GMO soy oil, flour, milk, autolyzed yeast, inulin, cornstarch, sucrose.
Carriers and fillers, synthetic	Micro-crystalline cellulose, propylene glycol, stearic acid, dicalcium phosphate.
Preservatives	sodium benzoate, potassium sorbate, ascorbic acid
Stabilizers	Maltodextrin
Cytoprotectants used to freeze-dry dairy cultures	liquid nitrogen, maltodextrin, magnesium sulfate, dimethyl sulfoxide, sodium aspartate, mannitol, sorbitol
Substrate that may remain in final product	milk, lactose

3. More information is sought about other ancillary substances that may be in use and not listed, ancillary substances that are listed here but are not in use in formulations approved for organic, and other functional classes of ancillary substances that are not in this chart.
4. Information is sought on specifically why any of the ancillary substances in dairy cultures do not meet the review criteria in the organic rule.

Diatomaceous earth

Reference: 205.605(a) - food filtering aid only

Technical Report: [1995 TAP](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Additional information requested by NOSB

NONE



Enzymes

Reference: 205.605(a) - must be derived from edible, nontoxic plants, nonpathogenic fungi, or nonpathogenic bacteria.

Technical Report: [1995 TAP](#); [1996 TAP](#); [2011 TR](#); 2015 TR for Ancillary Substances in development

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [04/2011 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Additional information requested by NOSB

1. Below is a chart of ancillary substances that may be used in enzyme preparations. Please submit spec sheets or names of any ancillary substances that are not listed on the chart.

Ancillary Substances by Food Additive Functional Class¹	
Anti-caking & anti-stick agents	Magnesium stearate, calcium silicate, silicon dioxide
Carriers and fillers, agricultural or nonsynthetic	Lactose, maltodextrins, sucrose, dextrose, potato starch, non-GMO soy oil, rice protein, grain (rice, wheat, corn, barley) flour, milk, autolyzed yeast, inulin, cornstarch, sucrose, glycerol, potassium chloride, ammonium sulfate
Carriers and fillers, synthetic	Micro-crystalline cellulose, propylene glycol, stearic acid, dicalcium phosphate.
Preservatives	sodium benzoate, potassium sorbate, ascorbic acid
Stabilizers	maltodextrin

¹ this list does not include ancillary substances that are already on the National List. From the Technical Report and spec sheets

Flavors

Reference: 205.605(a), nonsynthetic sources only and must not be produced using synthetic solvents



and carrier systems or any artificial preservative.

Technical Report: [2005 TR](#)

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [04/2006 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Additional information requested by NOSB

1. Supply: Organic flavors of various types are available in the marketplace (extracts, essential oils, compounded natural flavors, essences, distillates, etc.). Is the supply of some specific organic flavors sufficient to warrant the sunset of some specific natural (non-organic) flavors on 205.605 of the National List? If so which ones?
2. Commercial Availability: Given the availability of some organic flavors, do you think that commercial availability should apply to the use of natural flavors in organic products (i.e. use organic when commercially available in quantity, quality and form)?
3. Would it be appropriate to retain all natural flavors on the National List if organic flavors were required to be used when available? Please explain your reasoning and provide specific examples.
4. Essentiality: Are flavors essential to the continued success of the organic sector? Describe the effects to your operation should you no longer be allowed to use non-organic flavors. Specify which flavors you use.
5. Would certifiers and Material Review Organizations (MROs) find a standardized industry questionnaire to verify compliance a helpful document?

Kaolin

Reference: 205.605(a)

Technical Report: [1995 TAP](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Additional information requested by NOSB

Are Bentonite and Kaolin essential in organic processing?



Magnesium sulfate

Reference: 205.605(a) - nonsynthetic sources only.

Technical Report: [1995 TAP \(Processing\)](#); [2011 TR](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [04/2011 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Additional information requested by NOSB

1. If you use this material please let us know what you use it for and why, and what would be the impact on your operation if it was removed from the list.
2. Could Material Review Organizations (MROs) and certifiers please clarify availability of non-synthetic magnesium sulfate.

Nitrogen

Reference: 205.605(a) - oil-free grades.

Technical Report: [1995 TAP](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Additional information requested by NOSB

NONE

Oxygen

Reference: 205.605(a) - oil-free grades.

Technical Report: [1995 TAP](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)



Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))
Sunset Date: 10/21/17

Additional information requested by NOSB

NONE

Perlite

Reference: 205.605(a) -for use only as a filter aid in food processing.

Technical Report: [1996 TAP](#)

Petition(s): N/A

Past NOSB Actions: [NOSB minutes and vote 09/1996](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Additional information requested by NOSB

NONE

Potassium chloride

Reference: (a) Nonsynthetics allowed:

Technical Report: [1995 TAP](#); 2015 TR

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Additional information requested by NOSB

NONE

Potassium iodide

Reference: 205.605(a)

Technical Report: [1995 TAP](#); [2011 TR](#); 2015 TR

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset](#)



[recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Additional information requested by NOSB

NONE

Sodium bicarbonate

Reference: 205.605(a)

Technical Report: [1995 TAP](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Additional information requested by NOSB

NONE

Sodium carbonate

Reference: 205.605(a)

Technical Report: [1995 TAP](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Additional information requested by NOSB

NONE

Waxes (Carnauba)

Reference: 205.605(a) Waxes – nonsynthetic (Carnauba wax; and Wood resin).

Technical Report: [1996 TAP](#); [2014 TR - Carnauba Wax](#)

Petition(s): N/A



Past NOSB Actions: [NOSB minutes and vote 09/1996](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Additional information requested by NOSB

1. Would changing this substance to an agricultural designation is a good idea? Comments are sought on this paragraph from the 2014 Technical Report: "However, it is possible that carnauba wax could be considered agricultural based on the definition of "agricultural product" at §205.2. It is derived from a plant, the carnauba palm, and does have intended uses for "human consumption." FDA regulations permit its use on food, and certified organic carnauba wax is available in the marketplace. There are seven operations in Germany, Brazil, and the U.S. that produce or handle organic carnauba wax according to the 2012 list of certified USDA organic operations (National Organic Program, 2012)." (TR page 7, lines 340-345)
2. Input is requested on ancillary substances that may be part of wax formulations. Note that all the nonsynthetic waxes are often used in combination with each other, but these are not considered ancillary to each other. Potential ancillaries identified in the TR include residues of processing aids such as sodium carbonate, emulsifiers, plasticizers, coloring and de-colorization agents, surfactants and preservatives. Potential ancillaries identified in the TR include emulsifiers (fatty acids such as oleic, linoleic, palmitic, myristic or lauric acid), basic counterions (hydroxides of sodium, potassium salts, or ammonium, morpholine), and anti-foam agents. Additional components in Table 3 of the TR (page 7) that may function as ancillaries include alkaline agents, emulsifiers, and protective colloids, as well as plant extracts and vegetable oils.

Waxes (Wood rosin) (sic. Resin)

Reference: (a) Nonsynthetics allowed: Waxes—nonsynthetic (Carnauba wax; and Wood resin).

Technical Report: [1996 TAP](#); [2014 TR - Wood Rosin](#)

Petition(s): N/A

Past NOSB Actions: [NOSB minutes and vote 09/1996](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Additional information requested by NOSB

1. Whether there will be any adverse impacts to the organic community from making a technical correction. See the TR for a detailed discussion of the identification of rosin.
2. It is not known if there are any wood rosin based waxes that are combined with substances on the National list available on the market. The public is requested to submit brand names and specification sheets for any such products. (TR lines 155-156, page 4).
3. Input is requested on ancillary substances that may be part of wax formulations. Note that all the nonsynthetic waxes are often used in combination with each other, but these are not considered



ancillary to each other. Potential ancillaries identified in the TR include coumarone indene resin (synthetic resins of low molecular weight), emulsifiers, plasticizers, anti-foam agents, surfactants and preservatives. Additional components in Table 3 of the TR (page 4) that may function as ancillaries include alkaline agents, emulsifiers, and protective colloids, as well as plant extracts and vegetable oils. Without knowing of any products in use, it is unknown whether any of these may have been reviewed by materials review organizations for use in organic handling.

Yeast

Listing: 205.605(a) - When used as food or a fermentation agent, yeast must be organic if its end use is for human consumption; nonorganic yeast may be used when equivalent organic yeast is not commercially available. Growth on petrochemical substrate and sulfite waste liquor is prohibited. For smoked yeast, nonsynthetic smoke flavoring process must be documented.

Technical Report: [1995 TAP \(Smoked Yeast\)](#); [1995 TAP \(Baker's Yeast\)](#); [2014 TR](#)

Petition(s): [2006 Petition](#); [2010 Petition Supplement](#); [2010 Petition memo](#)

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/17

Additional information requested by NOSB

1. Since the change to this listing in 2010, has organic yeast become available in all forms, including extracted ("autolysate") yeast?

The following ancillary substances have been identified in yeast so far from the TER:

Ancillary substances in yeast by functional class:

Functional class	Substance name
Antioxidants	butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), propyl gallate (PG).
Preservatives	ascorbic acid
Emulsifiers	soybean oil, cottonseed oil, sorbitan monostearate, sorbitan tristearate, sorbitan monolaurate, sorbitan monooleate, sorbitan monpalmitate, sorbitol.
Carriers	Malt Syrup
Defoaming agents	many in TR



Substrate that may remain in final product	food waste, microorganisms, molasses
--	--------------------------------------

2. The Handling Subcommittee is seeking more information about others that may be in use, which of the many defoaming agents are used in formulations approved for organic, and other functional classes that are not in this chart.
3. The Handling Subcommittee is seeking more information on why, specifically, any of the ancillary substances in yeast do not meet the review criteria in the organic rule.



Sunset 2017 Review Summary Meeting 1 - Request for Public Comment Handling Substances §205.605(b) April 2015

Introduction

As part of the [Sunset Process](#), the National Organic Program (NOP) announces substances on the National List of Allowed and Prohibited Substances (National List) that are coming up for sunset review by the National Organic Standard Board (NOSB). The following list announces substances that are on the National List for use in organic crop production that must be reviewed by the NOSB and renewed by the USDA before their sunset dates in 2017. This list provides the substance's current status on the National List, use description, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, this is noted in this list. To see if any new technical report is available, please check for updates under the substance name in the [Petitioned Substances Database](#).

Request for Comments

While the NOSB will not complete its review and any recommendations on these substances until the fall 2015 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the spring 2015 public meeting. These comments should be provided through www.regulations.gov by April 7, 2015 as explained in the meeting notice published in the [Federal Register](#).

These comments are necessary to guide the NOSB's review of each substance against the criteria in the Organic Foods Production Act (7 U.S.C. 6518(m)) and the USDA organic regulations (7 CFR 205.600). The current substances on the National List were originally recommended by the NOSB based on evidence available to the NOSB at the time of their last review which demonstrated that the substances were found to be: (1) not harmful to human health or the environment, (2) necessary because of the unavailability of wholly nonsynthetic alternatives, and (3) consistent and compatible with organic practices.

Public comments should focus on providing new information about a substance since its last NOSB review. Such information could include research or data that may support a change in the NOSB's determination for a substance. Public comment should also address the continuing need for a substance or whether the substance is no longer needed or in demand.

Guidance on Submitting Your Comments

Comments should clearly indicate your position on the allowance or prohibition of substances on the list and explain the reasons for your position. You should include relevant information and data to support your position (e.g., scientific, environmental, manufacturing, industry impact information, etc.).

For Comments That Support Substances Under Review:

If you provide comments in support of an allowance of a substance on the National List, you should provide information demonstrating that the substance is:

- (1) not harmful to human health or the environment;
- (2) necessary to the production of the agricultural products because of the unavailability of wholly nonsynthetic substitute products; and



(3) consistent with organic crop production.

For Comments That Do Not Support Substances Under Review:

If you provide comments that do not support a substance on the National List, you should provide reasons why the use of the substance should no longer be allowed in organic production or handling. Specifically, comments that support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:

- (1) harmful to human health or the environment;
- (2) unnecessary because of the availability of alternatives; and
- (3) inconsistent with crop production.

For Comments Addressing the Availability of Alternatives:

Comments may present information about the viability of alternatives for a substance under sunset review. Viable alternatives include, but are not limited to:

- Alternative management practices that would eliminate the need for the specific substance;
- Other currently exempted substances that are on the National List, which could eliminate the need for this specific substance; and
- Other organic or nonorganic agricultural substances.

Your comments should address whether any alternatives have a function and effect equivalent to or better than the allowed substance, and whether you want the substance to be allowed or removed from the National List. Assertions about alternative substances, except for those alternatives that already appear on the National List, should, if possible, include the name and address of the manufacturer of the alternative. Further, your comments should include a copy or the specific source of any supportive literature, which could include product or practice descriptions; performance and test data; reference standards; names and addresses of producers or handlers who have used the alternative under similar conditions and the date of use; and an itemized comparison of the function and effect of the proposed alternative(s) with substance under review. The following table can help you describe recommended alternatives in place of a current substance that you do not want to be continued.

For Comments on Nonorganic Agricultural Substances at Section 205.606.

For nonorganic agricultural substances on section 205.606, the NOSB Handling Subcommittee requests current industry information regarding availability of and history of unavailability of an organic form of the substance in the appropriate form, quality, or quantity of the substance. The NOSB Handling Subcommittee would like to know if there is a change in supply of organic forms of the substance or demand for the substance (i.e. is an allowance for the nonorganic form still needed), as well as any new information about alternative substances that the NOSB did not previously consider.

Written public comments will be accepted through April 7, 2015 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.



**Sunset 2017 Review Summary
Meeting 1 - Request for Public Comment
Handling Substances §205.605(b)
April 2015**

Reference: 7 CFR 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)).”

§205.605(b) Synthetics allowed:

[Acidified sodium chlorite](#)

[Alginates](#)

[Ammonium bicarbonate](#)

[Ammonium carbonate](#)

[Ascorbic acid](#)

[Calcium citrate](#)

[Calcium hydroxide](#)

[Calcium phosphates: monobasic, dibasic, tribasic](#)

[Carbon dioxide](#)

[Chlorine Materials: calcium hypochlorite, chlorine dioxide, sodium hypochlorite](#)

[Ethylene](#)

[Ferrous sulfate](#)

[Glycerides: mono and di](#)

[Glycerin](#)

[Hydrogen peroxide](#)

[Magnesium carbonate](#)

[Magnesium chloride](#)

[Magnesium stearate](#)

[Nutrient vitamins and minerals](#)

[Ozone](#)

[Phosphoric acid](#)

[Potassium acid tartrate](#)

[Potassium carbonate](#)

[Potassium citrate](#)

[Potassium phosphate](#)

[Sodium citrate](#)

[Sodium hydroxide](#)

[Sodium phosphates](#)

[Sulfur dioxide](#)

[Tocopherols](#)

[Xanthan gum](#)



Acidified sodium chlorite

Reference: 205.605(b) - Secondary direct antimicrobial food treatment and indirect food contact surface sanitizing. Acidified with citric acid only.

Technical Report: [2008 TAP](#)

Petition(s): [2006 Sodium Chlorite, Acidified](#)

Past NOSB Actions: [2009 NOSB recommendation](#)

Recent Regulatory Background: Added to NL effective 03/15/2012 ([77 FR 8089](#))

Sunset Date: 03/15/17

Additional information requested by NOSB

Is the substance essential for organic food production? Since the material was last reviewed, have additional commercially available alternatives emerged? The Handling Subcommittee encourages current users of acidified sodium chlorite to provide detailed comments describing the situations in which it is the most appropriate or effective antimicrobial for a given application.

Alginates

Reference: 205.605(b) Synthetics allowed

Technical Report: [1995 TAP](#)

Petition(s): [1995 Alginates](#)

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/2017

Additional information requested by NOSB

Please bring forth any information regarding the effect of Alginic Acid and/or Alginates on human digestion.

Ammonium bicarbonate

Reference: 205.605(b) - for use only as a leavening agent

Technical Report: [1995 TAP](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset](#)



[recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/2017

Additional information requested by NOSB

NONE

Ammonium carbonate

Reference: 205.605(b) –for use only as a leavening agent

Technical Report: [1995 TAP](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/2017

Additional information requested by NOSB

NONE

Ascorbic acid

Reference: 205.605(b)

Technical Report: [1995 TAP](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/2017

Additional information requested by NOSB

NONE

Calcium citrate



Reference: 205.605(b)

Technical Report: [1995 TAP](#)

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/2017

Additional information requested by NOSB

NONE

Calcium hydroxide

Reference: 205.605(b)

Technical Report: [1995 TAP](#)

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/2017

Additional information requested by NOSB

NONE

Calcium phosphates (monobasic, dibasic, and tribasic)

Reference: 205.605(b)

Technical Report: [1995 TAP](#)

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/2017

Additional information requested by NOSB



Have there been any changes in the sources of the raw materials from which the calcium or the phosphate are derived from? Any changes in the manufacturing process?

Carbon dioxide

Reference: 205.605(b)

Technical Report: [1995 TAP](#); [2006 TAP](#)

Petition(s): [2007 Carbon Dioxide](#)

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [2007 NOSB Committee recommendation](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/2017

Additional information requested by NOSB

NONE

Chlorine materials

Reference: 205.605(b) Chlorine materials- —disinfecting and sanitizing food contact surfaces, *Except*, That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (Calcium hypochlorite; Chlorine dioxide; and Sodium hypochlorite).

Technical Report: [2006 TR - Handling](#)

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [04/2006 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/2017

Additional information requested by NOSB

Is the substance essential for organic food production? Since the material was last reviewed, have additional commercially available alternatives emerged? The Handling Subcommittee encourages current users of chlorine materials to provide detailed comments describing the situations in which they are the most appropriate or effective antimicrobial for a given application.

Ethylene



Reference: 205.605(b) allowed for postharvest ripening of tropical fruit and degreening of citrus.

Technical Report: [1995 TAP](#); [1999 TAP - Processing](#)

Petition(s): 1995 N/A, [2008 Ethylene \(for use with pears\)](#)

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [10/1999 NOSB minutes and vote \(add tropical fruit and citrus\)](#); [11/2005 sunset recommendation](#); [11/2008 recommendation for pears](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/2017

Additional information requested by NOSB

The subcommittee is considering editing the annotation and removing its allowed use for the de-greening of citrus. If you use this material for the de-greening of citrus please let us know why you need to use it, and what the impact on your operation would be if it was removed from the List.

Ferrous sulfate

Reference: 205.605(b) - for iron enrichment or fortification of foods when required by regulation or recommended (independent organization).

Technical Report: [1995 TAP](#); 2015 TR in development

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/2017

Additional information requested by NOSB

NONE

Glycerides (mono and di)

Reference: 205.605(b) for use only in drum drying of food.

Technical Report: [1995 TAP](#); [2015 TR](#)

Petition(s): [N/A](#)

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)



Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/2017

Additional information requested by NOSB

1. The subcommittee would like to better understand the extent of use of glycerides (mon- and di-) in drum drying. Are glycerides essential to organic food production? Describe the effects on your operation if glycerides were removed from the National List
2. There appear to be many alternatives to use of glycerides for drum drying of foods, such as spray drying, freeze drying, fluidized bed dryers, air lift dryers, etc. Freeze drying is said to be an acceptable alternative to drum drying. Which of these alternatives have you found to be effective in your business?

Glycerin

Reference: 205.605(b) - produced by hydrolysis of fats and oils.

Technical Report: [1995 TAP](#); [2013 TR](#)

Petition(s): 1995 N/A, [Glycerin \(2012 Petition to remove\)](#)

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/2017

Additional information requested by NOSB

The Handling subcommittee requests public comment regarding the current use and essentiality of glycerin as a filter aid.

Hydrogen peroxide

Reference: 205.605(b)

Technical Report: N/A for handling use

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/2017

Additional information requested by NOSB



Is hydrogen peroxide essential for organic food production? Since the material was last reviewed, have additional commercially available alternatives emerged? The Handling Subcommittee encourages current users of hydrogen peroxide to provide detailed comments describing the situations in which it is the most effective antimicrobial for a given application

Magnesium carbonate

Reference: 205.605 (b) — for use only in agricultural products labeled “made with organic (specified ingredients or food group(s)),” prohibited in agricultural products labeled “organic”.

Technical Report: [1996 TAP](#)

Petition(s): [Magnesium Carbonate \(2005\)](#)

Past NOSB Actions: [09/1996 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/2017

Additional information requested by NOSB

The subcommittee is considering removing this material from the National List. If you use this material please let us know what you use it for and why, and what would be the impact on your operation if it was removed from the List.

Magnesium chloride

Reference: 205.605(b) – derived from sea water.

Technical Report: [1995 TAP](#)

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [10/1999 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/2017

Additional information requested by NOSB

1. If you use this material please let us know what you use it for and why, and what would be the impact on your operation if it was removed from the List.
2. If this material continues to be allowed should it be reclassified as Non-synthetic because it is derived from seawater by brine drying or should the annotation be changed?



3. If this material continues to be allowed should its uses be limited to production of tofu?
4. Is Nigari an FDA allowed food ingredient?

Magnesium stearate

Reference: 205.605(b) - for use only in agricultural products labeled “made with organic (specified ingredients or food group(s)),” prohibited in agricultural products labeled “organic”.

Technical Report: [1995 TAP](#)

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/2017

Additional information requested by NOSB

1. The CCFA in 2010 recommended that magnesium stearate be deleted from Codex. Presently magnesium stearate is only allowed in the “made with organic” category. The Handling subcommittee may be recommending that magnesium stearate be removed from the National List. If magnesium stearate was removed from the National List what impact would this have on your operation?
2. Since last review are there alternatives to the use of this material? If so which ones are most effective in your operation.
3. Since the last review what health impacts have been clearly associated with magnesium stearate?

Nutrient vitamins and minerals

Reference: 205.605(b) Nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines For Foods.

Technical Report: [1995 TAP - Minerals](#); [1995 TAP - Vitamins](#); 2015 TRs in development

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [03/2011 Handling Subcommittee Proposal](#); [04/2011 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/21/2017

Additional information requested by NOSB



Since the technical review document was not back in time for review, the Handling subcommittee urges input regarding ancillary substances used with these materials.

Ozone

Reference: 205.605(b)

Technical Report: [1995 TAP](#)

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/2017

Additional information requested by NOSB

Is ozone essential for organic food production? Since the material was last reviewed, have additional commercially available alternatives emerged? The Handling Subcommittee encourages current users of ozone to provide detailed comments describing the situations in which it is the most effective antimicrobial for a given application.

Phosphoric acid

Reference: 205.605(b) - cleaning of food-contact surfaces and equipment only

Technical Report: [2003 TAP](#)

Petition(s):N/A

Past NOSB Actions: [10/1999 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/2017

Additional information requested by NOSB

Is the substance essential for organic food production? Since the material was last reviewed, have additional commercially available alternatives emerged? The Handling Subcommittee encourages current users of phosphoric acid to provide detailed comments describing the situations in which it is the most effective cleaner for a given application

Potassium acid tartrate



Reference: 205.605(b)

Technical Report: [1995 TAP](#)

Petition(s): [N/A](#)

Past NOSB Actions [10/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/2017

Additional information requested by NOSB

1. Is clarification needed as to precisely which material is allowed?
2. If you use this material please let us know what you use it for and why, and what would be the impact on your operation if it was removed from the List.

Potassium carbonate

Reference: 205.605(b)

Technical Report: [1995 TAP](#)

Petition(s): [N/A](#)

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/2017

Additional information requested by NOSB

If you use this material please let us know what you use it for and why, and what would be the impact on your operation if it was removed from the List.

Potassium citrate

Reference: 205.605(b)

Technical Report: [1995 TAP](#); [2015 TR](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/2017



Additional information requested by NOSB

NONE

Potassium phosphate

Reference: 205.605(b) - for use only in agricultural products labeled “made with organic (specific ingredients or food group(s)),” prohibited in agricultural products labeled “organic”.

Technical Report: [1995 TAP](#)

Petition(s): [N/A](#)

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/2017

Additional information requested by NOSB

If you use this material please let us know what you use it for and why, and what would be the impact on your operation if it was removed from the List

Sodium citrate

Reference: 205.605(b)

Technical Report: [1995 TAP](#); [2015 TR](#)

Petition(s): [N/A](#)

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/2017

Additional information requested by NOSB

The subcommittee is considering removing this material from the National List based on availability of alternatives that include citric acid and potassium citrate. If you use this material please let us know if an alternative material would be sufficient in your operation and if Sodium Citrate is removed from the National List please let us know if this would have an impact on your operation:



Sodium hydroxide

Reference: 205.605(b) - prohibited for use in lye peeling of fruits and vegetables.

Technical Report: [1995 TAP](#)

Petition(s): [N/A](#)

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/2017

Additional information requested by NOSB

If you use this material please let us know what you use it for and why, and what would be the impact on your operation if it was removed from the List.

Sodium phosphate

Reference: 205.605(b) - for use only in dairy foods.

Technical Report: [2001 TAP](#)

Petition(s): 1995 N/A, [2001 Sodium Phosphate](#)

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [10/2001 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/2017

Additional information requested by NOSB

If you use this material please let us know what you use it for and why, and what would be the impact on your operation if it was removed from the List.

Sulfur dioxide

Reference: 205.605(b) for use only in wine labeled “made with organic grapes,” Provided, That, total sulfite concentration does not exceed 100 ppm.

Technical Report: [1995 TAP](#); [2011 TR](#)

Petition(s): 1995 N/A; [2010 Sulfur Dioxide](#)



Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#); [12/2011 petition review](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/2017

Additional information requested by NOSB

NONE

Tocopherols

Reference: 205.605(b) derived from vegetable oil when rosemary extracts are not a suitable alternative

Technical Report: [1995 TAP](#); [2015 limited scope TR](#)

Petition(s): [N/A](#)

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [04/2011 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/2017

Additional information requested by NOSB

The following table shows ancillary substances used in common tocopherol formulations. Please provide information as to whether these ancillary substances or others are also used in organic tocopherol formulations.

Table 1. Commercially Available Tocopherols Products Used as Antioxidants in Foods

Manufacturer	Product Name	Formulation	Ancillary Substance(s)	Source(s)
Advanced Organic Technologies (Buenos Aires, Argentina)	Tocomix™	Liquid	Sunflower oil	AOM, 2014
Archer Daniels Midland Company (Decatur, IL)	Decanox™	Liquid	Unknown	ADM, 2014
		Powder	Unknown	
BASF (Germany)	Covi-ox®	Liquid	Soybean oil	Brenntag Specialties, Inc., date unknown;
		Powder	Gum acacia	BASF, 2013

BTSA (Madrid, Spain)	Tocobiol®	Liquid	Sterols, squalene, monodiglycerides*, soybean or sunflower oil	BTSA, 2014a; BTSA, 2013
		Powder	Calcium carbonate	
	Nutrabiol® T	Liquid	Soybean or sunflower oil	BTSA, 2014b; BTSA, 2012
		Powder	Silica	
DuPont Danisco (global)	Guardian® tocopherol extract	Unknown	Unknown	DuPont Nutrition and Health, 2014a
Kemin Industries, Inc. (Des Moines, IA)	Fortium® mixed tocopherols	Liquid	Sunflower oil	Kemin, 2014a; 2014b
		Powder	Rice maltodextrin	
Nutralliance (supplier) (Yorba Linda, CA)	Sunvitol™ MT	Powder	Unknown	Nutralliance, 2014
Organic Technologies (Coshocton, OH)	Natural mixed tocopherols	Liquid	Organic sunflower oil	Organic Technologies, 2013
		Powder	Tapioca starch	
Sigma-Aldrich (St. Louis, MO)	Mixed tocopherols	Liquid	Unknown	Sigma-Aldrich Co. LLC, 2014
The Scoular Company (Minneapolis, MN)	Natural source mixed tocopherols	Liquid	Unknown	The Scoular Company, 2014
		Powder	Unknown	
Vitablend (Wolvega, The Netherlands)	Tocoblend®	Liquid	Unknown	Vitablend, 2014
		Powder	Unknown	
VitaeNaturals (Toledo, Spain)	Vitapherole® T	Liquid	Unknown	Vitae Caps S.A., 2012
		Powder	Unknown	
Wilmar Spring Fruit Nutrition Products Co. (Jiangsu, China)	Natural mixed tocopherols	Liquid	Soybean or sunflower oil	Wilmar International Ltd., 2014
		Powder	Unknown	
ZMC-USA (The	CaroleE™ ET and PT	Liquid	Unknown	ZMC-USA, date



Woodlands, TX)		Powder	Unknown	unknown
----------------	--	--------	---------	---------

* Piñol del Olmo (date unknown) reports that sterols, squalene, and monodiglycerides are naturally present in Tocobiol® from the source vegetable oil

Xanthan gum

Reference: 205.605(b)

Technical Report: [1995 TAP](#)

Petition(s): [N/A](#)

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/2017

Additional information requested by NOSB

Are there any ancillary substances used in xanthan gum such as carriers or solvent remaining in the final product?



Sunset 2017 Review Summary Meeting 1 - Request for Public Comment Handling Substances §205.606 April 2015

Introduction

As part of the [Sunset Process](#), the National Organic Program (NOP) announces substances on the National List of Allowed and Prohibited Substances (National List) that are coming up for sunset review by the National Organic Standard Board (NOSB). The following list announces substances that are on the National List for use in organic crop production that must be reviewed by the NOSB and renewed by the USDA before their sunset dates in 2017. This list provides the substance's current status on the National List, use description, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, this is noted in this list. To see if any new technical report is available, please check for updates under the substance name in the [Petitioned Substances Database](#).

Request for Comments

While the NOSB will not complete its review and any recommendations on these substances until the fall 2015 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the spring 2015 public meeting. These comments should be provided through www.regulations.gov by April 7, 2015 as explained in the meeting notice published in the [Federal Register](#).

These comments are necessary to guide the NOSB's review of each substance against the criteria in the Organic Foods Production Act (7 U.S.C. 6518(m)) and the USDA organic regulations (7 CFR 205.600). The current substances on the National List were originally recommended by the NOSB based on evidence available to the NOSB at the time of their last review which demonstrated that the substances were found to be: (1) not harmful to human health or the environment, (2) necessary because of the unavailability of wholly nonsynthetic alternatives, and (3) consistent and compatible with organic practices.

Public comments should focus on providing new information about a substance since its last NOSB review. Such information could include research or data that may support a change in the NOSB's determination for a substance. Public comment should also address the continuing need for a substance or whether the substance is no longer needed or in demand.

Guidance on Submitting Your Comments

Comments should clearly indicate your position on the allowance or prohibition of substances on the list and explain the reasons for your position. You should include relevant information and data to support your position (e.g., scientific, environmental, manufacturing, industry impact information, etc.).

For Comments That Support Substances Under Review:

If you provide comments in support of an allowance of a substance on the National List, you should provide information demonstrating that the substance is:

- (1) not harmful to human health or the environment;
- (2) necessary to the production of the agricultural products because of the unavailability of wholly nonsynthetic substitute products; and
- (3) consistent with organic crop production.

For Comments That Do Not Support Substances Under Review:

If you provide comments that do not support a substance on the National List, you should provide reasons why the use of the substance should no longer be allowed in organic production or handling. Specifically, comments that support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:

- (1) harmful to human health or the environment;
- (2) unnecessary because of the availability of alternatives; and
- (3) inconsistent with crop production.

For Comments Addressing the Availability of Alternatives:

Comments may present information about the viability of alternatives for a substance under sunset review. Viable alternatives include, but are not limited to:

- Alternative management practices that would eliminate the need for the specific substance;
- Other currently exempted substances that are on the National List, which could eliminate the need for this specific substance; and
- Other organic or nonorganic agricultural substances.

Your comments should address whether any alternatives have a function and effect equivalent to or better than the allowed substance, and whether you want the substance to be allowed or removed from the National List. Assertions about alternative substances, except for those alternatives that already appear on the National List, should, if possible, include the name and address of the manufacturer of the alternative. Further, your comments should include a copy or the specific source of any supportive literature, which could include product or practice descriptions; performance and test data; reference standards; names and addresses of producers or handlers who have used the alternative under similar conditions and the date of use; and an itemized comparison of the function and effect of the proposed alternative(s) with substance under review. The following table can help you describe recommended alternatives in place of a current substance that you do not want to be continued.

For Comments on Nonorganic Agricultural Substances at Section 205.606.

For nonorganic agricultural substances on section 205.606, the NOSB Handling Subcommittee requests current industry information regarding availability of and history of unavailability of an organic form of the substance in the appropriate form, quality, or quantity of the substance. The NOSB Handling Subcommittee would like to know if there is a change in supply of organic forms of the substance or demand for the substance (i.e. is an allowance for the nonorganic form still needed), as well as any new information about alternative substances that the NOSB did not previously consider.

Written public comments will be accepted through April 7, 2015 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.



Reference: 7 CFR §205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”

[Casings](#)

[Celery powder](#)

[Chia \(Salvia hispanica L.\)](#)

[Colors \(various\)](#)

[Dillweed oil](#)

[Fish oil](#)

[Fructooligosaccharides](#)

[Galangal, frozen](#)

[Gelatin](#)

[Gums: Arabic, Carob bean, Guar, Locust bean](#)

[Inulin-oligofructose enriched](#)

[Kelp](#)

[Konjac flour](#)

[Lecithin—de-oiled](#)

[Lemongrass-frozen](#)

[Orange pulp, dried](#)

[Orange Shellac - unbleached](#)

[Pectin \(non-amidated forms only\)](#)

[Peppers \(Chipotle chile\)](#)

[Seaweed, Pacific kombu](#)

[Starches, Cornstarch \(native\), Sweet potato](#)

[Turkish bay leaves](#)

[Wakame seaweed \(Undaria pinnatifida\)](#)

[Whey protein concentrate](#)



Sunset 2017 Review Summary Meeting 1 - Request for Public Comment Handling Substances §205.606 April 2015

Casings

Reference: 205.606(a) casings, from processed intestines

Technical Report: N/A

Petition(s): [2006 Petition](#)

Past NOSB Actions: [04/2007 NOSB recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Added to NL effective 06/21/07 ([72 FR 35137](#)); Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

1. Are there any companies manufacturing casings made from certified organic livestock?
2. Are casings from intestines of organic certified animals commercially available in the USA or international?
3. What chemicals other than salt are used to process animal intestines into casings?

Celery powder

Reference: 205.606(b)

Technical Report: N/A

Petition(s): [2007 Petition](#)

Past NOSB Actions: [04/2007 NOSB recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

As of February 2014 a review of the USDA list of certified operations (2013 data) showed 423 organic crops certificates listing celery and 2 organic handling certificates listing celery powder. As of February 2014 606organic.com and the OTA Organic Pages do not list any suppliers of organic celery powder. Based on this information the handling subcommittee believes sufficient supply may be available to remove this material from 205.606.

1. The Handling Subcommittee requests that the public provide comment regarding the current use of and commercial demand for celery powder in organic products and provide comments on the impact that removing it from 205.606 would have on organic business and/or organic products.



2. Has the industry attempted to locate organic sources of celery powder and with what degree of success?
3. Are there other ingredients with suitable flavor profiles that could be used in place of celery powder, given adequate transition time for ingredient inventory and label depletion?
4. In what organic products is non-organic celery powder currently used, and what are the specific reasons for its necessity in these products?

Chia (*Salvia hispanica* L.)

Reference: 205.606(c)(*Salvia hispanica* L.)

Technical Report: N/A

Petition(s): [2007 Petition](#)

Past NOSB Actions: [03/2007 NOSB recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: : Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

As of February 2014, a review of the USDA list of certified operations (2013 data) showed 71 organic crops certificates listing chia (from 9 countries in North and South America) and 99 organic handling certificates listing chia. As of February 2014 606organic.com and the OTA Organic Pages both list suppliers of organic chia. Based on this information the handling subcommittee believes sufficient supply may be available to remove this material from 205.606.

1. The Handling Subcommittee requests that the public provide comment regarding the current use of and commercial demand for chia in organic products and provide comments on the impact that removing it from 205.606 would have on organic business and/or organic products.
2. Has the industry attempted to locate organic sources of chia and with what degree of success?
3. Are there other ingredients with suitable flavor profiles that could be used in place of chia, given adequate transition time for ingredient inventory and label depletion?
4. In what organic products is non-organic chia currently used, and what are the specific reasons for its necessity in these products?

Colors - Beet juice extract color

Reference: 205.606(d) Colors derived from agricultural products - Must not be produced using synthetic solvents and carrier systems or any artificial preservative



(1) Beet juice extract color (pigment CAS #7659-95-2)

Technical Report: [2015 TR - Colors \(all\)](#)

Petition(s): [2007 Petition](#)

Past NOSB Actions: [04/2007 NOSB recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Added to NL effective 06/21/07 ([72 FR 35137](#)); Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

1. Availability: Colors were added to 205.606 of the National List after the 205.605 listing was allowed to sunset off the National List in 2007. Has the availability of organic colors increased?
2. Is the supply of individual organic colors sufficient to warrant the removal of some or all colors from the National List? If not, why?
3. Are colors essential to the continued success of the organic sector? Describe the effects to your operation should you no longer be allowed to use non-organic colors.
4. Are there ancillary substances associated with the manufacture of colors? If so describe and explain their uses.

Colors - Black currant juice color

Reference: 205.606(d) Colors derived from agricultural products—Must not be produced using synthetic solvents and carrier systems or any artificial preservative

(3) Black currant juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)

Technical Report: [2015 TR - Colors \(all\)](#)

Petition(s): [2007 Petition](#)

Past NOSB Actions: [04/2007 NOSB recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

See the summary for **Colors - Beet juice extract** above for questions pertaining to all 17 colors.



Colors - Black/Purple carrot juice color

Reference: 205.606(d) Colors derived from agricultural products—Must not be produced using synthetic solvents and carrier systems or any artificial preservative

(4) Black/Purple carrot juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)

Technical Report: [2015 TR - Colors \(all\)](#)

Petition(s): [2007 Petition](#)

Past NOSB Actions: [04/2007 NOSB recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

See the summary for **Colors - Beet juice extract** above for questions pertaining to all 17 colors.

Colors - Blueberry juice color

Reference: 205.606(d) Colors derived from agricultural products—Must not be produced using synthetic solvents and carrier systems or any artificial preservative

(5) Blueberry juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)

Technical Report: [2015 TR - Colors \(all\)](#)

Petition(s): [2007 Petition](#)

Past NOSB Actions: [04/2007 NOSB recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

See the summary for **Colors - Beet juice extract** above for questions pertaining to all 17 colors.

Colors - Carrot juice color

Reference: 205.606(d) Colors derived from agricultural products—Must not be produced using synthetic solvents and carrier systems or any artificial preservative

(6) Carrot juice color (pigment CAS #1393-63-1)



Technical Report: [2015 TR - Colors \(all\)](#)

Petition(s): [2007 Petition](#)

Past NOSB Actions: [04/2007 NOSB recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

See the summary for **Colors - Beet juice extract** above for questions pertaining to all 17 colors.

Colors - Cherry juice color

Reference: 205.606(d) Colors derived from agricultural products—Must not be produced using synthetic solvents and carrier systems or any artificial preservative

(7) Cherry juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)

Technical Report: [2015 TR - Colors \(all\)](#)

Petition(s): [2007 Petition](#)

Past NOSB Actions: [04/2007 NOSB recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

See the summary for **Colors - Beet juice extract** above for questions pertaining to all 17 colors.

Colors - Chokeberry—Aronia juice color

Reference: 205.606(d) Colors derived from agricultural products—Must not be produced using synthetic solvents and carrier systems or any artificial preservative

(8) Chokeberry—Aronia juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)

Technical Report: [2015 TR - Colors \(all\)](#)

Petition(s): [2007Petition](#)

Past NOSB Actions: [04/2007 NOSB recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

See the summary for **Colors - Beet juice extract** above for questions pertaining to all 17 colors.



Colors - Elderberry juice color

Reference: 205.606(d) Colors derived from agricultural products—Must not be produced using synthetic solvents and carrier systems or any artificial preservative

(9) Elderberry juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)

Technical Report: [2015 TR - Colors \(all\)](#)

Petition(s): [2007 Petition](#)

Past NOSB Actions: [04/2007 NOSB recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

See the summary for **Colors - Beet juice extract** above for questions pertaining to all 17 colors.

Colors - Grape juice color

Reference: 205.606(d) Colors derived from agricultural products—Must not be produced using synthetic solvents and carrier systems or any artificial preservative

(10) Grape juice color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)

Technical Report: [2015 TR - Colors \(all\)](#)

Petition(s): [2007 Petition](#)

Past NOSB Actions: [04/2007 NOSB recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: : Sunset renewal notice effective 06/27/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

See the summary for **Colors - Beet juice extract** above for questions pertaining to all 17 colors.

Colors - Grape skin extract color

Reference: 205.606(d) Colors derived from agricultural products—Must not be produced using synthetic solvents and carrier systems or any artificial preservative

(11) Grape skin extract color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)



Technical Report: [2015 TR - Colors \(all\)](#)

Petition(s): [2007 Petition](#)

Past NOSB Actions: [04/2007 NOSB recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

See the summary for **Colors - Beet juice extract** above for questions pertaining to all 17 colors.

Colors - Paprika color

Reference: 205.606(d) Colors derived from agricultural products—Must not be produced using synthetic solvents and carrier systems or any artificial preservative

(12) Paprika color (CAS #68917-78-2)—dried, and oil extracted

Technical Report: [2015 TR - Colors \(all\)](#)

Petition(s): [2007 Petition](#); [2007 Petition Amendment](#)

Past NOSB Actions: [04/2007 NOSB recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

See the summary for **Colors - Beet juice extract** above for questions pertaining to all 17 colors.

Colors - Pumpkin juice color

Reference: 205.606(d) Colors derived from agricultural products—Must not be produced using synthetic solvents and carrier systems or any artificial preservative

(13) Pumpkin juice color (pigment CAS #127-40-2)

Technical Report: [2015 TR - Colors \(all\)](#)

Petition(s): [2007 Petition](#)

Past NOSB Actions: [04/2007 NOSB recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

See the summary for **Colors - Beet juice extract** above for questions pertaining to all 17 colors.



Colors - Purple potato juice

Reference: 205.606(d) Colors derived from agricultural products—Must not be produced using synthetic solvents and carrier systems or any artificial preservative

(14) 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)

Technical Report: [2015 TR - Colors \(all\)](#)

Petition(s): [2007 Petition](#)

Past NOSB Actions: [04/2007 NOSB recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

See the summary for **Colors - Beet juice extract** above for questions pertaining to all 17 colors.

Colors - Red cabbage extract color

Reference: 205.606(d) Colors derived from agricultural products—Must not be produced using synthetic solvents and carrier systems or any artificial preservative

(15) Red cabbage extract color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)

Technical Report: [2015 TR - Colors \(all\)](#)

Petition(s): [2007 Petition](#)

Past NOSB Actions: [04/2007 NOSB recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

See the summary for **Colors - Beet juice extract** above for questions pertaining to all 17 colors.

Colors - Red radish extract color

Reference: 205.606(d) Colors derived from agricultural products—Must not be produced using synthetic solvents and carrier systems or any artificial preservative

(16) Red radish extract color (pigment CAS #'s: 528-58-5, 528-53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)



Technical Report: [2015 TR - Colors \(all\)](#)

Petition(s): [2007 Petition](#)

Past NOSB Actions: [04/2007 NOSB recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

See the summary for **Colors - Beet juice extract** above for questions pertaining to all 17 colors.

Colors - Saffron extract color

Reference: 205.606(d) Colors derived from agricultural products—Must not be produced using synthetic solvents and carrier systems or any artificial preservative

(17) Saffron extract color (pigment CAS #1393-63-1).

Technical Report: [2015 TR - Colors \(all\)](#)

Petition(s): [2007 Petition](#)

Past NOSB Actions: [04/2007 NOSB recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

See the summary for **Colors - Beet juice extract** above for questions pertaining to all 17 colors.

Colors - Turmeric extract color

Reference: 205.606(d) Colors derived from agricultural products - Must not be produced using synthetic solvents and carrier systems or any artificial preservative

(18) Turmeric extract color (CAS #458-37-7)

Technical Report: [2015 TR - Colors \(all\)](#)

Petition(s): [2007 Petition](#)

Past NOSB Actions: [04/2007 NOSB recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

See the summary for **Colors - Beet juice extract** above for questions pertaining to all 17 colors.



Dillweed oil

Reference: 205.606(e) Dillweed oil (CAS # 8006-75-5)

Technical Report: none

Petition(s): [2006 Petition](#)

Past NOSB Actions: [2007 NOSB recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

As of February 2014, a review of the USDA list of certified operations (2013 data) showed 380 organic crops certificates listing dill and 5 organic handling certificates listing dillweed oil or dill oil. As of February 2014, the website 606organic.com and the OTA Organic Pages both list suppliers of organic dillweed oil. Based on this information the handling subcommittee believes sufficient supply may be available to remove this material from 205.606.

1. The Handling Subcommittee requests that the public provide comment regarding the current use of and commercial demand for dillweed oil in organic products and provide comments on the impact that removing it from 205.606 would have on organic business and/or organic products.
2. Has the industry attempted to locate organic sources of dillweed oil and with what degree of success?
3. Are there other ingredients with suitable flavor profiles that could be used in place of dillweed oil, given adequate transition time for ingredient inventory and label depletion?
4. In what organic products is non-organic dillweed oil currently used, and what are the specific reasons for its necessity in these products?

Fish oil

Reference: 205.606(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

Technical Report: 2015 TR in development

Petition(s): [2007 Petition](#)

Past NOSB Actions: [04/2007 NOSB recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

1. What are the primary geographic sources of Fish oil and primary fish species harvested for purpose



of oil extraction?

2. Are there conservation and environmental issues surrounding harvest of wild caught fish for fish oil?
3. What is the manufacturing and purification process?
4. Is there a mandatory standard for fish oil purity with limits on contaminants dioxins and PCB's for example? How is purity assessed?
5. Is the Voluntary Standard from the Council of Responsible Nutrition (CRN) for contaminant limits still in effect?
6. What is the most current research on plant-derived alternatives such as flax and chia and how comparable are they to the Omega 3 in fish and algal oils?

Fructooligosaccharides

Reference: 205.606(h) Fructooligosaccharides (CAS # 308066-66-2)

Technical Report: [2006 TAP](#); [2015 TR](#)

Petition(s): [2006 Petition](#)

Past NOSB Actions: [04/2007 NOSB recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

1. Input is requested on ancillary substances that may be part of fructooligosaccharides formulations. Potential ancillaries identified in the TR include residues of processing aids such as glucose, sucrose, calcium gluconate, glucose oxidase enzyme, catalase enzyme, or ethyl alcohol. Manufacturers of fructooligosaccharides, organic handlers and material review organization are urged to send in brand names and specification sheets of products in use so that specific ancillary substances can be identified.
2. Input is requested regarding the current use of and commercial demand for fructooligosaccharides in organic products and comments on the impact that removing it from 205.606 would have on organic business and/or organic products.
3. A review of 2013 USDA database of certified operations and the websites [theorganicpages.com](#) and [606organic.com](#) in February 2015 revealed no organic sources for fructooligosaccharides (FOS). Has the industry attempted to locate or develop organic sources of FOS and with what degree of success?
4. Are there other ingredients with suitable functionality and sufficient supply that could be used in place of fructooligosaccharides, given adequate transition time for ingredient inventory and label depletion?



5. In what organic products are non-organic fructooligosaccharides currently used, and what are the specific reasons for its necessity in these products?

Galangal, frozen

Reference: 205.606(i) Galangal, frozen

Technical Report: none

Petition(s): [2006 Petition](#)

Past NOSB Actions: [04/2007 NOSB recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

As of February 2014, a review of the USDA list of certified operations (2013 data) showed 380 organic crops certificates listing galangal (in the US and Southeast Asia) 2 organic handling certificates listing frozen galangal. As of February 2014, the website www.606organic.com listed no suppliers of organic frozen galangal but the OTA Organic Pages list 1 supplier of organic frozen galangal. Based on this information the handling subcommittee believes sufficient supply may be available to remove this material from 205.606.

1. The Handling Subcommittee requests that the public provide comment regarding the current use of and commercial demand for frozen galangal in organic products and provide comments on the impact that removing it from 205.606 would have on organic business and/or organic products.
2. Has the industry attempted to locate organic sources of frozen galangal and with what degree of success?
3. Are there other ingredients with suitable flavor profiles that could be used in place of frozen galangal, given adequate transition time for ingredient inventory and label depletion?
4. In what organic products is non-organic frozen galangal currently used, and what are the specific reasons for its necessity in these products?

Gelatin

Reference: 205.606(j) Gelatin (CAS # 9000-70-8)

Technical Report: [2002 TAP](#)

Petition(s): [2001 Petition](#); [2007 Petition](#)

Past NOSB Actions: [05/2002 NOSB recommendation for addition to the National List](#); [10/2010 NOSB sunset recommendation](#)



Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

NONE

Gums: (Arabic, Guar , Locust bean , and Carob bean)

Reference: 205.606(k) Gums - water extracted only (Arabic; Guar; Locust bean; and Carob bean)

Technical Report: [1995 TAP](#)

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

The HS is aware of organically grown Guar and Locust Bean Gums. Is there enough source of these organic gums to remove them from the list

Inulin-oligofructose enriched

Reference: 205.606(l) Inulin-oligofructose enriched (CAS # 9005-80-5)

Technical Report: [2015 TR](#)

Petition(s): [2007 Petition](#)

Past NOSB Actions: [04/2007 recommendation](#); [2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

1. Input is requested on ancillary substances that may be part of Inulin-oligofructose enriched formulations. Potential ancillaries identified in the TR include residues of processing aids such as glucose, sucrose, calcium gluconate, glucose oxidase enzyme, catalase enzyme, or ethyl alcohol (from the TR of fructooligosaccharides). Manufacturers of Inulin-oligofructose enriched, organic handlers and material review organization are urged to send in brand names and specification sheets of products in use so that specific ancillary substances can be identified.
2. Input is requested on the current use of and commercial demand for Inulin-oligofructose enriched in organic products and comments on the impact that removing it from 205.606 would have on



organic business and/or organic products.

3. A review of 2013 USDA database of certified operations and the websites theorganicpages.com and 606organic.com in February 2015 revealed no sources for Inulin Oligofructose Enriched specifically, however there were 32 organic certificates for operations handling Inulin (operations were concentrated in the US, Mexico and China). Has the industry attempted to locate or develop organic sources of Inulin-oligofructose enriched and with what degree of success?
4. Are there other ingredients with suitable functionality and sufficient supply that could be used in place of Inulin-oligofructose enriched, given adequate transition time for ingredient inventory and label depletion? Specifically, is it possible to use organic inulin along with non-organic fructooligosaccharides that are already listed on §205.606 in place of non-organic Inulin Oligofructose Enriched?

Kelp

Reference: 205.606(m) Kelp—for use only as a thickener and dietary supplement

Technical Report: [1995 TAP](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

The HS is considering removing the annotation, since some types of kelp are used as flavoring and there appears to be little basis for the reason for the annotation. In light of separate listings for Kombu and Wakame, does this annotation make sense?

Konjac flour

Reference: 205.606(n) Konjac flour (CAS # 37220-17-0)

Technical Report: None

Petition(s): [2001 Petition](#)

Past NOSB Actions: [05/2002 NOSB minutes](#) (determined to be agricultural); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: 2007 Interim Rule ([72 FR 35137](#)); Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017



Additional information requested by NOSB

1. Is organically grown Konjac flour available?
2. In what unique situations is Konjac flour a better choice than an organic alternative such as potato flour?

Lecithin -de-oiled

Reference: 205.606(o) Lecithin – de-oiled

Technical Report: [1995 TAP](#); [2009 TR](#)

Petition(s): [Lecithin, bleached \(remove 2008\)](#)

Past NOSB Actions: [04/1995 minutes and vote](#); [05/2009 recommendation \(remove from 605b\)](#); [05/2009 Recommendation \(amend 606\)](#)

Recent Regulatory Background: Annotation change effective 03/15/2012 ([77 FR 8089](#))

Sunset Date: 03/15/17

Additional information requested by NOSB

1. Has the supply of dry forms of organic unbleached lecithin increased sufficiently since 2009 that this can be removed from the list?
2. The 2009 Technical Report refers to at least several ancillary substances: vegetable oil as a carrier and other "fluidizing additives". Please submit spec sheets or names of any ancillary substances that may be used with de-oiled lecithin formulations.

Lemongrass

Reference: 205.606(p) Lemongrass—frozen.

Technical Report: N/A

Petition(s): [2006 Petition](#)

Past NOSB Actions: [04/2007 recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

As of February 2014 a review of the USDA list of certified operations (2013 data) showed 73 organic crops certificates listing lemongrass but no organic handling certificates listing frozen lemongrass specifically. As of February 2014 606organic.com and the OTA Organic Pages do not list any suppliers of organic frozen lemongrass but did list 8 suppliers of other organic lemongrass products. Based on this



information the handling subcommittee believes sufficient supply may be available to remove this material from 205.606.

1. The Handling Subcommittee requests that the public provide comment regarding the current use of and commercial demand for frozen lemongrass in organic products and provide comments on the impact that removing it from 205.606 would have on organic business and/or organic products.
2. Has the industry attempted to locate organic sources of frozen lemongrass and with what degree of success?
3. Are there other ingredients with suitable flavor profiles that could be used in place of frozen lemongrass, given adequate transition time for ingredient inventory and label depletion?
4. In what organic products is non-organic frozen lemongrass currently used, and what are the specific reasons for its necessity in these products?

Orange pulp, dried

Reference: 205.606(q) Orange pulp, dried

Technical Report: N/A

Petition(s): [2008 Petition](#)

Past NOSB Actions: [11/2008 NOSB recommendation for addition to the National List](#)

Recent Regulatory Background: Added to NL effective 03/15/2012 ([77 FR 8089](#))

Sunset Date: 03/15/17

Additional information requested by NOSB

As of February 2014 a review of the USDA list of certified operations (2013 data) showed 304 organic crops certificates listing oranges and 13 organic handling certificates listing orange pulp or dried oranges. No organic handling certificates specifically listed dried orange pulp. As of February 2014 606organic.com and the OTA Organic Pages do not list any suppliers of organic dried orange pulp. Based on this information the handling subcommittee believes sufficient supply may be available to remove this material from 205.606.

1. The Handling Subcommittee requests that the public provide comment regarding the current use of and commercial demand for dried orange pulp in organic products and provide comments on the impact that removing it from 205.606 would have on organic business and/or organic products.
2. Has the industry attempted to locate organic sources of dried orange pulp and with what degree of success?
3. Are there other ingredients with suitable functional profiles that could be used in place of dried orange pulp, given adequate transition time for ingredient inventory and label depletion?



4. In what organic products is non-organic dried orange pulp currently used, and what are the specific reasons for its necessity in these products?
5. Given the availability of organic oranges, why have manufacturers of dried orange pulp been unable to produce organic dried orange pulp?

Orange shellac

Reference: 205.606(r) Orange shellac-unbleached (CAS # 9000-59-3)

Technical Report: [2002 TAP](#); [2014 TR](#)

Petition(s): N/A

Past NOSB Actions: [10/1999 NOSB minutes and vote](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

Input is requested on ancillary substances that may be part of shellac formulations. Potential ancillaries identified in the TR include residues of processing aids such as sodium carbonate, emulsifiers, plasticizers (such as vegetable oils and fatty acids), coloring agents, and de-colorization agents. Organic handlers and Material Review Organization are urged to send in brand names and specification sheets of products in use so that specific ancillary substances can be identified.

Pectin

Reference: 205.606(s) Pectin (non-amidated forms only)

Technical Report: [1995 TAP](#); [2009 TR](#); [2010 supplemental TR](#); 2015 TR in development

Petition(s): [2005 Petition – low methoxy pectins](#)

Past NOSB Actions: [04/1995 minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 NOSB recommendation on petition](#)

Recent Regulatory Background: Sunset Review effective 06/27/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

Are there any ancillary substances used in pectin?

Peppers (Chipotle chile)



Reference: 205.606(t) Peppers (Chipotle chile)

Technical Report: N/A

Petition(s): [2006/2007 Petition](#)

Past NOSB Actions: [04/2007 NOSB recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

As of February 2014 a review of the USDA list of certified operations (2013 data) showed 618 organic crops certificates listing peppers or chilies (although only 1 specifically listed chipotle) and 20 organic handling certificates listing chipotle products. . As of February 2014 606organic.com listed no suppliers of organic chipotle peppers but the OTA Organic Pages list 3 suppliers of chipotle and 17 suppliers of chilies or peppers. Based on this information the handling subcommittee believes sufficient supply may be available to remove this material from 205.606.

The Handling Subcommittee requests that the public provide comment regarding the current use of and commercial demand for chipotle chile pepper in organic products and provide comments on the impact that removing it from 205.606 would have on organic business and/or organic products.

- 1.The Handling Subcommittee requests that the public provide comment regarding the current use of and commercial demand for chipotle chile pepper in organic products and provide comments on the impact that removing it from 205.606 would have on organic business and/or organic products.
- 2.Has the industry attempted to locate organic sources of chipotle chile pepper and with what degree of success?
3. Are there other ingredients with suitable flavor profiles that could be used in place of chipotle chile pepper, given adequate transition time for ingredient inventory and label depletion?
- 4.In what organic products is non-organic chipotle chile pepper currently used, and what are the specific reasons for its necessity in these products?

Seaweed, Pacific kombu

Reference: 205.606(u) Seaweed, Pacific kombu

Technical Report: N/A

Petition(s): [2007 Petition](#)

Past NOSB Actions: [05/2008 NOSB recommendation](#)

Recent Regulatory Background: Added to NL effective 03/15/12 ([77 FR 8089](#))

Sunset Date: 03/15/17

Additional information requested by NOSB



NONE

Starches; cornstarch, sweet potato

Reference: 205.606(v)

(1) Cornstarch (native)

(2) Sweet potato starch - for bean thread production only

Technical Report: [1995 TAP - Cornstarch](#)

Petition(s): N/A – Cornstarch; 2007 Petition - Sweet Potato Starch

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [10/2010 sunset review Sweet potato starch](#); [10/2010 sunset recommendation on cornstarch](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

1. The HS is would like to know if organic cornstarch is available.
2. Has organic sweet potato starch become commercially available since the last sunset review?

Turkish bay leaves

Reference: 205.606(x) Turkish bay leaves

Technical Report: N/A

Petition(s): [2006 Petition](#)

Past NOSB Actions: [04/2007 recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

As of February 2014 a review of the USDA list of certified operations (2013 data) showed 5 organic crops certificates listing bay leaves and 19 organic handling certificates listing bay leaves. Of the previously mentioned operations, 7 certificates specifically listed *Laurus Nobilis* the scientific name for Turkish bay leaves. As of February 2014 the website 606organic.com listed no suppliers of organic bay leaves but the OTA Organic Pages list 5 suppliers of bay leaves (but none specifying “Turkish”). Based on this information the handling subcommittee believes sufficient supply may be available to remove this material from 205.606.

1. The Handling Subcommittee requests that the public provide comment regarding the current use of



and commercial demand for Turkish bay leaves in organic products and provide comments on the impact that removing it from 205.606 would have on organic business and/or organic products.

2. Has the industry attempted to locate organic sources of Turkish bay leaves and with what degree of success?
3. Are there other ingredients with suitable flavor profiles that could be used in place of Turkish bay leaves, given adequate transition time for ingredient inventory and label depletion?
4. In what organic products is non-organic Turkish bay leaves currently used, and what are the specific reasons for its necessity in these products?

Wakame seaweed

Reference: 205.606(y) Wakame seaweed (*Undaria pinnatifida*)

Technical Report: N/A

Petition(s): [2007 Petition](#)

Past NOSB Actions: [04/2007 NOSB recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

NONE

Whey protein concentrate

Reference: 205.606(z) Whey protein concentrate

Technical Report: 2015 TR in development

Petition(s): [2007 Petition](#)

Past NOSB Actions: [05/2007 NOSB recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

1. Input is requested on ancillary substances that may be part of whey protein concentrate formulations. Manufacturers of whey protein concentrate, organic handlers and material review organization are urged to send in brand names and specification sheets of products in use so that specific ancillary substances can be identified.
2. Input is requested on the current use of and commercial demand for whey protein concentrate in



organic products and comments on the impact that removing it from 205.606 would have on organic business and/or organic products.

3. A review of 2013 USDA database of certified organic operations revealed 8 sources whey protein concentrate and 32 sources of whey. The websites theorganicpages.com and 606organic.com accessed in February 2015 revealed 8 sources whey products (1 specifically listing whey protein concentrate) and 2 sources of whey protein concentrate respectively. Is there sufficient supply of whey protein concentrate and what has the industry attempted to develop organic sources of whey protein concentrate and with what degree of success?
4. Are there other ingredients with suitable functionality and sufficient supply that could be used in place of whey protein concentrate, given adequate transition time for ingredient inventory and label depletion?
5. In what organic products is non-organic whey protein concentrate currently used, and what are the specific reasons for its necessity in these products?

**National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal & Checklist - Exhaust Gas
December 16, 2014**

Summary of Proposed Action:

Exhaust gas from internal combustion engines has been petitioned for use for control of burrowing rodents, under §205.601 Synthetic substances allowed for use in organic crop production. Exhaust gas contains carbon monoxide, which diminishes the oxygen-carrying capacity of red blood cells in the target rodents, and carbon dioxide, which displaces oxygen from the atmosphere of the burrow, leading to asphyxiation of the rodent. The Crops Subcommittee did not support this petition because of concerns about potential impacts on non-target species, especially threatened and endangered species as well as potential effects on soil microorganisms.

Background:

The original petition was for "Carbon Monoxide" and was sent to the NOP on 4/19/12. The Crops Subcommittee found the petition incomplete on 12 04 12 and asked the petitioner for additional information. The petitioner submitted a petition addendum on 2 22 13. The petition was determined sufficient by the Crops Subcommittee on 1 21 14. A technical review of exhaust gas for use as a rodenticide was received October 2014.

In an April 2011 sunset review, sulfur dioxide for use as a rodenticide failed to be relisted by a vote of 9 to 0 and was taken off the National List. In December 2011 a petition to add propane gas to the National List as a rodenticide was denied by a vote of 0 in favor and 14 opposed.

Evaluation Criteria (see attached checklist for criteria in each category)

1. Impact on Humans and Environment
2. Essential & Availability Criteria
3. Compatibility & Consistency

Criteria Satisfied?

- | | | |
|------------------------------|--|------------------------------|
| <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No | <input type="checkbox"/> N/A |
| <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No | <input type="checkbox"/> N/A |
| <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No | <input type="checkbox"/> N/A |

Substance Fails Criteria Category: 1, 2, 3

Subcommittee Action & Vote

Classification Motion: Move to classify Exhaust Gas as synthetic

Motion by: Francis Thicke

Seconded by: Harold Austin

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

Listing Motion: Move to list Exhaust Gas at §205.601 Synthetic substance allowed for use in organic crop production.

Motion by: Francis Thicke

Seconded by: Harold Austin

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

Proposed Annotation (if any): none

NOSB Evaluation Criteria for Substances Added To the National List – Crops

Category 1. Adverse impacts on humans or the environment?

Substance: Exhaust Gas

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is there a probability of environmental contamination during use or misuse? [§6518(m)(3)]	X			TR lines 299-302: “High volume releases of exhaust gases to the atmosphere are associated with a variety of adverse environmental impacts. Specifically, exhaust gas emissions contribute to air pollution, and four of its components (particulate matter, carbon monoxide, nitrogen oxides and sulfur dioxide) are criteria pollutants according to US EPA (2012.
2. Is there a probability of environmental contamination during, manufacture or disposal? [§6518(m)(3)]	X			Exhaust gas is “manufactured” by the burning of fuel in internal combustion engines. As noted in #1 above, the manufacture of exhaust gas contributes to air pollution.
3. Are there any adverse impacts on biodiversity? (§205.200)	X			If other animals are present in the rodent burrows, they could also be affected: TR 353-354: “Non-target animals may also dwell underground and be exposed to exhaust gas following its release in the treated area. Potentially affected non-target animals include other mammals, birds, reptiles, amphibians, invertebrates (e.g., bumble bees and earthworms), slugs, snails, protozoa and nematodes.” The TR (lines 354-355) states “Limited data is available regarding the effects of exhaust gas on soil organisms.”
4. Does the substance contain inerts classified by EPA as ‘inerts of toxicological concern’? [§6517(c)(1)(B)(ii)]		X		
5. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]		X		TR lines 337-338: “no interactions between exhaust gas or its component chemicals and other common substances used in agriculture were identified.”

6. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]	X		The CO is toxic (as it is intended to be). Long-term inhalation of exhaust gas can be harmful to health (TR lines 259-269). When exhaust gas is injected into rodent burrows the exposure to humans would be minimal, but there would be exposure of toxic compounds to non-target organisms, as noted in #3 above.
7. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]	X		<p>The exhaust gases that escape the rodent burrow after treatment disperse into the atmosphere where they are subject to many chemical transformations in the atmosphere (TR lines 219-254). TR lines 225-227: "CO₂ can be long-lived in the atmosphere, with half-lives ranging from five to 200 years, depending on the model parameters (IPCC, 2001; Moore, 1994)."</p> <p>In the soil, CO can be converted to CO₂ by soil microorganisms (TR line 224). Information is not available on other possible reactions in the soil.</p>
8. Would the use of the substance be harmful to human health or the environment? [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)]		X	Similar to, or less than, being around standard vehicles with internal combustion engines.
9. Are there adverse biological and chemical interactions in the agro-ecosystem? [§6518(m)(5)]		X	TR lines 337-338: "no interactions between exhaust gas or its component chemicals and other common substances used in agriculture were identified."
10. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)]	X		TR lines 352-355: "Non-target animals may also dwell underground and be exposed to exhaust gas following its release in the treated area. Potentially affected non-target animals include other mammals, birds, reptiles, amphibians, invertebrates (e.g., bumble bees and earthworms), slugs, snails, protozoa and nematodes. Limited data is available regarding the effects of exhaust gas on soil organisms."

NOSB Evaluation Criteria for Substances Added To the National List - Crops

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

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]		X		
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			It is “manufactured” by burning liquid fuel in an internal combustion engine.
3. 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		
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		
5. Is there a natural source of the substance? [§ 205.600(b)(1)]		X		
6. Is there an organic substitute? [§205.600(b)(1)]		X		
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]		X		
8. Are there any alternative substances? [§6518(m)(6)]	X			Vitamin D3 is on the National List §205.601(g). Vitamin D3 (cholecalciferol) produces hypercalcemia (i.e., excessive levels of calcium in the blood). Rodents generally die within two days following ingestion of a lethal dose (TR 473-474).
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]	X			Traps, barriers, natural predation, and other physical control methods can be used (TR lines 505-554).

NOSB Evaluation Criteria for Substances Added To the National List - Crops

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

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic farming and handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]		X		Internal combustion engines are used in organic farming. However, injecting exhaust gases into the soil profile is not a standard kind of practice in organic farming.
2. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]		X		Internal combustion engines are used in sustainable farming systems. However, injecting exhaust gases into the soil profile might be considered contrary to sustainable agriculture
3. If used in livestock feed or pet food, Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]			X	
4. If used in livestock feed or pet food, Is the primary use as a preservative? [§205.600(b)(4)]			X	
5. If used in livestock feed or pet food, Is the primary use to recreate or improve flavors, colors, textures, or nutritive value lost in processing (except when required by law)? [§205.600(b)(4)]			X	
6. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i);		X		There can be small amounts of sulfur compounds in exhaust gas, but they are not active ingredients.
copper and sulfur compounds				
toxins derived from bacteria		X		
pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals		X		
livestock parasiticides and medicines		X		
production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers		X		

**National Organic Standards Board
Crops Subcommittee
Petitioned Material Checklist - Calcium Sulfate (synthetic)
January 6, 2015**

Summary of Proposed Action:

The National Organic Standards Board (NOSB) received a petition from the American Coal Ash Association to add synthetic calcium sulfate (gypsum) to the National List of Approved Substances at §205.601. This substance is also known as flue gas desulfurization (FGD) gypsum, with the source being the FGD systems installed to control sulfur dioxide emissions from coal-fired power plants.

Background:

The petition for calcium sulfate was sufficiently complete so that the subcommittee chose not to request a Technical Report. The petition raised two key points. First, FGD gypsum is a by-product of energy production and not all of this by product is able to be used. Thus, unused FGD gypsum ends up in landfills. Secondly, accessibility of mined gypsum in states where it is not mined is an important barrier for farmers, as it is difficult to acquire it at a reasonable price.

There is no doubt that the use of gypsum is beneficial for many soils and crops. It is a very abundant mined mineral, with mines in more than 20 states, and most mining concentrated in the western United States. Other non-synthetic substances can easily substitute for gypsum if necessary, including limestone, bone meal, and elemental sulfur, as well as organic matter from compost or cover cropping.

The petition states that the process used to produce FGD gypsum produces a relatively pure product, but it does not say what contaminants might be in the product. Meanwhile, an Environmental Protection Agency (EPA) factsheet says, “[T]he amount and types of trace materials and unreacted sorbents found in the gypsum can vary among power plants and among mines. If you are considering using FGD gypsum products as a soil amendment, it is appropriate that the chemical analysis of the material be provided by all commercial sources to support decision-making in their use, as States may have regulations and standards that need to be followed.”¹ A study by the Electric Power Research Institute found the following elements in FGD gypsum in varying concentrations: aluminum, arsenic, boron, barium, beryllium, calcium, cadmium, cobalt, chromium, copper, iron, mercury, potassium, lithium, magnesium, manganese, molybdenum, sodium, nickel, phosphorus, lead, sulfur, tin, selenium, silicon, strontium, titanium, vanadium, and zinc.²

Based on this evidence demonstrating the potential for contamination, the NOSB, in following EPA’s recommendation, would need to specify allowable sources or allowable levels of contaminants if the Board chooses to approve the petition. Nevertheless, due to the many alternatives to synthetic gypsum that exist, the subcommittee believes that it is not essential for organic farming and that this criterion out-weighs the recycling benefits that are associated with the use of FGD gypsum.

¹ EPA factsheet, Agricultural Uses for Flue Gas Desulfurization (FGD) Gypsum.
<http://nepis.epa.gov/Exe/ZyPDF.cgi/P1001II9.PDF?Dockey=P1001II9.PDF>

² Electric Power Research Institute, 2011. Composition and Leaching of FGD Gypsum and Mined Gypsum. (p.A-1, 2; p.33-34)
<http://www.epri.com/abstracts/Pages/ProductAbstract.aspx?ProductId=00000000001022146>

Evaluation Criteria

- 1. Impact on Humans and Environment
- 2. Essential & Availability Criteria
- 3. Compatibility & Consistency

Criteria Satisfied?

- Yes No N/A
- Yes No N/A
- Yes No N/A

Substance Fails Criteria Category: 2, 3

Subcommittee Action & Vote

Classification Motion: Motion to classify Calcium Sulfate, produced by the flue gas desulfurization (FGD) process as petitioned as synthetic

Motion by: Zea Sonnabend

Seconded by: Harold Austin

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

Listing Motion: Motion to add Calcium Sulfate, produced by the flue gas desulfurization (SGD) process as petitioned to 205.601

Motion by: Zea Sonnabend

Seconded by: Harold Austin

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

Proposed Annotation (if any): none

Approved by Zea Sonnabend, Subcommittee Chair, to transmit to NOSB January 6, 2015

NOSB Evaluation Criteria for Substances Added To the National List - Crops

Category 1. Adverse impacts on humans or the environment? Calcium Sulfate - synthetic

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is there a probability of environmental contamination during use or misuse? [§6518(m)(3)]		X		This substance helps prevent environmental contamination from industrial pollution.
2. Is there a probability of environmental contamination during, manufacture or disposal? [§6518(m)(3)]		X		
3. Are there any adverse impacts on biodiversity? (§205.200)		X		
4. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517(c)(1)(B)(ii)]		X		
5. Is there potential for detrimental chemical interaction with other materials used in		X		

organic farming systems? [§6518(m)(1)]				
6. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]		X		See page 1, paragraph 4.
7. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		X		
8. Would the use of the substance be harmful to human health or the environment? [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)]		X		“Studies of gypsum mine workers have reported no lung fibrosis or pneumoconiosis...” (from NIEHS report included with the petition, page 21).
9. Are there adverse biological and chemical interactions in the agro-ecosystem? [§6518(m)(5)]		X		
10. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)]		X		

Category 2. Is the Substance Essential for Organic Production? Calcium Sulfate - synthetic

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]		X		
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			
3. 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	
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		
5. Is there a natural source of the substance? [§ 205.600(b)(1)]	X			There is abundant nonsynthetic gypsum.
6. Is there an organic substitute? [§205.600(b)(1)]		X		
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]	X			mined gypsum, limestone, bone meal
8. Are there any alternative substances? [§6518(m)(6)]	X			see above
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]	X			Compost and cover cropping can have a positive effect on soils and provide some calcium and sulfur.

NOSB Evaluation Criteria for Substances Added To the National List - Crops

Category 3. Is the substance compatible with organic production practices? Calcium Sulfate - synthetic:

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic farming and handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]		X		Organic farming regulations and philosophy favor using non-synthetic substances when available over synthetic.
2. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]		X		Because ample non-synthetic gypsum is available, and price and convenience are not among the evaluation criteria, this substance does not appear to be compatible.
3. If used in livestock feed or pet food, is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]			X	
4. If used in livestock feed or pet food, is the primary use as a preservative? [§205.600(b)(4)]			X	
5. If used in livestock feed or pet food, is the primary use to recreate or improve flavors, colors, textures, or nutritive value lost in processing (except when required by law)? [§205.600(b)(4)]			X	
6. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i);	X			
copper and sulfur compounds				
toxins derived from bacteria		X		
pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals		X		
livestock parasiticides and medicines		X		
production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers		X		

**National Organic Standards Board
Crops Subcommittee
Petitioned Material Checklist – 3-decen-2-one
January 27, 2015**

Summary of Proposed Action:

The National Organic Standards Board's (NOSB) Crops Subcommittee received a petition from AMVAC Chemical Corporation to add 3-decen-2-one to the National List of Approved Substances at §205.601 for use as a plant growth regulator. Specifically, the petition requests approval for the use of the substance on potatoes as a sprout inhibitor. 3-decen-2-one is a synthetic substance used in post-harvest handling of raw agricultural products. The material is manufactured using n-heptaldehyde (produced from castor oil) and acetone and is applied through thermal fogging in a post-harvest closed system storage facility.

Background:

The NOSB Crops Subcommittee found the petition submitted by AMVAC Chemical Company to be complete and did not request a technical report (TR). In the petition, the primary argument for listing the material under §205.601 is that it extends the potato shelf life, which is particularly advantageous for the export market. The use of 3-decen-2-one does not negatively impact the potato or the potato processing quality, nor does it reduce sugar levels.

Although not as effective as 3-decen-2-one, clove oil is listed as an alternative to the use of this synthetic. In addition, proper harvest, handling and cold storage techniques (to maintain optimal temperature, humidity, and ventilation) can also be used to help delay dormancy break.

Due to the availability of non-synthetic alternatives on the market, the Crops Subcommittee is in agreement that the material fails the *essentiality, compatibility and consistency* criteria and should not be allowed for use in organic production.

Evaluation Criteria (see attached checklist for criteria in each category)

	Criteria Satisfied?		
1. Impact on Humans and Environment	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2. Essential & Availability Criteria	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> N/A
3. Compatibility & Consistency	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> N/A

Substance Fails Criteria Category: 2, 3

Subcommittee Action & Vote

Classification Motion: Move to classify 3-decene-2-one (CAS # 10519-33-2) as petitioned as synthetic

Motion by: Carmela Beck

Seconded by: Colehour Bondera

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

Listing Motion: Move to list 3-decen-2-one on section §205.601 of the National List

Motion by: Carmela Beck

Seconded by: Harold Austin

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

Proposed Annotation (if any): none

Approved by, Zea Sonnabend, Subcommittee Chair, to transmit to NOSB January 27, 2015

NOSB Evaluation Criteria for Substances Added To the National List - Crops

Category 1. Adverse impacts on humans or the environment?

Substance: 3-decen-2-one

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is there a probability of environmental contamination during, use or misuse? [§6518(m)(3)]	X			Proposed indoor use only on potatoes in post-harvest storage. Applied by fogging, so environmental contamination is likely when fumigation chamber is opened.
2. Is there a probability of environmental contamination during, manufacture or disposal? [§6518(m)(3)]	X			Use according to label instructions. Raw material acetone: extremely flammable and explosive. Toxic through inhalation, ingestion, dermal exposure to eye, skin, respiratory system, central nervous system. ¹ Raw material heptaldehyde: volatile, flammable, causes serious eye damage, and is irritating to skin and respiratory system. Must be treated as hazardous waste. Very toxic to aquatic system, with long term effects. ²
3. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517(c)(1)(B)(ii)]		X		
4. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]		X		Material will be used for post-harvest storage of potatoes; the material is not expected to be utilized alongside other materials (Petition; page 9).
5. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]		X		No data available about most impacts. Toxic to aquatic life. ³ May be irritating to skin and eyes. ⁴
6. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		X		According to petition, it volatilizes.
7. Would the use of the substance be		X		3-decen-2-one is found in many common

¹ <http://mfc.engr.arizona.edu/safety/MSDS%20FOLDER/Acetone.pdf>

² <http://img1.guidechem.com/msdspd/111-71-7.pdf>

³

<http://www.sigmaaldrich.com/MSDS/MSDS/DisplayMSDSPage.do?country=US&language=en&productNumber=W353205&brand=ALDRICH&PageToGoToURL=http%3A%2F%2Fwww.sigmaaldrich.com%2Fcatalog%2Fproduct%2Faldrich%2FW353205%3Fflang%3Den>

⁴ http://www.bedoukian.com/product_images/mxts/613.txt

harmful to human health or the environment? [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)]				foods such as yogurt & tuna; the chemically synthesized form is approved as a direct food additive by the FDA & has been determined to be GRAS by FEMA (Petition; page 11) Label: Causes skin irritation and substantial but temporary eye injury. Harmful if inhaled.
8. Are there adverse biological and chemical interactions in the agro-ecosystem, including biodiversity? [§6518(m)(5)]		X		EPA did not evaluate impacts on non-target organisms because of the use pattern. Toxic to aquatic life with long lasting effects. ⁵
9. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)]		X		Data not available. Exhibit I (Petition; page 78) pertains to human toxicology.

Category 2. Is the Substance Essential for Organic Production? Substance: 3-decen-2-one

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]		X		
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			
3. 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			Acetone and heptaldehyde are reactants.
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		It occurs in small quantities in some fruits and yogurt.
5. Is there a natural source of the substance? [§ 205.600(b)(1)]		X		Not a practical one.
6. Is there an organic substitute? [§205.600(b)(1)]		X		
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]	X			Essential oils including: clove, mint and caraway seed; Shortcomings include: residual activity of oils is very short (2-3 weeks); does not control sprouts longer than .5 cm; clove oil supply recently

5

<http://www.sigmaaldrich.com/MSDS/MSDS/DisplayMSDSPage.do?country=US&language=en&productNumber=W353205&brand=ALDRICH&PageToGoToURL=http%3A%2F%2Fwww.sigmaaldrich.com%2Fcatalog%2Fproduct%2Faldrich%2FW353205%3Flang%3Den>

				erratic; potato taste can be compromised; multiple applications required (Petition; page 12); sugars spike with multiple applications and can turn the potato chip an undesirable color (Petition; page 209).
8. Are there any alternative substances? [§6518(m)(6)]	X			Herbs, essential oils.
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]	X			Proper harvest, handling, and storage.

Category 3. Is the substance compatible with organic production practices? Substance: 3-decen-2-one

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic farming and handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]		X		Synthetic preservative. Organic emphasizes “management practices in preference to the use of off-farm inputs;” uses “cultural, biological, and mechanical methods, as opposed to using synthetic materials.” ⁶
2. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]		X		Prevents use of potatoes for seed.
3. If used in livestock feed or pet food, is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]			X	
4. If used in livestock feed or pet food, is the primary use as a preservative? [§205.600(b)(4)]			X	
5. If used in livestock feed or pet food, is the primary use to recreate or improve flavors, colors, textures, or nutritive value lost in processing (except when required by law)? [§205.600(b)(4)]			X	
6. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i);		X		
copper and sulfur compounds				
toxins derived from bacteria		X		
pheromones, soaps, horticultural oils,		X		

⁶ NOSB Principles of Organic Production and Handling. October 17, 2001.

fish emulsions, treated seed, vitamins and minerals				
livestock parasiticides and medicines		X		
production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers		X		

**National Organic Standards Board (NOSB)
Crops Subcommittee Report
Contaminated Input Plan
February 24, 2015**

A Plan for Contaminated Inputs

Colehour Bondera (Jay Feldman, previous NOSB member, assisted with earlier drafts)
NOSB/Crops Subcommittee

Overview

The NOP regulations at §205.203 require organic producers to add organic materials, while avoiding contamination with substances prohibited in organic production (emphasis added):

§205.203 Soil fertility and crop nutrient management practice standard.

(a) The producer must select and implement tillage and cultivation practices that maintain or improve the physical, chemical, and biological condition of soil and minimize soil erosion.

(b) The producer must manage crop nutrients and soil fertility through rotations, cover crops, and the application of plant and animal materials.

(c) The producer must manage plant and animal materials to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances.

Animal and plant materials include:

- (1) Raw animal manure, which must be composted unless it is:
 - (i) Applied to land used for a crop not intended for human consumption;
 - (ii) Incorporated into the soil not less than 120 days prior to the harvest of a product whose edible portion has direct contact with the soil surface or soil particles; or
 - (iii) Incorporated into the soil not less than 90 days prior to the harvest of a product whose edible portion does not have direct contact with the soil surface or soil particles;
- (2) Composted plant and animal materials produced through a process that:
 - (i) Established an initial C:N ratio of between 25:1 and 40:1; and
 - (ii) Maintained a temperature of between 131 °F and 170 °F for 3 days using an in-vessel or static aerated pile system; or
 - (iii) Maintained a temperature of between 131 °F and 170 °F for 15 days using a windrow composting system, during which period, the materials must be turned a minimum of five times.
- (3) Uncomposted plant materials.

Some specific impacts of concern from compost and manures derived from nonorganic operations include: heavy metals, antibiotic residues, residues of insecticides, herbicide residues, and residues of toxic chemicals that could affect soil microorganisms. The same concerns about heavy metals exist in some mined minerals, and in fish that may accumulate mercury or other metals. Concerns about pathogens often transfer over to animal by-products as well. This document and the attached spreadsheet describe the plan developed by the Crops Subcommittee for ensuring that inputs of organic matter do not result in contamination “of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances.”

Our approach is to look at off-site inputs based on feedstocks/pathways. For each, ask: What contaminants might be present here? Which would survive currently prescribed requirements for composting? If there are remaining contaminants known to persist through the composting process at any level, is there a way to restrict the source so that those contaminants would not be present? (e.g., ask a farmer whether arsenic is fed to poultry.) If there are remaining contaminants, do they exceed unavoidable residual contamination levels from a historical, but not current use, of a toxic material? Are there treatments that could be applied to the compost that can eliminate those contaminants?

Where we're going...

The subcommittee is trying to prioritize future work on this subject. The attached spreadsheet starts with a feedstock/pathway of concern as an approach to how to establish these priorities. For example, we might consider manure from a conventional farm. (Into how many separate categories does this need to be separated? Is poultry vs. other enough? Poultry/horse/cattle/other?)

1. What contaminants might be present?
2. Of the contaminants that might be present, which ones are likely to survive already prescribed treatment methods?
3. Of those that are likely to survive already prescribed treatment methods, which can be treated with other (easy) removal or avoidance methods?
 - a. Use those removal or avoidance methods.
 - b. If there are other contaminants, test for them. (Figure out a fair testing requirement.)

The spreadsheet consists of ten columns, with an additional column for experts in possible contamination and remediation for each possible input. Issues under consideration, as captured in the columns of the spreadsheet, include:

1. off-farm input,
2. source,
3. components of interest,
4. likely or possible contaminants,
5. ability to persist through composting process,
6. avoidance methods,
7. environmental fate of inputs when applied to soil,
8. loading rates,
9. efficacy of remediation, and
10. testing methods.

What assistance do we need?

We need assistance identifying feedstocks/pathways and determining how to separate them into categories that can be grouped.

- Inputs from organic growers would be most helpful.
- Expert agronomists, composters, scientists from testing laboratories and other fields can guide this effort.

We need help determining which contaminants are associated with which feedstocks/pathways.

- For pesticides, searches of labels can identify those used on each input.¹
- For fertilizers, some departments of agriculture have registries of fertilizer products that contain an analysis of each product, including heavy metal contaminants.²

¹ Labels for a given use and use site can be found through a search at <http://premier.cdms.net/webapls/> Pesticide recommendations can be found through state land grant universities or extension agencies. For example, <http://content.ces.ncsu.edu/chemical-weed-control.pdf>.

² See, for example, <http://agr.wa.gov/PestFert/Fertilizers/FertDB/Product1.aspx>.

- For livestock drugs, a veterinarian or livestock expert could identify drugs given to livestock that might appear in manure.
- For feed ingredients and additives, a livestock expert could help identify the range of ingredients and additives that might be found through wasted feed or manure residues.

We need assistance determining which contaminants can be removed by currently prescribed treatment methods.

- This needs to be researched for each contaminant. A lot of research has been done on the biodegradation of some pesticides and some drugs. Composting is frequently used for bioremediation, but sometimes requires additions, including humic acids or microorganisms, that would not ordinarily be present. Mulches would not be subject to the same conditions as materials for compost.
- U.S. Composting Council can help with identifying contaminants that survive composting. Other experts in compost quality will also be consulted.
- Scientists have done research on uptake of antibiotics in crops from manure and degradation of antibiotics in manure during composting.³

We need assistance identifying questions that can be asked to avoid contaminants that will not be removed by currently prescribed treatments.

- This is a question that should be posed for public comment along with the question of which off-farm inputs are used.
- The list of contaminants that would pass through ordinary treatment will help generate questions.

We need assistance identifying additional contamination removal methods –e.g., bacterial cultures that might be added to compost; fungi that might be used for mycoremediation.

- Bioremediation⁴
- Mycoremediation: ^{5 6}

We need assistance identifying low-cost test methods, for example, bioassays with clear definitions of adverse effects.

- A bioassay for clopyralid has been developed by Washington State University and Washington State Department of Ecology.⁷

³ Kumar K, Gupta SC, Baidoo SK, Chander Y, Rosen CJ (2005) Antibiotic uptake by plants from soil fertilized with animal manure. *J Environ Qual* 34:2082–2085.

http://www.prepacvpm.org/wordpress/resources/Exam_Topics_2012/2_EnvironHealth-Toxicology/6_Waste/AnimalAgWasteManagement/Antibiotic_Uptake_Plants.pdf Dolliver, Holly, Kumar, Kuldeep, Gupta, Satish, Sulfamethazine Uptake by Plants from Manure-Amended Soil. *JOENQ* 2007. 36:1224–1230.

<https://dl.sciencesocieties.org/publications/jeq/abstracts/36/4/1224> Holly Dolliver, Satish Gupta, and Sally Noll, Antibiotic degradation during manure composting. *J. Environ. Qual.* 37:1245–1253 (2008).

⁴ Pruden, Amy, DG Joakim Larsson, Alejandro Amézquita, Peter Collignon, Kristian K. Brandt, David W. Graham, James M. Lazorchak et al. "Management options for reducing the release of antibiotics and antibiotic resistance genes to the environment." *Environ Health Perspect* 121, no. 8 (2013): 878-885. <http://ehp.niehs.nih.gov/wp-content/uploads/121/8/ehp.1206446.pdf>.

⁵ <http://www.fungi.com/about-paul-stamets.html>, <http://www.fungi.com/product-detail/product/mycelium-running.html>.

⁶ Rigot, J.; Matsumura, F. Assessment of the rhizosphere competency and pentachlorophenol-metabolizing activity of a pesticide-degrading strain of *Trichoderma harzianum* introduced into the root zone of corn seedlings. *Journal of Environmental Science and Health Part B Pesticides Food Contaminants and Agricultural Wastes*. May, 2002. B37(3):201-210.

- A similar bioassay has been developed by Washington State University for aminopyralid.⁸
- North Carolina State University recommends a similar bioassay for all of the pyridine carboxylic acid herbicides –clopyralid, aminopyralid, and picloram.⁹
- Woods End Lab has also produced a bioassay for herbicide damage.¹⁰

A start

We don't need to do all those things at once. Instead, we can start with one –say, dairy cow manure. (If that's too limited, we can broaden the category.) The next step is to find experts who can help answer the above questions for dairy manure.

Meanwhile, we should also identify people who can help us identify the different categories of inputs we should work on over the course of the workplan.

While this is presented as a report on progress and direction, comments from the public are welcome and encouraged.

See table below.

Off-farm inputs	Source	Components of Interest	Possible/likely Contaminants	Persists through Composting?	Avoidance Methods	Environmental Fate in Soil	Loading Rates	Remediation	Testing Methods	Experts
Yard waste	Municipal collection or compost	Lawn clippings	Gasoline/oil from mowers	No						
			Fertilizers	Not the fertilizer ingredients, but heavy metal contaminants would persist.						
			Insecticides --label search	Some?	Ordinances restricting use					

⁷ <http://puyallup.wsu.edu/soilmgmt/Pubs/CloBioassay.pdf>.

⁸ <http://whatcom.wsu.edu/ag/aminopyralid/bioassay.html>.

⁹ http://www.ces.ncsu.edu/fletcher/programs/ncorganic/special-pubs/herbicide_carryover.pdf.

¹⁰ <https://woodsend.org/compost/herbicide-bioassay/>.

			Herbicides - -label search	Pyridine carboxylic acid herbicides.	Ordinanc es restrictin g use				Bioa ssay s.	US Compo sting Council
Dairy manur e	Conven tional dairy	Feces	Antibiotics, other drugs --list		Use Organic source. Other?					
			Pesticides -- label search	Pyridine carboxylic acid herbicides	Use Organic source. Other?				Bioa ssay s for herbi cide s.	
			Antibiotic resistance genes							
		Hay/ straw/ other bedding	Pesticides -- label search		Use Organic source. Other?					
		Grain/ feed	GMO grain		Use Organic source. Other?					
			Pesticides -- label search		Use Organic source. Other?					
			Feed additives		Use Organic source. Other?					
Dairy manur e	CAFO	Feces	Antibiotics, other drugs --list		Use Organic source. Other?					
			Pesticides -- label search	Pyridine carboxylic acid herbicides	Use Organic source. Other?				Bioa ssay s for herbi cide s.	
			Antibiotic resistance genes							
		Hay/ straw/ other bedding	Pesticides -- label search		Use Organic source. Other?					

		Grain/ feed	GMO grain		Use Organic source. Other?					
			Pesticides -- label search		Use Organic source. Other?					
			Feed additives		Use Organic source. Other?					Dairy manure
Poultry manure	Conven- tional poultry opera- tion	Feces	Antibiotics, other drugs --list		Use Organic source. Other?					
			Arsenic		Use Organic source. Testing.					
		Hay/ straw/ other bedding	Pesticides -- label search	Pyridine carboxylic acid herbicides	Use Organic source. Other?					
		Grain/ feed	Feed additives		Use Organic source. Other?					
Hay for mulch	Conven- tional farm	Grass	Pesticides -- label search	Pyridine carboxylic acid herbicides	Use Organic source. Other?					
Straw for mulch	Conven- tional farm	Straw from grain	Pesticides -- label search		Use Organic source. Other?					
Conven- tional food scraps for compo- st	Various : grocery stores, restau- rants, etc.	Vege- tables	Pesticides -- label search							USCC
		Grains	Pesticides -- label search							USCC
			GMO grain							

Newspaper, other paper mulch materials	Newspapers, scrap paper	Inks, dyes	Heavy metals
			Polycyclic aromatic hydrocarbons
		Paper	Dioxins



Sunset 2016 Review Meeting 2 - Subcommittee Review Crops Substances February 25, 2015

As part of the National List Sunset Review process, the NOSB has evaluated the need for the continued allowance for or prohibition of the following substances for use in organic crop production.

Ferric phosphate

Reference: **7 CFR 205.601** As a synthetic substance allowed for use in organic crop production

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

Technical Report: [07/2004](#); [6/2010](#); [07/2012 supplemental TR](#)

Petition(s): [05/2003](#); [07/2009 petition to remove](#)

Past NOSB Actions: [03/2005](#) - NOSB review and recommendation for addition to the National List;

[04/2010](#) - Recommendation to renew; [10/2012](#) - NOSB recommendation on petition to remove.

Recent Regulatory Background: Added to National List effective 09/12/06 [71 FR 53299](#); Sunset renewal notice published 08/03/2011 [76 FR 46595](#)

Sunset Date: 9/12/2016

Subcommittee Review

The NOSB originally proposed to add ferric phosphate to the National List in 2005. The material was recommended for renewal in 2010. The 2008 petition to remove Ferric Phosphate failed to pass at the 2012, Fall NOSB meeting that took place in Rhode Island; please refer to the [October 2012 Crops Subcommittee Proposal](#) to review detailed background information and a checklist pertinent to our deliberations. To access this please you can also visit the USDA NOP website at: <http://www.ams.usda.gov/NOSBFinalRecommendations>. The material is once again on the agenda for a 2015 sunset vote. Ferric phosphate is the active ingredient utilized in snail and slug bait.

Note that the NOSB voted against a petition to add "Sodium Ferric Hydroxyl EDTA" also known as "Ferric Sodium EDTA" in 2007 because it "is not consistent with environmental and compatibility with organic farming OFPA criteria primarily due to the behavior of EDTA in the environment and the toxic chemicals used to manufacture." Based upon this precedent, ferric phosphate was petitioned for removal in 2009 using the argument that it cannot work by itself and is always used with EDTA. A TR was requested in 2009, published in 2010 and a Supplemental TR was published in 2012, as well as a review by ARS that supported the argument that ferric phosphate requires a chelating agent like EDTA to work as a molluscicide. However, the petition to remove ferric phosphate from the National List was voted down by the Board at the Fall, 2012 meeting. The Board concluded that "*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.*"

In preparation for the sunset review of this material, the Subcommittee did not request an updated TR because it was determined that no additional information would be available for review. The following is a summary of the public written comment provided at Meeting #1 that took place at the NOSB Fall, 2014 meeting. There were 5 written comments in favor of relisting and 2 organizations plus 45 general public written comments in favor of delisting. Additionally, two individuals spoke in support of the material at the meeting and one citizen lobbyist spoke against relisting.

Points raised in favor of renewing substances:

- Ferric phosphate baits provide organic growers with the only effective, compliant control of a challenging agronomic pest
- Ferric phosphate is not harmful to human health or to the environment, is consistent with organic farming and is essential
- No compelling evidence that EDTA causes significant harm to earthworms

Points raised against renewing substance:

- Ferric phosphate alone is not essential because it is not effective
- Ferric phosphate in combination with EDTA poses risks to earthworms, other soil organisms and humans, uses highly toxic materials in manufacture, and is not compatible with organic agriculture
- There are cultural practices and alternative control measures

Motion to Remove:

This proposal to remove will be considered by the NOSB at its public meeting.

The Crops Subcommittee believes that the full Board should have the opportunity to complete the review of each sunset material by voting. The NOP has stated that to do this a motion to remove should be brought from the Subcommittee for each substance. If the Subcommittee motion to remove fails to receive a majority, the motion will still be put forward to the full board for review. The motion to remove is voted by the full Board and needs to receive a 2/3 majority to recommend removal.

Based on the review, the Subcommittee proposes removal of this substance from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: OFPA criteria at 7 U.S.C. 6158(m), (7) its compatibility with a system of sustainable agriculture.

The subcommittee found no concerns regarding the continued listing of Ferric Phosphate. The justification for this motion is that the whole NOSB needs to consider and vote on each material, rather than just a subcommittee.

Motion to remove Ferric Phosphate (CAS # 10045–86–0) from 205.601(h)

Motion by: Carmela Beck

Seconded by: Colehour Bondera

Yes: 2 No: 3 Abstain: 0 Recuse: 0 Absent: 2

Hydrogen chloride

Reference: **7 CFR 205.601** As a synthetic substance allowed for use in organic crop production (n) Seed preparations. Hydrogen chloride (CAS # 7647 – 01 - 0) - for delinting cotton seed for planting.

Technical Report: [2003 TAP](#); [5/2014 Limited Scope TR](#)

Petition(s): [10/2002](#)

Past NOSB Actions: [05/2004](#) - NOSB review and recommendation for addition to the National List; [11/2009](#) - Recommendation to renew

Regulatory Background: Added to National List effective 09/12/06 [71 FR 53299](#); Sunset renewal notice published 08/03/2011 [76 FR 46595](#)

Sunset Date: 9/12/2016

Subcommittee Review

Hydrogen Chloride for delinting cottonseed was recommended by the NOSB to be added to the National List in April 2004, and was recommended for relisting in November 2009. A TAP review was completed in August 2003 and a limited-scope TR was completed May, 2014. The TR indicated that there are alternative, nonsynthetic delinting processes under development but not yet commercially available. Based on the lack of commercially available cottonseed which is not acid delinted, the Crops Subcommittee recommends relisting Hydrogen Chloride for cottonseed delinting, with hopes that mechanical or other delinting processes are available to organic cotton growers by the next sunset review, so this very corrosive acid can be removed from the National List.

For the first round of public comments in this sunset review, the Crops Subcommittee solicited some specific input: “The Crops Subcommittee is interested in hearing from the organic community as to the relative efficacy of mechanical delinting techniques and whether these techniques are feasible and/or available in commercial scale organic cotton production. The Crops Subcommittee is also interested in hearing whether the NOSB can encourage safer methods of delinting seeds.”

There were five written comments, all in favor of relisting HCl for delinting cotton seed. Several commented that there are no cotton seeds commercially available that are delinted with something other than acid, although there is a promising research project being conducted by the USDA-Agricultural Research Service to develop mechanical delinting equipment for cotton seeds. Several commenters mentioned the extreme corrosive nature of HCl and the need to develop an alternative delinting method as soon as possible.

Supplemental review Information

Motion to Remove:

This proposal to remove will be considered by the NOSB at its public meeting.

The Crops Subcommittee believes that the full board should have the opportunity to complete the review of each sunset material by voting. The NOP has stated that to do this a motion to remove should be brought from the Subcommittee for each substance. If the Subcommittee motion to remove fails to



receive a majority, the motion will still be put forward to the full board for review. The motion to remove is voted by the full board and needs to receive a 2/3 majority to recommend removal.

Based on the review, the Subcommittee proposes removal of this substance from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Consistency with Organic Production.

The subcommittee found no concerns regarding the continued listing of Hydrogen Chloride. The justification for this motion is that the whole NOSB needs to consider and vote on each material, rather than just a subcommittee.

Motion to remove Hydrogen Chloride, CAS # 7647-01-0, from §205.601(n)

Motion by: Francis Thicke

Seconded by: Harold Austin

Yes: 0 No: 5 Abstain: 0 Recuse: 0 Absent: 3

Approved by Zea Sonnabend, Subcommittee Chair, to transmit to NOSB February 25, 2015



Sunset 2017 Review Summary Meeting 1 - Request for Public Comment Crops Substances April 2015

Introduction

As part of the [Sunset Process](#), the National Organic Program (NOP) announces substances on the National List of Allowed and Prohibited Substances (National List) that are coming up for sunset review by the National Organic Standard Board (NOSB). The following list announces substances that are on the National List for use in organic crop production that must be reviewed by the NOSB and renewed by the USDA before their sunset dates in 2017. This list provides the substance's current status on the National List, use description, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, this is noted in this list. To see if any new technical report is available, please check for updates under the substance name in the [Petitioned Substances Database](#).

Request for Comments

While the NOSB will not complete its review and any recommendations on these substances until the fall 2015 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the spring 2015 public meeting. These comments should be provided through www.regulations.gov by April 7, 2015 as explained in the meeting notice published in the [Federal Register](#).

These comments are necessary to guide the NOSB's review of each substance against the criteria in the Organic Foods Production Act (7 U.S.C. 6518(m)) and the USDA organic regulations (7 CFR 205.600). The current substances on the National List were originally recommended by the NOSB based on evidence available to the NOSB at the time of their last review which demonstrated that the substances were found to be: (1) not harmful to human health or the environment, (2) necessary because of the unavailability of wholly nonsynthetic alternatives, and (3) consistent and compatible with organic practices.

Public comments should focus on providing new information about a substance since its last NOSB review. Such information could include research or data that may support a change in the NOSB's determination for a substance. Public comment should also address the continuing need for a substance or whether the substance is no longer needed or in demand.

Guidance on Submitting Your Comments

Comments should clearly indicate your position on the allowance or prohibition of substances on the list and explain the reasons for your position. You should include relevant information and data to support your position (e.g., scientific, environmental, manufacturing, industry impact information, etc.).

For Comments That Support Substances Under Review:

If you provide comments in support of an allowance of a substance on the National List, you should provide information demonstrating that the substance is:

- (1) not harmful to human health or the environment;



- (2) necessary to the production of the agricultural products because of the unavailability of wholly nonsynthetic substitute products; and
- (3) consistent with organic crop production.

For Comments That Do Not Support Substances Under Review:

If you provide comments that do not support a substance on the National List, you should provide reasons why the use of the substance should no longer be allowed in organic production or handling. Specifically, comments that support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:

- (1) harmful to human health or the environment;
- (2) unnecessary because of the availability of alternatives; and
- (3) inconsistent with crop production.

For Comments Addressing the Availability of Alternatives:

Comments may present information about the viability of alternatives for a substance under sunset review. Viable alternatives include, but are not limited to:

- Alternative management practices that would eliminate the need for the specific substance;
- Other currently exempted substances that are on the National List, which could eliminate the need for this specific substance; and
- Other organic or nonorganic agricultural substances.

Your comments should address whether any alternatives have a function and effect equivalent to or better than the allowed substance, and whether you want the substance to be allowed or removed from the National List. Assertions about alternative substances, except for those alternatives that already appear on the National List, should, if possible, include the name and address of the manufacturer of the alternative. Further, your comments should include a copy or the specific source of any supportive literature, which could include product or practice descriptions; performance and test data; reference standards; names and addresses of producers or handlers who have used the alternative under similar conditions and the date of use; and an itemized comparison of the function and effect of the proposed alternative(s) with substance under review. The following table can help you describe recommended alternatives in place of a current substance that you do not want to be continued.

Written public comments will be accepted through April 7, 2015 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.



Sunset 2017 Review Summary Meeting 1 - Request for Public Comment Crops Substances April 2015

Reference: 7 CFR §205.601 Synthetic substances allowed for use in organic crop production.

[Alcohol: Ethanol, Isopropanol](#)

[Chlorine Materials: Calcium hypochlorite,](#)

[Chlorine dioxide, Sodium hypochlorite](#)

[Hydrogen peroxide](#)

[Soap-based algicide/demossers](#)

[Herbicides, soap-based](#)

[Newspaper or other recycled paper](#)

[Plastic mulch and covers](#)

[Soaps, ammonium](#)

[Ammonium carbonate](#)

[Boric acid](#)

[Elemental sulfur](#)

[Lime sulfur](#)

[Oils, horticultural](#)

[Soaps, insecticidal](#)

[Sticky traps/barriers](#)

[Sucrose octanoate esters](#)

[Pheromone](#)

[Vitamin D3](#)

[Coppers, fixed](#)

[Copper sulfate](#)

[Hydrated lime](#)

[Potassium bicarbonate](#)

[Aquatic plant extracts](#)

[Humic acids](#)

[Lignin sulfonate](#)

[Magnesium sulfate](#)

[Micronutrients: Soluble boron products,](#)

[Sulfates, carbonates, oxides, or silicates of zinc,](#)

[copper, iron, manganese, molybdenum,](#)

[selenium, and cobalt](#)

[Liquid fish products](#)

[Vitamin B1, C, E](#)

[Ethylene](#)

[Sodium silicate](#)

[EPA List 4 - Inerts of Minimal Concern](#)

[Microcrystalline cheesewax](#)

205.602 Prohibited nonsynthetic substances

[Ash from manure burning](#)

[Arsenic](#)

[Lead salts](#)

[Potassium chloride](#)

[Sodium fluoaluminate](#)

[Strychnine](#)

[Tobacco dust \(nicotine sulfate\)](#)



Alcohols (ethanol, isopropanol)

Reference: 205.601(a)(1)

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

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

Technical Report(s): [1995 TAP](#); [01/2014 TR - Ethanol](#); [02/2014 TR - Isopropanol](#)

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#) ; [11/2005 NOSB sunset recommendation](#); [04/2011 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Background from Subcommittee:

Ethanol (ethyl alcohol) is currently allowed for use in organic crop production as an algicide, disinfectant and sanitizer, including irrigation system cleaning. Ethanol was added to the National List in 1995 and has been relisted at sunset in the past. Ethanol provides broad-spectrum antimicrobial activity against vegetative bacteria, viruses and fungi, and is commonly used in organic production for disinfecting pruning tools. Essential oils can be used as disinfectants, but their efficacy is in question.

Isopropanol (isopropyl alcohol) is currently allowed for use in organic crop production as an algicide, disinfectant and sanitizer, including irrigation system cleaning. Isopropanol was added to the National List in 1995 and has been relisted at sunset in the past. Isopropanol provides broad-spectrum antimicrobial activity through the dissolution of lipid membranes and rapid denaturation of proteins and is used in organic production for disinfecting irrigation lines and disinfecting pruning tools. Commercial isopropanol is produced primarily through direct and indirect hydration of propylene. Isopropanol can be produced through natural fermentation processes.

[Supplemental Review Information](#)

Additional information requested by NOSB

NONE

Chlorine materials

Reference: 205.601(a) - As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems. (2) Chlorine materials -For pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, except that chlorine products may be used in edible sprout production according to EPA label directions.

(i) Calcium hypochlorite



(ii) Chlorine dioxide

(iii) Sodium hypochlorite

Technical Report(s): [1995 TAP](#); [2006 TR](#); [2011 TR](#)

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#) ; [11/2005 NOSB sunset recommendation](#) ;
[04/2011 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/27/12 ([77 FR 33290](#))

Sunset Date: 6/27/17

Background from Subcommittee

The chlorine materials Calcium hypochlorite, Chlorine dioxide and Sodium hypochlorite were added to the National List in 1995 without petition and have been relisted in subsequent sunsets. These chlorine materials are on the National List in three areas: 1) 205.601 Synthetic substances allowed for use in organic crop production, 2) 205.603 Synthetic substances allowed for use in organic livestock production, and 3) 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)).” Chlorine materials are widely used disinfectant and sanitizing materials. However, all three of these chlorine materials can be harmful to health and the environment, and care must be taken for safe handling.

Mode of action (from 2006 Technical Report): In water and soil, sodium and calcium hypochlorite separate into sodium, calcium, hypochlorite ions, and hydrochlorous acid molecules. Hydrochlorous acid molecules diffuse through the cell walls of bacteria, changing the oxidation-reduction potential of the cell and inactivating an enzyme essential for the digestion of glucose, destroying the microorganism’s ability to function. Chlorine dioxide kills microorganisms directly by disrupting the transport of nutrients across cell walls.

Calcium hypochlorite and sodium hypochlorite are highly caustic and are a concern for occupational exposures. Acute exposure to high concentrations can cause eye and skin injury; ingestion can cause gastrointestinal irritation and corrosive injuries to the mouth, throat, esophagus and stomach. Chlorine dioxide is a severe respiratory and eye irritant, and inhalation of chlorine dioxide can cause nose, throat and lung irritation. The reaction product of chlorine dioxide, chlorate, can cause oxidative damage to red blood cells. (2006 TR)

Alternative materials that could potentially be substituted for chlorine materials include hydrogen peroxide, peracetic acid and ozone.

Additional information requested by NOSB

1. Are there less toxic disinfecting and sanitizing materials that could be practically substituted for chlorine materials in organic crop production?
2. Are all three of these chlorine materials needed for use in organic crop production?



Hydrogen peroxide

Reference: 205.601(a)(4) - As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems.

Reference 205.601(i)(5) - As plant disease control.

Technical Report(s): [1995 TAP](#); [2015 TR](#)

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#) ; [11/2005 NOSB sunset recommendation - deferred](#); [06/2006 sunset recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/17

Additional information requested by NOSB

The 2015 Technical Report indicates that Hydrogen Peroxide can be used for Fire Blight control as an alternative to antibiotics. If you grow apple and pears, will you use this substance for Fire Blight, and if not, why not?

Soap-based algicide/demosers

Reference: 205.601(a)(7) - As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems.

Technical Report(s): [1996 TAP](#); [2015 TR in development](#)

Petition(s): N/A

Past NOSB Actions: **Actions:** [09/1996 NOSB recommendation](#); [11/2005 NOSB sunset recommendation](#); [04/2011 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/17

Additional information requested by NOSB

What alternative materials are available for use as an algicide/demoser?



Herbicides, soap-based/ (Soaps, herbicidal)

Reference: 205.601(b) As herbicides, weed barriers, as applicable (1) herbicides soap-based—for use in farmstead maintenance (roadways, ditches, right of ways, building perimeters) and ornamental crops.

Technical Report: [1996 TAP](#); [2015 TR in development](#)

Petition(s): N/A

Past NOSB Actions: **Actions:** [1996 recommendation](#); [11/2005 NOSB sunset recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/17

Background from subcommittee:

In April, 1995 soaps were approved in organic crop production, but not as herbicides. In September, 1996, soap-based herbicides were approved, but only for use in farmstead maintenance and ornamental crops. Soap-based herbicides were relisted in subsequent sunsets, without changes in annotation.

A Technical Report was requested for all the Soap listings, but was not received by the deadline for finalizing this posting.

Additional information requested by NOSB

1. Are soap-based herbicides needed or widely used on organic farms for farmstead maintenance or ornamental crops?
2. What alternatives to soap-based herbicides are available for those uses?

Newspaper or other recycled paper

Reference: 205.601(b) As herbicides, weed barriers, as applicable. (2) Mulches. (i) newspapers or other recycled paper, without glossy or colored inks.

Reference: 205.601(c) - As compost feedstocks - Newspapers or other recycled paper, without glossy or colored inks.

Technical Report: [1995 TAP](#); [2006 TAP](#)

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#) ; [11/2005 NOSB sunset recommendation](#); [04/2011 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/17

[Supplemental Review Information](#)

Additional information requested by NOSB



1. To what extent have newspapers shifted to soy ink?
2. What pigments are used in colored newspaper inks, and how does their toxicity compare with carbon black, the pigment used in black ink?
3. Does the diversion of newspaper to mulch significantly reduce the supply of recycled newsprint?

Plastic mulch and covers

Reference: 205.601(b) As herbicides, weed barriers, as applicable. (2) Mulches. (ii) Plastic mulch and covers (petroleum-based other than polyvinyl chloride (PVC)).

Technical Report: [1995 TAP](#)

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/17

[Supplemental Review Information](#)

Additional information requested by NOSB

NONE

Soaps, ammonium

Reference: 205.601(d) As animal repellents—Soaps, ammonium—for use as a large animal repellent only, no contact with soil or edible portion of crop.

Technical Report: [1999 TAP](#)

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/17

Additional information requested by NOSB

1. Are ammonium soaps effective as animal repellents?
2. What alternative animal repellants are available?



Ammonium carbonate

Reference: 205.601(e) As insecticides (including acaricides or mite control). (1) ammonium carbonate — for use as bait in insect traps only, no direct contact with crop or soil.

Technical Report: [1995 TAP](#)

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#) ; [11/2005 NOSB sunset recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/17

[Supplemental Review Information](#)

Additional information requested by NOSB

NONE

Boric acid

Reference: 205.601(e) As insecticides (including acaricides or mite control). (3)Boric acid - structural pest control, no direct contact with organic food or crops.

Technical Report: [1995 TAP](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/17

Background from Subcommittee

Boric acid, derived from the mineral borax, has long been considered a “least-toxic” pesticide because it is non-volatile when placed in bait or gel formulations, thus eliminating direct exposure. However, if misused boric acid is a reproductive toxicant, a suspected endocrine disruptor, and toxic to plants and animals. Borax mining causes environmental damage. Based on a life cycle analysis and if used in a manner that causes exposure, boric acid raises challenging issues of health and environmental/mining impacts, and there are alternative materials and practices that may be less harmful.

[Supplemental Review Information](#)

Additional information requested by NOSB

Are there situations in which boric acid is the only, or safest, means of controlling the pest?



Elemental sulfur

Reference: 205.601(e)(5) - As insecticides (including acaricides or mite control).

Reference: 205.601(i)(10) - As plant disease control.

Reference: 205.601(j)(2) - As plant or soil amendments.

Technical Report: [1995 TAP](#)

Petition(s): N/A

Past NOSB Actions: Actions: [04/1995 NOSB minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [04/2010 sunset recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/17

[Supplemental Review Information](#)

Additional information requested by NOSB

1. Is this substance still used in crop production in all three categories? If not what has changed?
2. Has the use of this substance increased or decreased during the current sunset cycle?
3. What are the specific purpose(s) you use elemental sulfur in your organic crop production? Are there any viable non-synthetic or management alternatives, for any of your current uses for elemental sulfur that might be able to provide adequate control of the targeted pest or disease?

Lime sulfur

Reference: 205.601(e)(6) - As insecticides (including acaricides or mite control).

Reference: 205.601(i)(6) - As plant disease control.

Technical Report: [1995 TAP](#); [2014 TR](#)

Petition(s): N/A

Past NOSB Actions: Actions: [04/1995 NOSB minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/17

[Supplemental Review Information](#)

Additional information requested by NOSB

1. How has the removal of the two previously allowed antibiotics (for fireblight control) impacted/or will impact your use of Lime Sulfur? Do you now (or will you) use lime sulfur as part of your organic control of fire blight in your organic apple or pear production?



2. Has the importance of lime sulfur in your organic farm system plan increased or decreased during the current sunset review cycle?
3. In the December 3, 2014 Technical Review it mentions many alternatives to Lime Sulfur as possible substitutes: Have you tried any of these materials in your organic farming and how effective were they and for what use: insecticide or plant disease control?

Oils, horticultural

Reference: 205.601(e)(7) - As insecticides (including acaricides or mite control). —narrow range oils as dormant, suffocating, and summer oils.

Reference: 205.601(i)(7) As plant disease control. - narrow range oils as dormant, suffocating, and summer oils.

Technical Report: [1995 TAP](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [04/2006 sunset recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/17

[Supplemental Review Information](#)

Additional information requested by NOSB

1. Is this substance still used in organic crop production in both listing categories? If not what has changed?
2. Has there been any change in the use patterns or alternatives that would make the need for continued listing for Horticultural Oils un-necessary?
3. Has the use of this substance increased or decreased during the current sunset cycle?

Soaps, insecticidal

Reference: 205.601(e)(8) - As insecticides (including acaricides or mite control).

Technical Report: [1994 TAP](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))



Sunset Date: 6/27/17

Additional information requested by NOSB

Has any information been published in the last 10 years regarding the effect of soap on beneficial insects?

Sticky traps/barriers

Reference: 205.601(e)(9) - As insecticides (including acaricides or mite control).

Technical Report: [1995 TAP](#)

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/17

[Supplemental Review Information](#)

Background from Subcommittee:

This listing covers a wide range of traps and coatings made with a number of different materials. Some are coated paper, some are coated plastic, and some are a sticky chemical that is brushed on plants. Coated plastic, at least, produces plastic waste that goes to the landfill. The sticky coating may contain petroleum distillates, and the traps may contain volatile attractants. Most are non-specific and kill non-target insects, spiders, mites, reptiles, and amphibians.

One TAP reviewer suggested the traps are compatible with organic only in processing plants. Another suggested they should be used only for monitoring or mass trapping.

Additional information requested by NOSB

1. Can/should the wide range of products covered by this listing be categorized by use and type of material?
2. Are some uses of sticky traps incompatible with organic production?

Sucrose octanoate esters

Reference: 205.601(e)(10) - As insecticides (including acaricides or mite control).

Technical Report: [2005 TR](#)

Petition(s): [2004 Sucrose Octanoate Esters](#); [Amendment #1](#); [Amendment #2](#)



Past NOSB Actions: [08/2005 NOSB recommendation for addition to NL](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/17

Additional information requested by NOSB

NONE

Pheromones

Reference: 205.601(f) - as insect management.

Technical Report: [1995 TAP](#); [2012 TR](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/17

[Supplemental Review Information](#)

Additional information requested by NOSB

1. The newest Technical Review, March 27, 2102 mentions some points of concerns with the micro-encapsulated forms of pheromones: How many, if any forms of micro-encapsulated pheromones are used in organic crop production? What are the concerns in using these, if any exist (as stated in the TR)?
2. Have the use of pheromones increased or decreased during the current sunset cycle?
3. Have the ways that pheromones are used/or applied changed during the current sunset cycle? Is there specific new technology or potential application methods that have shown promise for use in organic crop production during this current sunset cycle?

Vitamin D3

Reference: 205.601(g) - as rodenticides.

Technical Report: [1995 TAP](#); [2011 TR](#)

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [04/2011 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))



Sunset Date: 6/27/17

Additional information requested by NOSB

NONE

Coppers, fixed

Reference: 205.601(i) As plant disease control. (2) Coppers, fixed —copper hydroxide, copper oxide, copper oxychloride, includes products exempted from EPA tolerance, *Provided*, That, copper-based materials must be used in a manner that minimizes accumulation in the soil and shall not be used as herbicides.

Technical Report: [1995 TAP](#); [2011 TR](#)

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB meeting minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [04/2011 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/17

[Supplemental Review Information](#)

Additional information requested by NOSB

1. For growers: Has the removal of the two previously allowed antibiotics (for fireblight control) impacted/or will impact your use of Copper? Has the importance of copper in your organic system plan increased or decreased during the current sunset review cycle?
2. For growers: is testing for copper causing you to change your spray program in any way?
3. For ACA's: Are you requiring testing? Have there been situations where copper is accumulating in soil such that non-compliances have been issued?

Copper sulfate

Reference: 205.601(i) As plant disease control. (3) Copper sulfate —Substance must be used in a manner that minimizes accumulation of copper in the soil.

Technical Report: [1995 TAP](#); [2011 TR](#)

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB meeting minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [04/2011 NOSB sunset recommendation](#)



Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/17

Additional information requested by NOSB

1. For growers: Has the importance of copper in your organic system plan increased or decreased during the current sunset review cycle?
2. For ACA's: So, are you requiring testing? Have there been situations where copper is accumulating in soil such that non-compliances have been issued?

Hydrated lime

Reference: 205.601(i)(4) - As plant disease control.

Technical Report: [1995 TAP](#); [2001 TAP](#); [2002 TR for Calcium Hydroxide](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [04/2006 sunset recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/17

Additional information requested by NOSB

NONE

Potassium bicarbonate

Reference: 205.601(i)(9) - As plant disease control.

Technical Report: [1999 TAP](#); [2015 limited scope TR](#)

Petition(s): N/A

Past NOSB Actions: [10/1999 NOSB meeting minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [04/2010 sunset recommendation](#); [10/2010 NOSB sunset recommendation reaffirmation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/17

[Supplemental Review Information](#)

Additional information requested by NOSB

1. The newest TR dated January 22, 2015 lists a variety of possible alternative materials and practices that could potentially serve as possible replacements for Potassium Bicarbonate. Have you used any of these materials or methods in your organic farming and did they give you the desired result needed in your disease control program?

2. Is Potassium Bicarbonate still needed in your organic farming operation? If so why?

Aquatic plant extracts

Reference: 205.601(j) As plant or soil amendments (1) Aquatic plant extracts (other than hydrolyzed)—Extraction process is limited to the use of potassium hydroxide or sodium hydroxide; solvent amount used is limited to that amount necessary for extraction.

Technical Report: [2006 TR](#)

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [04/2006 sunset recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/17

Additional information requested by NOSB

NONE

Humic acids

Reference: 205.601(j) As plant or soil amendments (3). Humic acids - naturally occurring deposits, water and alkali extracts only.

Technical Report: [1996 TAP](#); [2006 TR](#)

Petition(s): N/A

Past NOSB Actions: [09/1996 meeting minutes and vote](#); [04/2006 sunset recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/17

Additional information requested by NOSB

NONE

Lignin sulfonate

Reference: 205.601(j) As plant or soil amendments. (4) Lignin sulfonate - chelating agent, dust suppressant.

Reference: 205.601(l)(1) - As floating agents in postharvest handling.



Technical Report: [1995 TAP](#); [2011 TR](#)

Petition(s): N/A, [2014 Petition to remove as floating agent](#)

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [04/2006 sunset recommendation](#); [04/2011 NOSB recommendation to amend](#); [04/2011 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/17

Additional information requested by NOSB

1. Note that the Crops Subcommittee has received a petition to remove lignin sulfonate for use as a floating agent. Will removal of this material create disruption to your business?
2. Lignin sulfonate is typically derived from the by-product in the spent liquor when pulped paper is chemically processed. It is soluble in water and can have negative impacts in aquatic ecosystems. Should use of lignin sulfonate be subject to documented monitoring of waste water in the OSP?

Magnesium sulfate

Reference: 205.601(j)(5) As plant or soil amendments. - allowed with a documented soil deficiency

Technical Report: [1995 TAP](#); [2011 TR](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [04/2011 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/17

Additional information requested by NOSB

Is non-synthetic magnesium sulfate available in the marketplace?

Micronutrients

Reference: 205.601(j) As plant or soil amendments. (6) Micronutrients - not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Soil deficiency must be documented by testing.

(i) Soluble boron products

(ii) Sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt

Technical Report: [2010 TR Micronutrients](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [10/2010](#)



[NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/17

Additional information requested by NOSB

Does the current annotation apply to today's practices and procedures?

Liquid fish products

Reference: 205.601(j) As plant or soil amendments (7) Liquid fish products —can be pH adjusted with sulfuric, citric or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5.

Technical Report: [1995 TAP](#); [2006 TR](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/17

Additional information requested by NOSB

Is the annotation sufficient for situations when fish is blended with other ingredients?

Vitamin B1, C, E

Reference: 205.601(j)(8) - As plant or soil amendments.

Technical Report: [1995 TAP](#); 2015 TR in development

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/17

Additional information requested by NOSB

NONE



Ethylene gas

Reference: 205.601(k) - As plant growth regulators. Ethylene gas - for regulation of pineapple flowering.

Technical Report: [02/2000 Supplemental TAP](#); [2007 TAP](#); [2011 Supplemental TR](#)

Petition(s): N/A

Past NOSB Actions: [11/1995 NOSB recommendation](#); [10/2001 recommendation](#); [11/2005 NOSB sunset recommendation](#); [04/2011 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/17

Additional information requested by NOSB

1. Could certifiers or organic pineapple growers provide the Crops Subcommittee with information of current application techniques used in applying Ethylene for pineapple flower induction? Please supply for both for small scale and large scale producers.
2. During the current Sunset cycle what alternative materials or practices have been looked at in organic operations? Have growers looked at any of those alternatives mentioned in the January 25, 2011 Supplemental Information Report to the NOSB and the Crops Subcommittee? If so please explain whether or not they could serve as possible alternative replacements to the current use of Ethylene for pineapple flower induction?
3. Have small scale organic pineapple producers looked at the alternative application methods mentioned for ethylene gas that would make it more feasible for smaller sized operations? If so how did it impact organic pineapple production?

Sodium silicate

Reference: 205.601(l)(2) - for tree fruit and fiber processing.

Technical Report: [1996 TAP](#); [2011 TR](#)

Petition(s): N/A

Past NOSB Actions: [09/1996 meeting minutes and vote](#); [04/2006 sunset recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/17

Additional information requested by NOSB

1. Are there any emerging practices (mechanical or physical) for pear or other tree fruit handling during the packing process that would be a reasonable alternative to using this "waterglass" material for a "wet dump"?
2. If lignin sulfates are removed from the list, what impact would that have on your level of use of sodium silicate materials?



EPA List 4 - Inerts of Minimal Concern

Reference: 205.601(m) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.
(1) EPA List 4 – Inerts of Minimal Concern.

Technical Report: [2015 Limited Scope TR: Nonylphenol ethoxylates \(NPEs\)](#)

Petition(s): N/A

Past NOSB Actions: [02/1999 NOSB minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [04/2010 recommendation](#), [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/17

Background

The Crops Subcommittee is working towards a solution to reviewing the inerts that were formerly on EPA List 4 by collaborating with the Design for the Environment Program of the EPA. Until this project is further along, the CS commissioned a Technical Report on the class of inerts known as Nonylphenol Ethoxylates (NPE). The US EPA is encouraging industry to eliminate the use of NPE (TR 2015, line 137) because of toxicity concerns and persistence in the environment. It is unlikely that the NPEs would pass favorably through the Design for Environment screening process. Therefore the Crops Subcommittee is considering removing them through an annotation at the next meeting, while maintaining the general listing for EPA List 4 at sunset while the new program starts up.

Additional information requested by NOSB

1. Commenters are urged to read the [TR for NPEs](#) linked here. Please comment on the suitability of the alternatives mentioned for specific types of generic product formulations in specific situations.
2. Would removing NPEs from use with 2 years notice (from now) be sufficient time? How would this affect your business?

Microcrystalline cheesewax

Reference: 205.601(o) - As production aids. Microcrystalline cheesewax (CAS #'s 64742-42-3, 8009-03-08, and 8002-74-2)-for use in log grown mushroom production. Must be made without either ethylene-propylene co-polymer or synthetic colors.

Technical Report: none

Petition(s): [2007 Petition](#); [2008 Petitioner response to questions](#)

Past NOSB Actions: [2008 NOSB recommendation](#)

Recent Regulatory Background: Federal Register rule amendment published 02/14/12 ([77 FR 8089](#))



Sunset Date: 3/15/17

Background from Subcommittee:

Microcrystalline cheese wax is used to seal the plug or sawdust spawn that is used to inoculate logs for growing mushrooms. It is a petroleum product and, though used in small quantities, does not biodegrade. There are many data gaps in the information concerning the allowed components of microcrystalline cheese wax. “Natural” soy wax from domestically-produced non-GMO soybeans—made by hydrogenating soy oil—is now available and was not considered when microcrystalline cheese wax was listed.

[Supplemental Review Information](#)

Additional information requested by NOSB

1. Is soy wax nonsynthetic?
2. Is soy wax sufficiently available to meet the needs of producers who grow organic mushrooms on logs?

Reference: 7 CFR §205.602 Nonsynthetic substances prohibited for use in organic crop production.

Ash from manure burning

Reference: 205.602(a)

Technical Report: none

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/17

Background from Subcommittee

Ash from manure burning was placed on §205.602 based on its incompatibility with organic production: “Burning these materials is not an appropriate method to use to recycle organic wastes and would not be considered a proper method in a manuring program because burning removes the carbon from these wastes and thereby destroys the value of the materials for restoring soil organic content. Burning as a disposal method of these materials would therefore not be consistent with section 2114(b)(1) of the OFPA (7 U.S.C. 6513(b)(1)).” (Preamble to proposed rule, December 16, 1997. 62 FR 241: 65874)



[Supplemental Review Information](#)

Additional information requested by NOSB

NONE

Arsenic

Reference: 205.602(b)

Technical Report: none

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/17

Background from Subcommittee:

Arsenic is prohibited by the Organic Foods Production Act (OFPA) 7 U.S.C. §6508(c)(1) CROP MANAGEMENT.—“For a farm to be certified under this title, producers on such farm shall not –

- (1) Use natural poisons such as arsenic or lead salts that have long-term effects and persist in the environment, as determined by the applicable governing State official or the Secretary.”

The Senate Committee report says, “The Committee recognizes that certain natural materials present environmental and health hazards. An example would be the use of arsenic which, although natural, is known to be extremely toxic, and which is therefore explicitly prohibited from use in organic production under this title.”

[Supplemental Review Information](#)

Additional information requested by NOSB

NONE

Lead salts

Reference: 205.602(d)

Technical Report: none

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/17



Background from Subcommittee:

Lead poisoning can cause a number of adverse human health effects, but is particularly detrimental to the neurological development of children. Lead accumulates in soils, so it is important to avoid soil applications of materials containing lead, whether the lead is in synthetic materials or naturally occurring (nonsynthetic) lead salts.

Additional information requested by NOSB

NONE

Potassium chloride

Reference: 205.602(e) - unless derived from a mined source and applied in a manner that minimizes chloride accumulation in the soil.

Technical Report: none

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/17

Additional information requested by NOSB

How widely is this used and is it primarily in blended products or by itself?

Sodium fluoaluminate

Reference: 205.602(f)

Technical Report: none

Petition(s): N/A

Past NOSB Actions: [1994 NOSB meeting minutes and vote](#); [11/2005 sunset recommendation](#); [2012 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/17

Additional information requested by NOSB

NONE



Strychnine

Reference: 205.602(h)

Technical Report: none

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/17

Additional information requested by NOSB

NONE

Tobacco dust (nicotine sulfate)

Reference: 205.602(i)

Technical Report: none

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/17

Background from Subcommittee:

This listing refers to the raw material from tobacco processing (tobacco dust) as well as the extracted active substance, nicotine sulfate. Both can very toxic to humans and the environment when used as fertilizer (tobacco dust) or pest control (nicotine sulfate). In 2008, EPA received a request from the registrant to cancel the registration of the last nicotine pesticide registered in the United States. This request was granted, and since January 1, 2014, this pesticide has not been available for sale.

[Supplemental Review Information](#)

Additional information requested by NOSB

NONE

**National Organic Standards Board
Materials/GMO Subcommittee
Discussion Document on Excluded Methods Terminology
August 22, 2014**

The Materials/GMO subcommittee is posting this discussion document a second time to allow for more public input. Those who commented during the last posting do not need to re-submit comments. The Materials Subcommittee thinks that because this is a complicated subject it would be beneficial for other stakeholders to participate in the conversation so as to collect as much input as possible before they proceed.

Introduction and Scope

A year ago the project was started to grapple with the definition of "excluded methods" in the USDA organic regulations. This is the definition that appears in the rule (7 CFR 205.2; Terms Defined):

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). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture. (Federal Register / Vol. 65, No. 246 / Thursday, December 21, 2000 / Rules and Regulations p. 80639)

The definition was based on the best efforts of the NOSB in 1995 and has provided adequate guidance to prohibit the use of the most obvious genetically engineered crops such as herbicide-resistant corn and soybeans and Bt cotton, as well as prohibit processing inputs such as genetically engineered yeasts and enzymes. However, this definition contains terms that are unclear, outdated and incomplete in light of new methods of recombinant DNA technology that have emerged since the definition was first adopted in 1995.

In 2011 and 2012 a number of confusing issues came before the NOSB and to the NOP which made it necessary to revisit the definition. These include genetically engineered vaccines for livestock, the use of cell fusion within plant families to create male sterility in brassica hybrids, whether or not GMOs could be used in biodegradable bioplastic mulches, and the question of whether mutated algae might therefore be genetically engineered. The current definition is inadequate to clarify these issues.

In 2013, NOSB first Discussion Document on excluded methods,¹ each of the terms in the above definition was discussed further, terms involved in traditional breeding, such as mutagenesis and conjugation, were defined and discussed, and new terms that may be considered to be genetic engineering were brought up. No conclusions were suggested except that there is a need to do more work on the subject. The discussion questions posed asked commenters to suggest principles on which to base GE distinctions, to offer opinions on what terms were and were not excluded methods, and to bring forward new terms that may need consideration. A list of the terms brought up is in Appendix 1.

¹ NOSB 2013. Excluded Methods Terminology Discussion Document. April 2013.
<http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5102656>

The NOSB received about 16 substantive public comments on the first discussion document, and also many general comments about keeping GMOs out of organic agriculture. The intention of this Second Discussion Document is to summarize the substantive public comments received on the previous one and to propose some further questions to move forward the issue of strengthening the Excluded Methods Terminology. The goal, as this effort continues, is to have concrete determinations for the National Organic Program, Accredited Certifiers, and organic producers to use in keeping GMOs out of organic food and farms.

This Discussion Document builds onto where the other one left off. The sections below titled "Relevance to Rulemaking", "Comments on Definition(s), Principles, and Criteria", "Process or Product" and "European Approaches" are all summaries of information that was submitted through public comments. The subsequent "Discussion" section includes the NOSB subcommittee analysis of the issues brought up. Finally, the questions at the end aim at collecting more input from the public on how to proceed.

Note: The Subcommittee recognizes that the usual public comment time period is not long enough to fully circulate, digest, discuss and respond to these issues. We strongly urge the NOP to create the ability for longer comment periods as was adopted by the NOSB in its Public Communications Recommendation on April 10, 2013.

Relevance to Rulemaking

In our first Discussion Document we did not state whether the subcommittee was proposing a change in the regulation or to address this subject through guidance.

Several commenters pointed out the language from the Senate report that accompanied OFPA, which was quoted in the first proposed rule. (62 Fed. Reg. 65850, 65875)

While the OFPA mandates that the Secretary develop organic standards, it is silent on the issue of genetically engineered organisms (GEOs) and their products. However, the accompanying Senate report language states that “as time goes on, various scientific breakthroughs, including biotechnology techniques, will require scrutiny for their application to organic production. The committee is concerned that production materials keep pace with our evolving knowledge of production systems.”²

This reference from the Senate report was quoted in the first proposed rule somewhat out of context. It appears to have been used by the congress as justification for a registration program for organic materials that was subsequently removed from the conference report. However, it implies the same need for flexibility as quoted below from the rule’s preamble.

From the preamble to the current rule (65 Fed. Reg. 13512, 13521):

We recognize that the phrases, “natural conditions or processes” and “not considered compatible with organic production,” may be subject to interpretation.

....

² U.S. Senate. 1990. Food, Agriculture, Conservation and Trade Act of 1990 - Report to Accompany S2830. Rpt 101-357, 101st Congress, 2nd Session. Government Printing Office, Washington, DC.

We recognize that industry and consumer expectations regarding the products of these techniques in organic production systems may evolve. We believe that, taken together, these phrases allow for a degree of flexibility to ensure that our regulations continue to accurately reflect industry practices and consumer preferences. In cases where questions may arise regarding a specific technique, we anticipate that such questions would be resolved by the Administrator based on recommendations from the NOSB.

The Materials/GMO subcommittee has discussed this issue and believes that NOP Guidance is the most appropriate form for any clarifications and interpretations to be made regarding excluded methods, for the very reasons mentioned by the Senate and the NOP.

Comments on Definition(s), Principles, and Criteria

This section is in two parts. Part 1 summarizes the public comment regarding principles and criteria to consider in clarifying or revising the excluded methods definition further. Part 2 consists of the additional terms brought up by commenters with some of their definitions provided. Appendix 1 contains the terms that were defined and discussed in the first Discussion Document.

1. Other definitions related to Excluded Methods to draw from –

A. The Cartagena Protocol definitions (CFS public comment):

"Living modified organism"

"[a] living modified organism is defined as any living organism that has a combination of genetic material obtained through the use of modern biotechnology.

"Modern Biotechnology" (also adopted by Codex Alimentarius):

(i) in vitro nucleic acid techniques, including recombinant DNA and direct injection of nucleic acid into cells or organelles, or (ii) fusion of cells beyond the taxonomic family that overcomes natural, physiological reproductive or recombination barriers, and that are not techniques used in conventional breeding and selection."³

"While this language is more specific, the underlying theme of the definition is the same. However, the distinctions presented by the Cartagena protocol definition could also be used to inform a newly created guidance document."⁴

B. Proposed new definition of Excluded Methods (Dag Falck public comment):

Methods that change the genetic material of an organism through recombining DNA⁵ through laboratory methods and in ways that are not dependent on the use of conjugating, sexual or asexual reproduction methods, including transgenic (intraspecific or intergeneric), or cisgenic (intrageneric) transfers of genes. Methods not included in the definition are: other natural, classical, or modern breeding techniques that depend on movement of genes only through a conjugative, sexual or asexual reproduction method with parent gene material from within the same taxonomic family⁶.

C. Ethical Criteria (FiBL public comment):

1. The genome is respected as an indivisible entity and technical/physical invasion into the plant genome is refrained from (e.g. through transmission of isolated DNA, RNA, or proteins).

³ Convention on Biological Diversity. 2013. The Cartagena Protocol on Biosafety. Available at:

<http://bch.cbd.int/protocol>.

⁴ Center for Food Safety 2013. Public Comment to NOSB. Docket AMS-NOP-12-0070

⁵ http://en.wikipedia.org/wiki/Recombinant_DNA.

⁶ Dag Falck, Nature's Path 2013. Public Comment to NOSB. Docket AMS-NOP-12-0070

2. The cell is respected as an indivisible functional entity and technical/physical invasion into an isolated cell on growth media is refrained from (e.g. digestion of the cell wall, destruction of the cell nucleus through cytoplasm fusions).
3. The ability of a variety to reproduce in species-specific manner has to be maintained and technologies that restrict the germination capacity of seed-propagated crops are refrained from (e.g. Terminator technology).⁷

D. Operational criteria (Rich Theuer public comment):

It is very helpful that you set forth these operational criteria for implementing the phrase "without the use of excluded methods:"

1. Keeping genetically modified organisms out of organic livestock feed, crops, and food; and
 2. Preventing the introduction of novel proteins into soil and water ecosystems.
- This is the kind of guidance that certifiers, producers, and handlers can execute.⁸

2. Terms not in the prior Discussion⁹

The descriptions provided here are our best attempts to summarize very technical issues. More information can be found in the cited sources. While some of these techniques may seem to obviously be consistent with the existing excluded methods definition, others are not, and some may or may not be depending on specifics. These are presented only as examples to give readers the context and descriptions of some terms that will be evaluated in our future work.

- o Doubled Haploid Technology – A breeding technique used to create homozygous inbred lines in one generation instead of the many required by traditional methods. Used widely in wheat, canola and corn, it involves the following steps: emasculation, pollination, 2,4-D treatment, embryo culture, and colchicine treatment. It often involves crosses between wheat and corn.
- o Targeted genetic modification (TagMo) – a collective term for the zinc finger nuclease techniques that create DNA double-stranded breaks at specific genomic locations that can then be used to alter the target gene. The genetic modification would not necessarily involve transfer of nucleic acids from another species, nor would it be easy to detect in a final product. It is unclear how these would be regulated in the U.S.
- o "FasTrack" – a breeding scheme that has so far been used in plums where an early-flowering gene from poplar is inserted into a plum tree. When the plum flowers in less than a year, it is crossed with non-transgenic varieties carrying desirable traits. Markers are used to identify the right traits and, at the end of the breeding program, only those are selected that do not have the transgene.
- o Synthetic Biology – practitioners generate new DNA sequences the way computer programmers write code, creating new life-forms. Called by one of its founders "genetic engineering on steroids"¹⁰. So far it has been used to generate a yeast that produces a malaria drug and to make synthetic vanilla.

⁷ FiBL Research Institute of Organic Agriculture 2013. Public Comment to NOSB. Docket AMS-NOP-12-0070

⁸ Richard Theuer 2013. Public Comment to NOSB. Docket AMS-NOP-12-0070

⁹ Among many sources used for definitions are the following: Kuzma J, Kokotovich A (2011) Renegotiating GM crop regulation. EMBO reports 12: 883–888; Podevin N, Devos Y, Davies HV, Nielsen (2012) Transgenic or not? No simple answer! EMBO reports 13: 1057 – 1061; Waltz E (2012) Tiptoeing around transgenics. Nature biotechnology 30: 215–217; Wikipedia for each term.

¹⁰ Phillpot, Tom 2014. Now your Food Has Fake DNA in It. Mother Jones
<http://www.motherjones.com/environment/2014/08/food-fake-dna-synbio-vanilla-ice-cream>

- Cisgenics – A genetic modification of a recipient organism with a gene (cisgene) from a crossable (sexually compatible) organism. This is not always interpreted as a prohibited technique because such crossing may be able to occur in nature.
- Intragenesis – genetic modification of a recipient organism that involves the insertion of a reorganized, full or partial coding region of a gene, often with a promoter and/or terminator from another gene of the same or crossable species.
- Plastid transformation – Plastids are semi-autonomous organelles within higher plants with a small, highly polyploid genome. Technology has been developed for genetic modification of this genome independent of nuclear DNA. Currently used commercially in tobacco, and widely researched.¹¹
- Gene silencing via RNAi and DNA methylation – Interfering with the regulation of gene expression through inserting methyl groups onto RNA and DNA that then suppress the expression of the gene. Can occur in nature, but is used as a recombinant technique in cancer research and plant breeding.
- RTDS (Rapid Trait Development System) – the next generation precision gene editing technology developed by Cibus company. Similar to the oligonucleotide targeted DNA modification (below) it does not leave behind transgenic material, only uses it to create a change in a precise area of a gene.
- Site directed mutagenesis via oligonucleotides, zinc finger nuclease (ZFN) – an introduction of recombinant DNA through transient molecules that are identified by zinc-finger nucleases, with or without a repair template. The techniques resemble transgenesis but the end products are similar to, and indistinguishable from, conventionally bred plants.
- Agro-infiltration – Similar to the zinc finger nuclease technique above, but using an *Agrobacterium* to inject several foreign DNA molecules into the plant cell.
- Reverse breeding – A process that uses several other techniques such as RNAi to suppress meiotic recombination, tissue culture, and then double haploidization to create parental lines that are homozygous to use in breeding F1 hybrids.
- Embryo transfer of animals – a technique used in animal breeding. It involves inducing superovulation of donor with gonadotropins, artificial insemination, recovery of embryos, isolation and storage of embryos, transfer of embryos back into animals, and then pregnancy.
- Marker Assisted Selection (MAS) – a process whereby a marker is used for indirect selection of a genetic trait. Markers are usually DNA but they can be morphological (such as seed color) or biochemical (specific enzymes). Very commonly in use is the antibiotic resistance marker so that any population can be exposed to antibiotics and the organisms that survive have the marker. This technique may not necessarily be considered genetic engineering in itself, but can be used in conjunction with other transgenic techniques or involve inserting recombinant markers.

Process or Product?

Public commenters offered several papers from Europe that discussed the difference between a process-based standard for GMOs and a product-based standard. This is relevant to the current discussion because the Federal Rule for organic is based on a process-based approach to all of organic production, yet there are some areas where the process is intertwined with the product or a quantitative tool can be used to assess the validity of a process approach. See discussion section for more.

¹¹ Maliga, P. 2004. Plastid transformation in higher plants. *Annu Rev Plant Biol.* 2004;55:289-313.
<http://www.ncbi.nlm.nih.gov/pubmed/15377222>

"The US oversight system was built mostly around the idea that GM plants should be regulated on the basis of characteristics of the end-product and not on the process that is used to create them."¹²

"The first challenge is to make sure that regulatory frameworks remain fit for purpose. However, frameworks that use process-based definitions as a trigger for regulatory oversight might not be functional over time (Sidebar B). Several authors have argued that new biotechnology-based plant breeding techniques might not fit into, or might rapidly outgrow, the established definitions for GMPs [COGEM 2006 (9), Morris SH 2008 (10) as cited in original] or other narrowly defined product definitions [Kuzma, J.2011 (8), Ledford, H. 2011 (11), Waltz, E. 2012 (12) as cited in original]. NPPs (new plant products) blur the sharp distinction between GMP and non-GMP, and introduce a new continuum between genetic engineering and conventional breeding. Process-based legislation will require not only updates to the lists of new biotechnological plant breeding techniques but also debate on their classification as GMP or non-GMP. However, such flexibility is rarely evident in regulatory frameworks.¹³

"Sidebar B / Process-based compared with product-based regulatory frameworks¹⁴
Process-based regulatory frameworks

Argentina, Brazil, the EU and many other countries have put new process-based regulatory systems in place to regulate the use of genetically modified organisms (GMOs), as the techniques used for their production were thought to raise specific safety concerns. In these jurisdictions, a GMO is mainly characterized by the transformation techniques used in its production. The definitions of GMOs used by these countries are often partly or fully based on those put forward by international organizations such as the United Nations Food and Agricultural Organization (FAO) and international treaties such as the Cartagena protocol.

Product-based regulatory frameworks

Canada and the USA opted to regulate all plants or products with new traits developed either through genetic engineering or any other plant breeding techniques under the same, yet existing, regulatory system [26,27]. The transformation techniques were not considered inherently risky. Therefore, the focus of product-based regulatory systems is on the risks of products and new traits or attributes introduced into a plant, rather than the method of production."

European Approaches to Classifying Genetic Manipulation Methods

The EU has made the distinction between "traditional" breeding methods and conventional (transgenic) breeding.¹⁵

FiBL submitted a comment that included a chart that describes methods with a yes/no column for compatibility with organic standards for both plants and animals. The NOSB could work on something similar and the methods that receive consensus can be incorporated into guidance. A subset of this chart is presented here as an example:¹⁶

¹² Kuzma J, Kokotovich A (2011) Renegotiating GM crop regulation. EMBO reports 12: 883–888

¹³ Podevin N, et. al. (2012) Transgenic or not? No simple answer! EMBO reports 13: 1057 – 1061

¹⁴ *ibid.*

¹⁵ (Directive 2001/18/EC. and an EU background paper 'Current plant breeding techniques', DOC.XI/464/92. - Clemens van de Wiel, Jan Schaart, Rients Niks & Richard Visser, "Traditional plant breeding methods", 2010 - <http://edepot.wur.nl/141713>)

¹⁶ FiBL Research Institute of Organic Agriculture 2013. Public Comment to NOSB. Docket AMS-NOP-12-0070

Method	Excluded (by FiBL)	Why
Embryo rescue	No / YES in animals	Plants: Embryo is maintained on artificial media, but no genetic changes occur. Animals: Embryo transfer on organic farms is rejected, therefore also embryo rescue
Microinjection	YES	Invasive technique that violates integrity of a cell
Biolistic device	YES	Invasive technique that violates integrity of a cell
Somaclonal variation	YES, if artificially introduced	Somaclonal variation results from mutation and is identified during in vitro culture, but might not necessarily be introduced by the tissue culture...
Transposons	Yes if artificially introduced	Transposons are a regulatory element influencing gene silencing and mutation rate. Transposons can be artificially introduced by genetic engineering, see genetic engineering
Transduction	No	Is a natural phenomenon

This type of evaluation in Europe has led to an independent effort to define and certify "Organic Varieties" and even Organic Animal Breeding.¹⁷ In this idea (which has not yet been written into any regulations), only approved non-GMO plant breeding methods would be used to create what could be certified as an Organic Variety or Organically Bred Animal. In this country, a parallel idea has been floated that organically grown seeds be held to different criteria regarding GMOs than conventional seeds, even those not called GMO.¹⁸ If such ideas were adopted, then a set of organic plant breeding standards could be developed, or at least organically produced varieties may be distinguished from other varieties, such as not being able to have used cell fusion for Cytoplasmic Male Sterility (CMS) or double haploid technologies.

Discussion

Definition(s), Principles, and Criteria

The subcommittee likes the definitions regarding biotechnology from the Cartagena Protocol for several reasons. First, it is more specific than the current definition regarding recombinant DNA and direct injections or fusion between families. Second, it is well accepted internationally and therefore provides the NOP with good justification for adopting into guidance. Third, it provides a better framework than the existing definition to further elaborate the various technologies that would be allowed as well as those which would be prohibited. This will be discussed further below.

The definition proposed by Mr. Falck in B above also attempts to make it clearer, but is not as widely accepted or known.

The criteria and principles in comments C and D above are valid points that the subcommittee appreciates the input on. The points raised in D as operational are accepted as part of our goals for how to interpret the principles and definition adopted, but they would be the subsequent step

¹⁷ Neff, A.S. & Augsten, F. 2009. Assessing Reproductive and Breeding Techniques in Organic Agriculture using Cattle Breeding as an Example. FiBL Discussion Paper. Submitted with FiBL public comment to docket AMS-NOP-12-0070

¹⁸ Still, Andrew, 2013. Adaptive Seed Catalog and Seed Ambassadors Blog. <http://www.seedambassadors.org/>

after the broader issues of definition and principles. Perhaps other operational criteria would be helpful as well. Operational criteria for determining acceptability of crop inputs derived from GMO feedstocks and/or fermenting organisms (potentially including corn gluten meal, corn steep liquor, and biodegradable mulch, for example), disinfectants like alcohols, and processing aids would be appropriate in guidance to certifiers and materials review organizations and/or in the materials listings. The subcommittee will be looking at this point in developing future work plans.

We are posing further discussion questions on some of the criteria raised in the FiBL comment (point C above) to see if these criteria are useful and realistic.

Process or Product?

Since the whole underpinning of the U.S. organic regulations is a process-based system, it would make sense that this concept carry over to defining excluded methods. This is indeed the basis of the current definition. However, this is not currently how U.S. government agencies regulate GMOs, as noted above, or handle other issues such as pesticide residues or water quality standards.

While some commenters seemed to feel that there might be advantages to a product-based definition, such a structural revision is beyond the scope of this current effort. Therefore, the rest of this discussion will assume a continuation of a process-based approach.

European Classification Concepts applied in the U.S.

It would seem to make sense to try to distinguish between traditional and transgenic breeding techniques for both plants and animals. The FiBL suggestion of doing this through a chart has some strong benefits, including:

- The chart could be developed over time, with the terms everyone agrees to adopted first and then the more controversial ones hammered out over time.
- such a chart can follow logically from the Cartagena Protocol definition to indicate recombinant DNA, direct injection, cell fusion outside of families and other guidance provided by that definition that is somewhat lacking in the current definition.
- A chart such as this would be easier for the NOP to maintain as instruction or guidance and would not be as lengthy as a list of crop varieties and inputs. Additionally, it does not have to be updated as frequently.
- It maintains a transparency to all stakeholders that is now somewhat lacking in how GMOs are regulated.
- It gives ACAs clear instruction on how to evaluate seeds, vaccines, microorganisms and other potential GMOs.

At this juncture, before we even start to create a table of excluded methods terms, we invite input from the public on whether or not this is a worthwhile effort and any ideas for how to implement such an idea.

Unresolved Issues

Exploring this issue has brought to the attention of the subcommittee that engineered genetic manipulation of plant breeding materials has already occurred in many of the crop varieties that are currently being used in organic farming. A partial list:

- Disease resistant tomatoes (embryo rescue to introduce resistance genes)
- wheat and barley (double haploid technology using wheat and corn crosses along with embryo rescue and colchicine gene doubling)
- hybrid corn parent lines (double haploid to get homozygosity in 1 generation)
- Seedless tangerines and mandarins (mutations through irradiation)

- Brassica hybrids (cell fusion from radish traits)¹⁹

Many of these techniques that were used in initial crosses that have now passed down through many generations may not be traceable any longer. There are also many new varieties in development that will strongly challenge any definitions or regulatory scheme. Without a revised definition and some guiding principles to use for past and future determinations about excluded methods, there may not be effective ways to regulate either past or future techniques and their products.

Discussion Questions

The Materials/GMO Subcommittee is seeking response from the organic community on the issues presented in this discussion. A few of the particular questions to address are:

1. Are the definitions presented from the Cartagena Protocol an appropriate basis for guidance to further enable NOP and the NOSB to sort out terminology? (on page 3)
2. Among the criteria suggested, we would like feedback on the ones mentioned below and ask whether there are any other important criteria to use in genetic engineering determinations.
 - Technical/physical invasion into the plant genome is refrained from (e.g. through transmission of isolated DNA, RNA, or proteins).
 - The cell is respected as an indivisible functional entity and technical/physical invasion into an isolated cell on growth media is refrained from (e.g. digestion of the cell wall, destruction of the cell nucleus through cytoplasm fusion).
 - The ability of a variety to reproduce in species-specific manner has to be maintained and technologies that restrict the germination capacity of seed-propagated crops are refrained from (e.g. Terminator technology).
3. Would it be a good approach to continue a process-based evaluation of the terms and techniques, determine whether they are a result of genetic engineering, and then list both the GE and non-GE terms in a chart maintained by the NOP in the public record? If so, please offer suggestions on how this could be implemented. If not, please suggest any alternatives.
4. Are there terms or methods not included in appendix 1 that should be added to the discussion? Briefly explain.

Subcommittee Vote (Recorded August 26, 2014)

Motion to adopt the proposed Second Discussion Document on Excluded Methods Terminology

Motion by: Zea Sonnabend

Seconded by: C. Reuben Walker

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

¹⁹ for detail on this issue, please see: Myers, Jim 2014. in Proceedings from the 7th Organic Seed Growers conference. https://seedalliance.org/index.php?mact=DocumentStore,cntnt01,download_form,0&cntnt01pid=30&cntnt01returnid=139

Appendix 1

Terms defined and discussed in the first Discussion Document. They are presented in the same order they were in the document.

In current definition of Excluded Methods:

- Cell Fusion
 - Protoplast Fusion
 - Somatic hybridization
- Micro-encapsulation
- Macro-encapsulation
- Recombinant DNA
- Gene Deletion
- Genetic Engineering
- Mutagenesis (mutation breeding)
- Conjugation, genetic
- Fermentation
- Hybridization
 - Hybrid
 - Nucleic Acid Hybridization
- In Vitro* Fertilization
- Tissue Culture
 - Cell Culture
 - Primary and Batch Cell Culture

Not in Definition of Excluded Methods

- Silencing
- Embryo Rescue
- Microinjection
- Biolistic device
- Somaclonal variation
- Transposons
- Transduction

Approved by C. Reuben Walker, Subcommittee Chair, to transmit to NOSB February 25, 2015

**National Organic Standards Board
Materials Subcommittee
Prevention Strategy Guidance for Excluded Methods
Discussion Document
February 10, 2015**

I. INTRODUCTION

The purpose of this document is to solicit input and feedback from the organic community on precautions that organic producers and handlers should take to prevent and minimize GMO contamination in organic production and processing. In an environment where GMOs are widely distributed throughout the food chain, it is imperative that organic producers and handlers have strategies and plans to prevent GMO contamination. A key tenet of "co-existence" is a shared responsibility for the exclusion of the methods and products of genetic engineering. The organic part of this shared responsibility is practiced extensively already, but it would be a stronger point in future policy statements and efforts against GMO contamination of organic products if it were spelled out thoroughly in guidance from the National Organic Program.

Some prevention strategies already exist in the organic and non-GMO community. These sources will be utilized to create a comprehensive set of steps and considerations that organic producers and handlers can use in their own operations and Accredited Certifying Agents (ACAs) can use to verify compliance with the contamination avoidance clause in the rule as it relates to GMOs.

II. BACKGROUND

The Organic Foods Production Act (OFPA) of 1990 does not mention biotechnology, genetic engineering or genetically modified organisms, but OFPA prohibits synthetics unless they are on the National List. The first NOP proposed rule (1997) did not prohibit GMOs, resulting in a huge public outcry against GMOs being considered for use in organic production and handling. The proposed rule was withdrawn and the second NOP proposed rule (2000) excluded the use of GMOs in organic production and handling.

The NOP regulations prohibit the use of GMOs as "excluded methods" under 7 CFR § 205.105: "Allowed and prohibited substances, methods, and ingredients in organic production and handling." Excluded methods are defined as:

A variety of methods 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). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture (7 CFR § 205.2-Terms defined)

Compliance with the organic Standards requires that operations have verifiable practices in place to avoid contact with GMOs. Since organic certification is process-based, the presence of detectable GMO residues alone does not necessarily constitute a violation of the regulation. The organic Standards make allowances for "Unavoidable residual environmental contamination,"

which is defined (§ 205.2) as “Background levels of naturally occurring or synthetic chemicals that are present in the soil or present in organically produced agricultural products that are below established tolerances.”

The NOP relies on organic certifiers and producers to determine preventive practices that most effectively avoid contact with GMOs on an organic operation.

III. RELEVANT AREAS OF THE RULE AND NOP GUIDANCE/POLICY

Rule 7 CFR

§205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling.

To be sold or labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” the product must be produced and handled without the use of:

(e) Excluded methods, except for vaccines: *Provided*, That, the vaccines are approved in accordance with §205.600(a);

§205.201 Organic production and handling system plan.

(a)...An organic production or handling system plan must include:

- (3) A description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented;
- (5) A description of the management practices and physical barriers established to prevent commingling of organic and nonorganic products on a split operation and to prevent contact of organic production and handling operations and products with prohibited substances;
- (6) Additional information deemed necessary by the certifying agent to evaluate compliance with the regulations.

§205.272 Commingling and contact with prohibited substance prevention practice standard.

(a) The handler of an organic handling operation must implement measures necessary to prevent the commingling of organic and nonorganic products and protect organic products from contact with prohibited substances.

(b) The following are prohibited for use in the handling of any organically produced agricultural product or ingredient labeled in accordance with subpart D of this part:

(1) Packaging materials, and storage containers, or bins that contain a synthetic fungicide, preservative, or fumigant;

(2) The use or reuse of any bag or container that has been in contact with any substance in such a manner as to compromise the organic integrity of any organically produced product or ingredient placed in those containers, unless such reusable bag or container has been thoroughly cleaned and poses no risk of contact of the organically produced product or ingredient with the substance used.

§205.600 Evaluation criteria for allowed and prohibited substances, methods, and ingredients.

(a) Synthetic and nonsynthetic substances considered for inclusion on or deletion from the National List of allowed and prohibited substances will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518).

§205.670 Inspection and testing of agricultural products to be sold or labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)).”

(a) All agricultural products that are to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” must be made accessible by certified organic production or handling operations for examination by the Administrator, the applicable State organic program's governing State official, or the certifying agent.

(b) The Administrator, applicable State organic program's governing State official, or the certifying agent may require pre-harvest or postharvest 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. Samples may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples. 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.

(c) A certifying agent must conduct periodic residue testing of agricultural products to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)).” Samples may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples. Such tests must be conducted by the certifying agent at the certifying agent's own expense.

(d) A certifying agent must, on an annual basis, sample and test from a minimum of five percent of the operations it certifies, rounded to the nearest whole number. A certifying agent that certifies fewer than thirty operations on an annual basis must sample and test from at least one operation annually. Tests conducted under paragraphs (b) and (c) of this section will apply to the minimum percentage of operations.

NOP Guidance

- NOP 5025 Commingling and Contamination Prevention in Organic Production and Handling (Effective date: 7/22/2011)

NOP Policy

- Policy Memo 11-13 Genetically modified organisms (Issue date: 4/15/11)

NOP Fact Sheets

- Can GMOs be Used in Organic Products? (Published May 2013)

IV. DISCUSSION

Best Management Practices

Because GMOs are widely used in conventional food and feed systems, they are nearly ubiquitous in our environment, and there are many potential opportunities for GMOs to contaminate organic food and feed. The following is a summary of management practices recommended to help prevent GMO contamination, drawn from the references listed at the end of this document and other sources.

Best Management Practices for seed and crop production

- Assess farm site and crops to be grown for potential sources of contamination.

- Identify at-risk crops* and potential points of contamination for each, including knowing what GMO crops are expected to be grown in the area.
- Communicate with neighboring farmers about what at-risk crops you will grow, if they will grow GMO varieties of those crops, and what might be done to help reduce the GMO contamination potential on your farm.
- Be certain that non-organic seeds that are used come with non-GMO verification from seed supplier.
- Test at-risk seed, or get verification of clean seed from supplier, before planting.
- Avoid using bee pollinators that have been used in proximity to GMO fields and determine if neighboring feral hives exist that could carry GMO pollen to your farm.
- Know the life cycles of crops being planted, if the crops are self- or cross-pollinating, if the pollen is transported by wind or insects, etc.
- Isolate at-risk organic crops from GMO crops with suitable distances and/or planting timing, conferring with neighbors as needed.
- Control plants that could contaminate your crops, including volunteers, feral populations and wild relatives in proximity to your fields.
- Verify that all inputs, such as fertility and pest control materials, are non-GMO.
- Clean all equipment and facilities prior to use.
- Document equipment cleanout and keep records of all practices used to limit contamination.
- Inspect and clean storage facilities and be sure they are isolated from GMO storage.
- Avoid mixing during harvest, cleaning, storage, transport and sales.
- Be aware that GMO-laden dust from neighboring fields may require more thorough cleaning and protection of organic products than just removing GMO seeds from equipment.
- Know the organic regulations for excluding GMOs and know your certifier's requirements
- Know your buyers' GMO requirements and testing protocols.

Best Management Practices for livestock

- Assess farm site and facilities for potential sources of contamination.
- Maintain separate, isolated facilities for feed storage of organic and GMO feeds (if a split operation).
- Inspect and clean storage facilities before use.
- Receiving practices: quarantine incoming product and do not release until all supporting non-GMO paperwork and labels are reviewed. Make sure the product received is the product approved in the OSP. Check lot numbers. Non-GMO documentation must be collected and maintained on-file.
- Thoroughly clean and purge feed processing and handling equipment if used for GMO products.
- Document and maintain records of cleanout of equipment and facilities used for GMO products.

Best Management Practices for handling

- Assess the site, facilities and organic products/inputs for possible sources of GMO contact.
- Receiving practices: quarantine incoming product and do not release until all supporting non-GMO paperwork and labels are reviewed. Make sure the product received is the

* High risk crops include alfalfa, canola, corn, cotton, soy, sugar beets, zucchini and yellow summer squash.

product approved in the OSP. Check lot numbers. Non-GMO documentation must be collected and maintained on-file.

- All inputs must be traceable and must be of non-GMO source, even the nonorganic inputs contained in “made with organic” products.
- Organic and non-GMO materials must be strictly segregated from any GMO materials.
- Equipment must be thoroughly cleaned and purged if used for processing and handling GMO materials.
- Know which ingredients pose a GMO-contamination risk and what, if any, contamination levels are present in them.
- Determine minimum thresholds of GMO contamination for rejecting inputs in at-risk inputs.
- Create quality assurance and quality control procedures and practices for traceability, segregation, sampling and testing lots of inputs for GMO content, with adequate training of personnel to assure routine adherence to those procedures and practices.

The Role of ACAs and Oversight

- On-site inspections (observation), review of the OSP and records, and periodic testing verify that farmers and handlers are following their organic system plan and that the measures described are effective.
- Role of testing (by ACAs) as a tool for verifying adequate contact prevention measures
 - Certifying agents may conduct residue testing to determine if these preventive practices are adequate to avoid contact with substances such as prohibited pesticides, antibiotics, and GMOs
 - If GMOs are suspected or detected, certifiers must conduct an investigation to determine if a violation of organic farming or processing standards occurred.
 - Note: Certifiers may need additional guidance from NOP on GMO testing (sampling procedures, testing options, choosing labs). Guidance is also needed to address positive results given that there aren't specific threshold levels in the USDA organic regulations. See Appendix A
- Any certified organic operation found to use GMOs may face enforcement actions, including loss of certification and financial penalties.

Seed Purity Requirement for Non-organic Seed

The longer we wait to set limits for controlling contamination in organic seed, feed and crops, the further we fall behind market demand, and the longer organic farmers are subject to the variability of the private market vs. the requirements of the organic regulations. A first step of action to protect organic seeds and crops from GMO contamination could be to require the evaluation of the non-GMO status of **nonorganic** seeds intended for use in organic production.

- The regulations require that non-organic seed be non-GMO. Organic producers must provide ACAs with supporting evidence that non-organic seed is non-GMO. To address this requirement, NOP could in guidance request that ACAs collect a seed purity declaration for high risk crops made (preferably on the seed tag of each bag of seed with a lot number) by the seed supplier or organic operation to verify the non-GMO status of non-organic seed.
- Since organic seed must comply with the organic standards and is subject to residue sampling by ACAs, requiring seed purity declaration for organic seed could undermine confidence in the process-based standards. For organic seed, an organic certificate is adequate. However, requiring a seed purity declaration on **non-organic seed** would

obligate seed suppliers or organic operations to test non-organic seed for GMOs and to withhold seeds that were contaminated from entering the organic supply chain. A suggested threshold for planting seed is 0.1%, a figure in common use.

Requiring a seed purity declaration for non-organic seed would:

- Shift the financial burden of routine GMO testing from organic seed producers to suppliers of non-organic seed;
- Significantly reduce the inadvertent introduction of GMOs into organic crops through seed;
- Show confidence in the processed based standards that have proved successful in preventing pesticide contamination on organic products; and
- Incentivize the expansion of the organic seed industry
- However, such a requirement might reduce crop seed and variety options for organic producers if seed suppliers were unwilling to test non-organic seeds for GMOs.

V. REQUEST FOR PUBLIC COMMENT

The Materials Subcommittee would like input from the public on the concepts presented in this discussion document and particularly asks the following questions to help inform a subcommittee proposal:

1. Do you agree with the preventive management strategies described in this document or have suggestions for improvement? If not, why? Please be specific.
2. Do you have suggestions for improvement on any of the preventive practices included in this discussion document? Please be specific.
3. Are there other preventive management strategies that should be included? Please describe.
4. Do you agree that a seed purity standard should be established for non-organic seed when used under the commercial availability clause of the regulations (organic seed is not available)? If yes, do you think there should be a threshold level established? Why or why not? What should the threshold level be?
5. Are there existing resources that are not listed here that NOSB should review and/or include in the proposal?

Subcommittee Vote

Motion to accept the Prevention Strategy Guidance for Excluded Methods Discussion Document

Motion by: Francis Thicke

Seconded by: Zea Sonnabend

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

Approved by C. Reuben Walker, Subcommittee Chair, to transmit to NOSB February 25, 2015

Sources/References

Blue River Hybrids - www.blueriverorgseed.com/docs/PuraMaize-Fact Sheet.pdf

Non-GMO Project Standard, 2013. Non GMO

Project. http://www.nongmoproject.org/?attachment_id=8561

OSGATA, 2014. *Protecting Organic Seed Integrity*. <http://www.osgata.org/organic-seed-integrity/>

Riddle, Jim 2012. *GMO Contamination Prevention - What Does it Take?* University of Minnesota Southwest Research and Outreach Center.

The Organic Center - <http://www.organic-center.org>

USDA/APHIS Biotech Regulatory Services (BRS) - <http://www.aphis.usda.gov/biotechnology/>

USDA National Organic Program - <http://www.ams.usda.gov/AMSV1.0/nop>

Appendix A

Guidance and training for ACAs on GMO testing

On November 9, 2012, NOP published a Final Rule on Periodic Residue Testing. The rule clarifies a provision of the Organic Foods Production Act (OFPA) of 1990 and the regulations issued that require periodic residue testing of organically produced agricultural products by ACAs. NOP received several comments regarding types of residues that would be considered acceptable targets for testing under the rule. Four commenters requested clarification on testing for GMOs.

NOP responded by saying that it does not intend for the testing conducted under section 205.670 to be limited to pesticides residues. Under the existing regulations, certifying agents have the flexibility to test for a range of prohibited materials and excluded methods, including, but not limited to, pesticides, hormones, antibiotics, and GMOs.

Given the regulatory requirements and NOP clarification, ACAs are required to test if there is reason to believe that an organic product has come into contact with GMOs. ACAs may also test for GMOs under the periodic residue testing requirements. To date, however, NOP has not issued any instruction or guidance on GMO testing.

The Materials/GMO Subcommittee could draft a recommendation to NOP to create guidance and provide training to ACAs on conducting GMO sampling and testing under the residue-testing rule. Providing NOP with a recommendation that includes further guidance on testing falls directly under the specific responsibilities outlined in the OFPA starting at section 2119(k):

5. PRODUCT RESIDUE TESTING.—The Board shall advise the Secretary concerning the testing of organically produced agricultural products for residues caused by unavoidable residual environmental contamination.

Although NOP guidance on pesticide residue testing is available and USDA resources for GMO testing in organic feed do exist, further guidance on GMO testing of other crops for human consumption is greatly needed. It is extremely important that guidance offer clear and consistent sampling and testing protocols so ACAs may accurately assess the efficacy of an organic operation's system for ensuring that GMOs do not come in contact with organic product. Testing is one of the most definite and effective tools ACAs can use to evaluate whether an organic operation has adequate measures in place to prevent commingling with non-organic GMO crops as well as intentional or unintentional contact with GMOs.

**National Organic Standards Board
Certification, Accreditation, and Compliance Subcommittee
National Organic Program Accreditation Peer Review Process
January 7, 2015**

I. INTRODUCTION

The National Organic Program (NOP) is establishing a repeatable and transparent peer review process to respond to previous recommendations of the National Organic Standards Board (NOSB). The NOSB has made three recommendations (2001, 2005, and 2009) concerning Peer Review Panels (PRP) under section 7 U.S.C. 6516 of the Organic Foods Production Act (OFPA). In a memorandum dated November 19, 2014, the NOP asked the NOSB's Certification, Accreditation and Compliance Subcommittee (CACS) to review a 'Peer Review of National Organic Program (NOP) Accreditation' process provided with the memorandum and provide feedback on NOP's process. Furthermore, the NOP requested that the (CACS) provide feedback to the NOSB during the spring 2015 NOSB meeting and that the feedback be in the form of a proposal, which might include (1) support for the NOP's peer review process and/or (2) any recommendations for how the process should be changed to be successful, and/or (3) any suggestions the NOP should consider in its implementation.

II. BACKGROUND & RELEVANT AREAS OF THE RULE

There are three prior NOSB recommendations concerning PRPs. The 2001 recommendation is, in one sense, the most relevant; it speaks to the operating procedures and selection criteria for the PRP, though it uses slightly different terminology. The 2005 recommendation is essentially an assessment of the 2003 ANSI audit and speaks little to the current request of the NOP, *per se*. The 2009 recommendation is a very brief recap of the history of the subject and suggestion for regular American National Standards Institute (ANSI) and OIG audits with a mandatory NOSB review. No part of the prior NOSB recommendations runs counter to the intention and general concepts expressed in the present NOP request for input. In the past there has been various and regular, albeit infrequent, public comment supporting the establishment of a formal PRP as described in the process recently provided by the NOP.

Section 205.509 of the USDA organic regulations requires the USDA Agricultural Marketing Service (AMS) Administrator to establish a panel pursuant to the Federal Advisory Committee Act (FACA) to conduct peer reviews of the NOP's accreditation process and decisions. To satisfy the requirements of §205.509, the NOP has previously contracted with third-party auditing organizations to conduct peer reviews. The NOP contracted with the American National Standards Institute (ANSI) in 2005 and 2014 and the National Institute of Standards and Technology (NIST) in 2010. During the last few years, foreign governments have also conducted peer reviews of the NOP: the European Commission in 2010, the Canadian Food Inspection Agency in 2011 and 2013, and both South Korea and the European Commission in 2014.

A 2010 Office of the Inspector General (OIG) audit of the NOP found that using third-party review organizations to conduct peer reviews does not satisfy the requirement for a peer review panel described in §205.509 of the regulations. The OIG recommended that the NOP either form a peer review panel in accordance with the regulations or change the regulations.

III. DISCUSSION

The CACS discussed the NOP's request and supports: 1) the concept and practice of a formal Peer Review Panel process and 2) the general direction of the process outlined by the NOP and provided with the recent memorandum; with some modifications as provided in the following section. In general, the suggested changes concern the number, composition, and experience of the PRP members. The CACS feels that three members cannot provide adequate breadth of experience to adequately approach the issues involved. In suggesting the inclusion of a standing NOSB member, the CACS intends that it be either the Vice-Chair or Chair of the CACS as they are both experienced and positioned to provide a coherent lens for the Board as a whole and their Board workloads will generally allow for this additional responsibility. Lastly, we suggest giving priority to PRP members with inspection, certification, *and* accreditation experience; these valuable experiences provide for a comprehensive view of the Peer Review Process. The CACS left the majority of the NOP's draft process unchanged and finds it appropriate and necessary.

The CACS recommends – outside the scope of this proposal – that the NOP pursue a rule change to §205.509 removing the FACA reference and allow the hiring of contractors as an independent assessment body, in a manner consistent with the OIG findings.

IV. PROPOSAL

The CACS proposes the following process for the National Organic Program Accreditation Peer Review Process:

- 1) Contract with assessment body. AMS will contract with a peer assessment body to coordinate and manage the peer review panel, once established.
- 2) Select peer review panel. The peer assessment body, in consultation with the NOP Deputy Administrator, will select the peer review panel for each peer review assessment effort.
 - a) The panel will include at least five individuals, the majority of which are not employees of the USDA.
 - b) All members must have knowledge or experience with ISO/IEC 17011 or conformity assessment activities.
 - c) All members of the panel must sign a confidentiality statement to not copy, disclose, or distribute any documents they review while participating on the panel.
 - d) At least three members must have expertise in organic production and handling methods, pursuant to the OFPA, specifically in the areas of organic certification and inspection.
 - e) At the discretion of the NOP Deputy Administrator, a current member of the NOSB may be selected to augment the PRP in an *ex officio* capacity, if and when the member is free

- from conflicts of interest as defined by the Secretary, to function as a conduit to the NOSB about PRP activities.
- f) A staff member of the NOP Accreditation and International Activities (AIA) Division will provide support for the panel. This person will be responsible for selecting, redacting, copying, assembling, and distributing copies of documents for panel review.
- 3) Select a representative sample of accreditation decisions. The panel will select at least three, but not more than five, samples from final accreditation decisions rendered by the NOP.
 - a) The decisions subject to sampling will be those signed during the 12 months immediately preceding the date of the panel's first organizational meeting.
 - b) The date of the accreditation decisions to be considered for sampling will be the date on which the NOP Deputy Administrator signed the decision.
 - c) The samples may be selected randomly or as individual items of interest at the discretion of the peer review panel. If only three or fewer decisions were issued during the prior 12 months, then all the decisions will be selected for review.
 - d) If possible, panel members should select accreditation decisions for at least one large, one medium, and one small certifier for review. This is not, however, a mandatory requirement. The selection of sample decisions is at the panel's complete discretion.
 - e) In addition to the above files, select additional files will be reviewed if necessary to ensure that each of the following type of file is sampled (if such activities were conducted during the sampling period):
 - i) Initial accreditation of a certifier;
 - ii) Renewal of accreditation of a certifier;
 - iii) Surveillance (routine or directed) of a certifier;
 - iv) Suspension of accreditation of a certifier;
 - v) Revocation (withdrawal) of accreditation of a certifier;
 - vi) Amendment of scope of accreditation of a certifier;
 - vii) Appeal of proposed adverse action(s) against a certifier; and
 - viii) Audits and resulting decisions in response to formal complaints filed against a certifier.
 - f) Files with allegations of wrongdoing by a certifier that may be the subject of investigations beyond the scope of the NOP accreditation process should not be selected.
 - 4) Prepare NOP accreditation process documents for review by the panel. A staff member of the AIA Division will assemble all relevant NOP AIA procedural documents for review by the panel, including findings and corrective actions from past peer reviews. These may be saved as files, or as links to public documents that are already available on the NOP Web site, as applicable.
 - 5) Prepare certifier documents for review. The staff member of the AIA Division will provide the following documents for each certifier selected for review:
 - a) Application for accreditation or renewal, including all attachments;
 - b) AIA document review summary sheet;
 - c) NOP audit plan;
 - d) NOP audit report;
 - e) Letters and any Notices sent to the certifier;
 - f) Proposed corrective action from the applicant;
 - g) Notes and decision summary from accreditation committee meeting;
 - h) Signed agreement from the certifier;
 - i) Decision letter from the Deputy Administrator; and
 - j) Certificate of accreditation.

- 6) Review accreditation procedures. Each member of the review panel will review the NOP accreditation procedural documents for the following criteria:
 - a) Compliance with the accreditation procedures in Subpart F of the USDA organic regulations (7 C.F.R. §§ 205.500 - 205.510); and
 - b) Compliance with ISO/IEC 17011.
- 7) Review accreditation decision documents in preparation for meeting. Each member of the peer review panel will review the accreditation decision documents provided. Panel members should consider whether the NOP and/or AIA Division followed established NOP procedures for accrediting certifiers, or renewing their accreditations.
- 8) Prepare individual opinions. Each member of the panel will complete a peer review report form for the review of the accreditation procedures and for each of the decision files. Reports will identify:
 - a) Any elements of the NOP accreditation procedures that are not aligned with Subpart F of the regulations or ISO/IEC 17011;
 - b) Any instances where records indicate AMS personnel or committees did not adhere to established NOP procedures for accrediting certifiers or renewing their accreditations; and
 - c) Completeness and effectiveness of corrective actions from past reviews.
- 9) Prepare draft consensus report. The peer review assessment body will consolidate the reports into a single narrative summary report. The draft report, along with copies of individual reports, will be circulated to the peer review panel.
- 10) Peer review panel meeting. After reviewing the report, the peer review panel will meet by conference call to discuss their findings and the draft report. The panel will provide comments to the peer review assessment body and agree on language for the final report.
- 11) Peer review panel report. The peer review assessment body will consider the comments and prepare a final report. The final report will be sent to the NOP Deputy Administrator with copies to the peer review panel.
- 12) Presentation. The peer review panel report, along with any NOP response, will be presented at the next NOSB public meeting.
- 13) Publication. After the public meeting, the NOP will post a copy of the peer review panel report and the NOP response, on the NOP Web site. A USDA Organic Insider notice will announce the availability of the report.

Motion to accept the Peer Review Proposal

Motion by: John Foster

Seconded by: Jean Richardson

Yes: 8 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Motion passed

Approved by Carmela beck, Subcommittee Chair, to transmit to NOSB January 17, 2015

**National Organic Standards Board
Livestock Subcommittee
Synthetic Methionine (MET) in Organic Poultry Feed Proposal
Revised January 31, 2015**

Summary of Proposed Action

The Livestock Subcommittee proposes to revise the current allowance of synthetic methionine (MET) to read:

DL- Methionine, DL- Methionine - hydroxy analog, and DL- Methionine - hydroxy analog calcium (CAS #'s 59-51-8, 583-91-5, 4857-44-7, and 922-50-9) - for use only in organic poultry production at the following pounds of synthetic 100% Methionine per ton of feed in the diet, averaged over the life of the flock: Laying chickens - 2 pounds; Broiler chickens - 2.5 pounds; Turkeys and all other poultry - 3 pounds.

The Livestock Subcommittee would also like to propose that the NOP develop guidance for Certifying Agents and industry on how to calculate and verify the use and allowance of synthetic MET expressed as an average: pounds of synthetic 100% Methionine per ton of feed in the diet over the life of the bird.

Introduction

The current organic standards allow for the use of synthetic MET for use only in organic poultry production at the following maximum levels of synthetic MET per ton of feed: Laying and broiler chickens—2 pounds; turkeys and all other poultry—3 pounds.

The allowed rates represent “step down” levels that were recommended by NOSB in April 2010, codified in a final rule on September 19, 2012, and went into effect on October 2, 2012.

NOSB recommended the step down rates in order to balance various interests including: (i) providing for the basic maintenance requirements of organic poultry; (ii) satisfying consumer preference to reduce the use of synthetic MET in organic poultry production; and (iii) motivating the organic poultry industry to continue the pursuit of commercially sufficient sources of allowable natural sources of MET.

However, in the attempt to balance interests, the 2010 NOSB recommendation included an allowance for synthetic methionine expressed as a total maximum limit of pounds of MET per ton of feed, while the Methionine Task Force (MTF) July 2009 petition requested that methionine rates be expressed as an average over the life of the flock. The rates expressed as a maximum limit do not address MET demands when laying chicks first come into production. Further the MTF has brought it to the Livestock Subcommittee’s attention that the step-down for broiler chickens constituted a higher percentage decrease than for other poultry categories.

In the NOP Proposed Rule published in the Federal Register on February 6, 2012, the NOP recognized that on April 8, 2011, the MTF submitted a new petition for revised maximum allowable levels of synthetic MET expressed as an average per ton of feed over the life of the bird as originally requested in the 2009 petition. As stated in the preamble to the Proposed Rule:

“The NOP anticipates that the NOSB will consider this petition at a future meeting. In the meantime, the NOP believes it is necessary to move forward issuing this proposed rule to

address the April 2010 NOSB recommendation. This is necessary to prevent any gap in the allowance of synthetic methionine in the diets of organic poultry due to the current expiration date of October 1, 2012.” (Federal Register/Vol. 77, No. 24/Monday, February 6, 2012 pg. 5719).

This NOSB proposal addresses the petition submitted by the MTF on April 8, 2011.

Background

The NOSB initiated a review of this substance in 1999, as a result of a petition requesting to add synthetic MET to the National List for poultry. In 2001, the NOSB evaluated a technical advisory panel (TAP) analysis of MET against the criteria provided in the OFPA (7 U.S.C. 6517–6518), and determined that the use of synthetic MET feed supplementation is compatible with a system of organic poultry production. Consistent with the NOSB’s recommendation, the Secretary amended § 205.603 of the National List on October 31, 2003, to allow MET as a synthetic substance for use in organic poultry production until October 21, 2005 (68 FR 61987).

Based upon subsequent NOSB recommendations in March 2005 and May 2008, the Secretary amended the listing for MET to continue the use through October 21, 2008 (70 FR 61217), and again through October 1, 2010 (73 FR 54057). The 2005 and 2008 NOSB recommendations to continue the allowance for MET were informed by updates on the development of allowable natural alternatives, none of which had attained commercial viability. While expressing a strong preference for supplementation with allowable natural sources of MET, the NOSB concluded that terminating the allowance for synthetic MET would disrupt the well-established organic poultry market, and cause substantial economic harm to organic poultry producers. The NOSB and stakeholders agreed that the organic feed sector would continue to research and develop sufficient supplies of allowable organic and natural sources.

On July 31, 2009, the MTF, which is comprised of organic poultry producers, submitted a new petition requesting to extend the allowance for synthetic MET for five years until October 2014. In addition, the MTF proposed that the total amount of synthetic MET in the diet remain below the following levels, calculated as the average pounds of 100% synthetic MET per ton of feed over the life of the bird:

Laying chickens—4 pounds; broiler chickens— 5 pounds; and, turkey and all other poultry—6 pounds.

In consideration of the July 2009 petition and public comments, the NOSB issued two recommendations on April 29, 2010. These recommendations acknowledged a need for the continued allowance of synthetic MET, and conveyed the intent to decrease the amount of synthetic MET allowed in organic poultry production and encourage development of natural alternatives. One recommendation proposed to allow synthetic MET in organic poultry production until October 1, 2012, at the following maximum levels per ton of feed:

Laying chickens—4 pounds; broiler chickens—5 pounds; and turkey and all other poultry—6 pounds.

The NOP codified this recommendation through a National List amendment published in the **Federal Register** on August 24, 2010 (75 FR 51919), and reaffirmed on March 14, 2011 (76 FR 13501).

The second NOSB recommendation from April 2010 proposed reduced maximum levels of synthetic MET after October 1, 2015. The NOSB recommended that the annotation or synthetic MET be revised to read:

For use only in organic poultry after October 1, 2012, at the following maximum levels per ton: laying and broiler chickens—2 pounds per ton; turkeys and all other poultry—3 pounds per ton.

The NOP issued a proposed rule in the Federal Register to amend the National List to reflect the 2010 recommendation on February 6, 2012 followed by a final rule published in the Federal Register on September 19, 2012:

DL-Methionine, DL-Methionine-hydroxy analog, and DL-Methionine-hydroxy analog calcium (CAS #'s 59-51-8, 583-91-5, 4857-44-7, and 922-50-9)—for use only in organic poultry production at the following maximum levels of synthetic methionine per ton of feed: Laying and broiler chickens—2 pounds; turkeys and all other poultry—3 pounds

The amended listing removed the expiration date of 2012 and subjected synthetic MET at rates listed above to review within five years in accordance with the OFPA provision for the sunset of National List substances (7 U.S.C 6517(e)). Synthetic MET for the step-down for laying and broiler chickens – 2 pounds; turkeys and all other poultry – 3 pounds is now subject to a sunset review by the NOSB by 2017.

Relevant Areas in the Rule

7 CFR §205.603(d)(1) - Synthetic substances allowed for use in organic livestock production. As feed additives.

Impact on Industry of Step-Down Rates

Producers are feeding additional levels of protein, commonly soybean meal, in an attempt to meet the MET needs of the birds. This in effect is over feeding numerous amino acids in order to get enough MET into the birds. During the winter months, the birds consume enough feed to meet their needs, but the additional protein in the feed is excreted into the barns causing ammonia levels to rise and blisters on the bird's feet. During the summer months, the birds naturally consume less feed, as their nutritional maintenance requirement is lower, and cannot consume enough feed to meet the necessary level of MET. Producers and certifiers are seeing an increase in feather pecking which can lead to cannibalism, agitation, nervousness, and other behavioral issues. These are animal welfare issues and the organic producers fail to understand why a logical solution cannot be adopted. If the rations could be tailored to the needs of the animal, why would the organic regulations prevent them from doing the right thing for the bird, especially if the overall intake would be at or below the allowed maximum over the course of its life?

Previous NOSB deliberations have discussed alternative sources for synthetic MET. The MTF has invested significant time and money seeking viable alternatives for their industry in an effort to meet consumer expectations. High MET corn has production and yield issues. Corn variety trials are ongoing with the hopes this breeding work will be able to develop varieties that supply the appropriate amount of necessary amino acids. Pasture may provide some supplementation during the right conditions, but is certainly not a dependable solution. Other feed grains may have higher MET levels than corn, but have lower overall protein or may be limiting in other

amino acids which makes them improbable solutions. The EU uses corn gluten meal to balance the MET demand since synthetic MET is not allowed, but 5% of their rations do not have to be organic. Organic corn gluten meal is not available to US producers. Fishmeal and crab meal are used by some organic producers, while others are concerned about off flavors. Availability of fish- and crab meal is very low as most of these products are stabilized for transport with non-compliant stabilizers. Many organic consumers are looking for vegetarian based production systems as well. The NOSB Livestock Subcommittee put forth a discussion document on feeding animal byproducts to poultry as an alternative source of MET and while there was a minority that agreed with the proposal, the majority deemed that consumers would be concerned that organic principles would be compromised. Because there is so much interest in finding an alternative to synthetic MET for organic producers, numerous projects around the world are evaluating herbal and insect based sources. However, due to the need for U.S. Food and Drug Administration (FDA) approval, these will be many years out if determined to be suitable alternatives.

Discussion

MET is classified as an essential amino acid because it cannot be biologically produced by poultry and is necessary to maintain viability. MET is required for proper cell development and feathering in poultry. Natural feed sources with a high percentage of MET include blood meal, fish meal, crab meal, corn gluten meal, alfalfa meal, and sunflower seed meal. Synthetic MET is also used in poultry feed. This substance is a colorless or white crystalline powder that is soluble in water. MET is regulated as an animal feed nutritional supplement by the Food and Drug Administration (21 CFR 582.5475). The dietary demand for total MET declines with age for broilers and turkeys, and while there is a decline during the early stages of pullet development, it increases just before laying begins and trails off as the birds age.

The National Research Council (NRC) recommended rates for Methionine are expressed as a percentage of diet:

	% Methionine	MET Per Ton of Feed
Broilers		
0-3 weeks	.50	10.0 lbs
3-6 weeks	.38	7.6 lbs
6-8 weeks	.32	6.4 lbs
Layers (White –Egg laying Strains+		
0-6 weeks If intake is 100g/day	.30	6.0 lbs
6-12 weeks If intake is 120g/day	.25	5.0 lbs
12-18 weeks	.20	4.0 lbs
18 weeks to first egg	.22	4.4 lbs

Source: National Research Council (NRC): Nutrients Requirements for Poultry: Ninth Revised Edition, 1994

+NRC values from NRC: Nutrients Requirements for Poultry: Ninth Revised Edition, 1994 for Brown-egg laying strains, turkeys, and other poultry types.

The current annotation restricts the addition of synthetic MET to no more than 2 pounds per ton (or .1% of total weight) for layers and broilers, and 3 pounds per ton (or .15% of total weight) for

turkeys and all other poultry. While a typical soybean/corn ration does supply some natural sources of MET, that amount plus the amount of synthetic MET which can be added under an organic program, leaves a significant shortfall from the NRC recommended levels for proper animal development. Further, the current annotation does not take into account the fluctuating demands for MET based on the life stage of the birds.

At the April 2014 NOSB meeting in San Antonio, the Livestock Subcommittee brought forth a proposal to revise the annotation for MET, allowing for the maximum average over the life of the flock to be 2 pounds per ton for layers and broilers, and 3 pounds per ton for turkeys and all other poultry. There was considerable debate on whether or not the annotation should be changed. The majority of the discussion surrounded two issues: 1) the question as to whether a change in annotation would decrease the incentive for the poultry industry to develop alternatives to synthetic Methionine; and 2) the concern that since the change in annotation would effectively reset the Sunset date of the material, MET would stay on the National List for an additional 5 years, further than its original Sunset date of 2017. In order to try to seek a solution that would address these concerns, the Livestock Subcommittee elected to send the proposal back to committee for further discussion.

Since that time, the Livestock Subcommittee has spent a considerable amount of time studying the issues around Methionine; in particular, the commercial availability and/or development status of any non-synthetic alternatives to synthetic MET. The Subcommittee also sought to understand the impact the stepped down rates have had on animal welfare and what role outdoor access has on naturally available sources of MET, i.e., insects and worms that might be foraged by pastured chickens. The Subcommittee received input from a variety of stakeholders in organic poultry production, including both smaller and larger producers, university researchers, poultry nutritionists and agronomists. While there was some debate around the timeline for commercial availability of non-synthetic alternatives, there was consensus that as long as consumers have the expectation of all vegetarian diets for poultry (laying hens, in particular) MTH will continue to be a major issue. There are currently no acceptable alternatives to synthetic MET. And from most, the feedback was that the likelihood of newly developed materials being commercially available before the 2017 Sunset of MET is highly unlikely.

Since the implementation of the new step-down rates for MET went into effect in 2012, public oral and written comments from organic poultry producers generally expressed an observed decrease in overall animal welfare. Therefore, during this information gathering stage, the Subcommittee sought to understand the impact on animal welfare that the stepped down rates of Methionine were having on both large- and small-scale producers. In general, the responses were mixed. However, there emerged a trend that flocks on the lower rates of MET had an increased tendency to demonstrate more stress related issues, including feather pecking and cannibalism. In discussion with stakeholders who provided input, the availability of outdoor access did not seem to have a significant impact on this trend. In some cases, a statistically significant increase in animal mortality was observed at the restricted MET rates.

The levels of MET put forth in this proposed annotation change reflect the Livestock Subcommittee's understanding of the minimum average levels of MET that organic producers need in order to effectively balance the nutritional needs of their flocks with consumer preference for vegetarian poultry diets.

Under this proposal, producers will have an increased liability to document feeding rates to confirm compliance with the regulation. Certifiers will have to develop tracking systems with producers and their feed mills to verify compliance. Larger poultry operations change the

rations frequently to keep cost down by only feeding to meet the bird's needs. These operations will have detailed records on flock age, size, and feed rations fed on a daily basis. However, it will be somewhat complicated if a pullet flock is transferred to for egg production to another farmer who is with another certifier. All the feed documentation will have to follow as well. Smaller operations often feed the same ration throughout the life cycle of the bird and therefore would never feed more than the average. Certifiers have indicated that mechanisms can be developed with their clients, suitable to verify compliance with the regulation. They are in part motivated by the behavioral issues being reported by their inspectors during this first season under the new cap. The NOP may need to issue Guidance Documents or Instructions to certifiers to clarify how verification can be obtained. Certifiers affiliated with the Accredited Certifiers Association (ACA) often work together and help each other gain consistency in areas like this. This could also be a part of the annual training for certifiers conducted by the NOP and ACA.

The NOSB Livestock Subcommittee is unsure of how certifiers will handle a situation if the flock goes out of production prior to the average being below the regulatory cap. We are uncertain as to whether this would be a noncompliance that must not be repeated or a willful violation indicating civil penalties.

Calculating MET allowances average over the life of the flock will result in the following:

- Feed rations can better adjust to the naturally changing demands of the bird. Poultry farmers will have more flexibility to appropriately adjust diets for stage of life, seasonality, breed, etc.;
- Overall usage of MET will likely be lowered. Producers can only add MET to the average cap, not consistently add MET at the maximum rate. Feedback from industry indicate that given the flexibility to adjust MET rates as appropriate, the total actual average MET usage may be below the maximum cap;
- Farmers and nutritionists will still be only marginally capable of meeting the bird's basic needs. The organic poultry industry will continue to have a tremendous incentive to actively evaluate novel sources of MET. With continued research and the development of effective alternatives proven to meet the demands of the organic poultry sector, the NOSB Livestock Subcommittee believes that MET can eventually be eliminated from organic production.

Current listing on the National List:

DL-Methionine, DL-Methionine-hydroxy analog, and DL-Methionine-hydroxy analog calcium (CAS #'s 59-51-8, 583-91-5, 4857-44-7, and 922-50-9)—for use only in organic poultry production at the following maximum levels of synthetic methionine per ton of feed: Laying and broiler chickens—2 pounds; turkeys and all other poultry—3 pounds.

The regulations currently express a total maximum limit of pounds of MET per ton of feed. Consistent with the petition from July 2009 and April 2011, this proposal requests that MET rates be expressed as an average per ton of feed over the life of the flock.

Recommended Committee Action & Vote

Motion to accept the following amendment at §205.603(d):

DL–Methionine, DL–Methionine—hydroxy analog, and DL–Methionine—hydroxy analog calcium (CAS #'s 59-51-8, 583-91-5, 4857-44-7, and 922-50-9) -for use only in organic poultry production at the following maximum average pounds per ton of 100% synthetic methionine in the diet over the life of the flock: Laying chickens – 2 pounds; Broiler chickens – 2.5 pounds; Turkeys and all other poultry – 3 pounds.

Motion by: Tracy Favre

Seconded by: Jean Richardson

Yes: 6 No: 2 Abstain: 0 Absent: 0 Recuse: 0

Motion to adopt the following resolution:

Resolution: The National Organic Standards Board is committed to the phase-out of synthetic methionine for organic poultry production, and encourages aggressive industry and independent research on natural alternative sources of methionine, breeding poultry that perform well on less methionine, and management practices for improved poultry animal welfare.

Motion by: Tracy Favre

Seconded by: Colehour Bondera

Yes: 8 No: 0 Abstain: 0 Absent:0 Recuse: 0

Further Clarification of the Proposed Amendment

Under this recommendation, producers would be able to exceed the above levels in a particular formulation, provided that there was an offsetting formulation below the level, such that the average inclusion rate of 100% synthetic MET over the entire life cycle of the flock was below the allowed maximum level.

Reference is specifically made to 100% synthetic MET, as some forms of synthetic MET (e.g. the liquid form Alimet) are not 100% MET. The maximum pounds as shown above is based on the 100% synthetic MET equivalent so that a consistent standard can be applied to all organic operations, irrespective of the form of MET they are using (e.g. wet vs. dry).

Approved by Tracy Favre, Subcommittee Chair, to transmit to NOSB February 17, 2015

Methionine Minority Opinion

Submitted February 25, 2015

Note: The minority opinion members are Colehour Bondera and C. Reuben Walker. The minority opinion was written AFTER the NOSB-LS voted in support of the synthetic methionine proposal on Tuesday, February 17, 2015..

The minority opinion and majority opinion agree to the commitment by the National Organic Standards Board (NOSB) to the phase-out of synthetic methionine for organic poultry production and encourage aggressive research on natural sources of methionine, as well as research into breeding poultry that perform well on less methionine.

However, the minority opinion will (1) outline points of opposition; (2) cite where the oppositions are in the recommendation, and (3) offer reasonably and humane alternatives.

The outline points of opposition and citations where the oppositions are in the majority recommendation are:

1. There is no science or sufficient evidence for changing the current Step down Method on the record from 2 pounds of synthetic methionine/ton of feed for layers and broilers and 3 pounds of synthetic methionine/ton of feed for turkeys and other poultry.
2. The majority opinion changes the amount of synthetic methionine for broilers from a maximum of 2 pounds/ton to an average of 2.5 pounds/ton per ton over the life of the flock. However, there is no strong scientific evidence or case at the writing of this document to support this change.
3. The use of averaging has been voted down by previous NOSB livestock committees and all previous NOSBs, and it is being petitioned again without new scientific information. In addition, averaging raises serious enforcement problems.

The Methionine Task Force (MTF) or someone should provide feeding schedules showing synthetic methionine levels at the various stages of life.

Conversely, by the majority opinion raising the allowance of synthetic methionine for broilers from 2.0 pounds/ton to an average of 2.5 pounds/ton, the expectation is that during early stages of life the levels of synthetic methionine would increase considerably. The later life stages – at least for broilers – require less methionine, but consume more food, thus amount of synthetic methionine in the early stages of life can be quite high – perhaps as much as 2-4 times the limit of 2.5 pounds/ ton.

In essence synthetic methionine will increase beyond 2.5 pounds/ton and possibly greater than 8 or more pounds of synthetic methionine/ton. This is NOT the intent of previous NOSB boards. Why? It does NOT step down the use of synthetic methionine in a fashion that encourages aggressive research on natural sources of methionine, NOR meet consumer expectation of phasing out the use of synthetic methionine, NOR encourage research into breeding poultry that perform well on less synthetic methionine as stated in the majority opinion of this proposal.

For the sake of transparency, the MTF and/or the LS should supply some real examples showing how the diets will be balanced over the lifetime of the birds and move toward the phasing out of the use of synthetic methionine in organic poultry diets.

Also, the majority is changing one of the three organic poultry categories without scientific rigor

or strong justifications while changing a previous NOSB Step-Down recommendation that has been vetted through the NOSB and National Organic Program (NOP) Rule Making processes. The dissenting opinion believes that the previous Boards' intentions must be upheld. Thus, the dissenting opinion seeks a fairer and balanced consensus by offering a few recommendations that focus on the Step-Down or Modified Step-Down and Phasing-Out approach of synthetic methionine RATHER than Modified Step-Up approach that the majority is seemingly proposing.

Take Away #1: The minority opinion seeks to offer recommendations that should help lead to the phasing-out of synthetic methionine in organic poultry production in a Modified Step Down approach.

These approaches thereof should allow for the scientific experimentation on alternatives to synthetic methionine, prevent severe hardship on existing organic poultry producers, provide greater expectation for new organic poultry producers, meet consumer expectations of phasing out the use of synthetic methionine, and respect the tenor and intent of previous NOSB board and current NOSB desire to phase-out the use of synthetic methionine in organic poultry diets.

Take Away #2: There is no scientific or strong justification for increasing broiler synthetic methionine levels and not addressing layers, turkeys, and other poultry.

There are two (2) methionine documents that NOSB-LS will be addressing at this meeting. The two (2) methionine documents are:

1. A Methionine Petition Proposal – The petition seeks to average and increase the use of synthetic methionine over the life of the bird with no step down or phase out plan.
The majority proposal:
 - a. Proposes allowance of an average of 2 pounds/ton of synthetic methionine for layers over the lifetime of the birds, resulting in increases in synthetic methionine the diet during different life stages,
 - b. Propose increases synthetic methionine at certain times in broilers diets from 2 pounds/ton to an average of 2.5 pounds/ton over the life of the birds without stating the scientific or strong evidence to support the change, and
 - c. Allows an average of 3 pounds/ton of synthetic methionine for turkey and other poultry of resulting in increases in the diet during different life stages.
2. The Sunset Methionine Proposal of 2017 – Since the NOSB cannot annotate materials on the National List at sunset, unless the petition is adopted by the Board, the current listing for methionine would be voted up or down.

The majority opinion at this time does not reveal how much synthetic methionine will be fed beyond the 2 pounds/ton synthetic methionine for layers, 2.5 pounds/ton of synthetic methionine for broilers, and 3 pounds/ton of synthetic methionine for turkeys and other poultry. Therefore, the levels can rise to levels of 6-8 pounds per ton or higher. In essence, this will be no step down, no modified step down, but a means to negate the LS intent of the phase-out of synthetic methionine for organic poultry production to encourage aggressive research on natural sources of methionine, as well as research into breeding poultry that perform well on less methionine.

Also, the current petition before the Board amends the current listing for synthetic methionine to allow increases in the feeding of synthetic methionine at different (presumably younger) stages of poultry's lives. Why? Because the language proposes averaging without any specific calculations of allowable levels during starter, grower, laying, and finishing life stages. Realistically, under the majority proposal, the stages of life as outlined in the National Research Council (NRC) for Poultry for layers, broilers, turkeys, ducks, geese, and other poultry could be exceeded. Thus, we could see the levels of synthetic methionine fed poultry increase from the current 2 pounds/ ton to possibly 6-8 or more pounds/ ton during the younger stage of poultry's lives. Conversely, these stages of live of the birds could be a few days or few weeks. Moreover, the lack of specific allowable delineated levels (lowest to highest) makes the enforceability of the proposal almost impossible and/or time consuming or burdensome. Previous NOSB board has not approved the averaging approach for synthetic methionine.

The majority opinion science or evidence supporting the need for increased synthetic methionine consumption (above currently allowable levels) during specific phases of life is not provided; nor how the passage of the proposal will promote the phasing out of synthetic methionine as stated in the proposal resolution. Is synthetic methionine necessary for animal welfare?

The claim has been made that the use of synthetic methionine is essential for the welfare of poultry. This claim is not supported with established measures of animal welfare and data separating the impact of synthetic methionine from that of management choices. It is not supported by the research results reported by the Methionine Task Force (MTF) in its 2009 petition. The European Union (EU) does not allow the use of synthetic methionine in organic poultry, but does require more space per bird, fewer birds per house, and more access to the outdoors (European Union, 2008). Significantly, the EU also requires that poultry be of slow-growing breeds or be slaughtered at an older age. The contribution of all these factors to the welfare of poultry has been documented. Studies show that reduced stocking rates (both density and group size), outdoor access, and slower-growing birds (who use the outdoors more effectively), but not synthetic methionine and cysteine, have a positive impact on the welfare of poultry (Kjaer and Sorensen, 2002).

Goldstein, 2014 of the Mandaamin Institute submitted to the NOSB evidence that synthetic methionine “up-regulates production of growth hormone insulin-like growth factor I (IGF-1).” However, Jacob, 2015, disputed this claim. Further discussion and research on this issue will probably continue.

The majority proposal says, “there emerged a trend that flocks on the lower rates of methionine had an increased tendency to demonstrate more stress related issues, including feather pecking and cannibalism. No peer-reviewed research has been cited to support this opinion.

Take Away #3: If the current of synthetic methionine is voted down, organic poultry producers will still be able to use synthetic methionine in organic poultry diets. Why? Because there is another methionine proposal with a current sunset date of October 2, 2017 for synthetic methionine. At this point, the NOSB would consider the national listing for this material. The majority proposal does not provide adequate scientific support or justification to propose a drastic change in the allowance of synthetic methionine in feed.

Table 1. General History of Methionine and NOSB

1999	1st petition submitted.
2001	Technical Advisory Panel (TAP) review.
2001	NOSB determines that synthetic methionine is not consistent with organic agriculture but approves it for interim use , until October 21, 2005, by the organic poultry industry to allow the phasing out of their use. <i>(14 synthetic, 0 natural, 0 abstaining; 14 approve, 0 prohibit, 0 abstaining)</i>
2003	USDA adds methionine to NL until October 21, 2005.
2005	2nd Petition - Methionine Task Force (MTF) petitions for continued inclusion on NL.
2005	1st Expiration Date Extension - NOSB votes to extend expiration date to October 21, 2008.
2007	3rd Petition - MTF petitions to remove the expiration date.
2008	2nd Expiration Date Extension - NOSB votes to extend expiration date to October 1, 2010.
2009	4th Petition - MTF petitions to extend the allowance for synthetic MET for five years until October 2014. In addition, the MTF proposed that the total amount of synthetic MET in the diet remain below the following levels, calculated as the average pounds per ton of 100% synthetic MET over the life of the bird: Laying chickens—4 pounds; broiler chickens— 5 pounds; and, turkey and all other poultry—6 pounds.
2010	NOSB votes to (1) allow synthetic MET in organic poultry production until October 1, 2012, at the following <u>maximum levels</u> per ton of feed: Laying chickens—4 pounds, broiler chickens—5 pounds, and turkey and all other poultry—6 pounds; and (2) allow reduced <u>maximum levels</u> of synthetic MET after October 1, 2012, the following <u>maximum levels</u> per ton: laying and broiler chickens—2 pounds per ton; turkeys and all other poultry—3 pounds per ton. Note: Averaging was not approved by NOSB.
2010-2011	The NOP codified the first recommendation through a National List amendment published in the Federal Register (FR) on August 24, 2010 (75 FR 51919), and reaffirmed on March 14, 2011 (76 FR 13501).
2011	5th Petition - MTF petitions to change the limits from pounds per ton of feed to average pounds per ton of feed over the lifetime of the birds.
2012 ¹	The NOP issued a proposed rule in the Federal Register to amend the National List to reflect the 2010 recommendation on February 6, 2012 followed by a final rule published in the Federal Register on September 19, 2012. The amended listing removed the expiration date and put methionine back into the sunset cycle (2017 sunset.) NOP acknowledges MTF petition.
2013	Fall 2013 NOSB meeting canceled. Methionine proposal carried over to 2014.
2014 ²	The LS proposes to allow synthetic methionine at the following maximum average pounds per ton of 100% synthetic methionine in the diet over the life of the flock: Laying and broiler chickens – 2 pounds; Turkeys and all other poultry – 3 pounds.
2014 ³	Expiration Date Consideration - <i>Some NOSB members want an expiration date. NOSB sends proposal back to LS. Chair indicates that the subcommittee could bring back two motions –one for the variable rate and one for the expiration date.</i>

¹ <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5104939>.

² <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5106664>.

³ <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5107796>, pages 1562-1615.

Realistic Phase-Out Date is Needed

The resolution of the current LS proposal vote was 8-0 in the commitment to phase out synthetic methionine. The resolution is laudable. It is consistent with previous LS committee and NOSB boards for the desire to phase out of organic poultry production the use of synthetic methionine. If, as the resolution in the majority proposal states, the NOSB is committed to a phase-out of synthetic methionine, then it is essential that a phase out date be attached or a phase-out plan be outlined. It is only by adopting into regulation a phase-out plan that includes endpoints to each phase that the Board can adopt further step-down requirements.

If the Board put this listing back into sunset, a petition would be required to effect the changes that the majority resolution is proposing. Who would petition? What is the process for petitioning? These unknowns are unacceptable.

Recommendation Option #1

The minority opinion suggests that the listing be changed to read:

DL–Methionine, DL–Methionine—hydroxy analog, and DL–Methionine—hydroxy analog calcium (CAS #'s 59-51-8, 583-91-5, 4857-44-7, and 922-50-9)—for use only in organic poultry production at the following pounds of synthetic 100% Methionine per ton of feed in the diet: Laying and broiler chickens – 2 pounds; Turkeys and all other poultry – 3 pounds. Until December 31, 2019.

Benefits of the phase out are:

1. Negate the need to using *average over the life of the birds*. The averaging is too variable from farm to farm, thus leading to feeding methionine back to in the range of 6 to 8 or more pounds/ton.
2. It honors previous NOSB boards' intent of phasing out the use of synthetic methionine.
3. Satisfy consumer preference for phasing out methionine in poultry diets. The approach should help spur creative management approaches, breed selection, alternative methionine sourcing, and creating a demand for feed manufacturers to market, etc.
4. Provide a means for signaling NOSB intention of phasing out the synthetic methionine
5. It helps to spur research on alternatives and provide time for updates, if additional time is beyond December 31, 2019 is needed, then another phase-out date can be recommended. **The approach has been used previously by NOSB boards and while averaging have been denied. See table 1.**

Recommendation Option #2

Cap the levels of synthetic methionine for new organic poultry operations in productions after 2015. Some modified schedule could be adopted. The following is just one example, and grandfathering of existing operations at a different level has also been considered. The grandfathering issue and phase out can be developed by the LS and brought back for a vote in the fall of 2015.

Step #1: Grandfather in all organic poultry operations in production prior to 2015 by capping synthetic methionine at modified step down rate. A change in ownership and expansion of an existing structure are excluded. Table 2 and 3 give examples.

Table 2. Cap levels of synthetic methionine for grandfathered organic poultry operations prior to 2015 without averaging.

Poultry Level	Methionine Level	2010	2015	>2020
		Lbs./Ton	Lbs./Ton	Lbs./Ton
Layers	.20	4	3	2.25
Broilers	.25	5	4	3
Turkeys and all Other Poultry	.30	6	5	3.75

Table 3. Cap levels of synthetic methionine for new organic poultry operations in productions after 2015 without averaging.

Poultry Level	Methionine Level	2010	2015	2020	2025	2030	2035	2040 Phase Out
		Lbs./Ton	Lbs./Ton	Lbs./Ton	Lbs./Ton	Lbs./Ton	Lbs./Ton	Lbs./Ton
Layers	.20	4	3	2.25	1.69	1.27	.95	End
Broilers	.25	5	4	3	2.25	1.70	1.30	End
Turkeys and all Other Poultry	.30	6	5	3.75	2.80	2.20	1.65	End

Benefits of the Modified Step Down

1. Provide a more gradual (25% rather than a 50%, 60%, and 50%) reduction for layers, broilers, and turkeys and other poultry, respectively and eventual reduction in synthetic methionine over time,
2. Allows time more time for independent and on-farm research efforts,
3. Allow more time for natural alternatives explorations,
4. Negate the need to using *average over the life of the birds*. The existing averaging is too variable from farm to farm, thus leading to feeding methionine back to in the range of 6 to 8 or more pounds/ton,
5. It honors previous NOSB board's intent of reducing the use of synthetic methionine in a step-down manner,
6. Help satisfy consumer preference for phasing out methionine in organic poultry diets. The approach should help spur creative management approaches, breed selection, alternative methionine sourcing, and creating a demand for feed manufacturers to market, etc., and
7. It conforms to the majority unanimous vote of 8-0 in this proposal for a possible approach to phasing out synthetic methionine in a humane manner.

Conclusion

The minority opinion and majority opinion members **BOTH** agree to the commitment by the NOSB to the phase-out of synthetic methionine for organic poultry production and encourage aggressive research on natural sources of methionine, as well as research into breeding poultry that perform well on less methionine. The minority opinion seeks to address the issue of synthetic methionine in a way (1) to encourage more independent research, (2) keep the organic poultry industry strong, (3) meet consumer expectations, and (4) honor previous NOSB boards' decisions to phase out synthetic methionine and not approve the averaging of synthetic

methionine in organic poultry production.

References

EC regulation No. 889-2008, Article 12.

<http://www.ams.usa.gov/AMSV1.0/getfile?dDocName=STELPRDC5104939>.

<http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5106664>.

<http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5107796>, pages 1562-1615.

Kjaer, J. B., & Sorensen, P. (2002). Feather pecking and cannibalism in free-range laying hens as affected by genotype, dietary level of methionine+cystine, light intensity during rearing and age at first access to the range area. *Applied Animal Behavior Science*, 76(1), 21-39.

Jacob, J. 2015. Personal communication. Letter sent to NOSB-LS committee.

Walter Goldstein. 2014. Letter to National Organic Standards Board dated November 26, 2014. Pgs. 5-9.

**National Organic Standards Board
Livestock Subcommittee Petitioned Material Proposal
Acidified Sodium Chlorite (ASC), Sodium Chlorite, Acidified
January 27, 2014**

Summary of Proposed Action:

Sodium Chlorite, Acidified - Acidified Sodium Chlorite, (ASC) - CAS#13898-47-0 (Chlorous Acid), 7758-19-2 (Sodium Chlorite) – is a synthetic substance petitioned to be added to the National List at 205.603(a) as a disinfectant, sanitizer and medical treatment, and at 205.603(b) for use as a topical treatment, for the intended use on organic livestock as a pre and post teat dip.

The Livestock Subcommittee proposes to recommend this material be added to the National List.

Background:

The Petition, dated 4/30/12, was received by the NOSB, and a Technical Report was requested. The Technical Report was received in May 2013 and the Livestock subcommittee developed a Proposal with recommendation not to list this materials based on issues of non-essentiality - Proposal and Recommendation dated August 30, 2013.

Acidified sodium chlorite was considered at the NOSB meeting in April 2014 and tabled based on public comment and returned to the subcommittee for further review.

ASC was reviewed but no revisions were made - Proposal and Recommendation dated January 7th, 2014.

On July 29 2014 and July 31 2014 the Petitioner submitted further detailed and lengthy documentation, with References, to address concerns raised by the NOSB and the public.

On January 7 2015 the subcommittee, as part of Sunset Review of Iodine, received a Technical Report on Iodine, an ingredient common in teat dips. This report provides comparative data on ASC and other teat dips.

Discussion:

Preventive health care is an essential part of organic farming, and mastitis prevention through clean milking parlors and clean animals is always of paramount importance on a dairy farm. Organic farmers cannot use antibiotics and thus the use of pre-milking and post milking teat dips is a normal practice and may be the most critical factor in preventing mastitis. Mastitis is caused by several commonly found bacteria. Mastitis causes inflammation and infection and is painful to the animal. There are several teat dips available on the market, but some may be more irritating to the animal than others, and some bacteria may become resistant, and thus a broader array of teat dip ingredient choices for organic farmers seems essential.

Research indicates that alternative practices to teat dipping/spraying or udder washing are not advised, as the exclusion of a disinfecting step from a mastitis control program would significantly increase the likelihood of infection.

Acidified Sodium Chlorite (ASC) was petitioned for use as a pre and post teat dip treatment in organic livestock production. ASC, also listed as Sodium Chlorite, Acidified, is currently on the

National List as an allowed disinfectant for direct food contact under 205.605(b). After reviewing the ASC petition, along with the Technical Evaluation Report prepared for the NOSB in 2013, the NOSB found that ASC satisfies the criteria related to impact on humans and the environment, and is compatible with organic agriculture. However, in preparation for a vote on ASC at the spring 2014 NOSB meeting, the Livestock Subcommittee had unanimously recommended not adding ASC to the National List because of current alternatives available and a lack of written comments from organic dairy producers in support of listing ASC, leading the Subcommittee to believe ASC did not meet the essentiality criteria. However, at the spring 2014 NOSB meeting the NOSB received a number of public comments indicating a strong need for ASC as an effective alternative teat dip that could be used in cases of microbiological resistance to teat dips currently listed. Therefore, the NOSB voted to table ASC at the spring 2014 meeting in order to further review ASC.

The Livestock Subcommittee has reviewed the additional data provided by the petitioner in summer of 2014, and reviewed all written and oral public comment. In addition, as part of the Sunset Review process, the Livestock subcommittee has been reviewing iodine, in both its primary molecular form and in the various complexed iodophor forms. Iodine is widely used in teat dips. As part of this iodine review the subcommittee requested a Technical Report for iodine. This report, received on January 7th 2015, provides some recent research information and comparative data on iodine based teat dips and on teat dips whose primary ingredient is acidified sodium chlorite.

The following is excerpted from the Iodine Technical Report in its discussion of Alternatives to Iodine in teat dips:

“Information regarding the availability of natural, non-synthetic agricultural commodities or products that could substitute for iodine and iodophor disinfectants is limited. Nisin, a naturally occurring antimicrobial protein known as a bacteriocin, has been incorporated into pre- and post-milking teat dips and is highly effective against Gram-positive as well as Gram-negative bacteria (citation provided). Formulated products containing nisin, are currently available for mastitis prevention (citation provided). Nisin naturally present in milk is also instrumental in preventing milk spoilage due to bacterial contamination (citation provided). The antimicrobial mode of action for nisin involves lysis of the cytoplasmic membrane phospholipid components (citation provided).

Nisin, generally considered a natural product, is not listed as a prohibited non-synthetic substance in organic livestock production (7 CFR 205.604). However, the NOSB classified nisin as synthetic during their 1995 review of the substance for organic processing (USDA, 1995a). Nisin was not recommended for inclusion on the National List for use in the processing of food labeled as “organic” and “made with organic ingredients” (USDA, 1995b; OMRI, 2014).

Small-scale milk producers use homemade udder washes containing lavender essential oil, water, and apple cider vinegar (i.e., acetic acid) as the active antimicrobial agent (citation provided). Other procedures for pre- and post-milking treatments include an udder wash (warm water or warm water with a splash of vinegar) in combination with a teat dip (1 part vinegar, 1 part water, plus 3–4 drops Tea Tree oil per ounce). Naturally-derived acids (e.g., lactic acid) may be used as standalone germicides or further activated through the synergistic interaction with hydrogen peroxide to provide a bactericidal teat cleansing treatment (citation provided). In addition to the natural substances mentioned above, a small number of synthetic substances are currently allowed as disinfectants, topical treatments, and external parasiticides in organic livestock production (7 CFR 205.603 (a) and (b)... “. Iodine TR, 2015, 723-744.

“Suppliers of livestock and dairy products have indicated that iodine is traditionally the preferred germicide used as a teat dip for mastitis prevention. Recent natural disasters in Japan and water shortages in Chile led to increasing prices for iodophor products and resultant interest in alternative teat dips (citation provided). Animal health researchers recently found that acidified sodium chlorite (ASC)-chlorine dioxide solutions are equally effective in preventing new intramammary infections (IMI) in lactating dairy cows naturally exposed to mastitis pathogens when compared to an established iodophor teat dip product (citation provided). Alternatively, the results of experimental challenge studies (cows intentionally exposed to mastitis pathogens) suggest that ASC may actually provide enhanced antimicrobial activity against the mastitis bacteria *Staphylococcus aureus* and *Streptococcus agalactiae* relative to a commercial iodophor (citation provided). These studies also indicate that the tested ASC products had no deleterious effects on teat condition. Further, ASC components exhibit minimal persistence in the environment and are highly unlikely to contaminate the milk from treated animals (USDA, 2013). Commercial ASC teat dips are being increasingly used in conventional dairies. (iodine TR, 2015, 761-776).”

ASC thus appears to be a potentially important ingredient in teat dips and the Livestock subcommittee recommends its addition to the National List as petitioned.

Evaluation Criteria (see attached checklist for criteria in each category)

	Criteria Satisfied?		
1. Impact on Humans and Environment	x Yes	No	<input type="checkbox"/> N/A
2. Essential & Availability Criteria	x Yes	No	<input type="checkbox"/> N/A
3. Compatibility & Consistency	x Yes	No	<input type="checkbox"/> N/A

Subcommittee Action & Vote

Classification Motion: Motion to classify Acidified Sodium Chlorite (CAS # 7758-19-2 (sodium chlorite) and CAS # 14998-27-7 (chlorous acid)) as synthetic.

Motion by: Jean Richardson

Seconded by: Francis Thicke

Yes: 5 No: 0 Abstain: 0 Absent: 3 Recuse: 0

Listing Motion: Motion to list Acidified Sodium Chlorite (CAS #s 13898-47-0 (Chlorous Acid), 7758-19-2 (Sodium Chlorite)) at §205.603(a) and 205.603(b) of the National List annotated as follows: Acidified Sodium Chlorite, allowed for use on organic livestock as a pre and post teat dip treatment.

Motion by: Jean Richardson

Seconded by: Francis Thicke

Yes: 4 No: 1 Abstain: 0 Absent: 3 Recuse: 0

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

Approved by Tracy Favre, Subcommittee Chair, to transmit to NOSB January 27, 2015

NOSB Evaluation Criteria for Substances Added To the National List: Livestock

Category 1. Adverse impacts on humans or the environment? Acidified Sodium Chlorite

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is there a probability of environmental contamination during use or misuse,? [§6518(m)(3)]		x		Risk is minimal. TR page 9, lines 359-369.
2. Is there a probability of environmental contamination during manufacture or disposal? [§6518(m)(3)]		x		TR page 9, lines 359-390.
3. Does the substance contain inerts classified by EPA as ‘inerts of toxicological concern’? [§6517 (c)(1)(B)(ii)]		x		
4. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]		x		As petitioned, substance does not interact with the agroecosystem. TR page 10 lines 410-411.
5. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]		x		Breakdown products are citric acid, salt and water (2009 handling recommendation).
6. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		x		When used as petitioned, SCA and its components exhibit minimal likelihood of persistence in the environment. TR page 7 lines 296-298.
7. Would the use of the substance be harmful to human health or the environment? [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)]		x		“When used as petitioned, acidified sodium chlorite and its component chemicals exhibit minimal likelihood of persistence or accumulation in the environment.” TR page 10, lines 436-428. The material is both GRAS and on the USDA National List for handling.
8. Are there adverse biological and chemical interactions in the agroecosystem, including biodiversity? [§6518(m)(5)]		x		As petitioned, substance does not interact with the agroecosystem. TR page 10 lines 410-411.
9. Are there detrimental physiological effects on soil organisms, crop- s, or livestock? [§6518(m)(5)]		x		As petitioned, substance does not interact with the agroecosystem. TR page 10 lines 410-411.

Category 2. Is the Substance Essential for Organic Production: Acidified Sodium Chlorite

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]		x		TR page 7, lines 280-293.

2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	x			TR page 6, lines 222-279
3. 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 substance is synthetically produced. TR page 7, lines 280-293.
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		x		The substance is synthetically produced. TR page 7, lines 280-293.
5. Is there a natural source of the substance? [§ 205.600(b)(1)]		x		TR page 7.
6. Is there an organic substitute? [§205.600(b)(1)]		x		Nisin, a natural material that may be a substitute, is not authorized for use as a teat dip due to earlier rejection by NOSB as an antibiotic . A number of essential oils and organic acids may also be used as teat dips. TR page 12, lines 503-514
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]	x			See above.
8. Are there any alternative substances? [§6518(m)(6)]	x			There are a number of alternative substances, including iodine, alcohols, chlorine materials, hydrogen peroxide, chlorhexadine and certain essential oils may function as alternatives. TR 524-539 At the spring 2014 NOSB meeting, comments from dairy industry representatives indicated that there was a need for another effective teat dip to be available to organic dairy producers as a substitute in cases of microbiological resistance to teat dips on the National List.
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]		x		Teat dips are critical in commercial dairy production to prevent mastitis. TR page 12.

NOSB Evaluation Criteria for Substances Added To the National List: Livestock

Category 3. Is the substance compatible with organic production practices? Acidified Sodium Chlorite

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic farming and handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]	x			TR, petition. Substance is already allowed for use in handling in direct food contact.
2. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]	x			
3. If used in livestock feed or pet food, Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]			x	
4. If used in livestock feed or pet food, Is the primary use as a preservative? [§205.600(b)(4)]			x	
5. If used in livestock feed or pet food, Is the primary use to recreate or improve flavors, colors, textures, or nutritive value lost in processing (except when required by law)? [§205.600(b)(4)]			x	
6. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i);		x		TR page 6, lines 210-221
copper and sulfur compounds				
toxins derived from bacteria		x		TR page 6, lines 210-221
pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals		x		TR page 6, lines 210-221
livestock parasiticides and medicines		x		TR page 6, lines 210-221
production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers		x		TR page 6, lines 210-221

**National Organic Standards Board
Crops or Livestock Subcommittee
Petitioned Material Proposal
Zinc Sulfate
February 24, 2015**

Summary of Proposed Action:

A petition has been received to allow zinc sulfate to be used as a footbath for control of foot rot in livestock, particularly dairy cattle, sheep and goats. Zinc, a trace element, is necessary for all living organisms. It plays a role in many cell regulatory processes, including the innate immune response. Commercially, zinc sulfate is manufactured from zinc ore mined from underground or open pit mines. Zinc ore deposits are spread widely throughout the world. Zinc ores are extracted in more than 50 countries. China, Australia, Peru, Europe and Canada are the biggest zinc mining countries. Zinc sulfate is most commonly produced by the interaction of zinc salts and sulfuric acid.

Foot rot is a contagious disease. Temperature and moisture play an important role in the transmission and invasion of the bacteria that causes the disease. Most outbreaks occur in seasons with high rainfall, warm temperatures and lush pasture growth. Infectious material may be transferred directly from the soil to animals.

Foot rot is a significant cause of lameness in sheep, goats and cattle caused by the interaction of three bacterial species. Since the first identification of foot rot in sheep, cattle and goats several substances have been used for treatment with varying degrees of efficacy including ethanol, copper sulfate, formalin, and other materials. They vary in side effects and cost. However, most of the substances that are used are not included in the National List. Copper sulfate and zinc sulfate are two of the most accepted treatments and are comparable in efficacy. Zinc sulfate has proven particularly effective at controlling the bacteria associated with foot rot, and is sometimes used in combination with other materials, including copper sulfate. The combination of zinc sulfate with sodium lauryl sulfate (as an excipient) has proven to be more effective than zinc sulfate with copper sulfate. Aspirin (Salicylic Acid) is allowed for use in organic livestock production for health care use to reduce inflammation. Salicylic acid has also been shown to be effective in treatment of foot rot in dairy cattle. A combination of Australian Tea Tree Oil, Jojoba oil, Benzathonium Chloride, water, propylene glycol and emulsifiers (Hoofmate™) as a topical application has been used with some success in treating foot rot (Schivera, 2014). Literature mentions that peracetic acid and hydrogen peroxide foams are also used in the treatment and control of foot rot, although the efficacy of these treatments is controversial.

Spent footbath liquids are typically discarded in the on-farm lagoon system and/or washed out with manure. Water from lagoons is then applied to agricultural lands, leading to concerns regarding the accumulation of the footbath active ingredients in soils. The potential for the accumulation of copper in the environment has led to serious concerns about continued use of copper sulfate as an ingredient in footbaths. Zinc sulfate has the potential to accumulate in the soil, but the bioavailability levels of zinc are dependent upon a number of factors including soil pH, soil aggregates and moisture levels, and therefore it is difficult to determine what level of zinc in soils would be considered toxic. Unlike copper contamination, excess zinc can be successfully removed from soil by planting sunflower and canola.

Request for public comment:

The Livestock subcommittee seeks input from the public regarding the effectiveness of alternative methods for controlling foot rot, including management practices, and the use of hydrogen peroxide, peracetic acid or other materials. Further, the subcommittee seeks feedback on whether the availability of zinc sulfate for use in organic livestock production would likely reduce the use of copper sulfate for treatment of foot rot.

Evaluation Criteria (see attached checklist for criteria in each category)

	Criteria Satisfied?		
1. Impact on Humans and Environment	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2. Essential & Availability Criteria	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
3. Compatibility & Consistency	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A

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

Subcommittee Action & Vote

Classification Motion: Move to classify zinc sulfate as synthetic

Motion by: Tracy Favre

Seconded by: Jean Richardson

Yes: 7 No: 0 Absent: 1 Abstain: # Recuse: #

Listing Motion: Move to list zinc sulfate for use as a footbath only, at §205.603(b) of the National List,

Motion by: Tracy Favre

Seconded by: Calvin Walker

Yes: 4 No: 3 Absent: 1 Abstain: 0 Recuse: 0

Proposed Annotation (if any): For use as a footbath only

Basis for annotation: X To meet criteria above

Approved by Tracy Favre, Subcommittee Chair, to transmit to NOSB February 24, 2015

NOSB Evaluation Criteria for Substances Added To the National List - Livestock

Category 1. Adverse impacts on humans or the environment?

Substance: Zinc Sulfate

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is there a probability of environmental contamination during use or misuse? [§6518(m)(3)]	X	X		Zinc sulfate has a particular mode of action in soils which makes it very difficult to assess regarding contamination levels. Soil pH, soil composition, moisture and other factors all affect the amount of bioavailability of zinc.
2. Is there a probability of environmental contamination during, manufacture or disposal? [§6518(m)(3)]	X	X		Using good manufacturing practice, the likelihood of contamination from manufacture is unlikely. However, some less developed countries are less likely to have environmental controls on the manufacturing process.
3. Are there any adverse impacts on biodiversity? (§205.200)	X	X		Perhaps. See comments #1 above. High levels of zinc in the soil could have negative impact on soil organisms.
4. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517 (c)(1)(B)(ii)]		X		Zinc Sulfate is considered an inert, not listed as one of toxicological concern. It is also considered as GRAS by FDA and is used as a nutritional supplement.
5. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]	X			Can bind with other metals (particularly copper compounds) to form compounds less likely to degrade in soils.
6. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]	X	X		In some cases, and depending upon soil pH and other characteristics, zinc can change forms into those that are more persistent in the environment.
7. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]	X	X		Yes, but again, depends upon soil conditions.
8. Would the use of the substance be harmful to human health or the environment? [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)]		X		Zinc is actually an essential nutrient. It is unlikely that there would be the possibility of high levels of zinc affecting human health, given its petitioned use.
9. Are there adverse biological and chemical interactions in the agro-ecosystem? [§6518(m)(5)]	X	X		Unclear what the levels of zinc are that would be detrimental to the environment. Some soil microorganisms have the ability to adapt to higher zinc levels.

10. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)]				Perhaps. Difficult to determine because of the way zinc interacts with the soil. Zinc sulfate foot bath water is typically discarded in the farm lagoon system with the water later applied to the agricultural land. A buildup of zinc in the soils could be the result.
---	--	--	--	---

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

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]		X		Mineral mined and then refined and purified.
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			Produced using either high heat of an acid agent to create Zinc sulfide compound.
3. 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			Mined or reclaimed from zinc ore.
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		
5. Is there a natural source of the substance? [§ 205.600(b)(1)]		X		Zinc salts do exist but produced using sulfuric acid.
6. Is there an organic substitute? [§205.600(b)(1)]		X		Mineral source
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]		X		
8. Are there any alternative substances? [§6518(m)(6)]	X			Copper sulfate, hydrogen peroxide and other materials can be used as foot baths to eradicate foot rot, but in some cases are not as effective, and in the case of sheep, can be toxic.
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]	X	X		Hoof trimming, dry flooring and isolation of infected animals can help control foot rot. However, the infection can become increasing debilitating to the animal as it progresses, and can be difficult to control without proper treatment.

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

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic farming and handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]	X	X		If used after other management practices are put in place, it can be effective means of controlling an infectious disease in cattle, sheep and goats. But there are some drawbacks to using this material, including the potential for buildup of zinc in agricultural soils when lagoon water is applied to the land.
2. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]				
3. If used in livestock feed or pet food, is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]			X	
4. If used in livestock feed or pet food, is the primary use as a preservative? [§205.600(b)(4)]			X	Zinc sulfate is allowed as a feed supplement, but in this case is being petitioned for foot bath.
5. If used in livestock feed or pet food, is the primary use to recreate or improve flavors, colors, textures, or nutritive value lost in processing (except when required by law)? [§205.600(b)(4)]			X	
6. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i);	X			Zinc interacting with sulfuric acid to create zinc sulfate.
copper and sulfur compounds				
toxins derived from bacteria		X		
pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals		X		
livestock parasiticides and medicines	X			
production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers		X		

**National Organic Standards Board
Livestock Subcommittee
Aquaculture Materials Review Update Report
February 2015**

Overview

This document is being prepared in order to provide some institutional memory and a frame of reference for future National Organic Standards Board (NOSB) members as it relates to Aquaculture materials review.

Background on Regulation Development

The Organic Foods Production Act of 1990 (OFPA), also known as Title XXI of the Food, Agriculture, Conservation, and Trade Act of 1990, provided references that support the development of standards for aquatic animals and their products. OFPA includes “fish used for food” in its definition of livestock. OFPA has been amended twice; first to add general provisions to allow certification of wild caught seafood as organic; and second, to address a ruling in a lawsuit filed by Arthur Harvey. One aspect of the Harvey lawsuit pertaining to the rearing of aquatic animals is that it clarified, among other things, that the agricultural products fed to organic animals must be organic.

On March 13, 2000 the Agricultural Marketing Service (AMS) issued a Federal Register notice announcing plans to hold three public meeting to consider the certification of aquatic animal production. AMS convened public meetings on April 10, 2000 in Mobile, Alabama, April 12, 2000 in Anchorage, Alaska, and May 3, 2000 in Providence, Rhode Island and received a total of 71 written and oral comments.

AMS also participated in an organic certification workshop for wild capture operations in Seattle, WA on April 9, 2000 and the National Organic Aquaculture Workshop held at the University of Minnesota on June 23 and 24, 2000.

In September 2000, the NOSB named 6 of its members to an aquatic animals task force to evaluate aquaculture and wild capture aquatic animal operations and to assess the feasibility of developing organic production and handling standards for their certification. The task force assembled two working groups; one on aquaculture and the other on wild capture operations.

Beginning their deliberations in November 2000, the Working Groups engaged in an expansive dialogue over four months and presented their final reports to the Task Force at the NOSB meeting in Buena Park, CA in March 2001.

The Task Force reviewed the working groups findings and, on May 30, 2001, NOSB Aquatic Animal Task Force issued its report on development of organic standards for aquatic animals. The report provided recommended standards for the production of seafood to be sold as organic. On the subject of wild caught seafood, the report concluded that OFPA requires the management of organic animals and that wild caught fish do not meet that level of management. They also concluded that mollusk production was incompatible with OFPA and that mollusk producers were not called upon to make a sufficient number of management decisions to differentiate between organic and nonorganic operations.

At its October 2001 NOSB meeting, the Board made its recommendations for aquatic animals. The Board recommended the development of standards for aquatic animals, no standards for

wild caught, and to use the Aquatic Animals Task Force report as the basis for developing standards for organic aquatic animals.

On April 16, 2003, Congress amended section 6506 of OFPA to provide for the certification of wild caught fish as organic. The legislation was sponsored by Senators Stevens and Murkowski of Alaska. The amendment drew sharp criticism from some in the organic industry, including the Organic Trade Association.

At its October 2004 meeting, the NOSB recommended the formation of an aquatic animal task force to develop proposed production, handling and labeling standards for aquaculture. This task force was to be comprised of two working groups— aquaculture (Aquaculture Working Group) and wild fisheries (Wild Caught Working Group).

On January 24, 2005, Federal Register notice (FR 70 3356) announced the intention to develop draft organic production and handling standards for aquatic animals produced in aquaculture and called for volunteers.

In May 2005, the NOP named 12 individuals to the Aquaculture Working Group (AWG). A Wild Caught Working Group was never appointed due to a lack of nominees interested in participating.

The AWG's discussions were informed by the May 24, 2005 National Organic Aquaculture Working Group (NOAWG) white paper¹. The NOAWG was a private sector ad hoc group of approximately 85 individuals interested in advancing organic aquaculture in the United States.

On January 13, 2006, the AWG issued an Interim Final Report of the Aquaculture Working Group for the USDA National Organic Program, with recommendations for Aquaculture standards.²

Public comments on the Interim Report were received until April 10, 2006.

In March 2007, the NOSB issued a formal recommendation to the NOP on Aquaculture standards, which identified some issues of concern and indicated where additional public comment was requested. Specifically, the issues of feeding wild caught fish to fish being raised in aquaculture facilities and open net pens were of concern. The sections of the AWG's recommendations addressing these issues were removed from the formal recommendation to the NOP pending public comment.³

In July 2007, the AWG issued a Supplement to the Interim Report (Bivalve Molluscs) of the Aquaculture Working Group.⁴ This supplement included recommendations for standards for production, handling and transportation of bi-valves, including oysters, clams, mussels, and

¹ [National Organic Aquaculture Working Group \(NOAWG\) white paper. May 2005](#)

² [Aquaculture Working Group; "Interim Final Report of the Aquaculture Working Group, for the USDA National Organic Program", Winter 2006](#)

³ [National Organic Standards Board; "Formal Recommendation By the National Organic Standards Board to the National Organic Program, Aquaculture Standards Recommendation", March 2007](#)

⁴ Aquaculture Working Group; "Supplement to the Interim Final Report (Bivalve Molluscs) of the Aquaculture Working Group for the USDA National Organic Program"; <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5062437&acct=nopgeninfo>, July 2007

scallops. Gastropod molluscs, such as abalone and conch, and cephalopods, such as octopus and squid, were not included. Public comments were received through November 9, 2007.

At the November 2007 NOSB meeting in Washington DC, the NOSB hosted the Organic Aquaculture Symposium on fish feed and net pens to explore the range and depth of scientific and environmental challenges facing global aquaculture. Of particular focus of the symposium was the challenge around providing adequate supplies of essential nutrients to a new industry with non-existing sources of organic fish meal and fish oil. The meeting was marked with the NOP's first activist demonstration where protesters opposing net pens and feeding forage fish to salmon paraded through the meeting wearing fish hats.

On May 22, 2008, the NOSB submitted to the NOP Recommendations on Farmed Aquatic Plants in Organic Agriculture.⁵ These recommendations were based upon a joint document from the Livestock and Crops committees, and were intended to provide clarification around recommendations for farmed aquatic plants.

On September 8, 2008, the AWG issued a revision to the Supplement to the Interim Report (Bivalve Molluscs), in response to public comments.⁶

In November of 2008, the NOSB submitted to the NOP final recommendations on fish feed and related issues, and net pens and related issues.^{7,8}

These two recommendations addressed the issues of concern raised by the NOSB in March 2007 in response to the AWG's Interim Final Report for aquaculture standards, and sought to modify sections of the rule language originally proposed by the AWG. Specifically, the use of wild caught fish for feed sources had proposed step-downs to allow for the development of certified organic sources for fishmeal and fish oil. Further, the allowance for net pens included stringent environmental considerations including non-point source and point source pollution documentation, living conditions and aquaculture facilities.

In November 2009, the NOSB submitted final recommendations to the NOP on Bivalves and Molluscan Shellfish. The recommendation placed emphasis on strict environmental monitoring of living areas and careful harvesting techniques, and included an appendix, which outlined the differences between conventional and proposed organic standards for bivalve production.⁹ This document rounded out the recommendations by the NOSB on aquaculture. The Livestock Committee had already presented three other parts of aquaculture to the entire Board for vote (fin fish in March 2007; fish feed and net pens in November 2008). All recommendations had

⁵ [National Organic Standards Board; "Recommendation to the National Organic Program on Farmed Aquatic Plants in Organic Agriculture"](#), May 22, 2008

⁶ [Aquaculture Working Group; "Revised Supplement to the Interim Final Report \(Bivalve Molluscs\) of the Aquaculture Working Group for the USDA National Organic Program"](#), September 8, 2008

⁷ [National Organic Standards Board; "Formal Recommendation by the National Organic Standards Board to the National Organic Program, Aquaculture: Fish Feed – Fish Oil and Fish Meal and Related Issues"](#), November 19, 2008

⁸ [National Organic Standards Board; "Formal Recommendation by the National Organic Standards Board to the National Organic Program, Aquaculture: Net Pens and Related Issues"](#), November 19, 2008

⁹ [National Organic Standards Board; "Formal Recommendation by the National Organic Standards Board to the National Organic Program, Molluscan Shellfish \(Bivalves\)"](#), November 5, 2009

passed and were recommended to the Program for inclusion in the regulation. At the Spring 2010 NOSB meeting, the board adopted recommendations for Bivalves. With this action, the board had provided a complete set of recommendations for NOP rulemaking for organic aquaculture.

In October 2010, the AWG submitted to the NOSB, Comments and Proposed Revisions by the Aquaculture Working Group Pertaining to the Recommendations of the USDA National Organic Standards Board for Organic Aquaculture Standards. (Footnote for hyperlink).

Written and Oral Public Testimony

A thorough analysis of available written and oral testimony presented to the NOSB on aquaculture demonstrates a number of repetitive areas of concern. Prior to 2006, public comments primarily focused on if an organic aquaculture standard should be developed in the first place, and whether wild aquatic species should be certified organic. More specific areas of concern emerged in public comments beginning in 2006 and coincided with the Aquaculture Working Group's Final Report

The greatest number of public comments span from Fall 2006 through Fall 2008. In some cases, testimony was submitted on behalf of multiple organizations and/or signed by multiple members of the public.

There has been overwhelming agreement within the public record of written and oral public comments about two important issues:¹⁰

- 99.1 percent (54,994) of comments oppose open ocean pen facilities being certified organic.
- 99.1 percent (54,990) of comments oppose the use of wild-caught fishmeal and oils in organic aquaculture feed.

From 2006 to present, public comment on organic aquaculture largely focused on these two issues.

Materials Petition and Review

Beginning in June 2010 and at the request of the NOP, the AWG started submission of petitions for materials to be used in Organic Aquaculture. There was the thought among AWG members that it was important to start the petition process with those materials that were absolutely crucial to successful organic aquaculture operations, but by no means was the initial list considered to be comprehensive of all materials that might eventually be needed.

It should be noted that Aquaculture standards were still going through the clearance process within the NOP and had not yet been promulgated. However, subcommittee members were encouraged by the NOP to evaluate materials using the standards recommended by the NOSB to the NOP between 2007 and 2010.

Per NOP staff, most petitions are revised at least once to address incomplete information identified by NOP before they are submitted to the NOSB for review. It is fairly common to have a delay of a few months or more while the petitioner revises the information.

As an example, the first aquaculture petition, for carbon dioxide, was submitted to NOP as a draft on June 25, 2010, but was revised and later submitted to the NOSB for review in April 2012.

¹⁰ [Information compiled from public records](#)

The following table shows the ten (10) materials petitioned for use in organic aquaculture and their current status as of October 2014:

Table 1: Materials Petitioned for Organic Aquaculture as of October 2014				
Petition Submittal Date*	Substance	Type	Technical Report	Notes
1/6/12	Vitamins (PDF)	Aquaculture - Animals	Technical Report (2013) (PDF)	Initial petition insufficient; Petitioner notified 8/10/11; revised petition sent to MC on 1/9/2012; sent to LS on 5/30/2012; TR requested on 8/6/12; TR sent to LS on 4/29/2013; TR accepted as final 6/18/2013; Spring 2015 Agenda
3/27/12	Trace minerals (PDF)	Aquaculture - Animals	Technical Report (2013) (PDF)	Petition sent to LS on 6/8/2012; TR requested on 8/6/12; TR sent to LS on 6/25/2013; TR accepted on 7/16/2013; LS vote complete; Spring 2015 Agenda
4/19/12	Chlorine (PDF)	Aquaculture - Animals	Chlorine, Livestock (2006) (PDF)	Petition sent to Livestock on 5/30/2012; petition determined to be sufficient on 7/3/2012; no TR requested; LS vote complete; Spring 2015 Agenda
4/19/12	Chlorine (PDF)	Aquaculture - Plants	Chlorine, Crops (2011) (PDF)	Petition sent to Crops on 5/30/2012; Petitioner notified of more info needed on 11/20/12; chlorine TR determined sufficient on 11/20/12; Spring 2015 Agenda
4/27/12	Tocopherols (PDF)	Aquaculture - Animals	Technical Report (2013) (PDF)	Petition sent to LS on 5/30/12; TR requested on 8/6/12; TR sent to LS on 4/16/2013; TR determined complete 6/4/2013; Spring 2015 Agenda
6/7/12	Micronutrients (PDF)	Aquaculture - Plants	Micronutrients (2010) (PDF)	Petition sent to CS on 6/8/2012; additional Q for petitioner and TR request received 12/4/12; clarification requested from CS on 1/7/13; petition accepted as sufficient on 7/2/2013; Spring 2015 Agenda
6/12/12	Vaccines	Aquaculture - Animals	Technical Report (2014) (PDF)	Petition sent to LS on 6/14/2012; petition sufficient on 5/21/2013; TR request sent to contractor on 6/14/2013; TR accepted as sufficient on 2/12/2014; Spring 2015 Agenda

6/27/12	Lignin Sulfonate (PDF)	Aquaculture - Plants	Lignin Sulfonate (2011) (PDF)	Note: there are two petitions for lignin sulfonate for aquaculture (plants and animals). Petition sent to CS on 7/3/2012; additional Q for petitioner and TR request received 12/4/12; clarification requested from CS on 1/7/13; petition accepted as sufficient on 7/2/2013; Spring 2015 Agenda
8/3/12	Vitamins, B1, B12, H (PDF)	Aquaculture - Plants		Petition sent to CS on 8/10/2012; accepted as sufficient by CS on 6/18/13; Spring 2015 Agenda
4/3/12; updated 11/20/12	Carbon dioxide (PDF)	Aquaculture - Plants	Carbon Dioxide, Processing, 2006 (PDF)	Initial petition insufficient; Petitioner notified 8/10/11; revised petition sent to MC on 4/17/12; sent to CS on 5/30/2012; petition & TR determined sufficient on 11/20/12; Spring 2015 Agenda
* - <i>Petition Submittal Date reflects the date when a completed petition has been forwarded to the NOSB for review, not necessarily the first date of submission of a draft petition to the NOP.</i>				

Significant NOSB institutional memory had been lost due to the rotation of members off the board and due to the time lapse between the NOSB's adoption of recommendations for organic aquaculture standards and the petition for aquaculture materials. Both the Crops and Livestock committees (now designated as subcommittees going forward) sought additional education of subcommittee members on general principles of aquaculture. A series of guests joined the standing subcommittee calls for both Crops and Livestock in an effort to provide a context from which to begin materials review. The subcommittees made concerted effort to invite speakers such that a diverse and balanced view was presented.

In January 2012, the NOP provided an aquaculture briefing to a joint meeting of the Crops and Livestock subcommittees. The intent of the briefing was to provide some historical perspective on the work completed by previous NOSB on standards development, to provide an update regarding where recommended Organic Aquaculture Standards were in the clearance process, and to address concerns of NOSB members on the absence of standards while reviewing materials petitions for use in Organic Aquaculture.

Initially, five (5) materials for aquatic plants were assigned to the Crops subcommittee, and six (6) materials were assigned to the Livestock subcommittee for review. Subsequently one material, Lignin Sulfonate, for use with aquatic animals, was withdrawn by the petitioner.

On July 25, 2013, the NOP arranged for a few members of the Livestock and Crops subcommittees to tour and familiarize themselves with aquaculture facilities in Maine and to ask specific questions of the operators of the facilities. The tour included both land based and open net pen operations. Prior to the tour, the NOSB prepared questions for the facilities operators. Two attending members submitted to the NOSB reports of the facilities tour. While many questions were answered, one NOSB member continued to express concerns regarding the evolving nature of the technology around net pens and around the strength of regulations governing aquaculture facilities.

In preparation for the Fall 2013 NOSB meeting, the Crops and Livestock subcommittees began to develop proposals for their assigned Organic Aquaculture materials, to be brought before the entire NOSB. While the Livestock subcommittee completed proposals for all of its materials,

the Crops subcommittee was unable to complete proposals that met with the approval of all its subcommittee members. As a result, in August of 2013 the Crops subcommittee voted to table all proposals for materials to be used in aquatic plants.

Government shutdown in October 2013 necessitated the cancellation of the Fall 2013 NOSB meeting. However, prior to the shutdown, public comments were received regarding the proposals prepared by the Livestock subcommittee. Generally, the comments reflected concern that materials were being reviewed prior to promulgation of regulations governing Organic Aquaculture.

In January 2014, the NOSB chair re-assigned all Organic Aquaculture petitioned materials to the Livestock subcommittee citing the need to consider all materials as a group and the need for consistency in analysis and presentation of materials, while acknowledging the gridlock in the Crops subcommittee. All aquatic plant materials were assigned to Livestock subcommittee members and a review of the existing draft proposals from the Crops subcommittee was undertaken. In the end, each of the aquatic plant materials proposals was rewritten, with the additional step of a single member of the Livestock subcommittee providing a final consistency check across all materials – both for aquatic plants and aquatic animals. In order to address some committee members’ and public comment concerns, the following sentence was added to each proposal:

“It should be noted that at the time of drafting this proposal there are no federal standards promulgated for aquatic plant or animal production and this proposal is based on NOSB recommendations of standards voted in 2007, 2008, and 2009.”

Some members from the Crops and Livestock subcommittees felt that minority perspectives were lost with the re-writing of the proposals, and after significant debate, the Livestock subcommittee agreed that a Minority Opinion would be included as an attachment to each material proposal sent to the entire board.

Public comments for the Spring 2014 meeting again addressed concerns regarding the evaluation of materials in the absence of Organic Aquaculture regulations. The Livestock subcommittee recognized the public concern and made the decision to continue bring all material proposals forward so that the full NOSB could have the opportunity to discuss the materials and to allow for further public oral comments at the Spring 2014 meeting.

At the Spring 2014 meeting, each material proposal was brought for the full board to discuss. Out of those discussions, and based upon written and oral public testimony, the NOSB decided to send all ten (10) materials proposals back to the Livestock subcommittee for further evaluation. Specifically, the board and public comments indicated a preference for the materials to be reviewed within the framework of Organic Aquaculture regulations. It should be noted that there were no written comments submitted by individuals or companies who were seeking to use these materials in their organic fish farming business. No one from industry or the general public came to the meeting or provided oral testimony, which made it difficult for the NOSB to understand any market demand for any of the materials petitioned. Specific issues by material are as follows:

Table 2: Aquaculture Materials – Issues for Review**			
Substance	Type	Current Proposal	Notes

Vitamins (PDF)	Aquaculture - Animals	Vitamins Proposal	Are there different requirements for closed systems versus net pens? Need discussion on how the differences might affect usage.
Trace minerals (PDF)	Aquaculture - Animals	Trace minerals proposal	Characterization (or list) of the types of minerals to be used.
Chlorine (PDF)	Aquaculture - Animals	Chlorine proposal	Culture water issues not clear. Need to change annotation to include culture water. Specific questions for a limited scope TR or expert opinion to address the purposes and use of chlorine for culture water. Category 1, Question 6: need discussion of the impact of chlorine on culture water.
Chlorine (PDF)	Aquaculture - Plants	Chlorine proposal	Similar as for aquatic animals. Need more robust and detailed checklist. Need discussion of culture water.
Tocopherols (PDF)	Aquaculture - Animals	Tocopherols proposal	Question regarding feed manufacturing using tocopherols. Cold water vs. warm water vitamins. Is there a difference? What is the availability of tocopherols made without synthetic solvents (i.e., rosemary oil) for animal feeds?
Micronutrients (PDF)	Aquaculture - Plants	Micronutrients proposal	Need a discussion on multi-tropic systems and their impact on the need for routine application of micronutrients. Compare and contrast hydroponics vs. aquaculture plants – clarification needed.
Vaccines	Aquaculture - Animals	Biologics – Vaccines in Aquatic Animal Production	How does stocking density affect the need for vaccines? Is there a competitive advantage if vaccinated animals escape into the ocean? Need specificity on vaccination techniques. Need discussion on management techniques that would reduce the need for vaccinations.
Lignin Sulfonate (PDF)	Aquaculture - Plants	Lignin Sulfonate proposal	Essentiality as it relates to the need for Lignin Sulfonate to be used as synthetic micronutrient.
Vitamins, B1, B12, H (PDF)	Aquaculture - Plants	Vitamins, B1, B12 and H proposal	Discuss types of systems where these are now used.
Carbon dioxide (PDF)	Aquaculture - Plants	Carbon Dioxide proposal	Comment that CO2 might only be needed at the very early stages in aquaculture system set up. Clarify. Need more information on specific uses in AQ system. Suggestion that a stronger annotation is needed to address closed tanks and possible release of CO2 into the environment. Need update on the use of CO2 internationally. What are alternatives for pH adjustment?
** - All materials should be reviewed using the framework of Organic Aquaculture standards as promulgated by the NOP.			

As of October 2014, all materials are currently tabled within the Livestock subcommittee with the intention to re-evaluate all materials as soon as a proposed rule for Organic Aquaculture standards is available.

Respectfully Submitted,

Tracy Favre
Livestock Subcommittee Chair



Sunset 2017 Review Summary Meeting 1 - Request for Public Comment Livestock Substances §205.602, §205.603 April 30, 2015

Introduction

As part of the [Sunset Process](#), the National Organic Program (NOP) announces substances on the National List of Allowed and Prohibited Substances (National List) that are coming up for sunset review by the National Organic Standard Board (NOSB). The following list announces substances that are on the National List for use in organic livestock production that must be reviewed by the NOSB and renewed by the USDA before their sunset dates in 2017. This list provides the substance's current status on the National List, use description, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, this is noted in this list. To see if any new technical report is available, please check for updates under the substance name in the [Petitioned Substances Database](#).

Request for Comments

While the NOSB will not complete its review and any recommendations on these substances until the fall 2015 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the spring 2015 public meeting. These comments should be provided through www.regulations.gov by April 7, 2015 as explained in the meeting notice published in the [Federal Register](#).

These comments are necessary to guide the NOSB's review of each substance against the criteria in the Organic Foods Production Act (7 U.S.C. 6518(m)) and the USDA organic regulations (7 CFR 205.600). The current substances on the National List were originally recommended by the NOSB based on evidence available to the NOSB at the time of their last review which demonstrated that the substances were found to be: (1) not harmful to human health or the environment, (2) necessary because of the unavailability of wholly nonsynthetic alternatives, and (3) consistent and compatible with organic practices.

Public comments should focus on providing new information about a substance since its last NOSB review. Such information could include research or data that may support a change in the NOSB's determination for a substance. Public comment should also address the continuing need for a substance or whether the substance is no longer needed or in demand.

Guidance on Submitting Your Comments

Comments should clearly indicate your position on the allowance or prohibition of substances on the list and explain the reasons for your position. You should include relevant information and data to support your position (e.g., scientific, environmental, manufacturing, industry impact information, etc.).

For Comments That Support Substances Under Review:

If you provide comments in support of an allowance of a substance on the National List, you should provide information demonstrating that the substance is:

- (1) not harmful to human health or the environment;
- (2) necessary to the production of the agricultural products because of the unavailability of wholly nonsynthetic substitute products; and
- (3) consistent with organic livestock production.

For Comments That Do Not Support Substances Under Review:

If you provide comments that do not support a substance on the National List, you should provide reasons why the use of the substance should no longer be allowed in organic production or handling. Specifically, comments that support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:

- (1) harmful to human health or the environment;
- (2) unnecessary because of the availability of alternatives; and
- (3) inconsistent with livestock production.

For Comments Addressing the Availability of Alternatives:

Comments may present information about the viability of alternatives for a substance under sunset review. Viable alternatives include, but are not limited to:

- Alternative management practices that would eliminate the need for the specific substance;
- Other currently exempted substances that are on the National List, which could eliminate the need for this specific substance; and
- Other organic or nonorganic agricultural substances.

Your comments should address whether any alternatives have a function and effect equivalent to or better than the allowed substance, and whether you want the substance to be allowed or removed from the National List. Assertions about alternative substances, except for those alternatives that already appear on the National List, should, if possible, include the name and address of the manufacturer of the alternative. Further, your comments should include a copy or the specific source of any supportive literature, which could include product or practice descriptions; performance and test data; reference standards; names and addresses of producers or handlers who have used the alternative under similar conditions and the date of use; and an itemized comparison of the function and effect of the proposed alternative(s) with substance under review. The following table can help you describe recommended alternatives in place of a current substance that you do not want to be continued.

Written public comments will be accepted through April 7, 2015 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.



Sunset 2017 Review Summary
Meeting 1 - Request for Public Comment
Livestock Substances §205.602, §205.603
April 30, 2015

Reference: 7 CFR 205.603 Synthetic substances allowed for use in organic livestock production

[Alcohols: Ethanol, Isopropanol](#)

[Aspirin](#)

[Atropine](#)

[Biologics, Vaccines](#)

[Butorphanol](#)

[Chlorhexidine](#)

[Chlorine Materials: Calcium hypochlorite, chlorine dioxide, sodium hypochlorite](#)

[Electrolytes](#)

[Flunixin](#)

[Furosemide](#)

[Glucose](#)

[Glycerin](#)

[Hydrogen peroxide](#)

[Iodine](#)

[Magnesium hydroxide](#)

[Magnesium sulfate](#)

[Oxytocin](#)

[Parasiticides: Fenbendazole](#)

[Parasiticides: Ivermectin](#)

[Parasiticides: Moxidectin](#)

[Peroxyacetic/Peracetic acid](#)

[Phosphoric acid](#)

[Poloxalene](#)

[Tolazoline](#)

[Xylazine](#)

[Copper sulfate](#)

[Formic Acid](#)

[Iodine](#)

[Lidocaine](#)

[Lime, hydrated](#)

[Mineral oil](#)

[Procaine](#)

[Sucrose octanoate esters](#)

[Methionine](#)

[Trace minerals](#)

[Vitamins](#)

[EPA List 4 - Inerts of Minimal Concern](#)

[Excipients](#)

Livestock 205.602 Prohibited nonsynthetic substances

[Strychnine](#)



Alcohols

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable

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

Technical Report: [1995 TAP](#); [2014 TR Ethanol](#); [2014 TR Isopropanol](#)

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/17

Additional information requested by NOSB

1. Please provide any information regarding the denaturing material typically used in ethanol used in organic livestock production.
2. What are the most common uses of ethanol?

Aspirin

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable

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

Technical Report: [1995 TAP](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 meeting minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [10/2010 NOSB recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/15

Additional information requested by NOSB

1. Since this material was last reviewed have alternative materials emerged?
2. Is this material essential to organic livestock production?

Atropine

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable

- (3) Atropine (CAS #-51-55-8) - federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food



and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires:

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

Technical Report: [2002 TR](#)

Petition(s): [2002](#)

Past NOSB Actions: [05/2003 NOSB recommendation](#); [04/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/24/17

Additional information requested by NOSB

1. How common is the use of Atropine as a pre-medication before anesthesia?
2. The 2005 Livestock subcommittee mentions the use of Atropine to treat eye infections. Is this still a common practice?

Biologics - Vaccines

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(4) Biologics - Vaccines

Technical Report: [2014 TR](#) (Aquaculture); [2011 TR \(Vaccines from Excluded Methods\)](#)

Petition(s): [2012 Petition \(Aquaculture\)](#)

Past NOSB Actions: [11/2005 NOSB sunset recommendation](#); [11/2009 NOSB recommendation on Vaccines at §205.105](#); [04/2010 NOSB sunset recommendation](#); [10/2014 recommendation on Vaccines from Excluded Methods](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

1. Since vaccines were last reviewed have alternative materials emerged?
2. Should all vaccines be allowed for preventive livestock healthcare?

Butorphanol

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable

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

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

Technical Report: [2002 TR](#)



Petition(s): [2002 Petition](#)

Past NOSB Action : [2002 Livestock Subcommittee recommendation](#); [09/2002 Meeting minutes and vote](#); [04/2010 sunset recommendation](#)

Recent Regulatory Background: National List Amended 12/12/2007 ([72 FR 7049](#)); Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/17

Background from Subcommittee

The TAP review was thorough with respect to the use of butorphanol as a drug, but information about impacts of butorphanol and its metabolites when excreted was missing. Since metabolites of the drug can cross the placenta and pass into the mammary gland and into milk, more information about the metabolites would be helpful. When petitioned, it was considered as a safe and necessary option.

Additional information requested by NOSB

1. Do metabolites have an impact on unborn animals if the mother is treated during pregnancy?
2. What are the effects of metabolites that are excreted?
3. Is butorphanol considered the preferred choice at this time, or are there other options?

Chlorhexidine

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.

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

Technical Report: [1999 TAP](#); [01/2010 TR](#); [2015 TR](#)

Petition(s): N/A

Past NOSB Actions: [10/1999 NOSB meeting minutes and vote](#); [11/2005 NOSB sunset recommendation](#); [11/2009 Annotation change/clarification](#); [04/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/17

Additional information requested by NOSB

Chlorhexidine is a disinfectant that is used as a topical antiseptic during surgery, for “cold sterilization” of surgical instruments, and as a teat dip. Because chlorhexidine can have residual effects, it is only allowed for use as a teat dip when other teat dips have lost their effectiveness.

1. Have you used chlorhexidine as a teat dip? If so, why did you need to use it?

Chlorine materials



Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.

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

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

Technical Report: [2006 TR](#)

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [05/2006 NOSB sunset recommendation](#); [10/2010 NOSB recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/17

Additional information requested by NOSB

1. Are there less toxic disinfecting and sanitizing materials that could be substituted for chlorine materials?
2. Are all three chlorine materials needed for use in livestock production?

Electrolytes

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable

(8) Electrolytes—without antibiotics

Technical Report: [1995 TAP](#); 2015 TR in development

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#), [04/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/17

Additional information requested by NOSB

NONE

Flunixin

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable

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

Technical Report: [2007 TAP Report](#)

Petition(s): N/A

Past NOSB Actions: [10/2002 NOSB recommendation](#); [10/2010 NOSB sunset recommendation](#)

Recent Regulatory Background: National List Amended 12/12/2007 ([72 FR 7049](#)); Sunset renewal notice



published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/17

Additional information requested by NOSB

1. In the event the NOSB votes to remove Flunixin from the National List, would aspirin serve as a replacement? If not, why not?

Furosemide

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable (10) Furosemide (CAS #-54-31-9)—in accordance with approved labeling; except that for use under 7 CFR part 205, the NOP requires a withdrawal period of at least two-times that required that required by the FDA

Technical Report: [2003 TR](#)

Petition(s): [2002 Petition](#)

Past NOSB Actions: [05/2003 NOSB recommendation for addition to the National List](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: National List Amended 12/12/2007 ([72 FR 7049](#)); Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/17

Additional information requested by NOSB

NONE

Glucose

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable (11) Glucose

Technical Report: [1995 TAP](#)

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/17

Additional information requested by NOSB

1. What is the ongoing use of glucose?
2. Is this glucose currently necessary or essential in organic livestock production? Please explain.
3. Are there commercially available alternative(s) since glucose last sunset review in 2012?



4. Are there any annotation(s) needed for glucose? If so, explain and reference evidence.

Glycerine

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(12) Glycerine - Allowed as a livestock teat dip, must be produced through the hydrolysis of fats or oils

Technical Report: [1995 TAP \(Livestock\)](#); [2010 TAP \(Livestock\)](#)

Petition(s): N/A

Past NOSB Actions: [1997 NOSB recommendation](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/17

Additional information requested by NOSB

NONE

Hydrogen peroxide

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(13) Hydrogen peroxide

Technical Report: [1995 TAP \(Crops\)](#); [2015 TR \(Crops\)](#)

Petition(s): N/A

Past NOSB Actions: [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/17

Additional information requested by NOSB

1. What is the ongoing use of hydrogen peroxide?
2. Is this hydrogen peroxide currently necessary or essential in organic livestock production?
Please explain.
3. Are there commercially available alternative(s) for hydrogen peroxide last sunset review in 2012?
4. Are there any annotation(s) needed for hydrogen peroxide? If so, explain and reference evidence.

Iodine



Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable

(14) Iodine

Reference: 205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable

(3) Iodine

Technical Report: [1995 TAP](#); [2014 TR](#)

Petition(s): N/A

Past NOSB Actions: [04/1995 meeting minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/17

Additional information requested by NOSB

1. Can iodophor forms of iodine be produced using less toxic surfactants than nonphenol polyethylene glycol ether (NPE) and similar NPE's? If so what might be substituted?
2. If the use of NPE surfactants was prohibited in teat dips for use in organic livestock production how would this impact your farm?
3. Are there equally effective alternatives to iodophor based teat dips for commercial use in organic livestock production?

Magnesium hydroxide

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable

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

Technical Report: [2007 TR](#)

Petition(s): [2002 Petition](#)

Past NOSB Actions: [2002 NOSB recommendation](#); [11/2005 NOSB sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/17

Additional information requested by NOSB

NONE

Magnesium sulfate

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable

(16) Magnesium sulfate

Technical Report: [1995 TAP](#); [2011 TR](#)

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [10/2010 sunset recommendation](#)



Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))
Sunset Date: 06/27/17

Additional information requested by NOSB
NONE

Oxytocin

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(17) Oxytocin -use in post parturition therapeutic applications

Technical Report: [1995 TAP](#); [2005 TR](#),

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#), [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))
Sunset Date: 06/27/17

Additional information requested by NOSB

1. What is the ongoing use of oxytocin?
2. Is this oxytocin currently necessary or essential in organic livestock production? Please explain.
3. Are there commercially available alternative(s) since oxytocin last sunset review in 2012?
4. Are there any annotation(s) needed for oxytocin? If so, explain and reference evidence.

Parasiticides, Fenbendazole

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable

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

(i) Fenbendazole (CAS #43210-67-9)—only for use by or on the lawful written order of a licensed veterinarian

(ii) Ivermectin (CAS #70288-86-7)

(iii) Moxidectin (CAS #113507-06-5)—for control of internal parasites only

Technical Report: [1999 TAP](#) (Fenbendazole, Ivermectin); 2015 TR in development,

Petition(s): [Fenbendazole](#)

Past NOSB Actions: [2008 NOSB recommendation](#)

Recent Regulatory Background: Added to National List , effective May 16, 2012 ([77 FR 28472](#))

Sunset Date: 5/16/2017

Background from Subcommittee

In the October 1999 NOSB meeting, Ivermectin was voted to be put on the National List (8-3-0). Two other parasiticides failed to pass at that meeting: Fenbendazole (5-6-0) and Levamisole (0-11-0). In April 2004, Moxidectin was recommended to be added to the List (11-1-1-1) with NOSB members expressing reservation about putting it on the List, but thinking it was preferable to Ivermectin, which was already on the List. In May 2008 Fenbendazole was recommended for addition to the list, with discussion among NOSB members that Fenbendazole was safer and more environmentally benign, particularly so because it did not harm dung beetles as Ivermectin does. The Livestock Committee indicated that they would like to eventually see all of the parasiticides come off the List except the best one.

Additional information requested by NOSB

Are the three parasiticides (Ivermectin, Moxidectin and Fenbendazole) different enough in their modes of action that they should all remain on the National List? If not, which one(s) would you recommend be removed from the List, and why?

Parasiticides, Ivermectin

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable

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

(i) Fenbendazole (CAS #43210-67-9)—only for use by or on the lawful written order of a licensed veterinarian.

(ii) Ivermectin (CAS #70288-86-7).

(iii) Moxidectin (CAS #113507-06-5)—for control of internal parasites only.

Technical Report: [1999 TAP](#) (Fenbendazole, Ivermectin);

Petition(s): N/A

Past NOSB Actions: [10/1999 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 06/27/17

Background from Subcommittee

In the October 1999 NOSB meeting, Ivermectin was voted to be put on the National List (8-3-0). Two other parasiticides failed to pass at that meeting: Fenbendazole (5-6-0) and Levamisole (0-11-0). In April 2004, Moxidectin was recommended to be added to the List (11-1-1-1) with NOSB members expressing reservation about putting it on the List, but thinking it was preferable to Ivermectin, which was already on the List. In May 2008 Fenbendazole was recommended for addition to the list, with discussion among NOSB members that Fenbendazole was safer and more environmentally benign, particularly so because it did not harm dung beetles as Ivermectin does. The Livestock Committee indicated that they would like to eventually see all of the parasiticides come off the List except the best one.



Additional information requested by NOSB

Are the three parasiticides (Ivermectin, Moxidectin and Fenbendazole) different enough in their modes of action that they should all remain on the National List? If not, which one(s) would you recommend be removed from the List, and why?

Parasiticides, Moxidectin

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable

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

(i) Fenbendazole (CAS #43210-67-9)—only for use by or on the lawful written order of a licensed veterinarian.

(ii) Ivermectin (CAS #70288-86-7).

(iii) Moxidectin (CAS #113507-06-5)—for control of internal parasites only.

Technical Report: [2003 TAP](#) (Moxidectin); 2015 TR in development,

Petition(s): [Moxidectin](#)

Past NOSB Actions: [2004 NOSB recommendation](#)

Recent Regulatory Background: Added to National List , effective May 16, 2012 ([77 FR 28472](#))

Sunset Date: 5/16/2017

Background from Subcommittee

In the October 1999 NOSB meeting, Ivermectin was voted to be put on the National List (8-3-0). Two other parasiticides failed to pass at that meeting: Fenbendazole (5-6-0) and Levamisole (0-11-0). In April 2004, Moxidectin was recommended to be added to the List (11-1-1-1) with NOSB members expressing reservation about putting it on the List, but thinking it was preferable to Ivermectin, which was already on the List. In May 2008 Fenbendazole was recommended for addition to the list, with discussion among NOSB members that Fenbendazole was safer and more environmentally benign, particularly so because it did not harm dung beetles as Ivermectin does. The Livestock Committee indicated that they would like to eventually see all of the parasiticides come off the List except the best one.

Additional information requested by NOSB

Are the three parasiticides (Ivermectin, Moxidectin and Fenbendazole) different enough in their modes of action that they should all remain on the National List? If not, which one(s) would you recommend be removed from the List, and why?

Peroxyacetic/peracetic acid

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.

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

Technical Report: [2000 TAP](#)



Petition(s): [2008 Petition](#)

Past NOSB Actions: [11/2000 NOSB recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

1. Since this material was last reviewed have alternative materials emerged?
2. Is this material essential to organic livestock production?

Phosphoric acid

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(20) Phosphoric acid - allowed as an equipment cleaner, Provided, That, no direct contact with organically managed livestock or land occurs

Technical Report: [2003 TAP \(Handling\)](#)

Petition(s): N/A

Past NOSB Actions: [10/1999 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

1. Since this material was last reviewed have alternative materials emerged?
2. Is this material essential for organic livestock production?

Poloxalene

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable
(21) Poloxalene (CAS #-9003-11-6)—for use under 7 CFR part 205, the NOP requires that poloxalene only be used for the emergency treatment of bloat

Technical Report: [2001 TAP](#)

Petition(s): [2000 Petition](#)

Past NOSB Actions: 03/2001 NOSB minutes and vote; [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Background from Subcommittee

Poloxalene is a synthetic substance that can be used in an emergency to reverse the process of bloating in ruminant animals. Bloat can be an acute condition which can occur in ruminant animals when they



eat lush forage legumes. When foaming of the rumen contents becomes persistent foam, gases are produced in the rumen faster than they can be expelled. Rapid expansion of the rumen from the gases can lead to asphyxiation of the animal. There are preventative strategies for bloat, and there are alternative treatments for bloat, but poloxalene is a fast acting treatment for acute bloat and is approved only for emergency treatment of bloat.

Additional information requested by NOSB

NONE

Tolazoline

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable

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

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

Technical Report: [2002 TAP](#)

Petition(s): [2002 Petition](#)

Past NOSB Actions: [09/002 NOSB recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Background from Subcommittee

Tolazoline is used in conjunction with Xylazine. Xylazine is used as a sedative, analgesic (pain killer) and muscle relaxant in veterinary medicine. Tolazoline is used to reverse the effects of Xylazine.

Additional information requested by NOSB

1. Are there alternative materials that should be petitioned for use?
2. What alternative practices are available?

Xylazine

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable

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



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

Technical Report: [2002 TAP](#)

Petition(s): [2002 Petition](#)

Past NOSB Actions: [09/002 NOSB recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Background from Subcommittee

Tolazoline is used in conjunction with Xylazine. Xylazine is used as a sedative, analgesic (pain killer) and muscle relaxant in veterinary medicine. Tolazoline is used to reverse the effects of Xylazine.

Additional information requested by NOSB

- 3. Are there alternative materials that should be petitioned for use?
- 4. What alternative practices are available?

Copper sulfate

Reference: [§205.603\(b\)](#) As topical treatment, external parasiticide or local anesthetic as applicable (1) Copper sulfate.

Technical Report: [1995 TAP](#); [2015 TR](#)

Petition(s); N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); 04/2011 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

Zinc Sulfate has recently been petitioned for use as a footbath treatment. In the event that the NOSB votes to add Zinc Sulfate to the National List, how likely are you to use this material instead of Copper Sulfate?

Formic acid

Reference: [§205.603\(b\)](#) As topical treatment, external parasiticide or local anesthetic as applicable (2) Formic acid (CAS # 64-18-6) - for use as a pesticide solely within honeybee hives

Technical Report: [2011 TR](#)

Petition(s): [2010 Petition](#)

Past NOSB Actions: [2010 NOSB recommendation](#)



Recent Regulatory Background: Added to National List, effective August 3, 2012 [[77 FR 45903](#)]
Sunset Date: 8/3/2017

Additional information requested by NOSB

1. Do the alternatives documented in the TR control varroa and tracheal mites?
2. Are the alternatives discussed in the TR available for organic beekeepers?

Lidocaine

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable
(4) Lidocaine—as a local anesthetic. Use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals

Technical Report: None

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

1. Since this material was last reviewed have alternative materials emerged?
2. What is the scientific rationale for what appears to be an excessively long withdrawal period?
3. Is there research to indicate that a shorter withdrawal period would be appropriate?

Lime, hydrated

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable
(5) Lime, hydrated—as an external pest control, not permitted to cauterize physical alterations or deodorize animal wastes

Technical Report: [1995 TAP](#); 2015 TR in development

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); 04/2006 sunset recommendation; [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

NONE



Mineral oil

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable
(6) Mineral oil - for topical use and as a lubricant

Technical Report: [2002 TAP](#); 2015 TR in development

Petition(s): [2002 Petition](#)

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [2003 NOSB recommendation](#), [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

NONE

Procaine

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.
(7) Procaine—as a local anesthetic, use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals

Technical Report: N/A

Petition(s): N/A

Past NOSB Actions: [10/1995 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

1. Since this material was last reviewed have alternative materials emerged?
2. What is the scientific rationale for what appears to be an excessively long withdrawal period?
3. Is there research to indicate that a shorter withdrawal period would be appropriate?

Sucrose octanoate esters

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable
(8) Sucrose octanoate esters (CAS #s-42922-74-7; 58064-47-4)—in accordance with approved labeling

Technical Report: [2005 TR](#)

Petition(s): [2004 Petition](#); [05/2004 petition amendment](#); [09/2004 petition amendment](#)

Past NOSB Actions: [08/2005 NOSB recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Background from Subcommittee



Sucrose octanoate esters (SOEs) are surfactants that lower the surface tension of a liquid, allowing easier spreading and evaporation. SOE is an EPA-registered biopesticide. As a biopesticide, SOEs are currently used as an insecticide to control certain soft-bodied insects, including mites (varroa) on adult honey bees. Sucrose octanoate esters act as biopesticides by dissolving the waxy protective coating (cuticle) of target pests (e.g. mites), causing them to dry out and die.

Additional information requested by NOSB

NONE

DL-Methionine

Reference: [205.603\(d\)](#) As feed additives

(1) DL-Methionine, DL-Methionine-hydroxy analog, and DL-Methionine-hydroxy analog calcium (CAS #'s 59-51-8, 583-91-5, 4857-44-7, and 922-50-9) - for use only in organic poultry production at the following maximum levels of synthetic methionine per ton of feed: Laying and broiler chickens—2 pounds; turkeys and all other poultry - 3 pounds.

Technical Report: [2001 TAP](#); [2011 TR](#)

Petition(s): [2005 Methionine](#); [2007 Methionine](#); [2009 Methionine](#); [M2011 Methionine](#)

Past NOSB Actions: [10/2001 NOSB recommendation](#); [04/2010 NOSB recommendation on Methionine annotation through October 2012](#); [04/2010 NOSB recommendation on Methionine step-down annotation after October 2012](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 10/02/17

Additional information requested by NOSB

What would be the impact on your poultry operation should the current annotation remain in effect for an additional 5 years?

Trace minerals

Reference: [205.603\(d\)](#) As feed additives

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

Technical Report: none

Petition(s): N/A

Past NOSB Actions: [1995 NOSB recommendation](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Background from Subcommittee

From the Livestock Committee's October 1995 recommendations: "Producers often may not be able to control the quantity of vitamins and minerals naturally occurring in feedstuffs. Non-synthetic vitamins and minerals should be used if available, but synthetics are allowed...Synthetic vitamins and minerals



should be used in keeping with the recommendations of the National Research Council and the Association of Animal Feed Control Officials,... specific to each species.”

Additional information requested by NOSB

NONE

Vitamins

Reference: 205.603(d) As feed additives

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

Technical Report: 2015 TR in development

Petition(s): N/A

Past NOSB Actions: [1995 NOSB recommendation](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

1. What is the ongoing use of vitamins?
2. Is this listing for vitamins currently necessary or essential in organic livestock production? Please explain.
3. Are there commercially available alternative(s) for vitamins since the last sunset review in 2012?
4. Are there any annotation(s) needed for vitamins? If so, explain and reference evidence.

EPA List 4—Inerts of Minimal Concern

Reference: 205.603(e) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

(1) EPA List 4 -Inerts of Minimal Concern

Technical Report: [2015 TR Nonylphenol Ethoxylates \(NPEs\)](#) (one group only of List 4 inerts)

Petition(s): N/A

Past NOSB Actions: [02/1999 NOSB minutes and vote](#); [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

NONE

Right COt



Excipients

Reference: **205.603(f)** Excipients, only for use in the manufacture of drugs used to treat organic livestock when the excipient is: Identified by the FDA as Generally Recognized As Safe; Approved by the FDA as a food additive; or Included in the FDA review and approval of a New Animal Drug Application or New Drug Application

Technical Report: [2015 TR](#)

Petition(s): N/A

Past NOSB Actions: [10/2002 NOSB minutes and vote](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

In reviewing the recent Technical Report, does the present annotation for Excipients continue to provide adequate guidance to MRO's and certifiers doing material review?

Strychnine

Reference: **§205.604** Nonsynthetic substances prohibited for use in organic livestock production. The following nonsynthetic substances may not be used in organic livestock production:

(a) Strychnine

Technical Report: None

Petition(s): N/A

Past NOSB Actions: [04/1995 NOSB minutes and vote](#) (crops only), [11/2005 sunset recommendation](#); [10/2010 sunset recommendation](#)

Recent Regulatory Background: Sunset renewal notice published 06/06/12 ([77 FR 33290](#))

Sunset Date: 6/27/2017

Additional information requested by NOSB

NONE