National Organic Standards Board Meeting
Doubletree Hotel & Suites Pittsburgh City Center | One Bigelow Square
Pittsburgh, Pennsylvania | Pennsylvania Ballroom
October 23-25, 2019

PLEASE NOTE:
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Sunset 2021
Meeting 2 - Review
Handling Substances §§205.605(a), 205.605(b), 205.606
October 2019

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 handling that must be reviewed by the NOSB and renewed by the USDA before their sunset dates in 2021. 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.

Request for Comments

Written public comments will be accepted through October 3, 2019 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the October meeting.

Sunset 2021
Meeting 2 - Review
Handling Substances §§205.605(a), 205.605(b), 205.606
October 2019

Note: With the exception of activated charcoal, L-malic acid, microorganisms, peracetic acid/peroxyacetic acid, and sodium acid pyrophosphate, the materials included in this list are undergoing early sunset review as part of the November 18, 2016, NOSB recommendation on efficient workload re-organization.

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, Citric
Acid, Lactic
Calcium chloride
Dairy cultures
Enzymes
L-Malic acid
Magnesium sulfate
Microorganisms
Perlite
Potassium iodide
Yeast

§205.605(b) *Synthetics allowed:*

Activated charcoal
Alginic acid
Ascorbic acid
Calcium citrate
Ferrous sulfate
Hydrogen peroxide
Nutrient vitamins and minerals
Peracetic acid
Potassium citrate
Potassium phosphate
Sodium acid pyrophosphate
Sodium citrate
Tocopherols

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

Celery powder
Fish oil
Gelatin
Orange pulp, dried
Seaweed, Pacific kombu
Wakame seaweed (*Undaria pinnatifida*)

Links to additional references and supporting materials for each substance can be found on the NOP website: http://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned

Acids – Citric

§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))."

Reference: 205.605(a) Nonsynthetics allowed: **Acids** (**Citric – produced by microbial fermentation of carbohydrate substances; and Lactic**).
Technical Report: 1995 TAP - Citric; 2015 TR - Citric; 1995 TAP - Lactic; 2015 TR - Lactic
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 03/2010 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Use:
Citric acid is widely used in food processing. It is used as an ingredient, acidulant, pH control agent, flavoring, and as a sequestrant. It is used as a dispersant in flavor or color additives. It is also an ingredient in dietary supplements and a nutrient, sequestrant, buffer, antioxidant, firming agent, acidity regulator (in jams and jellies, soft drinks and wines), raising agent, and emulsifying salt for many other products. It is also used to improve baking properties of flours, and as a stabilizer, and to inhibit color and flavor deterioration in fruits. Roughly 75% of all citric acid commercially produced is used by the food industry with the remainder used in cleaning agents, or in the cosmetics and pharmaceutical industries.

Manufacture:
First isolated from lemons, it was extracted from lemons and limes until 1919 when production shifted to fermentation (a biological process by which sugars are metabolized to acids, gases, and/or alcohol). Today, the mold *Aspergillus niger* is cultured with low pH values and high levels of sugars and mineral salts to economically produce high yields through fermentation. Various chemical synthesis of citric acid appeared but none have reached the economics derived from the fermentation process. The fermentation process has been refined over the years to produce high levels of citric acid instead of high levels of the by-product oxalic acid. Some public commenters expressed a concern that the fermentation process involves the use of synthetic chemical reactions that were not considered in the original 1995 classification.

International Acceptance:
Citric acid is an allowed ingredient in all international organic standards reviewed in the 2015 TR. The only noted annotation is that Japan Agriculture Standards allow citric acid but only as a pH adjuster for processed fruits and processed vegetables.

Environmental Issues:
Although it is a weak acid, exposure to pure citric acid may cause coughing, shortness of breath, and skin irritation. The fermentation process does produce by-products including oxalic acid. Citric acid will degrade to produce non-toxic and non-persistent environmental products. The last time EPA evaluated citric acid was 1992 at which time they found it posed no environmental risk.

Discussion:
Citric acid has GRAS status (Generally Recognized as Safe) by the FDA. Citric acid has many uses in food production. It has a history of safe use in organic foods dating back to 1995. Natural citric acid may be

isolated from organically grown fruit but has not been commercially available in the quantities that would be required to service the organic sector.

According to 2019 spring public comment citric acid is used to control PH, as an acidulant, a buffer, in gel formation, to stabilize colors, and as an ingredient in dietary supplements. In the organic produce sector it's widely used in the formulation of disinfectants and sanitizers allowed for use in direct contract with organic food without the need for a rinse, a practice essential for complying with FSMA requirements. It's also used for controlling pH in wash water used for the post-harvest handling of fresh fruits and vegetables. Additionally, neutralizing the PH of wash water thereby reduces the amount of chlorine that needs to be added to the water (in order to achieve the desired levels of "free chlorine"). Four certifiers submitted public comment indicating a total of 240 Organic Systems Plans which include citric acid.

Two commenters wrote that citric acid should be classified as synthetic unless it is possible to define non-synthetic citric acid by annotation. The TR found citric acid to be non-synthetic since it is processed via fermentation.

No new information was brought forward in terms of harm to human health or the environment.

Questions:
1. Are there any commercially available sources of citric acid derived from organically grown crops?

Subcommittee Vote:
Motion to remove citric acid based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.605(a) if applicable: NA
Motion by: Lisa de Lima
Seconded by: Scott Rice
Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

Acids – Lactic

§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))."
Reference: 205.605(a) Nonsynthetics allowed: **Acids** (**Citric – produced by microbial fermentation of carbohydrate substances; and Lactic**).
Technical Report: 1995 TAP - Citric; 2015 TR - Citric; 1995 TAP – Lactic; 2015 TR - Lactic
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 03/2010 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Use:
Lactic acid is widely used in almost every segment of the food industry, where it carries out a wide range of functions. The major use of lactic acid is in food and food-related applications, which in the U.S. accounts for approximately 85% of the demand. It is found naturally in milk, meat, and beer but is normally associated with sour milk. Lactic acid controls the growth of bacteria including listeria (NOSB Fall Meeting

Transcript 2015 pp. 263). It has been in use as an acidulant and pH regulator for many years. Lactic acid appears on the National List, 7 CFR Part 205.605(a), as a non-synthetic material with no restrictions on use.

Common uses include, but not limited to:

1. In sugar confectionery, it is used in a continuous production line for high boiled sweets to make perfectly clear sweets with minimum sugar inversion and with no air trapped.
2. In bakery products it is used for direct acidification of bread.
3. It increases butter stability and volume.
4. It produces a mild and pleasant taste in acid pickles, relishes and salad dressings.
5. Lactic acid suppresses Coliform and Mesentericur groups of bacteria.
6. Lactic acid can be used as a meat carcass "wash" or in meat products to reduce microbial contamination.
7. It is used in jams, jellies, and frozen fruit desserts.
8. In dairy products such as cottage cheese, the addition of lactic acid is preferred by some manufacturers to fermentation.
9. Used in imitation dairy products such as non-dairy cheese and non-dairy yogurt powder.
10. Lactic acid is widely used in preserving fruits, for example helping to maintain firmness of apple slices during processing. It also inhibits discoloration of fruits and some vegetables.
11. Buffered lactic acid improves the taste and flavor of many beverages, such as soft drinks, mineral water and carbonated fruit juices.
12. In breweries, lactic acid is used for pre-adjustments during the mashing process and during cooking.
13. Acidification of lager beer with lactic acid improves the microbial stability as well as flavor.
14. It is used in processing of meal in sauces for canned fish, to improve the taste and flavors and to mask amine flavor from fish meal.
15. Lactic acid is used for flavor development and the control of microorganisms in soy cheese.

Manufacture:

First isolated in 1780 from sour milk, lactic acid can be produced both naturally and synthetically. It can be produced in either a solid, water-soluble state, or a colorless liquid state. Lactic acid is produced on an industrial scale through carbohydrate fermentation performed by lactic acid bacteria converting simple carbohydrates such as glucose, sucrose, or galactose to lactic acid.

International Acceptance:

Lactic acid is permitted under all five major organic standards (US, EU, Canada, Japan Agriculture, and IFOAM). Canada classifies it as non-organic "for fermented vegetable products or in sausage". CODEX permits its use "food of plant origin", or "food of animal origin". European Economic Council permits use in processing foodstuffs of both plant and animal origin, or for the regulation of pH in yeast production. Japan Agriculture Standards permits use in processed vegetables or rice products, sausage, for dairy products, and for cheese.

Environmental Issues:

The fermentation process produces calcium sulfate waste (sometimes sold as fertilizer) but it is not known to create any negative environmental impacts.

Discussion:

Lactic acid is a "Direct Food Substance Affirmed as Generally Recognized as Safe," or GRAS, as an antimicrobial agent, curing and pickling agent, flavor enhancer, flavoring agent and adjuvant, pH control agent, and as a solvent and vehicle, with no limitation other than current good manufacturing practice according to FDA regulations at 21 CFR 184.1061.

Uses from the 2019 spring public comment period include: an acidulant, flavor enhancer, buffer, coagulating agent, pH. control agent, as a carcass wash, and as a processing aid in conjunction with celery powder. In the organic produce sector it's widely used in the formulation of disinfectants and sanitizers allowed for use in direct contract with organic food without the need for a rinse, a practice essential for complying with FSMA requirements.

Two commenters commented that lactic acid should be classified as synthetic, due to the material being a product of fermentation.

No new information was brought forward in terms of harm to human health or the environment.

Subcommittee Vote:
Motion to remove lactic acid based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.605(a) if applicable: NA
Motion by: Lisa de Lima
Seconded by: Asa Bradman
Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

Calcium chloride

§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))."
Reference: 205.605(a) Nonsynthetics allowed: **Calcium chloride.**
Technical Report: 1995 TAP
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 03/2010 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Use: Used in a wide variety of food processing applications including as a firming agent (in tofu, cut fruit and canning applications), as a sodium replacement, to adjust water mineral content in brewing applications and as a nutritional electrolyte application.

Manufacturing: Calcium chloride can be obtained by extraction of nonsynthetic brines. When calcium chloride is extracted from a nonsynthetic source, its molecular structure is not changed during extraction and thus should be classified as nonsynthetic. The starting material is a natural brine solution that is pumped out from underground salt beds. Synthetic materials are used in the purification process, but without changing the chemical structure of the material. Calcium chloride may also be commercially obtained as a byproduct in the ammonia-soda (Solvay) process (TR 2015)

International: Calcium Chloride is allowed for use with various annotations under the Canadian, EU, Japanese, IFOAM and Codex standards.

Discussion: For the Spring 2019 NOSB meeting the Handling Subcommittee posed the following question: Is this material currently in use by the organic food processing industry and in what applications? Public comment from trade associations, certifiers and manufacturers were supportive of relisting, noting that it is in use as a buffering agent in fruit preps, in cheese-making, in olive packing, in dairy analogs, as a disinfectant when used in conjunction with chlorine to mitigate effects on plant tissues, and as a tool to mitigate acrylamide in baking applications. Other comments were received from interest groups questioning the purity of commercially available calcium chloride at 6% impurities. The current United States Pharmacopeia **Food Chemicals Codex** (USP FCC) monograph for calcium chloride allows for up to 7% impurities. No context was given for why this is an area of concern.

No new information was received by the NOSB supporting removal of this substance.

Subcommittee Vote:
Motion to remove calcium chloride from §205.605(a) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Tom Chapman
Seconded by: Harriet Behar
Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

Dairy cultures

§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))."
Reference: 205.605(a) Nonsynthetics allowed: **Dairy cultures.**
Technical Report: 1995 TAP; 2014 TR for Ancillary Substances
Petition(s): N/A
Past NOSB Actions: 05/2003 NOSB minutes and vote; 11/2005 sunset recommendation; 03/2010 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Dairy cultures are used by organic dairy processors to make yogurt, cheese, cultured sour cream and other fermented milk products. The use of these cultures can increase the digestibility of milk products, create different flavors and textures, and provide potential health benefits to the consumer.
There are a variety of ways a dairy culture can be produced but generally a dairy or other medium is inoculated with a sample of the fermented food to produce a starter culture. Different microbiological species produce different flavor compounds and in turn produce different traditional dairy products. According to the 2014 technical report (TR) on microorganisms, there is widespread international acceptance of microorganisms and dairy cultures.

Ancillary substances may be present in dairy cultures. 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.

The Handling Subcommittee put forth a document listing the ancillary substances permitted for use in dairy cultures in 2015. These include:

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. potassium phosphate, potassium sulfate, tricalcium phosphate.
Preservatives	sodium benzoate, potassium sorbate, ascorbic acid, sodium formate
Stabilizers	maltodextrin
Cryoprotectants used to freeze-dry (& freeze) microorganisms and Dairy Cultures	liquid nitrogen, maltodextrin, magnesium sulfate, dimethyl sulfoxide, sodium aspartate, mannitol, sorbitol , polysorbate
Substrate that may remain in final product	milk, lactose, grain (rice, barley, wheat) flour, brewed black tea and sugar, soy

That document noted that use of these ancillary substances had not been found to cause negative effects. Additionally, as with all organic materials, any culture that is genetically modified is disallowed.

Dairy cultures have been a staple in food production for centuries and they are generally viewed as a necessary input for organic production of certain dairy products. They pose minimal health risks, and in many cases can enhance health. In the October 2015, NOSB review of dairy cultures comments were received from trade associations, industry, certifiers and a technical organization. All comments were generally in favor of continued allowance of dairy cultures. The question was asked whether these should be listed separately or combined with microorganisms. Most industry stakeholders, while agreeing the dairy cultures were covered under microorganisms, still wanted a separate listing for dairy cultures. Several certifiers and a technical organization agreed that the listing of dairy cultures was redundant to microorganisms and could be removed. The ancillary substances used in dairy cultures has raised potential concerns about their compatibility with organic handling standards, but that has not prevented the support for continued listing of these cultures.

Public comments received during the Spring 2019 NOSB meeting showed widespread support for relisting of the dairy cultures. Several comments noted issues with ancillary substances. One commenter noted that it was their understanding that liquid dairy cultures might contain preservatives such as sodium benzoate and that it should be reviewed as an ancillary substance. Additionally, the Food Additives Council submitted additional ancillary substances that should be added to dairy cultures:

Food Additives Council list of ancillary substances submitted to NOSB meeting docket: AMS-NOP-18-0071, April 2019. Page 10 of document #: AMS-NOP-18-0071-0790

Ancillary Substances for Food Cultures	
Substance	**Function**
Magnesium sulphate	Anti-caking
Silicon dioxide	Anti-caking
Calcium chloride	Carriers - Fillers
Casein hydrolysate	Carriers - Fillers
Casein peptone	Carriers - Fillers
Corn starch	Carriers - Fillers
Dextrose monohydrate	Carriers - Fillers
Fructose	Carriers - Fillers
Lactose	Carriers - Fillers
Maltodextrin	Carriers - Fillers
Maltose	Carriers - Fillers
Milk powder	Carriers - Fillers
Peptone	Carriers - Fillers
Rice hydrolizate	Carriers - Fillers
Skim milk powder	Carriers - Fillers
Sodium caseinate	Carriers - Fillers
Sorbitol	Carriers - Fillers
Starch	Carriers - Fillers
Sucrose	Carriers - Fillers
Trehalose	Carriers - Fillers
Whey (powder)	Carriers - Fillers
Whey protein	Carriers - Fillers
Yeast Extract	Carriers - Fillers
Zein from corn	Carriers - Fillers
Lactase	Enzyme
Nitrogen, liquid	Freezing agent
Acetic acid	pH control - buffer
Ammonium chloride	pH control - buffer
Ammonium hydroxide	pH control - buffer
Calcium carbonate	pH control - buffer
Calcium phosphate dibasic	pH control - buffer
Citric acid	pH control - buffer
Dipotassium hydrogen phosphate	pH control - buffer
Formic acid	pH control - buffer
Monoammonium phosphate	pH control - buffer
Monopotassium phosphate	pH control - buffer
Phosphoric acid	pH control - buffer
Potassium citrate	pH control - buffer
Potassium hydroxide	pH control - buffer
Sodium citrate	pH control - buffer
Sodium hydroxide	pH control - buffer
Sodium phosphate, monobasic	pH control - buffer
Trisodium citrate dihydrate	pH control - buffer

Other commenters noted that the dairy culture listing no longer needs to be separated from the listing for microorganisms. One commenter stated: "During previous comment periods we have urged the NOSB to retain dairy cultures as a separate listing on the National List. This was in large part because at the time the NOSB was just beginning to have a more thorough review of ancillary substances, and we had some questions about whether this would affect the listing for dairy cultures. We now can see that the discussion document for microorganisms lists the same ancillary substances as those listed for dairy cultures, allaying our concern that combining these listings might inadvertently impact ancillary substances understood to be in dairy cultures. Now that there is more clarity on this point, we would not object to combining the dairy culture listing with the listing for microorganisms."

While there is widespread support for the use of dairy cultures, the Handling Committee believes that this listing is now redundant and is covered by the listing for microorganisms. We would suggest that removing dairy cultures from the National List would have no negative impact since they are already covered under the microorganism listing. Functionally, these dairy cultures would continue to be allowed, just not listed under a separate category.

Subcommittee Vote:
Motion to remove dairy cultures from §205.605(a) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Steve Ela
Seconded by: Scott Rice
Yes: 5 No: 0 Abstain: 0 Absent: 2 Recuse: 0

Enzymes

§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)).")
Reference: 205.605(a) Nonsynthetics allowed: **Enzymes—must be derived from edible, nontoxic plants, nonpathogenic fungi, or nonpathogenic bacteria.**
Technical Report: 1995 TAP; 1996 TAP; 2011 TR; 2015 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2011 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Enzymes are naturally occurring proteins that act as highly efficient catalysts in biochemical reactions. They are used to carry out naturally occurring biological processes that are useful in the processing of food products or ingredients. Commonly used in the production of sweeteners, chocolate syrups, bakery products, alcoholic beverages, precooked cereals, infant foods, fish meal, cheese and dairy products, egg products, fruit juice, soft drinks, vegetable oil and puree, candy, spice and flavor extracts, and liquid coffee, and are used for dough conditioning, chill proofing of beer, flavor development, and meat tenderizing. Enzymes can also be used to help reduce production costs, reduce the length of time required for aging foods such as cheese, clarify or stabilize food products, and control the content of alcohol and sugar in certain foods (Enzyme Technical Association 2001). (Technical Report 2011 lines 140-148)

Microbial rennet describes a coagulating agent produced by a specific type of mold, fungus, or yeast organism, grown and fermented in a lab. (TR 2011 466-467)

Fermentation produced chymosin (FPC) rennet is derived from genetically modified organisms and is not allowed in organic agriculture.

Bromelain is extracted from the pineapple's fruit, stem, peel and juice. First the fruit is crushed. Bromelain is then further isolated, separated, and purified using chromatography, ultrafiltration, precipitation, freeze drying, and other procedures. (TR 2011 494-496)

Pectinase is produced by the controlled fermentation of nonpathogenic and nontoxicogenic strains of *Aspergillus niger* that are isolated from growth medium (FOA, 2000). (TR 2011 504-505)

Ancillary substances are explained in the Enzymes Technical Evaluation Report – Limited Scope, (NOP 2015):

> "Enzyme products used in food processing may be single ingredient, stand-alone preparations of the enzyme, or formulated with other ingredients (OMRI, 2015). In many cases the enzyme product which results from a fermentation process is not effective in food applications without further formulation (Whitehurst & Van Oort , 2009). Enzyme preparations therefore commonly contain other substances, not only as incidental secondary metabolites and residual growth media from the enzyme production, but also intentionally added ingredients which function as diluents, preservatives, stabilizers, antioxidants, etc. (FDA, 2010). These additives must be generally recognized as safe (GRAS), or be FDA approved food additives for this use (FDA, 2014)."

To prevent the loss of enzyme activity, ancillary substances, such as stabilizers, are added. This is especially true for liquid enzyme preparations due to the destabilizing effect of water. Stabilizers are also used to combat the degradation of enzyme structures due to autolysis or proteolysis.

To control microbial contamination of enzyme preparations, preservatives are added. The development of alternatives to preservatives (plant extracts, peptides, compounds from herbs and spices) is increasing but there are microbial resistance challenges and the need for continued research. Currently it is unknown if natural preservatives are being used in any enzyme formulations.

The following additional ancillary substances were identified through public comment during the last sunset review:

> Anti-caking & anti-stick agents: calcium stearate, magnesium silicate/talc, magnesium sulfate, sodium aluminosilicate.
>
> Carriers and fillers: calcium phosphate, calcium acetate, calcium carbonate, calcium chloride, calcium sulfate, dextrin, dried glucose syrup, ethyl alcohol, glucose, glycol, lactic acid, maltose, mannitol, mineral oil, palm oil, propylene, purity gum (starch), saccharose, sorbitol, soy flour, soy oil, sunflower oil, trehalose, vegetable oil.
>
> Preservatives: alpha (hops) extract, benzoic acids and their salts, calcium propionate, citric acid, potassium chloride, potassium phosphate, sodium acetate, sodium chloride, sodium propionate, sodium sulfate, sorbic acid and its salts, stearic acid, tannic acide, trisodium citrate, zinc sulfate.

Stabilizers: betaine (trimethylglycine), glucose, glycerol, sodium chloride, sodium phytate, sorbitol, sucrose.

pH control, buffers: acetic acid, citric acid anhydrous, sodium citrate, sodium phosphate, trisodium citrate.

Public comment submitted during the Spring 2019 NOSB meeting suggest adding several other ancillary substances to this list:

Anti-Caking & Anti-Stick Agents: manganese sulphate, magnesium sulphate, microcrystalline cellulose powder

Carriers and Fillers: corn gluten, corn steep powder, dextrose, lactose, propylene glycol, soya flour, soya oil, soyatone, sucrose.

Preservatives: propyl p-Hydroxybenzoate, sodium metabisulfite, sodium nitrate.

Stabilizers: calcium lactate, ethylene diamine tetra acetic acid, glycerine, sodium alginate.

pH control, Buffers: adipic acid, di potassium phosphate (K2HPO4), diammonium phosphate, disodium phosphate (Na2HPO4), hydrochloric acid, mono potassium phosphate (KH2PO4), tri ammonium citrate.

During the last sunset review in 2015, a variety of organizations and manufacturers commented in support of keeping enzymes on the National List. There were no commenters opposed. One organization suggested that enzymes be classified as synthetic unless annotated to define those that have not undergone synthetic chemical change. The 2011 TR does not find the manufacture or use of enzymes to be harmful to the environment or biodiversity. Enzymes are used in small amounts, are biodegradable, and the release of enzymes into the environment is not an environmental concern.

The 2011 TR does not find significant effects upon human health. Enzymes can remain active after they are digested and, as proteins, cause allergic reactions in sensitive individuals. FDA reports it is not aware of any allergic reactions associate with the ingestion of food containing enzymes commonly used in food processing (TR 2011 752- 758).

Public comments received during the Spring 2019 NOSB meeting widely favored relisting of enzymes and numerous examples were listed of their use in organic handling. One group did object to the review of enzymes as a class noting that this broad review was insufficient to address classification and adherence to all OFPA criteria. They noted that enzymes should be classified as synthetic unless annotated to define those that have not undergone synthetic chemical change.

Subcommittee Vote:
Motion to remove enzymes from §205.605(a) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Steve Ela
Seconded by: Harriet Behar
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

L-Malic acid

§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))."

Reference: 205.605(a) Nonsynthetics allowed: **L-malic acid (CAS # 97-67-6).**
Technical Report: 2003 TR; 2019 TR
Petition(s): L-Malic Acid 11/01/02
Past NOSB Actions: 05/2003 sunset recommendation; 11/2009 sunset recommendation
Recent Regulatory Background: Added to National List 09/11/06 (71 FR 53299)
Renewed 08/03/2011 (76 FR 46595); Renewed 09/12/16 (81 FR 8821)
Sunset Date: 9/12/2021

Subcommittee Review:
(This summary references the 2019 TR unless otherwise noted)

Uses
Malic acid exists in D-, L-, and racemic DL-forms, which is a mixture of equal parts of D- and L-. L-malic acid is the form listed at 205.605(a), while the D- and DL-forms are not approved for use in organic production. L-malic acid is used as a flavor enhancer, flavoring agent, adjuvant, and pH control agent in a variety of foods. The 2002 malic acid petition also notes it is used dry mix beverages, carbonated beverages, bakery products, fruit juices, candies, gelatins, desserts, frozen specialties, and tea as a flavor enhancer and food acidulant, and that malic acid provides greater tartness and better taste retention than other major food acids.

Malic acid has a smooth, persistent sourness and can be blended with other organic acids, sugars, sweeteners, and flavors. It also intensifies and extends the impact of flavors, allowing producers to reduce the amount of added flavoring.

U.S. Food and Drug Administration (FDA) lists L-malic acid as a Generally Recognized as Safe (GRAS) food additive as a pH control agent, flavor enhancer, flavoring agent, and adjuvant in all food types except for baby food. The listing also includes maximum good manufacturing practice (GMP) levels for various applications. (21 CFR Section 184.1069; U.S. FDA 2018)

Manufacture
L-malic acid occurs naturally in many fruits and vegetables, including apples and cherries and can be obtained by enzymatic conversion of fumaric acid and by fermentation of glucose and other carbohydrates. It is not economical to extract L-malic acid from natural foodstuffs such as apple juice.

In the first round of sunset review in Spring 2019, a number of commenters questioned whether commercially available L-malic acid is indeed from nonsynthetic sources, as this listing restricts. Commenters noted that while supporting documentation may state L-malic acid is produced naturally via enzymatic fermentation, this statement refers to only the second half of the process.

Industrial quantities of L-malic acid are made using biological processes, with the major industrial process to produce L-malic acid being a two-step procedure:

1. Production of fumaric acid either synthetically from petroleum or by fermentation of carbohydrates; and
2. Enzymatic conversion of fumaric acid to L-malic acid by immobilized microbes producing the enzyme fumarase.

There are two options for obtaining the fumaric acid in the first step in this process; more detailed information on the two-step process can be found in Appendix A of the 2019 Technical Report.

1. The fumaric acid precursor is obtained through the fermentation of carbohydrates (i.e., Rhizopus spp.)
2. The fumaric acid precursor is obtained as a synthetic product from maleic acid of petroleum origin

Commercial quantities of nonsynthetic L-malic acid may also be produced using a one-step fermentation process through biological methods such as microbial fermentation using *Aureobasidium pullulans* and *Penicillium vitacola*, though it is not believed that this process is occurring on a scale that would accommodate the needs of the current market. The major commercial source of L-malic acid is enzymatic conversion of synthetic fumaric acid to L-malic acid by immobilized microbes (Chibata et al. 1983; Chi et al. 2016a; Dai et al. 2018). If the malic acid produced by this method is synthetic, most if not all, of the L-malic acid on the market is therefore synthetic (Goldberg et al. 2006; Chibata et al. 1983; Engel et al. 2008; Chi et al. 2016a; Dai et al. 2018).

L-malic acid can also be made from ethanol and biodiesel production waste but again, this is not the production method that commonly supplies the market. Thin stillage is a byproduct of corn fermentation in the production of ethanol from which *Aspergillus niger* ATCC 9142 can produce L-malic acid (West 2017). Another L-malic acid production process is the fermentation of crude glycerol obtained from production of biodiesel. Non-engineered *Ustilago trichophora* can be used for high yield production. *A. niger* MTCC 281 can also produce L-malic acid from crude glycerol (Iyyappan et al. 2018ab).

L-malic acid can also be produced by microbes in a one-step fermentation processes fueled by glucose or other carbohydrates. Reaction conditions are adjusted to cause overproduction of L-malic acid, which is an essential product of microbe metabolism.

The production of DL-malic acid is a synthetic process according to NOP Guidance 5033-1; the maleic acid undergoes a chemical change that is not the result of a naturally occurring biological process (USDA 2016b). Note this is similar to the method of production for synthetic fumaric acid used as precursor for industrial L-malic production.

Research quantities of D-malic acid and L-malic acid can be obtained by chemically separating the racemic DL-malic acid into its components in a process called chiral resolution. Chiral resolution is an expensive process that is not used to make large commercial quantities. D- or L-malic acid produced by chiral resolution is synthetic according to NOP Guidance 5033-1 because the isomers are isolated by chemical processes (USDA 2016b; West 2017).

International Acceptance

Canada, Canadian General Standards Board—CAN/CGSB-32.311-2015, Organic Production Systems Permitted Substances List

http://www.inspection.gc.ca/food/organic-products/standards/eng/1300368619837/1300368673172

In Table 6.3, “Ingredients classified as food additives,” “Malic acid” is listed as a food additive with no restrictions (Canada 2018).

CODEX Alimentarius Commission—Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)

http://www.fao.org/docrep/005/Y2772E/Y2772E00.HTM

In Table 3 of "Annex 2: "Permitted substances for production of organic foods," "Malic acid" with INS 296 is a permitted food additive listed without conditions (Codex 2001).

European Economic Community (EEC) Council Regulation—EC No. 834/2007 and 889/2008

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32007R0834

http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32008R0889

Malic acid is not specifically mentioned in EC No. 834/2007. In EC No. 889/2008, Annex 8, "Certain productions and substances for use in organic processed foods," "Malic acid" with E number 296 is allowed as a food additive (EU 2007; EU 2008).

Japan Agricultural Standard (JAS) for Organic Production

http://www.maff.go.jp/e/jas/specific/criteria_o.html

On page 4, "Attached Table 1, Food Additives," DL-malic acid INS 296, is an approved food additive with the annotation, "Limited to be used for processed foods of plant origin"(JAS 2012).

IFOAM – Organics International

http://www.ifoam.bio/en/ifoam-norms

L-malic acid assigned INS 296 is listed on page 79 in Appendix 4, "Table 1: List of approved additives and processing aids for post-harvest handling." L-malic acid is listed both as a food additive and post-harvest handling aid without restrictions (IFOAM 2014).

Environmental & Human Health Issues

The manufacture of L-malic acid by fermentation is fairly benign to the environment. Waste products such as spent cells and fermentation media can be composted. Processing chemicals include low toxicity acids and bases; while some of these can be recycled, they may end up in industrial landfills (West 2017; Dai et al. 2018). L-malic acid is found extensively throughout the environment in rotting fruit in agricultural or garden applications. Because it is soluble in water, L-malic acid eventually leaches out into the soil, where it is degraded by microbes. Manufactured malic acid is not deliberately released into the environment, and the amounts released incidentally into the environment through manufacturing processes and spills are likely to be small compared to the amounts already found in nature. The impacts of the manufactured material on beneficial insects, diversity, and other important aspects of environmental quality are negligible compared to natural exposures from rotting vegetation (Baker and Grant 2016).

Animal tests show that malic acid has low acute toxicity. Because it is easily metabolized in the body and occurs naturally in many fruits, there are no known reports of animal or human toxicity (Cornell Cooperative Extension 2016). Malic acid is an eye and skin irritant. The consumption of acidic soft drinks can lead to erosion of tooth enamel, and can cause tooth decay.

Discussion

A number of commenters noted that while there may have been nonsynthetic versions available in the past, it is unlikely that commercially available nonsynthetic quantities exist. As certifiers, material review organizations, and the 2019 TR attest, applying NOP Guidance 5033 and 5033-1 to this full production method would result in classifying L-Malic acid as a synthetic material. Until this material is reclassified, certifiers have been verifying the following for L-malic acid: that it is not made using the "big 3" (genetic modification, sewage sludge, irradiation); that it is L-malic acid (not DL- or D-); and that it is the form with the same CAS# as is identified on the National List.

A number of certifiers noted that L-malic acid appears on the organic system plans of their certified operations and is still widely used. Several manufacturers also commented on the essentiality of this material to their production. A couple of organizations opposed relisting this material as information was based on an older TR that did not sufficiently address the manufacturing process. The updated 2019 TR appears to address these concerns with extensive information on the manufacturing process.

It is clear to the Subcommittee that this material should be reclassified and placed on 205.605(b) to reflect that the commercially available sources are a product of a synthetic manufacturing process. This reclassification cannot be completed via sunset review, so the subcommittee is proposing to relist this material and address the reclassification as a separate work plan item for consideration at a future meeting.

Subcommittee Vote:
Motion to remove L-malic acid from §205.605(a) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Scott Rice
Seconded by: Tom Chapman
Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

Magnesium sulfate

§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))."
Reference: 205.605(a) Nonsynthetics allowed. **Magnesium sulfate, nonsynthetic sources only.**
Technical Report:1995 TAP; 2011 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2011 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Use:
Magnesium sulfate has a wide variety of uses in food processing and personal care products. It is used as a firming agent in the production of tofu. According to the 2011 technical report (TR), magnesium sulfate is sometimes combined with other coagulators in the production of tofu. Magnesium sulfate is also used as a nutrient in salt-replacer products, dietary supplements, carbonated beverages, sports drinks and fortified water beverages, and as a fermentation and malting aid in beer, ale, and other malt beverages.
Magnesium sulfate is generally regarded as safe (GRAS), listed at 21 CFR 184.1443. The Food and Nutrition Board, an organization established by the Institute of Medicine that provides guidance to the public and policy makers on nutrition and food sciences, has recommended that cereal grain products be fortified with magnesium in response to the potential risk of deficiency among significant segments of the population. A common name for magnesium sulfate is Epsom salt.

Manufacture:
Several mineral forms of magnesium sulfate are recovered from the ground. The magnesium sulfate generally found in nature is in the hydrated form (i.e., contains water). Specifically, magnesium sulfate monohydrate and magnesium sulfate heptahydrate occur in nature as the minerals kieserite ($MgSO_4 \bullet H_2O$) and epsomite (($MgSO_4 \bullet 7H_2O$), respectively.

International:
The Canada Food Inspection Agency, Food and Drug Regulations permit the use of non-synthetic sources of magnesium sulfate, which are classified as a food additive. Sulfates produced using sulfuric acid are prohibited.

Ancillary Substances:
None identified.

Discussion:
The 2011 TR notes that dietary doses of magnesium generally do not pose health risks. The TR does not fully address the environmental impact of mined forms of magnesium sulfate, noting it is not mined in the U.S. and therefore mining-related impacts are not an issue in the U.S. The TR does not address international mining impacts.

A number of alternative coagulants can be used in tofu production; however, these alternatives will affect texture, chewiness, color and other properties of the final product.

Calcium sulfate can be used in beer processing as an alternative to magnesium sulfate to increase water hardness and its mined form is on the National List.

While many other flavor enhancers are on the National List, it is unclear if any of these substances are suitable alternatives to magnesium sulfate.

Two food manufacturers noted their support of this material however, it was not clear if these manufacturers use this material. The Subcommittee is still seeking comment on the specific use and essentiality of this material.

Subcommittee Vote:
Motion to remove magnesium sulfate from §205.605(a) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Scott Rice
Seconded by: Harriet Behar
Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

Microorganisms

§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))."
Reference: 205.605(a) Nonsynthetics allowed: **Microorganisms—any food grade bacteria, fungi, and other microorganism.**
Technical Report: 2003 TAP; 2014 TR; 2015 Ancillary Substances
Petition(s): 2002 petition
Past NOSB Actions: 09/2002 minutes and vote; 11/2009 sunset recommendation

Recent Regulatory Background: Added to National List with annotation 09/11/06 (71 FR 53299)
Renewed 08/03/2011 (76 FR 46595); Renewed 09/12/16 (81 FR 8821)
Sunset Date 9/12/2021

Subcommittee Review:
Microorganisms used in organic handling include those that are used as probiotics, for fermentation, and bacteriophages used for food safety. Microorganisms are used by organic processors to make many well-known products including miso, shoyu, sake, and yogurts. The use of these microorganisms can increase the digestibility of products, create different flavors and textures, and provide potential health benefits to the consumer. Additionally, bacteriophages can work to decrease harmful food organisms and increase the safety of processed foods.

There are a variety of ways microorganisms can be produced. As noted in the 2014 technical report (TR), generally a medium is inoculated with a sample of the fermented food to produce a starter culture. Different microbiological species produce different flavor compounds and in turn produce different products. Depending on the organism desired, different mediums ranging from milk products to rice may be used to create the starter culture. After a culture is generated, the starter culture may be inoculated directly into a product that will be altered by the microorganisms or the culture may be preserved by drying, encapsulating, freezing or other method and used at a later time in the handling process.

Ancillary substances may be present in microorganism cultures. 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.

The Handling Subcommittee put forth a document listing the ancillary substances permitted for use in microorganisms in 2015. These include:

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. potassium phosphate, potassium sulfate, tricalcium phosphate.
Preservatives	sodium benzoate, potassium sorbate, ascorbic acid, sodium formate
Stabilizers	maltodextrin
Cryoprotectants used to freeze-dry (& freeze) microorganisms and Dairy Cultures	liquid nitrogen, maltodextrin, magnesium sulfate, dimethyl sulfoxide, sodium aspartate, mannitol, sorbitol , polysorbate
Substrate that may remain in final product	milk, lactose, grain (rice, barley, wheat) flour, brewed black tea and sugar, soy

That document noted that use of these ancillary substances had not been found to cause negative effects. Additionally, the Food Additives Council submitted additional ancillary substances that should be added to microorganisms:

Food Additives Council list of ancillary substances submitted to NOSB meeting docket: AMS-NOP-18-0071, April 2019. Page 10 of document #: AMS-NOP-18-0071-0790

Ancillary Substances for Food Cultures	
Substance	**Function**
Magnesium sulphate	Anti-caking
Silicon dioxide	Anti-caking
Calcium chloride	Carriers - Fillers
Casein hydrolysate	Carriers - Fillers
Casein peptone	Carriers - Fillers
Corn starch	Carriers - Fillers
Dextrose monohydrate	Carriers - Fillers
Fructose	Carriers - Fillers
Lactose	Carriers - Fillers
Maltodextrin	Carriers - Fillers
Maltose	Carriers - Fillers
Milk powder	Carriers - Fillers
Peptone	Carriers - Fillers
Rice hydrolizate	Carriers - Fillers
Skim milk powder	Carriers - Fillers
Sodium caseinate	Carriers - Fillers
Sorbitol	Carriers - Fillers
Starch	Carriers - Fillers
Sucrose	Carriers - Fillers
Trehalose	Carriers - Fillers
Whey (powder)	Carriers - Fillers
Whey protein	Carriers - Fillers
Yeast Extract	Carriers - Fillers
Zein from corn	Carriers - Fillers
Lactase	Enzyme
Nitrogen, liquid	Freezing agent
Acetic acid	pH control - buffer
Ammonium chloride	pH control - buffer
Ammonium hydroxide	pH control - buffer
Calcium carbonate	pH control - buffer
Calcium phosphate dibasic	pH control - buffer
Citric acid	pH control - buffer
Dipotassium hydrogen phosphate	pH control - buffer
Formic acid	pH control - buffer
Monoammonium phosphate	pH control - buffer
Monopotassium phosphate	pH control - buffer
Phosphoric acid	pH control - buffer
Potassium citrate	pH control - buffer
Potassium hydroxide	pH control - buffer
Sodium citrate	pH control - buffer
Sodium hydroxide	pH control - buffer
Sodium phosphate, monobasic	pH control - buffer
Trisodium citrate dihydrate	pH control - buffer

Potential concerns have been raised about ancillary substances used in cultures and their compatibility with organic handling standards. Functional foods may contain a combination of probiotic culture with a prebiotic substrate that favors its growth (2014 TR). The use of ancillary substances has not prevented the relisting and general support for microorganisms. In general, they have not been implicated in negative health effects, but are something that should be continually monitored. Additionally, as with all organic materials, any culture that is genetically modified is disallowed.

Microorganisms have been a staple in food production for centuries and they are generally viewed as a necessary input for organic production of many products. They pose minimal health risks, and in many cases can enhance health. As noted in the 2014 TR, the health effects can be expressed directly through the interactions of the ingestion of the live microorganisms (probiotic effect) or indirectly as the result of ingesting the metabolites synthesized by the microbes during fermentation (biogenic effect). Food-grade bacteria may also be used for improved vitamin production, raw food materials are often fortified with food grade bacteria that produce an excess of B vitamins in situ and bacteriophages are utilized as an antimicrobial to control bacteria during the production of foods on the farm, on perishable foods post-harvest, and during food processing (2014 TR).

In general, microorganisms are essential to the production of many organic foods and they are widely used in the industry. Public comments received as part of the Spring 2019 NOSB meeting noted that microorganisms are essential to organic handling and there was widespread support for their relisting. Additional comments suggested combining the dairy culture listing with the microorganism listing since diary cultures are microorganisms. In the past there have been some commenters wanting to keep those listings separate due to the ancillary substances list being different for the two listings, however, at this point in time the ancillary substance list is suggested to be equivalent. Commenters that were against combining the two listings are now in favor of just listing microorganisms and having the dairy culture listing be part of the microorganism listing.

Finally, there were several comments about the definition of microorganisms. The definition is critical for microorganisms in use currently, and can be used to determine whether additional organisms, such as unicellular algae, should be considered microorganisms. One commenter noted that this listing is not clear stating: “It is apparent that it is intended to cover those microorganisms present as living organisms in foods such as cheese, yogurt, vinegar, pickles, tempeh, wine, and so forth. However, there are other products that are made from (or with the assistance of) microorganisms, and it is not clear whether the listing is intended to cover them. These include nutritional yeast and spirulina, both cultured microorganisms that are no longer living. They also include products of fermentation that have been isolated from the fermentation organisms, including glycerin, gellan gum, L-malic acid, and others. We assume that the listing does not cover the last group, but that those organisms and their manufacture should be evaluated in the course of evaluating their products that are on the National List (NL). If the listing is intended to cover the group of killed microbial products, then the evaluation should include algae as well as the other organisms addressed in the technical review. These comments do not suggest that microorganisms should be delisted, but rather that additional attention needs to be paid to this particular listing and the definitions associated with it.

Subcommittee Vote:
Motion to remove microorganisms from §205.605(a) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Steve Ela
Seconded by: Lisa de Lima
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

Perlite

§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))."

Reference: 205.605(a) Nonsynthetics allowed: **Perlite—for use only as a filter aid in food processing.**
Technical Report: 1996 TAP

Petition(s): N/A

Past NOSB Actions: 09/1996 NOSB minutes and vote; 11/2005 sunset recommendation; 03/2010 sunset recommendation; 10/2015 NOSB Final Review

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Uses
Perlite is used as a filter aid in food processing, such as filtration of juices, beer, wine, and vegetable oils.

Manufacture
Perlite is an amorphous volcanic glass that occurs naturally and is sourced primarily from mines in the U.S., Greece, Turkey and China. The high-water content of the mineral causes it to expand many times its original volume when exposed to temperatures of 850-900 °C.

International
Canada General Standards Board Permitted Substances List allows the use of perlite as a filtering aid.

Codex Alimentarius lists perlite as a processing aid which may be used for the preparation of products of agricultural origin.

European Economic Community Council Commission Regulations (EC) No 834/2007 lists perlite for the preparation of foodstuffs of plant origin. In reference to use in foodstuffs of animal origin, its use is limited to gelatin.

IFOAM Norms Appendix 4 – Table 1 lists perlite as allowed for use as a processing and post-harvest handling aid.

Japan Ministry of Agriculture, Forestry, and Fisheries limits the use of perlite for processed foods of plant origin.

UK Soil Association Standards for Food and Drink lists perlite for the preparation of foodstuffs of plant origin. In reference to use in foodstuffs of animal origin, its use is limited to gelatin.

Ancillary Substances
None identified.

Discussion
The listing of perlite has been consistently supported by the NOSB and organic stakeholders. There is some concern with the potential human health hazard of inhalation of fine silica dust when using this material. Personal protective equipment such as a dust mask can minimize this risk.

During the first round of comments in spring 2019, several food manufacturers noted the use of this material for filtration and several certifiers noted its presence on the organic system plans of operations they certify.

Subcommittee Vote:
Motion to remove perlite from §205.605(a) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Scott Rice
Seconded by: Harriet Behar
Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

Potassium iodide

§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))."
Reference: 205.605(a) Nonsynthetics allowed: **Potassium iodide.**
Technical Report: 1995 TAP; 2011 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2011 Formal recommendation by the NOSB; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Use:
Potassium iodide is used as a form of iodine in trace mineral supplements. Iodine is an essential component of the thyroid hormones that regulate basal metabolism. Iodine deficiency causes thyroid enlargement (goiter), mental retardation that can be severe (cretinism in 10% of the population), and hypothyroidism. The developing brain is the most sensitive organ; iodine deficiency reduces IQ by 13.5 points. Iodization of salt completely eliminated new cases of cretinism in Switzerland. According to FDA, potassium iodide may be used as food additive in the following functions:

- A nutrient in table salt as a source of iodine
- A dietary supplement for human consumption and in animal feeds.
- A sanitizing agent for food processing equipment. (2015 TR pg 15)

Manufacture: Potassium iodide can be refined nonsynthetically from sea water and in salt deposits. It can be produced synthetically by reacting hydriodic acid with potassium bicarbonate or by electrolysis of hydriodic acid and potassium bicarbonate or, industrially, by treating potassium hydroxide with iodine. [21 CFR 184.1634] (2015 TR pg 27).

International: Nonsynthetic potassium iodide is listed on the Canadian standards for use where required by law and the synthetic form is allowed in products in the 70-95% category. It could be used under the EU/Codex standards where required elsewhere by law. It is not listed on the Japanese or IFOAM standards.

Discussion: For the Spring 2019 NOSB meeting the Handling Subcommittee posed the following questions: Is Iodine utilized as a sanitizing agent for food processing equipment? If so, in what applications? If applications are for nutritional supplementation only – is this substance redundant to the current Nutrient Vitamin and Mineral listing? If so, should this separate listing be removed and are certifiers limiting the use of iodine to non-synthetic forms even with the synthetic allowance at 205.605(b) for the Nutrient Vitamin and Mineral listing?

The NOSB did not receive any public comment about its use as a sanitizer. Public comment was received about its use in infant formula and in fortified foods. Regarding its redundant listing, one certifier commented in support of this being redundant to the more general nutrient vitamin and minerals listing. However, several comments about the general nutrient vitamin and minerals listing favored individual listing over the group listing. Lastly, one comment was received requesting an annotation to state "as a source of iodine" when required by law, however no context was given why the requiring law was not sufficient.

No new information was received by the NOSB supporting removal of this substance.

Subcommittee Vote:
Motion to remove potassium iodide from §205.605(a) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Tom Chapman
Seconded by: Scott Rice
Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

Yeast

§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)).

Reference: 205.605(a) Nonsynthetics allowed: **Yeast—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; 3/2007 NOSB committee recommendation; 10/2010 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290): Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Yeast is a microorganism that is commonly used for fermentation, baking, food flavors, adding nutritional value and providing health benefits. Yeasts are in kingdom Fungi and are single celled eukaryotic organisms. They utilize organic materials for energy by releasing enzymes that digest organic matter or by absorbing simple molecules directly through their cell walls. Yeasts differ from other fungi, such as molds and mushrooms, in that they exist as individual cells rather than forming hyphae that interconnect with other cells.

In general, yeast species (brewer's yeast) used in anaerobic conditions are for fermentation whereby they convert sugars to ethanol. This process includes ciders, beers, wines, and distilled spirits. Other uses for yeast are generally in aerobic conditions where they may be used as leavening agents (baker's yeast), for the addition of vitamins or minerals (nutritional yeast, chromium yeast, selenium yeast, torula yeast), as probiotics that may prevent or treat pathological conditions (probiotic yeast), and for flavoring (smoked yeast, torula yeast) (2014 TR). As the TR notes, they may be used synergistically or in conjunction with bacteria or other materials to create specific foods such as when kombucha is fermented with yeast and acetic acid bacteria to create fermented, sweetened tea.

The way the yeast is used in processing as well as the action of the yeast depends on the type of end products produced as well as the specific type of yeast being utilized.

Many yeasts are ubiquitous in the environment and in some cases handlers use these wild yeasts to make breads or for fermentation. However, since most handlers prefer more control over the specific type and strain of yeast that is utilized, most yeasts are grown under controlled conditions and then sold to end users. Typically, yeast is grown in a lab environment so as to prevent contamination from undesirable or pathogenic organisms. The lab grown yeast is then used to inoculate growth media for industrial production (2014 TR). In a number of cases there are several iterations of inoculation and addition of growth media in order to achieve the desired quantities. The yeast may then be used directly for food production or be concentrated and packaged for future use. Traditionally, smoked yeast is made by passing smoke through dried yeast, but it may also be manufactured using chemical processes. This necessitated the annotation that when smoked yeast is used, documentation that the yeast is smoked by natural processes must be submitted by the user.

According to the 2014 TR, There are a few yeast species that are formulated with no ancillary substances, however, many commercially available yeasts are formulated with other ingredients. These substances, such as ascorbic acid, may be listed on the National List. However, other ancillary ingredients not appearing on the National List are routinely combined with yeast on a commercial scale. These may be water, emulsifiers, and cutting oils. The compounds used for emulsifiers are enumerated in the TR (2014 TR) and that extensive list should be referred to for specific details of ancillary substances in yeast products. During the prior sunset review in 2015, the following Functional Classes were reviewed for ancillary substances in yeasts: Antioxidants, preservatives, emulsifiers, defoaming agents, and substrate that may remain in the final product. It was suggested that starch be added to this list during that review. One substance on the chart, BHT, was questioned as problematic for exposure.

Yeast is widely used and has been for centuries. Many organic products rely on the use of yeast for their distinctive features and characteristics. While there has been broad support for the relisting of yeast on the National List in past reviews, significant discussion has been centered on ancillary substances and whether organic forms of yeast are available. Yeast underwent a significant review that led to a change in the listing in 2010. The 2014 Technical Review added information about the current status of various yeasts and looked at the ancillary substances. There are many types of yeast and yeast is used to produce many substances, so this is a constantly changing playing field. As part of the prior sunset review many commenters noted that organic yeast forms are readily available, but that for certain uses there are some forms that are not yet organically produced in sufficient quantity or quality. These included torula yeast, nutritional yeast for livestock feed, gluten-free yeast, fresh yeast, and some types of wine yeast. This led to the extensive annotation for the listing of yeast on the National List.

During the prior sunset review in 2015, the following Functional Classes were reviewed for ancillary substances in yeasts: Antioxidants, preservatives, emulsifiers, defoaming agents, and substrate that may

remain in the final product. It was suggested that starch be added to this list during that review. One substance on the chart, BHT, was questioned as problematic for exposure.

Finally, it should be noted that while yeast itself is often considered as a minimal risk material to both the environment and in use, there can be negative environmental impacts from the manufacturing processes used to create yeast formulations. Appropriate mitigation strategies for these impacts, such as the emissions of acetaldehyde and ethanol, exist and when appropriately used minimize environmental impact (2014 TR).

Public comment from the Spring 2019 meeting was overwhelmingly in favor of relisting of yeasts as annotated. Commenters noted that since yeast is commonly not available in organic form necessary for certain flavors, yeasts are not always available in the quantities needed, and that organic yeast quality can vary, the annotation and listing should remain as is.

Subcommittee Vote:
Motion to remove yeast from §205.605(a) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Steve Ela
Seconded by: Asa Bradman
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

§205.605(b) Synthetics allowed:

Activated charcoal

§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))."
Reference: 205.605(b) Synthetics allowed: **Activated charcoal (CAS #s 7440-44-0; 64365-11-3)—only from vegetative sources; for use only as a filtering aid.**
Technical Report: 2002 TAP
Petition(s): 2002 petition
Past NOSB Actions: 09/2002 sunset recommendation ; 11/2009 sunset recommendation.
Regulatory Background:
Added to National List with annotation 9/11/06 (71 FR 53299); Renewed 8/03/2011 (76 FR 46595); Renewed 09/12/16 (81 FR 8821)
Sunset Date: 9/12/2021

Subcommittee Review:

Use
Activated charcoal is used in processing as mechanical filtration involving the physical separation of suspended solids from a liquid passing through carbon arrayed as a porous media in a column or bed. This type of filtration is used as a taste and odor-removing agent and purification agent in water and food. Activated carbon has a very large surface area and pore volume that gives it its unique adsorption capacity.

Manufacture
Activated charcoal of vegetative origin can be made from a large variety of sources such as hardwoods, grain hulls, corn cobs and nut shells. The material undergoes pyrolysis at a very high heat. These agricultural byproducts may be chemically activated using a variety of acids and bases. Acids may be acetic acid, and potassium hydroxide and sodium hydroxide are possible bases. The charcoal may also be activated through exposure to oxygenated gas or steam.

International
Canada General Standards Board Permitted Substances List allows the use of activated charcoal as an ingredient classified as a food additive. Shall be of plant origin. Prohibited for use in the production of maple syrup.

Codex Alimentarius lists activated carbon as a processing aid which may be used for the preparation of products of agricultural origin.

European Economic Community Council Commission Regulations (EC) No 834/2007 lists activated carbon for the preparation of foodstuffs of plant origin.

IFOAM Norms Appendix 4 – Table 1 lists activated carbon as allowed for use as a processing and post-harvest handling aid.

Japan Ministry of Agriculture, Forestry, and Fisheries limits the use of active carbon for processed foods of plant origin.

UK Soil Association Standards for Food and Drink lists charcoal for oenological use, with a restriction that limits use to musts and new wines still in fermentation, rectified concentrated grape must and white wines. No more than 100g dry production per hl.

Ancillary Substances
None identified.

Discussion
Activated charcoal has minimal impact on human health and the environment. It may cause respiratory problems for those who handle it, especially as the particle size decreases. Its use in processing doesn't generally have an effect or chemical interaction in the agroecosystem. The greatest impact of activated charcoal from vegetative sources is the removal of organic matter from the system.

During the first round of comments in the spring, several food manufacturers noted the use of this product, with at least one stating they have not identified a suitable non-synthetic alternative. One organization wishes to see its use limited to filtration of water and limit the available forms to those made via steam activation.

Subcommittee Vote:
Motion to remove activated charcoal from §205.605(b) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): N/A
Motion by: Scott Rice
Seconded by: Asa Bradman
Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

Alginic Acid

§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))."
Reference: 205.605(b) Synthetics allowed: **Alginic acid (CAS #9005-32-7).**
Technical Report: 2015 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 03/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2015 formal recommendation (reclassification)
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Proposed rule 1/17/2018 (83 FR 2498); Reclassified effective 01/28/2019 (83 FR 66559)
Sunset Date: 01/28/2024

Subcommittee Review:

Use:
Alginic acid is used in the food industry as an emulsifier, emulsifier salt, formulation aid, stabilizer, and thickener for soups and soup mixes. FDA limits the use of alginic acid to soups and soup mixes.

Manufacture:
Alginic acid is derived from wild harvested brown cold-water seaweeds. Alginic acid exists naturally in both brown seaweeds and two bacterial genera. However, alginic acid is manufactured on an industrial scale through a chemical separation process that involves the maceration, alkali treatment, and acid precipitation of alginic acid from brown seaweeds. In order to separate alginic acid from its salt form, it is subjected to numerous pH adjustments to promote ion exchange. These chemical processes result in a pure alginic acid and its classification as a synthetic. Since alginic acid is present in seaweeds in its calcium, sodium, magnesium or other salt forms, and not in the free acid form, the free acid form does not appear in nature (2015 TR - Alginic Acid, Lines 283-286).

International Acceptance:
The 2015 TR noted the following:
Canadian General Standards Board - permits the use of alginic acid under the Organic Production Systems Permitted List as a non-organic food additive. It is also found in the same table under the heading Alginates.
CODEX – alginic acid is permitted under the Guidelines for the Production of Organically Produced Foods as a food additive of non-agricultural origin for foods of plant origin. The General Standard for Food Additives within CODEX list a number of provisional uses that FDA does not identify such as a bulking agent, foaming gent, glazing agent, in various food types.
European Economic Community (EEC) lists alginic acid as an approved food additive for use in the production of processed organic foods.
Japan Agricultural Standards (JAS) allows alginic acid as a food additive limited to only processed foods of plant origin.
The International Federation of Organic Agriculture movements (IFOAM) lists alginic acid as an approved additive for use in organic processed products without any annotations.

Environmental Issues:
Alginic acid is derived from harvesting brown wild seaweed. There has been little research into production of alginic acid and alginates from a biological fermentation process. However, commercially available quantities are sourced from brown seaweed, (2015 Technical Review – Alginic Acid, Lines 299-300). Most are derived from wild harvested seaweed, but some seaweed is cultivated. Brown seaweed is harvested in cold water. Recent public comments expressed concern of over-harvesting and the impact on local ecosystems. Some negative comments cited that wild harvested seaweed is a bio-accumulator of heavy metals.

Discussion:
In the 1995 TAP review for alginic acid, reviewers determined the material was non-synthetic. However, given the Classification of Materials document (in draft form in 2015) and the information presented in the 2015 TR, it was recommended by the NOSB that alginic acid be reclassified as synthetic. In January 2019, it was relisted from 205.605(a) nonsynthetic, to 205.605(b) synthetic. The majority of public comment from the 2015 sunset review was in favor of relisting alginic acid. Those in favor of its relisting noted the long history of use with no ill effects on either the human digestive system or on the ecosystem due to harvesting and assert that the properties imparted by alginic acid are essential for some processed food formulations. Those opposed cited that wild seaweed is a bio-accumulator of heavy metals, and over harvesting was detrimental to local ecosystems.
The Federal Register Notice published December 27, 2018, effective January 28, 2019 (Vol. 83, No.247, pp 66559-66574), amends the National List and moves Alginic Acid from 606.605(a), nonsynthetic substances allowed etc. to 606.605(b), synthetic substances allowed etc. The complete listing under 205.605(b) is Alginic acid (CAS# 9005-32-7)

During the spring 2019 public comment period the board received no comments from manufacturers citing their use of alginic acid and there were no reports from certifiers of the material being included in any

Organic Systems Plans. One interest group asked that the listing be reviewed with the broader context of marine materials and to consider adding an annotation related to harvest restrictions and risk-based testing for toxic materials. Another commenter thought alginic acid should be delisted due to lack of essentiality and environmental impacts of seaweed cultivation.

The TR reported no residues of heavy metals in excess of FDA tolerances. In regard to seaweed harvesting the TR reported that the majority of brown seaweed species harvested for production of alginic acid are wild harvested. However in countries like China & Japan large scale seaweed cultivation and production can negatively affect coastal waterways.

Questions:

1. Is alginic acid essential for handling operations? If so, why?
2. The 2015 TR cites possible hydrocolloids alternatives including agar agar, carrageenan, gellan gum and xanthan gum. Please comment on whether or not these alternatives have been used successfully in place of alginic acid.

Subcommittee Vote:
Motion to remove alginic acid based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.605(b) if applicable: Essentiality
Motion by: Lisa de Lima
Seconded by: Harriet Behar
Yes: 5 No: 0 Abstain: 0 Absent: 2 Recuse: 0

Ascorbic acid

§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)).")
Reference: 205.605(b) Synthetics allowed: **Ascorbic acid.**
Technical Report: 1995 TAP; *2019 TR pending (to be posted at https://www.ams.usda.gov/rules-regulations/organic/national-list/a)*
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Use:
Ascorbic acid is used as a dietary supplement and nutrient, flavor ingredient, used in meat and meat containing products, curing and pickling, in flour to improve baking quality, as an antioxidant in fats and oils, and a wide variety of other food processing uses. It is also used in frozen and precut fruits as an antioxidant. Industrially produced L-ascorbic acid is widely used in the feed, food, and pharmaceutical sector as a nutritional supplement and preservative, making use of its antioxidative properties. Ascorbic acid is often added to processed foods for nutritional purposes and is one of the most common sources of Vitamin C, which provides many important biological functions. Several animals, including humans, a

variety of primates and guinea pigs have lost the ability to produce ascorbic acid and must obtain this essential vitamin through their diets. As it is water soluble, and cannot be stored in the body, it must be consumed daily.

However, its addition as a nutritional fortifier also provides preservative properties. The preservative nature of the compound is derived from its reducing nature, through which it reacts with oxidized species (including radicals and molecular oxygen) to prevent enzymatic browning and food spoilage.

Ascorbic acid is GRAS as a chemical preservative (21 CFR 182.3013), a dietary supplement (21 CFR 182.5013), and nutrient (21 CFR 182.8013) when used in accordance with Good Manufacturing Practices. The FDA has identified ascorbic acid as a required nutrient in infant formula (21 CFR 107.100).

Manufacture:
For more than 50 years, the predominant industrial production of ascorbic acid involved synthesis using the Reichstein and Grussner process, a six-step process developed in the 1930's. The process begins with D-glucose and involves hydrogenation, oxidizing, and treatment with acetone and then hydrogen chloride to yield L-ascorbic acid. Despite the effectiveness of the purely synthetic production of ascorbic acid with the Reichstein process, most modern industrial production processes use fermentation with additional bio-oxidation steps adding a bio-catalyst which eliminates the need for the chemical steps. Despite the use of various microorganisms for the bulk of the synthesis, the use of acid in the final step of the process to convert the 2-keto-L-gluconic acid to ascorbic acid results in the substance's classification as "synthetic," according to the guidelines in NOP 5033-1.

International Acceptance:
Canadian General Standards Board Permitted Substances List
Ascorbic acid is listed in the Canadian General Standards Board Permitted Substances List (CAN/CGSB-32.311-2015) in Table 4.2 as allowed for "soil amendments and crop nutrition," and "synthetic and non-synthetic sources may be used as a pH regulator." Ascorbic acid is listed in Table 6.3 as an "ingredient classified as a food additive," and in Table 6.5 as a "processing aid for use as an anti-browning agent prior to the extraction or concentration of fruit or vegetable juice." Table 7.3 lists ascorbic acid as a "food-grade cleaner, disinfectant, and sanitizer permitted without a mandatory removal event."

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Ascorbic acid is listed in the CODEX (GL 32-1999) in Table 3.1 as a "food additive, including carriers."

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Ascorbic acid is not listed in EC No. 834-151 2007. Ascorbic acid is listed in EC No. 889/2008 as a "food additive, including carriers," and is approved for "preparation of foodstuffs of plant origin and animal origin."

Japan Agricultural Standard (JAS) for Organic Production
Ascorbic acid is listed in the JAS for Organic Production Notification No. 1606 as a "food additive, limited to be used for processed foods of plant origin."

International Federation of Organic Agriculture Movements (IFOAM)
Ascorbic acid is listed in IFOAM as an "approved additive and processing/post-harvest handling aid."

Environmental Issues:
The 2019 Technical Report found no published studies on the persistence or impacts to biodiversity of ascorbic acid. Given the natural prevalence of the substance in plants and animals, the incorporation of

ascorbic acid in the handling/processing of organic food products is unlikely to provide any significant increase to environmental levels of the substance.

Discussion:
During the first review in Spring 2019, the Subcommittee requested additional information on the use of excluded methods in the production of ascorbic acid. In the 2019 Technical Report, the authors note that the microorganisms employed for the synthesis of ascorbic acid are not genetically modified.

During the first review, public comment from a juice products trade group supported its relisting. Other comments noted its necessity for flavoring food products, as a pH adjustor for protein coagulation such as in protein processing and cheese production, color stabilization in fruit juice, and as an antioxidant and vitamin C source. Several certifiers noted its widespread presence in the organic system plans of the operations they certify.
One interest group noted the predominant use of ascorbic acid is to fortify processed foods to pre-processing vitamin C levels. They further noted it is primarily used as a synthetic antioxidant and preservative and should be removed from the National List. The subcommittee notes that evaluation criteria at 205.600(b) restricting a material's use as a preservative or its use to recreate or improve flavors, colors, textures, or nutritive value lost during processing is limited to processing aids and adjuvants.

The 2019 Technical Report notes alternative acids such as citric and lactic acid, nonsynthetic substances permitted at 7 CFR 205.605(a). These weak acids inhibit food discoloration, however the inability of these acids to provide the reducing power of ascorbic acid prevents preservative action against reactive oxidized species and limits their efficacy against viral contamination. The Technical Report cites the use of controlled atmosphere with little to no oxygen to retard microbial-based spoilage. However, the use of controlled atmospheres in packaging and processing has also been known to affect the color and other organoleptic properties of the foods. Other alternatives include the use of fruit juices to fortify foods. However, this strategy is limited; the relative instability of ascorbic acid and the presence of additional substances present in fruit juices that may result in undesired changes to the organoleptic properties of the processed foods.

Subcommittee Vote:
Motion to remove ascorbic acid from §205.605(b) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Scott Rice
Seconded by: Harriet Behar
Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

Calcium citrate

§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)).")
Reference: 205.605(b) Synthetics allowed: **Calcium citrate.**
Technical Report: 1995 TAP; 2015 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 4/2010 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Use:
Calcium citrate is used as an ingredient in dietary supplements, although there are other calcium sources for supplementation purposes permitted at §205.605(b) under the listing Nutrient Vitamins and Minerals. Calcium citrate can be used as a sequestrant, buffer, antioxidant, firming agent, acidity regulator (in jams and jellies, soft drinks and wines), as a raising agent and an emulsifying salt. It is also used to improve the baking properties of flours and as a stabilizer. It can also be used as a water softener due to its chelation properties. It is used to wash processing equipment in order to eliminate off flavors, and as a pH adjuster and chelator in cleaning and sanitizing products. It is also used for its chelating properties to remove scale from boilers, evaporators and other processing equipment. Calcium citrate is widely used in cosmetic and personal care products for many of these same functions.

Manufacture:
Calcium citrate is the calcium salt of citric acid. It is prepared by neutralizing citric acid with calcium hydroxide or calcium carbonate and subsequent crystallization.
Citric acid is listed under 21 CFR 184.1195 as Generally Recognized as Safe (GRAS). It is prepared by neutralizing citric acid with calcium hydroxide or calcium carbonate. It is permitted in food with no limitations other than current good manufacturing practice. It is also permitted by FDA in infant formula.
Calcium citrate is GRAS as listed at 184.1195
The EPA listed citric acid and its salts in the 2004 List 4A (minimal risk inerts).
International:
Allowed by Canada, European Economic Community (EEC) (as an ingredient in the preparation of foods of animal origin), and International Federation of Organic Agriculture Movements (IFOAM) (allowed as an additive).

Ancillary Substances:
According to the 2015 TR, citric acid and its salts (including calcium citrate) are commercially supplied as pure compounds and do not contain ancillary substances.

Discussion:
According to the 2015 TR, based on various toxicology studies, citric acid and its salts (including calcium citrate) are not expected to pose any significant health hazard upon ingestion. The manufacture of calcium citrate was not addressed in terms of potential harm to the environment.
The TR cited the versatility of citric acid and its salts as the reason why no alternative practices could be used to substitute for all functions they provide. Additionally, there are no nonsynthetic sources or alternatives for the citrate salts.

2019 spring public comment was supportive and mentioned uses including: to fortify nutritional supplements with calcium, used in fruit filling to thicken and stabilize gel structures (yogurt, pastries), to develop a sugar-acid-pectin gel found in jams/jellies/fruit spreads, and as a buffer in fruit and flavor preps. One commenter would like to see all the citrates be restricted to uses that are compliant with 205.600(b)(4), however that restriction only applies to processing aid and adjuvants.

No new information was brought forward in terms of harm to human health or the environment.

Additional information requested by subcommittee: None

Subcommittee Vote:
Motion to remove calcium citrate based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.605(b) if applicable: NA
Motion by: Lisa de Lima
Seconded by: Asa Bradman
Yes: 0 No: 5 Abstain: 2 Absent: 0 Recuse: 0

Ferrous sulfate

§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))."
Reference: 205.605(b) Synthetics allowed: **Ferrous sulfate—for iron enrichment or fortification of foods when required by regulation or recommended (independent organization).**
Technical Report: 1995 TAP; 2015 TR Nutrient Vitamins and Minerals
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Use: Ferrous sulfate is commonly added to flours and cereal products to make an optional enriched claim and often found in baked products and infant snacks (oat cereal, teething biscuits, etc.). Iron is an essential component of hemoglobin, enzymes involved in energy metabolism, and other enzymes. Hemoglobin transports oxygen to body tissues. Iron deficiency leads to anemia, poor work performance and endurance, persistent cognitive and developmental impairment, increased maternal perinatal mortality and a greater rate of premature labor and delivery, and depressed immune function. (2015 TR, pg 15)

Manufacture: Ferrous sulfate is made by reacting sulfuric acid with iron. [21 CFR 184.1315] (TR 2015, pg 28)

International: Ferrous sulfate is listed on the Canadian standards for use where required or allowed, it could be used under the EU/Codex standards where required elsewhere by law. It is not listed on the Japanese or IFOAM standards.

Discussion: For the Spring 2019 NOSB meeting the Handling Subcommittee posed the following question: If applications are for nutritional supplementation only – is this substance redundant to the current Nutrient Vitamin and Mineral listing? If yes, should this item be removed? Comments were received in support of this listing from industry, noting its use in infant formulas. There was some support for removing this listing as redundant to the Nutrient Vitamins and Minerals listing but there was also opposition to the group listing of vitamins and minerals. One interest group questioned if ferrous sulfate was the best source of iron supplementation or if alternatives were available. They also noted a whole-food diet could be sufficient to meet iron deficiencies. Alternatives were not offered and details on how a whole-food diet would be sufficient for various and diverse populations, including those at risk for iron deficiency were not provided.

No new information was received by the NOSB supporting removal of this substance.

Subcommittee Vote:
Motion to remove ferrous sulfate from §205.605(b) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Tom Chapman
Seconded by: Asa Bradman
Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

Hydrogen peroxide

§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))."
Reference: 205.605(b) Synthetics allowed: **Hydrogen peroxide.**
Technical Report: N/A (2015 TR Crops)
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Use:
Hydrogen Peroxide (CAS# 7722-84-1) is a very simple molecule with a formula of H_2O_2. It is a weak acid but also a strong oxidizer which makes it an effective microbial pesticide for organic handling purposes. It is used as a disinfectant and sanitizer and also for post-harvest treatment of produce. USDA organic regulations currently allow the use of hydrogen peroxide in organic crop production under 7 CFR §205.601(a) as an algicide, disinfectant and sanitizer, and under 7 CFR 205.601(i) for plant disease control as a fungicide. Hydrogen peroxide is also permitted for use in organic livestock production as a disinfectant, sanitizer and medical treatment (7 CFR 205.603(a)). Lastly, synthetic hydrogen peroxide may be used as an ingredient in or on processed products labeled as "organic" or "made with organic(specified ingredients or food group(s))." (7 CFR 205.605(b)).

Manufacture:
According to the TR, commercially available hydrogen peroxide is industrially produced using the anthraquinone autoxidation (AO) process. The AO method involves initial catalytic reduction of an alkyl anthraquinone with hydrogen to form the corresponding hydroquinone. Subsequent autoxidation of the hydroquinone intermediate in air regenerates the anthraquinone with concomitant liberation of hydrogen peroxide. The simplified overall reaction involves direct combination of gaseous hydrogen (H_2) and oxygen (O_2): $H_2 + O_2 \rightarrow H_2O_2$

International:
Canada: Allowed for many uses, including as food-grade cleaners, disinfectants and sanitizers" that are allowed without mandatory removal of residues, and "cleaners, disinfectants and sanitizers allowed on food contact surfaces including equipment, provided that substances are removed from food contact surfaces prior to organic production".

European Union: Allowed for similar uses to Canada and U.S.

IFOAM: Allowed as cleanser and disinfectant among other uses.

Japan: Not listed.

Codex: Allowed as a cleanser and disinfectant among other uses

Ancillary substances:
Other ingredients may include peroxyacetic acid (listed separately on the National List). The TR reports other potential materials present including caprylic acid and mono-and di-potassium salts of phosphorous acid, which is an oxidant stabilizer. Phosphorous acid is listed on the EPA Safer Choice list as a yellow triangle.[1]

Human Health and the Environment:
Concentrated solutions may be corrosive to eyes, exposed skin, and mucous membranes. Warnings for high concentrations include:
Corrosive. Causes irreversible eye damage. May be fatal if swallowed or absorbed through the skin. Causes skin burns or temporary discoloration on exposed skin. Do not breathe vapor. Do not get in eyes, on skin or on clothing. Wear protective eyewear such as goggles or face shield. Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing before reuse.

Extensive toxicological testing of hydrogen peroxide has been completed, and it is unlikely to cause chronic systemic toxicity or reproductive, development, or carcinogenic effects. However, chronic exposure to vapors may damage lungs. Hydrogen peroxide is reported to have low to moderate toxicity to aquatic invertebrates and no danger to fish. Because hydrogen peroxide is unstable and breaks down into water and oxygen gas, long-term impacts on the environment are unlikely. According to the TR, some toxic chemicals used to manufacture hydrogen peroxide including alkyl anthraquinones, aromatic solvents and metal catalysts (e.g., nickel and palladium) are removed from the product and can be returned to the reactors to make more product. Overall, this material is relatively safe but should be used according to FDA, USDA, and EPA labels and regulations.

No new information was brought forward in terms of harm to human health or the environment.

Discussion:
Hydrogen peroxide (HP) continues to receive strong support by the organic community and has been consistently relisted on the National List. Oral and written comments submitted for the Spring 2019 NOSB meeting represent hundreds if not thousands of crop and livestock farmers and processors who uniformly support relisting this essential and relatively safe material. When used appropriately HP should not have adverse impacts on human health and the environment.

Additional information requested by subcommittee: None

Subcommittee Vote:
Motion to remove hydrogen peroxide from 205.605(b) of the National List based on the following criteria in

[1] Yellow triangle - The chemical has met Safer Choice Criteria for its functional ingredient-class, but has some hazard profile issues. Specifically, a chemical with this code is not associated with a low level of hazard concern for all human health and environmental endpoints. (See Safer Choice Criteria). While it is a best-in-class chemical and among the safest available for a particular function, the function fulfilled by the chemical should be considered an area for safer chemistry innovation.

the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Asa Bradman
Seconded by: Steve Ela
Yes: 0 No: 4 Abstain: 0 Absent: 3 Recuse: 0

Nutrient vitamins and minerals

§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)).")
Reference: 205.605(b) Synthetics allowed: **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 TR
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; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Use:
Nutrient Vitamins and Minerals are used to recreate or add nutritional content to foods. Sometimes this nutritional content is added due to public health guidance (e.g. Iron in cereal to combat iron anemia), to mimic analog products (calcium fortification of non-dairy milks, fortification of infant formulas), to make up nutrients lost in processing (Vitamin A in skim milk) or for product marketing purposes (enriched flours). There are very few legally required fortified foods. Those that are required are listed on the chart below, noted from the 2015 technical review:

Standards of Identity in Title 21 CFR that require Nutrient Fortification

Food class	Regulation	Specific vitamins or minerals required by FDA
Infant formula	21 CFR 107.100 21 CFR 107.10	All nutrients known to be essential and listed therein
Margarine	21 CFR 166.110	Vitamin A
Milk	21 CFR Part 131	Vitamins A & D (required by some states)

There are more food classes with standards of identity that allow for the use of fortification, however these fortifications are optional. It should be noted that foods eligible for the "Women, Infants and Children" federal programs may be required to be the fortified standard of identity form.

The specific use of vitamins and minerals will depend application and on the specific substances being used. Vitamins in application are substances with vitamin activity and there are several substances that may have a vitamin activity for a specific vitamin. Similarly, for minerals the substances used are those with bioavailable mineral content. These substances will often be processed with accessory additives to make the vitamins or minerals stable and useable in food applications.

Manufacturing: The 2015 technical review states:

According to Vandamme (Vandamme 1992), “vitamins are now either prepared chemically or biotechnologically via fermentation or bioconversion processes. Several vitamins and related biofactors are now (1992) only or mainly produced chemically (vitamin A, cholecalciferol (D3), tocopherol (E), vitamin 432 K2, thiamine (B1), niacin (PP or B3), pantothenic acid (B5), pyridoxine (B6), biotin (H or B8), folic acid (B9)]or via extraction processes (β-carotene or provitamin A, provitamin D3, tocopherol, vitamin F-group). However, for several of these compounds microbiological or algal methods also exist or are rapidly emerging. Other vitamins are produced practically exclusively via fermentation (ergosterol or provitamin D2, riboflavin (B2), cyanocobalamin (B12), orotic acid (B13), vitamin F-group ATP, nucleosides, coenzymes, etc.] or via microalgal culture (β-carotene, E, F). Both chemical and microbial processes are run industrially for vitamin B2, while vitamin C (ascorbic acid) is produced via a combination of chemical reactions and fermentation processes. In the past twenty-five years, numerous patents have been issued disclosing fermentations by genetically modified microorganisms to produce various water-soluble vitamins… As the above descriptions detail, most vitamin and mineral nutrients are synthetic substances, even including some with natural or agricultural origins… Most vitamins and minerals are not available from nonsynthetic sources…. The current National List listings creates confusion for those nutrient vitamins and minerals specifically listed at §205.605(a), which requires a nonsynthetic source, whereas “Nutrient vitamins and mineral” are a class of “allowed synthetics.” For example, the producer of a nutritional product may not be sure if supplemental magnesium as magnesium sulfate is restricted to a nonsynthetic source. “

The technical report details many individual manufacturing methods.

International:
The Codex and EU standards only allow the use of synthetic vitamin and minerals where required by law. The Canadian standards allow synthetic vitamin and minerals where required by law as well as in “non-dairy substitute products” on a “voluntary basis, if legally permitted.” Canadian standards also allow for use of “Ferrous sulphate—Shall be used if legally required and may be used, on a voluntary basis, if legally permitted.” IFOAM allows by law or when “strongly recommended in food products in which they are incorporated.” Japanese standards do not allow for vitamins and minerals (2015 TR, pg 20-21). All standards list some substances that may be considered vitamins and minerals (i.e. ascorbic acid or calcium carbonate) – the review above does not include these individual substances, just categorical listings.

Discussion:
Brief History of this issue

- In 1995 the NOSB added nutrient vitamins and minerals to the National List with the following annotation, ‘‘Accepted for use in organic foods for enrichment or fortification when required by regulation or recommended by an independent professional organization.’’ A second recommendation was also passed entitled ‘‘Final Recommendation Addendum Number 13, The Use of Nutrient Supplementation in Organic Food.’’ This stated, ‘‘Upon implementation of the National Organic Program (NOP), the use of synthetic vitamins, minerals, and/or accessory nutrients in products labeled as organic must be limited to that which is required by regulation or recommended for enrichment and fortification by independent professional associations.’’

- The final rule that was published in 2000 (65 FR 13512) had the current annotation. It was recognized soon after that the cross reference to the FDA’s fortification policy for food at 21 CFR 104.20 was not accurate and that a correction to the current listing was necessary.

- In 2007 the NOP provided an interpretation of the regulation that mistakenly concluded that 21 CFR 104.20 allowed a wide variety of nutrients that were not limited to just vitamin and minerals.

In 2010 the NOP met with the FDA to clarify the meaning of the FDA guidance at 21 CFR 104.20. The NOP issued a memo to the NOSB in April 2010 explaining this clarification.

- The existing annotation is not what the original NOSB recommended in 1995. In 2011 the Handling Subcommittee proposed to change the annotation at sunset but received approximately 2000 comments against it due to concerns about broadening the scope. The Subcommittee withdrew the proposal prior to the April 2011 NOSB meeting and the NOSB supported relisting with the existing annotation for the 2012 sunset review.

- On January 12, 2012 a proposed rule was published in the Federal Register (77 FR 1980) to change the annotation to: § 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as ''organic'' or ''made with organic (specified ingredients or food groups(s)).''

  (b) Synthetics allowed,

  Vitamins and minerals. For food— vitamins and minerals identified as essential in 21 CFR 101.9. For infant formula—vitamins and minerals as required by 21 CFR 107.100 or § 107.10.

- This proposed rule clarified that the "nutrients" that were not on these CFR sections had to be petitioned individually for the National List because this listing did not cover them.

- NOP did not finalize the proposed rule, but on September 27, 2012 published an Interim Rule (77 FR 59287), which renewed without change the original listing, as per the NOSB April 2011 recommendation.

- In 2011 through 2013 many other nutrients were petitioned. Some were recommended to be listed by the NOSB while others were not. No rulemaking in this area has occurred.

- In 2014 the Handling Subcommittee commissioned a new Technical Report in preparation for Sunset 2017 reviews. This was completed in February 2015 and clarifies which substances are required and permitted and which are covered by the 21 CFR citations or other regulations.

- In 2015 the NOSB voted to renew the listing and included the following note about the technical review and public comment:

  "Since this is a huge group of different substances, the TR went into length about their manufacturing processes, effects on human health, effects on the environment and uses. There was no information among these pages that gave concern that these substances did not meet the review criteria. Likewise public comment was received with concerns about the unnecessary use of synthetic ingredients, but no new information was provided in comments from the first posting regarding the review criteria beyond the alternatives and compatibility issues.

  Regarding alternatives, the primary alternative is for people to get their vitamins and minerals from the food itself rather than supplementation. …There is no literature to suggest that the manufacture or use of vitamins and minerals with ancillary substances is harmful to the environment or to biodiversity."

- In 2016 the Handling Subcommittee brought forward a discussion document with two options:

  Option 1

  > Proposed Annotation #1: §205.605 (b) Vitamins and minerals, synthetic. For food – Minerals (including trace elements), vitamins and similar isolated ingredients are allowed

only when their use is required by law or to meet an FDA standard of identity in which they are incorporated.

Proposed Annotation #2: §205.605 (b) Vitamins and minerals, synthetic. For food – Minerals (including trace elements) and vitamins identified as essential in 21 CFR 101.9. For infant formula—vitamins and minerals as required by 21 CFR 107.100 or § 107.10 are allowed for use in agricultural products labeled “made with organic (specified ingredients or food group(s)),” prohibited in agricultural products labeled “organic” (except as noted in annotation #1).

Proposed Annotation #3: §205.605 (a) Vitamins and minerals, non-synthetic. For food – Minerals (including trace elements) and vitamins identified as essential in 21 CFR 101.9. For infant formula—vitamins and minerals as required by 21 CFR 107.100 or § 107.10 are allowed for use in agricultural products labeled Organic.

Option 2

Proposed Annotation #4: §205.605 (b) Vitamins and minerals, synthetic. For food – Minerals (including trace elements) and vitamins identified as essential in 21 CFR 101.9. For infant formula—vitamins and minerals as required by 21 CFR 107.100 or § 107.10 are allowed for use in agricultural products labeled "organic" and “made with organic (specified ingredients or food group(s))”.

- To Date the NOSB has taken no further action on this subject

During the 2019 sunset cycle the NOSB posed the following questions for public comment at the Spring meeting:

1. Is the current listing meeting the needs of the organic community, certifiers and industry – if not, how should it be revised?
2. How are certifiers dealing with non-synthetic nutrient vitamins and minerals currently?
3. It is speculated that the 2012 rulemaking was stopped due to the impact this change would have on the currently established organic infant formula market which has both established manufacturers and consumers. How should the NOSB move this topic forward in light of this issue?
4. Given added Vitamins and Minerals need to be listed on ingredient panels, are consumers enabled enough to make educated purchasing decisions on fortified foods – if not, please explain.

In response to the first question – public comment was mixed, with some commenters wanting more restrictions and some wanting a wide interpretation. Those using the widest interpretation either supported status quo or a change in annotation that would enshrine the status quo. Most certifiers thought the accuracy of the citations needed improvement, and it needed to be clearly enforceable. Others are seeking a more restricted listing. It should be noted that any annotation changes would need to be completed separate from this sunset review.

In response to question 2: Certifiers indicated that all were using the synthetic allowance as an allowance for non-synthetic usage and generally did not go into detail about how these materials are being manufactured. One certifier noted that non-synthetic versions were sometimes agricultural and would potentially require listing on 205.606. While clarification was supported by certifiers, no problematic or conflicting interpretations were raised.

In response to question 3: Commenters provided many suggestions on how to move forward on this topic, ranging from re-reviewing previous NOSB decisions on petitioned items, to supporting the 2012 proposed rulemaking to removing the categorical listing all together. Short of removing this listing in its entirety during a sunset review, recommendations on annotation changes would need to be considered as part of different work agenda item other than this sunset review.

Lastly, all commenters responded to the fourth question stating consumers were empowered with enough information to understand which products are fortified.

Overall there was strong support of this listing from industry and trade associations – noting the use of materials for reasons such as compliance with the law, to compete with conventional product, due to consumer expectations, or to make products for specific markets like infant food or enteral feeding products. Opposition to this listing came from interest groups who opposed the categorical listing of nutrient vitamins and minerals, that opposed a listing pointing to an incorrect FDA reference, and a reference to a list maintained by someone other than the NOSB. Concern was also raised over allowing the fortification of food in instances not required by law, and lastly about the categorical listing allowing for the continued usage of individual substances that had been reviewed but not recommended by the NOSB.

The public comment received in 2019 was similar to the public comment received in 2015 and no substantial new information was received supporting the removal of this listing.

Subcommittee Vote:
Motion to remove nutrient vitamins and minerals from §205.605(b) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Tom Chapman
Seconded by: Harriet Behar
Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

Peracetic acid

§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))."
Reference: 205.605(b) Synthetics allowed: **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; 2016 TR
Petition(s): 2008 Petition
Past NOSB Actions: 11/2000 sunset recommendation; 04/2004 NODB meeting summary; 11/2009 NOSB formal recommendation
Recent Regulatory Background: Added to National List with annotation 9/11/06 (71 FR 53299); Renewed 8/03/2011 (76 FR 46595); Renewed 09/12/16 (81 FR 8821)
Sunset Date: 9/12/2021

Subcommittee Review:

Use:
Peracetic acid (CAS # 79-21-0) is currently allowed for use in organic handling in wash water and rinse water, including during post-harvest handling, to disinfect organically produced agricultural products according to FDA limitations, and to sanitize food contact surfaces, including dairy-processing equipment and food-processing equipment and utensils. It 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 on the National List at §205.601 and §205.603 for use in Crops and

Livestock respectively). Peracetic acid disinfects by oxidizing the outer cell membrane of vegetative bacterial cells, endospores, yeast, and mold spores, making it an effective sanitizer against all microorganisms, including bacterial spores. The end products of peracetic acid oxidation are acetic acid and water.

Manufacture:
According to the 2016 technical report (TR), solutions of peracetic acid used as sanitizers are created by combining aqueous mixtures of two substances: acetic acid (the acid in vinegar) and hydrogen peroxide. At cool temperatures, acetic acid and hydrogen peroxide react over a few days to form an equilibrium solution containing peracetic acid, acetic acid, and hydrogen peroxide. The equilibrium solution is the substance sold commercially as the sanitizer "peracetic acid." Solutions of peracetic acid, hydrogen peroxide, acetic acid and water are produced by reacting glacial acetic acid with hydrogen peroxide, often in the presence of a catalyst such as a mineral acid (e.g., sulfuric acid). Commercial grades are available in concentrations ranging from about 0.3 to 40 % by weight. A peracetic acid solution can also be generated in situ by dissolving an activator and a persalt in water or on site by adding sodium hydroxide to triacetin and hydrogen peroxide.

International:
Japan: Not listed
Codex: Not listed.
Canada: Allowed
IFOAM: Allowed
European Union: Allowed

Ancillary substances:
HEDP and dipicolinic acid (DPA) are added to peracetic acid solutions to chelate metals, especially iron, copper and manganese, because decomposition of peracetic acid and, thus, loss of sanitizing power is accelerated by these impurities. However, in past reviews, stakeholders did not declare the inclusion of ancillary substances (See below).

Human Health Environment:
peracetic acid likely has no significant environmental impacts. Like other oxidative sanitizers (i.e., chlorine compounds), concentrated solutions of peracetic acid are strong irritants to the skin, eyes, mucous membranes, and respiratory system. As reviewed in the TR, when using fully diluted sanitizing solutions, no special eye, hand, skin, or respiratory protective equipment is normally required. No risk through dietary exposure is anticipated. All uses of this material should be consistent with FDA, USDA, and EPA labels and regulations and utilize personal protective equipment as needed.

Discussion:
Peracetic acid has been relisted each time it was reviewed during the sunset review process. There has been strong support for continued availability of this material. Oral and written comments submitted for the Spring 2019 NOSB meeting represent hundreds if not thousands of crop and livestock farmers and processors who uniformly support relisting this essential and relatively safe material. In particular, many processors identified the need for a "no-rinse" material as essential for treating equipment and other food contact surfaces. Overall, this material is considered effective and offers a less toxic profile then several other sanitizing materials, including many chlorine compounds. The TR does not offer new evidence of unacceptable adverse impacts on human health or the environment. During the last review, use of 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 were judged to be "inerts" for EPA registration as an antimicrobial and not subject to review as an ancillary substance.

However, comments submitted for the Spring 2019 meeting that at least "dipicolinic acid is a former List 3 "inert" and not allowed in products used in organic production" and identifies additional "inert" materials that warrant review. Only products with allowable "inert" ingredients should be used.

Additional information requested by subcommittee: None

Subcommittee Vote:
Motion to remove peracetic acid from 205.605(b) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Asa Bradman
Seconded by: Steve Ela
Yes: 0 No: 4 Abstain: 0 Absent: 3 Recuse: 0

Potassium citrate

§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))."
Reference: 205.605(b) Synthetics allowed: **Potassium citrate.**
Technical Report: 1995 TAP; 2015 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Uses: Antioxidant, acidulant, pH control, flavoring agent, sequestrant, emulsifying salt, stabilizer, and as a dispersant in flavor or color additives. Commonly used in biscuits, baby food, soup mixes, soft drinks, and fermented meat products. It is also used to wash processing equipment to remove off flavors.
Potassium citrate is used to replaced sodium citrate whenever a low sodium content is desired.

Manufacture:
Potassium citrate is the potassium salt of citric acid. It is prepared by neutralizing citric acid with potassium hydroxide or potassium carbonate and subsequent crystallization.
Potassium citrate is Generally Recognized as Safe (GRAS) as listed under 21 CFR 184.1625.

International:
Allowed by Canada and International Federation of Organic Agriculture Movements (IFOAM) (allowed as an additive).

Ancillary substances:
According to the 2015 TR, citric acid and its salts (including calcium citrate) are commercially supplied as pure compounds and do not contain ancillary substances.

Discussion:
According to the 2015 TR, based on various toxicology studies, citric acid and its salts (including potassium citrate) are not expected to pose any significant health hazard upon ingestion. The manufacture of potassium citrate was not addressed in terms of potential harm to the environment.
The TR cited the versatility of citric acid and its salts as the reason why no alternative practices could be used to substitute for all functions they provide. Additionally, there are no nonsynthetic sources or alternatives for the citrate salts.

2019 spring public comment was supportive and mentioned uses including: acidity regulator in the wine making process; buffer in confectionary products; when combined with citric acid the pair provides tartness without a significant drop in pH which is important in preventing the degradation of sucrose in confectionary products and for achieving consistent pH for the gelling on pectin; offers an advantage over sodium citrate in that it does not add additional sodium to the product. One commenter would like to see all the citrates be restricted to uses that are in compliant with 205.600(b)(4), however that restriction only applies to processing aid and adjuvants.

No new information was brought forward in terms of harm to human health or the environment.

Additional information requested by subcommittee: None

Subcommittee Vote:
Motion to remove potassium citrate based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.605(b) if applicable: NA
Motion by: Lisa de Lima
Seconded by: Asa Bradman
Yes: 0 No: 4 Abstain: 3 Absent: 0 Recuse: 0

Potassium phosphate

§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)).")
Reference: 205.605(b) Synthetics allowed: **Potassium phosphate—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, 2016 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Uses:
Potassium phosphate can be used as a pH control in milk and dairy products, to make acidified milk products and in milk protein stabilization. It can also be used as a nutritional additive for a source of potassium and as a nutrient in yeast. Potassium phosphate can also be used in prepared meat applications

and liquid eggs. The initial Technical Advisory Panel report (TAP) included a recommendation to list this material as an approved synthetic in products labeled "organic," but was only approved for use in "made with" products.

Manufacture:
The initial TAP noted potassium phosphates are isolated from brines or salt deposits. However, the 2015 TR explained the manufacturing process to be as follows: All of the orthophosphate derivatives of potassium can be generated by neutralization of phosphoric acid with potassium hydroxide (Budavari 1996). Phosphoric acid is produced by treating phosphate rock (tricalcium phosphate) with sulfuric acid, forming phosphoric acid and calcium sulfate (Budavari 1996). Potassium hydroxide is obtained commercially from the electrolysis of potassium chloride solution in the presence of a porous diaphragm. [21 CFR 184.1631]. (2015 TR, pg 30-31)

International:
Potassium phosphate is not listed in CODEX, does not appear on the EU, JAS or IFOAM organic standards, but is listed in the Canadian organic standard for products in the 70%-95% category only.

Discussion:
During the 2017 sunset cycle public comment was received in support of potassium phosphate noting it is an efficient pH buffering substance with no organic alternatives. The industry indicated that potassium phosphate is used in non-dairy beverages; that it prevents precipitation and impaired mouthfeel; that the alternatives are not as good; and loss of this product would mean impaired quality and marketability. Other commenters noted a concern with the use of phosphates in production of processed foods and that phosphorus may not appear on the nutritional panel making it difficult to be informed about total phosphorous intake– although they would appear on the ingredient list. In particular there were concerns raised about the cumulative health impacts of phosphorous additives in food and in 2015 the NOSB requested a technical review and work agenda item to study this issue further. Concerns were based on peer reviewed research indicating that the cumulative effects of phosphates as a group contributing to renal damage and failure, osteoporosis, and heart failure. A brief literature review shows clinical research from 2010 (Journal of Kidney Disease: April 2010 4(2):89-100), and 2013 (Sim et al, American Journal of Medicine, January 2013) suggesting potential serious renal impacts in subjects with normal renal function, from cumulative phosphorus. A daily limit of 70 mg/kg/day was recommended in one study. Populations at risk for bone health and kidney failure were especially impacted. In 2016 the NOSB Handling Subcommittee published a discussion document on the cumulative health impacts of phosphates and the NOSB decided to address phosphates individually during sunset reviews. Sodium phosphate was reviewed in 2017 and the NOSB came to the following conclusion:

> No single phosphate food additive or ingredient can be implicated as an isolated risk factor. Concerns arise from the increase in cumulative use of phosphates and possible health effects on the general population. Given the new information and research since last Sunset Review, the Handling Subcommittee requested a new Technical Report (TR) which it received in 2016. The TR indicates that small amounts of sodium phosphates may not cause human health problems, but long-term cumulative impacts are not fully understood.

During the 2019 public comment period we posed the following questions: Does industry still find the listing for potassium phosphate necessary – in what applications is this substance currently be used in products being marketed as "made with organic."; and if applications are for nutritional supplementation only – is this substance redundant to the current Nutrient Vitamin and Mineral listing? If yes, should this listing be removed?

We heard from a certifier that noted at least 2 operations were using potassium phosphate for fortification purposes. Comments were also received from an industry trade association about the various possible uses

of phosphates and responses to the long term exposure risks to human health of phosphate products in general. It was not clear their comments were specifically about applications of phosphates in organic certified products. There was some support for removing this listing as redundant to the Nutrient Vitamins and Minerals listing but there was also opposition to the group listing of vitamins and minerals.

No new information was received by the NOSB supporting removal of this substance.

Subcommittee Vote:
Motion to remove potassium phosphate from §205.605(b) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Tom Chapman
Seconded by: Steve Ela
Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

Sodium acid pyrophosphate

§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))."
Reference: 205.605(b) Synthetics allowed: **Sodium acid pyrophosphate (CAS # 7758-16-9)—for use only as a leavening agent.**
Technical Report: 2001 TAP (Sodium Phosphates); 2010 TR; 2016 TR
Petition(s): 10/2002 petition; 03/2007 petition for expand use
Past NOSB Actions: 05/2003 sunset recommendation; 11/2009 sunset recommendation; 04/2011 sunset recommendation
Regulatory Background: Added to National List 09/12/06 (71 FR 53299); Renewed 8/03/2011 (76 FR 46595); Renewed 09/12/16 (81 FR 8821)
Sunset Date: 9/12/2021

Subcommittee Review:

Uses
Sodium acid pyrophosphate is a common food additive for the purpose of a sequestrant/chelating agent in processed potatoes, an emulsifying agent in cheese, an inhibitor agent in canned tuna, and a curing accelerator in processed meats. This listing limits its use as a leavening agent. Sodium acid pyrophosphate is used as a leavening agent in baked goods, where it reacts with baking soda (sodium bicarbonate) to liberate carbon dioxide, 'leavening' the dough and creating the desired 'airy' texture that consumers expect of baked goods such as cakes and cookies. It is GRAS, listed at 21 CFR 182.1087.

Manufacture
Sodium carbonate is reacted with phosphoric acid to form monosodium phosphate, followed by heating the monosodium carbonate to 220ºC to form sodium acid pyrophosphate. It is expressed by the formula Na2H2P2O7 and is composed of 20.72% Na, 0.91% H, 27.91% P, and 50.46% O. Sodium is isolated from brines or salt deposits. Phosphorous is isolated from phosphate rock. Food grade phosphates are formed by reacting purified phosphoric acid with sodium, potassium, or calcium hydroxides.

International
The Canadian General Standards Board Permitted Substances List (CAN/CGSB 32.311-2006) permits these phosphate salts with usage annotations identical to the NOP regulations.

CODEX Alimentarius Commission Guidelines for the Production, Processing, Labelling and Marketing

of Organically Produced Foods (GL 32-1999)

These guidelines only permit monocalcium phosphate (341(i)) and “only for raising flour” (as a leavening agent).

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008

ANNEX VIII, Certain products and substances for use in production of processed organic food referred to in Article 27(1)(a), Section A – Food Additives, including Carriers, lists only monocalcium phosphate (341(i)) as a “Raising agent for self-rising flour” (as a leavening agent).

Japanese Agricultural Standard for Organic Processed Foods (Notification No. 1606 of the Ministry of

Agriculture, Forestry and Fisheries of October 27, 2005)

Table 1, “Food Additives,” lists INS 341(i), Calcium dihydrogen phosphate (a.k.a. monocalcium phosphate), with the annotation “Limited to be used for powders as expanding agent” (as a leavening agent).

IFOAM – Organics International (IFOAM)

The IFOAM norms for Organic Production and Processing, Version 2014, list monocalcium phosphate, INS 341, as a food additive “Only for ‘raising flour’” (as a leavening agent).

Ancillary Substances
None identified.

Discussion
During the last sunset review, this material received positive support from stakeholders. While excess phosphates in wastewater contributed to environmental degradation in the past, this was largely due to its use in detergents. Its use in detergents has waned and in this use as a food additive, phosphates would have little environmental impact.

The 2016 technical report (TR) on phosphates includes extensive discussion on the impact of phosphorous on the human diet, with particular focus on health effects of phosphorous provided by phosphate additives versus natural phosphorous in foods. Added phosphorous, as is found in sodium acid pyrophosphate, is immediately and completely bioavailable upon consumption whereas “food” phosphorous is much less available.

High blood phosphate levels are associated with kidney and vascular disease. A sufficiently high intake of calcium appears to counteract some of the ill effects of excess dietary phosphorus but leads to an increased requirement for magnesium. Due to the restrictions on phosphate use in organic foods, it would be expected that basing a diet on organic foods would reduce phosphorus intake.

Yeast, a natural leavener used for time immemorial, is a common alternative to chemical leavening. However, yeast leavened baked goods have a different physical texture and require more time than chemically-leavened foods. Chemical leavening is used instead of yeast for products where fermentation flavors would be undesirable or where the batter lacks the elastic structure to hold gas bubbles for more than a few minutes such as found with muffins, pancakes and cookies.

During the first round of comments in the Spring of 2019, a number of food manufacturers and trade groups noted the essentiality of this material as it is the only chemical leavener available to the baking sector. One organization does not support relisting as the focus of the TR is on negative human health and environment effects is on the final product and not the primary manufacture of phosphoric acid.

Subcommittee Vote:
Motion to remove sodium acid pyrophosphate from §205.605(b) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Scott Rice
Seconded by: Steve Ela
Yes: 0 No: 4 Abstain: 1 Absent: 2 Recuse: 0

Sodium citrate

§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)).")
Reference: 205.605(b) Synthetics allowed: **Sodium citrate.**
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; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Uses:
Acidulant, pH control, flavoring agent, sequestrant, and buffering agent. Used as an emulsifier in dairy products to keep fats from separating, and in cheese making where it allows the cheeses to melt without becoming greasy. Also used as dispersants in flavor or color additives, and to wash processing equipment in order to eliminate off flavors.
During the last review of sodium citrate in 2015, public comment included these specific reasons for use:

- Potassium citrate is an option, but it has an unpleasant metallic taste. Sodium phosphates are another option, but they need to be used in higher quantities and are not as effective.
- We use sodium citrate as part of the process of preparing fresh fruit for use in our yogurts. We use sodium citrate primarily for its ability to buffer pH, neither citric acid nor potassium citrate would have the same buffering effect in our products.
- Sodium citrate is used in a personal care product (lubricant).

Manufacture:
Sodium citrate is the sodium salt of citric acid. It is prepared by neutralizing citric acid with sodium hydroxide or sodium carbonate and subsequent crystallization.
Sodium citrate is listed under 21 CFR 184.1751 as Generally Recognized as Safe (GRAS). The listing allows its production from citric acid and sodium hydroxide or sodium carbonate. It is allowed as an ingredient used in food with no limitation other than current good manufacturing practice.
The EPA lists citric acid and its salts in the 2004 List 4A (minimal risk inerts).

International:
Canada: Sodium citrate is allowed but restricted to use with sausages or milk products.

CODEX Alimentarius Commission: Sodium citrate is listed for sausages/pasteurization of egg whites/milk products.
European Economic Community (EEC): Sodium citrate is allowed as an ingredient in the preparation of foods of animal origin.
Japan Agricultural Standard (JAS): Sodium citrate is allowed, but limited to use for dairy products, or for albumen and sausage as low temperature pasteurization.
International Federation of Organic Agriculture Movements (IFOAM): allowed as an additive.

Ancillary substances:
According to the 2015 TR, citric acid and its salts (including calcium citrate) are commercially supplied as pure compounds and do not contain ancillary substances.

Discussion:
According to the 2015 TR, based on various toxicology studies, citric acid and its salts (including sodium citrate) are not expected to pose any significant health hazard upon ingestion. The manufacture of sodium citrate was not addressed in terms of potential harm to the environment.
The TR cited the versatility of citric acid and its salts as the reason why no alternative practices could be used to substitute for all functions they provide. Additionally, there are no nonsynthetic sources or alternatives for the citrate salts.

2019 spring public comment was supportive and mentioned uses including: antioxidant, stabilizing salt, buffer, and when combined with citric acid the pair provides tartness without a significant drop in pH which is important for preventing degradation of sucrose in confectionary products and for achieving a consistent pH for the gelling of pectin. It's part of process of preparing fresh fruits for yogurt, neither citric acid or potassium citrate wouldn't have the same buffering affect. It's also found in Organic System Plans (OSPs) used for meat processing and in manufacturing dietary supplements and personal care products. One commenter would like to see all the citrates be restricted to uses that are compliant with 205.600(b)(4), however that restriction only applies to processing aids and adjuvants.

No new information was brought forward in terms of harm to human health or the environment.

Additional information requested by subcommittee: None

Subcommittee Vote:
Motion to remove sodium citrate based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.605(b) if applicable: NA
Motion by: Lisa de Lima
Seconded by: Harriet Behar
Yes: 0 No: 4 Abstain: 3 Absent: 0 Recuse: 0

Tocopherols

§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)).")
Reference: 205.605(b) Synthetics allowed: **Tocopherols—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; 10/2015 NOSB Final Review; 09/2016 Handling Subcommittee proposal additional listing of Tocopherol
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Use:
Synthetic tocopherols are currently permitted for use in organic agriculture handling/processing as an antioxidant ingredient in foods (2015 TR). Tocopherols are added to foods to help prevent oxidation of the fatty acids present in the lipid components of the food. Tocopherols derived from vegetable oil are allowed for use as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group[s])" when rosemary extracts are not a suitable alternative (7 CFR 205.605[b]).

Manufacture:
Tocopherols are a group of lipophilic phenolic antioxidants that occur naturally in a variety of plant species. Sources of naturally-occurring tocopherols include cereal grains, oilseeds, nuts, and vegetables. As described in the 2015 TR, tocopherols are separated from the other compounds in the oil distillate by multiple extraction and refining steps. These steps can include solvent extraction, chemical treatment, crystallization, complexation, and vacuum or molecular distillation. The total tocopherol content of the resulting product is usually 30 - 80%. Liquid forms of mixed tocopherols are commercially available diluted in vegetable oils and are also available as mixtures with rosemary extracts, ascorbyl palmitate/ascorbic acid, lecithin and/or citric acid. Powdered forms of tocopherols are produced by spray-drying the liquid tocopherol oils onto a carrier or mixture of carriers.

International:
Japan: Listed for processed meats.
Codex: Allowed.
Canada: Allowed
IFOAM: Allowed
European Union: Allowed

Ancillary Substances:
Table 1 from the most recent technical review (TR) shows some of the more common formulations along with their ancillary substances.

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; BASF, 2013
		Powder	Gum acacia	
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 Woodlands, TX)	CarolE™ ET and PT	Liquid	Unknown	ZMC-USA, date unknown
		Powder	Unknown	

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

Discussion:

The NOSB has consistently relisted this material due to its essentiality for many processed food products. However, there has been extensive discussion about the need for synthetically derived tocopherols. Public comment has historically been divided on the relisting due to concerns that the

material's primary use is as a preservative and therefore inconsistent with organic production. Additionally, commenters have asserted that non-synthetic tocopherols are commercially available and should be used instead of synthetic. However, many past commenters have expressed strong support of relisting, stating that tocopherols are critically essential to maintaining food safety, preventing rancidity, and providing nutrients to their products, and that rosemary oil imparted off flavors or fragrances to their products that were not acceptable to consumers. Many comments were submitted during the April 2019 meeting and were uniformly supportive of relisting this material, including assertions that adequate non-synthetic sources were not available or that rosemary or other derived tocopherol product were not adequate. One comment recommended that the Handling Subcommittee investigate the availability of natural tocopherols manufactured without solvents, and, depending on availability, that they be removed from §205.605(b) and petitioned for §205.605(a). The Handling Subcommittee considered the possibility of reclassifying tocopherols to 205.605(a), or listing on both 205.605(a) and 205.605(b) with different uses annotated for each listing and/or an annotation about availability; however, as discussed at the Fall 2017 meeting, the Handling Subcommittee concluded to not move forward with the tocopherol annotation change. The meeting transcripts note that "if there is sufficient commercial availability of this material in another form, we encourage members of the public or industry to petition the NOSB to make this change, and we would take it up at that time".

Human Health and the Environment:
Tocopherols are one of the main sources of Vitamin E. No major impacts on human health or the environment are likely.

Additional information requested by Subcommittee: None

Subcommittee Vote:
Motion to remove tocopherols from §205.605(b) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Asa Bradman
Seconded by: Steve Ela
Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

Reference: 7 CFR §205.606

Celery powder

§205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."
Reference: 205.606(c) **Celery powder.**
Technical Report: N/A
Petition(s): 2007 Petition
Past NOSB Actions: 03/2007 NOSB recommendation; 04/2010 sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Use:
Meat preservation via natural nitrites/lactic acid is an ancient technology. In the organic sector, celery powder is used in a variety of processed meat products (hot dogs, bacon, ham, corned beef, pastrami, pepperoni, salami, etc.) to provide "cured" meat attributes without using prohibited nitrites. Celery powder is naturally high in nitrates that are converted to nitrites during fermentation by a lactic acid culture. Celery powder and the presence of nitrate and nitrites protects against spoilage (as an antioxidant) and also reduces risk from food borne pathogens, including clostridium botulinum, which produces botulin toxin. Celery powder is used in place of synthetic chemical nitrate and nitrite which are not currently permitted in U.S. organic agriculture. Although functionally similar to the use of synthetic nitrate and nitrite, meat products processed with celery powder must be labeled "uncured."

Manufacture:
Celery is cleaned, macerated, physically separated (liquid/solid), and the liquid is concentrated by evaporation, then heated and vacuum dried. According to the original petition, 0.2-0.5% celery powder and 0.01-0.5% of lactic acid starter culture are used to convert the nitrates to nitrite and thus create the curing agent. According to the Kerry Inc. patent (https://patentimages.storage.googleapis.com/1b/75/a5/082eb2538620f2/US20080305213A1.pdf), "the curing agent can further comprise additional components, including but not limited to, yeast extract, protein hydrolyzates, amino acids, vitamins, minerals, and carbohydrates. Prior to the conversion of nitrate to nitrite, the pH and salt content of the plant material can be adjusted with the addition of a suitable acid, base, salt, or combination thereof. The plant material can be subjected to additional processing steps prior to conversion of nitrate to nitrite. Such processing steps can include, but are not limited to, heat treatment, filter sterilization, or a process which reduces the initial microbial load." Celery powder is typically standardized to a specific nitrite content. See discussion below for more information about source material.

International:
There is no list of individual non-organic agricultural commodities allowed under the Japanese Agricultural Standards (JAS), International Federation of Organic Agricultural Movements (IFOAM) or Codex standards – however these standards allow for up to 5% non-organic content. Celery powder is not listed in the EU Organic Standards; however, sodium nitrate is allowed for meat products (an alternative to celery powder not currently listed on the National List).

Ancillary substances:
Possibly materials listed in the patent: "including but not limited to, yeast extract, protein hydrolyzates, amino acids, vitamins, minerals, and carbohydrates."

Human Health and the Environment
Nonorganic celery is used to produce celery powder, with concomitant use of allowed conventional pesticides and fertilizers. These materials may pose risks to workers, consumers and the environment. Additionally, health concerns have been raised about the use of synthetic nitrates and nitrites in processed meats (allowed in the European Union). For example, the International Association for Research in Cancer (IARC) listed processed meats as carcinogenic to humans due to the formation of nitrosamines, albeit with low potency, and the review committee was not unanimous. In terms of human health risks from nitrates/nitrites in food, there is no difference between celery or other plant-based nitrate sources versus synthetic nitrates and nitrites used on non-organic meats. In summary, nitrates and nitrites from celery powder would pose similar risks. Nitrates in food may provide some health benefits. For example, formation of nitrous oxide may result in lowered blood pressure and better cardiovascular function.

Discussion (including OFPA criteria):
Celery powder was listed as a nonorganic handling material in response to a 2007 petition asserting the need for a uniform, agriculturally produced material necessary to produce organic processed meats such as bacon, hot dogs, and sausage. Several commenters argue that this material allowed substantial growth of the organic meat industry while complying with the "organic" or "made with organic" claims of processed foods. However, concerns were, and continue to be, raised about the direct dependence on a conventionally grown agricultural product in organic trade and concomitant impacts on human health and the environment. Particular concerns have been raised about the possibility of enhanced use of nitrate fertilizers to "supercharge" the product used for celery powder manufacture.

In lieu of a technical report, a celery powder expert panel was convened for the April 2019 NOSB meeting. Experts spoke to key questions addressing nitrate safety, organic celery powder production, processing and manufacture of celery powder, progress toward organically sources celery or other substrates that could be used process organic meats, and the scale of the organic processed meat industry. Presentations and discussion addressed concerns raised during past reviews that production of high nitrate conventional nonorganic celery used for celery powder production requires enhanced use of synthetic nitrate fertilizers. In summary:

- Celery powder remains an essential curing agent for organic cured meats. Alternative source material such as swiss chard or other crops do not fill the need for a uniform product;
- Currently, celery powder is the only option available to comply with FSIS food safety requirements;
- Organic cured meat products represent a multi-million dollar industry and have increased opportunities for organic agricultural production;
- Because celery powder is used in small amounts, it is difficult to leverage investment to develop alternative sources;
- In various trials, nitrate levels in organically produced celery were ~1,000 ppm and ranged from ~500 to ~2000, but there was very high variability between varieties, farms, and years. Overall, organic levels were not uniform and generally below thresholds needed for meat processing;
- Nitrate levels in mature conventional celery were much higher – in the range of ~2500 ppm;
- No information was available as to whether agronomic methods to produce conventional celery for celery powder production entailed the use of extra nitrate use;
- More research is needed to identify varieties and methods to produce organically produced celery

powder source material.

Overall, trade and industry members of the organic community supported relisting of celery powder at §205.606, with the caveat that more research is needed to produce a viable organic alternative. There was little opposition to relisting celery powder except one consumer group that reflected concerns about the direct dependence of the large organic processed meat industry on a conventionally grown agricultural product and whether its use is a direct violation of OFPA and organic regulations and artificially adding nitrate as a preservative at levels not possible to achieve through use of organic celery. Concerns were raised about the cancer health risks of nitrates and nitrites, but as noted above there are also potential health benefits to nitrate intake. Given the importance of the organic processed meat industry, public and NOSB comments encouraged the USDA to fund additional research to develop organic alternatives to conventionally produced celery powder.

Additional information requested by Subcommittee: None

Subcommittee Vote:
Motion to remove celery powder from the National List at §205.606(c) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Asa Bradman
Seconded by: Scott Rice
Yes: 0 No: 6 Abstain: 0 Absent: 1 Recuse: 0

Fish oil

§205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."
Reference: 205.606(e) **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
Petition(s): 2007 Petition
Past NOSB Actions: 03/2007 sunset recommendation; 04/2010 sunset recommendation ; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Section 205.606 allows for use of non-organically produced ingredients to be used in processed products labeled "organic" when the ingredient is not commercially available in organic form.

The NOP does not presently have production standards for aquaculture, therefore organic fish cannot be commercially available as organic.

Uses: Fish oil is used in organic processing and handling as an ingredient to increase the content of omega-3 fatty acids - primarily, eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) - in foods to benefit human health by contributing to healthy brain development and reducing risks of cardiovascular disease, diabetes, inflammation, atherosclerosis (Chang et al., 2009; Lee et al., 2014). Fish oil is used in a variety of food products, including breads, pies, cereals, yogurt, cheese products, frozen dairy products, meat

products, cookies, crackers, snack foods, condiments, sauces, and soup mixes (Rizliya and Mendis, 25 2014). (Technical Report 2015 lines 19-25).

In addition to aquaculture - estimated to use about 81% of the fish oil produced worldwide - fish oil is used in feed for livestock such as pigs, cattle, poultry, and sheep. Industrial applications of fish oil include paint production, leather making, and biodiesel manufacture.

History: Fish oil was added to the National List in 2007, based on a petition from a manufacturer. At that time the NOSB did not request a technical report (TR) or Technical Advisory Panel Report (TAP). The NOSB 2007 recommendation indicated that the OFPA criteria were met in all categories but provided no scientific rationale or citations to support such findings. However, the NOSB final recommendation from May 9, 2007 stated …"pursuant to the judgment in Harvey v. Johanns, the NOSB was instructed to develop criteria for determining commercial availability, an essential tool in evaluating whether or not petitioned materials could be listed at § 205.606. These criteria were finalized in the NOSB "Recommendation for the Establishment of Commercial Availability Criteria National List § 205.606" of October 19, 2006. "That recommendation allows for pro-active listing on § 205.606 of materials that may currently be available in an organic form, but the supply of which has a history of fragility due to factors such as limited growing regions, weather, or trade-related issues. Furthermore, the recommendation reiterates the role of the Accredited Certifying Agent (ACA) in making the ultimate decision as to whether a § 205.606-listed material may be used, on a case by case basis. …" "…. After discussion, the Board decided to add an annotation to the recommendation to list fish oil to the National List. The annotation is "stabilized using only allowed ingredients on the National List." The Board felt that this annotation was not overly prescriptive since a nonorganic material that falls within the annotation exists on the market." The NOSB (2007) further noted that "There were no public comments specifically opposing the listing of fish oil on §205.606…."

In its five-year review in April 2010 the NOSB received no public comment and fish oil remained on the List. In February 2015 the NOSB posed the following questions in the first posting of this material under the new Sunset procedure:

1. What are the primary geographic sources of fish oil and primary fish species harvested for the 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?

In addition, in preparing for the 2017 Sunset Review the NOSB requested a full TR which was received in March 2015 after the posting of the initial sunset review. The 2015 TR provides a valuable in-depth analysis and provides up-to-date research and citations allowing the Subcommittee to re-evaluate fish oil comprehensively against the OFPA criteria. Sources: Fish oil is derived from a wide range of wild caught fish species including, tuna, mackerel, sardines, anchovy, halibut, (TR lines 69-79). NOTE: The TR also lists fish oil from whales and seal under fish, although these are mammals. (TR lines 75-76).

Fish oil is produced from fish by-products or from fish that are caught specifically for the purpose of making fish oil (TR lines 283-284). Farmed fish are not a source of fish oil; they are often fed fish oil supplements to boost their own levels of omega 3 fatty acids (TR 332-333). Based on 2009 data from the 2010 International Fishmeal and Fish Oil Organization (IFFO) Fishmeal and Fish Oil Statistical Yearbook, Peru

produces the most fish oil worldwide and is responsible for one-third of the global production of fish oil, followed by Chile and the United States (Fréon et al., 2014; SEAFISH, 2011). Denmark, Japan, and Iceland are also prominent producers of fish oil. Overall, Peru is the world's largest exporter of fish oil; together, Peru and Chile are responsible for 39% of global fish oil exports Most of the fish oil produced in Peru and Chile is refined by companies in Norway, the United States, and Canada although domestic refineries for fish oil are emerging in Peru, Chile, and other South American countries (Dowling, 2012; GOED, 2014). (TR 90-110)

Manufacturing: Fish oil remains intact through the purification process and is not chemically modified (TR 338). Fish oil used for feed, aquaculture, supplements, or food applications is further purified using a carbon filter to reduce contaminants (e.g., dioxins/furans, polybrominated diphenyl ethers [PBDEs], polychlorinated biphenyl [PCBs], polycyclic aromatic hydrocarbons [PAHs]) that may be present in the oil (Rizliya and Mendis, 2014). Further extraction and purification of the oil can be performed by selective hydrolysis, followed by filtration, neutralization with sodium hydroxide, removal of oxidized oil by clay, and deodorization using steam distillation (EPAX Norway, undated; U.S. FDA, 2002) (TR 307320). There are also other purification methods, which are discussed in the TR.

International: Fish oil is not listed as allowed for organic processing in Canada, Japan, EU, or under IFOAM and is not listed in CODEX (TR 245-275). However, it should be noted that CODEX, IFOAM and JAS do not have discreet lists for non-organic agricultural substances. The EU does have a positive list and it does not list fish oil, but the EU Organic Standards also allow for organic certification of aquaculture. There are EU organic fish oil products being sold.

Discussion: Human Health: Fish oil is a naturally sourced product which appears to provide a multitude of health benefits (as listed above under "Uses"). It is one of the best sources of Omega 3 EPA and DHA fatty acids. Fish oil such as cod liver oil which has been given to children in many areas of the world for generations to promote healthy brain development and prevent inflammation. Fish oils are added to many foods and taken as dietary food supplements to promote heart health and reduce risk of atherosclerosis.

However, the health benefits from consumption of fish oil is currently a debated topic in the scientific community (TR 471) and some sources suggest that there are health risks from fish consumption that may outweigh the benefit of omega 3 fatty acids from fish oil (TR 489-494). However, this statement is contradicted by the FDA's *A Quantitative Assessment of the Net Effects on Fetal Neurodevelopment from Eating Commercial Fish*, which states "the assessment estimates that for each of the endpoints modeled, consumption of commercial fish during pregnancy is net beneficial for most children in the United States."[2] Fish bioaccumulate many contaminants (TR 503-507). A laboratory analysis of 31 fish oil supplements found that every product contained measurable amounts of mercury, with an average concentration of 2.9 parts per billion (ppb) across all brands (TR 403-408, LabDoor, 2014). The highest level of mercury recorded in the supplements was 6 ppb (LabDoor, 2014). It should be noted however, that these tests were on fish oil supplements, not on fish oil used in food products which is controlled under different regulations than dietary supplements. The FDA action level for methylmercury in fish is 1 part per million (ppm) (U.S. FDA, 2011). The Global Organization for and DHA Omega-3 (GOED) sets voluntary standards for fish oil. GOED recommends a maximum value of 0.1 mg/kg (i.e., 0.1 ppm or 100 ppb) mercury in fish oil. The GOED has set the same 0.1-ppm voluntary standard value for lead, cadmium, and inorganic arsenic (GOED, 2012).

PCBs might also be present in fish oil. The levels of PCBs and other lipophilic organochlorine chemicals will be more concentrated in the oil fraction of the fish than in the whole fish (U.S. FDA, 2011). The FDA tolerance for PCBs is 2 ppm for all fish (U.S. FDA, 2011). An analysis of 13 over-the-counter children's fish oil

[2] https://www.fda.gov/media/88491/download

dietary supplements showed that every supplement contained PCBs, with a mean concentration of 9 (± 415 8) ppb (TR 413-415, Ashley et al., 2013). The GOED maximum value for PCBs in fish oil is 0.09 ppm (GOED, 2012). Dioxins and furans are hazardous environmental compounds that may also be found in fish and fish oil. In one study, 30 samples of omega-3-enriched dietary supplements were analyzed for the presence of dioxins/furans and PBDEs. Twenty-four of the samples had dioxin levels above detection, while all samples had PBDE levels above detection. Average intake estimates for dioxins and PBDE's from the supplements were 4.3 picograms (pg) and 25,100 pg per day, respectively (Rawn et al., 2009).

The GOED maximum values for dioxins; dioxin-like PCBs; and total dioxins, furans, and dioxin like PCBs are 2 pg, 3 pg, and 4 pg, respectively (GOED, 2012). There are no FDA action levels for dioxins and PBDEs, nor are their guidance levels of these compounds in supplements. (TR 404-426). Note: The TR addresses the February 2015 NOSB Questions 1, 2, 3 and 6 listed above under History, and partially answers Question 4, but it is not clear if the Voluntary Standard for contaminant limits is still in effect (Question 5).

Conservation issues: There is a very high demand for fish oil. 81% of fish oil goes to aquaculture. Demands on fisheries may overburden the current supply of fish (TR 441-450). Fish oil used is from wild caught and not farmed fish. Overfishing may also lead to species extinctions and a decrease in biodiversity. There are more than 100 confirmed cases of extinctions in marine fish populations worldwide (Jenkins et al., 2009). Exploitation of fisheries is the largest contributor to marine extinctions, higher than habitat loss, climate change, invasive species, pollution, and disease (Dulvy et al., 2003) (TR 462-465). While some countries have highly regulated fisheries to prevent overfishing, many do not. According the Food and Agriculture Organization's (FAO) State of the World's Fisheries and Aquaculture, most of the pelagic fish stocks, globally, are considered either fully fished or overfished. Food and Agriculture Organization of the United Nations Fisheries and Aquaculture Department (2014). The State of the World Fisheries and Aquaculture. pp. 39. While many different species are used for fishmeal and fish oil, small pelagics are most commonly used due to their high oil content. Peruvian anchoveta, Japanese anchovy, and Atlantic herring are the most common pelagic species harvested for fishmeal and fish oil, with primary stocks in the Southeast Pacific, Northwest Pacific, and Northeast and Northwest Atlantic, respectively. In 2010, all of these were either fully exploited or depleted. (Food and Agriculture Organization of the United Nations Fisheries and Aquaculture Department. (2010) The State of the World Fisheries and Aquaculture. pp. 35. Available at: http://www.fao.org/docrep/013/i1820e/i1820e.pdf)

In the Mediterranean, sardine and anchovy stocks have been assessed as fully fished (FAO 2014, p 40). According to FAO, fisheries that target species of a specific trophic level, such as those that target pelagics for fishmeal and fish oil production, remove "one ecosystem component without considering cascading effects on the dependent species…Concerns about the impacts of harvest strategies that fail to consider trophic relationships in a given ecosystem have been recognized for decades, and abundant scientific literature exists underpinning its possible negative impacts on the structure and functioning of aquatic ecosystems." (FAO 2014, p 136). Sardines, anchovies, and herring play a key ecological role in the survival of larger predatory fish, mammals, and seabirds, serving as an important link in the transfer of energy from plankton to species higher in the marine food web, some of which are endangered (FAO 2014, p 137), such as humpback whales.

There was a divided opinion of the Board and public in the 2015 review of this substances. There was a high consumer demand and industry strongly supports continued listing, especially as there are no organic sources. Industry comments (April 2015) include the following: "Used in Gummy Confections, Gummy Nutritional Supplements, Panned Jelly Beans…. Fish Oil is used in our products as a natural source of DHA. An organic form is not available…. No alternative management practices that would eliminate the need for the specific substance. This ingredient is essential to our organic products." Other Industry comments: "Fish oil provides nutritional benefits which our consumers are seeking"; "Peru fisheries are well regulated"; "specification sheets indicate levels of PCB's, arsenic, cadmium and lead are tested 3 times a year to meet

very strict guidelines; plant sources of omega 3 are not as complete as found in fish oil". On the other hand, conservation groups are concerned about impact on word fisheries, and NGO's are concerned about the cumulative risk impact of fish oil on human health recommend removing fish oil as it fails to meet OFPA criteria relating to human health, environmental conservation and compatibility with a sustainable system of agriculture. Public comment was also received about the essentiality of this substance however, essentiality is not a criterion used to review agricultural substances in OFPA/NOP regulations. Essentiality is only a criterion applied to synthetic substances, adjuvants, and processing aids. In the end the NOSB voted to not remove fish oil and the substance was renewed.

During the 2019 sunset cycle we posed four questions at the spring meeting:

1. Is there a mandatory standard for fish oil purity with limits on contaminants, dioxins and PCB's for example? How is purity assessed?
2. How is industry controlling for the risk of contaminants such as heavy metals and PCBs?
3. Is the Voluntary Standard from the Council of Responsible Nutrition (CRN) for contaminant limits still in effect?
4. How can the annotation be modified to control for the note conservation concerns?

Public comment indicated there was no mandatory standard for fish oil purity limits but that the GOED, a trade association representing the 85-90% of the fish oil industry, requires members to comply with a monograph for fish oils. As of this review limits were as follows:

- PCBs: Maximum 0.09 mg/kg
- PCDDs and PCDFs: Maximum 1.75 pg WHO-PCDD/F-TEQ/g
- Dioxin-like PCBs: Maximum 3 pg WHO-TEQ/g
- Total Dioxins, Furans and dioxin-like PCBs: Maximum 3 pg WHO-TEQ/g
- Lead (Pb): Less than 0.05 mg/kg
- Cadmium (Cd): Less than 0.1 mg/kg
- Mercury (Hg): Less than 0.1 mg/kg
- In-organic Arsenic (As): Less than 0.1 mg/kg[3]

The organization states control is established via randomized testing but no details on this program were provided. The same organization noted that the CRN monograph and its Omega-3 Working Group were the foundations for the GOED trade association. The current GOED monograph is the successor to the CRN monograph.

Support was received from several commenters, including the GOED trade association, for annotations that further address conservation concerns. The NOSB has submitted a separate work agenda request on this topic, however, annotation changes are handled separately from sunset reviews.

Support was received from organic dairies and industry that speak to the consumer demand for omega-3 enriched products and having an opportunity to compete with conventional products that market themselves similarly. Opposition was received from several interest groups who questioned the environmental impact from overfishing, human health impact from heavy metal exposure, and compatibility due to its usage as a supplement. Comments are consistent with previous comments received by the Board during earlier reviews and did not provide new information on fish oil. Furthermore, there is no relevant criteria in OFPA or the Organic regulations for delisting this material based on its use as a nutritional supplement.

No new information was received by the NOSB supporting removal of this substance.

[3] https://goedomega3.com/storage/app/media/Governance%20docs/goedmonograph-2019-03-01-r.pdf.

Subcommittee Vote:
Motion to remove fish oil from §205.606 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Tom Chapman
Seconded by: Scott Rice
Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

Gelatin

§205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."
Reference: 205.606(g) **Gelatin (CAS # 9000-70-8).**
Technical Report: 2002 TAP; 2019 TR Gelatin, collagen gel, and casings
Petition(s): 2001 Petition ; 2007 Petition
Past NOSB Actions: 05/2002 NOSB Recommendation; 05/2007 Recommendation to add to the national list; 04/2010 NOSB sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Use:
Gelatin is used in a wide range of products as a clarification or fining agent in teas, juice, and wine, as a stabilizer, texturizer, thickener, and in capsules. It may either be an ingredient or a processing aid in candies (gummy bears), desserts (puddings, jello, marshmallows), dairy products (yogurt, sour cream, ice cream), cereals and cosmetics. Fish gelatin is widely preferred for uses in kosher foods. Collagen gel has recently been petitioned for inclusion on the National List at §205.606. Collagen is the native form of gelatin and chemically the two are indistinguishable.

Manufacture:
Gelatin can be made from many different sources of collagen. Cattle bones, hides, pigskin, and fish are the principle commercial sources. Gelatin may be prepared in a way that is more like cooking and could be considered nonsynthetic. However, gelatin may also be processed in ways that would render it synthetic. All manufacturing operations extract and hydrolyze collagen found in fish skins, bovine bone, and porcine skin with subsequent purification, concentration, and drying operations. These can be either simple or complicated operations.

International:
EU 2092/91 — Annex VI — Gelatin is listed under "Processing aids and other products which may be used for processing of ingredients of agricultural origin" in Section B and under "Ingredients of Agricultural Origin Which Have Not Been Produced Organically" in Section C.
Codex Alimentarius — Guideline for the Production, Processing, Labelling, and Marketing of Organically Produced Foods CAC/GL 32-1999, Table 2 Substance for Plant Pest and Disease Control, 1. Plant and Animal: listed. Table 4: Listed under "processing aids which may be used for the preparation of products of agricultural origin."

IFOAM — Basic Standards for Organic Production and Processing, September 2000, Appendix 4 List of Approved Ingredients of Non Agricultural Origin and Processing Aids Used in Food Processing, Processing Aids and Other Products: listed for use in fruit & vegetable products and wine.
Ministry of Agricultural, Forestry and Fisheries of Japan (MAFF) — Japan Agricultural Standard, Notification #60, Table 2 of food additives: allowed, with no annotation.
Canada — Canadian General Standards Board National Standard for Organic Agriculture (CAN/CGSB-32.310-99), June 1999: permitted as a clarifying agent.
Certified Organic Associations of British Columbia (COABC) — British Columbia Certified Organic Production Operation Policies and Farm Management Standards, Section 9.14 Processing and Handling Materials List, March 2001: non hydrolyzed or hydrolyzed, regulated as a processing production aid; Either form of gelatin maybe used as a product processing aid, for now, but the producer must submit to the certifying agency written details of their search to replace the hydrolyzed gelatin format with a non-hydrolyzed gelatin or a completely different product. Allowed for fruits and vegetables and in winemaking.
Naturland, Germany — Listed in the August 1999 General Processing Standards in the "List of Permitted Ingredients, Additives, and Auxiliary Products" as "food gelatin without additives (exclusively for cream-like masses)."

Ancillary Substances:
It does not appear that there are any ancillary ingredients used regularly for gelatin, such as anti-caking agents, preservatives, colorings etc.

Discussion:
There are currently no NOP standards for organic aquaculture, and therefore no possibility of obtaining fish gelatin in any form, quantity or quality from a certified organic source. Public comment stated concern over gelatin sourced from conventional animal sources. The Subcommittee briefly discussed gelatin in relation to collagen gel, currently being petitioned, because gelatin is derived from processing collagen.

During the review period, the Subcommittee posted the following questions:

1) Are there organic sources of collagen that preclude the listing as a non-organically produced agricultural product allowed as ingredients in or on processed products labeled as 'organic'?
2) Are there any ancillary ingredients typically found in commercially available gelatin?

In response to the questions, several commenters said that the organic meat market has not sufficiently reached the "magnitude of mass" needed to produce organic gelatin and that the industry is currently working on the supply chain for future development of the organic gelatin market. However, detailed information about what the barriers are to organic gelatin development were not specified. Several commenters mentioned other alternatives to gelatin such as organic pea starch and pectin. However, in discussions with organic gummy manufacturers, it was noted that pectin and pea starch may add a flavor residue that is undesirable. The 2019 TR did not have any new information indicating that organic gelatin would be commercially available in the near future. The Handling Subcommittee hopes that at the next sunset review, the barriers to production of organic gelatin will no longer be present.

Subcommittee Vote:
Motion to remove gelatin from §205.606(f) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Harriet Behar
Seconded by: Asa Bradman
Yes: 0 No: 5 Abstain: 0 Absent: 2 Recuse: 0

Orange pulp, dried

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

Reference: 205.606(n) **Orange pulp, dried.**

Technical Report: N/A

Petition(s): 2008 Petition

Past NOSB Actions: 11/2008 NOSB recommendation for addition to the National List; 10/2015 NOSB Final Review

Recent Regulatory Background: Added to NL effective 03/15/2012 (77 FR 8089); Renewed 03/15/2017 (82 FR 14420)

Sunset Date: 3/15/2022

Subcommittee Review:

Uses:
According to the petitioner, dried orange pulp is a fiber with about 33.3% soluble fiber and 34.9% insoluble fiber. It is used as a moisture retention agent and fat substitute in baked goods, pastas, salad dressing, confectionary, processed cheese spreads, beverages, meat products and frozen foods. Dried orange pulp is used in rates up to 5 percent depending on use, but is self-limiting after that point due to loss of desirable eating qualities.

Manufacture:
Dried orange pulp is a byproduct of the orange juice industry and is manufactured from the washed orange peel, core and rag (membrane) remaining after juicing. The pulp is then mechanically dewatered, stabilized with heat, dried, and mill-ground to a powder. The only processing aid used is water. No chemicals are used to process the product. The petitioner notes, due to food safety and economics, dried orange pulp manufacture must be co-located with orange juice processing facilities.

International:
There is no list of individual non-organic agricultural commodities allowed under the Japanese Agricultural Standards (JAS), International Federation of Organic Agricultural Movements (IFOAM) or Codex standards – however these standards allow for up to 5% non-organic content. The EU Organic Standards do not list dried orange pulp.

Ancillary substances:
No ancillary substances were provided.

Discussion:
The 2015 NOSB requested information from the public related to (1) commercial demand, (2) commercial availability, (3) alternatives, and (4) necessity and use. No specific comments supported relisting or addressed commercial availability of dried orange pulp. No organic handler commented in favor of the material. While the NOSB could not find organic dried orange pulp during a search of publicly available sourcing resources in February 2015, there were several listings for organic suppliers of oranges, organic juice, dried oranges and orange pulp – feedstock raw materials and byproduct industries for dried orange pulp. During the review period, the Subcommittee asked the following questions:

1) Is there an organic supply of international orange pulp, dried?
2) Is there a domestic supply of organic orange pulp, dried?
3) Is it essential?

There were no commenters who listed orange pulp, dried, as an ingredient in their products nor any certifiers who listed it in their review of materials in organic products. However, orange peel and orange pulp were listed as ingredients in organic products. During the Spring 2019 public subcommittee discussion, the Handling Subcommittee noted that this listing also has a patent which may limit its use in organic products. Other commenters requested that the Board consider the use of conventional pesticides in conventional orange production that may leave residue in the final product of orange pulp, dried.
The Handling Subcommittee has voted to remove this item from the National List because orange pulp dried does not seem to be necessary for or consistent with organic handling (failing OFPA criteria at 7 U.S.C. § 6517(c)(ii)–(iii)), and alternatives exist (failing OFPA criteria at § 6518(m)(6)). There were no comments that supported it use, nor no known organic products that include it as an ingredient. There is sufficient supply of organic oranges to produce dried orange pulp, and those wishing to purchase this product organically could work with manufacturers to source organic raw material. It is inconsistent with organic farming and handling to use a nonorganic product in organic foods, when an organic ingredient could be produced.

Subcommittee Vote:
Motion to remove orange pulp, dried from §205.606(n) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): Not necessary for, or consistent with, organic handling and alternatives exist (§§ 6517 and 6518)
Motion by: Harriet Behar
Seconded by: Asa Bradman
Yes: 4 No: 1 Abstain: 0 Absent: 2 Recuse: 0

Seaweed, Pacific kombu

§205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."
Reference: 205.606(r) **Seaweed, Pacific kombu.**
Technical Report: 2016 TR (Marine Plants & Algae)
Petition(s): 2007 Petition
Past NOSB Actions: 05/2008 NOSB recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Added to NL effective 03/15/12 (77 FR 8089); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 03/15/2022

Subcommittee Review:

Uses:
Marine plants (seaweed) and algae are included on the National List in several sections and allowed for use in organic production and handling:

1) At §205.601(j)(1), Aquatic plant extracts are synthetic substances allowed in organic crop production, as plant or soil amendments, from other than hydrolyzed extracts where the extraction process is limited to the use of potassium hydroxide or sodium hydroxide; the solvent amount used is limited to that amount necessary for extraction.
2) At §205.605 (a) and (b), products from marine plants and algae including non-synthetic substances: alginic acid, agar, carrageenan, and the alginates are nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as ''organic'' or ''made with organic (specified ingredients or food group(s))'' and may be used as ingredients in or on processed products labeled as

''organic'' or ''made with organic (specified ingredients or food group(s)).'' In addition, some minerals used for nutrient fortification, such as calcium, may be derived from marine plants.

3) At §205.606(d), four substances from marine plants and algae are specifically identified as nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as ''organic'' when the specific product is not commercially available in "organic" form: (d)(2) beta-carotene extract color, derived from algae (*Dunaliella salina*), not produced using synthetic solvents and carrier systems or any artificial preservative; (k) Kelp used only as a thickener and dietary supplement; (r) Pacific kombu; and (v) Wakame seaweed (*Undaria pinnatifida*).
4) In addition, calcium used for fortification may be derived from marine plants. In 2012, about 23.8 million metric tons worldwide of seaweed and other algae were harvested from aquaculture. Capture production, also known as wildcrafting produced about 1.1 million metric tons. Seaweed was used as food, in cosmetics and fertilizers, processed to extract thickening agents, and as an additive to animal feed (FAO, 2014).

Currently, Kombu is used as an ingredient to make stock for instant miso soup and Yuzu Ponzu. Kombu is integral to the preparation of many Japanese traditional foods such as stock.

Manufacture:

Kombu is harvested from the ocean. After the crop is harvested, it is sun-dried. In general, for the preparation of stock for Japanese traditional food, dried Kombu is boiled in water.

International:

Canada - Canadian General Standards Board Permitted Substances List. This list was updated in November 2015. Although there is a Canadian organic aquaculture standard and accredited certifying bodies can certify to it, the standard itself is not referenced in government regulations and organic aquaculture products may not carry the Canada Organic logo. Aquatic plants and aquatic plant products not containing synthetic preservatives, such as formaldehyde, either extracted naturally (non-synthetic) or with potassium hydroxide or sodium hydroxide in approved situations are allowed as soil nutrients and amendments. Agar is also permitted as a medium for mushroom spawn production.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999) - A proposal to amend the Codex guidelines to include organic aquaculture, including algae and products of algae, has been under consideration. Due to consensus issues, it is unclear whether this proposal will be adopted in the future (CAC, 2016). The Codex guidelines for organic also allow: 1) seaweed and seaweed products as a soil conditioner, 2) seaweed, seaweed meal, seaweed extracts, sea salts and salty water for pest control, 3) Carrageenan, 4) Alginic acid/sodium alginate/potassium alginate and 5) agar.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008. Aquaculture is defined by the EEC as the rearing or cultivation of aquatic organisms including marine plants and algae using techniques designed to increase the production of the organisms in question beyond the natural capacity of the environment; the organisms remain the property of a natural or legal person throughout the rearing or culture stage, up to and including harvesting. Algae, including seaweed, can be used in the processing of organic food. Aquaculture production must be based on the maintenance of the biodiversity of natural aquatic ecosystems, the continuing health of the aquatic environment and the quality of surrounding aquatic and terrestrial ecosystems.

Japan Agricultural Standard (JAS) for Organic Production— The Japanese Agricultural Standard for Organic Plants (Notification 1065 of the Ministry of Agriculture, Forestry and Fisheries of October 27, 2005) allows the use of dried algae as fertilizer for terrestrial plants.

International Federation of Organic Agriculture Movements (IFOAM) – IFOAM is developing a standard for marine algae in its aquaculture expert forum. Seaweed is allowed as a soil input in appendix 2 of the IFOAM norms (IFOAM, 2014). In addition, several hydrocolloids derived from algae such as carrageenan and alginates are allowed as food additives (IFOAM, 2014).

Ancillary substances:

It does not appear that any ancillary substances such as anti-caking agents, preservatives or colorings are used in the manufacture of Pacific Kombu products.

Discussion:

As a marine material, use of Kombu seaweed is part of an ongoing discussion focused on environmental concerns about the harvesting and use of marine algae and related materials (see https://www.ams.usda.gov/sites/default/files/media/Marine%20Plants%20and%20Algae%20TR.pdf; and https://www.ams.usda.gov/sites/default/files/media/MSMarineMaterialsDiscDocOct2018Web.pdf) and whether standards preventing overharvesting are needed to protect ocean environments. No written or oral comments were submitted for the April 2019 NOSB meeting by users of Kombu seaweed. Written comments addressed environmental concerns about overharvesting and also the potential for Kombu seaweed to concentrate heavy metals and/or radioactive isotopes of iodine which may be present in contaminated waters. Annotations were recommended for risk-based testing for toxic materials, using a decision tree to identify harvesting areas where testing would need to be performed. One commenter suggested that certification as a wild-crafted organic product could prevent overharvesting and contamination, and in the absence of such standards, the material should not be relisted.

Additional information requested by Subcommittee: None

Subcommittee Vote:

Motion to remove seaweed, Pacific kombu from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Asa Bradman
Seconded by: Steve Ela
Yes: 1 No: 6 Abstain: 0 Absent: 0 Recuse: 0

Wakame seaweed

§205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."
Reference: 205.606(v) **Wakame seaweed (*Undaria pinnatifida*).**
Technical Report: 2016 TR (Marine Plants & Algae)
Petition(s): 2007 Petition
Past NOSB Actions: 04/2007 NOSB recommendation; 04/2010 NOSB sunset recommendation; 10/2015 NOSB Final Review
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Uses:
Acidulant, pH control, flavoring agent, sequestrant, and buffering agent. Used as an emulsifier in dairy. Marine plants (seaweed) and algae are included on the National List in several sections and allowed for use in organic production and handling:

1) At §205.601(j)(1), Aquatic plant extracts are synthetic substances allowed in organic crop production, as plant or soil amendments, from other than hydrolyzed extracts where the 46-extraction process is limited to the use of potassium hydroxide or sodium hydroxide; the solvent amount used is limited to that amount necessary for extraction.
2) At §205.605 (a) and (b), products from marine plants and algae including non-synthetic substances: alginic acid, agar and carrageenan, and the alginates are nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as ''organic'' or ''made with organic (specified ingredients or food group(s))'' and may be used as ingredients in or on processed products labeled as ''organic'' or ''made with organic (specified ingredients or food group(s)).'' In addition, some minerals used for nutrient fortification, such as calcium, may be derived from marine plants.
3) In §205.606(d), four substances from marine plants and algae are specifically identified as nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as ''organic'' when the specific product is not commercially available in "organic" form: (d)(2) beta-carotene extract color, derived from algae (*Dunaliella salina*), not produced using synthetic solvents and carrier systems or any artificial preservative; (k) Kelp used only as a thickener and dietary supplement; (r) Pacific kombu; and (v) Wakame seaweed (*Undaria pinnatifida*).
4) In addition, calcium used for fortification may be derived from marine plants

In 2012, about 23.8 million metric tons worldwide of seaweed and other algae were harvested from aquaculture. Capture production or wildcrafting produced about 1.1 million metric tons. Seaweed was used as food, in cosmetics and fertilizers, processed to extract thickening agents, and as an additive to animal feed (FAO, 2014).

Wakame seaweed is a traditional accompaniment to Miso Soup in Japanese cuisine.

Manufacture:
Wakame is naturally occurring in the ocean. It is harvested and sun dried. It is often cut into smaller pieces and salted for shelf life.

International:
Canada - Canadian General Standards Board Permitted Substances List. This list was updated in November 2015. Although there is a Canadian organic aquaculture standard and accredited certifying bodies can certify to it, the standard itself is not referenced in government regulations and organic aquaculture products may not carry the Canada Organic logo. Aquatic plants and aquatic plant products not containing synthetic preservatives, such as formaldehyde, either extracted naturally (non-synthetic) or with potassium hydroxide or sodium hydroxide in approved situations are allowed as soil nutrients and amendments. Agar is also permitted a medium for mushroom spawn production.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999) - A proposal to amend the Codex guidelines to include organic aquaculture, including algae and products of algae, has been under consideration. Due to

consensus issues, it is unclear whether this proposal will be adopted in the future (CAC, 2016). The Codex guidelines for organic also allow: 1) seaweed and seaweed products as a soil conditioner, 2) seaweed, seaweed meal, seaweed extracts, sea salts and salty water for pest control, 3) Carrageenan, 4) Alginic acid/sodium alginate/potassium alginate and 5) agar.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008. Aquaculture is defined by the EEC as the rearing or cultivation of aquatic organisms including marine plants and algae using techniques designed to increase the production of the organisms in question beyond the natural capacity of the environment; the organisms remain the property of a natural or legal person throughout the rearing or culture stage, up to and including harvesting. Algae, including seaweed, can be used in the processing of organic food. Aquaculture production must be based on the maintenance of the biodiversity of natural aquatic ecosystems, the continuing health of the aquatic environment and the quality of surrounding aquatic and terrestrial ecosystems.

Japan Agricultural Standard (JAS) for Organic Production— The Japanese Agricultural Standard for Organic Plants (Notification 1065 of the Ministry of Agriculture, Forestry and Fisheries of October 27, 2005) allows the use of dried algae as fertilizer for terrestrial plants.

International Federation of Organic Agriculture Movements (IFOAM) – IFOAM is developing a standard for marine algae in its aquaculture expert forum. Seaweed is allowed as a soil input in Appendix 2 of the IFOAM norms (IFOAM, 2014). In addition, several hydrocolloids derived from algae such as carrageenan and alginates are allowed as additives (IFOAM, 2014).

Ancillary substances:

It does not appear that any ancillary substances such as anti-caking agents, preservatives or colorings are used in the manufacture of wakame products, other than salt.

Discussion:

As a marine material, use of Wakame seaweed is part of an ongoing discussion focused on environmental concerns about the harvesting and use of marine algae and related materials (see https://www.ams.usda.gov/sites/default/files/media/Marine%20Plants%20and%20Algae%20TR.pdf; and https://www.ams.usda.gov/sites/default/files/media/MSMarineMaterialsDiscDocOct2018Web.pdf) and whether standards preventing overharvesting are needed to protect ocean environments. Among written and oral comments submitted for the April 2019 NOSB, only one user of this materials was noted. Written comments addressed environmental concerns about overharvesting and also the potential for Wakame seaweed to concentrate heavy metals and/or other contaminants which may be present in polluted waters. Annotations were recommended for risk-based testing for toxic materials, using a decision tree to identify harvesting areas where testing would need to be performed. As with Kombu seaweed, one commenter suggested that certification as a wild-crafted organic product could prevent overharvesting and contamination, and in the absence of such standards, the material should not be relisted.

Additional information requested by Subcommittee: None

Subcommittee Vote:

Motion to remove seaweed, wakame (*Undaria pinnatifida*) from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Asa Bradman
Seconded by: Steve Ela
Yes: 0 No: 7 Abstain: 0 Absent: 0 Recuse: 0

National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal
C6, C8, C10, C12 Naturally Derived Fatty Alcohol/MASCOL80
July 16, 2019

Summary of Petition

A petition requesting the addition of revised active ingredient C6, C8, C10, C12 naturally derived fatty alcohol was received by the NOSB in December 2018 to be added to section §205.601(k) of the National List. The Petition asks for the substance to be annotated for "sucker control on organic tobacco crops". The petitioner has made numerous revisions to the original petition (2015). According to Dr. Clarissa Matthews, "the original petition was for use in tobacco and other crops, contained reference to multiple materials including inerts, and did not specify the range of fatty alcohols in the material MASCOL80. The re-petition as revised specifies use on tobacco only, clarifies material being petitioned, and includes the full range of alcohols (i.e., C6-C12) in MASCOL80."

The NOSB's Formal recommendation on November 2, 2017 to the NOP, stated among other issues, the use of a synthetic growth regulator is not compatible with a system of sustainable and organic agriculture. The re-petition specifies the need of this synthetic growth regulator on organic tobacco for sucker control. There could be a human health concern caused by exposure to nicotine when hand suckering. The NOSB also received a petitioned signed by many tobacco farmers, stating they need this material, which had been allowed by a few organic certifiers in the past. Growing organic tobacco can be one organic crop in a longer crop rotation. Some producers have stated if this material is not approved, they may choose to no longer grow the other crops organically on their farms.

The NOSB will review the action of fatty alcohols as a synthetic growth regulator and its compatibility with a system of sustainable and organic agriculture. Currently, EPA's registration for this material is limited to use on tobacco and the technical review received by the NOSB only discussed fatty alcohols for the EPA registered use.

Category: Synthetic Substance Allowed for Use in Organic Crop Production
NOP Reference: 205.601 Synthetic Substance Allowed for use in Organic Crop Production.
NOP Section: 205.601(k)(2) - As a Plant Growth Regulator

Requested Annotation: For sucker control in organic tobacco production

Category 1: Classification

1. For CROP use: This substance is **Synthetic.**
   Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [OFPA §6502(21)] If so, describe, using NOP 5033-1 as a guide.

   Fatty alcohols can be produced from natural fats from plants or animals, or from petroleum sources. In either case, chemical changes are required to produce fatty alcohols.

2. Reference to appropriate OFPA category:
   Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i)]; copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers; or (ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern?

   Fatty alcohols do not fall into any of the OFPA categories. Fatty alcohols produced as a mixture of four aliphatic alcohols are not considered inert by the Environmental Protection Agency nor are they included in List 4. Fatty alcohols may be registered with the EPA only for tobacco sucker control. N-decyl alcohol (decanol) and n-octyl alcohol (octanol) are individually approved by the US Food and Drug Administration (FDA) for food and non-food use as solvents or co-solvents.

Category 2: Adverse Impacts

1. What is the potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems?
   There appears to be no known detrimental chemical interactions between fatty alcohols and other materials used in organic farming systems. Mineral oil, cooking oil or paraffin oil are currently the only topping and suckering substances used by organic crop producers and there is no proven adverse impact with these substances.

2. What is the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment? [§6518(m)(2)]

   The log Kow is an indicator of a chemical's tendency to bioaccumulate. The TR reports log Kow's for octanal and decanol at 3.15 and 4.57 respectively, which are moderately low. The TR also notes that linear fatty alcohols in general are easily biodegradable.

3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)]
   According to the Safer Choice determination of the EPA, 1-decanol, 1-octanol, 1-dodecanol and the C_6-C_{12} alcohols are expected to be of low concern for environmental contamination based on experimental and modeled data. Linear fatty alcohols in general are easily biodegradable. The solubility of fatty alcohols in water decreases with an increasing C-chain length. Fatty alcohols possess only moderate acute toxicity for aquatic organisms. In general, in their range of water solubility no toxic effects are observed.

   The fatty alcohols from both natural and manufactured sources represent a low risk for environmental contamination.

4. Discuss the effect of the substance on human health.

   There is no evidence to suggest that the aliphatic alcohols cause increased susceptibility to health problems in infants and children. Based on the results of the available studies, no endpoints of toxicological concern have been identified for human health risk assessment

purposes. The EPA concluded that there are no human risks of concern for aliphatic alcohols (TR lines 396 – 399).

5. Discuss any effects the substance may have on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock. [§6518(m)(5)]

   When fatty alcohols are applied to tobacco plants for suckering with a surfactant such as tween 80, an average residue of 1.6 parts per million (ppm) of the applied fatty alcohols and 1.0 ppm of the surfactant remain on the cured leaves. Over 7000 ppm of naturally occurring fatty alcohols are also present in and on the cured leaves. Fatty alcohols induce a low incidence of polynucleate root tip cells or root tip cells with fragmented nuclei. The fatty alcohols are produced naturally, in all living organisms, from bacteria to man, and thus, are widely present throughout the natural world. In any agro-ecosystem, fatty alcohols will be present from natural sources. The introduction of C_6-C_{12} fatty alcohols for topping and suckering may produce short term toxicity to many organisms in the range of 1-100 milligrams/liter, however; because the application rate is intermittent, and biodegradability and removal rate are high for this substance no readily observable effects occur in the agroecosystem (TR lines 342-352).

6. Are there any adverse impacts on biodiversity? (§205.200)
   Fatty alcohols are chemicals that naturally occur in all plants and animals. They are known for their high level of biodegradability in the environments. Their derivative products are additionally designed to rapidly degrade after use and are not considered endocrine disrupters.

Category 3: Alternatives/Compatibility

1. Are there alternatives to using the substance? Evaluate alternative practices as well as non-synthetic and synthetic available materials. [§6518(m)(6)]

   Topping may be done by hand or with special machines that cut the flower heads and sacrifice a few leaves. Topping requires two or three trips over the field to catch all the plants. Suckers can be removed by hand as well as stunted by carefully applying approved soybean oil or mineral oil to the top of the plant. Topping and suckering are the most time-consuming tasks associated with growing organic tobacco and may be necessary every week for 10 weeks.

   One issue with suckering and topping is tobacco toxicity to workers performing the task. Tobacco is well documented as having negative human health effects (i.e. cancer, heart attack, lung disease) when in contact with skin or mucous membranes. Workers in contact with tobacco plants may also experience nausea and other health concerns from tobacco poisoning.

2. In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]

   The review and subsequent denial of the fatty alcohol petition at the Fall 2017 NOSB revolved around several issues. First, the uses requested for the petitioned material were broad and extended beyond the limited use for tobacco desuckering. Since other uses for the petitioned material were not allowed by the Environmental Protection Agency, the board was faced with either adding an annotation to the listing or denying the petition. Secondly, the petition was not clear as to which fatty alcohols were being requested. The petition contained reference to multiple materials including inerts, and did not specify the range of fatty alcohols being

requested. Thirdly, there was little evidence provided for essentiality to organic production in the original petition. The Board received few comments noting that this material was essential for organic tobacco production. The Board was also not aware that fatty alcohols had been approved by some certifiers and not by others and that some growers were already using this material.

During review of the current petition several of these issues have been addressed. First, the current petition is limited to the use of fatty alcohols for organic tobacco production. Secondly, the fatty alcohols being requested are clearly spelled out and match those available in the products previously allowed by some certifiers. Thirdly, the Board received numerous comments during the Spring 2019 Board meeting noting the essentiality of this material to organic tobacco growers. These comments were received even though the material was not on the meeting agenda. Numerous tobacco growers noted that without this material, they would be unable to produce organic tobacco and would most likely drop their organic certification, including the certification for crops they use in rotation with tobacco. The reasons for essentiality included:

- Other currently available materials are ineffective or sporadically effective whereas fatty alcohols are effective and reliable.
- Manual desuckering involves numerous passes through the fields and exposes workers to the potential for tobacco poisoning and numerous health issues. The use of fatty alcohols prevents this exposure and is necessary to protect human health.
- The suckers on tobacco plants provide habit for aphids and increase the susceptibility of the plant to other pests. Desuckering the plants reduces pest pressure.

The crops subcommittee is well aware of the negative impacts on human health of tobacco use. However, tobacco is a legal crop and a crop eligible for organic certification. Like any other material reviewed for use on organic crops, the committee is limiting our review to whether the material meets the criteria necessary for adding it to the National List as a crop production aid. Since fatty alcohols occur naturally throughout the plant world, break down readily after use, help to prevent worker exposure to tobacco poisoning, and reduce insect problems, they are compatible with a system of sustainable agriculture.

Minority opinion:

During its Fall 2017 board meeting, the NOSB determined that the use of a synthetic plant growth regulator for sucker control of tobacco is not compatible with a system of organic agriculture. Following the re-petition of this material, the NOSB heard from numerous organic tobacco farmers in the spring of 2019 who rely on this material. While the testimony provided by growers was compelling and included worker health concerns and some associated pest prevention benefits, the primary reason for the petition of this material is to enable greater economic returns.

The TR for this material notes that fatty alcohols do not fall into any of the OFPA categories. Additionally, it states:
"The aim of sucker control is to focus the plant's energy into filling the leaves rather than growing the flower. Because tobacco sells by weight, heavier leaves are favored economically. In organic tobacco production, early topping to improve yield and quality is usually done by hand. Suckers can be removed by hand as well as stunted by carefully applying approved soybean oil or mineral oil to the top of the plant." (TR Lines 494-498)

Although manual control is clearly more expensive, the same can be said for manual sucker removal on tomatoes, for example, a task that requires weekly labor during the growing season. Allowing fatty alcohols to replace manual practices in tobacco would have the effect of subsidizing tobacco with a synthetic material over a crop like tomatoes, where similar hand removal of suckers is often required.

The foundation of organic agriculture is predicated on using natural, manual, mechanical, and cultural controls over synthetic materials. In many cases, this means utilizing hand labor and is part of why organic receives a price premium. Labor saving and greater economic returns are insufficient criteria for adding a synthetic material to the National List.

Classification Motion:

Motion to classify fatty alcohols C6, C8, C10, C12 naturally derived fatty alcohol as synthetic.
Motion by: Jesse Buie
Seconded by: Harriet Behar
Yes: 7 No: 0 Abstain: 0 Absent: 1 Recuse: 0

National List Motion:

Motion to add fatty alcohols C6, C8, C10, C12 Naturally Derived Fatty Alcohol at 205.601 for sucker control on organic tobacco crops.
Motion by: Jesse Buie
Seconded by: Rick Greenwood
Yes: 4 No: 2 Abstain: 1 Absent: 1 Recuse: 0

Approved by Steve Ela, Crop Subcommittee Chair, to transmit to NOSB August 14, 2019

National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal
Potassium Hypochlorite
July 16, 2019

Summary of Petition
[https://www.ams.usda.gov/sites/default/files/media/PotassiumHypochloriteRevisedPetition03262019.pdf]:

The petitioner is requesting potassium hypochlorite solution be included on the National List as follows: § 205.601 Synthetic substances allowed for use in organic crop production: (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.

Potassium hypochlorite is produced by the reaction of chlorine with a solution of potassium hydroxide:

$$Cl_2 + 2\ KOH \rightarrow KCl + KClO + H_2O$$

Potassium hypochlorite (KOCl) is registered by EPA and is FDA approved. This material is approved for use in many agricultural applications. This product can address needs for irrigation equipment maintenance and to meet Food Safety Modernization Act (FSMA) requirements to provide sanitation to pre-harvest water for irrigation. The material can also incidentally provide a source of potassium for plants.

As described in the petition, potassium hypochlorite shares similar chemistry and uses as sodium hypochlorite (bleach), except for the replacement of sodium for potassium, potentially reducing issues with salinization of soils. At the request of the petitioner, the FDA reviewed this product in comparison to NaOCl. FDA found the substitution of potassium ions for sodium, in such applications as NaOCl solutions, would not raise new safety concerns. They also stated that a Food Contact Notification (FCN) would not be required to use KOCl in the same manner that NaOCl is permitted. KOCl is exempt from requirements for a food tolerance (https://www.federalregister.gov/documents/2011/03/02/2011-4534/potassium-hypochlorite-exemption-from-the-requirement-of-a-tolerance)

Like bleach and other chlorine sanitizing compounds currently on the National List, KOCl is a strong oxidant and can pose serious risks to human health if acute high exposure occurs or from chronic lower level exposures. It is a dermal, respiratory, ocular, and mucous membrane irritant. Bleach is a known asthmagen, and, given the similar chemistries and mechanism of action, KOCL is also likely to cause or exacerbate asthma. KOCL is toxic to fish and other aquatic organisms. Like bleach and other chlorine compounds, strict adherence to the label is required. Use of chlorine compounds in organic crop production, including calcium hypochlorite, sodium hypochlorite, and chlorine dioxide, were reviewed in a 2011 Technical Report (TR) (https://www.ams.usda.gov/sites/default/files/media/Chlorine%202%20TR%202011.pdf). Information in this TR is transferable to the KOCl.

Given the nearly identical chemistry and human and environmental risks to sodium and calcium hypochlorite, currently listed under (§ 205.601(2), and the potential benefit of avoiding application of

sodium to soils, the Crops Subcommittee recommends listing of KOCl for the treatment of irrigation water not to exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.
Summary of Review:

Category 1: Classification

1. For CROP use: Is the substance _____ **Non-synthetic** or **____X___ Synthetic?**
   Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [OFPA § 6502(21)] If so, describe, using NOP 5033-1 as a guide.

2. Reference to appropriate OFPA category:
   Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§ 6517(c)(1)(B)(i)]; copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers; or (ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern?

No.

Category 2: Adverse Impacts

1. What is the potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems? [§ 6518(m)(1)]

   When used in irrigation water and compliant with maximum residual disinfectant limit under the Safe Drinking Water Act [4 ppm free chlorine], the substance is unlikely to have detrimental chemical interactions with other materials used in organic farming systems.

2. What is the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment? [§ 6518(m)(2)]

   Like bleach and other chlorine sanitizing compounds currently on the National List, KOCl is a strong oxidant and can pose serious risks to human health if acute high exposure occurs or from chronic lower level exposures. It is a dermal, respiratory, ocular, and mucous membrane irritant. Bleach is a known asthmagen, and, given the similar chemistries and mechanism of action, KOCL is also likely to cause or exacerbate asthma. KOCL is toxic to fish and other aquatic organisms. Like bleach and other chlorine compounds, strict adherence to the label is required.

   According to the petition, "…hypochlorite salts break down rapidly in to non-toxic compounds when exposed to sunlight. In seawater, chlorine levels decline rapidly: however, hypobromite (which is acutely toxic to aquatic organisms) is formed. Due to the presence of 65 ppm of bromide ion in seawater, hypochlorite salts form hypobromite salts. Hypobromite salts are very unstable to photolysis and rapidly break down back to bromide ion under the influence of ultra violet light [sunlight].

3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§ 6518(m)(3)]

   If the material is used according to label requirements, the probability of adverse environmental contamination is low. The petitioned use is in irrigation water, so the material will be directly released to the environment. The levels, generally 1-2 ppm and not to exceed 4 ppm, are consistent with drinking water standards and unlikely to pose a threat to human health or the environment. KOCl is not persistent. The major environmental risks are due to accidental releases of concentrated precursor material during manufacture (Cl_2) or transport of finished product before dilution for irrigation purposes.

4. Discuss the effect of the substance on human health. [§ 6517(c)(1)(A)(i); § 6517(c)(2)(A)(i); § 6518(m)(4)].

   Like bleach and other chlorine sanitizing compounds currently on the National List, KOCl is a strong oxidant and can pose serious risks to human health if acute high exposure occurs or from chronic lower level exposures. It is a dermal, respiratory, ocular, and mucous membrane irritant. Bleach is a known asthmagen, and, given the similar chemistries and mechanism of action, KOCL is also likely to cause or exacerbate asthma. The threshold or duration of exposures that might result in long-term respiratory problems is unknown. Short low level term exposures may result in transitory respiratory and eye irritation. Like bleach and other chlorine compounds, strict adherence to the label is required and care must be taken to protect workers diluting material for irrigation use.

5. Discuss any effects the substance may have on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock. [§ 6518(m)(5)]

   The application rate of 1-2 ppm, not to exceed free chlorine of 4 ppm, is consistent with drinking water standards for human. Use at this level in irrigation water is unlikely to have adverse biological and chemical interactions in the agroecosystem. Because KOCL substitutes potassium for sodium, it will not increase soil salinization.

6. Are there any adverse impacts on biodiversity? (§ 205.200)

   Unlikely.

Category 3: Alternatives/Compatibility

1. Are there alternatives to using the substance? Evaluate alternative practices as well as non-synthetic and synthetic available materials. [§ 6518(m)(6)]

   Sodium and calcium hypochlorite can be used for the same purposes as the petitioned material. KOCl has the distinct benefit over NaOCL because it does not contain sodium and potassium and is a plant nutrient.

2. In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§ 6518(m)(7)]

Overall, yes. Like other chlorine compounds, KOCl poses human health and environmental concerns, reviewed in part in the chlorine materials 2011 TR. However, FSMA requires that irrigation water used during certain growing activities have an acceptable microbial water quality profile (MWQP) and KOCL can meet this need and can also reduce fouling of irrigation equipment. These purposes are consistent with allowed uses of other chlorine materials. KOCl provides another tool to meet these requirements, and avoids application of sodium to soils.

Classification Motion:

Motion to classify potassium hypochlorite as synthetic
Motion by: Steve Ela
Seconded by: Dan Seitz
Yes: 7 No: 0 Abstain: 0 Absent: 1 Recuse: 0

National List Motion:

Motion to add potassium hypochlorite at § 205.601(2): Chlorine materials - For use in water for irrigation purposes, 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.
Motion by: Steve Ela
Seconded by: Rick Greenwood
Yes: 7 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Sunset 2021
Meeting 2 - Review
Crops Substances §205.601, §205.602
October 2019

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 2021. 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.

Request for Comments

Written public comments will be accepted through October 3, 2019 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the October meeting.

Sunset 2021
Meeting 2 - Review
Crops Substances §205.601, §205.602
October 2019

Note: With the exception of ferric phosphate and hydrogen chloride the materials included in this list are undergoing early sunset review as part of the November 18, 2016, NOSB recommendation on efficient workload re-organization.

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

Hydrogen peroxide (a)
Hydrogen peroxide (i)
Soaps, ammonium
Oils, horticultural (e)
Oils, horticultural (i)
Pheromones
Ferric phosphate
Potassium bicarbonate
Magnesium sulfate
Hydrogen chloride

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

Ash from manure burning
Sodium fluoaluminate

Hydrogen peroxide—§205.601(a)

§205.601 Synthetic substances allowed for use in organic crop production.
Reference: 205.601(a) As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems. **(4) Hydrogen peroxide.**
Technical Report(s): 1995 TAP; 2015 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation -deferred; 06/2006 sunset recommendation; 10/2010 sunset recommendation
10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Hydrogen peroxide is widely used as a disinfectant and bleaching agent. It is an effective and an environmentally benign substance used to reduce and control microorganisms for food safety purposes. It is critical for sanitizing aseptic packaging. It is a weak acid but a strong oxidizer and this makes it very useful as a fungicide, cleaning agent, and for disease control.

Hydrogen peroxide is a very simple molecule with a formula of H2O2. Virtually all modern production facilities manufacture commercial hydrogen peroxide solutions using large, strategically located anthraquinone autoxidation processes. Improved production methods and facilities based on the anthraquinone (AO) process have recently appeared in the commercial patent literature.

Hydrogen peroxide is a naturally occurring inorganic compound; however, the sources of hydrogen peroxide used in commercial fungicides, disinfectants and antiseptic products are produced through chemical synthesis. Industrial methods for the preparation of hydrogen peroxide are categorized as oxidation-reduction reactions. Modern commercial methods for hydrogen peroxide synthesis involve the transition-metal catalyzed chemical reduction of an alkyl anthraquinone with hydrogen (H2) gas to the corresponding hydroquinone followed by regenerative oxidation of the latter species in air.

Contamination is not expected when purified forms of hydrogen peroxide are released to the environment following normal use. At typical pesticide concentrations, hydrogen peroxide is expected to rapidly degrade to oxygen gas and water (US EPA, 2007). Large-volume spills and other releases of concentrated hydrogen peroxide could present a fire hazard since the substance readily decomposes to release oxygen gas. Pure hydrogen peroxide is not flammable and can be diluted with clean water to minimize the risk of fire. Although concentrated hydrogen peroxide is nonflammable, it is a powerful oxidizing agent that may spontaneously combust on contact with organic material and becomes explosive when heated. Combustion reactions and explosions resulting from accidental spills of concentrated hydrogen peroxide could therefore lead to environmental degradation.

A Technical Report (TR) was commissioned in 2015 for hydrogen peroxide since the information from the previous 1995 TAP was old and incomplete. It showed that hydrogen peroxide is inherently unstable and breaks down readily into oxygen and water. (TR Evaluation question 3-5). While it is toxic to disease spores and cells on contact, it has absolutely no residual effect. It has low or no impacts on birds, humans, or fish if it is used according to the label and protective application measures are taken. There can be some effects on soil microbiota in the very top layer of soil where it may come in contact, but because it breaks down so quickly, soil life is quickly restored. (TR 2015 Evaluation Question #8).

While there are some alternatives on the National List for sanitizers and disinfectants, as well as some essential oils with antiseptic properties, the National List items are not necessarily any better or safer than hydrogen peroxide, and the essential oils have not been studied to compare with Hydrogen peroxide side-by side to see if they are equally as effective and benign. (TR Evaluation question 11). Certain bacterial and fungal products that are beneficial in controlling plant diseases may be valid alternatives for some uses as a fungicide, but often these are best used as preventatives and are not effective once a disease has taken hold, and they are not good substitutes in all situations. Likewise, some biological, cultural and physical methods keep the need for use of hydrogen peroxide to a minimum, but don't apply to every situation. (TR Evaluation question 12).

In the 2015 sunset review most public comment supported keeping hydrogen peroxide on the National List. It was frequently mentioned that it is one of the few tools left against fire blight now that antibiotics cannot be used. It is widely used to clean equipment, in mushroom production, and to alternate with other materials for resistance management. No comments were put forward with new information that would contribute to the OFPA criteria review. The NOSB found the material to meet OFPA criteria and had no objection to continued listing. No significant new issues were raised by the public.

During the Spring 2019 NOSB meeting the Crops Committee received comments in favor of relisting hydrogen peroxide and no comments against relisting. Comments included the following:

- Hydrogen peroxide is an effective microbial pesticide used in the orchard setting for the sanitation of equipment such as picking bags and pruning shears. It is also used as an algicide and disinfectant, including for irrigation system cleaning.
- With the loss of antibiotics, hydrogen peroxide has become an extremely important tool in controlling fire blight in both organic apples and pears.

Subcommittee Vote:
Motion to remove hydrogen peroxide from §205.601(a) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Jesse Buie
Seconded by: Harriet Behar
Yes: 0 No: 8 Abstain: 0 Absent: 0 Recuse: 0

Hydrogen peroxide—§205.601(i)

§205.601 Synthetic substances allowed for use in organic crop production.
Reference: 205.601(i) As plant disease control. **(5) Hydrogen peroxide.**
Technical Report(s): 1995 TAP; 2015 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation -deferred; 06/2006 sunset recommendation; 10/2010 sunset recommendation
10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022
Subcommittee Review:
Hydrogen peroxide is widely used as a disinfectant and bleaching agent. It is an effective and an environmentally benign substance used to reduce and control microorganisms for food safety purposes.

It is critical for sanitizing aseptic packaging. It is a weak acid but a strong oxidizer and this makes it very useful as a fungicide, cleaning agent, and for disease control.

Hydrogen peroxide is a very simple molecule with a formula of H2O2. Virtually all modern production facilities manufacture commercial hydrogen peroxide solutions using large, strategically located anthraquinone autoxidation processes. Improved production methods and facilities based on the anthraquinone (AO) process have recently appeared in the commercial patent literature.

Hydrogen peroxide is a naturally occurring inorganic compound; however, the sources of hydrogen peroxide used in commercial fungicides, disinfectants and antiseptic products are produced through chemical synthesis. Industrial methods for the preparation of hydrogen peroxide are categorized as oxidation-reduction reactions. Modern commercial methods for hydrogen peroxide synthesis involve the transition-metal catalyzed chemical reduction of an alkyl anthraquinone with hydrogen (H2) gas to the corresponding hydroquinone followed by regenerative oxidation of the latter species in air.

Contamination is not expected when purified forms of hydrogen peroxide are released to the environment following normal use. At typical pesticide concentrations, hydrogen peroxide is expected to rapidly degrade to oxygen gas and water (US EPA, 2007). Large-volume spills and other releases of concentrated hydrogen peroxide could present a fire hazard since the substance readily decomposes to release oxygen gas. Pure hydrogen peroxide is not flammable and can be diluted with clean water to minimize the risk of fire. Although concentrated hydrogen peroxide is nonflammable, it is a powerful oxidizing agent that may spontaneously combust on contact with organic material and becomes explosive when heated. Combustion reactions and explosions resulting from accidental spills of concentrated hydrogen peroxide could therefore lead to environmental degradation.

A Technical Report (TR) was commissioned in 2015 for hydrogen peroxide since the information from the previous 1995 TAP was old and incomplete. It showed that hydrogen peroxide is inherently unstable and breaks down readily into oxygen and water. (TR Evaluation question 3-5). While it is toxic to disease spores and cells on contact, it has absolutely no residual effect. It has low or no impacts on birds, humans, or fish if it is used according to the label and protective application measures are taken. There can be some effects on soil microbiota in the very top layer of soil where it may come in contact, but because it breaks down so quickly, soil life is quickly restored. (TR 2015 Evaluation Question #8).

While there are some alternatives on the National List for sanitizers and disinfectants, as well as some essential oils with antiseptic properties, the National List items are not necessarily any better or safer than hydrogen peroxide, and the essential oils have not been studied to compare with Hydrogen peroxide side-by side to see if they are equally as effective and benign. (TR Evaluation question 11). Certain bacterial and fungal products that are beneficial in controlling plant diseases may be valid alternatives for some uses as a fungicide, but often these are best used as preventatives and are not effective once a disease has taken hold, and they are not good substitutes in all situations. Likewise, some biological, cultural and physical methods keep the need for use of hydrogen peroxide to a minimum, but don't apply to every situation. (TR Evaluation question 12).

In the 2015 sunset review most public comment supported keeping hydrogen peroxide on the National List. It was frequently mentioned that it is one of the few tools left against fire blight now that antibiotics cannot be used. It is widely used to clean equipment, in mushroom production, and to alternate with other materials for resistance management. No comments were put forward with new information that would contribute to the OFPA criteria review. The NOSB found the material to meet OFPA criteria and had no objection to continued listing. No significant new issues were raised by the public.

During the Spring 2019 NOSB meeting the Crops Committee received comments in favor of relisting hydrogen peroxide and no comments against relisting. Comments included the following:

- Hydrogen peroxide is an effective microbial pesticide used in the orchard setting for the sanitation of equipment such as picking bags and pruning shears. It is also used as an algicide and disinfectant, including for irrigation system cleaning.
- With the loss of antibiotics, hydrogen peroxide has become an extremely important tool in controlling fire blight in both organic apples and pears.

Subcommittee Vote:
Motion to remove hydrogen peroxide from §205.601(a) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Jesse Buie
Seconded by: Harriet Behar
Yes: 0 No: 8 Abstain: 0 Absent: 0 Recuse: 0

Soaps, ammonium

§205.601 Synthetic substances allowed for use in organic crop production.
Reference: 205.601(d) **As animal repellents—Soaps, ammonium—for use as a large animal repellant only, no contact with soil or edible portion of crop.**
Technical Report: 1996 TAP; 2019 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Ammonium soaps are used as animal repellents to protect organically produced crops from unwanted browsing, primarily from deer and rabbits. USDA organic regulations allow ammonium soaps as a "synthetic substance allowed for use in organic crop production" at 7 CFR 205.601.

Ammonium soaps are manufactured by hydrolysis of fats (triglycerides) with an alkaline source in a saponification process. In this process, the base reacts with the fatty ester to break the ester linkages, resulting in the formation of a salt with the cation of the base and the carboxylate anion that remains at the end of the hydrolysis. A wide range of fats may be used in the saponification process, including both plant and animal fats. Because of the relative abundance of fats and their low cost, most soaps are produced by the saponification of natural fats. Ammonium cations also exist in nature and play an important role in the metabolic pathways of a range of organisms , as well as being a key component of the nitrogen cycle. Soaps, however, do not naturally exist in nature but are manufactured.

Ammonium soaps are permitted by the Canadian General Standards Board Permitted Substances List - Ammonium soaps are listed in the CAN/CGSB-32.311-2015 - Organic production systems - permitted substances lists.

Studies conducted by the EPA estimate that ammonium soaps will undergo rapid degradation in the environment, primarily through microbial metabolism, yielding an environmental half-life of less than one day. Interesting to note that the toxicological profile of the substance differs based on the environment in which it is located. They are regarded as having low toxicity to terrestrial organisms,

with little impact to mammals and avian animals. The EPA has placed them in Toxicity Category IV, the lowest available classification. They are, however, moderately toxic in aquatic environments. Ammonium soaps have been classified as "highly toxic" to crustaceans by the EPA. Due to the potential toxicity to aquatic environments, ammonium soap repellent product labels stipulate "This product may be hazardous to aquatic invertebrates. Do not apply to water bodies such as ponds or creeks.

The EPA has given ammonium soaps the lowest possible toxicity classification (Toxicity Category IV). They have also concluded that the oral intake of dangerous levels of the substance is highly unlikely due to the recognizable and undesirable soap taste. Despite the low toxicity of ammonium soaps there are some health risks. They are primarily irritation-based. Occasional skin irritation upon prolonged exposure has been reported as potential problems with direct exposure in the eye.

There are some alternative methods that make the use of ammonium soaps unnecessary. They include population control of animals, alteration of habitat or physical barriers. As such, fencing is widely acknowledged as the most effective means of preventing crop damage from unintended browsing.

There are also natural (non-synthetic) substances which may be used in place of ammonium soaps. These all to have similar limitations to the soaps and include fear-based area repellents such as coyote urine, smell-based area repellents such as human hair and contact repellents that include capsaicin and black pepper oil.

There were approximately 10 comments all supporting the continued listing of ammonium soaps on the National List of Allowed and Prohibited Substances. No comments for removal were received.

Subcommittee Vote:
Motion to remove soaps, ammonium, from §205.601 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7CFR205.600(b): NA
Motion by: Rick Greenwood
Seconded by: Emily Oakley
Yes: 0 No: 7 Abstain: 0 Absent: 1 Recuse: 0

Oils, horticultural—§205.601(e)

§205.601 Synthetic substances allowed for use in organic crop production.
Reference: 205.601(e) As insecticides (including acaricides or mite control). **(7) Oils, horticultural—narrow range oils as dormant, suffocating, and summer oils.**
Technical Report: 1995 TAP; 2019 TR

Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation – deferred; 06/2006 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Horticultural oils have widespread use in organic fruit and vegetable production. They can be used in nearly every season and may be used alone or in mixes that include other nutrient or pest control products. Oils may be used for control of multiple plant diseases as well as acaricides, miticides, and

insecticides. According to the 2018 technical report (TR), oils have different modes of action on insects, mites and plant pathogens. They target multiple sites and not specific receptors and thus do not act like most synthetic insecticides. This action also helps to prevent resistance to their action. The multiple actions include smothering insect eggs by preventing atmospheric gas exchange, softening or disrupting insect cuticles, interfering with molting, as well as altering behaviors such as egg laying.

Horticultural oils may be called by many different names; however, the 2018 TR generally refers to them as petroleum-derived spray oils (PDSO's) or mineral oils. Their use has increased and has been refined over the last century. Recognition that different fractions of oils have higher efficacy for pest control and that the range of phytotoxic effects on the plant goes from none to high depending on the fraction used led to the selection of a narrow range of oils exhibiting the dual characteristics of being effective against pests and non-toxic to plants. They are often classified by boiling point, although modern terminology may refer to many other characteristics such as chain length and chemical structure (2018 TR).

Most PDSOs are produced from the extraction, distillation, and further refinement of petroleum. The 2018 TR describes in detail the potential processes by which crude petroleum may be transformed to a narrow range horticultural oil. In general, the crude petroleum may be converted chemically by either catalytic or thermal methods. Once the oils are converted to a certain fraction, additional chemical treatments are applied to the distillates to remove phytotoxic compounds, such as sulfur, while keeping compounds toxic to pests and diseases. Additionally, the 2018 TR states horticultural oils are often formulated with wetting agents or surfactants that allow them to be mixed and diluted with water. Most spray oils in the United States contain a non-ionic surfactant dissolved in the oil concentrate at a concentration of 0.35 percent for citrus use and 0.5 percent for deciduous use.

The exploration and extraction of petroleum has a number of environmental effects that include land use issues, spills, emissions, pipeline and infrastructure construction, among others. However, once the oil is refined and applied as a pest control material, the environmental impact of these oils decreases. The EPA exempts petroleum oils, or mineral oil, from the requirement of a tolerance when applied to growing crops [40 CFR 180.905]. The 2018 TR cites a number of studies that show that actual persistence in the field is highly variable and depends on many factors including temperature, precipitation, sunlight, how the oil is applied, and droplet size. Soil biota degrade these oils over time with the amount of time necessary for degradation dependent on many environmental factors. Various grasses and legumes may also be an effective means of removing petroleum hydrocarbons from the soil.

The effect of spray oils on non-target beneficial organisms varies based on the mobility of the organism, its stage of development, and its ability to reinvade after the oil application (2018 TR). The timing of the oil application may also alter the effects on beneficial organisms. For example, dormant applications of oil may be applied before beneficial organisms become active. Even where oil is applied repeatedly and in the non-dormant season, excellent biocontrol may still be achieved in organic systems. In general, non-dormant application rates are lower than dormant rates in order to prevent plant phytotoxicity. These lower rates may also limit the negative effects on biocontrol agents. Various studies have confirmed that the use of oils is compatible with integrated pest management systems (2018 TR).

Horticultural oils form the basis for many organic pest control systems. They may prevent the need for higher toxicity insecticides and keep pest populations below economic thresholds. They are widely used in organic tree fruits, traditionally in the dormant season, and more recently, throughout the growing season. They may be used alone or in combination with other materials - the use of oil in these combinations may help increase the activity of the other material through the "spreading" action of the oil in addition to the pest control effect of the oil itself.

Materials such as kaolin, botanical insecticides and plant-based oils may also be alternative to oils. Kaolin may be effective in certain cases but does not have the spectrum of activity that oils do. Botanical insecticides may disrupt biocontrol programs. Other plant-based oils may be alternatives to petroleum-based oils, however, they are not widely used and may not be widely available. The 2018 TR notes a number of alternatives and cites one study that showed that castor, cottonseed, and linseed oils had comparable or better activity than petroleum oils against scales, but the vegetable oils were also more phytotoxic to the plants. Some studies show that plant-based oils may be superior to PDSO's in pest controls, while others indicate lower efficacy.

Biopesticides may also have efficacy against target pests. These include a number of different fungi, bacteria and viruses such as codling moth granulosis virus, *Chromobacterium subtsuga,* and *Bacillus thuringiensis* (*Bt).* Oils may target a variety of pests while these various biopesticides either target a single pest species or a limited range of pest species. Additionally, these biocontrol agents may be applied at different timings than oils and may work better when used in conjunction with oils rather than as alternatives (2018 TR).

Previous sunset reviews included discussions around whether vegetable oils could serve as a natural replacement for the horticultural oils. During those discussions it was discovered that vegetable oils contained synthetic emulsifiers (mainly derived from a petroleum base), that if excluded, would prevent the oils from working properly. Both vegetable and horticultural oils require the addition of emulsifiers to allow them to stay in suspension when added to water for application to the targeted crop. It was also determined that the vegetable oils would not control certain pests adequately compared to the horticultural spray oils.

In past sunset reviews there has been overwhelming support for the continued listing of this material. Organic stakeholders provided a clear message to the full NOSB that this material remains a necessary tool in organic crop production and in fact has increased in use due to the recent growth of organic production. It was also pointed out during public comment that these oils are allowed for use world-wide by most organic certifying bodies for use in organic crop production.

Public comments during the Spring 2019 NOSB meeting echoed earlier comments. Many commenters noted the extensive benefits and need for these oils. One commenter noted that there is no known alternative for control of bugs in soybean fields. Another noted that while other types of oils are available, they will not work in place of horticultural spray oils. They continued by saying that other oils, such as fish or vegetable oils, can be phytotoxic to the foliage or fruit/crop itself and can have compatibility issues with other materials used in organic production. One comment was received asking for an annotation that would protect workers from inhalation hazards and nontarget arthropods from harm and if that annotation is not possible that the oils should be delisted. Other than that comment, there was broad support for the relisting of horticultural oils.

Subcommittee Vote:
Motion to remove horticultural oils from §205.601(e) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Steve Ela
Seconded by: Dave Mortenson
Yes: 0 No: 8 Abstain: Absent: 0 Recuse: 0

Oils, horticultural—§205.601(i)

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

Reference: 205.601(i) As plant disease control. **(7) Oils, horticultural—narrow range oils as dormant, suffocating, and summer oils.**
Technical Report: 1995 TAP; 2019 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation – deferred; 06/2006 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Horticultural oils have widespread use in organic fruit and vegetable production. They can be used in nearly every season and may be used alone or in mixes that include other nutrient or pest control products. Oils may be used for control of multiple plant diseases as well as acaricides, miticides, and insecticides. According to the 2018 technical report (TR), oils have different modes of action on insects, mites and plant pathogens. They target multiple sites and not specific receptors and thus do not act like most synthetic insecticides. This action also helps to prevent resistance to their action. The multiple actions include smothering insect eggs by preventing atmospheric gas exchange, softening or disrupting insect cuticles, interfering with molting, as well as altering behaviors such as egg laying.

Horticultural oils may be called by many different names; however, the 2018 TR generally refers to them as petroleum-derived spray oils (PDSO's) or mineral oils. Their use has increased and has been refined over the last century. Recognition that different fractions of oils have higher efficacy for pest control and that the range of phytotoxic effects on the plant goes from none to high depending on the fraction used led to the selection of a narrow range of oils exhibiting the dual characteristics of being effective against pests and non-toxic to plants. They are often classified by boiling point, although modern terminology may refer to many other characteristics such as chain length and chemical structure (2018 TR).

Most PDSOs are produced from the extraction, distillation, and further refinement of petroleum. The 2018 TR describes in detail the potential processes by which crude petroleum may be transformed to a narrow range horticultural oil. In general, the crude petroleum may be converted chemically by either catalytic or thermal methods. Once the oils are converted to a certain fraction, additional chemical treatments are applied to the distillates to remove phytotoxic compounds, such as sulfur, while keeping compounds toxic to pests and diseases. Additionally, the 2018 TR states horticultural oils are often formulated with wetting agents or surfactants that allow them to be mixed and diluted with water. Most spray oils in the United States contain a non-ionic surfactant dissolved in the oil concentrate at a concentration of 0.35 percent for citrus use and 0.5 percent for deciduous use.

The exploration and extraction of petroleum has a number of environmental effects that include land use issues, spills, emissions, pipeline and infrastructure construction, among others. However, once the oil is refined and applied as a pest control material, the environmental impact of these oils decreases. The EPA exempts petroleum oils, or mineral oil, from the requirement of a tolerance when applied to growing crops [40 CFR 180.905]. The 2018 TR cites a number of studies that show that actual persistence in the field is highly variable and depends on many factors including temperature, precipitation, sunlight, how the oil is applied, and droplet size. Soil biota degrade these oils over time

with the amount of time necessary for degradation dependent on many environmental factors. Various grasses and legumes may also be an effective means of removing petroleum hydrocarbons from the soil.

The effect of spray oils on non-target beneficial organisms varies based on the mobility of the organism, its stage of development, and its ability to reinvade after the oil application (2018 TR). The timing of the oil application may also alter the effects on beneficial organisms. For example, dormant applications of oil may be applied before beneficial organisms become active. Even where oil is applied repeatedly and in the non-dormant season, excellent biocontrol may still be achieved in organic systems. In general, non-dormant application rates are lower than dormant rates in order to prevent plant phytotoxicity. These lower rates may also limit the negative effects on biocontrol agents. Various studies have confirmed that the use of oils is compatible with integrated pest management systems (2018 TR).

Horticultural oils form the basis for many organic pest control systems. They may prevent the need for higher toxicity insecticides and keep pest populations below economic thresholds. They are widely used in organic tree fruits, traditionally in the dormant season, and more recently, throughout the growing season. They may be used alone or in combination with other materials - the use of oil in these combinations may help increase the activity of the other material through the "spreading" action of the oil in addition to the pest control effect of the oil itself.

Materials such as kaolin, botanical insecticides and plant-based oils may also be alternative to oils. Kaolin may be effective in certain cases but does not have the spectrum of activity that oils do. Botanical insecticides may disrupt biocontrol programs. Other plant-based oils may be alternatives to petroleum-based oils, however, they are not widely used and may not be widely available. The 2018 TR notes a number of alternatives and cites one study that showed that castor, cottonseed, and linseed oils had comparable or better activity than petroleum oils against scales, but the vegetable oils were also more phytotoxic to the plants. Some studies show that plant-based oils may be superior to PDSO's in pest controls, while others indicate lower efficacy.

Biopesticides may also have efficacy against target pests. These include a number of different fungi, bacteria and viruses such as codling moth granulosis virus, *Chromobacterium subtsuga,* and *Bacillus thuringiensis* (*Bt).* Oils may target a variety of pests while these various biopesticides either target a single pest species or a limited range of pest species. Additionally, these biocontrol agents may be applied at different timings than oils and may work better when used in conjunction with oils rather than as alternatives (2018 TR).

Previous sunset reviews included discussions around whether vegetable oils could serve as a natural replacement for the horticultural oils. During those discussions it was discovered that vegetable oils contained synthetic emulsifiers (mainly derived from a petroleum base), that if excluded, would prevent the oils from working properly. Both vegetable and horticultural oils require the addition of emulsifiers to allow them to stay in suspension when added to water for application to the targeted crop. It was also determined that the vegetable oils would not control certain pests adequately compared to the horticultural spray oils.

In past sunset reviews there has been overwhelming support for the continued listing of this material. Organic stakeholders provided a clear message to the full NOSB that this material remains a necessary tool in organic crop production and in fact has increased in use due to the recent growth of organic production. It was also pointed out during public comment that these oils are allowed for use world-wide by most organic certifying bodies for use in organic crop production.

Public comments during the Spring 2019 NOSB meeting echoed earlier comments. Many commenters noted the extensive benefits and need for these oils. One commenter noted that there is no known

alternative for control of bugs in soybean fields. Another noted that while other types of oils are available, they will not work in place of horticultural spray oils. They continued by saying that other oils, such as fish or vegetable oils, can be phytotoxic to the foliage or fruit/crop itself and can have compatibility issues with other materials used in organic production. One comment was received asking for an annotation that would protect workers from inhalation hazards and nontarget arthropods from harm and if that annotation is not possible that the oils should be delisted. Other than that comment, there was broad support for the relisting of horticultural oils.

Subcommittee Vote:
Motion to remove horticultural oils from §205.601(i) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Steve Ela
Seconded by: Harriet Behar
Yes: 0 No: 8 Abstain: 0 Absent: 0 Recuse: 0

Pheromones

§205.601 Synthetic substances allowed for use in organic crop production.
Reference: 205.601(f) As insect management. **Pheromones.**
Technical Report: 1995 TAP; 2012 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Pheromones are volatile chemicals produced in nature by a given species to communicate with other individuals of the same species to affect their behavior. Pheromones are produced naturally by many organisms and are synthetically produced for use in agriculture. Insect pheromones are generally comprised of very specific esters, that alone, or in combination, create a species-specific communication system. Pheromones may be released from various types of dispensers into the surrounding air. Inert ingredients may be used as part of the formulation process but generally do not contact crops since they are contained within the dispensers. Pheromones are considered generally non-toxic and have a low persistence in the environment.

Pheromones are used by organic (and many conventional) crop producers and are especially important for organic tree fruit production. Pheromones are used by growers in a variety of ways such as monitoring insect presence and population density, mass trapping, 'attract and kill' systems, and for use in mating disruption or confusion.

The use of pheromones to attract insects to traps has long been used as a means of monitoring populations, determining whether controls need to be applied, and infer the timing of controls applications. Varying types of dispensers are impregnated with the pheromone and then placed in some sort of monitoring trap. Trapping can field check insect development models as well as be used to determine when a threshold has been reached that might require further action by a farmer. Mass trapping using pheromones as an attractant can also be used to help in reducing the overall numbers of

an insect pest. A variant of mass trapping is the attract and kill system. Rather than trapping the insect, these systems use the synthetic pheromone as an attractant to get the insect to come into contact with an insecticide.

Mating disruption/confusion uses a synthetic pheromone to saturate a targeted area. The male of the targeted species is unable to differentiate between the pheromone released by the female and that applied by dispensers. This can cause the male to become confused and disoriented and thus unable to locate the species female for mating. Normally in organic crop production these pheromones are dispersed for use via a passive or active pheromone dispenser (including traps and lures). Some forms of passive dispensers are pheromone-impregnated polymer spirals, ropes, coils, twist ties, or tubes. The use of wires, clips, or circular tubes allows these pheromone dispensers to be placed directly in the intended area of usage. Active dispensers, commonly called puffers, distribute a larger amount of pheromone on a programmed schedule. They are usually used at lower densities than passive dispensers and can be programmed to only release pheromone when the target insect might be active.

As the 2012 technical report notes, while pheromones are produced naturally by insects and other organisms, they are difficult to isolate in sufficient quantities for commercial production. Thus, most commercially used pheromones are synthetically produced and attempt to replicate the natural pheromone. The synthesis of the pheromones is complex and normally involves a number of conversion steps.

The TR further cites various studies showing that insect pheromones are generally comprised of very specific esters. These esters vary in carbon chain length. The primary components of sex pheromones (esters) are the most critical part of the chemical complex, but are reliant on the presence or absence of secondary components, which greatly affect an insect's response sequence.

During past reviews there has been concern raised over the inerts used in pheromones because they do include known irritants, sensitizers, and allergens. The 2012 TR mentions that some compounds could potentially be linked to asthma, cancer, or endocrine disruption. However, under the current use of pheromones it is not believed that they would release enough volume to leave any kind of residue on the agricultural crops being treated. It also states that dissipation takes place via volatilization and degradation, rapidly into the environment.

In past reviews, some concerns were raised around the use of "encapsulated pheromones" (those concerns mentioned harm to honey bees and concerns over aerial applications). These involve small pheromone containing capsules that might be applied in water or by air and could have direct crop contact. However, use of these forms of pheromones has not generally reached commercial application.

The 2012 TR notes that based on low observed toxicity in animal testing, and expected low exposure to humans, there is no risk to human health expected from the use of pheromones. EPA data shows that no human health concerns had been reported in the ten years prior to the TR.

Pheromones continue to be an integral and highly used component of organic agriculture. Their use in trapping and monitoring provides a basis for integrated pest management and helps to ensure that other pest control materials are only applied where and when needed. For certain pests in organic systems their use in mating disruption may be the only viable control option and in other systems their use precludes the need for more disruptive control options.

Public comments from previous sunset reviews have been strongly supportive of the relisting of pheromones. Other commenters have noted that their delisting would lead to the loss of many acres of organic tree fruits. Comments noted that the use of pheromones in organic crop production has continued to increase, as various formulations have been developed for specific target species.

Public comments received during the Spring 2019 NOSB meeting were in favor of relisting pheromones. There were many comments noting their widespread use, insect specificity, use in monitoring populations, and benign nature. Several commenters did support relisting with the caveat that the pheromones are identical to or substantially similar to natural pheromones, in passive dispensers, without added toxicants and with only approved inert ingredients. There is currently no annotation for pheromones, but comments received indicate that their use generally fits this request. Microencapsulated pheromones which might be sprayed and have direct fruit contact have not become commercially available. Active dispensers (also known as puffers) are in current use, but act in similar fashion to the passive dispensers in terms of fruit contact or type of pheromone used.

Subcommittee Vote:
Motion to remove pheromones from §205.601(f) of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Steve Ela
Seconded by: Dave Mortenson
Yes: 0 No: 8 Abstain: 0 Absent: 0 Recuse: 0

Ferric phosphate

§205.601 Synthetic substances allowed for use in organic crop production.
Reference: §205.601(h) As slug or snail bait. **Ferric phosphate (CAS #s 10045-86-0).**
Technical Report: 2004 TAP, 2010 TR, Supplemental TR 2012
Petition(s): 05/2003 , Supplemental Information 02/2005, Petition to remove: 07/2009
Past NOSB Actions: 03/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2012 recommendation on petition to remove from national list; XX/2016 sunset recommendation
Recent Regulatory Background: Added to National List 09/11/06 71 FR 53299; Renewed 08/03/2011 76 FR 46595; Renewed 09/12/16 81 FR 8821
Sunset Date: 9/12/2021

Subcommittee Review:

Use
Ferric phosphate is used as a molluscicide for slug and snail suppression. Ferric phosphate accumulates in the calcium spherules of slug and snail digestive glands, thereby interfering with calcium metabolism, and in turn, disrupting feeding and mucus production. After ingesting ferric phosphate slugs and snails stop feeding and death due to starvation will occur three to six days later. Ferric phosphate occurs naturally in soil but at considerably lower concentrations than that present in the formulated, baited product.

Manufacture
Ferric phosphate occurs naturally in the soil; however, to achieve concentrations toxic to molluscs ferric phosphate must be supplemented through applications, most often with ferric phosphate formulated with a chelating agent. To produce ferric phosphate synthetically, an aqueous iron sulfate solution is mixed with an aqueous disodium phosphate solution in a stainless steel boiler. The mixture is heated to 50-70 °C in order to precipitate ferric phosphate. The precipitate is filtered from the solution, washed with distilled

water, and dried with hot air. The baited pellets contain approximately 1% by mass of ferric phosphate with the remainder of the pellet comprised of a chelating agent and carbohydrate inerts. The EPA describes ferric phosphate as ubiquitous in nature. It is a solid. It is not volatile and does not readily dissolve in water, which minimizes its dispersal beyond where it is applied.

International acceptance by other international certifying bodies
The European Union, the Canadian General Standards Board, The International Federation of Organic Agriculture Movement and the Japanese Organic Standard for Organic Plants all list ferric phosphate for use as a molluscicide in the protection of plants.

Environmental/Health Issues
The EPA describes ferric phosphate as ubiquitous in nature. It is a solid. It is not volatile and does not readily dissolve in water, which minimizes its dispersal beyond where it is applied. Small concentrations of ferric phosphate are made available in soil solution when it is solubilized by commonly occurring soil microorganisms such as *Penicillium radicum*.

Ferric phosphate by itself appears to be less toxic to a range of soil borne organisms (including slugs and snails) than when formulated with a chelating agent (EDTA or EDDS for example). The chelating agent enhances iron uptake by organisms in general. A number of published studies document that when formulated with a chelating agent, the efficacy for control of slugs and snails increases significantly. However, the increased efficacy also means its activity on non-target organisms like earthworms, domestic animals and humans also increases. The LD50 for ferric phosphate alone is greater than 10,000 mg kg while it drops to 80 mg kg when it is formulated with the chelating agents EDTA or EDDS (Ethylene diamine tetracetic acid – EDTA and Ethylene diamine disuccinic acid (EDDS).

Discussion
The 2012 technical review addressed a series of concerns about the biological activity of ferric phosphate both in terms of its effectiveness in suppressing slugs and snails as well as its non-target effects on the ecology and abundance of soil dwelling organisms. Because the commercial formulations of ferric phosphate always included ferric phosphate itself and a chelating agent the NOSB was concerned about the effects of the formulated products used by farmers. Specifically, four questions regarding the efficacy of ferric phosphate alone and the synergizing effects of chelating agents (EDTA and EDDS) concluding without the chelating agent, ferric phosphate did not provide sufficient or consistent suppression of slugs and snails. In fact the efficacy was so low that it is hard to see why it would be used for slug and snail suppression without the chelating agent. The TR then asked, what risk does the use of ferric phosphate and its associated chelating agents pose to soil organisms and water quality. Here the existing data are scant. What has been researched (three studies published between 2006 and 2009) indicate a range of responses from non-significant to highly significant adverse effects of chelated ferric phosphate on a range of non-target organisms. A second technical review was sought and received to underpin this 2018 Sunset review. In that technical review, the Crops Subcommittee asked if additional research had been conducted addressing the following questions: 1) What new findings have been reported since 2009 that would inform our understanding of the influence of ferric phosphate alone and ferric phosphate in combination with commonly used chelating agents on the soil micro and macro fauna with particular attention to earthworm populations?; 2) To what extent is ferric phosphate used for slug and snail management in organic production?; 3) How are the products formulated that are detailed in (2) above?; 4) Since the July 26, 2012 technical review, have additional studies been conducted documenting the effects of fieldworker exposure to ferric phosphate bait handling including inhalation of dust resulting from field applications. The same questions were posed to the public with a particular focus on the second question, how widely is ferric phosphate used?

From the 2018 technical review we learned that little additional research has been conducted since the 2012 technical review quantifying the soil community response to ferric phosphate. The technical review did confirm that commercial formulations routinely include ferric phosphate and a chelating agent. We received considerable public comment on ferric phosphate learning that it is seen as an integral part of vegetable and fruit pest management and is widely used for slug and snail management in organic systems. We heard from some public comments that while a systems-approach is taken to address the slug and snail problem, attempts by organic farmers to increase reliance on cover-cropping and decreased tillage can lead to increased slug and snail abundance. The Subcommittee recognizes the efficacy of ferric phosphate is inextricably linked with the formulation; when formulated with a chelating agent, ferric phosphate effectively suppresses slugs and snails, unfortunately, the non-target effects on other soil organisms increase as well.

Vote in Subcommittee:
Motion to remove ferric phosphate from the National List at §205.605 based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Dave Mortensen
Seconded by: Harriet Behar
Yes: 0 No: 5 Abstain: 3 Absent: 0 Recuse: 0

Potassium bicarbonate

§205.601 Synthetic substances allowed for use in organic crop production.
Reference: 205.601(i) As plant disease control. **(9) Potassium bicarbonate.**
Technical Report: 1999 TAP; 2015 TR
Petition(s): N/A
Past NOSB Actions: 10/1999 NOSB meeting minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Potassium bicarbonate is a plant disease control material. It is used by organic crop producers to control *alternaria* in cucurbits and cole crops; anthracnose in cucurbits, blueberries, grapes, spinach, and strawberries; black dot root rot and early blight in potatoes; sooty blotch and powdery mildew in apples; downy mildew in cucurbits, cole crops, grapes, and lettuce; gray mold (*Botrytis cinerea*) in beans, lettuce, and strawberries. These are just a few of the crops and specific diseases it helps to control. It is best suited for many of the powdery mildew diseases (TR lines 80-1) and early blight (1999 TAP). It has proven to be an important disease control aid in organic crop production.

Potassium bicarbonate is produced by carbonating potassium hydroxide to K_2CO_3, which is then carbonated to $KHCO_3$. Carbonation is accomplished by injecting carbon dioxide gas into an aqueous solution of potassium hydroxide. (1999 TAP)

The 1999 TAP review states that the decomposition products are potassium carbonate, water, and carbon dioxide, all of which readily dissipate in the environment. It found this material to be compatible with

organic crop production, safe, and more environmentally friendly than many of the synthetic alternatives. Potassium bicarbonate is a mild respiratory and eye irritant.

During the 2015 sunset review, a limited scope Technical Report (TR) was requested. The TR provided possible alternative materials or practices that might replace this material. *Bacillus amyliquifaciens* strain D747, *Bacillus subtilis, Bacillus pumilis,* gibberellic acid, and *Streptomyces griseovirdis and lydicus, Gliocladium catenulatum,* and extracts of giant knotweed are all listed as natural alternatives for numerous plant diseases across many crops. Bordeaux mixture, kaolin, lime sulfur and sulfur, hydrogen dioxide, and neem extracts are offered as alternatives for both treatment and disease prevention across myriad crops and diseases, in addition to a variety of cultural and mechanical practices. Further clarification was sought in 2015 from stakeholders using this material to help explain under what conditions or scenarios the alternatives might be applied. Organic producers responded that while alternative materials and/or practices exist, potassium bicarbonate remains necessary for their particular crop production practices. Potassium bicarbonate is an important tool in powdery mildew resistance management. In addition to its efficacy on powdery mildew, stakeholders said its unique mode of action helps control other diseases under certain conditions or scenarios better than the alternative materials or practices.

There was continued support for the continued listing of this material in 2015. One commenter was concerned that this material does not fit into any of the categories under §6517(c)(1)(B)(i) of OFPA. Others noted its extensive listing in Organic Systems Plans. Based on extensive public comment, the NOSB continued to find potassium bicarbonate compliant with OFPA criteria and did not recommend removal from the National List.

As part of the Spring 2019 public meeting, the Crops Subcommittee asked about efficacy of alternatives and the continued need for potassium bicarbonate. Written and oral testimony expressed continued support for this material, stating that it is used to control a number of diseases across a wide range of crops, including strawberries, cucurbits, tomatoes, and fruit trees. It is used in field, high tunnel, and greenhouse applications, and it is employed by some as part of a material rotation. One commenter expressed that it does not fit any OFPA categories of allowable synthetics.

Subcommittee vote
Motion to remove potassium bicarbonate from §205.601 (i) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: NA
Motion by: Emily Oakley
Seconded by: Dave Mortenson
Yes: 0 No: 7 Abstain: 0 Absent: 1 Recuse: 0

Magnesium Sulfate

§205.601 Synthetic substances allowed for use in organic crop production.
Reference: 205.601(j) As a plant or soil amendment. **(6) Magnesium sulfate—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 sunset recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Magnesium sulfate is used to correct for magnesium soil deficiencies and helps to improve the uptake of nitrogen and phosphorus by crops, helps seeds germinate, increases chlorophyll production, aids in the production of flowering, and is vital in maintaining crop growth and yield.

Magnesium sulfate can be obtained from naturally occurring sources (kieserite or epsomite open-pit mines) or can be manufactured by a chemical process. Mineral forms of magnesium sulfate are dehydrated, purified, and reacted with sulfuric acid to create the synthetic version of magnesium sulfate. Historically, there have been no commercially available products containing mined, raw mineral magnesium sulfate in bulk quantities suitable for agriculture. For this reason, the production of synthetic magnesium sulfate has been necessary.

As stated in the 2011 Technical Report (TR) (lines 320-23): "If applied as a foliar feed in recommended doses (assuming also that a magnesium deficiency has been documented), magnesium sulfate would not be expected to produce toxic effects. However, if too much magnesium sulfate is added to the soil, or if the substance is added when a magnesium deficiency has not been determined, the uptake of other important nutrients will be affected." The TR goes on to state that when used properly, it is unlikely to cause environmental or human health harm.

During the 2015 review, the Crops Subcommittee asked stakeholders if non-synthetic magnesium sulfate is available in the marketplace. Public comment indicated that the only form of non-synthetic magnesium sulfate that has been reviewed is potassium magnesium sulfate, or langbeinite; however, this material is not a reliable alternative because it is only available in limited quantities, and it is impossible to determine upon purchase whether langbeinite is synthetic or non-synthetic. There was substantial public comment in support of relisting magnesium sulfate. It is actively used by stakeholders and continues to be considered necessary to the production of fruit and vegetables. One commenter opposed the relisting, stating that nonsynthetic magnesium sulfate is available as langbeinite and dolomite; however, langbeinite is constrained by supply and classification issues. While dolomite can be used to treat a magnesium deficiency, the TR states that it is not as effective as magnesium sulfate and was not referenced by other commenters as a viable alternative. No significant new issues were raised, and the NOSB continued to find magnesium sulfate compliant with OFPA criteria and did not recommend removal from the National List.

As part of the Spring 2019 public meeting, the Crops Subcommittee asked if non-synthetic magnesium sulfate is available and about growers' experiences using non-synthetic dolomite. Written and oral testimony expressed continued support for this material, stating that it is important in high tunnels and greenhouses as well as fruit tree production. Some growers commented that dolomite is not a suitable substitute in all cases as it cannot be used in high pH soils nor as a foliar application. It was also noted that there are few non-synthetic products on the market. Magnesium sulfate is also used in high pH soils when sulfur is needed but growers do not want to increase the pH. It is used alone and in blended products. Another commenter noted that use of magnesium sulfate should not take the place of soil building practices.

Subcommittee Vote:
Motion to remove magnesium sulfate from §205.601 (j) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: NA
Motion by: Emily Oakley
Seconded by: Asa Bradman
Yes: 0 No: 7 Abstain: 0 Absent: 1 Recuse: 0

Hydrogen chloride

§205.601 Synthetic substances allowed for use in organic crop production.
Reference: §205.601(n) Seed preparations. **Hydrogen chloride (CAS # 7647-01-0)—for delinting cotton seed for planting.**
Technical Report: 2003 TAP, 2014 Limited Scope TR
Petition(s): Hydrogen Chloride 10/30/02
Past NOSB Actions: 05/2004 NOSB recommendation for National List; 11/2009 sunset recommendation; 4/2015 recommendation
Recent Regulatory Background:
Added to National List 09/11/06 (71 FR 53299); Renewed 08/03/2011 (76 FR 46595)
Renewed 09/12/16 (81 FR 8821)
Sunset Date: 9/12/2021

Subcommittee Review:

Use
Hydrogen chloride (2HCl) (CAS# 7647-01-0) forms a strong acid used for delinting cotton seed for planting. Hydrogen chloride is a liquid anhydrous hydrogen gas that is vaporized and then sprayed on cotton seeds after the ginning process. The gas mixes with the moisture in the seeds, resulting in acidic properties under which the lint on the seeds becomes weakened and is buffed off before planting. Because many fibers are attached to the seeds even after ginning, delinting improves handling (i.e., flowability) for subsequent planting by mechanized equipment.

Manufacture
There are several methods used to produce hydrogen chloride. It can be synthesized directly or as a byproduct from manufacturing other chlorinated or fluorinated compounds.

International acceptance
Canadian General Standards Board Permitted Substances: Not listed.
CODEX Alimentarius: Not Listed
European Economic Community (EEC) and India (NPOP): Hydrogen chloride not listed. Hydrochloric acid is listed for gelatin production and cheese processing (EEC)
Japan Agricultural Standard (JAS) for Organic Production: Not listed
International Federation of Organic Agriculture Movements (IFOAM): Not listed.

Ancillary substances
None

Impacts on health and the environment

Hydrogen chloride gas and subsequently produced hydrochloric acid are strongly corrosive materials and can cause skin burns, severe respiratory damage, circulatory system failure and death. Spills during manufacture or handling can injure workers or locally damage the environment.

Discussion

Hydrogen chloride for delinting cottonseed was recommended by the NOSB to be added to the National List in April 2004, and has been recommended each time it has subsequently been reviewed. However, hydrogen chloride, and the subsequently formed hydrochloric acid, are very corrosive materials and pose potential environmental and health threats if not handled properly. The 2014 limited scope TR identified several alternative, nonsynthetic delinting processes under development that were not commercially available at that time. The decision to relist was based on the lack of viable alternatives and the hope "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." The 2014 limited TR included information (see Table 1 below) describing several alternatives to hydrogen chloride, and also referenced a mechanical cottonseed delinter under review by the USDA Agricultural Research Service. In follow-up to public comments from the Spring 2019 meeting, the Crops Subcommittee reached out to the Texas Organic Cotton Marketing Cooperative and Dr. Jane Dever, a professor and cotton breeder at Texas A&M for additional clarification on mechanical seed cleaning methods, obstacles to adopting non-chemical methods, and challenges addressing seed dormancy.

Table 1 Methods for preparing cottonseed for planting

Method	Applications	Approved for USDA Organic?
No treatment	Seed is planted manually. Not suitable for large farms	Yes
Concentrated Sulfuric Acid Delinting	Used commercially to permit metered planting	No
Dilute Sulfuric Acid Delinting	Used commercially to permit metered planting	No
Acid-Gas Delinting using Hydrogen Chloride	Used commercially to permit metered planting	Yes, allowed synthetic substance.
Power Roller Gin Relinting	Used in conjunction with coating	Yes
New Sawless Mechanical Delinter	No chemical treatment or coating is necessary. Not currently commercialized.	Yes
Baobab Tree Extract Delinting	Small scale, localized use.	Yes, nonsynthetic
Mud and Dung Coating	Small scale, localized use.	Yes, nonsynthetic
Starch Based Coating	In development for large scale use.	Only if starch is nonsynthetic. Dextrin was previously petitioned as a synthetic seed coating and was not recommended by NOSB.
Clay Based Coating	In development for large scale use.	Yes, if nonsynthetic
Chitosan	In use for rice, other seeds to follow	No.

Overall, comments and discussion reviewed for the Spring 2019 NOSB meeting and subsequent information

confirms that circumstances since 2014 are unchanged. Although progress has been made, viable alternatives to hydrogen chloride are not yet available. A key challenge is the small size of the U.S organic production market which does not economically incentivize companies to develop organic-specific technologies. Spring 2019 public comments were universally supportive of relisting hydrogen chloride as essential, and asserted that failure to do so would irreparably harm the U.S. organic cotton industry. Allowing the limited use of hydrogen chloride for seed preparation accrues economic and environmental benefits by supporting domestic organic cotton production and avoiding associated impacts of heavy pesticide use on conventional cotton. The need for additional specialized research to support alternatives to hydrogen chloride, a caustic and potentially harmful material, were emphasized, and is supported by the Crops Subcommittee.

Subcommittee Vote:
Motion to remove hydrogen chloride for delinting cotton seed for planting based on the following criteria in the Organic Foods Production Act (OFPA) and/or §205.601(n) seed preparations if applicable: NA
Motion by: Steve Ela
Seconded by: Harriet Behar
Yes: 0 No: 7 Abstain: 0 Absent: 1 Recuse: 0

Ash from manure burning

§205.602 Nonsynthetic substances prohibited for use in organic crop production.
Reference: 205.602(a) **Ash from manure burning.**
Technical Report: none
Petition(s): 2014
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation, 10/2015 sunset recommendation; 4/2016 NOSB formal recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Use: In some areas of nonorganic agriculture, the burning of manure to create an ash is used to lessen the volume of material (manure) transported to a field for fertilizer and to recover some of the nutrients in a more concentrated form (phosphorus, calcium, potassium and magnesium). The ash can then be used as a fertility input that is high in these nutrients. Large scale biochar manufacturing facilities claim that CAFOs can benefit from this manufacturing process, to lessen the impact of the volume of manure they need to dispose of from their facilities. This ash from manure has also been touted as a feed ingredient for livestock. The NOP organic standards do not allow re-feeding of manure to organic livestock.

Manufacture: Manure can be thermally decomposed through combustion to produce this ash.

International: Canadian standards do not allow ash from manure burning to be used on organic crops. The EU does not allow manure from confined animal operations to be used on organic crops.

Summary of Public Comment:
The vast majority of public comment addressing this material agreed with a continued listing as a prohibited material. However, one commenter discussed the benefits of controlled pyrolysis burning to create a manure-based biochar as being a good way to avoid the negative effects of nutrient leaching and other issues dealing with large volumes of raw manure. This commenter discussed the special property of heavy metal soil remediation in contaminated soils of manure-based biochars, over plant-based biochars. This was the only comment that answered the Subcommittee's question in our first review:

"*Does ash from manure burning supply nutrients or other benefits that cannot be obtained from any other material*?"

Discussion:
In April 2016, the NOSB responded to a petition to allow ash from manure burning with the following annotation: "except where the combustion reaction does not involve the use of synthetic additives and is controlled to separate and preserve nutrients". The petitioner stated they source manure from Concentrated Animal Feeding Operations (CAFOs) and use a staged thermochemical reactor to extract minerals from their poultry manure source. The NOSB stated the following to support their recommendation to keep this material, as listed, as a prohibited nonsynthetic:

"*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 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)"*

The USDA organic regulations require "soil-building" as a basic foundational principle, to improve soil tilth, water retention, nutrients and carbon sequestration. *"§205.203 (c) The producer must manage plant and animal materials to maintain or improve soil organic matter content*…."

Soil microbiological life increases when provided with carbon-based sources containing a variety of nutrients, and extraction of nutrients while destroying others (such as nitrogen) does not meet either the letter, nor spirit of the USDA organic law or regulations.

The current crop subcommittee agrees with the previous NOSB recommendation, and prefers manure retain its full carbon and nutrient content, when used as a fertility input on organic land.

Subcommittee Vote:
Motion to remove ash from manure burning from §205.602 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Harriet Behar
Seconded by: Jesse Buie
Yes: 0 No: 8 Abstain: 0 Absent: 0 Recuse: 0

Sodium fluoaluminate (mined)

§205.602 Nonsynthetic substances prohibited for use in organic crop production.
Reference: 205.602(g) **Sodium fluoaluminate (mined).**
Technical Report: none
Petition(s): N/A
Past NOSB Actions: 05/1996 NOSB meeting minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Sodium fluoaluminate (Na_3AlF_6)—also known as "sodium fluoroaluminate," "aluminum sodium fluoride," "trisodium hexafluoroaluminate," and "cryolite"—is a colorless to white halide mineral. It occurs in a large deposit at Ivigtut, Greenland, and in small amounts in Spain, Colorado, U.S., and elsewhere. It is used as a solvent for bauxite in the electrolytic production of aluminum and has various other metallurgical applications, and it is used in the glass and enamel industries, in bonded abrasives as a filler, and in the manufacture of insecticides (see www.britannica.com/science/cryolite for information on cryolite). Sodium fluoaluminate is also produced synthetically.

According to an EPA memorandum dated March 16, 2011, on the subject of "Cryolite. Human Health Assessment Scoping Document in Support of Registration Review" (link to document available via https://fluoridealert.org/researchers/pesticide/cryolite/):

> Cryolite [sodium aluminofluoride or sodium aluminum fluoride or sodium hexafluoroaluminate] is an insecticide used to control a variety of pests including various weevils, leaf rollers, various moth and worm species, and grape skeletonizers. Cryolite can be used on a wide array of agricultural crops including grapes (wine, table, raisin), cole crops, citrus, berries, tomatoes, cucumber, lettuce, and many types of ornamentals. Formulations include dusts, wettable powders, water dispersible granules, and baits/solids. Some formulations can contain as much as 96 percent active ingredient by weight. A recent evaluation of cryolite use indicates almost 2 million pounds per year are applied on about 300,000 acres, most of which are on grapes (92% of total pounds applied and 96% of treated acres) (Prieto, 2010). Use in California accounts for the vast majority of cryolite use (97%). In agriculture, groundboom, airblast, and aerial applications are typical but applications as a pure dust can also occur which may dictate other specialized forms of equipment being used. Applications to ornamentals may also be made using handheld equipment such as low and high pressure handgun sprayers and backpack sprayers. There are no cryolite containing products that appear to be marketed for sale to homeowners nor are there products which appear to be labeled for use by professionals in the residential marketplace (i.e., outdoors or indoors). Maximum application rates for most agricultural crops are in the 5 to 16 pounds product per acre range while some uses, especially on ornamentals can be higher (i.e., up to 30 lb/A using a 96% formulation).

The potential toxicity of sodium fluoaluminate/cryolite is due to the release of fluoride into the environment due to the dissociation of cryolite into fluoride. The EPA memorandum cited above references

a number of animal toxicological studies on this substance; other studies related generally to fluoride toxicity are also referenced, since fluoride enters the environment in multiple ways—including fluoridated water—and therefore can have a cumulative adverse impact on health.

There were no references to either sodium fluoaluminate or cryolite in the Canadian and European organic regulation websites.

Public Comment from the Spring 2019 NOSB Meeting
There were only a few written comments received regarding sodium fluoaluminate prior to the Spring 2019 NOSB meeting. All supported continued relisting of this substance as prohibited.

Conclusion
Given the toxicity associated with fluoride pollution in the environment and the multiple sources of such pollution, continued prohibition of this substance in organic production seems prudent.

Additional information requested by Subcommittee
Are there any reasons why the long-standing prohibition on using sodium fluoaluminate in organic production should be reconsidered by the NOSB?

Subcommittee Vote:
Motion to remove sodium fluoaluminate (mined) from § 205.602 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Dan Seitz
Seconded by: Jessie Buie
Yes: 0 No: 8 Abstain: 0 Absent: 0 Recuse: 0

National Organic Standards Board
Crops Subcommittee Petitioned Material Discussion Document
Paper (Plant Pots and Other Crop Production Aids)
August 15, 2019

Summary of Petition and Petition Addendum for Paper (Plant Pots and Containers):

The NOSB received a petition in August 2018 for the addition of paper planting pots to the National List: **§205.601(o) As production aids. Plant pot or growing container—hemp or other paper, without glossy or colored inks.**

This material has not been petitioned for inclusion on the National List in the past; however, paper chain pots have been historically allowed for the past 12 years by some organic certification agencies under the allowance for "Newspaper or Other Recycled Paper" as a mulch or compost feedstock.

In February 2018, the NOP notified all certifiers that paper chain pots are not allowed in organic systems; however, because some certifiers had previously approved their use, NOP allowed a phase-out period until the end of the 2018 crop season. The NOP's decision on this material was based primarily on the fact that paper (a synthetic substance) is not included on the National List for uses other than as mulch and as compost feedstock. The paper chain pots also contain other synthetic substances, such as adhesives. At the October 2018 and April 2019 NOSB meetings, there were numerous oral and written public comments requesting a longer time period for allowing these paper pots while the NOSB reviewed the petition. The NOSB also formally requested this extension of the NOP in November 2018, the NOP agreed to allow the use of paper pots in organic agriculture in late fall 2018, with no time restriction, in order to give the NOSB time to review this material.

Paper pots are used by small and mid-scale farming operations to efficiently transplant vegetable seedlings. More information on this transplanting method can be found on these websites: http://paper-pot.com/ and http://www.smallfarmworks.com/. The transplanting equipment and paper pot chains are imported from a manufacturer in Japan. According to the petition, the Nitten paper chain pot system uses paper produced from a non-bleached Kraft pulp, and adhesives. There have been synthetic polymers (also called "synthetic fibers" in this document) in small quantities in the paper pots, but experiments are taking place to determine if these can be replaced by a natural hemp fiber. The petitioner and public comment at the Spring and Fall 2018 NOSB meetings stated this system is unique and essential for growers. The alternative would be the much slower and more costly method of hand planting individual seedlings. The system is used for closely spaced crops such as onions, beets, baby salad, etc. The petition states that similar to newspaper, these pots decompose readily in the soil.

In addition to the Nitten petitioner, there are numerous other paper pot systems, both to be transplanted as single plants and in chains of pots. These other paper pot systems have various proportions of synthetic polymer fibers as well as other ingredients, such as cow manure. The subcommittee seeks to address all these products in our recommendation.

The petition states that in addition to information on paper, the 2017 Technical Report (TR) on newspaper and other recycled paper addresses the presence of adhesives in recycled paper as well. The three adhesives in the Nitten paper chain pots are vinyl-acetate resin (water soluble and stated to be leached from the pots before transplanting), ethylene-vinyl-acetate resin, and acrylic acid ester copolymer.

The crops subcommittee has seen paper pots, used as a crop production aid, as another use of paper beyond compost feedstocks and mulch, which are allowed under the NOP regulation; however, in order to conduct this review, the crops subcommittee requested a July 2019 Technical Report on Paper Pots and Containers to determine the extent of synthetic adhesives, synthetic polymer fibers, and other additives in paper pots and to determine whether or not they are substantively different than those found in paper already allowed as mulch and compost feedstocks (§§ 205.601(b) and 205.601(c)). Pots, compost, and mulch all degrade into the soil, and the crops subcommittee believes if the fibers and additives are allowed in the other listings for paper, then their use in pots should be allowed as well. However, since the subcommittee is proposing allowing the use of virgin paper, the subcommittee wants to make sure that the annotation does not allow for that virgin paper to include any amount or type of synthetic polymer and that those synthetic polymers used in the virgin paper are biobased and biodegrade in the soil.

The Technical Review clarified that the additives and synthetic fibers found in a variety of paper pots are also found in newspaper and other recycled paper currently allowed for compost feedstock and mulch. Other possible additives and synthetic fibers for paper pots that were not mentioned in the petition are described in the TR.

Summary of Public Comment:

Many users of the paper chain pot system provided written and verbal comment to the NOSB at the fall 2018 and spring 2019 meetings. They spoke in favor of its use due to its efficiency in transplanting, particularly in smaller scale production systems. Some certifiers spoke in favor of this material and noted that if the paper was torn off the pot before transplanting, it would then be allowed as a mulch or as a compost feedstock under the current regulation. Certifiers who had not previously allowed the use of these paper pots still supported the extended allowance for use while the NOSB performed its review.

There is more than one supplier of paper pots beyond the Nitten supplier noted in the petition. Approval of this material will likely lead to other manufacturers competing for their share of this market. Synthetic paper pots can be made from natural fiber feedstock or from a mixture of natural fiber feedstock and synthetic polymers. The pots with synthetic polymers are more typically used in the nursery trade where perennial plants may be in the pots for 9-12 months before transplanting into the field. Natural fiber pots are, at times, used in transplanting annual vegetable and floriculture seedlings, depending on the time frame between planting into the pot and planting out in the field and whether the pots need extra strength for a “chain of pots” planting system. All of the paper pots contain some type of synthetic adhesive, but these same adhesives are also found in the recycled paper already allowed in organic agriculture.

Numerous commenters mentioned that all uses of paper as a production aid should be included when the NOSB does its review for paper pots. Cloches or hot caps, seed tape, and cutworm prevention collars are other examples of production aids made from paper and typical paper adhesives that would decompose in the soil.

Specific Uses of the Substance:

Paper-chain pots are either single or in chains to allow for “mechanical” transplanting. The paper pots decompose in the soil and lessen transplant shock since the seedling root system is less disturbed, and the paper pots are part of a greenhouse-to-field growing system that requires considerably less labor

than hand transplanting. Use of paper pots may significantly reduce reliance on plastics. Growers can also use soil blocks, which are compressed soil without any container, to grow transplants.

Other paper crop production aids include: cloches, a temporary covering used to protect newly transplanted plants, seed tape on which individual seed is spaced correctly on a paper tape which lessens the need for thinning, and collars to prevent cutworm damage to plants at the soil line. There could be other uses of paper currently used as crop production aids, or there may be other uses developed over time.

Approved Legal Uses of the Substance:

Newspaper and recycled paper are allowed under the organic regulations in these two references:

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.

There have been two technical reports (TRs) on Newspaper and Other Recycled Paper in 2006 and 2017, which can be found here: https://www.ams.usda.gov/rules-regulations/organic/national-list/n.

NOP guidance 5034-1 "Materials for Organic Crop Production" from December 2016 excludes virgin paper from the "newspaper or other recycled paper" allowance for mulch or compost feed stocks. The guidance states: *"Includes newspaper and other recycled paper such as cardboard, without glossy or colored inks. Does not include paper that is not recycled (i.e., virgin paper)."*

The July 2019 Technical Report of Paper Pots and Containers, which detailed the specific possible synthetic and natural fibers as well as synthetic adhesives found in paper pots currently commercially available, provided more clarity about manufacture and use of paper pots for the NOSB.

Manufacture:

Paper can be made from various plant sources including wood, trees, straw, hemp, bamboo, reeds, kenaf, sisal, jute, sugarcane bagasse, sunflower stalks, and as recycled sources of pulp. Cellulose sources are typically mechanically ground and then chemically "cooked" using an alkali or sulfite process. Newspaper and recycled papers can also have a variety of inks, although colored ink and glossy paper are not allowed as compost feedstocks or mulch. Paper used as a production aid could include the typical adhesives found in newspaper and recycled paper.

Subcommittee Discussion:

The crops subcommittee has reviewed the petition, technical reviews, and public comments and has developed a listing and annotation that we believe meets the needs of producers, while addressing environmental concerns that might be associated with some types of paper. When discussing the possible allowance for paper used as a production aid, the subcommittee also considered the fact that we currently have an allowance for paper used in organic production. It is the subcommittee's view that there are few differences between the current paper allowance and the use of paper for plant pots and containers.

Category 1: Classification

1. **For CROP use: Is the substance _____ Non-synthetic or __x__ Synthetic?**
   Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [OFPA §6502(21)] If so, describe, using NOP 5033-1 as a guide.

   The paper pulp production process and the adhesives used in maintaining structural integrity of the paper pots currently rely on synthetically manufactured ingredients.

2. **For CROPS: Reference to appropriate OFPA category:**
   Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i)]; copper and sulfur compounds; toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers; or (ii) is used in production and contains synthetic inert ingredients that are not classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern?

   This material is a crop production aid, not a pesticide.

Category 2: Adverse Impacts

1. **What is the potential for the substance to have detrimental chemical interactions with other materials used in organic farming systems? [§6518(m)(1)]**

   Paper for plant pots/containers (as a crop production aid) is functionally identical to newspaper and recycled paper. This current listing of newspaper and recycled paper has been found to have no detrimental interactions with other materials in organic agriculture. Since virgin paper, with potentially different synthetic polymer makeup than recycled paper, would be allowed under this listing, a biodegradability standard in the annotation ensures that these paper products would not persist in the environment.

2. **What is the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment? [§6518(m)(2)]**

   No toxicity or negative mode of action has been found in the breakdown of paper (cellulose) in the environment. No colored or glossy inks would be allowed for paper as a crop production aid, which would be aligned with the current annotation for paper as a compost feedstock and/or mulch. The 2019 TR found many of the adhesives and synthetic fibers biodegrade with no negative impacts. There were some that were not as environmentally neutral as others, but all are also present in paper under the current allowance. The subcommittee wants to ensure that the fibers used in paper products described by this petition will similarly biodegrade in the soil, especially given that virgin paper, with potentially different quantities of synthetic polymers than recycled paper, would be allowed.

3. **Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)]**

There could be contaminants released into the environment during the manufacture of paper and environmental degradation caused by harvest of cellulose, but no more than newspaper or recycled paper. A difference between this paper and the previously approved newspaper and other recycled paper is that we are not restricting it to the use of only recycled paper products. The annotation will allow virgin stocks of cellulose to be used in the paper used as a production aid in organic agriculture. There are negative environmental impacts from harvesting trees to make paper such as deforestation, road building, soil erosion, and degraded water quality, but there are forestry best management practices that can help mitigate some these negative effects.

4. **Discuss the effect of the substance on human health. [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)].**

   The 2019 TR did not find any evidence of harmful effects to human health.

5. **Discuss any effects the substance may have on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock. [§6518(m)(5)]**

   Paper, as a material, is not harmful to the environment. The 2019 TR did not find any evidence of harmful effects to environmental health.

6. **Are there any adverse impacts on biodiversity? (§205.200)**

   No.

Category 3: Alternatives/Compatibility

1. **Are there alternatives to using the substance? Evaluate alternative practices as well as non-synthetic and synthetic available materials. [§6518(m)(6)]**

   There are biodegradable pots made from composted cow manure, but these have never been petitioned for use in organic agriculture. We do not know if they could be approved or not. These pots contain 10% newspaper. There are also tools to help growers roll up newspaper into a pot. The paper chain pots offer greater efficiency for transplanting, although mechanical or hand transplanting operations can be used in both small- and large-scale operations with other types of containers. The future use of hemp fibers may also offer an alternative to synthetic polymers.

2. **In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]**

   The crops subcommittee has developed the annotation "Virgin or recycled paper, without colored or glossy inks; any synthetic fibers included must not exceed 15% of the paper and must be 100% biobased with content determined using ASTM D6866 (incorporated by reference; see 205.3), and demonstrates at least 90% biodegradation absolute or relative to microcrystalline cellulose in less than two years, in soil, according to one of the following test methods: ISO 17556 or ASTM D5988 (both incorporated by reference; see § 205.3)". Continuing the prohibition on

colored and glossy inks prevents the incorporation into organic soil of the worst contaminants. Allowing the adhesives typically used in paper, makes this crop production aid equivalent to newspaper and recycled paper that is currently allowed. The allowance for virgin paper allows for special papers to be developed that meet the specific crop production needs for a variety of uses, and the amount of paper produced from virgin sources for these production aids would be very small compared to the amount of paper manufactured for all uses. Added fungicides, insecticides, or other synthetic materials not typically found in paper, would not be allowed under the current annotation. An unanswered question is whether it is practical and achievable to allow only natural fibers, using hemp or other fibers, to provide the strength needed in paper crop production aids. With the recommended annotation, paper as a crop production aid is compatible with a sustainable system of agriculture.

Discussion Questions:

1. Please comment on the following options under consideration by the subcommittee for listing at § 205.601(o) as production aids:
    a. "Virgin or recycled paper, without colored or glossy inks," or
    b. "Virgin or recycled paper, without colored or glossy inks; any synthetic polymer fibers included must not exceed 15% of the paper and must be 100% biobased with content determined using ASTM D6866 (incorporated by reference; see 205.3), and demonstrates at least 90% biodegradation absolute or relative to microcrystalline cellulose in less than two years, in soil, according to one of the following test methods: ISO 17556 or ASTM D5988 (both incorporated by reference; see § 205.3)"
2. Synthetic polymer content—
    a. Should a maximum synthetic polymer content be stated explicitly? If so, what is the appropriate level?
    b. What is the amount (or range) of synthetic polymer content in products currently available?
    c. How would synthetic content be measured? How would a certifier or Material Review Organization verify content? For example, if a product included recycled paper as an ingredient, how would the synthetic polymer content be determined?
    d. Is it possible to manufacture paper production aids that use only natural fiber sources and that meet the product specifications for their intended use?
3. Biodegradability—
    a. Should a biodegradability standard be included for these products? If so, is this the appropriate biodegradability standard?
    b. Does maximum synthetic polymer content need to be stated if there is a biodegradability requirement?
    c. As the products biodegrade, what is the impact on the soil? Also, can fragments be consumed by wildlife or livestock before it is completely degraded?
4. Biobased content—
    a. Should a minimum biobased content standard be included for these products?
    b. Is 100% biobased content achievable for these products? If not, what should be the minimum biobased content requirement?
5. Is genetic engineering involved in the production of these products?
6. Does the annotation need to specify that added fungicides, insecticides, or other synthetic materials not typically found in paper would not be allowed, or is that already understood?

Subcommittee Vote:

Motion to accept the petitioned material discussion document on Paper (Plant Pots and Other Crop Production Aids)
Motion by: Harriet Behar
Seconded by: Steve Ela
Yes: 8 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Approved by Steve Ela, Crop Subcommittee Chair, to transmit to NOP August 14, 2019

National Organic Standards Board
Materials/GMO Subcommittee Proposal
Excluded Methods Determinations October 2019
August 13, 2019

Introduction and background

At the November 18, 2016 in-person National Organic Standards Board (NOSB) meeting, the NOSB recommended that the National Organic Program (NOP) develop a formal guidance document for the determination and listing of excluded methods. The 2016 recommendation, entitled "Excluded Methods Terminology," clarifies excluded method definitions and criteria in response to the increasing diversity in the types of genetic manipulations performed on seed, livestock, and other biologically-based resources used in agriculture. Genetic engineering is a rapidly expanding field in science. To be responsive to this rapid expansion, the NOSB will continue to list new methods for review and will determine over time if the methods are or are not acceptable in organic agriculture. In addition to the 2016 recommendation, a discussion document provided a list of technologies needing further review to determine if they should be classified as excluded methods or not.

At the Fall 2017 NOSB in-person meeting, the NOSB passed a recommendation to add three technologies as excluded methods to the NOP guidance document. In Fall 2018, the NOSB recommended one technology be added to the list of methods that are not to be excluded in organic production. In April 2019, one more method was added to the list of methods to be excluded. The organic community, as well as the NOSB, has voiced a consistent stance that direct manipulation of genes through in vitro nucleic acid techniques should be considered an excluded method. This would include gene editing techniques such as CRISPR, which was determined to be an excluded method by the NOSB in November 2016. The NOSB will continue to review and determine various methods and technologies to provide clarity to the organic community on which methods could be allowed and which ones are excluded.

Goals of this proposal/document

This proposal addresses two more items on the "To Be Determined" list found in the November 2016 discussion document. At the April 2019 NOSB meeting, a discussion document was presented for public comment for the two items covered in this proposal: induced mutagenesis and embryo transfer in livestock.

Public comment at numerous NOSB meetings over the years continues to stress the view that technologies used to manipulate the genetic code in a manner that is outside traditional plant and animal breeding should remain prohibited in organic production. Among organic stakeholders, there is a strong belief that genetic engineering is a threat to the integrity of the organic label. Both organic producers and consumers reject the inclusion of genetic engineering in organic production. This document represents the continuing work of the NOSB to clarify which methods in the expanding field of genetic engineering can or cannot be used under the USDA organic seal.

The Materials Subcommittee recognizes the topic of genetic engineering and evaluation of excluded methods will remain on our work agenda to determine if new technologies do or do not meet our current definitions. We may also need to incorporate additional criteria to evaluate new and unique technologies.
We are aware that specific laboratory tests are not currently available to detect the use of several

new excluded genetic modification technologies in organisms. However, we still believe that the technology should be listed as an excluded method, when appropriate, and anticipate tests or other methods will be developed over time to detect the presence of these technologies. The Materials Subcommittee may put forward another discussion document in the future to aid the NOP in determining how to enforce this prohibition when there is no means to detect an excluded method that may have been used in production.

Definitions and Criteria

Under the National Organic Program organic regulations, methods that employ genetic engineering techniques are excluded from use in organic production. The current regulation defines an excluded method as:

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.

Below are the criteria listed in the 2016, 2017, 2018 and 2019 NOSB recommendations to determine if methods should be excluded. The table includes the NOSB vote in April 2019, to add transposons developed via use of in vitro nucleic acid techniques as an excluded method.

1. The genome is respected as an indivisible entity, and technical/physical insertion, deletions, or rearrangements in the genome is refrained from (e.g. through transmission of isolated DNA, RNA, or proteins). *In vitro* nucleic acid techniques are considered to be an invasion into the plant genome.
2. The ability of a variety to reproduce in a species-specific manner has to be maintained, and genetic use restriction technologies are refrained from (e.g. Terminator technology).
3. Novel proteins and other molecules produced from modern biotechnology must be prevented from being introduced into the agro-ecosystem and into the organic food supply.
4. The exchange of genetic resources is encouraged. In order to ensure farmers have a legal avenue to save seed and plant breeders have access to germplasm for research and developing new varieties, the application of restrictive intellectual property protection (e.g., utility patents and licensing agreements that restrict such uses to living organisms, their metabolites, gene sequences, or breeding processes) are refrained from.

The NOSB has voted and determined these to be excluded methods:

Method and synonyms	Types	Excluded Methods	Criteria Applied	Notes
Targeted genetic modification (TagMo) syn. Synthetic gene technologies syn. Genome engineering syn. Gene editing syn. Gene targeting	Sequence-specific nucleases (SSNs) Meganucleases Zinc finger nuclease (ZFN) Mutagenesis via Oligonucleotides CRISPR-Cas system (Clustered regularly interspaced short palindromic repeats) and associated protein genes TALENs (Transcription activator-like effector nucleases) Oligonucleotide directed mutagenesis (ODM) Rapid Trait Development System	YES	1, 3, 4	Most of these new techniques are not regulated by USDA and are currently difficult to determine through testing.
Gene Silencing	RNA-dependent DNA methylation (RdDM) Silencing via RNAi pathway RNAi pesticides	YES	1, 2, 4	
Accelerated plant breeding techniques	Reverse Breeding Genome Elimination FasTrack Fast flowering	YES	1, 2, 4	These may pose an enforcement problem for organics because they are not detectable in tests.
Synthetic Biology	Creating new DNA sequences Synthetic chromosomes Engineered biological functions and systems	YES	1, 3, 4	
Cloned animals and offspring	Somatic nuclear transfer	YES	1, 3	
Plastid transformation		YES	1, 3, 4	
Cisgenesis	The gene modification of a recipient plant with a natural gene from a crossable-sexually compatible-plant. The introduced gene includes its introns and is flanked by its native promoter and terminator in the normal-sense orientation.	YES	1, 3, 4	Even though the genetic manipulation may be within the same species; this method of gene insertion can create characteristics that are not possible within that individual with natural processes and can have unintended consequences.

Intragenesis	The full or partial coding of DNA sequences of genes originating from the sexually compatible gene pool of the recipient plant and arranged in sense or antisense orientation. In addition, the promoter, spacer, and terminator may originate from a sexually compatible gene pool of the recipient plant.	YES	1, 3, 4	Even though the genetic manipulation may be within the same species, this method of gene rearrangement can create characteristics that are not possible within that individual with natural processes and can have unintended consequences.
Agro-infiltration		YES	1, 3, 4	*In vitro* nucleic acids are introduced to plant leaves to be infiltrated into them. The resulting plants could not have been achieved through natural processes and are a manipulation of the genetic code within the nucleus of the organism.
Transposons-Developed via use of in vitro nucleic acid techniques		YES	1,3,4	Does not include transposons developed through environmental stress such as heat, drought or cold.

The following genetic engineering methods were found by the NOSB NOT to be excluded methods:

Method and synonyms	**Types**	**Excluded Methods**	**Criteria Applied**	**Notes**
Marker Assisted Selection		NO		
Transduction		NO		
Embryo rescue in plants		NO		IFOAM's 2018 position paper on Techniques in Organic Systems considers this technique compatible with organic systems.

The following methods will continue to be researched in future NOSB proposals:

Terminology				
Method and synonyms	Types	Excluded Methods	Criteria Used	Notes
Protoplast Fusion		*TBD*		There are many ways to achieve protoplast fusion, and until the criteria about cell wall integrity are
Cell Fusion within Plant Family		*TBD*		Subject of an NOP memo in 2013. The Crops Subcommittee will continue to explore the issue of
TILLING	Eco-TILLING	*TBD*		Stands for "Targeted Induced Local Lesions In Genomes." It is a type of mutagenesis
Doubled Haploid Technology (DHT)		*TBD*		There are several ways to make double haploids, and some do not involve genetic engineering while some do. It is difficult or impossible to
Induced Mutagenesis		*TBD*		Induced mutagenesis developed through exposure to UV light, chemicals, irradiation or other stress
Transposons		*TBD*		Produced from chemicals, ultraviolet radiation, or other synthetic activities

Discussion and Public Comment

<u>Induced Mutagenesis</u>

The April 2019 NOSB discussion document covered a variety of methods that could result in induced mutagenesis. Public comment overwhelmingly stated that environmental or other stresses that induce mutagenesis need more deliberate discussion. Impact on current plant breeding methods needs to be carefully considered, as well as consistency with what is allowed and not allowed, in organic agriculture. Having clear definitions and accessibility in determining which items may or may not have been developed through stress induced mutagenesis is needed to provide seed breeders and companies, certifiers, and producers the information they need to meet any possible restrictions discussed in the future.
However, it was clear that induced mutagenesis developed through in vitro nucleic acid techniques meets the criteria to be determined as an excluded method. Information is accessible in the marketplace to determine if the induced mutagenesis was produced through this method. This proposal adds this type of in vitro nucleic acid technique induced mutagenesis to the excluded

method table and keeps induced mutagenesis developed through exposure to UV light, chemicals, irradiation, or other stress-causing activities on the "To Be Determined" list for future discussion and review.

Embryo transfer, or embryo rescue, in animals

This technique used in animal breeding, involves inducing superovulation of the donor animal with gonadotropins (glycoprotein polypeptide hormones), artificial insemination of the donor animal, recovery of embryos from the donor, isolation and storage of embryos, and transfer of embryos into a recipient animal (either with or without hormones to synchronize estrus), which results in a pregnancy and hopefully a birth of a live animal at maturity. Many organic certifiers stated they currently allow this method of embryo transfer in organic agriculture. In nonorganic agriculture, the recipient animal may also be given hormones to improve the success of the embryo transfer, but no organic certifiers allowed the use of these hormones in the recipient animal to synchronize estrus.

In response to the question of whether this technique might narrow the genetic pool in livestock, commenters were sympathetic to this concern but felt that organic farmers would be careful in choosing embryos that would result in genetic diversity in their livestock. There were no concerns expressed for the health of the nonorganic donor animal after repeated use of hormones to produce multiple embryos, nor possible future health issues in the animals grown from those embryos. While embryo transfer was not found to be a necessary method by the public, numerous commenters stated it is a useful tool that should be allowed.

Future Work on this Topic

The NOSB encourages the public to continue the dialogue on the various methods that cause induced mutagenesis and provide information on which methods, chemical, UV light, irradiation, or others should or should not be considered excluded for organic production.

Subcommittee Proposal

The NOSB recommends the NOP add the following to the table of excluded methods, in the NOP excluded methods guidance:

1. **Induced mutagenesis - Developed via use of in vitro nucleic acid techniques.**

The NOSB recommends the NOP add the following to the table of "not excluded" methods, in the NOP excluded methods guidance:

2. **Embryo transfer, or embryo rescue, in animals. Use of hormones not allowed in recipient animals.**

Subcommittee Vote:

Motion to accept the proposal on excluded methods determinations October 2019
Motion by: Harriet Behar
Second: Dan Seitz
Yes: 5 No: 0 Absent: 0 Abstain: 0 Recuse: 0

Approved by Emily Oakley, Materials Subcommittee Chair, to transmit to NOSB August 13, 2019

National Organic Standards Board
Materials Subcommittee Proposal
Genetic Integrity Transparency of Seed Grown on Organic Land - Instructions to Certifiers
August 13, 2019

I INTRODUCTION

The USDA National Organic Program (NOP) regulations do not allow the use of materials developed using "excluded methods" in certified organic production. The USDA defines "excluded methods" as , "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…" (7 CFR 205.2). These organisms include, but are not limited to, seed, bacteria, insects, animals and vaccines. According to the most recent National Agricultural Statistics Survey (NASS), at least 94% of soybeans, 92% of corn, 94% of cotton, 75% of Hawaiian papaya, 98% of sugar beets, and 90% of canola are genetically engineered. This proposal will address seed planted on organic land that may have a Genetically Engineered (GE) equivalent.

II BACKGROUND

The National Organic Standards Board (NOSB), in separate recommendations in 2016, 2017, 2018, and 2019, defined terms used when describing gene altering technologies and the subset of those methods deemed to be excluded methods. This list is continually under review, with new methods being added periodically. The list of those excluded methods are as follows:

- Sequence-specific nucleases (SSNs)
- Meganucleases Zinc finger nuclease (ZFN)
- Mutagenesis via Oligonucleotides
- CRISPR-Cas system (Clustered regularly interspaced short palindromic repeats) and associated protein genes
- TALENs (Transcription activator-like effector nucleases)
- Oligonucleotide directed mutagenesis (ODM) Rapid Trait Development System
- RNA-dependent DNA methylation (RdDM)
- Silencing via RNAi pathway RNAi pesticides
- Reverse breeding
- Genome elimination
- FasTrack
- Fast flowering
- Creating new DNA sequences
- Synthetic chromosomes
- Engineered biological functions and systems
- Somatic nuclear transfer
- Plastid transformation
- Cisgenesis
- Intragenesis
- Agro-infiltration
- Transposons-Developed via use of in vitro nucleic acid techniques

Currently in the U.S., testing is not required to verify if seeds planted on organically certified farms were

produced using an excluded method. Organic farmers plant both organic and non-organic seed (when the organic seed is not commercially available in the form, variety, or quantity required). Some, but not all, certification agencies perform genetically engineered (GE) testing on a farmer client's harvested crop. Proposed here is an additional step; certifiers should recommend that their farmers request information on any GE testing performed on seed they may purchase.

To meet the current certification standard, farmers are required to provide documentation that the seed they plant was not produced using excluded methods. This standard is met in one of two ways. 1) Certified organic seed breeding companies must verify excluded methods were not used in the production of certified organic seed. 2) For non-organic seed, a non-GE affidavit is required if the crop has a genetically engineered equivalent in the marketplace. Affidavits typically state "to the best of the seed supplier's knowledge, the seed was not produced using excluded methods"; however, the affidavit does not address the issue of possible contamination of the seed lot with seed produced using excluded methods. The *intentional* use of seed produced by an excluded method is prohibited. Non-GE affidavits have been accepted as proof by organic certifiers that the seed is acceptable in organic systems.

In a previous discussion document the Material's Subcommittee discussed a proposed requirement that all field corn seed planted on organic land be accompanied by a statement detailing any presence of GE within specific percentages, such as .1%, .9% etc. levels. While many farmers, consumers, advocates, and certifiers liked the transparency this would have provided, there was significant concern from all groups, especially seed breeders, that there could be unintended negative consequences from this requirement. These potential negative consequences included added cost of disseminating this information, loss of germplasm and seed varieties to organic producers if there is significant presence of GE in the seed, loss of genetic diversity available to organic farmers, and more. This proposal recommends the NOP provide an instruction to certifiers informing producers they can request the results of any testing for presence of genetic engineering in the seeds they purchase.

In the development of this proposal, NOSB members and the public, specifically the Organic Seed Alliance, reached out to numerous suppliers of field corn seed that typically serve the organic market. This includes both organic and nonorganic seed growers. The vast majority of seed suppliers reported that they already test their field corn seed for detectable levels of genetic engineering, and, when asked, are willing to provide this testing information to those who buy their seed.. Most farmers are not aware that this testing is being done, and consequently, most do not currently request this information.

If farmers don't know what they are starting with, it puts them in a compromised position when they sell their crop; after all, they are committed to producing GE-free grains, fruits, and vegetables. On the other hand, the organic marketplace, or the "back end" of the food system, has developed a fairly robust testing protocol for organic foods intended for human consumption as well as livestock feeds. Various tolerance levels of genetic contamination must be met in order to sell into specific markets. Knowing the purity of the seed farmers plant on the "front end" is critically important for several reasons. The level of contamination at the beginning of the season will not decline and can only worsen by cross-pollination and post-harvest seed handling. To meet organic market demand and to provide farmers with what they need to make informed decisions when choosing seeds, transparency of GE contamination levels and the knowledge of the adventitious presence of genetic engineering in their seed has become a necessity.

The NOSB put forth discussion documents and proposals addressing the issue of clarity around genetic purity of the seed supply in 2013, 2014, 2015, 2016, 2017, and 2018. The strong response from the public in the form of many comments clearly demonstrates the importance of this issue for organic farmers,

processors, and consumers.

III RELEVANT AREAS OF THE STATUTE, RULE and RELATED DOCUMENTS

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

§205.670 Inspection and testing of agricultural product to be sold or labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))."

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

NOP Policy: The NOP issued a Policy Memo on April 15, 2011 (Policy Memo 11-13) on genetically engineered organisms. The memo clearly states that the use of genetically engineered organisms is prohibited and goes on to address questions that have been raised concerning the use of these organisms and how to minimize their presence in organic production and handling. The memo emphasizes that organic certification is a process-based standard, explaining the presence of detectable GMO residue alone does not necessarily constitute a violation of the regulation.

IV RESPONSE TO PUBLIC COMMENT

Public comment from most seed suppliers and producers, did not favor tolerance levels due to concerns that this approach would narrow the availability of needed crop traits and the overall crop choice. Concern was also raised that strict tolerance levels could result in the unintended consequences such as damage to the growth and integrity of organic agriculture, as well as negative impacts to organic growers and seed breeders. This proposal does not set tolerance levels that could prohibit the planting of seed that exceeds any specific tolerance. Instead, this proposal seeks to encourage certifiers and farmers to seek out the currently available information before planting seed that has a GE equivalent on organic land.

There are no current restrictions that would prevent a farmer from taking a sample of hybrid corn seed (a non-GMO variety) or other seeds they purchase and having them tested for the presence of GE. There are agreements that seed breeders might encounter when purchasing the foundation seed for building their own hybrid varieties that could restrict them from testing that seed for the presence of GE. However, this proposal only requires testing of the seed that would be planted by an organic producer who has no legal impediments to this testing. Farmers would not be required to do GE testing of their seed, but if their seed supplier does not provide GE contamination test results for their seed, this option is open to the farmer.

In addition, it is a good practice for farmers to retain seed samples of seed they plant on organic land, and certifiers can suggest this to farmers as another step in finding the source of GE contamination in case their crop is rejected by a buyer at harvest time.

The previous discussion documents on the issue of genetic integrity transparency of seed, focused only on field corn seed. This proposal addresses all seed or planting stock that has a GE equivalent in the marketplace. There is no specific requirement, other than for certifiers to instruct their clients about the option to request GE contamination test results from their seed and planting stock providers.

The NOSB continues to request that the NOP fund a task force that would collect information on the genetic integrity of seed planted on organic land so the organic community - from farmers to consumers - would have statistical information detailing GE contamination issues. This task force would be empowered to collect data for multiple years, since growing conditions and crop production issues change from year to year, and in order to collect useful information, numerous years and regions must be tracked. We know there are issues with some crops in some regions, but there has not been a comprehensive review of data to provide a clear picture of the problems. Without this information, the organic community cannot develop solutions.

V Proposal

The NOSB recommends the NOP provide an "Instruction to Certifiers".

The purpose of this instruction is to have certifiers inform their producers that GE contamination of seed or planting stock is being tested regularly by those suppliers who are at risk for GE contamination of their products. Producers are encouraged to discuss GE contamination with suppliers willing to share the results of the GE testing they are currently doing but typically do not disseminate, unless requested by the buyer of the product.

Certifiers should be proactive in encouraging their farmers who grow organic crops according to the USDA organic regulations, and who could be at risk of having crops rejected by their buyers due to presence of GE contamination, to obtain information from their seed or planting stock suppliers about any GE contamination found. Certifiers can request this GE contamination information from their organic producers, and they may choose to maintain that information in the client's organic certification records. Farmers can then make informed decisions about which seed or planting stock to use based upon the requirements of their buyers and their production situations that may or may not result in GE contamination in their fields. Obtaining this GE contamination information before planting can be beneficial in lessening the risk of significant economic losses due to GE contamination when that crop is sold. The discussion between growers and seed suppliers may also demonstrate there is a demand for seed with low GE contamination levels.

1. In order to aid producers in their goal of low-to-no detection of GE contamination of their organic crops (seed and planting stock) that have GE equivalents in the marketplace, certifiers should provide the following information to their organic farmers:

    A. Producers who are growing crops from seed or planting stock that could be subject to Genetic Engineering contamination of that seed or planting stock, can contact their suppliers to obtain GE contamination test results.
    B. The vast majority of seed and planting stock suppliers whose crops have GE equivalent varieties that could cause contamination are already doing GE contamination testing and are supplying information, at the request of the buyer of their seed or planting stock, of any GE contamination and the levels present.
    C. Certifiers may choose to obtain this information at the organic inspection. If presence of GE

contamination is found on the finished crop by the certifier in their testing program or by a buyer of the finished crop, this seed GE contamination information will be useful in determining the cause of the GE contamination.

D. Certifiers can inform farmers who wish to test seed they grew or test seed or planting stock they purchased, that they are legally allowed to test for GE contamination. A wide variety of laboratories around the U.S. and the world supply this testing service. This information could be provided to the organic certifier as well.

Subcommittee vote:
Motion to accept the "Genetic Integrity Transparency of Seed Grown on Organic Land Instructions to Certifiers" Proposal
Motion by: Harriet Behar
Seconded by: Dave Mortensen
Yes: 5 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Approved by Emily Oakley, Subcommittee Chair to transmit to NOSB, August 13, 2019

USDA National Organic Standards Board Research Priorities, 2019
Executive Summary

Overall: The National Organic Standards Board (NOSB) presents an annual list of research priorities for organic food and agriculture. The NOSB requests that integrated research be undertaken with consideration of the whole farm system, recognizing the interplay of agroecology, the surrounding environment, and both native and farmed species of plants and animals.

Livestock

1. Evaluation of methionine in the context of a system approach in organic poultry production.
2. Prevention and management of parasites, examining breeds, geographical differences, alternative treatments, and pasture species.
3. Organic livestock breeding for animals adapted to outdoor life and living vegetation.

Crops

1. Examination of decomposition rates, the effects of residues on soil biology, and the factors that affect the breakdown of biodegradable biobased mulch film.
2. Conduct whole farm ecosystem service assessments to determine the economic, social, and environmental impact of farming systems choices.
3. Organic no-till practices for diverse climates, crops, and soil types.
4. Develop cover cropping practices that come closer to meeting the annual fertility demands of commonly grown organic crops.
5. Development of systems-based plant disease management strategies are needed to address existing and emerging plant disease threats.
6. The demand for organic nursery stock far exceeds the supply. Research is needed to identify the barriers to expanding this market, then develop and assess organic methods for meeting the growing demand for organically grown nursery stock.
7. Strategies for the prevention, management, and control of invasive insects.
8. Factors impacting organic crop nutrition, and organic/conventional nutrition comparisons.
9. Side-by-side trials of organic synthetic materials, natural materials, and cultural methods, with a request for collaboration with the IR4 project.

Food Handling and Processing

1. Comparison of alternatives to chlorine materials in processing: impact mitigation, best management practices, and potential for chlorine absorption by produce.
2. Production of celery for celery powder yielding nitrates sufficient for cured meat applications, and investigation of agriculturally derived alternatives.
3. Suitable alternatives to BPA (Bisphenol-A) for linings of cans used for various products.

Coexistence with GE and Organic Crops

1. Outcome of genetically engineered (GMO/GE) material in organic compost.
2. Evaluation of public germplasm collections of at-risk crops for the presence of GE traits, and ways to mitigate small amounts of unwanted genetic material in breeding lines.
3. Develop then implement methods of assessing the genetic integrity of crops at risk in order to quantify the current state of the organic and conventionally produced non-GMO seed.

4. Techniques for preventing adventitious presence of GE material in organic crops, and evaluation of the effectiveness of current prevention strategies.
5. Testing for fraud by developing and implementing new technologies and practices.

General

1. Examination of the factors influencing access to organically produced foods.
2. Production and yield barriers to transitioning to organic production to help growers successfully complete the transition.

National Organic Standards Board
Materials Subcommittee Proposal
2019 Research Priorities
August 13, 2019

INTRODUCTION
The National Organic Standards Board (NOSB) presents an annual list of research priorities for organic food and agriculture. The NOSB's Livestock, Crops, Handling, and Materials/GMO Subcommittees propose the priorities at the fall board meeting and reflect both written and oral public comments received by the Board. The topics listed below are the 2019 priorities.

BACKGROUND
The list of priorities is revisited each year by the NOSB. The list is made meaningful by input through the written and oral public comments shared with the Board, through the expertise of the Board itself and through interactions throughout the year with those engaged in some dimension of the organic farm to fork continuum. When the NOSB has determined that a priority area has been sufficiently addressed, it is removed from the list of priorities. Priorities are also edited each year to more accurately reflect the existing need for new knowledge. Four new research priorities were added in 2019.

The NOSB encourages collaboration with and between laboratories, federal agencies, universities, foundations and organizations, business interests, organic farmers, and the entire organic community to seek solutions to pressing issues in organic agriculture and processing/handling.

PROPOSAL: 2019 RESEARCH PRIORITIES
The NOSB encourages integrated, whole farm research into the following areas:

Livestock

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

Continued research on the use of synthetic methionine in the context of a systems approach (nutrition, genetic selection, management practices, etc.) is consistent with the NOSB unanimous resolution passed at the La Jolla, California, Spring 2015 board meeting. A systems approach that includes industry and independent research by USDA/ARS, on farms, and by agricultural land grant universities is needed for (1) evaluation of the merits of natural alternative sources of methionine such as herbal methionine, high methionine corn, and corn gluten meal in organic poultry production systems; (2) evaluation of poultry breeds selection that could be adaptive to existing organic production systems – inclusive of breeds being able to adequately perform on less methionine; and (3) assessment of management practices for improving existing organic poultry welfare under different conditions. Research findings and collaborations under various climates, housing types, geographical regions, and countries should be noted and researched, where applicable. Certainly, the fruition of these types of research topics could take years to achieve the expressed NOSB resolution; however, an aggressive and/or heightened

research focus could lead to findings that can positively impact the organic poultry industry and the organic brand. The continued focus on methionine with a systems approach is imperative and necessary.

The key research areas should include the efficacy and viability of alternatives such as: herbal methionine, corn gluten meal, potato meal, fishmeal, animal by-products, and other non-plant materials. Additional research on the more promising alternatives to bring them into commercial production is also encouraged. Additionally, management practices impacting the flock's demand for methionine should be included, such as flock management practices, access to pasture, and pasture management.

2. Prevention and Management of Parasites

Livestock production places large numbers of cattle, sheep, goats, poultry etc. into relatively close contact with each other on fields and in barns. Organic production does not allow antibiotic use and requires that livestock be raised in a manner which approximates the animal's natural behavior. The organic farmer can use synthetic parasiticides in an emergency but not prophylactically. Synthetic parasiticides have many limitations. Even if prophylactic treatment with parasiticides were possible, it is clear that parasite immunity to chemical control will inevitably occur. Thus, prevention of parasites is critical.

The research question on prevention and management of parasites must be systems based. What farm systems, animal breeds, herd or flock management systems have shown the best results with parasite control over the last twenty years? What regional differences are there in the US in parasite prevention? Are there specific herbal, biodynamic, or other alternative treatments that have been proven to work over time? What are the parasite-resistant breeds? Are there plant species in pastures and scrublands that could be incorporated into the annual grazing system to reduce the spread of parasites or to provide prevention through the flora, fauna, and minerals ingested? Which pasture management systems appear to be best for parasite prevention in various parts of the country? Are pasture mixes being developed that include plants known to prevent parasites in various breeds?

3. Organic Livestock Breeding

Organic rules require livestock products originate from animals that are not confined and are adapted to outdoor living as well as obtaining feed from living vegetation. A current FAO report states that globally one third of pigs, half of all egg layers, two thirds of milk animals, and three quarters of meat chickens are produced with breeds more suited to confinement or "industrial" production systems than a typical organic farm or ranch. Similar to plant breeding, the organic community sees a great need for regionally-adapted and publicly available livestock breeds that can thrive in organic systems.

Heritage, native regional breeds, and breeds used in the EU and other areas of the world that are typically more adapted to organic systems are still present but in small numbers. Increased research on the breeding, production needs, and improvement of these breeds is needed. Traits for good conversion rates from grazing to milk or meat, meeting consumer expectations for quality, as well as having the constitution and temperament to thrive outdoors would increase both the profitability and resiliency of organic livestock operations. Animal breeds that may have immunity to a variety of diseases and parasites would be useful traits to research and incorporate in a breeding program.

Crops

1. Biodegradable Bio-based Mulch Film

This type of mulch film was recently approved by the NOSB but did not include a specific percentage of bio-based components it must contain. In 2015, NOP issued a Policy Memo[1] that states that certifiers and material organizations should review biodegradable bio-based mulch film products to verify that all of the polymer feedstocks are bio-based. This requirement makes bio-based mulches unavailable to organic producers due to the petroleum-based polymers in these mulch films. In order to provide a recommendation to the NOP addressing the presence of petroleum-based polymers in these mulches, the answers to the following questions would be useful to develop more clarity on mulch films and possibly develop an additional annotation to address any concerns:

- How rapidly do these mulches fully decompose, to what extent does cropping system, soil type, and climate mediate decomposition rates, and does the percentage of the polymers in the mulch film affect the decomposition rate? Are there metabolites of these mulches that do not fully decompose?
- Do breakdown byproducts influence the community ecology and ecosystem function of soils, plants, and the livestock that graze on crops grown in these soils?
- As fragments degrade, do they pose a problem to terrestrial and aquatic wildlife?
- Do the residues of these films accumulate after repeated use?
- Are the testing protocols in place to insure decomposition standards?

2. Ecosystem service provisioning and biodiversity of organic systems (New in 2019)

How do organic systems impact ecosystem service provisioning, both on-farm and through the materials and inputs sourced and used for production? For example, what impact does ocean harvesting of seaweed for use as a fertilizer have on ecosystem health and service provisioning? Can farm-mapping be performed to quantify the impact of the location of a farm (in a broader landscape) and the arrangement of fields and non-crop habitat to enhance biodiversity and ecosystem service provisioning?

3. Organic No-Till

Organic no-till, using a terminated cover crop for in-place mulching, can increase soil health and provide for increased biodiversity. Organic no-till preserves and builds soil organic matter, conserves soil moisture, reduces soil erosion, and requires less fuel and labor than standard organic row crop farming. There can also be some challenges from organic no-till using a cover crop, such as occasional insect infestation associated with the cover crop.

Even though this killed-in-place mulch practice has been used for more than a decade, widespread adoption has not occurred. Increased research is needed to develop organic no-till systems that function for a wide variety of crops in diverse climates and soil types. Annual crops such as commodity row crops and specialty crops, as well as perennial crops such as tree fruits, berries, and grapes would all benefit from these organic no-till practices. Research areas that could be covered include:

- Development of plant varieties that have specific characteristics, such as early ripening, to aid in the effectiveness and practicality of organic no-till.
- What combination of mulch crops and cultural systems sustain crop yields, provide soil health benefits, and suppress weeds?
- How does organic no-till influence pest, weed, and disease management?
- What specific insect problems can be caused or exacerbated by cover crops used as mulches, and how can those problems best be managed?
- In perennial cropping systems, such as fruits, what are the benefits or drawbacks of using this

[1] Policy Memo 15-1

mulching system on weed, pest, and disease management, as well as soil fertility?
- What are the biodiversity benefits to these living and/or killed mulches, and how does this contribute to pest, weed, and disease management?
- Does this system affect the nutrient balance of the soil and subsequent fertilization practices, including use of outside inputs?
- Based on the improved soil health, when there is less soil disturbance and more plant decomposition resulting in higher organic matter, how does this system affect soil microbial life and nutrient availability, and does this then result in crops that are less susceptible to disease and pests?

Finally, organic farmers use whole-farm planning when deciding what will be done in each of their fields. Research that assesses the ecosystem benefits of reducing tillage in patches (field-level) across a farm is also needed. For example, the relative benefits of reducing tillage are greater in areas prone to surface water runoff. Research is needed to "inform" where reduced tillage practices are likely to have their greatest impact.

4. Managing Cover Crops for On-Farm Fertility (*New in 2019*)

Growing cover crops and green manures is a foundational practice on many organic farms. In addition to conserving soil, increasing water holding capacity, and providing weed suppression, cover crops can supply important plant nutrients and increase soil organic matter. As farmers seek to grow their own fertility, more research is needed on the efficacy of relying exclusively or almost exclusively on cover crops to meet production needs. At present, there is inadequate data on the various nutrient benefits of different cover crop mixes and how those benefits vary according to species mix, mowing practices, tillage regimes, and subsequent planting time of the cash crops. This topic asks researchers to examine farm fertility needs using cover crops as the sole or primary form of nutrient delivery.

5. Disease Management

Disease management in organic fruit and vegetable production relies on a systems approach to succeed, but even with current systems plans in place, growers frequently struggle to manage commonly occurring blights and citrus greening. The NOSB underscores the need for systems research that addresses solutions to these and related diseases that are workable for farmers, that reduces adverse health effects on farmers and fieldworkers, and that also limits adverse effects on the soil and water in which the crops grow. To this end, we call for systems research that identifies disease resistant material while at the same time identifying biological controls that limit the use of copper-based compounds where possible.

Specifically, targeted research is needed to identify management practices and less toxic alternative materials for a wide range of crops. More research is needed on many of the crop/disease combinations, including:

- Comprehensive, systems-based approaches for managing individual crops in a way that decreases the need for copper-based materials, including researching crop rotations, sanitation practices, plant spacing, and other factors that influence disease.
- Breeding plants that are resistant to the diseases that copper controls.
- Developing alternative formulations of materials containing copper so that the amount of elemental copper is reduced.
- Developing biological agents that work on the same diseases that copper is now used on.
- Evaluating plant nutritional strategies to mitigate the impacts of plant diseases.
- Particular research on scum and algae control in rice and whether sodium carbonate peroxyhydrate or other materials are suitable alternatives in an aquatic environment.

6. Identify Barriers and Develop Protocols for Organic Nursery Stock Production *(new in 2019)*
The demand for organic nursery stock far exceeds the supply. Research is needed to identify the barriers to expanding this market, then develop and assess organic methods for meeting the growing demand for organically grown nursery stock. That work could include but is not limited to assessing phytosanitary rules for shipping plants and quantifying the production and demand for organic rootstock. Finally, research centered on development of practical organic methods for the nursery industry to implement is needed.

7. Management and Control of Invasive Insects
There is a large pool of research on the control of insects and diseases using organic methods. Many controls use a systems approach and are quite effective. The introduction of new invasive species into cropping systems threatens these systems approaches, and in several cases the organic control options are very limited or nonexistent. For example, spotted wing drosophila is a relatively recent invasive insect that infests soft fruits, such as berries, and many other fruits as well. Infestation renders fruit unusable since insect larvae feed inside the fruit and may reach critical levels before fruit is harvested. This insect is particularly problematic in that it has the ability to oviposit in green fruit, and it has multiple generations throughout the summer, creating an extensive control period. There is only one control material available, and it is in danger of overuse. The control period may also extend so long that maximum label rates are used before the season ends. A second invasive insect is brown marmorated stinkbug, and at this time there are no organic control measures beyond attempts at mass trapping. Research into organic control options for both these invasive pests, and others, is critical so that organic growers can integrate controls into their organic systems. Prevention is critical. Because invasive insect species lack native predators, the organic community needs more information on their biology in order to implement prevention strategies before they become established and are more difficult to control.

8. Nutrition in Organic Crops
How do organic production and shipping methods (including methods of production, handling, and time in transport) influence the nutritional quality, taste, palatability, and ultimately preference for organic vegetables and fruits? There is a lack of sound, rigorously conducted studies of this kind. How can growers and handlers retain nutrition through post-harvest handling and transportation? Additionally, can providing organic producers information on soil biology and soil nutrient composition help improve nutrition? Finally, more studies are needed examining how organic crops compare to conventional crops with regards to nutritional value.

11. Side-by-Side Efficacy Assessments of Organic Inputs
During its five-year review of sunset materials on the National List and in the evaluation of newly petitioned materials, the NOSB often lacks sufficient information of the effectiveness of these materials as compared with other synthetics on the National List, natural materials, and cultural methods. Side-by-side trials with approved organic inputs, both synthetic and natural, and cultural methods to evaluate efficacy would strengthen the review process and provide growers with valuable information in pest and disease management decisions. The NOSB specifically requests collaboration with the Minor Crop Pest Management Program Interregional Research Project #4 (IR4) to include materials on the National List in their product trials. Such studies would help inform the NOSB review process of sunset materials and to determine if materials are sufficiently effective for their intended purpose, particularly when weighed against the natural and cultural alternatives.

Handling

1. Chlorine Materials and Alternatives

The three chlorine materials currently allowed for use in organic agriculture are widely used in farming and handling to clean and disinfect equipment, surfaces, and produce. There have been some concerns raised about these materials and their impact on the environment and human health when/or if they form trihalomethanes and other toxic compounds. New FDA regulations on food safety (Food Safety Modernization Act) and best management practices for cleaning in handling operations both require a suitable level of cleanliness and disinfection to prevent pathogens from entering the food supply. Producers and handlers are looking for alternatives to chlorine while continuing to provide a safe end product to their customers and the consumer. Addressing food safety while adhering to the fundamental organic principles involving human health and environmental impact is a concern.

The organic industry needs better information on how either alternative materials or appropriate chlorine materials are best suited for a specific use and control measure. This is especially important in determining if the industry can move away from the use of chlorine compounds in the future.

Points of consideration for future research activities:

- Comparison of alternatives to chlorine such as: citric acid, hydrogen peroxide, ethanol, isopropanol, peracetic acid, and ozone. How would each compare to the different chlorine materials for specific uses? The strengths and weaknesses would need to be considered.
- Potential human health and environmental impacts of each chlorine material versus the possible alternative materials listed above. Are there ways that these impacts can be mitigated and still allow the material to work as needed?
- Determination of which of the above-mentioned alternatives would NOT be a suitable substitute for chlorine. What specific uses and/or conditions would this apply to?
- Identification of practices that could be used to help reduce the formation of trihalomethanes in those specific situations where chorine is the best material to use.
- Could the rotation of materials for cleaning and disinfecting help lower the risks from chlorine materials and still be effective in providing the desired control of pathogens?
- Research on the absorption of chlorine by produce from its quantity and use in wash tanks, including information about amount of time of exposure. Would this be a persistent residual effect or temporary (if temporary – how long is it a viable residue), and would it be harmful if consumed at these levels?

2. Celery Powder

Celery Powder is used in a variety of processed meat product (hot dogs, bacon, ham, corned beef, pastrami, pepperoni, salami, etc.) to provide “cured” meat attributes without using prohibited nitrites (note: products must still be labeled “uncured”). Celery powder is naturally high in nitrates that are converted to nitrites during fermentation by a lactic acid culture. It has proven difficult to produce celery powder under organic production practices with sufficient levels of nitrates for cured meat applications. Are there growing practices or regions that could produce celery under organic conditions that would yield a crop with sufficient nitrate content for cured meat applications? Are there agriculturally derived substances (other than celery) that could be produced under organic production practices that provide nitrate levels sufficient for cured meat product applications of comparable quality?

3. Alternatives to Bisphenol A (BPA)

The Handling subcommittee is examining the issue of whether to prohibit BPA in packaging materials used for organic foods in light of direct evidence that these uses result in human exposures and

mounting evidence that these exposures may be harmful. There is a need for increased research about alternatives for the linings of cans and jars used for organic products that do not result in human exposures and health risks.

Materials/GMO

In previous years, the Materials subcommittee has prioritized the Reduction of Genetically Modified Content of Breeding Lines (2013) and Seed Purity from GMOs (2014). These issues are currently being addressed through a Genetic Integrity of Seeds Ad Hoc Working Group.

1. Fate of Genetically Engineered Plant Material in Compost
What happens to transgenic DNA in the composting process? Materials such as cornstalks from GMO corn or manure from cows receiving rBGH are often composted, yet there is little information on whether the genetically engineered material and traits break down in composting process. Do these materials affect the microbial ecology of a compost pile? Is there trait expression of Bt (*bacillus thuringiensis*) after composting that would result in persistence in the environment or plant uptake?

2. Integrity of Breeding Lines and Ways to Mitigate Small Amounts of Unwanted Genetic Material
Are public germplasm collections that house at-risk crops threatened by transgenic content? Breeding lines may have been created through genetic engineering methods such as doubled haploid technology, or they may have had inadvertent presence of GMOs from pollen drift. The extent of this problem needs to be understood.

3. Assess the Genetic Integrity of Organic Crops At Risk (*New in 2019*)
Develop then implement methods of assessing the genetic integrity of crops at risk in order to quantify the current state of the organic and conventionally produced non-GMO seed. Such assessments are needed on the front (seed purchased by farmers) and back end (seed harvested from a farmer's field) of the production chain as well as on points of contamination in the production chain.

4. Prevention of GMO Crop Contamination: Evaluation of effectiveness
How well are some of the prevention strategies proposed by the NOSB working to keep GMOs out of organic crops? For instance, how many rows of buffer are needed for corn? How fast does contamination percentage go up or down if there are more or fewer buffer rows?

Other examples could be whether cleanout of combines and hauling vehicles reduces contamination using typical protocols for organic cleaning, whether situating at-risk crop fields upwind from GMO crops can reduce contamination, and what the role may be of pollinators in spreading GMO pollen.

Lastly, research is needed on a mechanism to provide conventional growers incentives to take their own prevention measures to prevent pollen drift and its impact on organic and identity-preserved crops. This is policy research rather than field research but is equally as important.

5. Testing for Fraud: Developing and implementing new technologies and practices
New technologies, tests, and methodologies are needed to differentiate organic crop production from conventional production to detect and deter fraud. Testing to differentiate conventional and organic livestock products, for example omega 3 or other indicators, is also needed. Additional tools to identify fraudulent processed and raw organic crops require research to combat this problem. Current methodologies include pesticide residue testing, in field soil chemical analysis, and GMO testing. Areas in need of further testing methodology include phostoxin residues, fumigant residues, carbon isotope rations for traceability, validating nitrogen sources using nitrogen isotope rations, or other experimental

testing instruments that can be utilized to distinguish organic raw and/or processed crops from conventional items. Additionally, there is a need to develop rapid detection technologies for adaptation to field-testing capacities.

General

1. Increasing Access to Organic Foods

What factors influence access to organically produced foods? Individual-based studies are needed to assess the constraints to accessing to organic food. Research should be funded that builds on an understanding of constraints by asking what community, market, and policy-based incentives would enhance access to organic foods.

2. Barriers to Transitioning to Organic Production

What are the specific production barriers and/or yield barriers that farmers face during the three-year transition period to organic? Statistical analysis of what to expect economically during the transition is needed to help transitioning growers prepare and successfully complete the transition process.

Subcommittee Vote:
Motion to adopt the proposal on 2019 NOSB Research Priorities
Motion by: Dave Mortensen
Seconded by: Lisa de Lima
Yes: 5 No: 0 Abstain: 0 Absent: 0 Recuse: 0

National Organic Standards Board
Materials Subcommittee Discussion Document
Marine Materials in Organic Crop Production
February 12, 2019

NOTE:
The discussion document on Marine Materials in Organic Crop Production was presented at the April 2019 NOSB meeting and is being posted a second time for additional comment. It is identical to the April 2019 version with the exception of the addition of question #8 (page 11).

SUMMARY:
At its Fall 2018 board meeting, the NOSB explored a means of addressing the environmental impact of harvesting marine algae[1] for use in organic crop production inputs through a proposed requirement that marine algae under §205.601 (j)(1) aquatic plant extracts and other nonsynthetic uses be certified organic. This discussion document highlights the public comments received, presents the various methods proposed, and puts forth additional discussion questions for stakeholders in anticipation of a fall 2019 proposal.

BACKGROUND:
The Organic Foods Production Act National List criteria require, among other things, that materials not be harmful to the environment (7 USC 6517(c)). The NOSB has received extensive public testimony over the past several years regarding overharvesting of many marine algae species and the potential for contamination and harm to ecosystems. Stakeholders have agreed that organic agriculture should not contribute to this problem. The NOSB is exploring the best means of accounting for and minimizing the environmental impact of marine algae used in organic crop production inputs. This discussion document reviews the various methods that have been suggested to achieve that goal in hopes of identifying a proposed change to the standards that will be supported by a diverse organic community.

For detailed information on the relevant areas of the rule, please see the Material Subcommittee's Fall 2018 Discussion Document.

PUBLIC COMMENT[2]:
A spectrum of written and oral public comments was received, from support for organic certification, to those stating that marine algae should not be harvested at all for use in organic crop inputs due to negative environmental effects, to those concerned about the feasibility of applying organic certification to a crop input. Despite the range of views, there was broad agreement on the importance of working on this issue.

[1] For the purposes of this document, the term "marine algae" is used to refer to aquatic plants, marine plants, seaweed, and marine vegetation.
[2] For a summary of public comments of NOSB documents on this topic prior to Fall 2018 and for a review of the 2016 Technical Report, please see the Materials Subcommittee's Fall 2018 Discussion Document. These cover issues of overharvesting, selective harvesting, and cultivation.

Authority to Require Certification for an Ingredient in an Organic Crop Input:

Some commenters questioned the authority of the NOSB to require organic certification of a crop input ingredient. One commenter explained that inputs are not under §205.100 which outlines what must be certified. Another said that while they understood the positive intentions of the proposal, they opposed applying §205.207 to crop inputs as they understand that section to apply only to crop outputs.

Some worried about a domino effect that might result in requiring organic certification on a crop input ingredient. One stated:

> Marine materials harvested for use as an agricultural input should not be equated to the definition of a wild crop or an agricultural product when its purpose is not for human or livestock consumption. Requiring the certification of crop production materials that are not intended for human or livestock consumption sets a precedent for all agricultural inputs that are marine (or terrestrial) plant-based.

One commenter expressed the sentiment that "certification of inputs has been found to be outside of the scope of the NOP as established by OFPA". These commenters noted the proposed recommendation would require the certification of "inputs to an input". One commenter thought this would conflict with NOP's guidance that inputs cannot be certified. They asked if certification of the input's formulator would also be required or if it would be deemed sufficient to check the certification of the marine algae ingredient during a Materials Review Organization's review of a brand name product.

These concerns were answered in detail by another commenter:

> …Organic certification under the crop or wild crop standards should be required only of the aquatic plant ingredient within a formulated crop input. Handlers that further process and/or formulate the organic aquatic plants into final crop fertility input products should not be required to be certified.
>
> This approach is similar to livestock feed additives that contain agricultural ingredients, in which the agricultural ingredient must be organic, but the final formulated product is not required to be certified as a processed product. As required by §205.237(a), agricultural ingredients included in the ingredients list for livestock feed additives and supplements must be certified organic. However, there is no requirement that that handlers that use organic agricultural ingredients in the formulation of final feed additive product have to be certified organic.
>
> This approach will avoid complications that might arise from crop fertility inputs being certified organic under NOP, which has historically excluded crop input materials from its scope of certification and enforcement. Crop fertilizers and pesticides are generally considered to be outside of NOP's scope of organic certification because they are not intended for human or livestock consumption, and therefore do not meet NOP's definition of "agricultural product" at §205.2. Furthermore, it would be confusing and unrealistic to expect that formulated crop input products meet organic certification for processed products in terms of permitted ingredients and organic product composition requirements.
>
> Clarification on the requirements for labeling crop inputs that contain organic ingredients will also be needed. NOP regulates the term "organic" as it applies to agricultural products, which has historically only included products intended for livestock or human consumption. Thus, NOP does not have enforcement authority over organic claims on fertilizers, soil amendments, and other crop input materials (i.e., fertilizers that are not certified organic can still be marketed as

> "organic" and without violating NOP regulations). Certifiers will not be able to use organic claims on crop inputs as a means of verify organic status and must obtain proper organic certification documents for the aquatic plant ingredient to verify organic status.

Several commenters said verifying the organic status of an ingredient is not onerous, and that requiring organic certification of the marine algae ingredient would be similar to the verification of molasses as an organic input. Others explained that §205.207 is already being used to certify marine algae for human food, as livestock feed, and as a crop input ingredient. There are already a number of crop input products on the market that contain a certified organic marine algae ingredient. A manufacturer of organic fertilizers shared support for additional guidance and shared that they use certified organic kelp meal for their products.

Effectiveness of Using Organic Certification to Address Environmental Impact:
There were a broad range of opinions as to whether requiring organic certification is the right means to ensure that the harvest of wild marine algae is not harmful to the environment. Some producers of crop input products using marine algae were satisfied with the status quo, saying that current government standards are sufficient. A manufacturer harvesting marine algae off the coast of Mexico said they are adequately regulated through permits that stipulate the methods and quantities of harvest. Another producer noted that while some government regulations limit harvest rates, no government entities do on-site boat inspections. Government harvest limits and reviews are performed off-site and through paper trail audits, unlike the organic certification process which involves on-boat inspection of harvest locations, among other areas. The producer emphasized that it is not in their interest to over-harvest and in their case, scientists are hired to prepare and implement management plans. Certain producers of rockweed currently certify some of their harvest to the wild crop standard, and one testified that they could expand organic certification to all of their harvest.

A substantial number of residents in Maine expressed reservations about habitat loss, by-catch, frequency of harvest, and re-growth rates with mechanical harvesting of rockweed (*Ascophyllum nodosum*). Some said the term "sustainable harvest" fails to recognize the habitat role of rockweed. A number were affiliated with wildlife refuges and conservation areas, and they asserted that rockweed in particular, cannot meet the criteria for certification under §205.207 because of ecosystem damage caused by large biomass removal. One former wildlife refuge manager said that state and federal officers cannot fully regulate and police mechanized harvest boats. A landowner documented that two different companies harvested rockweed off of his property within 18 months of each other, despite his requests that they not. Some commenters said that organic certification of rockweed pushes harvesters into conservation areas and offered first-hand experiences observing rockweed harvested repeatedly from preserves. Some commenters from Maine requested that rockweed be listed as a prohibited natural on §605.602.

A number of commenters stated that trying to use organic certification would be inadequate to resolve the environmental impact of harvesting. A commenter stated:

> Currently, the standards are not detailed enough to meet the needs of the seaweed populations, let alone protecting the ecological community from which they are taken. It may be necessary for the NOSB to develop recommendations for new regulations concerning the wild harvest of marine plant species for use in organic to best ensure that they meet the needs of seaweed populations and the surrounding benthic and trophic communities from which they are taken.

> At this time, we are concerned that certifiers that certify seaweed harvest as organic lack the expertise to make the judgement that harvesting is not negatively impacting the ecosystem. If they are using standards of the local states, these fall short, as they were crafted by the industry using heavy lobbying. Therefore, even organic seaweed may still be harvested in a way that alters the ecological balance to an unacceptable degree.

One commenter who supported the reasoning of looking to organic certification as a means of addressing the environmental impact of marine algae harvesting, noted that they agreed:

> with the subcommittee's logic of using existing organic certification tools as a means of verifying sustainable production practices. Organic is the strongest and most regulated food system in the world, so it is logical to use our existing standards and verification processes to ensure that crop materials are produced and harvested in a manner that would not be harmful to the environment. Although it is unprecedented for the NOP standards to require organic status of crop input materials, it is not without precedent in other international organic standards. For example, the Canadian Organic Standards require organic status of some crop inputs, such as molasses (shall be organic), alfalfa meal and pellets (shall be organic if commercially available) and oilseed meals (shall be organic if commercially available).
>
> Therefore, in short, it is feasible to require and achieve organic certification of aquatic plants under the existing NOP regulations. Additional complexities lie in the details of whether organic certification is feasible as a solution for achieving the subcommittee's intended sustainability goals, and if so, whether it is feasible for the organic industry to build up sufficient organic supply to accommodate the needs of organic producers.

Additionally, the commenter pointed out that both the crops certification scope and the wild crops certification scope prohibit the destruction of the environment. §205.200 requires that crop producers "maintain or improve the natural resources of the operation" while §205.207(b) requires that wild crops be "harvested in a manner that ensures that such harvesting or gathering will not be destructive to the environment and will sustain the growth and production of the wild crop".

<u>Alternatives to Organic Certification to Address Environmental Impact</u>:

It is important to emphasize that despite the diversity of opinions, there was near unanimous support for addressing the environmental impact of marine algae harvesting. This varied from general statements supportive of the concept of sustainable harvesting to specific suggestions for alternative means of verification. In addition to expressed support for requiring organic certification of marine algae ingredients used in organic crop inputs, other actionable positions were: 1) limited or no harvest of marine algae for organic crop inputs, 2) exploring existing third-party standards for "sustainable" harvesting, and 3) annotations to material listings within the National List of Allowed and Prohibited Substances.

1) *Limited or no harvest of marine algae for organic crop inputs* – Some commenters asserted that there is more to be gained from saving than exploiting this resource, and there are populations that are endangered or in decline that cannot be sustainably harvested. Some asked why farmers are using marine algae as a fertilizer and encouraged seeking alternatives that could replace it. Some suggested looking at invasive aquatic plant species as an alternative. Others explained that freshwater algae do not contain the same properties. One commenter suggested that it is more appropriate for organic farmers to source nutrients from waste streams rather than harvesting an input from a wild, native ecosystem. A few recommended allowing only farmed marine algae, particularly farmed kelp, for crop inputs.

Others noted that organic crop inputs containing marine algae are widely used by growers and include dried, liquid, and whole, unprocessed formulations. Some coastal growers use marine algae as a mulch. One commenter described that:

> It is not uncommon for organic farmers in New England to acquire seaweed from local municipalities that collect it from public beaches after storms. This "everybody wins" situation would not seem to present significant risk to adjacent aquatic ecosystems. Moreover, it seems unlikely that a municipality would bother with organic certification in order to ensure that organic farmers would be able to use the seaweed.

2) *Exploring existing third-party standards for "sustainable" harvesting* – Quite a few commenters suggested looking to third party sustainability standards to "explore the opportunity of integrating aspects of other standards or references into the NOP regulations or guidance". This could result in "identifying certain other standards as equivalent to NOP for the purposes of ensuring sustainable harvest of aquatic plants for use in crop inputs". An annotation could allow for "multiple options of third-party verifications, including organic". One commenter recommended that "a better alternative to organic certification for aquatic plant input materials may be phasing in a requirement that NOSB should consider establishing a goal of marine materials be sourced from third-party verified and/or certified sustainable fisheries in 10 years".

As one public commenter noted, however, the term "sustainable harvest" has different meanings across stakeholder groups. For example, some third-party standards focus on vegetative regrowth, but "because of the many roles that marine algae play in the ecosystem, standards should not be based on the level of disturbance that can sustain a harvest (recovery of biomass), but on recovery of ecosystem function and structure".

3) *Annotations to material listings within the National List of Allowed and Prohibited Substances* – Rather than requiring that marine algae ingredients in crop inputs be certified organic, one commenter recommended adopting the language at §205.207 and annotating the relevant listings. As such, annotations would be made under §205.601 (j)(1) for synthetic inputs and under §205.602 for nonsynthetic inputs:

> Marine algae should be listed on §205.602, prohibited nonsynthetic crop inputs, with the annotation, "unless harvested from a designated area that has had no prohibited substance, as set forth in §205.105, applied to it for a period of 3 years immediately preceding harvest and harvested in a manner that ensures that such harvesting or gathering will not be destructive to the environment and will sustain the growth and production of the population of the species".

Another commenter supported "the development of guidelines for seaweed harvested for fertilizer production, similar to compost, where certifiers verify that the product is made according to the NOP rules" and suggested that "this could be managed with the development of an annotation for seaweed under §205.601 (j)(1)".

<u>Need for Guidance</u>:

Any requirement for organic certification of marine algae input ingredients would have to be accompanied by NOP guidance on how to apply the standards to a marine environment. It was observed that the wild crop standards do not define what is meant by "not destructive to the environment". Suggestions included strengthening the interpretation of §205.207 through guidance developed with marine biology experts. Others noted that a certifier's ability to determine if a harvest is destructive to the environment depends on his/her knowledge of marine ecology. One harvester and

manufacturer of rockweed products for livestock feed and soil conditioners believes that the current standards "leave too much room for individual interpretation by certifying agents that are not necessarily qualified to assess the health of localized or coastwide marine environments". Several commenters illustrated that contaminants in the ocean are more mobile, presenting unique challenges to certifying that the crop hasn't come in contact with prohibited substances. Some specific suggestions included requiring documentation of the locations, inputs, and methods of harvest. Guidance should make clear that conservation areas should not be harvested.

A commenter provided the following specific examples of how to expand guidance through "Marine Algae Harvest Guidance":

> Documentation should occur before and after each marine algae harvest for all biodiversity: the seaweed itself, the bycatch from the harvest, and the wildlife that use seaweed as perches for hunting and cover from predators. For the seaweed, documentation of the three-dimensional structure in the seaweed bed (clump density, clump height, clump biomass, and branching) should be conducted. For bycatch, the harvester simply should record how much they had. For wildlife, documentation should include a survey of birds and marine mammals using the seaweed.

In looking to other standards, one commenter suggested a "working group could determine whether existing […] standards align 100% with the national organic standards, and if not, which elements may need to be added or modified in order to ensure ocean-sources inputs meet NOP standards". Recommendations could then be about "how to integrate [other] standards, plus any additional elements, into NOP standards, guidance, or instruction".

Another commenter noted that "the health of vertebrate wildlife (birds and fish species) also depends on seaweed beds". They suggest guidance should elucidate how wildlife is maintained when marine algae bed harvesting occurs. They recommend "an independent estimate of bird and other wildlife use of seaweed beds before and after harvest in each harvest area" in order to "verify that wildlife is being "maintained" in the harvest area". Additionally, they recommend field staff with marine biology training perform the certification of marine algae.

Feedback on the Discussion Document Questions:

The fall 2018 Discussion Document sought input on four questions. Extensive comments were received on the first question regarding the feasibility of requiring all seaweed harvested for use in organic crop production to be certified to the wild crop standards, and these are discussed above. There were limited responses on the question to certifiers currently certifying marine materials to the wild crop standard asking how they verify that biodiversity is conserved and how wildlife are maintained in the harvest areas, with the exception of one certifier who provided extensive information, including a link to their process for Certifying Sea Vegetables (an excerpt of which can be found in the Appendix). Mixed comments were reported as to the difficulty of listing species on a label, with some saying it would be challenging and others saying it is possible and already being done. There was widespread support to develop a working group for additional guidance on wild cropped and farmed marine algae and to clarify the definition and measurement of "not destructive to the environment". There seemed to be limited potential to replace marine algae with freshwater materials for crop production inputs due to the particular properties of marine species.

Other Comments:

A number of commenters advised a phase-in period to allow adequate time for input producers to come into compliance for any requirement of organic certification or third-party standards. A commenter

remarked that the rule requiring that livestock be fed organic kelp allowed for a twelve-month phase-in, and a phase-in for any rule requiring organic certification of marine algae should be at least as long. Another suggested examining commercial availability to ascertain an appropriate phase-in period.

DISCUSSION:

The goal of this work agenda item is to find the most effective and realistic means of addressing a complicated issue. No single solution will be satisfactory to all, nor will it be able to resolve all areas of conflict. Despite of the different opinions, there is consensus on the importance of ensuring that marine algae harvesting "maintains or improves the environment". The NOSB aims to bring a proposal forward this fall with a recommendation for meeting the environmental impact criteria.

Questions of Jurisdiction:
As noted in the previous section, there were some concerns 1) that it would be difficult for certifiers to verify organic claims for marine algae in crop inputs in the absence of NOP purview over fertilizer products and 2) about precedent setting.

Marine algae are currently treated as an agricultural "crop" for livestock feed and human consumption, and they are being certified to the wild crop or crops standard in each instance. Indeed, in some cases the same boat may harvest the same species of marine algae for both certified organic livestock feed and for non-certified crop inputs. As a point of clarification, any NOSB recommendation would only require that the marine algae *ingredient* be certified organic, not the entire crop input or product. Labels would list the certified organic marine algae ingredient(s). Certifiers and Material Review Organizations would look for the marine algae ingredient's organic certificate to accompany a product and could also use the Organic Integrity Database to verify production. Certifiers would perform the verification of agricultural ingredients in fertilizers the same way they already do for agricultural ingredients in livestock feed additives.

Several stakeholders cautioned that requiring organic certification of marine algae ingredients in organic crop inputs could lead to a similar requirement in other crop input materials. To be clear, that would not be the intention nor the focus of any proposal to require organic certification of marine algae ingredients; nor is the objective to remove tools or inputs from farmers. Opting for organic certification would use an existing standard and verification process to meet the requirement that already exists, namely that materials not be harmful to the environment.

Environmental implications form part of the NOSB's criteria when examining new petitioned synthetic materials for potential inclusion on the National List and when reviewing the continued listing of materials during the sunset process. Indeed, the issue of environmental impact in marine algae harvesting came to the NOSB's attention during the 2015 sunset review process.

The proposed requirement of organic certification for marine algae ingredients is a means of addressing conflicts over the environmental impact of harvesting these species, but it does not necessarily follow that organic certification would be the right mechanism to account for environmental impact in other crop inputs.

The environmental impact of natural materials used in organic production receives comparatively little consideration simply because they do not undergo the same review process as synthetic materials. Yet

the regulations specifically allow for the prohibition of natural materials "if the use of such substances would be harmful to human health or the environment" (7 USC 6517(c)). From this we understand that natural inputs should also minimize environmental impact. Natural input materials should not be exempt from deliberations of environmental impact simply because they do not go through a petitioned material and subsequent sunset review process.

There are few crop input ingredients that are themselves living organisms harvested directly from wild native ecosystems. The question posed by the NOSB of petitioned materials--are there any adverse impacts on biodiversity--arguably assumes a unique accountability when those input materials themselves (in this case, marine algae) form part of the biodiversity of a wild native ecosystem.

Identifying the Right Tool to Address Environmental Impact:
The status quo does not provide a means of verifying that marine algae inputs are not harmful to the environment. Can either the crop or wild crop organic standards adequately define, measure, and verify that through guidance? Should all or part of a third-party verification standard be adopted through an annotation? Should an annotation be developed that stipulates how marine algae should be harvested to meet the wild crop standard but without the requirement of certification?

Throughout the NOSB's Discussion Documents on this issue, numerous commenters have suggested that there may be some species, regions, and/or harvest methods for which a limited or prohibited harvest should be recommended. While this could inform future NOSB work, that is not within the capacity of this current discussion document and proposal effort. Additionally, a small number of commenters said that marine algae harvests are "sustainable" without further action. In the absence of a universally agreed upon definition, measurement, and enforcement of sustainable harvest in marine algae, making claims related to the term are difficult to support.

There are several independent non-profit organizations with third party certification services and ecolabels that certify "sustainable seaweed". Much of the focus has historically been on fisheries[3], though recent efforts have launched marine algae certification programs. The first two listed below certify both farmed and wild harvested marine algae, while the third certifies only farmed marine algae. Excerpts from these standards can be found in the Appendix.
1. The **Marine Stewardship Council** (MSC) has traditionally focused on standards for seafood products; however in 2017, MSC and the Aquaculture Stewardship Council (ASC) launched "a joint standard for environmentally sustainable and socially responsible seaweed production" under the ASC-MSC Seaweed Standard. These standards contain 31 performance indicators under five principles: sustainable wild populations; environmental impact; effective management; social responsibility; community relations and interactions.

> Sustainable wild populations: Seaweed harvesting and farming must be conducted in a manner that does not lead to depletion of the exploited wild populations. For depleted populations, harvesting operations must be conducted in a manner that demonstrably leads to their recovery. Where appropriate, stock status, harvest strategy, and the genetic impact of the assessment site on the wild stock are also assessed.

[3] For example, see The Monterey Bay Aquarium's Seafood Watch list of recommended Eco-Certifications for specific farmed and wild fish. These include ASC, Naturland, Global Aquaculture Alliance Best Aquaculture Practices, Canada Organic, MSC, and FishWise. For example, **FishWise**'s vision is promoting "the health and recovery of ocean ecosystems by providing innovative market-based tools to the seafood industry, supporting sustainability through environmentally and socially responsible business practices".

Environmental impacts: Seaweed harvesting and farming activities must allow for the maintenance of the structure, productivity, function, and diversity of the ecosystem (including habitat and associated dependent and ecologically related species) on which the activity depends. Seaweed operations must also adhere to criteria related to habitat, ecosystem structure and function, species status, species management, waste management and pollution control, energy efficiency, disease and pest management practices, and introduced species management.[4]

2. **Friend of the Sea** launched a sustainable marine algae harvesting and farming certification program in 2016 that reviews an operation's: "management system; legal compliance; biomass and Environmental Impact Assessment; water monitoring; air emissions monitoring; waste management; chemicals and hazardous substances; energy management; social accountability; and traceability".
3. The **Maine Seaweed Exchange** has a Seaweed Farmer Certification for farmed marine algae.

At least three international certification bodies provide specific marine algae standards. Others, like Japan, set standards for farmed marine algae[5]. Excerpts from these standards can be found in the Appendix.

1. **The Soil Association** Organic Seaweed Standards cover both farmed and wild harvested marine algae (see page 8 for the standards on wild harvested marine algae).
2. The **European Commission** Regulation 710/2009 sets "conditions for the aquatic production environment and impacts on other species".
3. **Canadian Organic Standards** has standards set out in its "Organic production systems : aquaculture - general principles, management standards and permitted substances lists".

The suggestion that the NOSB require certification to an existing third-party certification system raises questions of jurisdiction. The challenge of adopting a third-party standard rather than simply adapting from it is that they cover the social and economic tiers of "sustainability", such as working conditions and wages, which are beyond NOP purview. For the purposes of organic production, "sustainable" harvest in marine environments addresses environmental impact. Additionally, any third party would need to be both impartial and expert in ocean sustainability. Concern has been raised by some in the conservation community that existing third-party standards don't take an ecosystem-wide perspective.

There were several suggestions for adopting annotations to §605.601 (j)(1) and §605.602. These included 1) adapting and/or elaborating the wild crop standard wording at §605.207 and 2) looking to the various third-party standards to identify and adopt sustainability benchmarks. Any annotation wording would need to be feasible for Material Review Organizations (MROs) to assess. The challenge arises in making an annotation enforceable and verifiable without accompanying certification. Who would perform on-site/on-boat inspections of each harvester's operation to measure and substantiate that their harvest and management procedures met the annotation criteria without a certification process?

Opting for organic crop certification employs a tool already at our disposal for verification. As one NOSB member noted in the fall 2018 board meeting discussion, the only way to ensure compliance with environmental standards is regulatory action.

[4] The Aquaculture Stewardship Council. "The ASC-MSC Seaweed Standard". Accessed on January 25, 2019. https://www.asc-aqua.org/wp-content/uploads/2017/06/BC2146_ASC-MSC_A4_6pp_ARTWORK_LRES.pdf.
[5] See: JONA Organic Standards, "Section 8 Organic Macroalgae Standards", pg. 40 http://www.jona-japan.org/form/JONA_Standards.pdf.

The fall 2018 Discussion Document presented a recommended proposal to require that marine algae ingredients in organic crop production inputs be certified organic to the wild crop standard under §205.207. Based on public comments, that language has been modified to the following (proposed language changes are underlined):

§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 use is limited to that amount necessary for extraction. Marine algae ingredients must be certified organic.

and

§205.602 Nonsynthetic substances prohibited for use in organic crop production.
The following nonsynthetic substances may not be used in organic crop production:
(j) Marine algae -- unless certified organic.

Note that the term "marine algae" in any annotation would be clearly defined to avoid confusion about the differences with the more general term used in §205.601 (j)(1), "aquatic plants". Moreover, it was proposed by commenters that organic certification could occur under either the wild crop or crops standard.

The Role of Guidance:
Regardless of the recommended action, guidance is necessary. Guidance could borrow from multiple standards to improve organic certification or for an annotation. The excerpts from the Appendix: Other Certifier and Third-Party Marine Algae Standards can provide a starting reference. The Materials Subcommittee's Fall 2018 Discussion Document offered some guidance evaluation questions and parameters obtained from public comments.

In the case of requiring organic certification, guidance is needed to explain what is meant by "not destructive to the environment and will sustain the growth and production of the wild crop" (§605.207 (b)) and "maintain or improve the natural resources of the operation" (§205.200). With an annotation not tied to certification, guidance would be required to define and provide measurement tools for environmentally "sustainable" harvesting.

Some said certifiers don't typically have the skills needed to certify marine algae to the wild crop standard. There are certifiers already doing this; however, there is undoubtedly a need for additional guidance and explanation as to how to apply the standards to a marine environment. Certifiers should be qualified through adequate training and education.

CONCLUSION:
While this is a new way of looking at a wild harvested crop input, that does not mean it is outside of the scope or purview of the NOSB. Organic agriculture is about more than simply limiting the use of synthetic ingredients. Farmers and consumers rely on the NOSB and the NOP to affirm the environmental integrity of organic production, including inputs used. Although finding a middle ground is always challenging, failing to do so will not resolve this issue. There are strong reasons for using the existing instrument of organic certification for marine algae ingredients; nevertheless, the NOSB is interested in obtaining further suggestions from stakeholders.

DISCUSSION QUESTIONS:

1. If you are not in support of requiring organic certification, what approach do you support? Please describe the method for defining, measuring, and most importantly, enforcing, that the harvest would not be destructive to the environment under an alternative approach.

2. Some existing wild harvest marine algae standards from other certifiers and third-party entities are listed in the Appendix. Please comment on strengths in these standards that could be adapted for NOP guidance. Please identify areas of weakness or areas that are not covered.

3. What existing certification or private standards to support marine algae harvest sustainability have not been included in this document or the Appendix that can help inform the NOSB's understanding of the current work being done?

4. How many crop input products approved for use in organic production currently contain certified organic marine algae ingredients?

5. Are there any crop input products utilizing or developing farmed marine algae?

6. Are there enough certifiers able to offer certification services to meet the needs of the crop fertilizer markets if organic certification were required? If organic certification were required of marine algae ingredients, what would be an appropriate phase-in time to allow markets to meet the demand?

7. The NOSB hopes to convene an expert panel at the fall 2019 board meeting to include a marine algae harvester for crop inputs, scientist, conservationist, and certifier, among others. What are some questions that could be posed to help identify the issues and solutions?

8. What are the standards for evaluating environmental harm? For example, what measures of community biodiversity and marine algae species characteristics (density, maximum height, girth, area) could be collected pre- and post-harvest? How soon must these variables return to baseline to avoid environmental harm?

Vote in Subcommittee:
Motion to accept the marine materials in organic crop production discussion document
Motion by: Emily Oakley
Seconded by: Harriet Behar
Yes: 5 No: 0 Abstain: 0 Absent:0 Recuse: 0

Approved by Emily Oakley, Subcommittee Chair to transmit to NOSB, May 20, 2019

Appendix of Excerpts from Other Certifier and Third-Party Marine Algae Standards:

Note: This is not intended to be an exhaustive list and is meant to provide examples and references to some existing marine algae certification standards.

This Appendix includes:

A. Soil Association organic seaweed standards Version 1.0 – January 2016
B. European Commission Regulation (EC) No 710/2009 of 5 August 2009
C. Canadian General Standards Board: Organic production systems Aquaculture – General principles, management standards and permitted substances lists
D. The ASC-MSC Seaweed Standard
E. Friend of the Sea Certification Criteria Checklist For Seaweed Products: Seaweed Harvesting and Farming
F. MOFGA Sea Vegetable Supplement

A. Soil Association organic seaweed standards Version 1.0 – January 2016[6]

SP c. Sustainable harvesting of wild seaweed
1. You must harvest wild seaweed without significant impact on the aquatic environment.
2. You must put in place measures that ensure seaweed regeneration, taking into account:
    a. harvesting technique
    b. minimum sizes
    c. minimum ages
    d. reproductive cycles or
    e. size of remaining seaweed.
3. You must keep records that demonstrate:
    a. the history of harvesting activity for each species in named beds
    b. that the seaweed harvested is wild seaweed and that it is harvested according to these standards
    c. that where you harvest seaweed from a shared or common harvest area, the total harvest complies with these standards.
4. Your records of harvest estimates and sources of potential pollution must provide evidence that you are managing the harvesting areas sustainably with no long-term impact.

B. European Commission Regulation (EC) No 710/2009 of 5 August 2009[7]

CHAPTER 1a
Seaweed production

Article 6a
Scope

[6] Soil Association. "Soil Association organic seaweed standards Version 1.0 – January 2016". Accessed on January 25, 2019. https://www.soilassociation.org/media/5250/sa-seaweed-standards.pdf.
[7] European Commission. "Commission Regulation (EC) No 710/2009 of 5 August 2009 amending Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007, as regards laying down detailed rules on organic aquaculture animal and seaweed production".

This Chapter lays down detailed production rules for the collection and farming of seaweed. It applies *mutatis mutandis* to the production of all multi-cellular marine algae or phytoplankton and micro-algae for further use as feed for aquaculture animals.

Article 6b

Suitability of aquatic medium and sustainable management plan

1. Operations shall be situated in locations that are not subject to contamination by products or substances not authorised for organic production, or pollutants that would compromise the organic nature of the products.
2. Organic and non-organic production units shall be separated adequately. Such separation measures shall be based on the natural situation, separate water distribution systems, distances, the tidal flow, the upstream and the downstream location of the organic production unit. Member State authorities may designate locations or areas which they consider to be unsuitable for organic aquaculture or seaweed harvesting and may also set up minimum separation distances between organic and non-organic production units.

Where minimum separation distances are set Member States shall provide this information to operators, other Member States and the Commission.

3. An environmental assessment proportionate to the production unit shall be required for all new operations applying for organic production and producing more than 20 tonnes of aquaculture products per year to ascertain the conditions of the production unit and its immediate environment and likely effects of its operation. The operator shall provide the environmental assessment to the control body or control authority. The content of the environmental assessment shall be based on Annex IV to Council Directive 85/337/EEC [(21)]. If the unit has already been subject to an equivalent assessment, then its use shall be permitted for this purpose.
4. The operator shall provide a sustainable management plan proportionate to the production unit for aquaculture and seaweed harvesting.

The plan shall be updated annually and shall detail the environmental effects of the operation, the environmental monitoring to be undertaken, and list measures to be taken to minimise negative impacts on the surrounding aquatic and terrestrial environments, including, where applicable, nutrient discharge into the environment per production cycle or per annum. The plan shall record the surveillance and repair of technical equipment.

5. Aquaculture and seaweed business operators shall by preference use renewable energy sources and re-cycle materials and shall draw up as part of the sustainable management plan a waste reduction schedule to be put in place at the commencement of operations. Where possible, the use of residual heat shall be limited to energy from renewable sources.
6. For seaweed harvesting a once-off biomass estimate shall be undertaken at the outset.

Article 6c

Sustainable harvesting of wild seaweed

1. Documentary accounts shall be maintained in the unit or premises and shall enable the operator to identify and the control authority or control body to verify that the harvesters have supplied only wild seaweed produced in accordance with Regulation (EC) No 834/2007.
2. Harvesting shall be carried out in such a way that the amounts harvested do not cause a significant impact on the state of the aquatic environment. Measures shall be taken to ensure that seaweed can regenerate, such as harvest technique, minimum sizes, ages, reproductive cycles or size of remaining seaweed.
3. If seaweed is harvested from a shared or common harvest area, documentary evidence shall be available that the total harvest complies with this Regulation.

4. With respect to Article 73b(2)(b) and (c), these records must provide evidence of sustainable management and of no long-term impact on the harvesting areas.

C. Canadian General Standards Board: Organic production systems Aquaculture – General principles, management standards and permitted substances lists[8]

7.2 Wild crops

7.2.1 An organic wild crop shall be harvested from a clearly defined area or production unit in accordance with this standard. Documented evidence that prohibited substances have not been used for at least 36 months before the harvest of an organic crop shall be available.

7.2.2 The operator shall prepare an organic plan (see 4.1, 4.2 and 4.3) that includes:

a) a detailed description of production areas and harvest methods. If wild crops are harvested from a shared or common area, records shall be available to demonstrate that the total harvest complies with this standard;

b) management practices that preserve wild species and avoid disturbance of the environment; and

c) a record-keeping system that meets the requirements of 4.4.

7.2.3 Harvesting shall be carried out in such a way that the amounts harvested do not cause significant impact on the state of the environment. Measures shall be taken to ensure that crops can regenerate. Examples of such measures include harvest techniques and tools, minimum sizes, ages, reproductive cycles or size of remaining crops. Evidence of sustainable management and of no long-term impact on the harvesting areas shall be provided.

7.2.4 The production zone for wild crops shall be situated in locations where water is not subject to contamination by products or substances not authorized for organic production, or pollutants that would compromise the organic nature of the production.

D. The ASC-MSC Seaweed Standard[9]

Certified seaweed operations must be well-managed, environmentally sustainable and socially responsible.

If you decide to begin the audit process, an accredited third party conformity assessment body (CAB) will provide an assessment team to independently score your farm or wild harvest operation to some or all of the 31 performance indicators (PIs) that make up the ASC-MSC Seaweed Standard.

[8] Canadian General Standards Board- Standards Council of Canada. "Organic production systems Aquaculture – General principles, management standards and permitted substances lists", pg. 23. CAN/CGSB-32.312-2018. Accessed on January 25, 2019. http://publications.gc.ca/collections/collection_2018/ongc-cgsb/P29-32-312-2018-eng.pdf.

[9] The Aquaculture Stewardship Council. "Get certified! Your guide to the ASC-MSC Seaweed Standard audit process", pg. 8. Accessed on January 25, 2019. https://www.asc-aqua.org/wp-content/uploads/2017/11/Get-Certified-Guide-Seaweed.pdf.

The number of PIs scored depends on the type of seaweed production system that you use. Your CAB will explain exactly which of the PIs will be scored for your operation.

Table 1: List of performance indicators

Principle 1 Sustainable wild populations
PI 1.1 Stock status
PI 1.2 Harvest strategy
PI 1.3 Genetic impact on wild stock

Principle 2 Environmental Impacts
PI 2.1 Habitat
PI 2.2 Ecosystem structure and function
PI 2.3 ETP species
PI 2.4 Other species
PI 2.5 Waste management and pollution control
PI 2.6 Pest(s) and disease(s) and management
PI 2.7 Energy efficiency
PI 2.8 Translocations
PI 2.9 Introduction of alien species

Principle 3 Effective management
PI 3.1 Legal and/or customary framework
P1 3.2 Decision-making processes
P1 3.3 Compliance and enforcement

Principle 4 Social responsibility
PI 4.1 Child labour
PI 4.2 Forced, bonded or cumpulsory labour
PI 4.3 Discrimination
PI 4.4 Health, safety and insurance
PI 4.5 Fair and decent wages
PI 4.6 Freedom of association and collective bargaining
PI 4.7 Disciplinary practices
PI 4.8 Working hours
PI 4.9 Environmental and social training

Principle 5 Community relations and interaction
PI 5.1 Community impacts
PI 5.2 Conflict resolution
PI 5.3 Rights of indigenous groups
PI 5.4 Visability, positioning and orientation of farms or water-based
PI 5.5 Identification and recovery of substantial gear
PI 5.6 Noise, light and odour
PI 5.7 Decommissioning of abandoned production units

E. Friend of the Sea Certification Criteria Checklist For Seaweed Products: Seaweed Harvesting and Farming [10]

3 - Biomass and Environmental Impact Assessment

3.1 In case of seaweed harvesting activity, an assessment of the status of the seaweed and its biomass by appropriate research institutes or other recognised institutions unconnected to any harvesting and/or processing industries must be undertaken and it must conclude that the seaweed is not overexploited nor endangered. [The auditor must make reference to the biomass studies (title, date, author).]
3.2 This requirement applies to all harvesting operations and to those farming operations producing more than 20 tonnes per year. An EIA or equivalent assessment of the harvesting or farming activity has been carried out with a positive outcome by the presiding authority or by other recognized independent institute or laboratory. [The auditor must check whether an independent environmental impact assessment or equivalent was carried out. The auditor must specify the title, date, author and significant conclusions of the inspected EIA or equivalent document. *In case the Organisation is not compliant for 3.1, it must alternatively be compliant to 3.2 and sub requirements.]
3.3 In case of non compliance with 3.2, farming activities producing more than 20 tonnes per year must alternatively be compliant with the following requirements:

3.3.1 sea-based systems must not imply removal of rocks, corals or other obstructions leading to damage to the coastal ecosystem;

3.3.2 sea-based systems must not imply removal of competitive grasses or predators leading to damage to the coastal ecosystem;

3.3.3 large scale sea-based farms must not influence coastal water movement in a detrimental way. Protection from erosion or other positive impacts would not constitute a non-compliance with this requirement;

3.3.4 any multiuser conflict must have been solved positive and allow other users access to the sea and to the shore.

3.3.5 a careful assessment of potential impacts must precede the introduction of any non-native species.

3.3.6 removal of mangroves for farming purposes is prohibited. In case removal has occurred, a reforestation program must fully compensate the mangroves degradation occurred and caused by the seaweed farming activity.

3.3.7 carrying capacity must have been independently evaluated, considering in particular the potential impact of nutrients removal. [The auditor must acquire documented information and evidence (text, photos, official documents to be annexed to the audit report) of the environmental conditions of the ecosystem prior to the installation and assess whether the site has led to a negative impact on the ecosystem.]
3.4 In case of farming operations of less than 20 tonnes each per year, but more than 20 tonnes on a regional or national level, a regional or national level independent assessment must prove compliance with requirements 3.3 and sub. The study cannot be older than 5 years. [The auditor must make reference to the regional or national level assessment. The auditor must run sample onsite checks at small scale producers and produce / report evidence of compliance.]

[10] Friend of the Sea. "Certification Criteria Checklist For Seaweed Products: Seaweed Harvesting and Farming (Latest update: 19/03/2014)" pgs. 7-9. Accessed on January 25, 2019. http://www.friendofthesea.org/public/news/en%20-%20checklist%20fos%20seaweed%2019032014.pdf.

F. MOFGA Sea Vegetable Supplement[11]

Part 2. WILD CRAFTED SEA VEGETABLES – Wild Crafted sea vegetables are sea vegetables harvested from natural growing areas along ocean coastline. Wild crafted sea vegetables must meet the wild crafting requirements of the NOP rule.

Wild Crafted Sea Vegetable Variety	Harvest Method	Site Locations (harvest area) (Please include each site on the Harvest Area Form.)*

*Include maps and a Landowner Affidavit, if applicable for each site. On each harvest area map designate harvest areas, boundaries, buffer zones, and sources of possible contaminants and prohibited materials.

Part 3. GROWING AREA DESCRIPTION: Cultured and/or Wild Crafted Sea Vegetables

3.1. Describe the natural environment of the harvest area. List any rare or endangered terrestrial or aquatic plants or animals that occur in the harvest area. Lists of rare or endangered plants and animals are available from MNAP or MDIFW.

3.2. Describe methods used to prevent negative impact to the harvest area and monitoring procedures used to verify lack of impact on the aquatic ecosystem, water quality and biodiversity.

3.3. How do your harvest practices ensure the health, sustained growth, and long-term viability of the wild crop(s)?

3.4. Approximately what percentage of the wild crop is harvested at each harvest? Are you aware of other harvesters working the same area?

3.5. List harvester training provided including frequency of trainings and the procedures used to ensure your collectors harvest crops in accordance with answers provided above.

3.6. What procedures are in place to prevent contamination from adjoining land/water use or other sources of contamination?

3.7. Describe your record keeping system for wild crop area management, monitoring, harvest and sales.

[11] MOFGA Certification Services LLC. "Sea Vegetable Supplement" pgs. 3-4. Accessed on January 25, 2019. https://mofgacertification.org/wp-content/uploads/Crop_2019_SeaVegetableSupplement.pdf.

National Organic Standards Board
Policy Development Subcommittee Proposal
Policy and Procedures Manual Revision
July 9, 2019

Introduction and Background

The PPM was established to assist the Board in the implementation of its duties under OFPA and to establish operating procedures and policies for the NOSB. During the period since the last revision (October 2016) the Policy Development Subcommittee has been compiling a list of minor revisions and suggested changes. The PDS has reviewed these suggested changes and proposes the following as listed in the table below.

Below, please find a marked-up copy of the PPM that has been revised and updated by the Policy Development Subcommittee. In addition to some minor clerical changes we have made the following changes (noted in red text in the proposal):

Summary Table of Changes

Section/Page	Change
III. D Page 8	Added to the NOSB Secretary's duties: To monitor and notify Subcommittee Chairs periodically of public comments posted in the open docket between the period when the meeting notice is posted in the Federal Register and when the proposals are posted (pg 8).
IV. F. 1 Page 20	Clarified language about when the new NOSB Chair takes office to match the language that is in VIII. F.
IV. G. 2 Page 22	Another type of discussion document: Petition material discussion document
IV. H. Page 23	Clarified the steps in the material review process for a new petition
IV. H. Page 24 Steps 2 & 3	Added clarifying language about how a Subcommittee determines sufficiency of a petition
IV. H. Pages 25 - 26, Steps 4 & 7	Added a process for a Subcommittee to develop a discussion document based on a petition
VIII. E. Page 34	Added an additional bullet point under the section about the policy for public communication between NOSB meetings for posting discussion documents and proposals between public meetings for review and public comment

Motion to accept the changes to the Policy & Procedures Manual (PPM)
Motion by: Steve Ela
Seconded by: Tom Chapman
Yes: 5 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Rick Greenwood, Subcommittee Chair, to transmit to NOSB, July 9, 2019

NATIONAL ORGANIC STANDARDS BOARD

POLICY AND PROCEDURES MANUAL

Adopted October 19, 2002
Revised August 18, 2005
Revised March 29, 2007
Revised November 30, 2007
Revised May 22, 2008
Revised November 19, 2008
Revised May 6, 2009
Revised November 9, 2009
Revised April 29, 2010
Revised October 28, 2010
Revised April 29, 2011
Revised December 2, 2011
Revised April 11, 2012
Revised April 26, 2016
Revised November 18, 2016
Revised November 18, 2016

NATIONAL ORGANIC STANDARDS BOARD (NOSB)
POLICY AND PROCEDURES MANUAL

Contents

I. INTRODUCTION/PURPOSE

This document provides procedures for the functioning of the National Organic Standards Board (NOSB) and is designed to assist the NOSB in its responsibilities. This policy and procedures manual does not supersede authority or responsibilities as specified in the Federal Advisory Committee Act or the Organic Foods Production Act (OFPA). NOSB members are encouraged to review this manual in depth as well as to become familiar with the OFPA, the USDA organic regulations at 7 CFR Part 205, and the NOSB Member Guide. Members are advised to periodically review the contents to refresh their understanding of the NOSB's role and duties. NOSB members are entrusted with the responsibility to act in the best interests of all members of the organic community and the public at large. The NOSB's success relies upon the ability to understand each other's respective roles, and to develop successful working relationships.

The primary roles and duties of the National Organic Standards Board (NOSB):

- Serve as a link to the organic community
- Advise USDA on the implementation of OFPA
- Propose amendments to the National List of Allowed and Prohibited Substances
- Protect and defend the integrity of organic standards

A. NOSB VISION STATEMENT

(NOSB Recommendation adopted October 19, 2002, revised November 30, 2007).
The NOSB's vision is an agricultural community rooted in organic principles and values that instills trust among consumers, producers, processors, retailers and other stakeholders. Consistent and sustainable organic standards guard and advance the integrity of organic products and practices.

B. NOSB STATUTORY MISSION

(NOSB Recommendation adopted October 19, 2002, revised November 30, 2007).
To assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of this title. (OFPA, Sec 2119 (a))

C. NOSB MISSION STATEMENT

(NOSB Recommendation adopted October 19, 2002, revised November 30, 2007).
To provide effective and constructive advice, clarification and guidance to the Secretary of Agriculture concerning the National Organic Program (NOP), and the consensus of the organic community.

Key activities of the Board include:

- Assisting in the development and maintenance of organic standards and regulations
- Reviewing petitioned materials for inclusion on or removal from the National List of Approved and Prohibited Substances (National List)
- Recommending changes to the National List
- Communicating with the organic community, including conducting public meetings, soliciting and reviewing public comments
- Communicating, supporting and coordinating with the NOP staff

II. AUTHORIZATION

The National Organic Standards Board (NOSB) is authorized under Section 2119 of the Organic Foods Production Act of 1990 (OFPA) (7 U.S.C. 6519), part of the Food, Agriculture, Conservation, and Trade Act of 1990 (FACT Act). The OFPA specified that the NOSB be established in accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C. App. 2.

A. ORGANIC FOODS PRODUCTION ACT OF 1990

The Organic Foods Production Act of 1990 (OFPA) authorizes the Secretary of Agriculture to establish a National Organic Standards Board (NOSB) in accordance with the Federal Advisory Committee Act to assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of OFPA (OFPA, 7 U.S.C. Section 6518(a)).

B. FEDERAL ADVISORY COMMITTEE ACT

The Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2) and its implementing regulations (41 CFR Part 101-6.10) govern the creation, operation, and termination of advisory committees in the Executive Branch of the Federal Government. The National Organic Standards Board (NOSB) is a Department of Agriculture (USDA) non-discretionary advisory committee required by the Organic Foods Production Act of 1990, as amended.

C. NATIONAL ORGANIC STANDARDS BOARD CHARTER

The Federal Advisory Committee Act requires advisory committees to have an official charter prior to meeting or taking any action. An advisory committee charter is intended to provide a description of an advisory committee's mission, goals, and objectives. The NOSB charter is renewed every two years as a requirement of FACA. The NOSB charter describes the purpose of the NOSB to "assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of OFPA."

III. NOSB ADMINISTRATION

A. NOSB Membership

OFPA specifies the membership composition of the NOSB as follows. The NOSB shall be composed of 15 members, of which:

- Four shall be individuals who own or operate an organic farming operation;
- Two shall be individuals who own or operate an organic handling operation;
- One shall be an individual who owns or operates a retail establishment with significant trade in organic products;
- Three shall be individuals with expertise in areas of environmental protection and resource conservation;
- Three shall be individuals who represent public interest or consumer interest groups;
- One shall be an individual with expertise in the fields of toxicology, ecology, or biochemistry; and
- One shall be an individual who is a certifying agent as identified under OFPA, 7 U.S.C. § 6518(b)

B. Nomination and appointment process

(NOSB recommendation adopted June 10, 1999)

NOSB members are appointed by the Secretary of Agriculture to a five-year term. The terms are staggered, and the USDA periodically requests nominations to fill upcoming vacancies. Selection criteria include the following:

- A general understanding of organic principles, and practical experience in the organic community, particularly in the sector for which the person is applying
- Demonstrated experience in the development of public policy such as participation on public or private advisory boards, boards of directors or other comparable organizations
- Participation in standards development and/or involvement in educational outreach activities
- A commitment to the integrity and growth of the organic food and fiber industry
- The ability to evaluate technical information and to fully participate in Board deliberation and recommendations
- The willingness to commit the time and energy necessary to assume Board duties
- Not currently serving (or have been elected to serve) on another USDA advisory committee or research and promotions council/board during your term
- Not registered as a lobbyist with the federal or state government

NOSB members serve without compensation. NOSB members are reimbursed by the USDA for approved travel and associated lodging expenses as determined by official federal government guidelines and regulations. In accordance with USDA policies, equal opportunity practices are followed in all appointments to the NOSB. Membership shall include to the extent possible the diverse groups served by USDA, including minorities, women, and persons with disabilities. The USDA prohibits discrimination in all of its programs and activities on the basis of race, color, national origin, age, disability, and where applicable, sex, marital status, familial status, parental status, religion, sexual orientation, political beliefs, genetic information, reprisal, or because all or part of an individual's income is derived from any public assistance program.

C. Responsibilities of the NOSB

(OFPA, 7 USC 6518(k)):

(1) **In General**. The Board shall provide recommendations to the Secretary regarding the implementation of this chapter.

(2) **National List**. The Board shall develop the proposed National List or proposed amendments to the National List for submission to the Secretary in accordance with section 6517 of this title.

(3) **Technical Advisory Panels**. The Board shall convene technical advisory panels to provide scientific evaluation of the materials considered for inclusion in the National List. Such panels may include experts in agronomy, entomology, health sciences and other relevant disciplines.

(4) **Special Review of Botanical Pesticides**. The Board shall, prior to the establishment of the National List, review all botanical pesticides used in agricultural production and consider whether any such botanical pesticides should be included in the list of prohibited natural substances.

(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.

(6) **Emergency Spray Programs.** The Board shall advise the Secretary concerning rules for exemptions from specific requirements of this chapter (except the provisions of section 6511 of

this title) with respect to agricultural products produced on certified organic farms if such farms are subject to a Federal or State emergency pest or disease treatment program.

Requirements. (OFPA 6518(l)) In establishing the proposed National List or proposed amendments to the National List, the Board shall

(1) review available information from the Environmental Protection Agency, the National Institute of Environmental Health Studies, and other sources as appropriate, concerning the potential for adverse human and environmental effects of substances considered for inclusion in the proposed National List;

(2) work with manufacturers of substances considered for inclusion in the proposed National List to obtain a complete list of ingredients and determine whether such substances contain inert materials that are synthetically produced; and

(3) submit to the Secretary, along with the proposed National List or any proposed amendments to such list, the results of the Board's evaluation and the evaluation of the technical advisory panel of all substances considered for inclusion in the National List.

Evaluation. (7 USC 6518(m)) In evaluating substances considered for inclusion on the National List the NOSB shall consider:

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

Petitions. (7 USC 6518(n))
The board shall establish procedures for receiving petitions to evaluate substances for inclusion on the List

Sunset Provision. (7 USC 6517 (e)) No exemptions or prohibition contained in the National List shall be valid unless the National Organic Standards Board has reviewed such exemption or prohibition as provided in this section within 5 years of such exemption or prohibition being adopted or reviewed and the Secretary has renewed such exemption or prohibition.

D. NOSB OFFICERS

Three principal officers, Chair, Vice Chair and Secretary, guide the NOSB. The NOSB members hold an election each fall at the public meeting to elect these three members.

CHAIR

The Chair is responsible for ensuring the integrity of the NOSB process, effectiveness of meetings and adherence to NOSB policies and procedures. The primary duties of the Chair are as follows:

- Schedules meetings of the Executive Subcommittee, in collaboration with the NOP
- Serves as a member of, convenes, and facilitates Executive Subcommittee meetings
- Convenes and presides over NOSB meetings
- Participates in the administrative team meetings
- Drafts NOSB meeting agendas in consultation with Subcommittee chairs and the NOP
- Reviews Subcommittee work agendas
- Reviews NOSB meeting minutes for accuracy
- Assists with the annual election of NOSB officers and announces the new officers

VICE CHAIR

The Vice Chair acts in the absence of the Chair. The primary duties of the Vice Chair are as follows:

- Serves as a member of the Executive Subcommittee
- Participates in the administrative team meetings
- Serves as a member of the Policy Development Subcommittee
- Helps maintain the Policy and Procedures Manual and ensures its accuracy

SECRETARY

The primary duties of the Secretary are as follows:

- Serves as a member of the Executive Subcommittee
- Participates in the administrative team meetings
- Records all NOSB member votes at NOSB meetings, and in collaboration with the Advisory Committee Specialist (ACS), circulates that record to NOSB members for approval
- Assists with the annual election of NOSB officers
- Monitors and notifies Subcommittee Chairs periodically of public comments posted to the open docket between the period when the meeting notice is posted in the Federal Register and when the proposals are posted.
- May delegate tasks to others, but retains responsibility for the official record

ADMINISTRATIVE TEAM

The Administrative Team consists of the Chair, Vice Chair, Secretary, and Designated Federal Official/Advisory Committee Specialist. . This group is responsible for coordinating logistics and operations of the Board. The Administrative team meets via teleconference on an as-needed basis, to be determined by the Administrative Team. This team is not a subcommittee and makes no decisions. All items needing further discussion or action are placed on the Executive Subcommittee agenda and are recorded in the Executive Subcommittee notes.

E. NOSB-NOP COLLABORATION

In 1990, the Organic Foods Production Act (OFPA: 7 U.S.C. 6518 (a)) directed the Secretary of Agriculture to "establish a National Organic Standards Board (in accordance with the Federal Advisory Committee Act (FACA)) ... to assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation" of the Act. Section 6503 (a) of the OFPA requires that the Secretary "shall establish an organic certification program … and shall consult with the NOSB" (6503(c)). The National Organic Program (NOP) is the governmental institution responsible for implementing the OFPA and is the means through which the NOSB provides advice and assistance to the Secretary of Agriculture. The NOSB, as a FACA advisory committee, must conduct business in the open, under the requirements of P.L. 94-409, also known as "Government in the Sunshine Act" (5 U.S.C.552b).

The USDA cannot delegate its authority as a regulatory body to private citizens, even when those private citizens are appointed by the Secretary to provide advice. Therefore, the NOSB cannot direct USDA or bind the Secretary through its actions; for example, it cannot obligate funds, contract, make NOP staffing decisions, or initiate policies of its own accord

However, the NOSB has unique statutory authority related to the recommendation of materials as approved or prohibited substances for inclusion on the National List.

The unique nature of the NOSB and its relationship with the NOP, as established through OFPA, requires that the volunteer Board, which regularly receives stakeholder input through public comment, must work collaboratively with the NOP.

Similarly the NOP, as required through OFPA, must consult and collaborate with the NOSB

Team work and collaboration between the NOSB and the NOP, as well as others in the organic community, is needed to maintain, enhance and promote the integrity of organic principles and products. Successful collaboration is dependent on effective communication and constructive feedback. Communication is facilitated by the Advisory Committee Specialist, who participates in all NOSB calls. Additionally, the NOP Deputy Administrator or designee will participate in all ES calls, and in other standing Subcommittee calls upon request and mutual agreement. In addition, each standing Subcommittee will be assigned an NOP staff person to provide technical, legal, and logistical support.

The work of the NOP and NOSB since the 1990 passage of the OFPA clearly demonstrates the need for the high level of collaboration and consultation described above. NOP, NOSB and its associated stakeholders must continuously work to seek common ground, collaborate and consult in order to build organics and maintain organic integrity. Every aspect of this work must take place in a manner which clearly demonstrates mutual respect and positive intent.

F. NOSB WORK AGENDAS

The NOSB Work agenda is a list of projects for the upcoming semester or year for each of the Subcommittees. Agendas are developed via collaboration between the NOSB and the NOP and are revised based on AMS-NOP requests, NOSB priorities, and public comment.

Work agendas are developed based on the following criteria:

- **Within Scope**: Item must be within the scope of OFPA. NOP must have a clear sense of the intent and scope of the work agenda item. The public may petition additions or deletions from the National List that will be added to the work agenda. In addition, the public may submit comments to the NOSB or write to the NOP for potential additions to the work agenda. For the NOSB, work agenda items may emerge from discussions on current issues.

- **USDA and NOP Priority**: Item must be a priority for the USDA/NOP; something that the NOP is able to implement in a reasonable timeframe.

- **Clear Need**: Item must reflect a clear need for the NOP and/or organic community, for which new or additional information or advice is needed.

The NOSB work agenda establishes Subcommittee work for the upcoming semester or year, and is developed through the following process:

1. NOSB Subcommittees submit to the Executive Subcommittee draft work agenda items based on AMS-NOP requests, NOSB priorities, and requests from public comment.
2. The NOP and Executive Subcommittee review the draft NOSB work agenda. The content and schedule will be reviewed on an ongoing, as needed basis.
3. NOP confirms the final NOSB work agenda, and provides written confirmation.

Work agenda items should be prioritized accordingly:

1. Substance evaluations (e.g., 5-year sunset review, petitions)
2. NOP requests to the NOSB
3. NOSB requests to NOP
4. Other projects

Below are descriptions of common NOSB work agenda items and the corresponding NOP and NOSB responsibilities.

- **Review of materials proposed to be added to or removed from the National List**
  The NOSB has the statutory authority to consider and recommend materials for addition to, or deletion from, the National List of Approved and Prohibited Substances. The NOSB may also make recommendations to add, remove, or modify annotations restricting the use of such listed materials.

- **Changes to annotation or classification of materials**
  The NOSB may request to review an existing substance on the National List without a new petition when they have justification to support a revision of the annotation or reclassification of the substance. This may happen as a result of the sunset review process, or as new information is provided in a Technical Review, or from public comment**.**

- **Recommendation for modification of existing standards or new standards**
  The NOP may request that the NOSB develop recommendations for new or existing standards. The request should be in writing and include a statement of the problem to be

addressed, background, including the current policy or situation, statutory/regulatory authority, legal context, and desired timeframe for receiving the recommendation. The request will be posted on the NOP web site.

- **Advice on NOP policy and interpretation of standards**
  The NOSB may provide comments on guidance or policy memos included in the Program Handbook, or may also make recommendations for new guidance or policies.

- **Compliance and Enforcement**
  The NOP is responsible for compliance and enforcement. The NOP welcomes NOSB input on standards, but NOSB involvement in active investigations or enforcement actions is not appropriate. When timely and appropriate, the NOP reports to the NOSB the status of enforcement actions and also posts the status on the NOP web site.

- **Management Review**
  The NOSB may review the quality management system and internal audits to ensure that the NOP is managed effectively and efficiently. For example, the NOSB may be asked for informal feedback or to work on specific work agenda items that relate to the development or implementation of audit corrective actions.

G. Designated Federal Officer

FACA and its implementing regulations (5 U.S.C. App. 2) govern the roles and responsibilities of NOSB management including meeting coordination and facilitation. The Designated Federal Officer (DFO) is the individual designated to implement advisory committee procedures. The AMS/NOP Deputy Administrator is the DFO for the NOSB.

The NOP Deputy Administrator or designee acts as the Designated Federal Officer (DFO) during public meetings of the NOSB and meetings of the Executive Subcommittee. The Advisory Committee Specialist (ACS) or designee acts as the DFO for all other NOSB Subcommittee meetings. The DFO holds the authority to chair meetings when directed to do so by the official to whom the advisory committee reports.

The DFO's duties include but are not limited to:

- Approving and calling the meeting of the NOSB
- Approving the semi-annual meeting agenda
- Attending the semi-annual meetings
- Adjourning the meetings when such adjournment is in the public interest

H. Advisory Committee Specialist

The Advisory Committee Specialist (ACS) is an NOP staff member who is assigned to support the NOSB. The Advisory Committee Specialist prepares the Advisory Committee's and Subcommittees' meeting agendas and notes, and attends all meetings. The position of Advisory Committee Specialist (formerly called Executive Director) was added in 2005 to facilitate communication and collaboration between the NOP and the NOSB. Advisory Committee Specialist duties include but are not limited to:

- Ensuring that all FACA and OFPA requirements are implemented
- Managing calendars and work agendas to facilitate Subcommittee and NOSB activities
- Arranging, facilitating, and documenting the NOSB Subcommittee conference calls
- Ensuring NOSB members have all necessary materials and information to provide informed, structured and timely recommendations to the NOP
- Conducting meeting planning activities for the semi-annual NOSB meetings, including preparation of Federal Register notices and press releases, and facilitation of public comments
- Coordinating the NOSB nomination and chartering process
- Facilitating training of NOSB members
- Managing information reporting and communication between the NOSB and NOP

I. ADDITIONAL ADMINISTRATIVE ITEMS

- Official to whom the Committee Reports
  The NOSB shall provide recommendations to the USDA Secretary through the Designated Federal Officer, the Agricultural Marketing Service's NOP Deputy Administrator.

- Staff Support
  The NOP shall provide administrative support to the NOSB through the work of an Advisory Committee Specialist, who is a permanent NOP staff member. The NOP may also provide technical support to the NOSB based on need and available resources.

- Estimated Number and Frequency of Meetings
  The NOSB meets approximately twice per year for public meetings. Most NOSB Subcommittees meet approximately twice a month by conference call.

- Recordkeeping
  Records of the NOSB shall be defined and handled in accordance with General Records Schedule 6.2 or other approved agency records disposition schedule. . This schedule is available online at: https://www.archives.gov/records-mgmt/grs/grs06-2.pdf. These records shall be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552. Requests for records should be handled in accordance with the GSA March 14, 2000 memo that is available online here: http://www.gsa.gov/portal/content/100785. Information about the NOSB is available online at: http://www.ams.usda.gov/rules-regulations/organic/nosb

  While meeting transcripts are not required under FACA, the NOP provides transcripts or meeting notes to support the transparency of NOSB meetings and to support subsequent rulemaking activities. Minutes of each NOSB meeting, as approved by the DFO and the NOSB Chair and Secretary, shall contain a record of the persons present, documents provided to the board, a complete and accurate description of matters discussed and

conclusions, and the outcome of voting. If not included in the minutes, a voting summary will be published that contains votes by member.

FACA requires (5 U.S.C. App. Section 10 (b)): "Subject to section 552 of title 5, United States Code, the records, reports, transcripts, minutes, appendixes, working papers, drafts, studies, agenda, or other documents which were made available to or prepared for or by each advisory committee shall be available for public inspection and copying at a single location in the offices of the advisory committee or the agency to which the advisory committee reports until the advisory committee ceases to exist."
Any request for FACA records must be made to the NOP.

While requests for FACA Board records do not have to go through the formal FOIA request process, those records must be reviewed by AMS/NOP before release, to determine whether any FOIA exemptions apply (e.g., personal information, business proprietary information). In addition, OFPA itself requires that no confidential business information be released, so emails and documents need to be reviewed before release to ensure that this requirement is met.

- **Freedom of Information Act** (FOIA; 5 U.S.C. 552). Under this Act, the public may request documents and other information pertaining to USDA actions. NOSB communications with USDA (including email) are subject to these requests, with limited exemptions. Some USDA information is routinely exempt from disclosure in or otherwise protected from disclosure by statute, Executive Order or regulation; is designated as confidential by the agency or program; or has not actually been disseminated to the general public and is not authorized to be made available to the public upon request. When there is a FOIA request for information, the USDA will review all relevant information and determine what qualifies for release, then provide it to the requestor.

J. PROFESSIONAL AND ETHICAL STANDARDS

As appointees of the Secretary, NOSB members must maintain high professional and ethical standards both within and outside of the NOSB. Areas of particular concern include professional conduct and conflict of interest.

1) NOSB Member Professional Conduct Standards

NOSB members shall:

- Observe ethical principles above private gain in the service of public trust.
- Put forth an honest effort in the performance of their NOSB duties.
- Make no commitments or promises of any kind purporting to bind the Government.
- Act impartially and not give preferential treatment to any organization or individual.
- Participate in meetings – Subcommittee conference calls as well as semi-annual meetings
- Serve on Subcommittees as assigned - Each member must be willing to serve on Subcommittees as assigned by the NOSB Chair, and to participate in the work of those Subcommittees.
- Be informed about NOSB business - NOSB members are expected to seek and study the information needed to make reasoned decisions and/or recommendations on all business brought before the NOSB.

To maintain the highest levels of honesty, integrity, and ethical conduct, no NOSB member shall participate in any "specific party matters" (i.e., matters that are narrowly focused and typically involve specific transactions between identified parties) such as a lease, license, permit, contract, claim, grant, agreement, or related litigation with the Department in which the member has a direct or indirect financial interest. This includes the requirement for NOSB members to immediately disclose to the NOP's Advisory Board Specialist any specific party matter in which the member's immediate family, relatives, business partners, or employer would be directly seeking to financially benefit from the Board's recommendations.

All members receive ethics training annually to identify and avoid any actions that would cause the public to question the integrity of the NOSB's advice and recommendations. The provisions of these paragraphs are not meant to exhaustively cover all Federal ethics laws and do not affect any other statutory or regulatory obligations to which advisory committee members are subject.

2) Additional Standards of Conduct

NOSB members should adhere to the following basic "standards of conduct" while in government service:

- Do not accept improper gifts (from those seeking actions from the Board).
- Do not use board appointments for private gain.
- Do not misuse internal non-public government information.
- Do not use government property and time improperly.
- Do not accept compensation for teaching, speaking, and writing related to your board duties.
- Do not engage in partisan political activities while performing your board duties or while in a federal building.
- Alert the NOSB designated federal officer (DFO) if you or your employer enters into a lawsuit against USDA or its sub-agencies.
- Refrain from sharing working documents with the public. Working documents are defined as information that a board member gains by reason of participation in the NOSB and that he/she knows, or reasonably should know, has not been made available to the general public: e.g. is not on the NOP or other public websites, or is a draft document under development by an NOSB Subcommittee.
- Do not circulate draft Subcommittee documents until they are finalized and publicly available to all on the AMS/NOP website.
- Use a professional, respectful tone in NOSB email correspondence; remember that all correspondence with government officials is subject to FOIA requests.
- To the maximum extent possible, NOSB members should speak with one voice. Although there may be disagreements within NOSB Subcommittees or working group sessions, once NOSB members leave the session, they have the responsibility to support the integrity of the process, whether or not they agree with the final outcome. While NOSB members retain the right to express minority opinions, the public airing of dissension could strain interpersonal relationships and create distrust and conflict among NOSB members. Such stresses could undermine the NOSB's ability to effectively carry out its role as a governmental advisory board.

3) Failure to participate

The NOSB typically has a heavy work load and thus active participation by all 15

members is essential to carry out the mandates in OFPA. When one or more members fail to actively participate in Board work the entire NOSB and the organic community is negatively impacted. If a Board member finds that s/he cannot consistently attend Subcommittee meetings, take on work assignments, complete Subcommittee work in a timely manner, or cannot attend the twice-yearly public meetings and public comment listening sessions, the NOSB Chair shall discuss the matter with the Board member, bring the concerns to the attention of the Executive Subcommittee, and if necessary, encourage the Board member to resign.

K. DECLARATION OF INTERESTS/Conflict of Interest

NOSB members are classified as **representatives** under the Federal Advisory Committee Act (FACA). Each representative is appointed to articulate the viewpoints and interests of a particular interest group. The Organic Foods Production Act (OFPA) prescribes these interest groups, which include farmers/growers, handlers, certifiers, environmentalists/conservationists, scientists, consumers and public interest groups, and retailers. Representatives are appointed to speak in "we" terms, serving as the voice of the group represented (e.g., "we farmers/growers believe…"). As such, NOSB members are not expected to provide independent expert advice, but rather advice based on the interests of the groups served.

NOSB members represent the interests of a particular group. As such, many of the interests are **acceptable interests**. An interest is acceptable if it is carried out on behalf of a represented group, and if a Board member receives no disproportionate benefit from expressing the interest. True **conflicts of interest** arise when an interest:

- Directly and disproportionally benefits you or a person associated with that member;
- Could impair your objectivity in representing your group; or
- Has the potential to create an unfair competitive advantage.

The appearance of a personal conflict and loss of impartiality, while not a true conflict, must be considered when conducting NOSB business.

Declarations of Interest/Conflicts of Interest Procedures
Board members are appointed in part because of their interests. As such, each NOSB member needs to actively consider their interests with respect to topics being considered by the Board, and identify whether these interests would create appearance problems. This consideration should occur at two specific points during the Board's work on a particular topic. The first consideration should occur at the Subcommittee level, when a Subcommittee begins work on material or topic. The second is when a discussion document or proposal advances from the Subcommittee to the full Board for consideration.

At the Subcommittee Level
NOSB members represent the diverse interests of a broad stakeholder community, and make recommendations that may have wide-reaching regulatory impacts across all of these interest groups. As such, NOSB member actions are carefully scrutinized.

Given this, the NOP has provided the following guidelines for NOSB members working at the Subcommittee level:

- Avoid leading projects for which you could reasonably be viewed by others as having a particular interest that would hinder your ability to objectively and fairly represent broader group interests, and to allow other members to represent theirs. If leading a project would likely lead others to believe you are "self-dealing" to benefit yourself or someone close to you, you should refrain from leading.

- If you feel you may have an appearance problem or conflict of interest, you should inform the DFO that a conflict may exist, and describe the nature of that conflict. You should also tell the Subcommittee impacted that you may have a conflict; sharing as much or as little about the nature of the conflict with other board members as you wish. After this declaration, you may continue to contribute to the discussion on the topic. As long as it is known there is a conflict of interest, the conflict does not preclude the member from contributing his or her input to the Subcommittee.

- If you are uncertain as to whether an interest constitutes an appearance problem or a true conflict, then contact the DFO to discuss it. In this case, the NOP, working with the USDA office of ethics as needed, will make the determination about whether a problem exists.

At the Full Board Level
Once discussion documents and proposals are posted for public comment, each NOSB member is to review the documents across all Subcommittees, and research any potential conflicts of interest due to organizational affiliation or relationships.

The following procedures will take place at the Board level:

1. Approximately 2-4 weeks before the meeting, the NOP's DFO will provide a matrix to all NOSB members that lists the items being considered at the meeting.

2. If you determine that you do have a conflict of interest, use the matrix to disclose that information and to declare a recusal from voting on the item(s).

3. If you are not sure whether an interest is acceptable or poses a problem, or if you are uncertain whether recusal is needed, contact the NOP DFO to discuss. The NOP, working with the USDA office of ethics as needed, will make the determination about whether a conflict of interest exists, and will instruct the member accordingly as to whether to vote or not.

4. Return your completed matrix approximately one week before the board meeting. The NOP will then use these to compile a list of all recusals for the meeting.

5. At the meeting, at the beginning of each subcommittee session or at a time designated at the discretion of the Board chair, the DFO will state: "the following Board members have a conflict of interest with the following documents, and will not be voting: e.g. Bob has a conflict and will recuse himself from the proposals CleanGreenA and GreatChemB (etc.)."

6. Once the DFO completes listing the recusals, the NOSB Subcommittee chair leading the session may invite additional information from members on a voluntary basis, with a statement such as: "if Board members wish to disclose information about their conflict, or any other information about their interests, they are welcome to do so at this time." this is to be stated as a general and voluntary invitation; no specific NOSB member is to be called on.

7. For any documents deferred to the last day of the meeting, the DFO will repeat the declaration of statement above at the start of the voting session for each subcommittee. When it is time to vote, the NOSB member recusing her/his self should state "recuse" when it is his or her time to vote.

IV. SUBCOMMITTEES

Subcommittees play an important role in administering the NOSB's responsibilities to make informed decisions. The Subcommittees are responsible for conducting research and analyses, and drafting proposals for consideration by the full NOSB. No Subcommittees are authorized to act in place of the NOSB. Subcommittees are either standing or ad hoc.

A. STANDING SUBCOMMITTEES

The current standing Subcommittees are:

- Executive (ES)
- Certification, Accreditation, and Compliance (CACS)
- Crops (CS)
- Handling (HS)
- Livestock (including Aquaculture) (LS)
- Materials (including GMOs) (MS)
- Policy Development (PDS)

Executive Subcommittee (ES)
The Executive Subcommittee of the NOSB shall be comprised of the Chair, Vice Chair, Secretary, and the Chairs of each of the standing Subcommittees. The Executive Subcommittee provides overall coordination for the NOSB including finalizing the NOSB meeting agenda and NOSB work agendas.

Certification, Accreditation, and Compliance Subcommittee (CACS)
The CACS drafts proposals for consideration by the NOSB to provide guidance, clarification, or proposed standards for the certification, accreditation and compliance sections of the USDA organic regulations and OFPA.

Crops Subcommittee (CS)
The CS drafts proposals for consideration by the NOSB to provide guidance, clarification, or proposed standards for the crop production sections of the USDA organic regulations and OFPA. The CS reviews substances under sunset review and petitions for addition to, or removal from the National List of Allowed and Prohibited Substances. The CS reviews technical reports (TRs), technical advisory panel reports (TAPs), and public comments concerning materials used for organic crop production to draft their proposals.

Handling Subcommittee (HS)
The Handling Subcommittee drafts proposals for consideration by the NOSB to provide guidance, clarification, or proposed standards for the handling and labeling sections of the USDA organic regulations and OFPA. The HS reviews substances under sunset review and petitions for addition to or removal from the National List of Allowed and Prohibited Substances. The HS reviews technical reports (TRs), technical advisory panel reports (TAPs), and public comments concerning materials used for organic handling to draft their proposals.

Livestock Subcommittee (including Aquaculture) (LS)
The LS drafts proposals for consideration by the NOSB to provide guidance, clarification, or proposed standards for the livestock and livestock feed sections of the USDA organic regulations and OFPA. The LS reviews substances under sunset review and petitions for addition to or removal from the National List of Allowed and Prohibited Substances. The LS reviews technical reports (TRs), technical advisory panel reports (TAPs), and public comments concerning materials used for organic livestock and aquaculture production to draft their proposals.

Materials Subcommittee (including Genetically Modified Organisms) (MS)
The MS drafts proposals for consideration by the NOSB to provide guidance, clarification, or proposed standards for the pertinent National List sections of the USDA organic regulations and OFPA. The MS works with the NOP and other NOSB Subcommittees in managing the Materials Review Process, which may include determining which Subcommittee will conduct a review, as well as tracking technical reports and the status of reviews for petitions and sunset materials. The MS also drafts proposals and discussion documents regarding the prohibition on the use of Genetically Modified Organisms (excluded methods) under the USDA organic regulations. Research Priorities are also a critical component of the annual work agenda of the MS.
In addition to a Chair, who will be appointed by the NOSB Chair, the MS shall include in its membership a representative from each of the Livestock, Crops, and Handling Subcommittees.

Policy Development Subcommittee (PDS)
The Policy Development Subcommittee provides clarification and proposed changes for NOSB internal policies, and procedures as needed, in collaboration with the NOP. The PDS, in collaboration with the NOP, also updates and revises the NOSB Policy and Procedures Manual and the Member Guide.

B. AD HOC SUBCOMMITTEES
At the discretion of the NOSB Chair, and with approval of the Executive Subcommittee and the DFO, ad hoc NOSB Subcommittees may be formed to develop policy and guidance on specific issues that involve multiple standing Subcommittee jurisdictions, or for issues or tasks that are very large and require additional resources to complete. Ad hoc Subcommittees must be comprised of current NOSB members, and may be either a combination of two or more standing Subcommittees to form a “joint” Subcommittee, or may be a completely new Subcommittee comprised of selected NOSB members from various standing Subcommittees. Ad hoc Subcommittees can be dissolved at the recommendation of the NOSB chairperson with the approval of the Executive Subcommittee. Ad hoc Subcommittee Chairpersons are non-voting members of the

Executive Committee.

C. SUBCOMMITTEE MEETINGS

Subcommittees generally hold meetings once or twice a month via telephone conference calls. Calls are scheduled well in advance on a regular reoccurring interval. Additional meetings can be held if a Subcommittee requests additional time and the NOP agrees to provide the resources to support the additional meeting. A majority of the members of a Subcommittee shall constitute a quorum for the purpose of conducting Subcommittee business.

D. TASK FORCES

The NOSB may request the establishment of a Task Force to explore specific issues or concerns relevant to the organic community and industry, and present to the NOSB draft proposals, discussion documents, or reports. Each task force shall:

- Have a specific work agenda approved by the NOP
- Have a clearly articulated project deliverable
- Include at least one current member of the NOSB
- Record and maintain meeting or conference call minutes, made available to the NOSB and the NOP
- Submit a final report to the NOSB
- Disband when the NOP notifies the Task Force that its work has concluded or when the task force is no longer necessary.
- Have a specific start and end date, which may be extended by the Executive Subcommittee, with concurrence by NOP.

E. **DUTIES OF SUBCOMMITTEE CHAIRS AND VICE CHAIRS**

Subcommittee Chair duties:

- Appoint a Subcommittee Vice Chair in consultation with Board Chair
- Consult with the Board Chair regarding Subcommittee appointments
- Schedule Subcommittee meetings as needed
- Draft Subcommittee meeting agendas and work agendas in consultation with Subcommittee members, the Executive Committee, and NOP staff
- Convene and preside over Subcommittee meetings
- Ensure Subcommittee meeting notes are recorded
- Ensure that Subcommittee meeting notes are reviewed for accuracy
- Report actions of the Subcommittee to the Executive Subcommittee and Board
- Serve as mentor/trainer for new Subcommittee Chair during transition periods
- Designate a liaison to the Materials Subcommittee to collect, compile and present the research priorities proposals.

Subcommittee Vice Chair duties:

- Provide support in developing and completing Subcommittee work agendas
- Assist in reviewing Subcommittee meeting notes for accuracy
- Represent the Chair in the event of the Chair's absence
- The Vice Chairs of the Crops, Livestock and Handling Subcommittees will serve on the Materials Subcommittee as liaisons for reviewing all petitioned substances.

F. TRANSITION OF SUBCOMMITTEE CHAIRS, VICE CHAIRS, AND MEMBERS (NEW AND CONTINUING)

Subcommittee Chairs shall be appointed to serve annually by the Chair of the Board. Vice Chairs and Subcommittee members shall be appointed by their respective Subcommittee Chair in conjunction with the NOSB Chair. The annual Subcommittee term shall be concurrent with the one-year term established by the Secretary (beginning on January 24 and ending the following January 23). Newly appointed Chairs, Vice Chairs and Subcommittee members will assume their positions at the beginning of the new term, after a period of orientation and mentorship provided by the outgoing Chair, Vice Chair, and members.

To avoid disruption in the quality and volume of work produced by the NOSB, the following procedures will be observed:

After the election of NOSB Officers at the Fall Meeting:

1. **The new NOSB Chair takes Office**
   At the close of the meeting at which the election occurred, the newly elected Chair takes office.
2. **Appointment of Subcommittee Chairs**
   The Board Chair appoints Subcommittee Chairs preferably chosen from members with at least one year of NOSB experience**.**
3. **Appointment of Subcommittee Vice Chair**
   Vice Chairs shall be appointed by the incoming Subcommittee Chair, in conjunction with the Board Chair.
   Timeframe for Appointments
   Subcommittee Chairs shall be appointed by the NOSB Chair and seated within a reasonable time after the newly elected NOSB Chair takes office (or continues in office), and Vice Chairs shall be appointed by Subcommittee Chairs as soon as possible after that.
4. **Review of Subcommittee Files**
   New Subcommittee Chairs should review all work agenda items and active files involving Subcommittee work
   Mentorship Period
   The incoming Chair and Vice Chair of each Subcommittee shall participate in an orientation and mentorship period with the outgoing Chair and Vice Chair of their Subcommittee until seated in their positions at the beginning of the new term on January 24. The Board Chair, to facilitate an effective transition for new members of the Board and ensure effective participation in Committee and Board deliberations, shall ask incoming Board members to identify a mentor from existing Board members, or, if the Board member prefers, the Board Chair shall assign a mentor.
5. **Appointment of New NOSB Members:**
   The Board Chair will appoint each new NOSB member to appropriate Subcommittees as soon as possible, so that on January 24 all Subcommittees are in place. The NOSB Chair will consult with outgoing and incoming Subcommittee Chairs and other Board officers, with due consideration of the members interest, expertise,

and background, as well as the composition and needs of the new Board and scope of Subcommittee work agendas. Once appointed, incoming Subcommittee members shall be included in all email communication pertaining to the Subcommittees on which they serve.

Changing Subcommittee Appointments
Board members who would like to join or leave a Subcommittee shall submit a request to the Board Chair. If the request does not alter the preferred number of Subcommittee members, in the range of five to seven, the expectation is that the request will be approved, unless the Board Chair finds that such a change will interfere with the functioning of the Subcommittee or the Board. The Chair's determination should be made in consultation with Subcommittee Chairs and the Executive Subcommittee.

Filling a Subcommittee Chair and/or Vice Chair vacancy
If a Subcommittee Chair position becomes vacant, the Subcommittee Vice Chair shall assume the position as Chair and the new Subcommittee Chair shall appoint a new Vice Chair in accordance with the consultation procedures cited above.

G. PROCEDURES FOR COMPLETING SUBCOMMITTEE PROPOSALS AND DISCUSSION DOCUMENTS

1. **Development of proposals**
   Each of the NOSB Subcommittees will develop proposals, discussion documents or reports based on the current work agenda.

   - A Subcommittee drafts a proposal or discussion document based on that Subcommittee's work agenda.
   - By a simple majority, the Subcommittee can vote to pass a proposal or discussion document to the full Board for consideration at a subsequent NOSB meeting. In order to be considered for a vote during an NOSB meeting, all proposals must be voted on by the Subcommittee and submitted to the NOP at least forty-five (45) days prior to a scheduled NOSB meeting.
   - When it is not possible for a Subcommittee, during its regular deliberations on conference calls, to reach consensus on a proposed document/recommendation as it is being reviewed, and there are substantive irreconcilable differences, a minority of the Subcommittee may develop a written minority view for review by all members of the Subcommittee. The Subcommittee Chair has the responsibility to facilitate the process for the minority view.
     A minority view should:
     - Be short and concise, and include reasons for opposing the Subcommittees recommendation;
     - Should not include any data or information not introduced on a Subcommittee call;
     - Should be submitted in a timely manner, and will not be accepted after the Subcommittee has voted on its recommendation;
     - Will be included as a separate section at the end of the recommendation.
   - The NOP will post the proposal or discussion document for public comment.
   - At any point in the process prior to the Board's vote, a Subcommittee may convene and, by a simple majority, vote to withdraw its proposal from consideration by the Board.

- During a subsequent Board meeting, the Subcommittee presents the proposals and discussion documents as well as a summary of public comments and other relevant information for discussion and consideration by the full Board.

2. **Types of Proposals**
   (See Member Guide for examples)
   There are several formats for writing proposals and discussion documents, based on the subject under review:
   - Proposals related to material petitions, sunset reviews, annotation changes, or classification changes.
   - Proposals for policy or procedure changes
   - Discussion documents
   - Petitioned material discussion documents

3. **Presenting Subcommittee Proposals and Discussion Documents at NOSB Meetings**
   NOSB Subcommittees and task forces should follow the outline below when presenting proposals or discussion documents for consideration by the Board:

   1. **Introduction**: A brief summary of the issue or statement of the problem.
   2. **Background**: An explanation with sufficient detail and rationale to support the proposal, including reasons why the proposal should be adopted, historical context, and the regulatory framework pertinent to the issue.
   3. **Proposal**: A concise explanation of the recommended action.
   4. **Subcommittee Vote**: The Subcommittee vote shall be reported. In the case of petitions to add materials to the National List, two votes will be reported; one for classification of the material as a synthetic or non-synthetic, and the other a motion to list.
   5. **Public Comment:** A brief summary of the public comments
   6. **Minority View**: If applicable, the minority view of a Subcommittee or task force member shall be reported. After the Subcommittee's proposal has been presented and the motion to adopt has been made, it is usual to allow the minority to present their views. The minority report is presented for information purposes only. If the Board then determines that the minority view has merit, it may send the proposal back to Subcommittee for further work, since it would be a substantive change to the proposal as presented.

H. SUBSTANCE/MATERIALS REVIEW PROCESS

A primary function of the NOSB is "to assist in the development of standards for substances to be used in organic production" (OFPA 6518 (a)). "The Board shall develop the proposed National List or proposed amendments to the National List for submission to the Secretary …" (OFPA 6518(k)). The OFPA also establishes a petition process by which the public can request additions or deletions to the National List and also provides for a 5 –year "sunset" review by NOSB of all substances on the National List. The Materials Review Process is a collaborative effort between the NOP and NOSB. Some phases of the review process are handled exclusively by NOP and some by the NOSB.

The petition process is open to all. Petitions must be filed in accordance with the most recent Federal Register notice instructions and NOP 3011, Procedure- National List Petition Guidelines, effective March 11, 2016.

In lieu of a formal petition, a Subcommittee (Livestock, Crops, Handling) of the NOSB may propose to remove a material from the National List by developing a proposal for consideration by the whole Board, provided that all criteria in OFPA at Section 6518(m) are documented as having been addressed in the proposal. Procedures for such a petition will be the same as for changes to annotations or classification of materials, as amended at H2 in this PPM.

Steps in the material review process for a new petition:

1. NOP receives a petition, reviews it for completeness and eligibility according to OFPA and the petition guidelines. NOP forwards the petition to the appropriate Subcommittee with a courtesy copy to the Materials Subcommittee.
2. Subcommittee (SC) determines sufficiency of the petition. If found insufficient, the subcommittee will notify the NOP of additional questions or information, and NOP will send that feedback to the petitioner.
3. Subcommittee (SC) determines if a technical review (TR) is needed.
4. SC may develop a discussion document based on the petition and forward that document to the full board for posting, and to solicit public discussion.
5. Technical report is completed and sent to the subcommittee for review.
6. TR sufficiency is determined by SC, and the TR is posted on the NOSB website by the NOP.
7. SC reviews substance, develops proposal, discusses proposal and votes, and submits for posting ~45 days prior to public meeting.
8. The NOSB members analyze comments and vote on the proposal at the public meeting.
9. The NOSB chair delivers the final recommendations to NOP.

Step 1: Receipt of Petition

During this phase the NOP will:

- Notify the petitioner via letter and/or electronic mail of receipt of the petition.
- Determine whether the petition is complete and whether the petitioned substance is eligible for petition under the Organic Foods Production Act and its implementing regulations, and whether subject to other agency authority (e.g. EPA, FDA);
- NOP documents this review using two checklists.
    - OFPA Checklist, NOP 3005-1
    - Petition Checklist, NOP 3005-2

Ineligible petitions include:

- Formulated (brand name) products
- Food additive without FDA approval
- Pesticide without EPA tolerance or tolerance exemption
- Requests to add substances already allowed
- Synthetic macronutrient (e.g., NPK) fertilizers

- Materials otherwise prohibited by the USDA organic regulations (e.g., sewage sludge, GMOs, etc.)
- Previously petitioned/rejected materials (if no new information is provided)

Upon determination of completeness and eligibility, NOP will:

- Notify the petitioner, via letter and/or electronic mail, that the petition is complete and eligible;
- Publish the petition on NOP website; and
- Notify the NOSB Subcommittee that the substance is being petitioned for addition or prohibition from the National List and provide the OFPA and petition checklists.
- NOP is the primary point of contact for any correspondence between NOSB and petitioner

Step 2: Subcommittee (SC) determines sufficiency of the petition

During this phase, the applicable NOSB Subcommittee has 60 days to review the petition and determine if the petition is sufficient for SC review. This decision may be based on the following:

- Is there sufficient information in the petition for the SC to determine why or for what purpose the material is being petitioned?
- what is the petitioners proposed wording for listing the material?
- Is the information presented in the petition clear and consistent so that a proposal may easily be developed?

If the petition is found insufficient, the Subcommittee will notify the NOP of additional questions or information, and NOP will send that feedback to the petitioner.

Step 3: Subcommittee determines whether a Third-Party Technical Review is required

During this phase, which may occur simultaneously with the determination of petition sufficiency, the applicable NOSB Subcommittee has 60 days to review the petition and determine whether a third-party technical review is required. This decision is based on the following:

- Is there sufficient information in the petition that makes a technical review unnecessary?
- Do any previous technical reviews of other materials provide sufficient information?
- Can the Subcommittee reasonably research any needed technical information?
- Can sufficient information be obtained from public comment?
- Does the Subcommittee have the expertise needed to address the questions related to the petition? This includes impact on the environment, impact on human health, and sustainability and compatibility with organic principles.

If the Subcommittee decides a Technical Review is needed, the Subcommittee Chair will make the request to the National List Manager. The SC may also submit questions for

specific information based on the OFPA evaluation criteria (7 USC 6817(m)), or suggest recommended technical expertise. The NOSB may request more information from the petitioner if needed.

If the Subcommittee decides the Technical Review is not needed, the Subcommittee Chair will inform the National List Manager.

In some cases, the Subcommittee may decide the substance is ineligible for the National List without need for a Technical Review. In this case, they will develop a proposal to reject the substance at the next NOSB meeting, subject to a full board vote.

A limited scope or supplemental TR may be appropriate when the petition is to amend an existing listing, remove a listing, or for purposes of sunset review.

Option for a Technical Advisory Panel (TAP)
OFPA states: "The NOSB shall convene technical advisory panels to provide scientific evaluation of materials considered for the National List."(7 USC 6518 (k)(3))
The NOSB has not convened independent Technical Advisory Panels since 2005.
Currently the NOSB is relying on information within the Technical Reports provided by the NOP and public comment to make their final recommendations
In some cases, NOSB may wish to convene a TAP instead of requesting a TR, for review of complex or controversial substances.

Step 4: Subcommittee may develop a discussion document based on the petition and forward that document to the full board and post it for public discussion

At the discretion of the Subcommittee (SC), the SC may develop a discussion document to:

- Solicit public comment about the material prior to a proposal being developed
- Provide opportunity for full board discussion prior to a proposal being written
- Allow the petitioner to hear public and board comments and give them an opportunity to submit petition addendums prior to a Subcommittee proposal and vote

A petition discussion document is optional, but if used, could allow for full board discussion of a material while a technical review is in process or if the SC determines a full board discussion would benefit the writing of the SC proposal on the material.

Step 5: Third Party Technical Review

During this phase the NOP will:

- Assign a contractor to develop a Technical Review (TR) or Technical Advisory Panel (TAP). The third-party contractor must have technical expertise relevant to the petition, and will use the TR template provided by NOP.
- Review all TRs or TAP reports before they are distributed to the Subcommittee to ensure they meet the requirements of the contract.

- Ensure that TRs/TAP reports are sufficient and complete when they are distributed to the Subcommittee

Third party experts may consist of contractors, or employees of the USDA, such as AMS Science and Technology, AMS Agricultural Analytics Division, Agricultural Research Service, or other federal agencies with appropriate expertise, as needed.

Step 6: Technical Review Sufficiency Determination

During this phase the Subcommittee (Crops, Livestock or Handling) will:

Review the draft TR to ensure that it:

- Is consistent in format, level of detail, and tone
- Is technically objective and free from opinions or conjecture
- Is written in a style appropriate for non-technical readers (e.g. free of technical jargon)
- Is prepared using a well-defined and consistent procedure consisting of information gathering, information synthesis and document preparation, and quality assurance
- Is based on the best available information that can be obtained within the designated time frame
- Is thoroughly supported using literature citations
- Addresses all evaluation questions in the TR template

The Subcommittee chair will notify the NOP, within 60 days of receiving the TR, that the TR is sufficient. If the TR is not found sufficient, the Subcommittee must provide the NOP with an explanation of why, including a request for additional information or improvements.

If necessary, the NOP will seek improvements or supplemental information from the contractor. Once the Technical Reports are deemed sufficient, the NOP will post on the NOP website.

Step 7: Review by the Subcommittee (Crops, Livestock or Handling)

During this phase the Subcommittee conducting the review will:

- Read the review, along with the submitted petition, and any additional information available, such as literature referenced in the Technical Review, personal knowledge, public or board comments from the optional petition discussion document, and recommendations of a contracted panel of experts when utilized.
- Subcommittee members will prepare a written review of the substance according to the OFPA criteria.
- After discussion, the Subcommittee will vote on classification (e.g., synthetic, nonsynthetic, agricultural) for substances not previously classified, and vote on a proposed action (e.g., add to National List, remove, or amend)
- The review, including record of votes, will be finalized as a proposal for the next meeting.

- All proposals must be submitted to NOP for posting 45 days before the public meeting date.

Step 8: Action by Full NOSB

During this phase the NOP will:

- Publish the proposals on the NOP website and provide a minimum of 30 days of written public comment on the proposal prior to the public NOSB business meeting.
- Include sufficient time on the agenda at the NOSB meeting for the Board to discuss the proposal, listen to public comments, and make a recommendation.

At the NOSB meeting:

- The Subcommittee Chair or delegated lead reviewer for each Subcommittee will present the proposals at the NOSB meeting. The proposals are to be presented in the form of a seconded motion coming from the Subcommittee, and the Chair will open the motion for discussion. After discussion board members will vote on the motion.
- Voting may be by show of hands, roll call, or by use of modern voting devices.
- The NOSB Secretary will record the votes of each NOSB member and the Chair will announce whether or not the motion passed.

Step 9: The NOSB Chair will review all final recommendations and submit them to the NOP

Changes to annotations, classification of materials, or proposal to remove.

The NOSB may request to review an existing substance on the National List without a new petition when they have justification to support a revision of the annotation, a reclassification of the substance, or removal of a substance. This may happen as a result of the sunset review process, or based on new information provided in a Technical Review, or from public comment. The following procedure should be followed:

- The Subcommittee sends a written request for a new work agenda item to the Executive Subcommittee.
- The request should include a summary of the issue, brief justification for the change, and resources in hand or needed for the project.
- The ES considers the request and determines if it should go forward.
- NOP reviews the item for possible addition to the work agenda, and may propose to add to a future meeting schedule depending on NOSB workload.
- The Subcommittee develops a proposal for consideration that is separate from the sunset review of the substance. NOP will then consider rulemaking action in a timely manner, without constraints due to the sunset timeline.

Additional considerations concerning Technical Reviews

Basic principles that should be considered when consulting with a third-party expert:

- A Subcommittee cannot proceed with a recommendation to list a material if it is determined that there is insufficient valid scientific information on that material's impact on the environment, human health and its compatibility with organic principles.
- The decision to request a third-party expert needs to be made independently of the availability of funds. If there is a lack of funding to secure third party expert advice, the Subcommittee has the option to place the review of new petitions on hold.
- The Subcommittee determines the completeness of the petition and whether a Technical Review is needed.
- The decision to define the expertise of the third-party expert is the responsibility of the Subcommittee reviewing the material or issue.
- To incorporate a diversity of opinions and to minimize the risk of bias, a Subcommittee may seek information from a range of technical experts (individuals or institutions). The Subcommittee may also ask questions in their posted proposals, in order to gain needed information from the public.

  The NOP will seek Technical Reviews from a range of experts. The name of the contracted party will appear on the Technical Review. All Federal contracts, including those issued by USDA/NOP to Technical Report contractors, are governed by the Federal Acquisition Regulations (FAR). The FAR includes a "Subpart 3.11—Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions," which requires contractors to identify and prevent personal conflicts of interest for their covered employees. "Personal conflict of interest" means a situation in which a covered employee has a financial interest, personal activity, or relationship that could impair the employee's ability to act impartially and in the best interest of the Government when performing under the contract.

  Link: https://www.acquisition.gov/far/current/pdf/FAR.pdf

Definitions

Technical Review - A report prepared by a third-party expert under contract addressing the environmental, human, and industrial impact of a petitioned material per the OFPA and regulatory evaluation criteria to aid in the thorough evaluation of that material by the NOSB.

Technical Advisory Panel (TAP) - Group of third-party experts convened by the Board to provide a technical review related to a material petition under review by the NOSB.

V. Prioritization of Petitions

Petitions received and deemed eligible and sufficient by the NOP/NOSB will be prioritized as follows:

Priority 1: A petition or proposal to **remove** a material presently on the National list that raises serious health, environmental, or regulatory concerns, including petitions to reconsider previous decisions, will be given the highest priority - **Priority 1,** above all other petitions in the queue of the reviewing Subcommittee (Crops, Handling, or Livestock).

Priority 2: A petition or proposal to **remove** a material presently on the National list not based on serious health, environmental, or regulatory concerns, but based on other new information, such as commercial availability status, would be assigned a **Priority 2,** behind Priority 1 petitions, but above any petitions to list materials that are in the queue of the reviewing Subcommittee (Crops, Handling, or Livestock). This priority assignment would include any removal petitions requesting reconsideration of previous board decisions, if the resubmitted

petition contains substantive new information to warrant reconsideration.

Priority 3: A petition to **add** a material to the National List will be considered by the reviewing Subcommittee (Crops, Handling, or Livestock) in the chronological order in which it was received, and will be designated as **Priority 3**.

Priority 4: A petition to **reconsider** adding a material that had previously been rejected by a Board vote would be given the lowest priority - **Priority 4**, and would go to the bottom of the Subcommittee (Crops, Handling, or Livestock) queue of petitioned materials. Petitions submitted for reconsideration must contain substantive new information to warrant reconsideration.

This prioritization guideline is only that, a guideline. When situations occur beyond the control of the reviewing Subcommittee, such as, but not limited to, technical report budgetary constraints, or a delay in the delivery of a technical review for a petitioned substance, the work agenda may require adjustment by the NOSB and NOP.

VI. Withdrawal of a petition by a petitioner

A petition may be withdrawn at any point in the process, prior to the vote by Subcommittee. Once a Subcommittee develops a proposal, the outcome will be posted for public comment and the NOSB will vote at the next public meeting. When a petition is withdrawn by the petitioner prior to Subcommittee proposal, the Subcommittee will suspend its review and recommendation procedure. Withdrawals will not be accepted after the Subcommittee votes on a proposal.

If a petition is re-submitted, the NOSB will review it in the order in which it was received. Thus, a re-submitted petition should be considered a new request and will be placed at the end of the queue of materials pending review.

A petitioner has the opportunity to withdraw a petition with the intent of improving it (e.g., conducting additional research), and may also voluntarily submit supplemental information.

VII. Sunset Review Process

The Organic Foods Production Act of 1990 (OFPA) authorizes a National List of Allowed and Prohibited Substances (7 U.S. C. Section 6517). Sections 6517 (e) mandates a Sunset Provision as follows:

“No exception or prohibition in the National list shall be valid unless the National Organic Standards Board has reviewed such exemption or prohibition as provided in this section within 5 years of such exemption or prohibition being adopted and the Secretary has renewed such exemption or prohibition.”

The NOP published a Federal Register notice on Sept. 16, 2013 (78 FR 56811) describing current procedures for sunset review. Through the sunset review process, the NOSB can recommend to USDA the removal of substances based on adverse impact on human health, the environment, or other criteria under the Organic Foods Production Act (OFPA). If upon review the NOSB believes the substance no longer fits the criteria for an exemption or prohibition, the NOSB can recommend (by a decisive two thirds vote, 7 USC Section 6158 (i)) to remove the substance from the National List. After the NOSB has completed this "sunset" review, the USDA must renew or remove the substances on the National List to complete the process. All substances

under sunset review will be considered over two NOSB meetings, to provide ample opportunity for public notice and comment. The NOSB observes the following procedure.

A. Steps in the Sunset Review Process (See Member Guide for forms used in these steps.)

Step 1: The NOSB Subcommittees submit the initial **Sunset List Summary** for posting which may include requests for specific information. The NOP posts the list as well as the NOSB Meeting Announcement in the Federal Register which invites comments, at least 30 days prior to the first public meeting on these sunset substances.

Step 2: The public submits written comments, which are analyzed by Subcommittees.

Step 3 (Public Meeting #1): Subcommittees summarize background and public comment & receive oral comment.

Step 4: Subcommittees analyze written and oral comments from Meeting #1 and prepare a **Preliminary Review** that includes a motion to remove the substance from the National List. The NOP publishes the next meeting announcement in the Federal Register, inviting comment on the **Preliminary Reviews,** which are posted on the NOP website.

Step 5: Written public comments submitted and analyzed by Subcommittees

Step 6 (Public Meeting #2): Subcommittees present **Preliminary Review**, receive oral comment, and discuss the proposal with the full Board. When presented to the full NOSB, reviews will contain a motion and second taken in Subcommittee. Motions for removal based on the **Preliminary Review** are voted on by the full Board, and require a decisive two-thirds (2/3) majority to pass.

At Meeting #2, the NOSB completes the **Sunset Review** and submits the final documents to the NOP.

Step 7: AMS reviews the NOSB Sunset Review and considers rulemaking action for any recommended removals. This will include a proposed rule open for public comment before a final rule amendment is published.

Step 8: AMS issues Federal Register Notice announcing renewal of applicable substances

Note: this is a regulatory process for determining whether materials already approved or prohibited on the National List should be removed. Due to regulatory process constraints, it is not possible to modify existing listings, add new uses of a listed substance during sunset review, or change annotations. If there is a need to consider changing an annotation or re-classifying a material, a Subcommittee may request to develop a separate proposal that will be reviewed separately from the sunset review process. Decisions made through the Sunset review should be transparent, non-arbitrary, based on the best current information and in the interest of the organic community and public at large.

VIII. NOSB PROCEDURES

A. BOARD MEETINGS

All Board meetings, assembled for the purpose of making recommendations to the NOP, are subject to FACA (see appendix B for FACA facts) and as such must be open to the public and must meet public notification requirements. Not all meetings are subject to FACA and do not require public notification. Examples of these exempted meetings include: Subcommittee calls, assemblies for completing work, planning retreats, training or sharing information. The date and location of in-person Board Meetings, currently held twice each year in spring and fall, will to the extent possible, be set at the mutual scheduling convenience of the NOSB and the NOP.

B. CONDUCTING BUSINESS

NOSB public meetings in brief:

- Approximately 3 days long depending on workload
- Meetings are held in various venues across the country to allow for participation by stakeholders that otherwise may not be able to attend due to travel constraints
- A typical meeting agenda includes presentations by the NOP, presentations of proposals and discussion documents by the NOSB Subcommittees, discussion time and votes on each proposal, public comment, NOSB officer elections, and a review of work agendas

Quorum: As specified in OFPA, a majority of the members of the NOSB shall constitute a quorum for the purpose of conducting business. (7 USC 6518 (h)). In cases of a medical situation preventing attendance in person, a virtual presence is permitted.

Decisive votes: As specified in OFPA, two-thirds (2/3) of the votes cast at a meeting of the NOSB at which a quorum is present shall be decisive of any motion (7 USC Section 6518(i)). All abstentions will be recorded as such and will not be included as part of the total vote cast in case of decisive votes. Similarly, all NOSB members who recuse themselves due to conflicts of interest, or are absent, shall be recorded as such and their votes will not be counted towards the total number of votes cast. Both abstentions and recusals will be considered in order to establish a quorum.

Calculation of Decisive Votes

# Votes Cast	# Recusals and Abstentions	2/3 Majority*
15	0	10
14	1	10
13	2	9
12	3	8
11	4	8
10	5	7
9	6	6
8	7	6

C. PARLIAMENTARY PROCEDURES

No procedures or business of the NOSB shall be taken in conflict with OFPA, FACA or other pertinent laws (herein referred to as governing legislation). For parliamentary procedure, all motions and votes not covered under the governing legislation shall be governed by this Policy and Procedure Manual if directly addressed. If procedures, motions and votes are not directly addressed in the Policy and Procedures Manual, they shall be governed by Robert's Rules of Order Newly Revised. The NOSB adopted the use of Robert's Rules of Order in March 1992, but modified its use as only a non-mandatory guide in May 1993. Roberts Rules may be adapted to meet the special requirements of a group. Because the NOSB is also subject to the OFPA, FACA and USDA, a designated NOP staff member may act as an informal Parliamentarian to advise the Chair.

D. NOSB DELIBERATIONS AND RECOMMENDATIONS

Board actions include but are not limited to: adoption of a proposal as presented by the Subcommittee, non-substantive amendments* and then adoption of a proposal, rejection of a proposal, or referral of the proposal back to Subcommittee for further development.

*** Substantive vs. non-substantive amendments.**

The following criteria shall be considered when determining if a proposal will be amended at the NOSB meeting, or must be referred back to Subcommittee and resubmitted for the next Board meeting. The DFO or designee will determine whether a proposed amendment to a proposal is substantive.

- The extent to which a reasonable person affected by the recommendation would have understood that the published proposal would affect his or her interests
- The extent to which the subject of the recommendation or the issues determined in it are substantially different from the subject or issues involved in the proposal
- The extent to which the effects of the recommendation differ from the effects of the proposal

Procedure for submitting final recommendations to NOP

Within 30 days after the completion of the NOSB meeting all final recommendations must be submitted to the NOP using the following procedure:

Each proposal lead prepares the following documents:

- A recommendation cover sheet (See Member Guide). The cover sheet should contain all appropriate information, including the vote recorded at the meeting. (The NOP can provide the voting record)
- The proposal that was voted on at the meeting

The proposal leads will forward the documents to the appropriate Subcommittee Chair who will review them for accuracy and completeness, sign and date them, and then forward them to the Board Chair and the DFO/ACS.

E. PUBLIC COMMENT

The NOP and NOSB encourage public comment and work collaboratively to increase opportunities for greater participation by a broad range of people, employing various modes of communication and modern technology whenever possible. Individuals may present oral comment at either a pre-meeting electronic webinar or at the in-person NOSB meeting.

Before Public Meetings:

Written comment: All members of the public are encouraged to submit public comment in writing according to the Federal Register Notice. Written submissions: allow NOSB members the opportunity to read comments in advance, eliminate or decrease the need for paper copies to be distributed during the meeting and allow each NOSB member to review and analyze data and information well ahead of the public meeting and possible voting.

Oral Comments

Oral comments: May be received via a virtual meeting/webinar. Public notice of such electronic meetings will be included in the Federal Register notice announcing the public meeting. Such electronic pre-meetings may allow individuals more time to present their data or information, reduce the need to attend the public meeting in person, reduce our carbon footprint, and give the NOSB more time to absorb the information. Such electronic meetings shall be recorded and made available to the public and to NOSB members.

Comments at In-Person Public Meetings:

- All persons wishing to comment at NOSB meetings during public comment periods must, in general, sign-up in advance per the instructions in the Federal Register Notice for the meeting. Persons requesting time after the closing date in the Meeting Notice, or during last minute sign-up at the meeting, will be placed on a waiting list and will be considered at the discretion of the NOP working closely with the NOSB Chair and will depend on availability of time.

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

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

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

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

- Proxy speakers are not permitted.

- Public comments may be scheduled according to topic.

- Individuals providing public comment shall refrain from making any personal attacks or remarks that might impugn the character of any individual.

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

Policy for Public Communication between NOSB Meetings (Adopted April 11, 2013)

- The NOSB and NOP seek public communication outside of Board biannual meetings and public comment periods to inform the NOSB and NOP of stakeholders' interests, and to comment on the NOSB's and NOP's work activities year around.
- The NOSB may post draft discussion documents and proposals between public meetings for review and public comment. Timely submission of comments will assist the NOSB and its Subcommittees in revising such documents for subsequent NOSB review.

F. ELECTION OF OFFICERS

Nominations

- Any NOSB member is eligible for consideration for any officer position
- An NOSB member may self-nominate or may be nominated by another member of the NOSB
- Should the Chair, Vice Chair, or Secretary resign or fail to serve the full term, the Executive Subcommittee shall appoint an interim officer. The interim officer shall serve in that capacity until the next regularly scheduled meeting of the NOSB, during which an election will be held to fill the remainder of the term
- Members may serve more than one term in any officer position.

Voting schedule

- Officers shall be elected for one-year terms by majority vote at the fall NOSB meeting.
- Newly elected officers will assume their positions at the conclusion of the Fall NOSB meeting, and assume the responsibilities thereof at that time
- Outgoing NOSB officers will assist the incoming officers with the transition into their new roles, to be completed no later than January 23rd of the following year.

Counting of Votes

- Voting will be by secret ballot immediately following nominations for each office.
- Ballots for officers will be cast in the following order:
    1. Chair
    2. Vice Chair
    3. Secretary
- Ballots will be counted for one office and the Secretary will announce the tally before the next office is opened for nominations.
- The Secretary and Vice chair will prepare and distribute the ballots, then collect them after each vote.
- The Secretary will tally the votes and the Chair will verify the results.
- The first nominee to receive a majority of votes will be elected. If no nominee receives the majority of votes, the nominee with the least votes will be eliminated and a revote will occur with the remaining candidates. This process will be repeated until a nominee obtains

a majority.

- In the event of a tie there will be a revote until a nominee obtains a majority. All nominees will be included in the revote.
- Votes will remain confidential, and ballots will be disposed of by the Chair or Secretary.
- A nominee may withdraw at their discretion at any time.
- In the event of only one nominee for office, the vote may be by acclimation.

G. MISCELLANEOUS PROCEDURES

1. Invited Speakers

- Subcommittees, the NOSB or the NOP may identify the need for presentations and speakers regarding subjects of interest or concern to be addressed at NOSB meetings.

- Requests must be made by the NOSB chair to the NOP no less than 60 days prior to the target NOSB meeting.

- Speakers must be approved and invited by the NOP.

  If approved by the NOP, the purpose for the presentation, the subject area and the bio/resume of speaker(s) should be circulated via email to the entire Board at least 2 weeks prior to the Board meeting.

  Current petitioners cannot be invited to be speakers about the topic under discussion, unless invited by the NOSB Chair.
  Speakers are expected to disclose any financial interests that he or she has that can be reasonably assumed to influence his or her presentation content.

2. Surveys Conducted on Behalf of NOSB Subcommittees

- All surveys, including electronic surveys, conducted on behalf of the NOSB, must be approved by the NOSB Executive Subcommittee before they are submitted for approval to USDA, and

- A written report summarizing the results of the survey must be submitted to the full Board and the NOP as soon as possible after completion.

IX. REVISIONS TO THE POLICY AND PROCEDURES MANUAL

- The PDS will review the PPM each year and, working in collaboration with the NOP, determine if any updates are necessary.

- Proposed changes will be subject to review and approval by the NOP and the full NOSB.

X. APPENDICES

A. Appendix 1: FOUNDATIONS

1. NOSB PRINCIPLES OF ORGANIC PRODUCTION AND HANDLING

(NOSB Recommendation Adopted October 17, 2001)

1.1 Organic agriculture is an ecological production management system that promotes and enhances biodiversity, biological cycles, and soil biological activity. It emphasizes the use of management practices in preference to the use of off-farm inputs, taking into account that regional conditions require locally adapted systems. These goals are met, where possible, through the use of cultural, biological, and mechanical methods, as opposed to using synthetic materials to fulfill specific functions within the system.

1.2 An organic production system is designed to:

1.2.1 Optimize soil biological activity;
1.2.2 Maintain long-term fertility;
1.2.3 Minimize soil erosion;
1.2.4 Maintain or enhance the genetic and biological diversity of the production system and its surroundings;
1.2.5 Utilize production methods and breeds or varieties that are well adapted to the region;
1.2.6 Recycle materials of plant and animal origin in order to return nutrients to the land, thus minimizing the use of non-renewable resources;
1.2.7 Minimize pollution of soil, water, and air; and
1.2.8 Become established on an existing farm or field through a period of conversion (transition), during which no prohibited materials are applied and an organic plan is implemented.

1.3 The basis for organic livestock production is the development of a harmonious relationship between land, plants, and livestock, and respect for the physiological and behavioral needs of livestock. This is achieved by:

1.3.1 Providing good quality organically grown feed;
1.3.2 Maintaining appropriate stocking rates;
1.3.3 Designing husbandry systems adapted to the species' needs;
1.3.4 Promoting animal health and welfare while minimizing stress; and
1.3.5 Avoiding the routine use of chemical allopathic veterinary drugs, including antibiotics.

1.4 Organic handling practices are based on the following principles:

1.4.1 Organic processors and handlers implement organic good manufacturing and handling practices in order to maintain the integrity and quality of organic products through all stages of processing, handling, transport, and storage;
1.4.2 Organic products are not commingled with non-organic products, except when combining organic and non-organic ingredients in finished products which contain less than 100% organic ingredients;
1.4.3 Organic products and packaging materials used for organic products do not come in contact with prohibited materials;

1.4.4 Proper records, including accurate audit trails, are kept to verify that the integrity of organic products is maintained; and

1.4.5 Organic processors and handlers use practices that minimize environmental degradation and consumption of non-renewable resources. Efforts are made to reduce packaging; use recycled materials; use cultural and biological pest management strategies; and minimize solid, liquid, and airborne emissions.

1.5 Organic production and handling systems strive to achieve agro-ecosystems that are ecologically, socially, and economically sustainable.

1.6 Organic products are defined by specific production and handling standards that are intrinsic to the identification and labeling of such products.

1.7 Organic standards require that each certified operator must complete, and submit for approval by a certifying agent, an organic plan detailing the management of the organic crop, livestock, wild harvest, processing, or handling system. The organic plan outlines the management practices and inputs that will be used by the operation to comply with organic standards.

1.8 Organic certification is a regulatory system which allows consumers to identify and reward operators who meet organic standards. It allows consumers to be confident that organic products are produced according to approved management plans in accordance with organic standards. Certification requires informed effort on the part of producers and handlers, and careful vigilance with consistent, transparent decision making on the part of certifying agents.

1.9 Organic production and handling operations must comply with all applicable local, state, and federal laws and address food safety concerns adequately.

1.10 Organic certification, production, and handling systems serve to educate consumers regarding the source, quality, and content of organic foods and products. Product labels must be truthful regarding product names, claims, and content.

1.11 Genetic engineering (recombinant and technology) is a synthetic process designed to control nature at the molecular level, with the potential for unforeseen consequences. As such, it is not compatible with the principles of organic agriculture (either production or handling). Genetically engineered/modified organisms (GE/GMOs) and products produced by or through the use of genetic engineering are prohibited.

1.12 Although organic standards prohibit the use of certain materials such as synthetic fertilizers, pesticides, and genetically engineered organisms, they cannot ensure that organic products are completely free of residues due to background levels in the environment.

2. NOSB GUIDANCE ON COMPATIBILITY WITH A SYSTEM OF SUSTAINABLE AGRICULTURE AND CONSISTENCY WITH ORGANIC FARMING AND HANDLING

(NOSB Recommendation Adopted April 29, 2004)

A significant responsibility of the NOSB is to determine the suitability of materials for use in organic production and handling. Among the criteria the Board must consider, OFPA requires the NOSB to determine the compatibility of a material with organic practices. The following questions were developed by the NOSB to assist in determining the compatibility of materials with organic practices.

In order to determine if a substance, its use, and manufacture are compatible with a system of sustainable agriculture and consistent with organic farming and handling, and in consideration of the NOSB Principles of Organic Production and Handling, the following factors are to be considered:

- Does the substance promote plant and animal health by enhancing the soil's physical chemical, or biological properties?
- Does use of the substance encourage and enhance preventative techniques including cultural and biological methods for management of crop, livestock, and/or handling operations?
- Is the substance made from renewable resources? If the source of the product is non-renewable, are the materials used to produce the substance recyclable? Is the substance produced from recycled materials? Does use of the substance increase the efficiency of resources used by organic farms, complement the use of natural biological controls, or reduce the total amount of materials released into the environment?
- Does use of the substance have a positive influence on the health, natural behavior, and welfare of livestock?
- Does the substance satisfy expectations of organic consumers regarding the authenticity and integrity of organic products?
- Does the substance allow for an increase in the long-term viability of organic farm operations?
- Is there evidence that the substance is mined, manufactured, or produced through reliance on child labor or violations of applicable national labor regulations?
- If the substance is already on the National List, is the proposed use of the substance consistent with other listed uses of the substance?
- Is the use of the substance consistent with other substances historically allowed or disallowed in organic production and handling?
- Would approval of the substance be consistent with international organic regulations and guidelines, including Codex?
- Is there adequate information about the substance to make a reasonable determination on the substance's compliance with each of the other applicable criteria? If adequate information has not been provided, does an abundance of caution warrant rejection of the substance?
- Does use of the substance have a positive impact on biodiversity?

3. NOSB MEMBER DUTIES

To fulfill their responsibilities, Board members agree to adhere to the following Duties.

Duty of Care

The Duty of Care calls upon a member to participate in the decisions of the Board and to be informed as to the data relevant to such decisions. In essence, the Duty of Care requires that a member:

- Be reasonably informed - It is the duty of all Board members to seek and study the information needed to make a reasoned decision and/or recommendation on all business brought before the Board. The NOP will provide some of that information, but other information must be developed from independent sources.
- Participate in decisions - Board members are bound by responsibility to be active participants in decision making. Absence from a meeting is no protection from the responsibility for decisions made at the meeting.
- Make decisions with the care of an ordinary prudent person in a similar position - The law requires Board members to exercise the judgment of an ordinary prudent person who may be faced with a similar issue.

Duty of Loyalty

The Duty of Loyalty requires Board members to exercise their power in the interest of the organic community and the public at large, and not in their own interest or the interest of another entity or person. In dispatching their Duty of Loyalty, Board members must:

- Address conflicts of interest - Board members bring to the NOSB particular areas of expertise based upon their personal and business interests in organic production and marketing. Because Board members may have interests in conflict with those of the public they must be conscious of the potential for such conflicts and act with candor and care. Board members must abide by the NOSB conflict of interest policy.
- Recognize corporate opportunity - Before a Board member votes upon an issue in which they have a direct financial interest, that Board member must disclose the transaction to the Board in sufficient detail and adequate time to enable the Board to act, or decline to act, in regard to such transaction.

Duty of Obedience

Board members are bound to obey the tenants of the laws and regulations governing organic production, processing and marketing. To this effect, Board members must:

- Act within the requirements of the law - Board members must uphold all state and federal statutes, including the Federal Advisory Committee Act (FACA – 5 U.S.C. App. 2 et seq.)
- Adhere to the responsibilities of the Board as defined by the Organic Foods Production Act of 1990
- Adhere to the requirements specified in the NOSB Policy and Procedures Manual

B. Appendix 2: FACA FACTS

The Federal Advisory Committee Act (FACA) (5 U.S.C. App.2) and its implementing regulations (41 CFR Part 101-6.10) govern the creation, operation, and termination of advisory committees in the Executive Branch of the Federal Government. The National Organic Standards Board (NOSB) is a Department of Agriculture (USDA) non-discretionary advisory committee required by the Organic Foods Production Act of 1990, as amended.

- Advisory committees must be chartered before they can meet or conduct any business. Charters must be renewed every two years, or they will be terminated under the sunset provisions of Section 14 of the FACA, unless otherwise provided by law.
- Advisory committee meetings are required to be open to the public, with limited exceptions as provided for in Section 552b of title 5, United States Code. Meetings not subject to FACA include NOSB briefing meetings initiated by the USDA to exchange facts and information, member orientation and training, and NOSB Subcommittee meetings. Such meetings are not subject to FACA because they are not conducted for the purpose of providing the USDA with NOSB advice or recommendations.
- Designated Federal Officers must approve all meetings and agendas, and attend meetings. The Advisory Board Specialist is the NOSB's Designated Federal Officer.
- Meeting notices and agendas must be published in the Federal Register to accommodate public participation. Although not required by FACA, the NOP strives to:
    - Post a provisional agenda on its web site no later than 90 days before the meeting is scheduled to begin
    - Post a final agenda, on its web site, no later than 45 days before the meeting is scheduled to begin
    - The NOP will strive to publish notice of the next NOSB meeting in the Federal Register as early after the previous NOSB meeting as possible. This notice will serve as an "open docket" in which public comment can be received by the NOP and NOSB. Notwithstanding the above, the NOP will publish notice of the meeting in the Federal Register no later than 45 days before the meeting is scheduled to begin
- While meeting transcripts are not required under FACA, the NOP provides transcripts or meeting notes to support the transparency of Board meetings and to support subsequent rulemaking activities. The NOP also issues a short meeting summary, which is required by FACA, after each biannual meeting that summarizes the key issues discussed, and the outcome of voting.
- Advisory committee documents must be available for public inspection and copying until the committee ceases to exist.
- Interested persons shall be permitted to attend, appear before, or file statements with any advisory committee, subject to reasonable rules or regulations.
- Additional information may be found at the FACA homepage: http://www.gsa.gov/portal/content/100916

National Organic Standards Board
Livestock Subcommittee Proposal
Use of Excluded Method Vaccines in Organic Livestock Production
July 16, 2019

Introduction and Background

There are two areas in the organic regulations that address use of vaccines; one on the National List (NL) of allowed and prohibited substances, and one in the section that details excluded methods. Through public comment and direct interaction with certifiers and organic producers, it became apparent that there are inconsistencies between certifiers about which vaccines are allowed. Some certifiers do not allow the use of excluded method vaccines, relying on the NOP regulation at §206.105 (e) which only allows use of this type of vaccine if it has gone through NOSB review and NOP placement on the National List. Other certifiers allow any type of vaccine to be used, and may or may not inquire if the vaccine has been produced through excluded methods. These certifiers rely on the presence of vaccines on the National List at §205.603(a)(4) without any restriction or clarifying annotation.

This issue was reviewed by the NOSB in October 2014: "Findings and Recommendations in Response to September 2010 NOP Memorandum on Livestock Vaccines Made With Excluded Methods". Challenges that prevented immediate attention to this issue included: having an updated definition of excluded methods that determines if new technologies were to be excluded methods for organic, having a clear understanding if there were non-excluded method vaccine equivalents to excluded-method-derived vaccines, and how to provide for use of excluded method vaccines if there was an emergency when only an excluded method vaccine could address the problem in a timely way.

In November 2017, the NOSB passed a recommendation that addresses how to determine if specific technologies should be considered excluded or not, with descriptions, terminology, and a listing of excluded, not excluded, and yet-to-be-determined methods. The NOSB will use this recommendation to review new technologies as they develop. The October 2014 NOSB recommendation lists commonly used vaccines that are known to have been made through excluded method technology. The NOSB strives to correct this inconsistency, to increase the trust of the organic certification system and provide consistency and certainty for organic livestock producers.

The Subcommittee recognizes the importance vaccines play in the prevention of livestock disease. When an organic livestock producer loses one or more of their animals, there is the loss of the animal's production capability, as well as a loss of time and resources associated with the breeding and selection that resulted in that specific animal. Breeding and selection often take years or even decades. When an animal is lost, all of those years of breeding and their unique genetics are also lost. The use of vaccines as a preventative can protect this long-term investment in genetic improvement, and vaccines remain an important tool in the organic livestock producer's toolbox to protect the investments that producers have in individual animals as well as their herds or flocks. The possibility of a livestock health emergency is real, and the NOSB is putting forth this proposal to have clarity in the use of vaccines from excluded methods, to provide certainty and consistency to both producers and certifiers in the determination of which specific vaccines can be used with organic livestock.

Relevant Areas of the Rule and Guidance
From the NOP Rule:

§205.2 Terms defined

Biologics. All viruses, serums, toxins, and analogous products of natural or synthetic origin, such as diagnostics, antitoxins, vaccines, live microorganisms, killed microorganisms, and the antigenic or immunizing components of microorganisms intended for use in the diagnosis, treatment, or prevention of diseases of animals.

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

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.

§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)

§205.600 Evaluation criteria for allowed and prohibited substances, methods, and ingredients.
The following criteria will be utilized in the evaluation of substances or ingredients for the organic production and handling sections of the National List:

(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).

The preamble to the National Organic Program final rule (65 FR 80547, December 21, 2000) states:

The Act allows use of animal vaccines in organic livestock production. Given the general prohibition on the use of excluded methods, however, we believe that animal vaccines produced using excluded methods should not be allowed without an explicit consideration of such materials by the NOSB and without an affirmative determination from the NOSB that they meet the criteria for inclusion on the National List. It is for that reason that we have not granted this request of commenters but, rather, provided an opportunity for review of this narrow range of materials produced using excluded methods through the National List process.

Excerpt from NOP Memo to NOSB dated September 30, 2010:

> The NOP's understanding is that excluded methods are prohibited under Section §205.105(e) *except for* vaccines. Further, this exception applies to vaccines that are produced through excluded methods only if those GMO vaccines are approved according to 205.600(a). Vaccines are listed under §205.603(a)(4) under "Biologics-Vaccines". The NOSB has not reviewed vaccines in accordance with §205.600(a). The listing under §205.603(a)(4) of Biologics-Vaccines does not include the allowance of GMO vaccines. The NOP requested a legal review from USDA's Office of General Counsel (OGC) to determine whether vaccines produced through excluded methods are currently allowed under 205.603(a)(4). The OGC opinion supports the position that GMO vaccines are allowed only if they are approved according to 205.600(a).
>
> The NOP recommends that the NOSB review GMO vaccines under the provisions of §205.600(a). The NOP suggests that the Board request a technical review for biologics-vaccines, including the status of genetically modified vaccines and an assessment of the economic impact of using commercial availability criteria for non-genetically modified vaccines. After the Board completes the evaluation according to the OFPA criteria, it may submit a recommendation to the NOP to add GMO vaccines to the National List of Allowed and Prohibited Substances.

Discussion and Goals of this Proposal

The Livestock Subcommittee strongly supports the use of vaccines as an essential component of maintaining animal health and promoting animal welfare. Vaccines are an essential tool for livestock producers to prevent serious health events in both individual animals as well as their entire herds or flocks. Interstate and international movement of livestock may require specific vaccinations for animals to be transported and sold. Currently, § 205.105(e) requires excluded method vaccines be reviewed and placed on the National List before use. This approach is impractical for a variety of reasons:

- There are new individual vaccines continually being developed; the NOSB will have difficulty reviewing these in a timely manner.
- Putting each of the excluded method vaccines on the NL is a lengthy process (2+ years) and puts organic livestock at risk in emergency situations when that vaccine may be needed immediately.
- Some excluded method vaccines may be patented and there may be confidential information that will not allow NOSB standard review of the material.
- Both the European Union and Canadian organic standards do not differentiate between the use of excluded method vaccines or standard vaccines, putting US organic livestock producers at a disadvantage when addressing animal disease.
- Some certifiers observe this restriction, and do not currently allow any excluded method vaccines, while others ignore this restriction and allow excluded method vaccines, or do not determine if a vaccine is made from an excluded method. This inconsistency causes problems for some producers and may lead to "certifier-shopping". Any time we can correct an inconsistency, we increase the trust of the organic certification system for both producers and consumers.

The NOSB, supported by the majority of public comment, is committed to not endorsing the blanket use of excluded method technologies. We seek to find a pragmatic way to stand against pervasive use of excluded methods in organic agriculture and foods, while being practical in accepting the fact that sometimes the only vaccines that are available are those made with excluded method technology.

In our discussion, we reviewed three options:

1. Allow all vaccines without any review or consideration if they were produced through excluded methods.
2. Allow vaccines from excluded methods, but only if they were individually reviewed and approved by the NOSB and placed on the National List by the NOP.
3. Allow vaccines from excluded methods, but only if a vaccine is not "commercially available" that had not been produced from excluded methods to effectively treat that health issue.

For option 1, the NOSB considered the issues below if there would be an allowance of excluded method vaccines "as a class" with no restriction.

- This is what is currently done in Europe and Canada.
- Less documentation needed by operators and certifiers.
- Allows for use of needed vaccines in an emergency with no restrictions.
- New excluded method technologies might provide additional animal health effects beyond just control of a specific disease, having a carte blanche approach might have unintended consequences beyond our intention of preventing animal illness.
- Might open the door to more use of excluded methods in organic.

For option 2, the NOSB considered these issues if there was no change to the current two references in the USDA organic regulations, both within the regulatory text and on the National List.

- Use of vaccines from excluded methods, at times the only vaccine to prevent the health issue, would not be available to some producers since their certifiers will continue to follow the current regulation as written.
- Certifiers who currently allow the use of excluded method vaccines, would continue to ignore the language of the regulation that requires these vaccines be in the National List before use, leading to a lack of consistency in implementation of the regulation, as well as confusion in the certification community resulting in some areas of the regulation to be ignored without consequences.
- The NOSB would need to solicit petitions for review of excluded method vaccines that are currently in use, to place them on the National List. Optimistically, the placement of these vaccines on the NL would take 2 to 4 years.
- In the case of a livestock disease outbreak, that can only be treated by excluded method vaccines, organic livestock producers would be at a disadvantage due to the lag time between the petitioning of a new excluded method vaccine and its eventual possible placement on the National List.

For option 3- change to the regulatory language could require that vaccines from excluded methods only be used when there are no commercially available vaccines produced without excluded methods. Allowance for the use of nonorganic seeds and some nonorganic agricultural products in processed organic foods, is currently allowed when there is no "commercially available" organic alternative. The term "commercially available" is defined in the USDA organic regulations as:

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

- A clear definition of how “commercial availability” will be applied when searching for vaccines made without excluded method technology and what documentation is sufficient to prove this search.
- Operators and certifiers are accustomed to “commercial availability” since it applies to use of organic seed and agricultural products found on §205.606.
- Would allow for quick use of an excluded vaccine in an emergency, when no other option is available.
- Encourages market availability of vaccines not made with excluded methods by providing organic buyers for these vaccines and showing a need for their continued manufacture.
- Might be difficult to clearly identify which vaccines are from excluded methods and which are not. Currently there is a list of widely used vaccines, but there may be others in use regionally or sporadically that are not listed.

Public Comment

At the April 2019 NOSB meeting, a discussion document was circulated with the following options and questions provided to the public for comment.

1. Follow the requirements of § 205.105 (e) and start reviewing known excluded method vaccines for individual placement on the National List.

2. Approve all vaccines produced through excluded methods as a “class” of vaccines and place this class of vaccines on § 205.603(a)(4).

3. Change § 205.105 (e) to read as follows:

   (e) Excluded methods, except for vaccines: Provided, That, there are no commercially available vaccines that are not produced through excluded methods to prevent that specific animal disease or health problem.

In addition, please provide information on the following:

4. What type of documentation would be used to prove non-commercial availability of vaccines produced without excluded methods?

5. When reviewing vaccines under commercial availability, are there special issues that should be considered?

The significant majority of the public responses supported option 3, changing the regulatory language to allow use of vaccines from excluded methods when no other vaccines were commercially available. There were some commenters that supported allowing all vaccines as a class, with no consideration applied if the vaccine was produced from excluded methods or not. There were no comments supporting the current regulatory language, which has led to inconsistency among certifiers in implementation of the regulation.

Determining commercial availability of a vaccine not produced through excluded method technology

The definition of commercial availability can be applied to vaccines in this manner.

- The vaccine is available in the specific route of delivery required by the operator (Injection, needle-free or transdermal, intranasal, ocular, oral, spray, topical.) (FORM)

- Information is present that details similar or not similar efficacies of the excluded and non-excluded method vaccines for that specific illness or health problem (QUALITY)
- Sufficient volume of the vaccine is present for the operator to purchase in their region, within the timeframe necessary for perishable vaccines, to vaccinate their livestock. (QUANTITY)

Resources to determine if a vaccine had or had not been produced through excluded methods

Commenters expressed concern that it could be difficult for both operators and certifiers to determine if there are commercially available vaccines not made from excluded methods. There are some references to aid in this determination. The August 2014 NOSB document, entitled "Findings and Recommendation in Response to September 2010 NOP Memorandum on Livestock Vaccines Made With Excluded Methods", provides a variety of references and labeling options to aid producers and certifiers in determining if the vaccine may have been produced using excluded method. A summary is excerpted here, with more detail found in the original document.

Label Guidelines: CVB (Center for Veterinary Biologics) regulations require that certain vaccine seed configurations have specific terms on the labels of branded vaccine products. These terms are required for a subset of biotechnology derived vaccines. While these terms are not added to the labels because an excluded method was used, CVB states that all such vaccines were created using methods that the NOP would exclude. The terms on labels that identify vaccines were made with excluded method are "Subunit," "Vector," and "Chimera." Because these vaccines are labeled with the identified terms, CVB can disclose a trade names list for all of these vaccines.

Product Code: The CVB requires that every biologic, including vaccines, produced must have a product code. The CVB guide on true names and product codes notes that the 5th digit of the product code may contain "D" or "R." The letter "D" in the fifth digit signifies that the vaccine is a nucleic acid vaccine. Such vaccines, also called DNA vaccines, are made with excluded methods and depend upon foreign genes being expressed in some of the cells of the vaccinated animals. The letter "R" in the fifth digit signifies the vaccine has a recombinant component or is a subunit protein derived from a recombinant organism. The recombinant designation only applies to components in the vaccine and not to methods used to make the vaccine such as genetically engineered cells that are used for cell culturing the vaccine seed.

In addition, the terms nucleic acid vaccine, naked DNA vaccine, RNA vaccine and genetic vaccine may be used to label vaccines produced through methods that are considered excluded by the NOSB.

An important reference is the USDA publication "*Veterinary Biological Products- Licensees and Permittees*", with the most current version from July 1, 2019 present at this link https://www.aphis.usda.gov/animal_health/vet_biologics/publications/CurrentProdCodeBook.pdf

Operators and certifiers can refer to this publication, and when using the coding system discussed above by the CVB, it would be the first step to determine if a vaccine, had or had not been produced through excluded method technologies. As a final confirmation, certifiers could provide an affidavit for manufacturers to complete detailing whether or not their vaccines were produced through excluded methods, using the list of excluded method technologies maintained by the NOSB. The APHIS publication also lists vaccines that had not been produced through excluded technologies that target the same disease, and would facilitate the search for commercially available vaccines that had not been produced through excluded methods.

Another source of information is present in the NOSB requested Technical Review of "Vaccines Made from Genetically Modified Organisms" from 2011. While this information is somewhat dated, it can be used as a starting point for updating using more recent information.

Table 1. Selected Conventional and GMO Vaccines Used for Food Animals[a]		
Disease	**Conventional vaccine/strain**	**GMO vaccine/strain**
Bacterial		
Brucellosis (ruminants)	*Brucella abortus*, strain 19, strain RB51	None identified
Brucellosis (swine)	*Brucella suis*, strain 2	None identified
Anthrax (bovine, ovine, equine)	*Bacillus anthracis*, strain Sterne	None identified
Johne's disease	*Mycobacterium paratuberculosis* strain 316F	None identified
Contagious bovine pleuropneumonia	*Mycoplasma mycoides* subsp. *mycoides* SC, strain T1/44	None identified
Avian salmonellosis	*Salmonella enteric* servo. Gallinarium, strain R9	*Salmonella typhimurium* vaccine, live culture

Table 1. Selected Conventional and GMO Vaccines Used for Food Animals[a]		
Disease	**Conventional vaccine/strain**	**GMO vaccine/strain**

Bovine salmonellosis	None identified	*Salmonella dublin* vaccine
Poultry cholera	*Pasturella multocida* (various strains)	None identified
Cattle pasteurellosis	Manheimia (*Pasteurella*) *haemolytica* (various strains)	None identified
Swine atropic rhinitis	*Bordetella bronchiseptica* (various strains)	None identified
Bovine clostridiosis	*Clostridium perfringens*	None identified
Escherichia Coli in poultry	*Escherichia coli* vaccine, avirulent live culture	*Escherichia coli* vaccine, live culture
Viral		
Avian encephalomyelitis	Live and modified live virus	Avian encephalomyelitis-fowl pox-laryngotracheitis vaccine
Porcine circovirus (swine)	Type 2, killed virus	Porcine circovirus vaccine (Type 1 -Type 2 chimera, killed virus; and Type 2 killed, baculovirus vector)
Marek's disease (poultry)	Live strains of Marek's disease virus, serotypes 1, 2, or 3	Marek's Disease-Newcastle Disease live virus vaccine, Serotypes 1 & 2 & 3, live Marek's disease vector; and Marek's disease live herpesvirus chimera
Newcastle disease (poultry)	Bursal-disease-newcastle disease-bronchitis vaccine, killed or live virus; live virus VG/GA strain; killed virus; and B1 type, B1 strain live virus	Newcastle disease-fowl pox vaccine, live fowl pox vector; and Marek's disease-Newcastle disease vaccine, serotype 3, live Marek's disease vector

Bursal disease (poultry)	Live or killed avian *bursitidis infectivae* virus type 1	Bursal disease-Marek's disease vaccine, Serotype 3, live Marek's disease vector
Fowl pox	Live fowl pox vaccine	Fowl pox-laryngotracheitis vaccine, live fowl pox vector
Fowl laryngotracheitis	Modified live virus vaccine	Fowl pox-laryngotracheitis vaccine, live fowl pox vector

[a]Sources: Frey (2007); USDA (2011)

Lastly, certifiers and the NOP could communicate with each other and develop a listing of excluded method vaccines, that do not have any commercially available equivalents and that were not produced through prohibited technologies, as well as excluded method vaccines that do have a commercially available equivalent that were not produced through excluded method technologies. Manufacturers of vaccines not produced through excluded method technologies, could choose to be OMRI listed as well. Public interest groups may also choose to do some of the research to aid certifiers and operators in understanding which vaccines are or are not produced through excluded methods.

The NOSB understands that this will add another layer of review for some operators, however, with the 2+ years of lag time between NOSB approval of this regulatory change, and a NOP final rule, the identification and tracking system for the various types of vaccines could be put in place.

The NOSB continues to work on determining which types of technologies should be excluded from allowance in organic production, with a complete list of the reviewed technologies provided in the most recent recommendation. The NOSB, through this work, can provide the organic community with the excluded method determinations needed when new technologies are put into commercial use.

The current rule reads:
§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)

Subcommittee proposal

The NOSB Livestock Subcommittee recommends the following change to the National Organic Program Final Rule §205.105 (e) (Changes to the current rule noted in bold).

Motion to change the USDA organic regulations at §205.105 (e). (Additions to the current rule noted in bold).

> *(e) Excluded methods, except for vaccines: Provided, That**, vaccines produced through excluded methods may be used when an equivalent vaccine not produced through excluded methods is not commercially available.***

Subcommittee Vote

Motion to change the USDA organic regulations at § 205.105 (e). Addition to the current rule noted in bold.

> *(e) Excluded methods, except for vaccines: Provided, That**, vaccines produced through excluded methods may be used when an equivalent vaccine not produced through excluded methods is not commercially available.***

Motion by: Harriet Behar
Seconded by: Ashley Swaffar
Yes: 5 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Sue Baird, Subcommittee Chair, to transmit to NOSB July 17, 2019

Sunset 2021
Meeting 2 - Review
Livestock Substances §205.603
October 2019

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 2021. 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.

Request for Comments

Written public comments will be accepted through October 3, 2019 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the October meeting.

Sunset 2021
Meeting 2 - Review
Livestock Substances §205.603
October 2019

Note: The materials included in this list are undergoing early sunset review as part of the November 18, 2016, NOSB recommendation on efficient workload re-organization.

Reference: 7 CFR 205.603 Synthetic substances allowed for use in organic livestock production

Atropine
Hydrogen peroxide
Iodine (§205.603(a))
Iodine (§205.603(b))
Magnesium sulfate
Parasiticides: Fenbendazole
Parasiticides: Moxidectin
Peroxyacetic/Peracetic acid
Xylazine
DL-Methionine
Trace minerals
Vitamins

Atropine

§205.603 Synthetic substances allowed for use in organic livestock production.
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 TAP; 2019 Technical Report
Petition(s): 2002 Petition
Past NOSB Actions: 05/2003 sunset recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Background
Atropine sulfate, typically referred to as **a**tropine, is an anti-cholinergic derived from *atropa belladonna* (deadly nightshade) roots; it is isolated via various synthetic extraction processes. Atropine sulfate belongs to a group of medicines called antimuscarinic agents and can be administered by tablet, intravenously, injection, or can be absorbed through the skin. It is a highly controlled substance, administered under orders of a licensed veterinarian. The withdrawal periods of 56 days and 12 days are twice the listed FARAD Withdrawal Interval (WDI). According to the 2019 TR, atropine is itself toxic, with the risk of toxicity dependent on the relative ability of various species to metabolize atropine (cattle and pigs are the agriculturally most sensitive to atropine toxicity).

Range of uses
Atropine is administered to block or reverse the adverse effects caused by some medicines and is used to relieve the symptoms of organophosphate poisoning. Atropine is commonly administered as a pretreatment for anesthesia during surgical procedures (EMEA 1998, USDA 2002). The same antimuscarinic properties that provide relief for organophosphate poisoning also works to reduce secretions (e.g., sweat, saliva) and relax smooth muscles prior to the administration of anesthesia, reducing the risk of airway obstruction (Jones et al. 1977, USDA 2002, Brunton et al. 2006, EFSA 2008). Atropine, typically given intravenously or by injection into a muscle, is often administered with many anesthetic agents to prevent the slowing of the heart rate during surgery. After surgery Atropine is effective as a bradycardia treatment to raise heart rates following anesthesia in surgical procedures. Atropine has several ophthalmic (eye-care) applications due to its ability to induce pupil dilation and cycloplegic properties (paralysis of eye muscles) (EMEA 1998, Herring et al. 2000). When applied to the eye, these relaxations act to reduce pain and dilate pupils, making it useful for treatment in equine uveitis and as a presurgical treatment for cataract extractions. Atropine also affects iris permeability for glaucoma treatments…." (Herring et al. 2000, Williams et al. 2000, 106 MedlinePlus 2017)

International allowance for use
According to the 2019 TR, atropine is listed on the Canadian General Standards Board Permitted Substances List. However, it is not listed for use under:

- CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods;
- European Economic Community (EEC) Council Regulations;
- Japan Agricultural Standard (JAS) for Organic Production; or
- International Federation of Organic Agriculture Movements (IFOAM).

Environmental contamination
According to the 2019 TR, "Due to the limited application of atropine (for veterinary medicine, approved for use only when used or ordered by a veterinarian), and the small quantities administered (milligrams), atropine is unlikely to be a source of environmental contamination…." The 2019 TR also states that "There are no reported studies on the persistence or concentration of atropine (neither D-hyoscyamine nor L-hyoscyamine), or the metabolized products tropine and tropic acid, although tropine has been identified as 'readily biodegradable' …. Tropine has also been identified as toxic to aquatic invertebrates, including *Daphnia magna* (water fleas) at concentrations of 54.7 mg/L…."

Effect on human health
According to the 2019 TR, "Atropine is most commonly administered intravenously, although it may also be applied via ingestion, or ocular absorption (applied directly to the eye) …. Intravenous administration of the substance using proper medical protocols (e.g., gloves, premeasured doses) makes inadvertent human absorption unlikely. Due to the neurophysiological profile of atropine, its absorption also poses toxicological concerns. Atropine intoxication is associated with symptoms including abdominal pain, confusion and disorientation, hallucinations, urinary retention, hypothermia and tachycardia …. Atropine toxicity can be lethal in humans, however, the level of toxicity and its relationship to fatal outcomes is not well defined."

Natural (non-synthetic) alternatives
According to the 2019 TR, "Atropine is recognized as the most efficient treatment option for organophosphate poisoning within both human and veterinary medicine…." The TR also states that "Magnesium sulfate ($MgSO_4$) is approved for use in organic livestock production at 7 CFR 205.603, and is being studied as a potential alternative or additional treatment to atropine administration for organophosphate treatment protocols…." However, this substance "has seen little clinical applications, and more studies are required to evaluate its effectiveness compared to traditional atropine and atropine oxime combination treatments…."

Public Comment from the Spring 2019 NOSB Meeting
In written comments submitted for the spring 2019 NOSB meeting, five commenters supported relisting atropine as essential for use in organic animal production. Two more commenters stated that atropine was included in the organic system plan of operations they certified. No commenters expressed opposition to relisting.

Subcommittee Vote:
Motion to remove atropine from §205.603(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: NA
Motion by: Dan Seitz
Seconded by: Scott Rice
Yes: 0 No: 6 Abstain: 0 Absent: 0 Recuse: 0

Hydrogen peroxide

§205.603 Synthetic substances allowed for use in organic livestock production.
Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable**. (15) Hydrogen peroxide.**
Technical Report: 1995 TAP (Crops); 2015 TR (Crops)
Petition(s): N/A
Past NOSB Actions: 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Hydrogen peroxide is used as a readily available disinfectant and broad-spectrum germicide. It is an important cleaning agent for use on contact surfaces, such as equipment, calf pails, bottles, and utensils. The material is used to clean wounds and was first registered with the EPA in 1977.

Hydrogen peroxide is a very simple molecule with a formula of H_2O_2. Virtually all modern production facilities manufacture commercial hydrogen peroxide solutions using large, strategically located anthraquinone autoxidation processes. Improved production methods and facilities based on the anthraquinone (AO) process have recently appeared in the commercial patent literature.

Hydrogen peroxide is a naturally occurring inorganic compound; however, the sources of hydrogen peroxide used in commercial fungicides, disinfectants and antiseptic products are produced through chemical synthesis. Industrial methods for the preparation of hydrogen peroxide are categorized as oxidation-reduction reactions. Modern commercial methods for hydrogen peroxide synthesis involve the transition-metal catalyzed chemical reduction of an alkyl anthraquinone with hydrogen (H_2) gas to the corresponding hydroquinone followed by regenerative oxidation of the latter species in air.

Contamination is not expected when purified forms of hydrogen peroxide are released to the environment following normal use. At typical pesticide concentrations, hydrogen peroxide is expected to rapidly degrade to oxygen gas and water (US EPA, 2007). Large-volume spills and other releases of concentrated hydrogen peroxide could present a fire hazard since the substance readily decomposes to release oxygen gas. Pure hydrogen peroxide is not flammable and can be diluted with clean water to minimize the risk of fire. Although concentrated hydrogen peroxide is nonflammable, it is a powerful oxidizing agent that may spontaneously combust on contact with organic material and becomes explosive when heated. Combustion reactions and explosions resulting from accidental spills of concentrated hydrogen peroxide could therefore lead to environmental degradation.

During the Spring 2019 NOSB review the Livestock Subcommittee received comments in favor of relisting hydrogen peroxide and no comments against relisting. One commenter stated hydrogen peroxide is one of the most widely used hard-surface sanitizers and is Generally Recognized as Safe (GRAS) as an antimicrobial agent and for other purposes by the FDA. Unlike many alternatives available to organic producers, it is an excellent choice as it rapidly degrades to oxygen and water, leaving no residue.

Hydrogen peroxide is recommended for relisting based on the available technical advisory panel (TAP) of October of 1995 (Crops), the technical review of October 2015, the unanimous NOSB 2017 support of this material, and the lack of new scientific or meritorious information.

Questions
Is this synthetic material a necessary input in organic livestock production?

Subcommittee Vote:
Motion to remove hydrogen peroxide from §205.603(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: NA
Motion by: Jesse Buie
Seconded by: Ashley Swaffar
Yes: 0 No: 6 Abstain: 0 Absent: 0 Recuse: 0

Iodine—§205.603(a)

§205.603 Synthetic substances allowed for use in organic livestock production.
Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable**. (16) Iodine.**
Technical Report: 1994 TAP; 2015 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 meeting minutes and vote; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Background from Subcommittee
Iodine has excellent antimicrobial qualities and is widely used in organic livestock production as a topical treatment, disinfectant, and antimicrobial, especially as a teat dip used both pre-milking and post milking.

Mastitis is a painful inflammation with infection. Antibiotic use is prohibited in organic agriculture so preventive healthcare is of critical importance. While a clean barn, clean milking parlor and clean cows are a vital aspect of an organic milk production system, barns are not sterile environments and thus anti-microbial teat dips used in pre and post milking are vital preventive healthcare products. There are many teat dips available commercially. Iodine based teat dips are the most commonly used in organic livestock production. Iodine can be in molecular form or iodophor form.

Typically, molecular iodine is “complexed” into a variety of iodophors where surfactants are mixed with molecular iodine to enhance water solubility and sequester the molecular iodine for extended release in disinfectant products. There may also be several other ingredients in iodine-based teat dips, some of which may be excipients.

Additional information requested from subcommittee

1. Can iodophor forms of iodine be produced using fewer toxic surfactants than nonphenol polyethylene glycol ether (NPE) and similar NPEs? 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 the organic industry?

3. Are there equally effective alternatives to iodophor based teat dips for commercial use in organic livestock production?

Public Comments
During the Spring 2019 NOSB the Livestock Subcommittee received several comments in favor of relisting iodine and no comments against relisting iodine. Comments in favor of relisting included the following:

- This product is widely used as a teat dip
- This is a critically important product

Subcommittee Discussion
This material satisfies the OFPA evaluation criteria and the Livestock Subcommittee supports the relisting of iodine.

Subcommittee Vote:
Motion to remove iodine from §205.603(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: NA
Motion by: Ashley Swaffar
Seconded by: Jesse Buie
Yes: 0 No: 5 Abstain: 0 Absent: 1 Recuse: 0

Iodine—§205.603(b)

§205.603 Synthetic substances allowed for use in organic livestock production.
Reference: 205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.
(4) Iodine.
Technical Report: 1994 TAP; 2015 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 meeting minutes and vote; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Iodine has excellent antimicrobial qualities and is widely used in organic livestock production as a topical treatment, disinfectant, and antimicrobial, especially as a teat dip used both pre-milking and post milking.

Mastitis is a painful inflammation with infection. Antibiotic use is prohibited in organic agriculture so preventive healthcare is of critical importance. While a clean barn, clean milking parlor and clean cows are a vital aspect of an organic milk production system, barns are not sterile environments and thus anti-microbial teat dips used in pre and post milking are vital preventive healthcare products. There are many teat dips available commercially. Iodine based teat dips are the most commonly used in organic livestock production. Iodine can be in molecular form or iodophor form.

Typically, molecular iodine is “complexed” into a variety of iodophors where surfactants are mixed with molecular iodine to enhance water solubility and sequester the molecular iodine for extended release in

disinfectant products. There may also be several other ingredients in iodine-based teat dips, some of which may be excipients.

Additional information requested from Subcommittee

1. Can iodophor forms of iodine be produced using fewer toxic surfactants than nonphenol polyethylene glycol ether (NPE) and similar NPEs? 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 the organic industry?

3. Are there equally effective alternatives to iodophor based teat dips for commercial use in organic livestock production?

Public Comments

During the Spring 2019 NOSB the Livestock Subcommittee received several comments in favor of relisting iodine and no comments against relisting iodine. Comments in favor of relisting included the following:

- This product is widely used as a teat dip
- This is a critically important product

Subcommittee Discussion

This material satisfies the OFPA evaluation criteria and the Livestock Subcommittee supports the relisting of iodine.

Subcommittee Vote:

Motion to remove iodine from §205.603(b) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: NA
Motion by: Ashley Swaffar
Seconded by: Jesse Buie
Yes: 0 No: 5 Abstain: 0 Absent: 1 Recuse: 0

Magnesium sulfate

§205.603 Synthetic substances allowed for use in organic livestock production.
Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable. **(19) Magnesium sulfate.**
Technical Report: 1995 TAP; 2011 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:
Specific Uses of the Substance
Magnesium sulfate has a number of veterinary uses. It acts as an anticonvulsant, laxative,

bronchodilator, electrolyte replacement aid with hypomagnesaemia, and may be used to treat cardiac arrhythmias. Specifically, in swine, magnesium sulfate is administered to treat malignant hypothermia.

Magnesium sulfate can be added to livestock feed to treat conditions stemming from a magnesium deficiency. Lactation tetany or grass tetany occurs when ruminants graze on grasses low in magnesium or suffer from a low level of magnesium in their diet. The condition is often realized after cases of sudden death in cattle. Clinical signs include convulsions and muscular spasms, and death may occur due to respiratory failure. If livestock are feeding on pastures with high potassium levels, which interfere with the uptake of magnesium by grasses, supplemental magnesium sulfate may be needed.

Magnesium capsules can be inserted into the rumen of livestock and after a one-week stabilization period, the capsule begins to release magnesium for up to 80 days. This capsule is recommended for use in high-risk or valuable animals. It is advised that, in addition to the capsule, the livestock be fed hay in order to increase absorption of the magnesium. If immediate treatment for magnesium deficiency is needed, magnesium sulfate can be administered intravenously.

A magnesium lick can also be provided for livestock to increase the amount of magnesium in the diet. Because magnesium sulfate is not palatable, molasses is added to the magnesium lick to encourage cattle's use. Licks are generally 80 percent molasses and 20 percent magnesium sulfate and are considered to be less reliable than supplementing feed with magnesium.

Magnesium sulfate, as Epsom salts, can be used to treat inflammation and abscesses in livestock. Soaking the affected area in a mixture containing Epsom salt and water can reduce signs of inflammation.

Additional information requested from subcommittee

1. Is this material still considered to be essential for organic livestock production?

Public Comments

During the Spring 2019 NOSB review the Livestock Subcommittee received several comments in favor of relisting magnesium sulfate and no comments against relisting. Some of the comments in favor of relisting included:

- Magnesium sulfate is essential for organic livestock production. It is used when grass tetany and organophosphate poisoning occur. Both are acute situations and an effective immediate treatment is necessary.
- This product is administered by the intravenous or intramuscular routes as an electrolyte replenisher or anticonvulsant. Magnesium sulfate is used as a laxative and bronchodilator. This product is also added to feed to treat magnesium deficiency. Accordingly, this product is important to the humane treatment of organic animals.

Subcommittee Discussion
Magnesium sulfate satisfies the OFPA evaluation criteria and the Livestock Subcommittee supports relisting.

Subcommittee Vote:
Motion to remove magnesium sulfate from §205.603(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: NA
Motion by: Ashley Swaffar
Seconded by: Scott Rice
Yes: 0 No: 5 Abstain: 0 Absent: 1 Recuse: 0

Parasiticides, Fenbendazole

§205.603 Synthetic substances allowed for use in organic livestock production.
Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable**.** (23) 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)— milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep, and other dairy species.
Technical Report: 1999 TAP (Fenbendazole, Ivermectin); 2015 TR

Petition(s): 03/2007 Fenbendazole

Past NOSB Actions: 05/2008 NOSB recommendation; 10/2015 sunset recommendation; 04/2016 recommendation – annotation change
Recent Regulatory Background: Added to National List , effective May 16, 2012 (77 FR 28472); Renewed 03/15/2017 (82 FR 14420); Proposed rule 01/17/2018 (83 FR 2498); Annotation change 12/27/2018 (83 FR 66559)
Sunset Date: 3/15/2022

Subcommittee Review:

Background from Subcommittee
In veterinary medicine the term parasiticide refers to anthelmintic drugs. Anthelmintics are medications capable of causing the evacuation of parasitic intestinal worms. As veterinary drugs, parasiticides are articles intended for use in treatment or prevention of disease in animals (Section 201(g)(1)(B) & (C) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321(g)(1)(B) & 234 (C)]). The use of parasiticides in organic production is strictly confined to emergencies and the practice of returning livestock production to a healthy steady state does not include the routine use of parasiticides. Parasitism may be the weakest link in organic livestock production (Karreman, 2004). Outbreaks of disease due to nematode parasites can happen even in well managed flocks. When changes in a production system occur as a result of land use, weather, or transient exposure of susceptible animals to parasites the natural imbalance favors parasite infestation. When unnoticed, undetected and without treatment parasite infestation can lead to disease and potentially death (Stockdale, 2008).

A petition for inclusion of fenbendazole on the National List was received by the NOP, March 23, 2007. Fenbendazole was added to the National List effective May 12, 2012. A Technical Review (TR) was completed in 2015 to review fenbendazole, ivermectin, and moxidectin as one group. The TR documented that parasiticide resistance management has become an important issue in animal health

and that increased use of anthelmintics in livestock production may lead to subsequent selection and increased parasiticide resistance (Xu et al., 1998; James et al., 2009). As a result, if resistance to one drug occurs, then other drugs with the same mode of action or binding site will also be ineffective.

Fenbendazole works very well for susceptible parasites; however, some worms have a natural mechanism that causes subtle mutations in the genes for the β-tubulin and ion channel proteins targeted by these anthelmintics, allowing the worms in subsequent generations to avoid drug binding and enables drug resistance. Fenbendazole acts selectively by binding to nematode β-tubulin, disrupting the nematode digestive system and preventing egg formation, while potentiating the GLUCL channel which causes spastic paralysis.

Fenbendazole is sold as Panacur and Safe Guard. The orally administered product contains polysorbate 80, simethicone emulsion 30%, benzyl alcohol and purified water. Fenbendazole paste contains the excipients carbome homopolymer type B (Allyl pentaerythritol crosslinked), propylene glycol, glycerin, sorbitol, sodium hydroxide, water, methylparaben and propylparaben.

Risks with the use of fenbendazole

The risks associated with chemical treatment of parasites include (1) immediate non-target effects, (2) obligation for repeat treatments, (3) potential risk to domestic animals and human health, (4) target organism resistance to the treatment, (5) potential residue buildup and (6) potential food chain contamination (Rudd, 1985). All FDA livestock approved parasiticides are synthetically produced substances shown by experimental and clinical studies to be safe for application to food animals. The excipients are usually United States Pharmacopoeia (USP) grade chemicals and also subject to FDA approval.

Fenbendazole is insoluble in water and excreted in the feces. Because it is not soluble, there is little mobility of fenbendazole in soils with low risk of groundwater contamination. Laboratory tests show that radiolabeled fenbendazole is degraded with a half-life of 54 days. The fate of fenbendazole in manure and manured soils has been studied under laboratory and field conditions. After a 102- day incubation period, 80% of fenbendazole remains. The latter was accompanied by 4% of the corresponding metabolite fenbendazole sulfoxide. Fenbendazole-sulfoxide remains in clay soil samples after 54 days (Kreuzig et al., 2007). Fenbendazole toxicity was demonstrated in pigeons and doves, leading the authors of the study to suggestion a toxic etiology for fenbendazole in birds of the order Columbiformes treatment (Howard et al., 2002).

International Status

The Canadian Organic Production Systems General Principles and Management Standards (CAN/CGSB-433, CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999), the European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008, and the Japan Agricultural Standard (JAS) for Organic Production all prohibit parasiticides on a routine basis. If there is a specific disease or health issue and natural methods are not effective, parasiticides may be used as long as there is a doubling of withdrawal times documented. The International Federation of Organic Agriculture Movements (IFOAM) additionally prohibits the usage of parasiticides to include a maximum of three courses of remedial treatments within 12 months, or one course of treatment if the productive lifecycle of the animal is less than one year.

Public Comments

During the Spring 2019 NOSB review the Livestock Subcommittee received all favorable comments in favor of relisting fenbendazole, with the exception of one commenter who stated that they believe the

listing of fenbendazole with a shorter withholding period in the absence adopting the NOSB-recommended definition of emergency would be a violation of OFPA §6517(d)(2).

Fenbendazole is recommended for relisting. This determination is based on information in the 2015 TAP review, the 2016 NOSB unanimous recommendation for an annotation change, the USDA-NOP publication of the amended annotation effective January 29, 2019, and because there is no new scientific or meritorious information.

Subcommittee Vote:
Motion to remove fenbendazole from §205.603(a)(23)(i) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: NA
Motion by: Sue Baird
Seconded by: Ashley Swaffar
Yes: 0 No: 6 Abstain: 0 Absent: 0 Recuse: 0

Parasiticides, Moxidectin

§205.603 Synthetic substances allowed for use in organic livestock production.
Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable**.** (23) 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 **(ii) Moxidectin (CAS #113507-06-5)— milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep, and other dairy species.**
Technical Report: 2003 TAP (Moxidectin); 2015 TR
Petition(s): Moxidectin
Past NOSB Actions: 05/2004 NOSB recommendation; 10/2015 sunset recommendation; 04/2016 NOSB recommendation - annotation change
Recent Regulatory Background: Added to National List , effective May 16, 2012 (77 FR 28472); Renewed 03/15/2017 82 FR 14420; Proposed rule 01/17/2018 (83 FR 2498); Annotation change 12/27/2018 (83 FR 66559)
Sunset Date: 3/15/2022

Subcommittee Review:

Background from Subcommittee
In veterinary medicine the term parasiticide refers to anthelmintic drugs, although moxidectin is also effective against arthropod parasites. As veterinary drugs, parasiticides are articles intended for use in treatment or prevention of disease in animals (Section 201(g)(1)(B) & (C) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321(g)(1)(B) & 234 (C)]). The use of parasiticides in organic production is strictly confined to emergencies and the practice of returning livestock production to a healthy steady state that does not include the routine use of parasiticides.

Moxidectin, a derivative of nemadectin, is a chemically modified Streptomyces cyanogriseus fermentation product (Asato and France, 1990). The NOSB recommended adding moxidectin to the National List in 2004 with the restriction that it only be allowed for use to control internal parasites; but

in the proposed rule published on July 17, 2006 USDA announced its decision that moxidectin would not be proposed for inclusion on the National List because of its macrolide antibiotic classification. Based upon the public comments received at the NOSB meeting July 17, 2006, the NOP verified the information supplied by commenters, and subsequently concurred that moxidectin does not function as an antibiotic when used as a parasiticide. In the Final Rule in 2012 NOP added moxidectin to National List for the first time.

The 2015 Technical Review (TR) reviewed moxidectin and fenbendazole. The TR documented that parasiticide resistance management had become an important issue in animal health and that increased use of anthelmintics in livestock production may lead to subsequent selection and increased parasiticide resistance. Moxidectin works very well for susceptible parasites; however, some worms have a natural mechanism that causes subtle mutations in the genes for the β-tubulin and ion channel proteins targeted by these anthelmintics, allowing worms in subsequent generations to avoid drug binding and enables drug resistance. Moxidectin, the only milblemycin approved for use in organic livestock production, selectively binds to nematode β-tubulin and potentiating the glutamate-gated chloride (GLUCL) channel. Binding β-tubulin disrupts the nematode digestive system and prevents egg formation, while potentiating the GLUCL channel causes spastic paralysis.

Risks with the use of Moxidectin

The risks associated with chemical treatment of parasites include (1) immediate non-target effects, (2) obligation for repeat treatments, (3) potential risk to domestic animals and human health, (4) target organism resistance to the treatment, (5) potential residue buildup and (6) potential food chain contamination (Rudd, 1985).

Moxidectin is excreted in feces but is both microbially and photo-degraded in dung pats in the soil. It is the least toxic to dung beetles of the macrocyclic lactone anthelmintics. Moxidectin peaks in 2 days in feces after treatment and decreases to less than 10 ppb by 37 days after treatment. The half-life for degradation of moxidectin in the environment may be up to 130 days.

International Status

Review of the International Organic Standards- The Canadian Organic Production Systems General Principles and Management Standards (CAN/CGSB-433, CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999), the European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008, and the Japan Agricultural Standard (JAS) for Organic Production- all shows a commonality: Parasiticides are prohibited on a routine basis. If there is a specific disease or health issue and natural methods are not effective, parasiticides may be used as long as there is a doubling of withdrawal times documented. The International Federation of Organic Agriculture Movements (IFOAM) has additional exception on the usage of parasiticides including a maximum of three courses of remedial treatments within 12 months, or one course of treatment if the productive lifecycle of the animal is less than one year.

Public Comments

During the Spring 2019 NOSB review the Livestock Subcommittee received all favorable comments for relisting moxidectin, with the exception of one commenter, who stated that they believe the listing of moxidectin with a shorter withholding period in the absence of adopting the NOSB-recommended definition of emergency would be a violation of OFPA §6517(d)(2).

Moxidectin is recommended for relisting. This determination is based on information in the 2015 TAP review, the 2016 NOSB unanimous recommendation for an annotation change, the USDA-NOP publication of the amended annotation effective January 29, 2019, and because there is no new scientific or meritorious information.

Subcommittee Vote:
Motion to remove moxidectin from §205.603(a)(23)(ii) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: NA
Motion by: Sue Baird
Seconded by: Harriet Behar
Yes: 0 No: 6 Abstain: 0 Absent: 0 Recuse: 0

Peroxyacetic/peracetic acid

§205.603 Synthetic substances allowed for use in organic livestock production.
Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable. **(24) Peroxyacetic/peracetic acid (CAS #-79-21-0)—for sanitizing facility and processing equipment.**
Technical Report: 2000 TAP ; 2016 TR
Petition(s): 2008 Petition
Past NOSB Actions: 11/2000 NOSB recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Background
According to TR (line 88), peracetic acid is listed for use in organic livestock production for sanitizing facility and processing equipment. This is consistent with the substance's primary use in the food industry as a bactericide and fungicide for sanitizing and disinfecting structures, equipment and hard surfaces. TR line 99 states, peracetic acid may be used in livestock production in dairies – milking parlors, dairy production and transfer facilities and equipment – as well as in poultry premises, hatcheries, livestock quarters, stables, stalls, pens, cages, and on feeding and watering equipment.

Beginning at TR line 288: The reason for the excellent and rapid antimicrobial effects of peracetic acid is its specific capability to penetrate the cell membrane. Once inside the cell, peracetic acid plays a role in denaturing proteins, disrupting cell wall permeability, and oxidizing sulfhydryl and sulfur bonds in enzymes and other proteins. PAA irreversibly disrupts enzyme systems, which destroys the microorganism. The end products of peracetic acid oxidation are acetic acid and water.

Solutions of peracetic acid used as sanitizers are created by combining aqueous mixtures of two substances: acetic acid (the acid in vinegar) and hydrogen peroxide. At cool temperatures, acetic acid and hydrogen peroxide react over a few days to form an equilibrium solution containing peracetic acid, acetic acid and hydrogen peroxide. This equilibrium solution is the substance sold commercially as the sanitizer "peracetic acid."

Peracetic acid is considered to be an environmentally friendly substance, with very little potential to cause contamination due to its rapid breakdown into benign substances already present in the environment. It has, however, been reported that peracetic acid in the atmosphere can react with photochemically produced hydroxyl radicals (reaction half-life of approximately 9 days) (U.S. National Library of Medicine 2012), with a suggested role in contributing to acid rain.

Both peracetic acid and hydrogen peroxide have been cited as potential contributors to acid rain. However, while peracetic acid and hydrogen peroxide can be involved in chemical reactions in the atmosphere that ultimately lead to acid rain, the literature does not cite them as being a significant contributor to or source of acid rain.

Peracetic acid has been found in some instances to have beneficial effects related to environmental contamination. One study reports peracetic acid to be effective in degrading toxic compounds benzo(a)pyrene and methylnaphthalene in lake sediments through oxidation of the parent compound.

During the Spring 2019 NOSB the Livestock Committee received comments in favor of relisting Peracetic Acid no comments against relisting. The commenter stated:

- Peracetic acid (PAA) is an important tool in the prevention of illness through its use as a hard surface sanitizer and disinfectant.
- PAA is an effective sanitizer for use against a large number of gram negative and gram positive bacteria, fungi and many human health pathogens.
- PAA is found in an aqueous solution of acetic acid and hydrogen peroxide. PAA rapidly degrades into acetic acid, oxygen and water, none of which are a toxicological concern.

The National Organic Standards Board (NOSB) previously reviewed peracetic acid as a disinfectant, sanitizer, and medical treatment in accordance with Code of Federal Regulation 7(CFR) § 205.603(a)(19). Peracetic acid is a relatively recent development, but has been used to clean stalls and to disinfect livestock, particularly dairy cattle. Acetic acid and hydrogen peroxide both have a longer history of use in livestock production than commercial preparations of peracetic acid, but the substance has, in effect, been used by farmers who combine vinegar and peroxide in a cleaning solution.

Peracetic acid is recommended for relisting based on the available 2000 technical advisory panel (TAP), the technical review of March 2016, the unanimous NOSB 2017 support of this material, and the lack of new scientific or meritorious information.

The NOSB has reviewed few materials for use in barns, stalls, stables and milking parlors, leaving relatively few options for producers.

Question
Is this still necessary for organic livestock production?

Subcommittee Vote:
Motion to remove peracetic acid from §205.603(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: NA
Motion by: Jesse Buie
Seconded by: Ashley Swaffar
Yes: 0 No: 6 Abstain: 0 Absent: 0 Recuse: 0

Xylazine

§205.603 Synthetic substances allowed for use in organic livestock production.
Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable**. (30) 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, and;
(ii) 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; 2019 Technical Report
Petition(s): 2002 Petition
Past NOSB Actions: 09/2002 NOSB recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 82 FR 14420; Proposed rule 01/17/2018 (83 FR 2498); Annotation change 12/27/2018 (83 FR 66559)
Sunset Date: 3/15/22

Subcommittee Review:

Background from Subcommittee
Xylazine is synthesized by reacting 2,6-dimethylphenylisothiocyanate with 3-amino-1-propanol in a polar solvent (ether) to form a thiourea. Concentrated hydrochloric acid is added after the solvent is removed. Water is added to the cooled mixture which is then filtered, and the filtrate is made basic to form a precipitate that is recrystallized as xylazine.

Xylazine is used as a sedative, analgesic, and muscle relaxant in veterinary medicine. As a medical treatment, it can be administered intravenously, intramuscularly, subcutaneously, or orally, usually as a water based injectable solution. Xylazine can also be found as a white crystalline powder. Xylazine sedative properties are due to its depressant mode of action on nervous system synaptic receptors. Sedation of animals is necessary for both planned medical procedures and emergency procedures to prevent the pain and suffering of animals as well as injury to the veterinarians performing the procedures. Xylazine is commonly used in conjunction with tolazoline, which is a reversal agent for sedatives such as xylazine.

According to information posted on the FARAD (Food Animal Residue Avoidance Databank) website (http://www.farad.org/amduca-law.html; accessed on Aug. 5, 2019), extra label use (i.e., off label use) of xylazine is permissible under the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) only if such use is by or on the lawful written or oral order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship. According to the FARAD Digest (published in JAVMA, Vol. 223, No. 9, Nov. 1, 2003), xylazine is used in as a medical treatment in livestock intended for food production as well as in dairy cows.

International allowance for use

- **Canadian General Standards Board Permitted Substances List**
  Xylazine is listed in the CAN/CGSB-32.311-2015 — Organic production systems - permitted substances list in Table 5.3 “health care products and production aids,” as a “sedative.”

  Tolazoline (most commonly used as a reversal agent for sedatives, including xylazine) is not listed in the CAN/CGSB-32.311-2015 — Organic production systems - permitted substances list.

- **CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)**
  Neither xylazine nor tolazoline are listed in the CODEX.

- **European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008**
  Neither xylazine nor tolazoline are listed in the EEC EC No. 834/2007 or 889/2008.

- **Japan Agricultural Standard (JAS) for Organic Production**
  Neither xylazine nor tolazoline are listed in the JAS for Organic Production.

- **International Federation of Organic Agriculture Movements (IFOAM)**
  Neither xylazine nor tolazoline are listed in IFOAM.

Persistence/concentration of xylazine or its by-products in the environment. According to the 2019 TR:

> Environmental studies on xylazine … highlight the possible persistence of the substance and its accumulation in soil systems as well as its role as an aquatic pollutant (Fabrega et al. 2013, Choi et al. 2014, Pugajeva et al. 2017). Reports of xylazine environmental contamination on the Iberian Peninsula may be linked with xylazine manufacturing, resulting in high contributions to water pollution in Iberian river systems (Fabrega et al. 2013, Pugajeva et al. 2017). The leaching ability of xylazine and its reported slow degradation in aquatic systems make wastewater pollution a concern in cases of improper use or disposal (Fabrega et al. 2013, Choi et al. 2014, Pugajeva et al. 2017).

Effects on human health. According to the 2019 TR:

> Xylazine is a substance with potent hypnotic and muscle-relaxation properties. The side effects of xylazine include significant cardiac arrythmias, which has resulted in its lack of approval for human medical applications (Green et al. 1981, EMEA 1999, Reyes et al. 2012). Due to the lack of approval for use in human medical applications, information on the mode of action and toxicity of xylazine is limited.
>
> Reported cases of xylazine in humans have shown physiological effects like those seen in veterinary applications (Samanta et al. 1990, JECFA 1998a). Upon absorption of xylazine, patients were difficult to rouse and showed signs of confusion (indicative of central nervous system and neuropathic depression) and expressed symptoms of bradycardia, hypotension (respiratory depression), and hyperglycemia (Gallanosa et al. 1981, Spoerke et al. 1986, Samanta et al. 1990)…. With regard to human carcinogenicity, no studies of direct effects have been published; however, the IARC has designated the xylazine metabolite xylidine as potentially carcinogenic to humans based on studies with laboratory animals (NTP 1990, IARC 1993, JECFA 1998a).
>
> The lethal dosage of xylazine in humans is not well known and appears to vary dramatically between individuals (Spoerke et al. 1986, Ruiz-Colon et al. 2014). Fatal doses of xylazine recorded have been as low as 40 mg, while other individuals have survived exposure to levels as high as 2400 mg (Spoerke et al. 1986, Ruiz-Colon et al. 2014).

Natural (non-synthetic) alternatives. According to the 2019 TR, "No natural alternatives are common for either [xylazine or tolazoline] (i.e., a sedative alternative for xylazine or a xylazine-reversal agent as a tolazoline alternative). Moreover, while there are several synthetic alternatives for both substances, no other synthetic alternatives have been approved by the USDA for use in organic agricultural production."

Public Comment from the Spring 2019 NOSB Meeting
In written comments submitted for the spring 2019 NOSB meeting, six commenters supported relisting xylazine as essential for use in veterinary surgical procedures, and two other commenters noted that xylazine was listed on the organic systems plans for operations they certified. No commenters opposed relisting. However, one commenter raised two potential issues with xylazine that the commenter considered worth investigating further: namely, whether there are alternative practices that could replace the need for xylazine, and whether there is an FDA prohibition regarding the use of xylazine in the treatment of food-producing animals; however, this commenter did not recommend removal of xylazine at this time.

Subcommittee Vote:
Motion to remove xylazine from §205.603(a) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: NA
Motion by: Dan Seitz
Seconded by: Ashley Swaffar
Yes: 0 No: 6 Abstain: 0 Absent: 0 Recuse: 0

DL-Methionine

§205.603 Synthetic substances allowed for use in organic livestock production.
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 pounds of synthetic 100 percent methionine per ton of feed in the diet, maximum rates as averaged per ton of feed over the life of the flock: Laying chickens—2 pounds; broiler chickens—2.5 pounds; turkeys and all other poultry—3 pounds.
Technical Report: 2001 TAP; 2011 TR
Petition(s): 2005 Methionine; 2007 Methionine; 2009 Methionine; 2011 Methionine
Past NOSB Actions: 10/2001 NOSB recommendation; 03/2005 NOSB recommendation; 2008 NOSB recommendation; 04/2010 NOSB recommendation on Methionine annotation through October 2012; 04/2010 NOSB recommendation on Methionine step-down annotation after October 2012; 04/2010 sunset recommendation; 08/2014 Organic poultry feed proposal; 04/2015 NOSB Formal recommendation; 10/2015 sunset recommendation;
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 82 FR 14420; Proposed rule 01/17/2018 (83 FR 2498); Annotation change 12/27/2018 (83 FR 66559)
Sunset Date: 3/15/2022

Subcommittee Review:

Use: Methionine is an essential amino acid for poultry since it cannot be produced biologically by the birds and is necessary for proper cell development for the growing chicks and for proper feathering. The USDA organic standards, which require all agricultural ingredients for livestock come from an organic source, as well as the prohibition of feeding poultry or mammalian by-products to organic poultry or mammals, narrow the options for natural sources of methionine.

Manufacture
Methionine is a sulfur-containing amino acid. The 2011 technical review lists these various methods of manufacture:

L-methionine may be isolated from naturally-occurring sources, produced from genetically-engineered organisms, or synthesized through many processes. While methionine has been produced by fermentation in the laboratory, racemic mixtures of D- and L-methionine (i.e., DL-methionine) are usually produced entirely by chemical methods (Araki and Ozeki, 1991). Most L-methionine is produced from synthetic DL- methionine, and DL-methionine can be produced in following ways:

- *Reaction of acrolein with methyl mercaptan in the presence of a catalyst (Fong et al., 1981);*
- *Reaction of propylene, hydrogen sulfide, methane, and ammonia to make the intermediates acrolein, methylthiol, and hydrocyanic acid (DeGussa, 1995; 1996);*
- *Use of the Strecker synthesis method with α-methylthiopropionaldehyde as the aldehyde (Fong et 275 al., 1981); or*
- *Reaction of 3-methylmercaptopropionaldehyde with ammonia, hydrogen cyanide, and carbon dioxide in the presence of water in three reaction steps (Geiger et al., 1998). In general, L-methionine is produced from DL-methionine via optical resolution resulting in separation into the D- and L-enantiomers (Ajinomoto Corporation, 2012) or by acetylation of synthetic DL-methionine and subsequent enzymatic selective deacetylation of the N-acetylated L-methionine (Usuda and Kurahashi, 2010). Because much of the DL-methionine supply is synthesized using chemical methods, the L methionine produced from it is also synthetic. While nonsynthetic L-methionine can be produced by fermentation, there are no commercial sources available that use this method (Kumar and Gomes, 2005).*

International

The European Union does not allow synthetic methionine in livestock feed. EU regulations do allow for some use of nonorganic non-GMO agricultural ingredients when organic forms are not available, and these ingredients (e.g., nonorganic corn gluten meal) could provide natural methionine. In 2015, there was non-organic corn gluten meal available in the United States, and a recent review of the NOP organic integrity database noted 12 sources or organic corn gluten meal, with one located in the U.S. and the others in China. Canadian standards allow the use of DL-methionine with no restrictions. However, there is a notation in the current list of allowed materials under the Canadian Organic Standard, that this use of synthetic methionine will be under review in the near future.

Background

A petition to allow use of this synthetic amino acid in organic poultry rations was presented to the NOSB in 1999. In 2001, a Technical Advisory Panel (TAP) analyzed the use of the synthetic DL-methionine and determined that feed supplementation with this material is compatible with an organic system of agriculture, since it is essential to maintain the health of the birds. Synthetic amino acids are not specifically listed as a category of approved synthetics in the Organic Food Production Act.

For almost two decades this material has been present on the National List of approved synthetics, resulting in many written and oral public comments both for and against its allowance in organic poultry production. Those against its allowance state synthetic methionine in the poultry ration enables high concentrations of organic birds to be raised in confinement, with minimal access to the outdoors. In addition, they state that birds who have access to vegetation and bugs on a healthy organic pasture can obtain methionine from these sources and do not suffer negative health effects when there is insufficient methionine (natural or synthetic) in their ration.

Those in favor of synthetic methionine have stated that natural sources of methionine are difficult to provide in sufficient quantities. Crops, such as soybeans, are a source of methionine, but when sufficient soybean meal is fed to meet methionine levels, other levels of amino acids become too high which results in a poorly balanced ration. Excess protein in the ration causes a significant rise in the ammonia levels from manure in the chicken houses, resulting in a lower quality of life for the birds.

Natural sources of methionine have a variety of issues. There are no organic sources of fish meal, crab meal or blood meal. Black soldier larvae would need to be fed in very large quantities, making it impractical since there are no sources producing enough dried larvae to feed the current flocks of organic poultry in the U.S. Algae is another promising area, but has not been developed to determine its acceptability. Items such as whey powder, nonfat dry milk and potato proteins have been tried, but were not fully digestible by the birds. These items and more have been researched by the Methionine Task Force, an ad-hoc citizen group that has provided information to the NOSB over the years, whose members consist of organic poultry operations and animal nutrition specialists.

A final rule published on December 27, 2018, and effective on January 28, 2019, incorporated the NOSB recommendation of April 2015 to adjust the amount of methionine in the feed ration to meet the demands of the birds at different stages of life, while still limiting the total amount of methionine that can be fed over the lifetime of the birds. This change allowed for a specific amount of methionine over the life of the bird rather than how much would be allowed per ton of feed prepared for the organic flock. Typically, a higher percentage of methionine is needed in the ration when the birds are young and growing. Organic poultry producers, through public comment, stated the previous annotation requiring a specific amount of methionine in each ration led to poor immune system development, poor feathering, feather pecking and cannibalism in their flocks. The new annotation, noted above, effective January 28, 2019, will be the listing that the NOSB will vote upon in Fall 2019. The previous annotation was as follows:
Synthetic substances allowed for use in organic livestock production.
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.

In addition to the 2015 NOSB recommendation to modify the annotation for DL-Methionine, the following resolution was passed unanimously by the Livestock Subcommittee.

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.

Public Comment
A short update was received from the “methionine task force” a group of stakeholders working on their own to find alternatives to synthetic methionine. A few experiments were done in the past few years, which did not result in a viable non-synthetic alternative. Natural materials that are high in methionine, typically are high in other amino acids as well. When these are added to the poultry ration, the balance of amino acids in the ration is inappropriate and causes health and environmental problems for the poultry. Excess amino acids can lead to higher ammonia levels in the poultry manure, resulting in high ammonia levels in the poultry houses. This organic egg producer group stated they will continue to work on this issue.

Certifiers responded to the change in the DL-methionine annotation and have developed spreadsheets for their certified organic poultry operations to use. These spreadsheets can track the current rations to meet the new annotation, which requires tracking of methionine fed over the full life of the birds, not by each ton of feed.

Some commenters stated that more access to living vegetation would lessen or remove the need for DL-methionine. Organic poultry producers stated they must have DL-methionine for the health and well-being of their animals, and pasture access would not provide sufficient quantities of methionine to promote healthy and productive flocks.

Subcommittee discussion
The Livestock Subcommittee continues to see a need for synthetic DL-methionine in the organic poultry diet. Discussion with the methionine task force on ways to lessen the reliance on this synthetic amino acid included blending numerous plant materials instead of just one as the source of methionine to achieve a better balance of amino acids, as well as researching natural herbal supplements that might enhance the absorption of natural methionine, resulting in less methionine needed in the ration. The methionine task force stated they are looking at these options, and they will continue to provide the NOSB updates over time.

Subcommittee Vote:
Motion to remove 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 percent methionine per ton of feed in the diet, maximum rates as averaged per ton of feed over the life of the flock: Laying chickens—2 pounds; broiler chickens—2.5 pounds; turkeys and all other poultry—3 pounds from §205.603 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Harriet Behar
Seconded by: Ashley Swaffar
Yes: 0 No: 6 Abstain: 0 Absent: 0 Recuse: 0

Trace minerals

§205.603 Synthetic substances allowed for use in organic livestock production.
Reference: 205.603(d) As feed additives. **(2) Trace minerals, used for enrichment or fortification when FDA approved.**
Technical Report: 2013 TR Aquatic Trace Minerals; 2019 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB recommendation; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 09/2014 aquatic trace minerals subcommittee proposal; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Information below references the 2019 TR, available at the link above.

Background from Subcommittee
Use
Minerals are required in animal nutrition for their vital roles in various metabolic, enzymatic, and biochemical reactions in the animal body. Forages and grains are good sources of calcium and phosphorus, respectively. Minerals may be provided through the intake of plant matter feedstuffs or

through synthetic supplements. Several factors directly or indirectly influence the levels of minerals in plants, including location, nature, and chemical composition of the soil; level of fertilization; and the presence of anti-nutritional factors that may reduce mineral bioavailability. Bioavailability is defined as the total proportion of the nutrient in a feedstuff that is available for use in normal body functions. As a result, the amounts of minerals for animals that depend on plants as feedstuffs will vary.

The dietary importance of each micro-mineral will depend on the animal species in question. When diet is insufficient to meet an animal's nutrient requirements, supplementation of minerals is typically done through inclusion in the diet either as an individual substance or as part of a trace mineral premix. NOP Guidance 5030 *Evaluating Allowed Ingredients and Sources of Vitamins and Minerals For Organic Livestock Feed* spells out in more detail which minerals are covered under this listing.

It should be noted that while it is beyond the scope of this sunset review to clarify which minerals are included in this listing, the Livestock Subcommittee acknowledges this listing also includes macro minerals. The 2019 TR addresses macro-minerals that are included in animal diet, though not in great detail as they are outside the focus of trace minerals.

Manufacture
Because this is a broad categorical listing, manufacture varies. In most cases, biologically active forms of trace minerals cannot be obtained by mining, so many trace minerals used as feed additives are produced by chemical reactions resulting in inorganic forms of the mineral. More recently, organic forms have become available. This would include the various chelates and complex forms. One of the limiting factors to the use of chelated minerals has been high cost. At the time of this review, chelated minerals cost 10 to 15 times more per milligram of mineral supplied, compared to inorganic sources.

Descriptions of the common processes used to manufacture many of the trace minerals in us are included in the 2019 TR. This level of detail is not provided for the class of substances called metal amino acid chelates since the processes used to manufacture those materials are largely the same.

International
Canadian General Standards Board (CGSB) Permitted Substance List
CAN/CGSB-32.310, §6.44(c) specifically restricts feeding supplements or additives beyond those required for adequate nutrition and health maintenance for the species at each specific stage of life.

CAN/CGSB-32.311, Table 5.3 includes "Minerals, trace minerals, elements" as substances permitted for use in organic livestock production in Canada and allows for "non-synthetic chelated or sulphated minerals" including oyster shell, calcium chloride, and magnesium oxide. Synthetic nutrient minerals may be used if non-synthetic sources are not commercially available. This annotation does not list all the specific minerals allowed; a note in CAN/CGSB-3211*2018, 5.1.2 references Feeds Regulations 1983 as the regulatory document to use when assessing mineral supplements to be used in livestock feed. It is important to note that chromium and molybdenum are not included in this regulation.

Feeds Regulations 1983 also defines a range of nutrient guarantees for complete feeds for use in the exemption of feeds from registration.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
The CODEX recommends that "feedstuffs of mineral origin, trace elements, vitamins, or provitamins can only be used if they are of natural origin. In case of shortage of these substances, or in exceptional circumstances, chemically well-defined analogic substances may be used."

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Trace minerals, referred to as "trace elements," are permitted as per article 14 which states that "Livestock should be fed on grass, fodder, and feeding stuffs produced in accordance with the rules of organic farms …In addition, in order to provide for basic nutritional requirements of livestock, certain minerals, trace elements, and vitamins may need to be used under well-defined conditions."

Annex VI lists all trace elements approved for inclusion in animal feeds, with the disclaimer that the additives must have been approved under Regulations (EC) No 1831/2003. Chromium is not included in this list.

Japan Agricultural Standard (JAS) for Organic Production
The Japan Agricultural Standards (JAS) for Organic Production defines feed additives as "Those specified by Article 2.3 of the Law Concerning Safety and Quality of Feeds (Law No. 35 1953)." JAS allows for "feed additives" as ingredients in livestock feed "which are natural substances, or those derived from natural substances without chemical treat. In case of a difficulty to obtain those feed additives, the use of similar agents to describe food additives are permitted only for supplementing nutrition and effective compounds in feeds."

Japanese standards for organic feed also allow the following macro-nutrients – "Limestone, shellfish fossils, shells, dolomite, phosphate rock, and diatomaceous earth (all referred to as 'limestones') and those derived from limestones without chemical treatments. This does not include any chemically synthesized substances from calcium carbonate, magnesium carbonate, dicalcium carbonate, tricalcium carbonate, magnesium carbonate, dicalcium phosphate, tricalcium phosphate, and silicic acid."

IFOAM – Organics International
The IFOAM standards indicate that "organic animal management provides animals with vitamins, trace elements and supplements only from natural sources unless they are not available in sufficient quantity and/ or quality."

IFOAM standards also state that "Synthetic vitamins, mineral and supplements may be used when natural sources are not available in sufficient quantity and quality.

Human Health and Environment
Based on information presented in the 2019 TR, the hazards associated with the use of the trace minerals are primarily associated with dust irritation of the skin and eyes.

When used as petitioned, trace minerals from unconsumed feed have the potential to be transferred to ground or surface waters. While trace minerals are essential dietary components for animal feeds, some are considered heavy metals with strong toxic potential. When included in animal feeds above required amounts, trace elements accumulate in urine and feces. The environmental risks include impairment of plant production, accumulation in edible animal products, and contamination of the water supply. In addition, there is a correlation between increased trace mineral loads and antimicrobial resistance; as a result, trace minerals have upper limits for inclusion. Concerns regarding specific minerals are included in the 2019 TR.

Discussion
The NOSB received comments during the first review cycle from a wide representation of the organic community supporting the continued use of trace minerals, noting their essentiality to livestock health and welfare and their importance in offsetting seasonal variables in forage nutrition.

Some commenters noted organic production should not be dependent on synthetic nutrients and that the current annotation is not restrictive enough to prevent reliance on synthetic materials. These commenters recommend adding "when forage and available natural feeds are poor quality" to the annotation. Annotations cannot be amended as part of sunset review; should the Subcommittee choose to consider amending the annotation, this would need to be added to the work plan.

According to the 2109 TR, forages alone do not satisfy the mineral requirements of grazing cattle. Mineral deficiencies and imbalances in grazing ruminants have been reported in almost all regions of the world. The choice of forage crop; the part of the plant consumed, and the plant's state of maturity; the soil type and condition; and climatic conditions and seasons when plant material is eaten/gathered are all factors in determining the level and availability of trace minerals.

Subcommittee Vote:
Motion to remove trace minerals from §205.603 of the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): NA
Motion by: Scott Rice
Seconded by: Ashley Swaffar
Yes: 0 No: 5 Abstain: 0 Absent: 1 Recuse: 0

Vitamins

§205.603 Synthetic substances allowed for use in organic livestock production.
Reference: 205.603(d) As feed additives. **(3) Vitamins, used for enrichment or fortification when FDA approved.**
Technical Report: 2015 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB recommendation; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290) ; Renewed 03/15/2017 (82 FR 14420)
Sunset Date: 3/15/2022

Subcommittee Review:

Background from Subcommittee
The National Organic Program (NOP) currently allows the use of vitamins as feed additives in organic livestock production under 7 CFR 205.603, "Synthetic Substances Allowed for Use in Organic Livestock Production" for enrichment or fortification when FDA approved in amounts needed for maintenance (7 CFR §205.237) and for adequate nutrition and health. Further, the USDA organic regulations require producers to meet certain standards for livestock health care practices. As part of this requirement, livestock feed rations must meet nutritional requirements, including vitamins, minerals, protein and/or amino acids, fatty acids, energy sources, and fiber (ruminants) (7 CFR 205.238(a)(2)).

Depending on the raw nutrients available, vitamins are combined in livestock feed rations of grains, beans, oilseeds, and other meals along with minerals and amino acids. There are 15 essential vitamins currently allowed for use in organic livestock production for fortification and enrichment: Vitamin A (vitamin A acetate), Vitamin B1 (thiamine hydrochloride), Vitamin B2 (riboflavin), Vitamin B3 (niacin,

nicotinic acid), Vitamin B5 (calcium pantothenate), Vitamin B6 (pyridoxine hydrochloride), Vitamin B7 (biotin), Vitamin B12 (cyanocobalamin), Vitamin C (ascorbic acid), Choline chloride, Vitamin D3 (cholecalciferol), Vitamin E (α-Tocopherol acetate), and Inositol. The scope of vitamin compounds is reflective of vitamins defined as "required nutrients" by the National Research Council's (NRC's) Nutrient Requirements for cattle, sheep, swine and poultry. Dietary intake of these essential vitamins is essential for the health and well- being of all animals, including livestock. Most vitamins aid in the metabolism of proteins, carbohydrates, and fats while some vitamin compounds have important antioxidant properties. Common signs of vitamin deficiency include anorexia, poor growth, reduced feeding efficiency and, in some cases, mortality.

Individual vitamin compounds are normally produced on an industrial scale by chemical synthesis or partial synthesis. While chemical synthesis remains the dominant industrial production method for many vitamins, an increasing number of fermentation processes are being developed for vitamin production. Many recently developed fermentation methods for manufacturing vitamins utilize genetically engineered microorganisms, generating concerns over the use of these vitamin sources in organic food production. The Technical Review conducted in 2015 stated that fermentation production using genetic modification may commonly being used in production of vitamins A, B2, B5, B6, C, E, and B12. Selection of the manufacturing processes typically depends on available technology, cost of raw materials/chemical feedstocks, market prices and size, cost of implementing fermentation versus chemical processes (synthesis or extraction) and, to a lesser extent, the overall environmental impact of the production method.

In response to the TR information, NOP dispersed Guidance 5030 "Guidance Evaluating Allowed Ingredients and Sources of Vitamins and Minerals For Organic Livestock Feed" which instructs certifiers to be diligent when reviewing vitamins for the presence of excluded methods. Specific to excluded methods in vitamins, NOP wrote, "The USDA organic regulations also prohibit use of excluded methods at § 205.105(e), and thus vitamins used in livestock feed should be reviewed for excluded methods." https://www.ams.usda.gov/sites/default/files/media/5030.pdf. OMRI acknowledged that vitamins may be produced using excluded methods in their Generic List and published a Decision Tree For Evaluation of GMO Inputs in Organic Livestock Production on page 85 of their Generic List. http://www.omri.org/sites/default/files/app_materials/OMRI-GML-Stan-2013small_0.pdf

The addition of vitamins directly or indirectly into animal food falls under the regulatory oversight of the U.S. Food and Drug Administration (FDA). According to FDA regulations, the addition of vitamins must be used according to the relevant food additive regulation, unless the substance is generally recognized as safe (GRAS) under 21 CFR 582/584 for that use pattern (FDA, 2014a).

Environmental Impact

No studies have been found indicating toxic effects of vitamins on soil-dwelling organisms. Strong acids and bases are used in the synthetic or extraction process of vitamin compounds. Improper use or disposal of these chemicals during the production of vitamins could affect both the pH and chemical composition of the soil, potentially resulting in physiological effects on soil organisms. Accidental release of chemical reagents during the production process may lead to ecological impairment. Aquatic ecosystems are particularly sensitive to the introduction of nutrients from nearby agricultural operations. Releasing excessive amount of agricultural materials—including phosphate and nitrate fertilizers, feed materials and manure—to waterways can encourage the growth of algae (algal bloom) and other aquatic plants and ultimately oxygen depletion in the affected water zone (Wu, 1995; NAS, 1969).

Heath Impact

In addition to being essential nutrients, vitamins are generally considered non-toxic and safe for livestock and human consumption at levels typically ingested through the diet and dietary supplements.

When given according to label directions, supplementation of animal feeds with vitamins is unlikely to result in excessive vitamin intake for humans.

International
The Canadian National Standards Board, the Codex Alimentarius Commission, the EU and the Japanese organic standards all prohibit the use of synthetic vitamins when natural sources are available. If natural sources are not available, synthetic forms of vitamins are allowed. The United Kingdom Soil Association adds additional stipulation that the producer to must demonstrate nutritional deficiency of the animals' feed.

Public Comments
During the Spring 2019 NOSB review the Livestock Subcommittee received limited comments on retaining vitamins at §205.603. The comments that were received were overwhelmingly favorable comments for relisting Vitamins to §205.603 (d)(3), with many of the commenters stating that the addition of vitamins to the livestock diet was essential for the health and well-being of the animal.

A commenter stated that livestock feed should rarely need supplementation with synthetic vitamins, and then the only synthetic vitamins that may be needed on a limited basis would be vitamins A, C, and D. They detailed that B6 vitamins are naturally produced in the rumens of ruminant livestock and could naturally be added to the diets of pork and poultry by adding meats, rice bran, molasses, potatoes, wheat germ, pistachio nuts, cottonseed, brown rice, amaranth grain, chickpeas, sesame seeds, beans, sunflower seeds, barley malt flour, soy flour, corn, Japanese chestnuts, whey protein powder into the livestock rations.

In regard to this comment, we must comply with §205.237 (b)(5) which states that it is prohibited to "*Feed mammalian or poultry slaughter by-products to mammals or poultry.*" which would eliminate the addition of meats or whey protein powders to the rations. Many of the above natural sources cited as good sources for the B Vitamins are not commonly used in livestock rations and may not be readily available for livestock feedstock. During the Spring 2015 sunset review, the NOSB received several written public comments indicating overwhelming support for retaining synthetic vitamins on the NL. The use of green forages and pastures are alternatives; however, concerns were expressed regarding the availability of enough year-round quantity of forages and other. The Subcommittee would like comments from stakeholders to determine the availability of feedstocks to naturally supply the B vitamins.

Vitamins are recommended for relisting to the National List, based on the 2015 Tap Review, the 2015 NOSB unanimous vote to add vitamins to the National List, and the lack of new scientific or meritorious information.

Questions
Are there sufficient year-round supplies of forages and livestock feedstocks available to naturally supply the B vitamins into the livestock rations, or should B vitamins be removed from §205.603?

Subcommittee Vote:

Motion to remove vitamins from §205.603(d)(3) based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b) if applicable: NA
Motion by: Sue Baird
Seconded by: Ashley Swaffar
Yes: 0 No: 6 Abstain: 0 Absent: 0 Recuse: 0

National Organic Standards Board
Livestock Subcommittee
Petitioned Material Discussion Document
Fenbendazole
August 16, 2019

Summary of Petition:
A petition requesting a revision to the annotation for Fenbendazole to expand the use to poultry. This petition requests an annotation to 7 CFR §205.603(a)(23)(i) to include laying hens and replacement chickens intended to become laying hens.

Background of Current Listing:

In May 2012, fenbendazole was added to the National List of organic materials for use in organic livestock, as specified in 7 CFR §205.603(a):

> *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.

In 2016 the NOSB recommended that the annotation for Fenbendazole be amended to include the following:

- *That parasiticides continue to be prohibited in slaughter stock.*
- *That the milk withholding period after treatment with fenbendazole be changed from 90 days to 2 days for dairy cows, and 36 days for goats and sheep.*
- *That fleece and wool from fiber bearing animals be allowed to be certified organic even if use of parasiticides was necessary at some time in the animal's life.*
- *That fenbendazole be allowed without written order of a veterinarian.*

The NOP issued a final rule with an effective date of January 28, 2019, with the following language:

> *Paragraph (a)(23)(i) is revised to read as follows: Fenbendazole (CAS #43210-67-9)—milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep and other dairy species. AMS has reviewed and agrees with the NOSB recommendation that the annotation for fenbendazole be amended to clarify its use in organic livestock production.*
>
> *In addition, paragraph (b)(2) of § 205.238(b) is revised and paragraph (b)(3) is added to § 205.238(b) as follows: (b)(2) Dairy animals, as allowed under § 205.603; and (b)(3) fiber bearing animals, as allowed under § 205.603. AMS has reviewed and agrees with the NOSB recommendation that § 205.238(b) be amended to clarify its use of parasiticides for dairy animals and for fiber bearing animals.*

In the Spring of 2018 the NOSB recommended clarifying "emergency" for use of synthetic parasiticides in organic livestock production. The following language was recommended for a rule change:

Add this definition to 205.2

Emergency treatment to allow synthetic parasiticide use in livestock: A livestock emergency is an urgent, non-routine situation in which the organic system plan's preventive measures and veterinary biologics are proven, by laboratory analysis or visual inspection, to be inadequate to prevent life-threatening illness or to alleviate pain and suffering. In such cases, a producer must administer the emergency treatment (§205.238(c)(7)). Organic certification will be retained, provided that such treatments are allowed under § 205.603 and the organic system plan is changed to prevent a similar livestock emergency in individual animals or the whole herd/flock in future years as required under §205.238(a).

Add this to § 205.238 (b)

(4) Organic livestock as provided in §205.238 (b) (1), (2), and (3) and only in the event of an emergency where management strategies have been proven insufficient to prevent or control parasites within the accepted threshold for specific parasites, age and species of the animal. These management strategies include but are not limited to, grazing systems and living conditions that prevent infestation and re-infestation, forage height diversity, use of allowed non-synthetic botanicals, biologics and minerals to maintain parasite levels below treatment thresholds, and could include monitoring and documentation of parasites through use of methods such as fecal monitoring and FAMACHA.

This NOSB recommendation is still pending NOP review.

Summary of Review:

The Livestock Subcommittee reviewed the petition seeking to add an annotation to fenbendazole to expand its use in laying hens and replacement chickens intended to become laying hens. The Subcommittee did not feel the need to request an update technical report (TR) on Fenbendazole since a TR was conducted in June 2015.

Many organic laying hens have meaningful direct access to the soil, and this is one area where birds that are truly out grazing the land are at a disadvantage compared to birds on concrete porches. With the shifting demand for eggs from hens with humane certifications such as Free Range or Pasture Raised production models requiring 2.0-108.9 square feet per bird of outdoor access, many laying hen flocks are seeing large internal parasite infestations. When birds are out grazing, they are scratching and digging in the dirt for worms and in return picking up intestinal parasites. When a chicken has intestinal parasites some of the issues include having lower feed absorption, increased mortality, parasite transmission into the egg, and disease transmission to the hens.

Currently poultry producers sometimes use a diatomaceous earth product to help control intestinal worms. There are several concerns with this product including the amount needed to be ingested in relation to daily feed intake (non-balanced diets), worker and animal health hazards when using diatomaceous earth (respiratory concerns), and lack of efficacy to control severe parasite infestations.

If fenbendazole is added to the national list for laying hens and replacement chickens, it would be allowed only for emergency treatment when organic system plan-approved preventive management does not prevent infestation. Producers and certifiers would need to work together to define what an

emergency is for each producer. Examples include the discovery of internal parasites during routine posting or autopsy sessions of flocks, and/or observation of parasites in manure droppings. The Subcommittee feels strongly that fenbendazole should be used only in emergency situations and not on a routine basis.

Even though the current listing for fenbendazole for cattle, sheep, goats, and other dairy species specifies withdrawal times, the Subcommittee does not intend to restrict the use of fenbendazole on poultry by specifying a withdrawal time. The FDA reviewed fenbendazole's use as an approved animal drug and determined that it did not require a withdrawal time for poultry. "The data in study #S12173-00-DWF-MET-PO show that total residues of fenbendazole in eggs of treated chickens at zero-day withdrawal are well below the safe concentration of 2.4 ppm for residues in eggs."[1]

Use of the Substance:

- 200 mg of fenbendazole/ml for oral administration via drinking water
- Safe-Guard® AquaSol must be administered orally to chickens via the drinking water at a daily dose of 1.0 mg/kg BW (0.454 mg/lb.) for 5 consecutive days.

Conventional poultry producers typically administer fenbendazole to pullets (replacement layers age 0-17 weeks of age) or before outdoor access is given to birds to ensure birds have no internal parasites before starting egg production. When birds receive access to the outdoors they come into contact with soil and in turn come into contact with internal parasites. Many producers find the need to re-treat their flocks after a period of time when birds have access to the soil and come into contact with many internal parasites. Organic producers will need to utilize preventative management practices defined in their Organic System Plan as a first line of defense for internal parasites and if those preventative practices fail, an emergency treatment of fenbendazole could be used to control internal parasites.

Mode of Action:

Fenbendazole binds to β-tubulin, inhibiting assembly of microtubules, resulting in cell and parasite death. According to the Merck Veterinary Manual, "The wide safety margin of benzimidazoles is due to their greater selective affinity for parasitic β-tubulin than for mammalian tissues." (Merck, 2006)

Questions:

1. Is this material needed by organic poultry producers? If so, why?

2. Do currently allowed alternatives work to control internal parasites? And at what level of effectiveness?

3. What are some of the "emergency" events that would trigger use of this product? And how would producers determine those events?

4. Is there a concern with the 2.4 ppm residue of fenbendazole in eggs? Please submit information that supports this concern, or lack of concern.

[1] https://animaldrugsatfda.fda.gov/adafda/app/search/public/document/downloadFoi/3083

Subcommittee Vote:
Motion to accept the fenbendazole petitioned-material discussion document
Motion by: Ashley Swaffar
Seconded by: Sue Baird
Yes: 6 No: 0 Abstain: 0 Absent: 0 Recuse: 0