National Organic Standards Board Meeting
April 19 & 21 (Comment webinars), and April 26 - 28, 2022 (NOSB meeting)

PLEASE NOTE:

Discussion documents, proposals, reports and/or other documents prepared by the National Organic Standards Board, including its subcommittees and task forces, represent the views of the National Organic Standards Board and do not necessarily represent the views and policies of the Department of Agriculture. Please see the NOP website for official NOP policy, regulations, guidance and instructions.

Sunset 2024
Meeting 1 - Request for Public Comment
Livestock Substances § 205.603
April 2022

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 which must be reviewed by the NOSB and renewed by the USDA before their sunset dates. This document provides the substance's current status on the National List, annotation, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, this is noted in this list. To see if any new technical report is available, please check for updates under the substance name in the Petitioned Substances Database.

Request for Comments
While the NOSB will not complete its review and any recommendations on these substances until the Fall 2022 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the Spring 2022 public meeting. Comments should be provided via Regulations.gov at www.regulations.gov on or before April 1, 2022, as explained in the meeting notice published in the Federal Register.

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

Public comments should clearly indicate the commentor's position on the allowance or prohibition of substances on the National List and explain the reasons for the position. Public comments should focus on providing relevant new information about a substance since its last NOSB review. Such information could include research or data that may support a change in the NOSB's determination for a substance (e.g., scientific, environmental, manufacturing, industry impact information, etc.). Public comment should also address the continuing need for a substance or whether the substance is no longer needed or in demand.

For Comments that Support the Continued Use of §205.603 Substances in Organic Production:
If you provide comments supporting the allowance of a substance at §205.603, you should provide information demonstrating that the substance is:
1. not harmful to human health or the environment;
2. necessary to the production of the agricultural products because of the unavailability of wholly nonsynthetic substitute products; and
3. consistent with organic livestock production.

For Comments that Do Not Support the Continued Use of §205.603 Substances in Organic Production:
If you provide comments that do not support a substance at §205.603, you should provide reasons why the use of the substance should no longer be allowed in organic production. Specifically, comments that support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:
1. harmful to human health or the environment;
2. unnecessary because of the availability of alternatives; and/or
3. inconsistent with organic livestock production.

For Comments that Support the Continued Prohibition of §205.604 Substances in Organic Production:
If you provide comments supporting the prohibition of a substance on the §205.604 section of the National List, you should provide information demonstrating that the substance is:

1. harmful to human health or the environment;
2. unnecessary because of the availability of alternatives; and
3. inconsistent with organic livestock production.

For Comments that Do Not Support the Continued Prohibition of §205.604 Substances in Organic Production:
If you provide comments that do not support the prohibition of a substance at §205.604, you should provide reasons why the use of the substance should no longer be prohibited in organic production. Specifically, comments that support the removal of a substance from the §205.604 section of the National List should provide new information since its last NOSB review to demonstrate that the substance is:

1. not harmful to human health or the environment; and/or
2. consistent with organic livestock production.

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

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

Your comments should address whether any alternatives have a function and effect equivalent to or better than the allowed substance, and whether you want the substance to be allowed or removed from the National List. Assertions about alternative substances, except for those alternatives that already appear on the National List, should, if possible, include the name and address of the manufacturer of the alternative. Further, your comments should include a copy or the specific source of any supportive literature, which could include: product or practice descriptions, performance and test data, reference standards, names and addresses of organic operations who have used the alternative under similar conditions and the date of use, and an itemized comparison of the function and effect of the proposed alternative(s) with substance under review.

Written public comments will be accepted through April 1, 2022, via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

§205.603 Sunsets: Synthetic substances allowed for use in organic livestock production:

- Chlorhexidine
- Glucose
- Tolazoline
- Copper sulfate
- Elemental sulfur
- Lidocaine

§205.604 Sunsets: Nonsynthetic substances prohibited for use in organic livestock production:

- None

Chlorhexidine

Reference: §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.
(6) Chlorhexidine—Allowed for surgical procedures conducted by a veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.
Technical Report: 2010 TR; 2015 TR.
Petition: N/A
Past NOSB Actions: 10/1999 minutes and vote; 11/2005 sunset recommendation; 11/2009 Annotation change/clarification; 04/2010 sunset recommendation; 10/2015 sunset recommendation; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Sunset renewal notice effective 3/15/2017 (82 FR 14420); Annotation amendment effective 1/28/2019 (83 FR 66559)
Sunset Date: 01/28/2024

Subcommittee Review

Use
Used as an antimicrobial during surgery for cleansing wounds, skin, and equipment. Also used as a pre and post teat dip to aid in controlling bacteria that cause mastitis. There are numerous synthetic disinfectants currently on the National List for organic livestock production, including iodine, ethanol, isopropanol, sodium hypochlorite, and hydrogen peroxide. Not all alternatives to chlorhexidine are useful in both a surgical environment and as a teat dip, as allowed under the chlorhexidine annotation. Chlorhexidine reportedly kills mastitis-causing pathogens faster than iodine and is more persistent in its disinfection activity. Chlorhexidine is gentler on the skin than iodine, which is especially useful in northern climates where an irritated udder and teats can be especially problematic for the animals in cold winter months. Approved legal uses of the substance include disinfection during livestock surgery, on teats pre and post milking, and on milking equipment. Chlorhexidine is also used in food processing as a hard surface disinfectant and in human dentistry as a mouth wash and to disinfect equipment.

Manufacture
Limited information is available regarding the manufacture of chlorhexidine for use in commercially available disinfectants, sanitizers, bactericides, and virucides. The general procedure for industrial-scale chlorhexidine production involves initial synthesis of the 1,6-hexamethylenebis(dicyandiamide) intermediate, followed by reaction of the intermediate with 4-chloroaniline hydrochloride. Once purified, chlorhexidine is combined with acetic acid or D-gluconic acid to generate the commercially relevant diacetate or digluconate salts of chlorhexidine.

International Acceptance
Canadian General Standards Board Permitted Substances List
The Canadian General Standards Board allows the use of chlorhexidine under Section 5.3 (Health Care Products and Production Aids) of the Permitted Substances Lists for Livestock Production (CAN, 2011). Specifically, the rule states that chlorhexidine may be used in the following ways: (1) for surgical procedures conducted by a veterinarian, and (2) as a post-milking teat dip when alternative germicidal agents and physical barriers have lost their effectiveness.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
According to Article 23 (4) of the Commission Regulation concerning organic production and labeling of organic products, *Housing, pens, equipment, and utensils shall be properly cleaned and disinfected to*

prevent cross-infection and the build-up of disease carrying organisms. Feces, urine and uneaten or split feed shall be removed as often as necessary to minimize smell and to avoid attracting insects or rodents.

The list of approved substances for cleaning and disinfection of building and installations for animal production includes "cleaning and disinfection products for teats and milking facilities." However, the rule does not explicitly describe the restrictions of use for available teat dip substances (EC, 2008). It is therefore uncertain whether European regulations allow the use of chlorhexidine as a topical disinfectant (e.g., teat dip) in organic livestock production.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
Chlorhexidine is not listed in CODEX.

International Federation of Organic Agriculture Movements (IFOAM) Norms
Appendix 5 of the IFOAM Norms, which provides a list of "substances for pest and disease control and disinfection in livestock housing and equipment," includes iodine and "cleaning and disinfection products for teats and milking facilities." However, the standard does not explicitly describe the restrictions of use for available teat dip substances (IFOAM, 2014). It is therefore uncertain whether IFOAM guidelines permit the use of chlorhexidine as a topical disinfectant (e.g., teat dip) in the organic production of dairy animals.

Japan Agricultural Standard (JAS) for Organic Production
According to Table 4 of the Japanese Agricultural Standards for Organic Livestock Products, chlorhexidine is an allowed synthetic agent for cleaning and disinfecting livestock housing (JMAFF, 2012). However, chlorhexidine is not explicitly allowed for use in pre- or post-milking teat dips under Japanese organic regulations.

Environmental Issues
The 2015 TR indicates that although data is limited, chlorhexidine is readily biodegradable in the atmosphere, with limited biodegradation in the terrestrial and aquatic compartments [TR 275-277] . However, chlorhexidine is not considered to be persistent, bioaccumulative, or toxic to humans. Production and use of chlorhexidine as an antiseptic and disinfectant will result in releases to the environment through waste streams and spills. Chlorhexidine exists primarily in protonated (cationic) form in the environment, and thus is expected to adsorb strongly to organic carbon and clay despite its predicted high mobility in soil. Likewise, chlorhexidine is expected to adsorb to suspended solids and sediments when released to water [TR 433 - 436]. Despite the relatively low risk associated with chlorhexidine, environmental hazards cannot be excluded for improper handling and disposal of chlorhexidine products. Specifically, chlorhexidine salts are highly toxic to aquatic life with long lasting effects [TR 438 - 439]. Registrant-submitted studies indicate that concentrations as low as 60 parts per billion are toxic to half of the freshwater water fleas in an acute toxicity test [TR 439 - 441](. Further, 4-chloroaniline used in the synthesis of chlorhexidine is highly toxic to red blood cells and DNA, and exposure to residues of this substance in contaminated chlorhexidine solutions may lead to toxic effects in terrestrial organisms [441 – 443]. As a general antimicrobial agent, chlorhexidine is potentially toxic to beneficial soil organisms, including nitrogen fixing bacteria and mycorrhizal fungi.

Discussion
When other products have lost their efficacy, chlorhexidine is used to treat mastitis. It is also used by veterinarians as an antimicrobial during surgery. Both uses are seen to be effective and safe, and chlorhexidine is not seen as an overused product.

Questions to our Stakeholders

1. How often is chlorhexidine used as an aid in controlling bacteria that causes mastitis?
2. Are naturally derived substances, as well as other approved synthetic substances, sufficient to remove chlorhexidine as a disinfectant or sanitizer from this listing?

Glucose

Reference: §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.
(13) Glucose.
Technical Report: 1995 TAP.
Petition: N/A
Past NOSB Actions: 10/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420); Sunset renewal notice effective 10/30/2019 (84 FR 53577).
Sunset Date: 10/30/2024

Subcommittee Review

Use
Glucose is a synthetic substance allowed in organic livestock production for medical treatment. For animal health purposes, glucose is used primarily as an aid in the treatment of ketosis in cattle. Additionally, glucose is an important remedy for dehydration, neonatal hypoglycemia, as an ingredient in formulated electrolyte solutions, and as an excipient.

Manufacture
An updated TR for 2021 notes that glucose is made through the hydrolysis of starches, mostly originating from corn, but could be sourced from wheat, rice, potato, barley, sago, or sorghum. In the process of hydrolysis, glucose can be formulated with enzymes or acids as the catalyst.

International Acceptance
Canadian General Standards Board Permitted Substances List
Glucose is permitted for use under section 5, Table 5.3 as a Health Care Product and Production Aide with no annotations or restrictions.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Article 14 addresses Livestock production rules.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
Annex 1, Principles of Organic Production, Section B, subsections 20 thru 24 address Health Care in Livestock.

International Federation of Organic Agriculture Movements (IFOAM) Norms
Section 5.6 addresses General Principles for use of Veterinary Medicines for Livestock.

Environmental Issues
According to the 2021 TR, glucose is abundant in the environment and is easily metabolized. It is not expected to accumulate in the environment, but as excreted in the urine of ruminants after treatment, is expected to be consumed by microbes in soil systems. As an important biomolecule, glucose has very low toxicity. Environmental concerns with glucose are associated with the agricultural production of starch-containing-crops used to produce glucose and the energy and materials consumed during manufacture. The TR goes on to describe the starch industry as causing very little waste due to the effective use of all side streams as economically valuable products, noting that very little waste is sent to a landfill or incineration. Glucose is not expected to negatively impact environmental or human health from chemical interactions in organic crop, livestock, or handling systems. The use of glucose in organic systems is not expected to threaten water or soil systems.

Discussion
Glucose is an essential animal health remedy in organic systems. It is typically used to treat ketosis and dehydration when preventative measures have failed. While ketosis is a concern in most dairy herds, some producers note that due to an elevated risk of ketosis, it is necessary to maximize pre-parturition confinement in order to prevent ketosis through a low potassium diet. With glucose in the "toolbox", producers can proceed with grazing pasture closer to parturition with the confidence that they will be able to address ketosis, should it arise. Previous sunset reviews have reflected low levels of glucose usage, but farmers and inspectors have consistently commented that glucose is an essential treatment and there is a high degree of support for keeping glucose on the National List. Since glucose is used as an excipient and in electrolyte formulations (for example), retaining glucose on the National List of allowed synthetics also maintains this important tool in formulations.

Questions to our Stakeholders
1. The National List does not currently place any use restriction on glucose other than the placement of the listing for use as a disinfectant, sanitizer, or medical treatment as applicable. Is further clarification or annotation needed for this substance on the National List?
2. The National List references multiple substances for the treatment of ketosis, including propylene glycol, calcium propionate, calcium borogluconate, and electrolytes. Is glucose equally necessary and effective as a tool for organic farmers for treatment of all stages of the development of this condition?

Tolazoline

Reference: §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.
(29) Tolazoline (CAS #-59-98-3)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires:
(i) Use by or on the lawful written order of a licensed veterinarian;
(ii) Use only to reverse the effects of sedation and analgesia caused by xylazine; and
(iii) A meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals.

Technical Report: 2002 TAP; 2019 TR.
Petition: 2002.
Past NOSB Actions: 9/2002 recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 11/2017 sunset recommendation.

Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420); Sunset renewal notice effective 10/30/2019 (84 FR 53577).
Sunset Date: 10/30/2024

Subcommittee Review

Use
Tolazoline is limited to use only by a veterinarian prescription and is further restricted for "use only to reverse the effects of sedation caused by xylazine." Xylazine is primarily used in veterinary medicine as a sedative, tranquilizer, and analgesic. Sedation of animals is necessary for both planned medical procedures and emergency procedures to prevent pain and suffering, well as injury to the veterinarians performing the procedures. Tolazoline is commonly used as a reversal agent for xylazine, by competing for the α2-adrenergic receptors, blocking binding events for xylazine. Structural similarities with xylazine allow tolazoline to compete with xylazine for biological binding sites, providing the mode of action for its approved use in organic livestock production as a reversal agent for xylazine.
Tolazoline is used only for veterinary applications, with no natural alternatives or USDA-approved synthetic alternatives. There are no alternative practices that would make the anesthetic agent unnecessary. Tolazoline may be made unnecessary by allowing the veterinary subject to recover from the effects of xylazine by natural metabolism of the substance, rather than its active reversal. However, the rate of xylazine metabolism is species-dependent; therefore, this may prove problematic in species with slower metabolic rates (e.g., cattle).
Manufacture
Tolazoline is a synthetic substance that is produced by a one-pot process (i.e., no intermediates are isolated) by the reaction of phenylacetaldehyde with ethylene diamine, with the incorporation of an iodine-based oxidation process.
International Allowance
Canadian General Standards Board Permitted Substances List
Although 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 (the most commonly used substance for a reversal agent for sedatives, including xylazine) is not listed in the CAN/CGSB-32.311-2015.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Tolazoline is not listed in the EEC EC No. 834/2007 or 889/2008.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
Tolazoline is not listed in the CODEX.
International Federation of Organic Agriculture Movements (IFOAM) Norms
Tolazoline is not listed in IFOAM.

Japan Agricultural Standard (JAS) for Organic Production
Tolazoline is not listed in the JAS for Organic Production.

Environmental Issues
Tolazoline is a synthetic α2-adrenergic antagonist that also interacts with histamine and cholinergic receptors in a temporary and reversible manner. Tolazoline affords several physiological effects, including vasodilation (increasing arterial oxygenation), transient hypotension, histaminic gastrointestinal effects. There are no published toxicity or carcinogenicity studies on the toxicity or lethal dosages of tolazoline.

Tolazoline is listed by the EPA as an inert ingredient of toxicological concern. There are no reported studies on the environmental toxicity, persistence, or concentration of tolazoline.

Questions to our Stakeholders
Tolazoline is a synthetic substance that is limited to use only by prescription from a veterinarian to reverse the effects of the sedative xylazine. Are there any new non-synthetic substances that can be used to reverse the effect of the sedative xylazine as effectively as tolazoline?

Copper sulfate

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.
(1) Copper sulfate.
Technical Report: 1995 TAP; 2015 TR.
Petition: N/A
Past NOSB Actions: 10/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420); Sunset renewal notice effective 10/30/2019 (84 FR 53577).
Sunset Date: 10/30/2024

Subcommittee Review

Use
Copper sulfate is listed on the National List of allowed synthetic substances for use in organic livestock production at § 205.603 as a topical treatment, external parasiticide or local anesthetic. Copper ions have been reported to have antimicrobial activity against a wide range of aerobic and anaerobic bacteria and fungi. The exact mechanisms by which copper sulfate exerts its biocidal effect is a source of numerous ongoing investigations in the scientific literature. Copper sulfate has been used as a footbath antiseptic to help control and prevent infectious hoof disease problems that affect the skin adjacent to the claw horn of dairy cattle and sheep i.e., digital dermatitis (DD) (hairy heel warts), foot rot lesions (interdigital area and invading the subcutaneous tissue), and heel erosions. Depending on the severity of the infection, the impact on managed cattle and or sheep ranges from minor discomfort to severe debilitating lameness, reproductive problems and in the dairy industry a reduction of milk production ranging from 20 to 50 percent [2015 TR, 93 – 98].

Manufacture
Copper sulfate is a synthetic compound produced by a chemical process. Copper sulfate is produced commercially by reacting various copper minerals and or metal with sulfuric acid [2015 TR 293 - 294.

International Acceptance
Canadian General Standards Board Permitted Substances List
Allowed as an essential nutrient (source of copper and sulfur) and for topical use (foot baths).

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Not listed.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
Not listed.

International Federation of Organic Agriculture Movements (IFOAM) Norms
Not listed.

Japan Agricultural Standard (JAS) for Organic Production
Not listed.

Environmental Issues
See 2015 TR for references.
Walk-through footbaths are used to help control and prevent hoof related diseases in dairy cattle and sheep. A five-to-ten percent copper sulfate solution is commonly used as the antimicrobial agent in the footbath and is considered effective for 150 to 300 animal passes. Spent solution is mixed with manure waste and ultimately disposed by land application. Regulators in several states (Ippolito et al., 2013, Rankin, 2012) have expressed concern that soil copper could be increased to an unhealthy level by this practice and have established maximum (lifetime) loading rates of copper. An 8 ft. x 2.5 ft. x 5-inch foot footbath will contain approximately 62 gallons of water and 26 pounds of copper sulfate (charged at the 5% concentration). Since copper sulfate is 25% copper, each time the footbath is dumped, 6.5 pounds of copper is added to the disposal burden. The environmental effect of this copper depends on the volume of footbath solution disposed (a function of the number of animals and intensity of footbath use), concentration of copper sulfate, and the land area of application. Without careful attention, maximum soil copper loading rates may be exceeded in relatively short times (5 to 30 years) (Epperson et al., 2007). Depending on the agricultural crop, the annual removal rate for copper is less than 0.5 pound/acre per year. Federal, state, and local environmental regulations require the development of manure management plans to protect water resources and soil quality. The EPA has specific guidelines for copper loading to agricultural land when sewage sludge or biosolids are applied. The EPA §503.13 standard limits annual loading of copper from biosolids to 66 pounds copper per acre and limits lifetime loading to 1,339 pounds copper per acre (limits are based on biosolids land application) (EPA, 2014). Reaching these limits is almost impossible with dairy waste applications and would devastate most agricultural crops long before the lifetime loading limits were met. Some states have lower limits for copper application. New York and Illinois have set lower lifetime loading limits for copper at 75 and 250 pounds per acre, respectively, in order to avoid the potential of irreversible toxic accumulations of copper in the soil (Socha et al., 2007, Ippolito et al., 2013, Rankin, 2012). While more studies are needed, Ippolito et al. recommended that alkaline soils with greater than 50 ppm extractable copper should not have additional copper load added to soil. This value is advisable for producers raising alfalfa for dairy cow consumption in order to avoid copper accumulation above the NRC 2005 recommendations for the maximum tolerable Cu level for cattle and sheep. Ippolito et al. suggested that soil samples be tested for extractable copper every two to three years from an accredited soil testing laboratory to determine if a copper accumulation problem exists.

Discussion
The Livestock subcommittee noted that while copper sulfate use in livestock appears to be essential as of this review, there are environmental impacts associated with its use. The subcommittee discussed whether zinc sulfate could be a reasonable replacement for copper sulfate on livestock operations and generally encourage organic industry stakeholders to help identify new research on alternatives.

Questions to our Stakeholders
1. Can the consistent use of foot trimming allow for the elimination of copper sulfate on dairy farms?
2. Have other foot bath treatments of similar efficacy come on to the market?

Elemental sulfur

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.
(2) Elemental sulfur—for treatment of livestock and livestock housing.
Technical Report: 2017 TR.
Petition: 2016.
Past NOSB Actions: 11/2017 recommendation to add.
Recent Regulatory Background: Added to National List on 5/30/2019 (84 FR 18133).
Sunset Date: 05/30/2024

Subcommittee Review

Use
Elemental sulfur is currently allowed for use in organic production as an insecticide, for plant disease control, as a plant or soil amendment, and as a pesticide for domestic livestock.

Elemental sulfur is granulated to a fine powder (325 mesh) for use as a pesticide (control for mites, insects, fungi, and rodents) in livestock production. The particle size for this powder is 44 microns (0.0017 inches) or less. Sulfur is dusted liberally and rubbed into feathers or hair. Sulfur dusting and or spraying is used for both the animals and their respective accommodations. Livestock species include chickens, turkeys, ducks, geese, game birds, pigeons, equine species, cattle, swine, sheep, and goats.

Manufacture
Sulfur is an abundant element on the earth. Elemental sulfur is found in volcanic sites and salt domes. Sulfur was classically mined from these using the Frasch process in the U.S. as late as the 1920s, but this is not a major source today.

Sulfur is also found in petroleum, natural gas, and fossil products from which it must be removed as a legal mandate to avoid the production of sulfur dioxide, a contaminant of the air. Hydrogen sulfide from petroleum refining and fossil fuels is converted to pure sulfur by the Claus process. The Claus process is used to produce the majority of sulfur available today. In a heating and cooling cycle, hydrogen sulfide recovered from fossil products is combusted to form water and elemental sulfur:

$$16\ H_2S + 10\ O_2 \rightarrow 2\ SO_2 + 7\ S_2 + 16\ H_2O$$

The addition of an aluminum or titanium catalyst permits the reaction of SO_2 formed during combustion with additional molecules of H_2S to yield sulfur and water:

$$2\ H_2S + SO_2 \rightarrow 3\ S + 2\ H_2O$$

In 2015, recovered elemental sulfur and its byproduct sulfuric acid were produced at 103 operations in 27 States. Total shipments were valued at about $933 million. Elemental sulfur production was 8.7 million tons; Louisiana and Texas accounted for about 52% of domestic production. Elemental sulfur was recovered, in descending order of tonnage, at petroleum refineries, natural-gas-processing plants, and coking plants by 39 companies at 96 plants in 26 States. Domestic elemental sulfur provided 64% of domestic consumption. About 11 million tons of sulfur were used in the US in 2015 (USGS, 2016; for references, please see the 2017 technical report for Elemental Sulfur: Livestock).

International Acceptance
Canadian General Standards Board Permitted Substances List
Sulfur is allowed for control of external parasites.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Commission Regulation (EC) No 889/2008 permits the use of elemental sulfur (98% pure) as a fertilizer or soil amendment and as a fungicide, acaricide and repellent in organic farming. Sulfur is not permitted for use as an insecticide in livestock.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
Codex Alimentarius guidelines (GL 32-2013) permit the use of sulfur for livestock and livestock products in bee husbandry for pest and disease control. With recognition by the certification body or authority, GL 32-2103 permits the use of sulfur in soil fertilizing and conditioning, and plant pest disease control.

International Federation of Organic Agriculture Movements (IFOAM) Norms
The IFOAM norms allow the use of sulfur as a fertilizer and soil conditioner and as a crop protectant in organic crop production. IFOAM allows the use of sulfur for pest and disease control in beekeeping. Sulfur is not permitted for use as an insecticide in livestock.

Japan Agricultural Standard (JAS) for Organic Production
The Japan Agriculture Standard for Organic Production permits the use of sulfur as a fertilizer or soil improvement. Sulfur is not permitted for use as an insecticide in livestock.

Environmental Issues
Elemental sulfur seems benign unless being handled or administered in very large amounts, for instance in transport in molten form or when stored in open piles. It can also be overfed in unusual cases.

Consumption by ruminants of a high dietary percentage (>0.3%) of sulfur as elemental sulfur or sulfate can cause toxic effects. Sulfur bacteria in the rumen produce the poisonous gases, hydrogen sulfide and sulfur dioxide that eructate from the rumen and are absorbed through the lungs. Diets rich in sulfate can depress feeding. In spite of the liver's capability for detoxifying sulfide in the blood, extreme cases of sulfur toxicity can lead to death (Kandylis, 1984).

In livestock production, hydrogen sulfide can be a hazard to human health. This colorless toxic gas with a rotten egg odor is produced during the degradation of liquid manure stored in anaerobic conditions within agricultural livestock operations. However, the contribution of elemental sulfur to the hydrogen sulfide livestock production hazard for workers is negligible (EPA, 2013a).

Current available U.S. Environmental Protection Agency toxicity studies and literature searches for elemental sulfur do not indicate any systemic human toxicity associated with elemental sulfur exposure and no endpoints of toxicological concern have been identified. The acute toxicity of sulfur is low. Only the word caution or no signal word is required on the label for elemental sulfur for acute toxicity, inhalation, and dermal exposure. Sulfur is an eye and skin irritant (category III, moderate irritation (erythema) at 72 hours), but is not a skin sensitizer. The EPA's review of incident data indicates that both the relative number of reported incidents and the severity of reported health effects are low.

Discussion
In 2017, public comments indicated that producers, especially poultry producers, supported the listing of this substance on the National List to help control mites. Producers also indicated that alternatives were not effective. The NOSB voted to add elemental sulfur to the National List based on public comment, and its compatibility with a system of sustainable agriculture.

However, the EEC, IFOAM, and Japan do not allow sulfur use on livestock. Evidently, their farmers use other practices or products for this purpose.

According to the 2017 TR, extracts of neem seeds diluted with water or soap have been shown to be effective treatments for mites, ticks, fleas, flies, and some insects for livestock (Schmahl et al., 2010). Pest control in poultry production depends upon the production system. In cage free production, where chickens can partake in dustbathing behaviors, both kaolin and diatomaceous earth in the dust bath can serve as a good treatment for mites and lice (Martin and Mullens, 2012). Several essential oils have been shown to be effective against lice and ticks (Rossini et al., 2008; Jaenson et al., 2005)).

Questions to our Stakeholders
Are alternatives sufficient to control external livestock pests?

Lidocaine

Reference: §205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.
(5) Lidocaine—as a local anesthetic. Use requires a withdrawal period of 8 days after administering to livestock intended for slaughter and 6 days after administering to dairy animals.
Technical Report: N/A
Petition: N/A
Past NOSB Actions: 10/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 2016 annotation change recommendation; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice 2017 (82 FR 14420). Annotation change effective 1/28/2019 83 FR 66559
Sunset Date: 01/28/2024

Subcommittee Review

Use
Lidocaine is a local anesthetic used to reduce or prevent pain during de-budding horns in livestock, or general minor surgery on mature livestock. They numb only the area to be worked on. Humane treatment of animals is critically important, and the public expects high standards of animal welfare for organic livestock. A lengthy withholding period after treatment may result in animals not being treated in a timely manner, or not being treated at all. Section 205.238 establishes a livestock healthcare practice standard permitting physical alterations needed to promote animal welfare in a manner which minimizes stress, and further that a producer must not withhold medical treatment in an effort to preserve its organic status.

Manufacture
Lidocaine, 2-(diethylamino)-*N*-(2,6-dimethylphenyl)acetamide (2.2.2), is synthesized from 2,6-dimethylaniline upon reaction with chloroacetic acid chloride, which gives α-chloro-2,6-dimethylacetanilide, and its subsequent reaction with diethylamine.

International Acceptance
Canadian General Standards Board Permitted Substances List

Use of pharmaceutical local anesthetics shall be followed by withdrawal periods of 90 days for livestock intended for slaughter, and seven days for dairy animals.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Not listed.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
Not listed.

International Federation of Organic Agriculture Movements (IFOAM) Norms
Not listed.

Japan Agricultural Standard (JAS) for Organic Production
Not listed.

Environmental Issues
Lidocaine is extensively and rapidly metabolized in the liver of mammals, followed by excretion via urine. No more than 10% of the dose is excreted as parent lidocaine. There is no excretion via feces. Lidocaine is not readily biodegradable and is not predicted to bioaccumulate in aquatic organisms. The Predicted Environmental Concentration (PEC) / Predicted No Effect Concentration (PNEC) ratio is 6.5 x 10-2 , which means use of lidocaine is predicted to present an insignificant risk to the environment.

Discussion
The subcommittee notes that animal welfare is an innate aspect of organic livestock production, and lidocaine has been a consistent tool to minimize livestock pain.

Questions to our Stakeholders
1. Since lidocaine was last reviewed have alternative anesthetic substances emerged?

National Organic Standards Board
Certification, Accreditation and Compliance Subcommittee
Proposal: NOP Risk Mitigation Table Review
February 8, 2022

Background:
On November 18, 2021, the National Organic Program (NOP) sent a memo to the National Organic Standards Board (NOSB) requesting that it review and facilitate public comment on the NOP Risk Mitigation Table. This table was developed in response to the 2020 Peer Review conducted by the American National Standards Institute (ANSI) National Accreditation Board and seeks to document the ways NOP safeguards impartiality in the delivery of services and oversight over accredited certifiers. International Standard ISO/IEC 17011; *Requirements for accreditation bodies accrediting conformity assessment bodies*, which is the standard NOP adheres to in carrying out its accreditation procedures, along with those required by the organic regulations themselves, was revised in 2017. The new ISO standard now recommends that an organization's risk mitigation controls be reviewed by a representative body. The NOSB is serving as this "representative body" given the board's prior interest in the NOP's Peer Review process.

Summary of Review:
The Certification, Accreditation and Compliance Subcommittee (CACS) reviewed the NOP Risk Mitigation Table and has determined that all potential conflicts were included and are clear. The CACS did not identify any additional potential conflicts to be included.

In addition to CACS's review and the full NOSB's review and consideration, the Board and program are seeking feedback from stakeholders to identify or clarify any potential conflicts of interest and mitigation strategies not covered in the table, so that these may be incorporated, as applicable.

Subcommittee Proposal:
CACS recommends that NOP incorporate the Risk Mitigation Table into their procedures.

Questions to Stakeholders:
1. What potential conflicts of interest and mitigation strategies are missing from the table?
2. Could any potential conflicts of interest and mitigation strategies identified in the table need further clarification?

Subcommittee Vote:
Motion to accept the proposal on the NOP's Risk Mitigation Table
Motion by: Kyla Smith
Second: Nate Powell-Palm
Yes: 5 No: 0 Absent: 0 Abstain: 0 Recuse: 0

National Organics Standards Board
Certification, Accreditation and Compliance Subcommittee (CACS)
Discussion Document: NOSB Technical Support Initiative
February 13, 2022

Background:
Much of the momentum for the initiative to seek technical support for the NOSB came from the Fall 2020 discussion document titled, [Human Capital Strategy for Organic Inspectors and Reviewers](). During its Spring 2021 meeting the NOSB considered a discussion document on Human Capital Management: Supporting the Work of the NOSB. Additionally, the NOP released a Request for Applications (RFA) for human capital in Spring 2021, which included a request for industry stakeholders to bring forth ideas on ways to support the NOSB through the public private partnership. No proposals were made for that component of the RFA. Therefore, the CACS developed this discussion document seeking feedback for NOSB support specifically. The rationale for this initiative is simple. NOSB positions are not financially compensated, and many Board members have full time jobs. The time investment and workload for NOSB members can be 10-15 hours per week and this can potentially limit the number of people willing to take on board membership.

To demonstrate the scope of work, NOSB members are tasked with the following activities:

- Review petitions to add or remove materials from the National List of Approved and Prohibited Substances (National List), and complete "Sunset" reviews of materials on the National List.
- Review and develop questions for Technical Reports to inform deliberations on materials.
- Complete materials-related checklists to assess the status of materials against the OFPA criteria for inclusion on the National List; conduct supporting research to determine the context of use of materials in the organic industry.
- Attend and participate in NOSB subcommittee calls and full Board meetings to discuss agenda items and deliberate on proposals.
- Conduct other research activities to support the development of proposals and recommendations on a range of topics of interest to the organic community.
- Review and prepare summaries of public comments in advance of public meetings.
- Write proposals and recommendations that summarize petitions, the Board's deliberations, Technical Reports, public comments, and justifications for Board positions.

Getting outside support could significantly reduce the time that Board members have to dedicate to NOSB tasks and could make tenure on the board a more attractive prospect to future members. While not all of the activities of the NOSB are amenable to support, the scope of activities and deliverables completed by the support team **could** involve:

- Conducting literature searches and research, and preparing research summaries for Board members to support their work. This may include research on the current context of material use, specific questions related to environmental or health impacts of materials, and/or research about alternative practices or materials.
- Review Technical Reports.
- Preparing summaries of public comments for Board member review.
- Drafting language for proposals and recommendations based on Board member input.

Written comments followed the Spring 2021 Board Meeting regarding the potential technical support for board members. Commenters were supportive of the idea, but not devoid of concerns. Several comments expressed the concern that the NOSB should be careful to not compromise the integrity of the process. Further concerns centered around not endangering the independent nature of the production and deliberation of the NOSB's proposals.

Summary of Recent Review by the CACS:

The CACS has had "NOSB Technical Support" as an agenda item for the past three subcommittee meetings. Two main questions have been discussed in some detail:

1. Where should the technical/advisory support come from?
2. Will the NOSB lose some of its autonomy if it receives technical support?

Source of Technical/Advisory Support
The question of where to source assistance focused on two broad categories. Technical support could come from within the government/USDA (but from outside of the NOP/AMS). Alternatively, support could come from outside organizations such as universities or nonprofits. The discussion thus far has appeared to lean towards an "inside" position but was not conclusive.

Autonomy of the NOSB
Regarding the preservation of autonomy, the subcommittee recognizes that there may be some concern, but felt confident that independence can be maintained with proper structuring of the relationship.

Questions for Further Discussion:

1. What are the advantages or disadvantages of having support come from within the government? From a nonprofit or university?

2. What NOSB tasks, if any, are critical to keep completely independent from the support team?

3. Should the support team be privy to all Subcommittee meetings and discussions?

4. What should be the scope of the NOP"s relationship with the contemplated support group, i.e., should they be able to task the group directly?

Subcommittee Vote:
Motion to accept the discussion document on NOSB technical support
Motion by: Jerry D'Amore
Seconded by: Kyla Smith
Yes: 5 No: 0 Abstain: 0 Absent: 0 Recuse: 0

National Organic Standards Board
Compliance, Accreditation & Certification Subcommittee (CACS)
Oversight Improvements to Deter Fraud:
Modernization of Supply Chain Traceability Spring 2022 Discussion Document
February 14, 2022

Introduction:
The NOSB and the CACS subcommittee, in particular, appreciate the level of community engagement received regarding the Fall 2021 discussion document focusing on the Modernization of Supply Chain Traceability. Since the Fall 2021 NOSB meeting, the Board has looked to identify opportunities to lay a strong foundation for what we all hope will become a continuously improving traceability system. The overall goal is to have organics be able to claim the title of the most traceable food system in America and the world one day. The organic seal derives trust from the consumer due to the assumption that the organic supply chain is transparent. As one commenter from the Fall meeting mentioned, "the NOSB makes the important point that we need key information regarding traceability and volume cataloged, and we need this to be readily accessible."

More consistent data reporting across the supply chain is a priority for the NOSB. Reflecting in oral and written comments at the Fall meeting, commenters indicated some steps that the community and the USDA can take in short order to enhance traceability efforts. In this discussion document, we highlight two key elements that are a low burden to the community and can aid in deterring fraud: 1) reporting acres per crop on a certified operation's certificate and 2) a universal bill of lading. Based on the Strengthening Organic Enforcement (SOE) proposed rule, it appears acres reporting on organic certificates would not be required as part of the final SOE rule.

Reporting Acres per crop:
Protecting integrity is foundational, and one commenter asked the question regarding the proposed rule on Strengthening Organic Enforcement (SOE), "Will the final rule require mandatory data reporting to NOP by crop type, acreage, and location; and number of animals by livestock type and location, at least on an annual basis to the Organic Integrity Database (OID)? A requirement for certifying agents to report production area certified by crop/livestock and location, on at least an annual basis, to the OID is one of the most impactful single actions that can be taken to increase the integrity in the global organic control systems." The commenter goes on to ask, "will the OID provide for global use? If not, then we recommend investing in some additional system that gives organic operations and certifying agents access to the same type of information about certified operations around the world that are operating under equivalency arrangements and selling products into the United States." The NOSB agrees with both comments from the community.

Is this currently being done?
As one commenter stated, "Currently, certifiers report acreage data from certified operations to the USDA's Organic Integrity Database (OID), but that data is incomplete because reporting acreage data is not mandatory for certifiers and is not reported in a consistent way by all certifiers." The commenter goes on to say that they "believe the NOP should make product and acreage reporting mandatory for certifiers."

At present, SOE appears to be poised to require the reporting of acres by crop into the OID. However, this information will not be public-facing in the OID. Since the NOP considers acres "confidential business information", It is understood that disclosure of acreage by crop will only be available to certifiers, leaving buyers and inspectors of organic crops, two of the key reporters of fraud, in the dark.

Why is reporting acres by crop important?
It is long acknowledged that fraud in organics is most often exposed by individuals reporting red flags to certifiers and the NOP. With this acknowledgment, the NOSB implores the USDA to elevate the ability of organic inspectors and buyers of organic crops to identify, in real-time, volume of sales. One means of doing this is to list the number of acres per crop on the organic certificate. Some innovative organic certifiers, specifically Ohio Ecological Food and Farm Association (OEFFA) and Organic Crop Improvement Association (OCIA), have already undertaken the practice of listing the number of acres per crop on organic certificates. In real-time, inspectors reviewing purchase records where this information is disclosed can identify any inconsistencies between sales levels and production capacity.

Furthermore, buyers of organic crops will be able to cross-check if the operations from whom they are buying have the ability to produce the volume of crops purchased. At the aggregation point, reasonably considered the first most risky point in the supply chain, aggregators of crops from multiple producers would supply all organic certificates to the inspector who can quickly check if the capacity of the supplying operations could support the buying levels.

The NOSB calls on the organic certifier community to report crops by acreage across all certifiers. Furthermore, the NOSB implores the NOP to make acreage reporting on organic certificates mandatory for all certifiers of all operations certified to the NOP, both foreign and domestic.

Reporting product and acreage data and displaying it on the organic certificate is a low burden and provides additional opportunities to identify red flags in the organic supply chain. Fraud Prevention Plans are being discussed amongst the community. Greater transparency can be achieved with incremental steps within the certified operations if size and certified organic products grown are captured in the OID, visible to certifiers, and displayed on the certified operation's organic certificate. With acres displayed on the certificate, needed insight can be provided to inspectors, handlers, importers, and brokers to help identify potential fraud in the supply chain. Under current organic certificates, most certifiers list the crops an operation is certified to grow in a given year, but not the number of acres. To not "lose the forest for the trees," auditing an operation's entire production capacity, not just a single field, would allow buyers and inspectors to identify concerning sales levels more effectively and efficiently than auditing just a single field. One commenter from the Fall stated, "Additionally, accurate operation-level organic acreage data that is segregated by crop would assist in conducting high-level, big picture mass balance audits, in addition to those performed during inspections, to determine if the output from a specific region matches production levels or is an indication of fraudulent activity."

Another commenter stated, "acreage data must be collected, if we don't have a system of good production data, any OLS (Organic Link System) will fail. Crops should be listed on the certificate or in the Organic Integrity Database, or both, with more specificity. The OID is a very important tool for inspectors and certifiers, and we greatly value it".

Listing an operation's acres by crop will be a significant aid to inspectors and other supply chain participants in the effort to identify fraud before it becomes pervasive.

Universal Bill of Lading:
To draw parallels when considering standardization of key data, it is important to consider the pending Origin of Livestock rule. With the pending Origin of Livestock rule, the certification community will necessarily be innovating their forms and auditing requirements to satisfy the requirements outlined in the rule. This is a potential opportunity for certifiers to collaborate and draft best practices so that on all dairy operation inspectors know to ask consistent questions no matter the record-keeping system. Also, inspectors can expect specific data, so rigorous audits on the origin of livestock can be completed. In turn, this same spirit of collaboration could reasonably be applied to a "universal bill of lading" for all agricultural commodities.

The expectation of what information is essential to confirm traceability can vary from one certifier to the next. "Sufficient in detail and readily understood and audited" can be a point of inconsistency in the certification process, especially for growers who are transitioning or are new to organic. One way to embrace the bespoke nature of record-keeping is to consistently require key reporting information in transactions between operations where bulk goods change form and lots of bulk goods are aggregated. For example, the provenance of organic grain may be lost if the grower operation provides key information to their buyer and if the buyer does not record that information in transaction documents that move down the supply chain. For this reason, we call on the organic community to require inspectors and reviewers to confirm that the following data points are identified on transaction documents from grower to buyer/aggregator:

- unique lot number
- crop year grown
- date of transaction
- crop
- buyer name
- seller name

Why is a universal bill of lading important?
Record keeping is unique from operation to operation, which is notable, as it allows record-keeping to be maximally well suited to each operation.

As one commenter in the fall mentioned, "Keep in mind that it is the responsibility of the operation to demonstrate the integrity and robustness of their record-keeping system to inspectors and certifiers. Site-specific and adaptable record-keeping systems do not excuse or allow operators to keep poor records. If records are not sufficient in detail to be readily understood and audited and sufficient to demonstrate compliance, as required by 7 CFR 205.103, the inspector will note the issue of concern for the certifier to address."

Additionally, a commenter added, "right now, record-keeping systems vary widely across production and handling operations, with systems often specifically suited to the type of operation. Choosing any one system for all operators to adopt will inevitably be more or less burdensome for each operator depending on a host of variables."

We, as a board, agree with this comment; however, there are core pieces of information that are or should be "standardized" that can move the community collectively in the same direction. With the implementation of SOE, certifiers are aware that additional scrutiny will be placed on assessing whether record-keeping by an operation is sufficiently auditable. As a community, greater cooperation amongst the certification community assessing what is "sufficient" will be a significant step forward to building a more robust traceability system. The NOSB calls on the certification community to embrace consistent key data reporting on transaction documents.

In Closing:
As one commenter mentioned, "The integrity and future success of the organic system are dependent on the awareness, collaboration, and cooperation of everyone involved--the regulators, the certifiers, and the certified operations. Similarly, the prevention, detection, and eradication of fraud must be a cooperative effort, endorsed and implemented." Both acreage reporting by crop and universal bills of lading are viewed as fundamental steps for increased consistency in the community, ultimately aiding in increased transparency. Both are minimally burdensome to certified organic operations and certifiers while offering the potential to be significant contributors to improving fraud detection and building a consistent, transparent, traceable system.

Questions:
1. Should acreage by crop be included on organic certificates?
2. In addition to total certified acres should acres per crop also be included on the organic certificate and be public-facing in the Organic Integrity Database?
3. How can the community better educate inspectors and certified operators on what is sufficiently auditable record-keeping? (e.g., organic learning center, etc.)
4. What opportunities are there for stakeholders to collaborate in creating additional resources (e.g., forms, etc.) for use by organic operations that incorporate key data elements?
5. How can the NOP assist certifiers in issuing non-compliances for insufficient record keeping?

Vote in Subcommittee:

Motion to accept the discussion document on Oversight Improvements to Deter Fraud: Modernization of Organic Supply Chain Traceability - Spring 2022
Motion By: Amy Bruch
Seconded By: Nate Powell-Palm
Yes: 5 No: 0 Abstain: 0 Absent: 0 Recuse: 0

National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
Cetylpyridinium Chloride (CPC)
February 15, 2022

Summary of Petition, Petition addendum #1
Cetylpyridinium chloride (CPC), CAS #123-03-5, is being petitioned by Safe Foods Corporation as an antimicrobial processing aid specifically for application onto poultry or poultry parts at slaughter or processing plants. As such it is being petitioned to be listed on the National List at 7 CFR 205.605(b), synthetic nonagricultural (nonorganic) substance allowed in or on processed products labeled as "organic" or "made with organic (specified ingredients)." CPC would be added to water used as a drench or dip to reduce populations of foodborne pathogens such as Salmonella and Campylobacter that may be present on raw poultry. The petitioner's proposed listing is "*Cetylpyridinium chloride – Antimicrobial food treatment for use according to FDA limitation.*" The petition was received on 12/4/2019 (referred to as "petition") and amended on 4/24/2021 (referred to as "addenda"). A Technical Review (TR) was completed and found sufficient on 8/5/2021 (referred to as "TR"). The Handling Subcommittee is bringing this petition forward for full NOSB review at its Spring 2022 meeting.

Summary of Review:
The Handling Subcommittee has reviewed the relevant information on the cetylpyridinium chloride petition and discussed a range of specific issues.

One critical issue outlined in this proposal relates to the fact that CPC residues have been discovered on treated surfaces and poultry skin, exposing consumers to unlabeled pesticide residues.

Another relates to continued concern about sanitizer usage and regulation in organics and whether or not expansion of the sanitizer toolkit to support food safety requirements is essential for organic production. Previously, the NOSB has heard from an expert panel on sanitizers on the need for appropriate sanitizer rotations to prevent pathogen resistance and what material rotations can ensure appropriate efficacy. CPC is a powerful antimicrobial and raises questions about its fit with organic production. Significantly, another antimicrobial petition – for peroxylactic acid (POLA) – is currently before the NOSB on a different timeline, and its relevance to the CPC review is expected.

The fact that CPC requires the use of an inert – propylene glycol (PG) – to complete its formulation, as outlined in full in the TR, raises another important question. Under OFPA reviews for handling do not include any guidance provisions for inerts like PG. However, because the inert PG is a functional requirement of the CPC formulation, the Subcommittee is facing – and has discussed – what is an unprecedented evaluation pathway for this material in its full application.

Nonetheless, the Subcommittee has reviewed CPC on the merits for its compatibility with OFPA and organic systems.

Reference Material:
Petition: https://www.ams.usda.gov/sites/default/files/media/CPC_PetitionAddendum1.pdf
Addendum: https://www.ams.usda.gov/sites/default/files/media/CPC_PetitionAddendum1.pdf
Technical Report (TR):
https://www.ams.usda.gov/sites/default/files/media/NOPCetylpyridiniumChlorideHandlingTR.pdf

Other – Biomonitoring California – Quaternary Ammonium Compounds (QACs):
https://biomonitoring.ca.gov/events/biomonitoring-california-scientific-guidance-panel-meeting-march-2021

Category 1: Classification

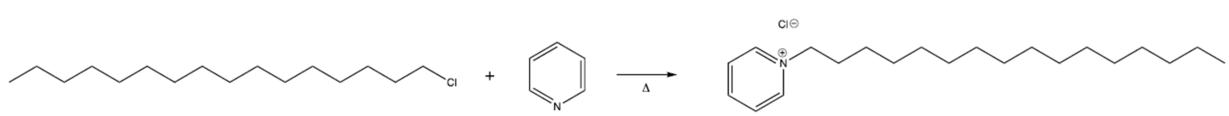
1. Substance is for: ____X___ **Handling** _______ **Livestock**

2. For HANDLING and LIVESTOCK use:
   a. Is the substance _______ **Agricultural** or ___X____ **Non-Agricultural?**
   Describe reasoning for this decision using NOP 5033-2 as a guide:

CPC is a non-agricultural synthetic substance.

   b. If the substance is **Non-agricultural**, 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:

According to the TR, "Cetylpyridinium chloride is a synthetic substance produced by reacting pyridine and cetyl chloride (1-chlorohexadecane) at an elevated temperature and pressure. The majority of commercial pyridine is produced through the Chichibabin reaction between acrolein, formaldehyde, and ammonia. According to the petition, the pyridine for this synthesis is produced exclusively from bioethanol components (USDA 2019). Bioethanol is formed through the fermentation of biomass such as corn or sugarcane to form biologically sourced ethanol... Once formed, ethanol and methanol can be oxidized to produce acetaldehyde and formaldehyde, respectively... Acetaldehyde and formaldehyde can then be combined to produce acrolein, which can be further reacted with formaldehyde and ammonia to form pyridine via the Chichibabin reaction…." Although not likely to be present in the final product, precursors to manufacture CPC include formaldehyde and acetaldehyde, both probable or known carcinogens ((https://oehha.ca.gov/proposition-65); https://www.epa.gov/iris), and acrolein is a respiratory irritant (https://oehha.ca.gov/chemicals/acrolein).



Equation 5

The pyridine ring is reacted with cetyl chloride to form CPC (Equation 5 from the TR). The source of cetyl chloride (CC) (synonym: 1-Chlorohexadecane/ CAS # 4860-03-1) is not described in the petition or TR. Manufacturing information about CC was not available from the petition, TR, PubChem, EPA, or ECHA. Cetyl chloride is considered an irritant with a "Warning" label but does not appear very toxic (https://pubchem.ncbi.nlm.nih.gov/compound/1-chlorohexadecane).

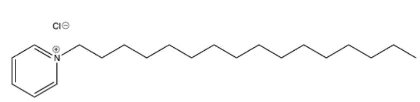


Figure 1. The chemical structure of cetylpyridinium chloride

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)]

As petitioned for use only as a drench or dip for poultry carcasses or parts, it is unlikely that that CPC will interact 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)]

CPC is a quaternary ammonium compound (QAC) used as a microbicide. QAC use in general has increased due to COVID-19 safety protocols. To date, no QACs are present on the National List. In contrast to many other sanitizers on the National List, CPC is not an oxidant. It "has been reported to be more effective against Gram-positive bacteria." As paraphrased from the TR: Gram-positive bacteria have membrane surfaces that bear a negative charge. The positively charged pyridinium portion of the substance binds to the negatively charged bacterial membrane through electrostatic interactions. The electrostatic attraction improves the ability of the substance to rearrange membrane lipids. Additionally, the binding of the positively charged pyridinium portion of the substance disrupts membrane function and bacterial metabolism, which may deactivate bacteria. Once initial bacterial populations have been reduced, cetylpyridinium-chloride-treated meat products have been shown to maintain reduced bacterial populations when stored between 14 and 42 days.

At high concentrations, CPC is toxic to humans. CPC is identified as a hazardous substance according to the Global Harmonized System of Classification and Labeling of Chemicals (GHS) and summarized in Table 3 from the TR:

Table 3. GHS classification of cetylpyridinium chloride

Hazard class	Hazard statement	Pictogram
Acute toxicity, oral, category 4	H302—Harmful if swallowed	
Skin corrosion/irritation, category 2	H315—Causes skin irritation	
Serious eye damage/eye irritation, category 1	H318—Causes serious eye damage	
Acute toxicity, inhalation, category 2	H330—Fatal if inhaled	
Specific target organ toxicity, single exposure, respiratory tract irritation, category 3	H335—May cause respiratory irritation	

Class 1 reflects the highest danger and Class 4 reflects the lowest danger. CPC represents higher risks (Class 1-2) for skin corrosion/irritation, ocular damage, and inhalation toxicity. Like many toxicants, the dose makes the poison, and lower health-based benchmarks have been established for CPC where adverse effects in humans, when exposed, would be unlikely to occur. QACs exposure in general was reviewed by the California Biomonitoring Science Guidance Panel, which raised some concerns about long-term exposure and recommended biomonitoring of QACs to better understand exposure trends. Of note, no occupational air monitoring data was reported in the petition, TR, or by EPA, NIOSH, ECHA, or aggregated data bases such as EWG. Similar to other sanitizers, it appears that there is little data to assess inhalation exposures in occupational environments where this sanitizer is approved for use. While exposures may be low because relatively dilute solutions are used as a microbicide, and because

QACs, in particular, are not highly volatile, information on potential exposures would be valuable. Toxicology data submitted by the petitioner does not address inhalation exposures.

CPC is approved for use in many consumer products, including mouthwash, toothpaste, and other products contacting oral cavities in humans. These uses almost certainly result in ingestion and dermal exposures that are deemed safe by FDA. As excerpted in the petition "…the FDA concluded that the no-observable effect level (NOEL) for the dog [study] … was 8 mg/kg body weight per day. By applying a 1000-fold safety factor to this value, the FDA determined the acceptable daily intake (ADI) for a 60-kg human as 0.48 mg/p/d." This is quoted as an excerpt from FDA Code of Federal Register (CFR 173.375). The FDA ADI converts to 0.008 mg/kg-bw, which are more common units used by EPA.

According to the TR: "FDA has approved the use of cetylpyridinium chloride "as an antimicrobial agent…to treat the surface of raw poultry carcasses" (21 CFR 173.375). The FDA requires cetylpyridinium chloride to be combined with propylene glycol (PG), which must be included "at a concentration of 1.5 times that of cetylpyridinium chloride." When used as an antimicrobial additive in poultry processing, the FDA has outlined its use in §173.375." Note, propylene glycol is on EPA List 4 and is on the National List at 205.603(a): only for treatment of ketosis in ruminants.

As described in the TR, CPC is petitioned for use as a drench or dip followed by a chiller solution or a potable water wash when used in post-chiller applications, as stipulated by FDA regulations (21 CFR 173.375). The continued processing is expected to remove the majority of CPC from treated surfaces. However, residual CPC has been detected on treated surfaces at the processing endpoint and is expected to be found in concentrations of 2.–25.9 mg/kg on poultry skin. The maximum reported concentration of 25.9 mg/kg found on the meat surface would result in an average concentration of 2.3 mg/kg of CPC on treated meat. In the information reviewed, CPC was not found in non-surface meat. The TR concludes that CPC exposure is not expected to pose safety concerns (EFSA 2012). Importantly, organic consumers would be exposed to unlabeled pesticide residues (and propylene glycol) in the food. For the proposed use PG will be regulated as an "inert" substance from the EPA List 4. Note, the List 4 is not supported by EPA and is a legacy guideline for organic pesticides.

As described in the TR (Table 2), CPC is "highly toxic to fish, crustaceans, molluscs, and other aquatic life."

According to the petition, "At the end of a processing day, the entire CPC application system is shut down and any solution remaining in the recycle tank is sent to a purge tank. The frequency of this purging varies from one plant to another, although a daily purging is typical. The purged solution is filtered to remove any remaining CPC using disposable carbon filters. The activated carbon treatment provides for complete removal of CPC from the aqueous treatment solution." The TR describes similar procedures.

Table 2. Aquatic toxicity values of cetylpyridinium chloride

Species	Endpoint	Concentration
Australorbis sp. (snail)	Lethal	5 mg/L
Penaeus monodon (jumbo tiger prawn)	LC_{50}	0.8 mg/L
Penaeus japonicus (Kuruma shrimp)	LC_{50}	3.1 mg/L
Penaeus semisulcatus (shrimp)	LC_{50}	1 mg/L
Fenneropenaeus penicillatus (redtail prawn)	LC_{50}	0.56 mg/L
Metapenaeus ensis (greasyback shrimp)	LC_{50}	2.1 mg/L
Macrobrachium rosenbergii (great river prawn)	LC_{50}	0.13 mg/L
Oncorhynchus mykiss (rainbow trout)	LC_{50}	0.15 mg/L
Cyprinus carpio (carp)	Not reported	0.01 mg/L
Daphnia magna (water flea)	EC_{50}	0.00736 mg/L

Sources: Vallejo-Freire et al. 1954, Liao et al. 1990, Fisher 2007, Parchem 2015, ECOTOX 2021

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

According to the petition, "the CPC is captured in carbon barrels and disposed of either in approved landfills or by incineration. Disposal of the carbon barrels by either method does not allow for free CPC to enter the environment. Typically, a plant will use and dispose of one carbon filter (55-gallon drum or 209-L drum) every two months. The filtered, CPC-free liquid is then combined with the plant wastewater. In addition, available data for commercial CPC applications indicate that CPC, if present at all in the effluent from wastewater treatment facilities following the capture and recycling processes, will be there in vanishingly low levels and will be of no environmental significance" and "under the Notice and Comment rulemaking for CPC use, the FDA issued a Finding of No Significant Impact (FONSI) for CPC application to raw poultry."

Based on the information provided, environmental contamination resulting from use as a processing aid in poultry manufacturing lines is unlikely as long as the controls described in the petition and TR are followed. As noted above and described in the TR, precursor materials are likely to include formaldehyde and acetaldehyde, both probable or known carcinogens ((https://oehha.ca.gov/proposition-65); https://www.epa.gov/iris) and acrolein is a respiratory irritant (https://oehha.ca.gov/chemicals/acrolein). CPC manufacture and use is regulated, but inappropriate handling or accidents could result in human exposures or environmental emissions along the supply chain. It is impossible to quantify the probability of such events.

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

See above.

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)]

Not applicable.

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

Not applicable.

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)]

Non-synthetic alternatives include plain water and organic acids (e.g., including citric acid, lactic acid, and tartaric acid). These materials may affect food quality or are not efficacious for an industrial poultry production line, or, in the case of lactic acid, is more commonly used in livestock.

Several existing materials on the National List are currently used as poultry processing aids and comply with food safety requirements. Peroxyacetic acid, in particular, is widely used. According to the TR, peroxyacetic acid is an oxidant microbicide applied as both a pre- and post-chill treatment as a spray or dip. Chlorine materials include chlorine dioxide and hypochlorous acid and acidified sodium chlorite (ASC), a related material. ASC is approved for poultry processing. As noted in the TR, the oxidizing nature of chlorine materials makes them susceptible to deactivation when interacting with organic matter.

2. **For Livestock substances, and Nonsynthetic substances used in Handling**: In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]

No. This synthetic material offers some benefits for pathogen control on poultry carcasses and parts. However, existing materials have supported a robust and growing organic poultry industry and currently allow compliance with food safety standards. Importantly, use of this material will result in unlabeled pesticide residues on organic food and exposures to organic consumers without their knowledge, factors antithetical to organic principles.

Category 4: Additional criteria for synthetic substances used in Handling (does not apply to nonsynthetic or agricultural substances used in organic handling):
Describe how the petitioned substance meets or fails to meet each numbered criterion.

1. The substance cannot be produced from a natural source and there are no organic substitutes; (§205.600(b)(1))

CPC is synthetic and cannot be produced from natural sources.

2. The substance's manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling; (§205.600(b)(2))

If good manufacturing and handling practices are followed, it is unlikely that the environmental contamination will result from the petitioned use. Use of the material does result in periodic waste material that must be disposed of in a landfill. As noted above and described in the TR, precursor materials are likely to include formaldehyde and acetaldehyde, both probable or known carcinogens ((https://oehha.ca.gov/proposition-65); https://www.epa.gov/iris) and acrolein is a respiratory irritant (https://oehha.ca.gov/chemicals/acrolein). CPC manufacture and handling is regulated, but inappropriate handling or accidents could result in human exposures or environmental emissions along the supply chain. It is impossible to quantify the probability of such events.

3. The nutritional quality of the food is maintained when the substance is used, and the substance, itself, or its breakdown products do not have an adverse effect on human health as defined by applicable Federal regulations; (§205.600(b)(3))

The nutritional quality of the food is not affected by use of CPC. Use of this material will result in unlabeled pesticide residues (and propylene glycol) on organic food and exposures to organic consumers without their knowledge, factors antithetical to organic principles.

4. The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law; (§205.600(b)(4))

CPC is not used as a preservative or to recreate or improve flavors, colors, textures.

The substance is listed as generally recognized as safe (GRAS) by the Food and Drug Administration (FDA) when used in accordance with FDA's good manufacturing practices (GMP) and contains no residues of heavy metals or other contaminants in excess of tolerances set by FDA; (§205.600(b)(5))

CPC is unlikely to contain heavy metals. Propylene glycol (PG) must be used in the formulation, as required by the FDA. PG has historically been on the now obsolete EPA List 4; however, the National List does not contain a provision for inerts in Handling (§205.606(b)).

5. The substance is essential for the handling of organically produced agricultural products. (§205.600(b)(6))

The substance is not essential for organic poultry production. A robust and growing organic poultry industry is supported by existing materials.

6. In balancing the responses to the criteria in Categories 2, 3 and 4, is the substance compatible with a system of sustainable agriculture [§6518(m)(7)] and compatible with organic handling? (see NOSB Recommendation, Compatibility with Organic Production and Handling, April 2004)

The NOSB finds merits for this material, particularly around the need for alternative sanitizers in organic processing. However, existing materials have supported a robust and growing organic poultry industry and currently allow compliance with food safety standards. Importantly, use of this material will result in unlabeled pesticide residues on organic food and exposures to organic consumers without their knowledge, factors antithetical to organic principles. At this time, the Subcommittee is not recommending this material for inclusion on the National List.

Questions for Stakeholders

1. Do stakeholders agree that this review of CPC – without a deeper review of the inert propylene glycol – is appropriate?
2. Since the FDA requires that propylene glycol be in a CPC formulation, how should the committee evaluate future petitions that include inerts in the formulation given that there is no provision for such inerts within the handling section of the National List?
3. In the current food safety regulatory environment, do organic producers have effective tools for pathogens in poultry processing (specifically antimicrobials)?

Classification Motion
Motion to classify cetylpyridinium chloride (CPC) as a non-agricultural synthetic substance
Motion by: Wood Turner
Seconded by: Kyla Smith
Yes: 6 No: 0 Abstain: 0 Absent: 0 Recuse: 0

National List Motion
Motion to add cetylpyridinium chloride (CPC) with the following annotation: "CPC can only be used in formulation with propylene glycol per FDA requirements" at 7 CFR 205.605(b)
Motion by: Wood Turner
Seconded by: Kyla Smith
Yes: 0 No: 6 Abstain: 0 Absent: 0 Recuse: 0

National Organic Standards Board
Handling Subcommittee Petitioned Material Proposal
Phosphoric Acid Annotation Change
February 1, 2022

Summary of Petition [Phosphoric Acid annotation change petition]
This document reviews the petitioned annotation change of phosphoric acid, which is currently listed on the National List at §205.605(b): Phosphoric acid - cleaning of food-contact surfaces and equipment only.

Introduction
In 2019, Kemin Food Technologies petitioned the United States Department of Agriculture (USDA) National Organic Program (NOP) to amend the existing annotation of phosphoric acid on the National List to include use as a synthetic substance for organic processing and handling (USDA 2019, USDA 2020a, USDA 2020b). This new petition requests the expansion of the use of phosphoric acid "as an acidifier to adjust pH of an extraction solvent to extract antioxidants or other target molecules from *lamiaceae* plants, provided the amount of acid used shall not exceed the minimum needed to lower pH to 2.5" (USDA 2020b).

Background
In 2002, Acadian Seaplants Limited petitioned the USDA NOP to expand the approved use of phosphoric acid within the National List to include production of organic aquatic plant extracts (USDA 2002). A technical report on phosphoric acid for organic processing was submitted in 2003 (USDA 2003). In 2004 the NOP contacted the petitioner and stated that phosphoric acid did not need to be petitioned for use in plant extraction "because its use as a pH adjuster in aquatic plant extracts is currently not prohibited through the inclusion of "aquatic plant extracts" in section 205.601(j)(1) of the National Organic Standards" . In 2013 the NOP sent a memorandum to the National Organic Standards Board (NOSB) requesting a review on the use of phosphoric acid in plant extracts to ensure that this use is consistent with the context on the National List (NOP 2013). The petitioner subsequently withdrew the petition in January 2014.

Use
Phosphoric acid is used in organic handling and processing as a cleaning agent for "food contact surfaces and equipment," as described in 7 CFR 205.605(b). Phosphoric acid has been approved for pH adjustment of some soil amendments (liquid fish products and squid byproducts) and as an equipment cleaner in both organic crop and livestock production. (7 CFR 205.601 and §205.603).

In addition to its appearance at 7 CFR 205.605, phosphoric acid has been used as an ingredient in plant extractions (USDA 2002, USDA 2019, USDA 2020a, USDA 2020b). When used in this manner, phosphoric acid acts as an acidifying agent and stabilizer to facilitate more efficient extraction of target compounds (Yoon et al. 2020). The petitioner is intending to use the substance in this manner, to extract target molecules, including but not limited to antioxidants, from various plant species of the *lamiaceae* family. In order to prepare the proper extraction solvent, tap water pH will be adjusted to lower pH.

The petitioner states, "This adjustment is critical to successful extraction because such low pH inhibits enzymatic oxidation that would otherwise destroy the target molecules. Regarding use of the extract, as consumer preferences begin to change and shift away from chemically sounding ingredients, consumers are looking to purchase and consume foods made with ingredients that come from natural sources. For food manufacturers, this means finding replacements for traditionally used synthetic ingredients, such as plant- based molecules. The petition is intended to be limited to extracting target molecules from plants of the *lamiaceae* family. The extracted target molecules may be subsequently blended with appropriate carriers for help in proper dispersal across the surface of finished food products. Application depends on the finished food matrix as different extracts have hydrophilic or lipophilic properties."

In addition to organic applications, phosphoric acid is a widely-used substance in conventional agriculture, with approximately 90% of wet process phosphoric acid used in the production of fertilizers (Shriver and Atkins 2008). Phosphoric acid has uses in food and beverage processing as a pH adjuster, flavor ingredient, and processing agent in dairy products (Wolke 2002, Gilmour 2019). Phosphoric acid is also a precursor to synthetic phosphates, which have a variety of uses including as fertilizers, surfactants, and detergents (Shriver and Atkins 2008). [TR 163-179]

Manufacture

Phosphoric acid is produced through two methods: the wet process, and the thermal process (EPA 1995, Gilmour 2019, Haghani and Daneshpazhuh 2020). Historically, the end-point use for the phosphoric acid was determined by its production method. High purity, technical and food grade phosphoric acid was produced by the thermal process (EPA 1995, Gilmour 2019). Lower purity phosphoric acid, primarily used in animal feed and fertilizer applications, was produced by the wet process (EPA 1995, Shriver and Atkins 2008, Gilmour 2019). Due to the expensive nature of the thermal process, there has been continued development of purification methods for wet process phosphoric acid, which now serve as the predominant method for the production of technical and food grade phosphoric acid (Gilmour 2019).

Thermal Process

The thermal process is broken down into three major steps: combustion, hydration, and demisting (collection) (EPA 1995, Gilmour 2019). In the combustion step, elemental yellow phosphorus (P_4) is reacted with oxygen gas, which oxidizes the phosphorous from its 0 to V oxidation state, as shown below in Equation 6 (EPA 1995, Gilmour 2019). The heat of combustion for phosphorus is highly endothermic and the reaction must be carried out at high temperatures (1650 – 2760 °C) (EPA 1995, Gilmour 2019).

$$P_4 + 5\ O_2 \rightarrow 2\ P_2O_5$$

Equation 6

Once the elemental phosphorus is oxidized to P_2O_5, it undergoes the hydration process to form orthophosphoric acid, as shown below in Equation 7 (EPA 1995, Gilmour 2019). In this process P_2O_5 is generally reacted with water, although in some cases dilute solutions of phosphoric acid are used instead of water alone (EPA 1995). Once phosphoric acid has been produced, it is isolated in the demisting process. In this step, phosphoric acid is collected as a mist with high-pressure drop demisters. The thermal process produces phosphoric acid with P_2O_5 concentrations between 54 and 62%, which are sufficiently pure for use in technical and food grade applications (EPA 1995, Gilmour 2019).

$$2\ P_2O_5 + 6\ H_2O \rightarrow 4\ H_3PO_4$$

Equation 7

Wet Process

The wet process produces phosphoric acid from naturally occurring phosphate mineral sources (fluorapatite [$Ca_{10}(PO_4)_6F_2$] and hydroxyapatite [$Ca_{10}(PO_4)_6(OH)_2$]) (EPA 1995, Shriver and Atkins 2008, Gilmour 2019, Haghani and Daneshpazhuh 2020). Once mined, these minerals are converted to phosphoric acid in four main steps, as outlined in Figure 5 below (Gilmour 2019). The phosphate rock is prepped in the initial step by being milled and ground to increase its surface area (EPA 1995, Haghani and Daneshpazhuh 2020).

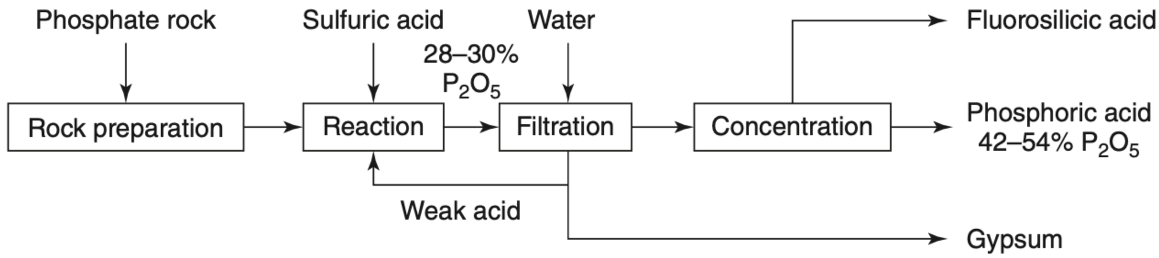


Figure 5

Once milled, the mineral phosphates are reacted with a strong mineral acid and converted to phosphoric acid, as shown in Equation 8 below (EPA 1995, Shriver and Atkins 2008, Gilmour 2019, Haghani and Daneshpazhuh 2020). While sulfuric acid is shown in both Figure 5 and Equation 8, other strong mineral acids [e.g., nitric acid (HNO_3) and hydrochloric acid (HCl)] may also be used (Jin et al. 2014, Haghani and Daneshpazhuh 2020). However, most commercial processes use sulfuric acid because it provides higher phosphoric acid yields, lower costs, and a solid form of calcium (Al-Fariss et al. 1992, EPA 1995, Shriver and Atkins 2008, Gilmour 2019). The specific reaction conditions dictate the type of calcium sulfate hydrate ($CaSO_4 \bullet n\ H_2O$) formed, with lower temperatures favoring the formation of gypsum ($CaSO_4 \bullet 2\ H_2O$), as shown in Equation 8 (EPA 1995). The prevalence of fluorapatite among mineral phosphates also produces hydrofluoric acid (HF), as shown below in Equation 8.

$$Ca_{10}(PO_4)_4F_{2\ (s)} + H_2SO_{4\ (aq)} + 20\ H_2O_{\ (l)} \rightarrow 6\ H_3PO_{4\ (aq)} + 10\ [CaSO_4 \bullet 2\ H_2O]_{\ (s)} + 2\ HF_{\ (aq)}$$

Equation 8

The gypsum formed during the reaction with the mineral acid is removed via filtration. Once removed, the gypsum solids undergo several aqueous wash cycles to remove residual phosphoric acid from the solid surface, producing phosphoric acids yields of 99.9% (EPA 1995, Gilmour 2019). As shown previously in Figure 5, the aqueous gypsum washes are sent back to the reaction vessel to aid in the conversion of mineral phosphates (EPA 1995, Gilmour 2019). The presence of mineral silicon in the initial composition reacts with hydrofluoric acid to produce less reactive forms of silicon tetrafluoride (SiF_4) and SiF_6^{2-} ions, some of which are removed as solids with the gypsum (Gilmour 2019).

The phosphoric acid isolated following the filtration process is dilute, with P_2O_5 concentrations between 26 – 30% (EPA 1995, Gilmour 2019). Vacuum evaporation is used to remove water and concentrate the phosphoric acid to 42 – 54% P_2O_5 (Gilmour 2019). Activated silica or clay is added during the concentration process to react with residual hydrofluoric acid. Silicon tetrafluoride isolated from the concentration step is hydrolyzed to fluorosilicic acid (H_2SiF_6), as shown in Figure 5 (Gilmour 2019).

Mineral impurities, including heavy metal contaminants, remain in phosphoric acid produced via the wet process, which have historically limited its use to agricultural fertilizer applications (EPA 1995, Shriver and Atkins 2008, Gilmour 2019, Haghani and Daneshpazhuh 2020). Wet process phosphoric acid results in concentrations of between 42 and 54% P_2O_5, which is largely unsuitable for technical applications (Gilmour 2019). The elemental phosphorous used in the thermal process can be purified via sublimation, resulting in no carry-over of heavy metal contaminants so that thermal phosphoric acid can be used in technical and food applications (Shriver and Atkins 2008). However, the thermal process is much more expensive and energy intensive than the wet process (~2000 °C vs ~80 °C) (EPA 1995, Gilmour 2019).

Wet process purification methods

Wet process phosphoric acid is commonly purified by crystallization or solvent extraction (Gilmour 2019). Crystallization is a common purification technique, which is based on the differing solubilities of pure and impure mixtures, with pure substances selectively crystallizing at reduced temperatures (Pavia et al. 1995). When phosphoric acid is concentrated to 61% P_2O_5 or higher, it selectively forms hemihydrate crystals ($H_3PO_4 \bullet ½\ H_2O$) when cooled to 8 – 12 °C (Gilmour 2019). The crystals are removed from the mixture and can be melted to undergo additional recrystallization cycles to improve purity, with each cycle yielding a 10 to 100 times increase in purity (Gilmour 2019).

Solvent extraction is another traditional purification method based on solubility. In solvent extraction, the target compound migrates between immiscible phases [usually aqueous (polar) and organic (nonpolar)] based on solubility (Pavia et al. 1995). The selectivity of phosphoric acid does not differ greatly compared to its impurities, requiring additional purification steps. Prior to solvent extraction, concentrated phosphoric acid undergoes precipitation with calcium or barium salts to remove sulfate (SO_4^{2-}), sodium salts to remove fluorosilicates, and sulfides to remove arsenic (Shlewitt and Alibrahim 2008, Gilmour 2019, Haghani and Daneshpazhuh 2020). Phosphoric acid extractions are performed in one or more extraction columns with many possible organic solvents, including alcohols, ethers, ketones, amines, and kerosene blends (Shlewitt and Alibrahim 2008, Jin et al. 2014, Gilmour 2019). Following extraction with an organic solvent, phosphoric acid is recovered with water. Residual organic solvents are removed via evaporation during the concentration of the recovered phosphoric acid from the aqueous solution (Shlewitt and Alibrahim 2008, Gilmour 2019). Solvent extraction of wet process phosphoric acid improves the purity of the substance from 42-54% P_2O_5 in the raw form to up to 97% P_2O_5 (Gilmour 2019). [TR 376-482]

International Acceptance

Canadian General Standards Board Permitted Substances List

Phosphoric acid is listed in the Organic Production Systems Permitted Substances List as an approved substance for pH adjustment of "fish meal, fish powder, fish wastes, hydrolysate, emulsions and solubles" that are used for "soil amendments and crop nutrition." Phosphoric acid is also listed as a "cleaner, disinfectant and sanitizer permitted on organic product contact surfaces for which a removal event is mandatory [for use] on dairy equipment." [TR 345-351]

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

Phosphoric acid is not listed in EC No. 834/2007 or EC No. 889/2008. [TR 357-358]

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

Phosphoric acid is not listed in the CODEX. [TR 353-355]

International Federation of Organic Agriculture Movements (IFOAM) Norms

Phosphoric acid is listed in the IFOAM NORMS for organic production and processing as an "equipment cleanser and equipment disinfectant only for dairy equipment," and as a "substance for pest and disease control and disinfection in livestock housing and equipment [for] dairy equipment." [TR 364-367]

Japan Agricultural Standard (JAS) for Organic Production

Phosphoric acid is not listed in the JAS. [TR 360-361]

Summary of Review
The Subcommittee's review and discussion were centered around the petitioner's stated essentiality as the most effective acid for pH adjustment to prepare extraction solvents, as there are other acids on the National List that can be used for this purpose, along with the allowance on the crops list for a similar extraction process (e.g., pH adjustment of liquid fish products and squid byproducts). However, it was also noted that phosphoric acid isn't allowed on the crops list for the extraction of aquatic plant extracts as the petition was withdrawn for this use. The Subcommittee further discussed the low negative impact on the environment and human health along with the fact that this material is already listed on the National List.

The NOSB is aware that this annotation change would be adding a synthetic substance for use in food. However, it does appear that due to the functionality of the petitioned use that it is unlikely for phosphoric acid to be present in the final food product. That said, the Subcommittee doesn't fully understand exactly how and in what finished food products this is going to be used based on the petition.

Category 1: Classification

1. Substance is for: __X__ **Handling** _____ **Livestock**

2. For HANDLING and LIVESTOCK use:
   a. Is the substance _____ **Agricultural** or __X__ **Non-Agricultural?**
   Describe reasoning for this decision using NOP 5033-2 as a guide:

Phosphoric Acid is currently listed on the National List at §205.605(b).

   b. If the substance is **Non-agricultural**, 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:

Phosphoric Acid is currently listed on the National List at §205.605(b).

3. For **LIVESTOCK**: 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?

N/A

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)]

The petition states “Phosphoric Acid itself combines readily with many other chemicals and no known detrimental interactions within organic farming systems is known.” Additionally, this material is already listed twice on the National List, therefore the potential for detrimental chemical reactions seems unlikely.

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 petition states “In the process of phytochemical extraction, phosphoric acid combines with water to form an acidified extraction solution. Phosphoric acid in its original form will break down quickly in the environment, so there are no toxicity issues directly related to its breakdown products. In this process, phosphoric acid will be partially neutralized by the plant components, and after extraction, the matrix has a pH of about 5.0-6.0. Consequently, the phosphoric acid will no longer exist in its acid form and the resulting liquid will not be corrosive. Therefore, while raw and concentrated phosphoric acid might be toxic to aquatic environments, the process mitigates contaminant persistence and/or concentration in the environment.”

The TR states that due to the low concentration in the extraction application, as well as the prevalence of phosphates throughput biology that the likelihood of toxicity and concentration in the environment are low.

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

When used as petitioned, phosphoric acid is used in low concentrations (1 - 3%), and is a source of phosphates for incorporation to biomolecules. The low concentration in extraction applications and the prevalence of phosphates throughout biology make phosphoric acid from plant extractions unlikely to be harmful to the environment or biodiversity.

However, the production of phosphoric acid does have the potential to be harmful to the environment. The thermal process for producing phosphoric acid is energy intensive and requires high temperatures. The high energy requirements of the thermal process may contribute to atmospheric CO_2 levels if the energy is produced from fossil fuels. The thermal process also requires the treatment of combustion gases by scrubbers, cyclonic separators, mist eliminators, and electrostatic precipitators to prevent the release of phosphoric acid to the environment (EPA 1995, Gilmour 2019). The small size ($< 3\ \mu$m diameter) makes these phosphoric acid and phosphorus oxide (P_2O_5) particles difficult to capture, and contributes their release to the atmosphere at levels of “< 25 mg P_2O_5 per dry standard cubic meter of stack gas” (Gilmour 2019).

Wet process phosphoric acid is produced from chemical changes to mined mineral phosphates. There may be initial harm to the environment and biodiversity in the mining process. Once the minerals are isolated, hydrofluoric acid presents the most likely source of environmental harm (Shriver and Atkins 2008). Hydrofluoric acid is removed as a solid or as fluorosilicic acid by reaction with silica sources. These include natural silicates present within the initial mineral, as well as activated silica and clay added during the manufacturing process (Shriver and Atkins 2008, Gilmour 2019). Additionally, scrubbers are used to remove gaseous fluorine compounds from concentration steps to prevent their release to the environment (EPA 1995).

In addition to the hazards from fluorine compounds, the gypsum produced may pose a hazard to the environment. Isolated gypsum may be used for other commercial applications if it is sufficiently pure (Gilmour 2019). In other cases, gypsum is left in gypsum stacks, or pumped out to sea (Gilmour 2019). However, the gypsum may also contain silicon fluorides, acids, and other impurities from the initial mineral source, which has resulted in its designation as a hazardous substance by the EPA in 40 CFR 261.4. [TR 566-594]

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

Concentrated phosphoric acid is corrosive and can result in burning and irritation of the eyes and skin on contact (Flomenbaum et al. 2002, NJDHSS 2004, Gilmour 2019). Phosphoric acid can desiccate epithelial cells, resulting in the drying and cracking of skin where long-term exposure occurs (Flomenbaum et al. 2002, NJDHSS 2004). Inhalation of phosphoric acid may result in irritation to the nose, lungs, and throat and may induce coughing and wheezing (NJDHSS 2004, Gilmour 2019). Ingestion of phosphoric acid may damage gastric and esophageal mucus linings (Flomenbaum et al. 2002).

Phosphoric acid is frequently used in food processing and production and is a common component of food and beverages (Wolke 2002). As described in Equations 2 – 4 in the “Composition of the Substance” section, phosphoric acid is the source of several phosphates, which are important components of biomolecules (e.g., ATP, DNA, etc.) (Shriver and Atkins 2008, Timberlake 2016, Gilmour 2019). When used as petitioned, phosphoric acid is used in low concentrations (1 – 3%), making it unlikely to be harmful to human health (Gilmour 2019). [TR 599-611]

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 petition states, “When stored, used and disposed of appropriately, Phosphoric acid use during phytochemical extraction will have no negative interactions with soil organisms, crops, or livestock.”

Additionally Phosphoric acid is allowed at §205.601(j)(8) as a pH adjuster which makes the likelihood that Phosphoric acid has negative physiological effects on soil organisms, crops, and livestock unlikely.

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

As previously stated, due to the low concentration in the extraction application, as well as the prevalence of phosphates throughput biology there doesn’t appear to be adverse impact on biodiversity.

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 alternative methods to extract target molecules from plant material. One of the simplest ways to improve solvent extraction processes is to increase the solvent temperature (Pavia et al. 1995, Silberberg 2003). Increased temperature improves the solvation of most solids and liquids by disrupting the intermolecular forces that prevent the target molecule from entering the solution (Silberberg 2003).

Supercritical carbon dioxide extraction offers an alternative to acidic extractions. This extraction method uses temperatures and pressures that push the solvent beyond its critical point, so that it no longer exists as a liquid or gas (Silberberg 2003, Babovic et al. 2010). Carbon dioxide is the most common supercritical fluid used in extraction applications due to its low cost and the low temperatures and pressures required to reach supercritical conditions (31.1 °C and 7.38 MPa) (Babovic et al. 2010). The selectivity of supercritical fluids can be modulated by changing its temperature and pressure to target different classes of molecules.

Subcritical extractions offer another alternative to acidic extractions. In such applications, the solvent remains in liquid form, although conditions may approach the critical point of the solvent (Ibañez et al. 2003). As with supercritical fluid extractions, the selectivity of the subcritical extractions can be manipulated by modifying temperature and pressure. Subcritical water extractions have been successful in the extraction of essential oils and antioxidants (Ibañez et al. 2003). However, some antioxidants and other compounds are sensitive to decomposition, and may not survive increased solvent temperatures or the high-pressure conditions needed in supercritical and subcritical extractions (Ibañez et al. 2003). [TR 616-634]

Many natural and currently allowed synthetic acids offer an alternative to phosphoric acid for plant extractions, such as acetic acid, citric acid, gibberellic acid, lactic acid, and tartaric acid (NOP 2016c). Polyprotic carboxylic acids (for example, ascorbic acid, citric acid, etc.) are also able to chelate positively charged species, facilitating improved extraction (Albuquerque et al. 2005).

However, the strength of the acid is important in determining the effectiveness in the extraction of the target molecules. Carboxylic acids are weaker acids than phosphoric acid (pKa ~5 vs 2.15) meaning that they may be less effective in extracting some molecules, including anthocyanin antioxidants (Silberberg 2003, Nicoué et al. 2007, Timberlake 2016). The target molecule and plant structure determine the optimal solvent conditions, although phosphoric acid solutions have been reported to be among the most effective for antioxidant extractions (Nicoué et al. 2007). [TR 640-650]

Alternatives to phosphoric acid are naturally acidic agricultural substances, including wine and vinegar. Both mixtures include natural acids that can provide an acidic extraction solution. However, as described in Evaluation Question 12, carboxylic acids are weaker than phosphoric acid and may be less effective in the extraction of some target molecules. Additionally, the complex mixture of compounds in wine and vinegar would make purification of the plant extracts more difficult. [TR 655-659]

Category 4: Additional criteria for synthetic substances used in Handling (does not apply to nonsynthetic or agricultural substances used in organic handling):

Describe how the petitioned substance meets or fails to meet each numbered criterion.

1. The substance cannot be produced from a natural source and there are no organic substitutes; (§205.600(b)(1))

Phosphoric acid is a synthetic substance that does not exist in nature. Therefore, there are no natural sources of phosphoric acid. [TR 500-501]

2. The substance's manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling; (§205.600(b)(2))

The petition states, “There are many environmental consequences from the manufacture, misuse and disposal of phosphates in general and these cannot be separated out for phosphoric acid in particular. In figures from world phosphorus consumption in 1980, about 90% of phosphate consumption is for fertilizer, while 4.5% is for all detergents including other cleaners such as trisodium phosphate. There are extreme environmental impacts from mining of phosphate ore which occurs in many parts of the world. Worker safety is of prime concern in the wet-process acid and elemental phosphorous used in the thermal process because of high acidity, heat released upon neutralization and toxic gases released. Plants will be equipped with proper safety procedures and equipment to deal with these issues.

The issues of phosphate pollution from disposal are discussed above, but in general the dilution of phosphoric acid will minimize disposal problems in the food processing or livestock facility.”

The TR, as previously stated, indicates that the use of Phosphoric acid is relatively benign regarding its impact on the environment. However, it does state that thermal production process is energy intensive and uses high temperatures, which could contribute to CO_2 levels if the energy is produced from fossil fuels. That said, as stated previously, due to the expensive nature of the thermal process, there has been continued development of purification methods for wet process phosphoric acid, which now serve as the predominant method for the production of technical and food grade phosphoric acid (Gilmour 2019).

3. The nutritional quality of the food is maintained when the substance is used, and the substance, itself, or its breakdown products do not have an adverse effect on human health as defined by applicable Federal regulations; (§205.600(b)(3)

When used as petitioned, phosphoric acid will be used in the extraction of target molecules from plant material. The extraction of antioxidants and other compounds from the initial plant material will reduce the nutritional quality of the material from which they are extracted. However, the purpose of plant extracts is to improve the quality of other products to which they are added. (Nicoué et al. 2007, Proestos 2020). Phosphoric acid is a source of phosphates, which are important nutrients in human health, and can be found in many biomolecules, including ATP and DNA (Shriver and Atkins 2008, Timberlake 2016, Gilmour 2019). However, phosphoric acid is typically used in low concentrations (1 – 3%) in extraction processes and is unlikely to contribute directly to improved nutritional quality. [TR 540-547]

4. The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law; (§205.600(b)(4))

When used as petitioned, the primary function of phosphoric acid is to improve the extraction of target molecules, not to act as a preservative. However, in some cases, the addition of phosphoric acid stabilizes target molecules from decomposition, as described above in the “Action of the Substance” section.

Phosphoric acid is also used as an equipment sanitizer in organic agriculture in 7 CFR 205.605 and §205.603. The low pH of phosphoric acid solutions makes it an antimicrobial substance, as high acid content is not tolerated by microorganisms (Winniczuk and Parish 1997, Prado et al. 2015). The antimicrobial nature of phosphoric acid may result in some preservative characteristics if incorporated into food and beverage products (Winniczuk and Parish 1997). [TR 518-526]

When used as petitioned, the primary function of phosphoric acid is to improve the extraction of target molecules, not to improve or recreate flavors in processed food products. However, phosphoric acid has been used as a flavoring agent in conventional food and beverage production, as described above in the "Specific Uses of the Substance" and "Historical Use" sections. [TR 532-535]

5. The substance is listed as generally recognized as safe (GRAS) by the Food and Drug Administration (FDA) when used in accordance with FDA's good manufacturing practices (GMP) and contains no residues of heavy metals or other contaminants in excess of tolerances set by FDA; (§205.600(b)(5))

As described in the "Approved Legal Uses of the Substance" section, the FDA has designated phosphoric acid generally recognized as safe (GRAS) for several uses. Phosphoric acid is listed as a "multiple purpose GRAS food substance" in 21 CFR 182. 1073, and as a GRAS "general purpose food additive" in §582.1073. Additionally, the FDA lists phosphoric acid as a substance used in the production of the GRAS substances monobasic ammonium phosphate in §184.1141, dibasic ammonium phosphate in §184.1141, magnesium phosphate in §184.1366, and hydrogen peroxide in §184.1366. [TR 507-512]

6. The substance is essential for the handling of organically produced agricultural products. (§205.600(b)(6))

The petition states, "Since effective extraction is a critical step in the ability to use biomolecules, the ultimately benefit of the applicable organic management program, and since phosphoric acid appears among the best and safest pH adjusters, this material seems compatible with an organic production and processing system."

7. In balancing the responses to the criteria in Categories 2, 3 and 4, is the substance compatible with a system of sustainable agriculture [§6518(m)(7)] and compatible with organic handling? (see NOSB Recommendation, Compatibility with Organic Production and Handling, April 2004)

The substance is compatible with a system of sustainable agriculture as phosphoric acid is already on the National List at §205.605(b) and is allowed as a pH adjuster of liquid fish products (§205.601(j)(8)). Additionally, phosphoric acid doesn't appear to have a negative impact on the environment or human health. Lastly, while there are other synthetic acids that are allowed (e.g., acetic acid, citric acid, gibberellic acid, lactic acid, and tartaric acid) as well as polyprotic carboxylic acids (for example, ascorbic acid, citric acid, etc.), these may not be as effective.

Carboxylic acids are weaker acids than phosphoric acid (pKa ~5 vs 2.15) meaning that they may be less effective in extracting some molecules, including anthocyanin antioxidants (Silberberg 2003, Nicoué et al. 2007, Timberlake 2016). The target molecule and plant structure determine the optimal solvent conditions, although phosphoric acid solutions have been reported to be among the most effective for antioxidant extractions (Nicoué et al. 2007). [TR 646-650]

Questions to our Stakeholders

1. If the use of phosphoric acid is expanded through this petitioned annotation change will it perform an essential function that is different than other already listed acids?
2. What is the application of phosphoric acid in the finished food product (i.e., what does "The extracted target molecules may be subsequently blended with appropriate carriers for help in proper dispersal across the surface of finished food products" mean in an actual use case)?

Subcommittee Vote:

National List Motion

Motion to amend the annotation of phosphoric acid to (underlined verbiage is the proposed addition) "cleaning of food-contact surfaces and equipment, <u>and as an acidifier to adjust pH of an extraction solvent to extract antioxidants or other target molecules from *lamiaceae* plants, provided the amount of acid used shall not exceed the minimum needed to lower pH to 2.5</u>." at § 205.605(b).

Motion by: Kyla Smith
Seconded by: Wood Turner
Yes: 5 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Sunset 2024
Meeting 1 - Request for Public Comment
Handling Substances § 205.605(a), § 205.605(b), § 205.606
April 2022

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 which must be reviewed by the NOSB and renewed by the USDA before their sunset dates. This document provides the substance's current status on the National List, annotation, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, this is noted in this list. To see if any new technical report is available, please check for updates under the substance name in the Petitioned Substances Database.

Request for Comments
While the NOSB will not complete its review and any recommendations on these substances until the Fall 2022 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the Spring 2022 public meeting. Comments should be provided via Regulations.gov at www.regulations.gov on or before April 1, 2022 as explained in the meeting notice published in the Federal Register.

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

Public comments should clearly indicate the commentor's position on the allowance or prohibition of substances on the National List and explain the reasons for the position. Public comments should focus on providing relevant new information about a substance since its last NOSB review. Such information could include research or data that may support a change in the NOSB's determination for a substance (*e.g.*, scientific, environmental, manufacturing, industry impact information, etc.). Public comment should also address the continuing need for a substance or whether the substance is no longer needed or in demand.

For Comments that Support the Continued Use of §205.605(a), §205.605(b), and/or §205.606 Substances in Organic Production:
If you provide comments supporting the allowance of a substance at §205.605(a), §205.605(b), and/or §205.606, you should provide information demonstrating that the substance is:
1. not harmful to human health or the environment;
2. necessary to the production of the agricultural products because of the unavailability of wholly nonsynthetic substitute products; and
3. consistent with organic handling.

For Comments that Do Not Support the Continued Use of §205.605(a), §205.605(b), and/or §205.606 Substances in Organic Production:
If you provide comments that do not support a substance on §205.605(a), §205.605(b), and/or §205.606, you should provide reasons why the use of the substance should no longer be allowed in

organic production. Specifically, comments that support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:

1. harmful to human health or the environment;
2. unnecessary because of the availability of alternatives; and
3. inconsistent with organic handling.

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

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

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

Your comments should address whether any alternatives have a function and effect equivalent to or better than the allowed substance, and whether you want the substance to be allowed or removed from the National List. Assertions about alternative substances, except for those alternatives that already appear on the National List, should, if possible, include the name and address of the manufacturer of the alternative. Further, your comments should include a copy or the specific source of any supportive literature, which could include: product or practice descriptions, performance and test data, reference standards, names and addresses of organic operations who have used the alternative under similar conditions and the date of use, and an itemized comparison of the function and effect of the proposed alternative(s) with substance under review.

Written public comments will be accepted through April 1, 2022 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

§205.605(a) Sunsets: Nonagricultural (Nonorganic) substances allowed as ingredients in or on processed products labeled as ''organic'' or ''made with organic (specified ingredients or food group(s)).'':

- Attapulgite
- Bentonite
- Diatomaceous earth
- Magnesium chloride
- Nitrogen
- Sodium carbonate

§205.605(b) Sunsets: Nonagricultural (Nonorganic) substances allowed as ingredients in or on processed products labeled as ''organic'' or ''made with organic (specified ingredients or food group(s)).'':

- Acidified sodium chlorite
- Carbon dioxide
- Sodium phosphates

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

- Casings
- Pectin
- Potassium acid tartrate

Attapulgite

Reference: §205.605(a) *Nonsynthetics allowed:*

Attapulgite—as a processing aid in the handling of plant and animal oils.

Technical Report: 2010 TR.
Petition: 2009.
Past NOSB Actions: 4/2011 recommendation; 10/2015 sunset review; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset Date: 10/30/2024

Subcommittee Review

Use
Attapulgite is used as a natural bleaching clay for the purification of vegetable and animal oils. The function of a bleaching clay is to remove undesirable by-products (impurities) for the vegetable oil and animal fat, thus improving the appearance, flavor, taste, and stability of the final product.

Manufacture
Attapulgus is the principal mineral of attapulgus clay, which is surface mined by open-pit method with stripping by scrapers, draglines, or bulldozers and extraction by shovels, backhoes, small draglines, or front-end loaders. The clay is then loaded onto trucks and transported to the processing plant. The clay is then dried, milled, and sieved to obtain a desired range of particle sizes.

International Acceptance
Note: In the United States, the term —attapulgite is used in place of palygorskite; however, the International Nomenclature Committee determined that palygorskite is the preferred name.

Canadian General Standards Board Permitted Substances List
Canadian Food Inspection Agency, Feed Program— Schedule IV of the Feeds Regulations, 1983, lists ingredients approved for use as livestock feed. Attapulgite clay (Schedule IV Number 8.111) is listed under Class 8. Miscellaneous Product of the Feeds Regulations. It stated, —Attapulgite clay (IFN6 8-14-008) is hydrated aluminum-magnesium silica, a naturally occurring mineral mined in Attapulgus, Georgia… It shall be labeled with the following statement: This product is for use in non-medicated feeds only as an anticaking agent or pelleting aid in an amount not to exceed 0.25% of the finished feed or as an emulsifier in liquid feed supplements at a level not to exceed 2.5% of the supplement.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Regulation (EC) 1831/2003— —Attapulgite (clay) CAS No. 12174-11-7‖, under silage additives functional group, listed in Community Register of Feed Additives. The date of first entry in the Register is July 11, 2005.

ECODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
Attapulgite/palygorskite is not specifically listed.

International Federation of Organic Agriculture Movements (IFOAM) Norms
Attapulgite/palygorskite is not specifically listed.

Japan Agricultural Standard (JAS) for Organic Production
Attapulgite/palygorskite is not specifically listed.

Environmental Issues
Attapulgite is surface mined, and, in most countries, the mining company is required by law to reclaim the land. Common practice is to open a cut, mine the clay, and then spoil the overburden from the next cut into the mined-out area. The spoil is leveled or sloped to meet the standards prescribed by the government, and grasses and/or trees are planted. Sometimes the topsoil is put back on top of the spoil and is used for agriculture. The major environmental issue is air quality because the dust during manufacture, use, or disposal. Repeated or prolonged inhalation of dust may cause delayed lung injury.

Discussion
From the most recent sunset review: There was public support for re-listing attapulgite due to active use of the material by certified operators. A couple comments were made that, overall, the material does not appear to be in widespread use and may not be necessary for the industry. Based on the Subcommittee review and public comment in 2017, the NOSB found attapulgite compliant with OFPA criteria, and did not recommend removal from the National List. However, the vote was not unanimous and there was concern that attapulgite is not necessary for organic production.

Questions to our Stakeholders
1. Is attapulgite used today in organic production?
2. What industries are most impacted if removed from the NL?
3. Do the health concerns from mining attapulgite outweigh the need for organic use?

Bentonite

Reference: §205.605(a) *Nonsynthetics allowed:*
Bentonite.
Technical Report: 1995 TAP.
Petition: N/A
Past NOSB Actions: 4/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset review; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset Date: 10/30/2024

Subcommittee Review

Use
Bentonite is used as a processing aid, not an ingredient. Its adsorptive qualities make it useful for removing impurities in edible oils like soy, palm, and canola. It can also be used to clarify beer, fruit juice, wine, sugar, and honey and is not present in the final product.

Manufacture
It is a naturally occurring porous rock of clay materials that derives from weathered volcanic ash. It is mined and thus subject to environmental mitigation and monitoring by other agencies. It is a fine white to yellowish white or graphic aluminum silicate clay with limited shrink-swell features. It darkens and takes on a distinct clayey smell in the presence of liquid. It is insoluble in water, alcohol, dilute acids, and alkali solutions.

International Acceptance
Canadian General Standards Board Permitted Substances List
The material is allowed in food handling.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
The material is not listed.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
The material is allowed in food handling.

International Federation of Organic Agriculture Movements (IFOAM) Norms
The material is not listed.

Japan Agricultural Standard (JAS) for Organic Production
The material is not listed as a food handling aid.

Environmental Issues
While mining activities are regulated by other agencies, bentonite does derive from mining activities, which do produce negative impacts by definition.

It is generally regarded as safe (GRAS) and does not produce human toxicity, although if consumed in large quantities, particularly during pregnancy, can produce iron deficiency.

Historically, there has been strong public support for the continued use of bentonite. Based on the Subcommittee review and public comment, the NOSB finds bentonite compliant with OFPA criteria, and does not expect to recommend removal from the National List.

Discussion
The Handling Subcommittee discussed the longstanding support for keeping bentonite on the National List in this use. At the same time, the subcommittee did note the similarity of bentonite as a food processing aid to other listed substances (for example, diatomaceous earth) and indicated a desire to understand more fully how, why, and to what extent the material is being used in organic applications.

Questions to our Stakeholders
The subcommittee seeks public comment to specifically address the ongoing need for bentonite, given other similar (although perhaps not identical) substances.

Diatomaceous earth

Reference: §205.605(a) *Nonsynthetics allowed:*
Diatomaceous earth—food filtering aid only.
Technical Report: 1995 TAP.
Petition: N/A
Past NOSB Actions: 4/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset review; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset Date: 10/30/2024

Subcommittee Review

Use
Used as a filtering aid in food production of syrups, juices, beer, beverages, and other products.

Manufacture
Diatomaceous earth is made from the fossilized remains of diatoms; their skeletons are made of a natural substance called silica. Diatoms accumulate in the sediment of rivers, streams, lakes, and oceans, and is mined in quarries or open-pit.

International Acceptance
The use of diatomaceous earth is permitted in organic processing by IFOAM, EU, and Codex.

Unsure if it is allowed by Canadian General Standards Board Permitted Substances List or Japan Agricultural Standard (JAS) for Organic Production

Environmental Issues
Dust produced during processing can be a human health concern for workers and would be subject to OSHA requirements (1995 TAP pg. 5). Waste material can, in some states, be considered a hazardous waste requiring special disposal requirements (1995 TAP pg. 5). The 1995 Technical Advisory Panel was made up of three people. One reviewer expressed concern for possible concentrations of mercury, lead, cadmium, arsenic, thallium, and antimony and the need to verify “food grade” quality of DE.

Discussion
The NOSB reviewed diatomaceous earth (DE) in November 2005, April 2010, and October 2015, and recommended relisting each time. Diatomaceous earth is comprised of accumulated shells of hydrous silica secreted by diatoms and is used as a filter aid in production of syrups, juices, beer, beverages, and other products (1995 TAP pg. 4). Diatomaceous earth does not exist within the final organic product and is classified as a processing aid and not an ingredient. Diatomaceous earth is a mined substance and processors must adhere to environmental regulations for removal and production purposes. Dust produced during processing can be a human health concern for workers and would be subject to OSHA requirements (1995 TAP pg. 5). Waste material can, in some states, be considered a hazardous waste requiring special disposal requirements (1995 TAP pg. 5). Other filtering aids includes bentonite (also on the NL). DE is also used in swimming pool filters, which is not a food grade form. At the Spring 2017 NOSB meeting, numerous stakeholders expressed strong support for the relisting of DE. A couple comments were made suggesting a need to review the impact of mining activities; no new information was provided regarding the mining concern.

Diatomaceous earth was found to satisfy the OFPA evaluation criteria in previous reviews.

Questions to our Stakeholders
1. Are stakeholders continuing to use DE today in organic production?
2. Have there been any changes to the environmental issues of DE production?
3. Are there alternative filtration aids allowing the removal of DE from the NL?

Magnesium chloride

Reference: §205.605(a) *Non-synthetics allowed:*
Magnesium chloride.
Technical Report: 1995 TAP; 2016 TR.
Petition: N/A
Past NOSB Actions: 10/1995 minutes and vote; 10/1999 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset review; 11/2017 sunset recommendation.

Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577); Classification change from synthetic to nonsynthetic effective 11/22/2019 (85 FR 56673).
Sunset Date: 11/22/2024

Subcommittee Review

Use
Magnesium chloride is used in organic food processing as a processing aid, as a coagulant/ firming agent in tofu production, and used in certified organic dietary supplements. It can also be used to dress cotton fibers, or as a color retention agent and as a source of essential mineral magnesium in infant formula.

The EPA regulates magnesium chloride as a pesticide on List D, pesticides of less concern (EPA 1998). Magnesium chloride has also been used to treat bovine hypomagnesemia (low blood magnesium levels).

Manufacture
Natural commercial sources of magnesium chloride can be classified as: (a) sea water; (b) terminal lake brines; (c) subsurface brine deposits; and (d) mineral ore deposits. Magnesium chloride produced from each of these natural sources is the product of a brine comprising soluble ions of various mineral elements, primarily sodium, potassium, magnesium, calcium, chloride, and sulfate (TR 2016, 186-189).

(a) Sea Water
Sea water is processed in solar ponds to produce concentrated brines from which specific minerals crystallize and are recovered. These specific minerals, called "evaporites," crystallize in a sequence based on the concentrations of anions and cations in the brine and their innate solubility in water (TR 192-194).

(b) Terminal lake brines
A terminal lake is a lake where water is flowing in, but no water flows out, so that the dissolved salts concentrate and form brine as the water evaporates. The Great Salt Lake in Utah is a familiar example. Great Salt Lake brine is the primary source of magnesium chloride in North America. The Great Salt Lake contains sodium-magnesium-chloride-sulfate brine with low alkalinity (Domagalski, Orem, and Eugester 1989). Like solarization of seawater, the first evaporite of Great Salt Lake brine to form is halite (sodium chloride), followed by schoenite (magnesium-potassium sulfate), kainite (potassium chloride-magnesium sulfate double salt), and carnallite (potassium-magnesium chloride), resulting in a magnesium chloride brine (Neitzel 1971). Evaporating the water in this magnesium chloride brine creates crude solid magnesium chloride (TR 2016, 221-234).

(c) Subsurface brine deposits
Brine deposits in Midland, Michigan, have been a source of magnesium chloride since the 1890s. The Dow company originally obtained its bromine, chlorine, sodium, calcium, and magnesium from the brine of ancient seas under Midland (TR 2016, 264-266).

(d) Mined mineral deposits
The two major mined mineral sources of magnesium chloride are bischofite and carnallite, both of which were formed during prehistoric solar evaporation of sea water (Butts 2004). Solution mining of these ore bodies creates a brine that is processed on the surface. Water is pumped into the ore body to dissolve these soluble minerals, forming a brine which is pumped to the surface. Most of the patented processes for purification and concentration of these brines rely on water and evaporation, without any additional chemicals However, because magnesium chloride is soluble in alcohol while potassium chloride is not, several patented processes for separating pure magnesium chloride from

carnallite employ a low molecular weight alcohol, such as methanol, to recover pure magnesium chloride (TR 2016, 291-297).

Synthesis of magnesium chloride by the reaction of a magnesium compound such as the oxide, hydroxide, or carbonate with hydrochloric acid is a chemical process, which involves chemical reaction of an acid and an alkali to form a salt. (TR 2016, 340-342).

GRAS: Magnesium chloride hexahydrate is affirmed by the FDA as Generally Recognized As Safe (GRAS) as a food ingredient (21 CFR 184.1426). It is allowed by the FDA as a flavoring agent, adjuvant, nutrient supplement, and may be used in infant formula (TR 2016, 94-96).

Ancillary substances: Magnesium chloride hexahydrate is commercially available as colorless, odorless flakes, crystals, granules, or lumps. Both JECFA and FCC require that the material assays at 99% to 105% $MgCl_2 \cdot 6H_2O$. Commercial sources contain no additional or ancillary ingredients (e.g., inert ingredients, stabilizers, preservatives, carriers, anti-caking agents or other materials) (TR 2016, 110- 113).

International Acceptance

Canadian General Standards Board Permitted Substances List

Magnesium chloride is a permitted processing substance listed in CAN/CGSB-32.311-2015, Table 6.3, "ingredients classified as food additives," with the annotation, "derived from seawater."

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

The European Community regulation permits the use of the magnesium chloride (or "nigari") in processing organic foods of plant origin as a coagulation agent (EC No. 889/2008 Annex VIII, Section B – Processing Aids).

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

The Codex organic guidelines permit the use of magnesium chloride (INS 511) in food category 06.8, soybean products (excluding soybean products of food category 12.9 and fermented soybean products of food category 12.10); food category 12.9.1, soybean protein products; and food category 12.10, fermented soybean products

International Federation of Organic Agriculture Movements (IFOAM) Norms

The IFOAM Norms, Appendix 4, Table 1, permit the use of magnesium chloride (INS 511) as an additive and also as a processing and post-harvest handling aid for soybean products only.

Japan Agricultural Standard (JAS) for Organic Production

Article 4, Table 1, Food Additives permits the use of food additive INS 511, magnesium chloride, and also "crude seawater magnesium chloride," for processed foods of plant origin as a coagulating agent or for processed bean products.

Environmental Issues

The historical process of solar evaporation of sea water to obtain salt and additional minerals such as magnesium chloride creates saline ponds and infertile soil. Solar salt ponds have been reused for several millennia in the Eastern Mediterranean so that the environmental damage is localized. With respect to terminal lakes such as the Great Salt Lake, the major environmental threat here is not related to mineral extraction operations; it is the reduction of water flow into this terminal lake caused by agricultural and other diversions (Wurtsbaugh et al. 2016). Winds blowing over dry lake beds cause dust storms and urban pollution. An environmental risk with solution mining is surface subsidence, as the underlying mineral is dissolved and removed, effectively creating a cavern. (TR 414-423).

Discussion
Magnesium chloride is currently allowed under the USDA organic regulations at 7 CFR 205.605(a) as a nonagricultural nonsynthetic substance for use as an ingredient in or on processed products labeled "organic" or "made with organic (specified ingredients or food group(s))." Magnesium chloride was previously listed at §205.605(b) with the annotation "derived from sea water." However, during the Spring 2018, the Board put forth a proposal to reclassify magnesium chloride as non-synthetic and to remove the annotation "derived from sea water" since there are multiple sources from which non-synthetic magnesium chloride can be derived. This proposal passed unanimously, went through the rulemaking process, and became effective on November 22, 2019.

During the 2015 and 2017 sunset reviews, public comment from tofu producers, trade associations and certifiers indicated that this material "makes a specific type of tofu texture that cannot be duplicated with other coagulants. Elimination from the National List would be extremely detrimental to all tofu manufacturers in the United States".

During the sunset review in 2015, the Handling Subcommittee asked whether this material should be annotated "for use only in tofu production". Public comment indicated that at least one organization recommended an annotation "as a coagulant in making tofu". Public comment suggested that while use of magnesium chloride for making tofu is consistent with organic practices, the use of this material for color enhancement may not be consistent with organic. Additionally public comment received during the Spring 2017 NOSB meeting pointed out that magnesium chloride is also used in certified organic dietary supplements.

Questions to our Stakeholders
1. Is the use of magnesium chloride as a color enhancement consistent with organic principles?
2. There appear to be other materials on the National List (e.g., Glucono delta-lactone and calcium sulfate) that perform the same or similar functions most specifically in tofu production. The subcommittee is requesting information as to whether these alternatives offer the same or similar functionality and essentiality?

Nitrogen

Reference: §205.605(a) *Nonsynthetics allowed:*
Nitrogen—oil-free grades.
Technical Report: 1995 TAP.
Petition: N/A
Past NOSB Actions: 4/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset review; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)

Subcommittee Review

Use
Nitrogen is used to displace oxygen and thereby reduce oxidation of product during processing, storage, and packaging. It can be used in the flash freezing of foods. It also functions as a propellant when used under pressure and doesn't have ozone-depleting properties.

Manufacture
Nitrogen is a colorless, odorless gas. Cryogenic distillation, where air is compressed, cooled, and then filtered, is the most economic and highest purity method for separating nitrogen from air.

International Acceptance
The use of nitrogen is permitted in organic processing in Canada, CODEX, EU, IFOAM, and Japan.

Canadian General Standards Board Permitted Substances List
The material is allowed in food handling.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
The material is allowed in food handling.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
The material is allowed in food handling.

International Federation of Organic Agriculture Movements (IFOAM) Norms
The material is allowed in food handling.

Japan Agricultural Standard (JAS) for Organic Production
The material is allowed in food handling.

Environmental Issues
None. Nitrogen is a naturally occurring inert atmospheric gas.

Discussion
During the 2017 Sunset review, there was strong public support for continued use of nitrogen. The Board voted unanimously to retain nitrogen on the National List.

Questions to our Stakeholders
None

Sodium carbonate

Reference: §205.605(a) *Nonsynthetics allowed:*
Sodium carbonate.
Technical Report: 1995 TAP.
Petition: N/A
Past NOSB Actions: 4/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset review; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)

Subcommittee Review

Use
Sodium carbonate is used as a raising (leavening) agent. Sodium carbonate (also referred to as washing soda or soda ash) can also be used as an anti-caking agent, as an acidity regulator, or as a

stabilizer, as well as a neutralizer for butter, cream, fluid milk, and ice cream. Sodium carbonate is the material used to give pretzels and lye rolls their brown crust without burning. Sodium carbonate is also used in the processingof olives prior to canning, in the making of ramen noodles, and in cocoa products.

Manufacture
Sodium carbonate is produced in North America from natural deposits of trona ore (sodium sesquicarbonate) that is heated and then mixed with water to dissolve the soda ash and separate out the impurities. This solution is then concentrated by evaporation to crystallization. This method is considered to be the most sustainable form of producing sodium carbonate. Additionally, in California, sodium carbonate can be produced from a similar method using natural brine (Searles Lake).

International
The use of Sodium carbonate is permitted in organic processing in Canada, CODEX, EU,IFOAM, and Japan.

Ancillary Substances
None

Discussion
Public comments during prior sunset reviews have stated that sodium carbonate is essential for use as a leavening agent, neutralizer in baked goods, frozen desserts, and soy base extraction. It is also used as apH adjuster in organic laundry detergents. One certifier commented that it is also used to clean fruit and remove mold. Past public comments have been supportive of sodium carbonate remaining on the National List. Prior comments have raised concerns about possible hazards during mining and manufacturing and requested a technical report to examine possible hazards during mining and manufacturing, and also evaluate the need for this material and alternatives. Past comments have also asked for clarification that manufacturing processes are considered non-synthetic and permitted under the current listing: 205.605(a) non-synthetics allowed. This material was most recently reviewed by the NOSB in Fall of 2017 and the Board voted unanimously to continue its listing on the National List. Public commenters supported the continued listing of this material.

Questions

1. Is this material still essential for organic handling and processing?
2. Are there alternative materials that can replace sodium carbonate?
3. What are the relative environmental impacts of trona mining or brine extraction during production of sodium carbonate?
4. Is sodium carbonate produced from trona or brine extraction non-synthetic?

Acidified sodium chlorite

Reference: §205.605(b) *Synthetics allowed:*

Acidified sodium chlorite—Secondary direct antimicrobial food treatment and indirect food contact surface sanitizing. Acidified with citric acid only.

Technical Report: 2008 TAP; 2013 TR (livestock).
Petition: 2006.
Past NOSB Actions: 2009 recommendation; 10/2015 sunset review; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)

Subcommittee Review

Use

Acidified sodium chlorite (ASC) solution is used as a processing aid in wash and/or rinse water, in accordance with the FDA limitation for use on direct food contact and indirect food contact:

- Direct Food Contact (Secondary Direct Food Additive) – Poultry carcass, organs and parts; red meat carcass, organs and parts, seafood (finfish and crustaceans), and fruits and vegetables (raw and further processed); processed, comminuted or formed meat products; and
- Indirect Food Contact – Hard surface food contact sanitation.

Manufacture

ASC solutions are made on-site and on-demand by mixing a solution of sodium chlorite with natural citric acid. Sodium chlorite (25%) and citric acid (50%) solutions are stored separately in bulk on site. Both solutions are pumped by proportional pumps and a water dilution module to make the final use dilution product, which typically contains 0.1% sodium chlorite and 0.6% citric acid and 99.3% water. Sodium chlorite is made by the reduction of chlorine dioxide, which is, in turn, from the reduction of sodium chlorate in the presence of sulfuric and hydrogen peroxide or sulfuric acid and sodium chloride. The resulting solution may be dried to a solid and the sodium chlorite content may be adjusted to about 80% by the addition of sodium chloride, sodium sulfate, or sodium carbonate. Sodium chlorite is marketed as a solid or an aqueous solution (such as 25% by weight).
The acid used to acidify sodium chlorite is natural citric acid, which was stated in the 2006 petition. However, there is no information in the petition regarding how the natural citric acid is manufactured.

International Acceptance

Canadian General Standards Board Permitted Substances List
Acidified sodium chlorite is not specifically listed.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
There is no specific listing for acidified sodium chlorite for use in handling.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
There is no specific listing for acidified sodium chlorite for use in handling.

International Federation of Organic Agriculture Movements (IFOAM) Norms
There is no specific listing for acidified sodium chlorite for use in handling.

Japan Agricultural Standard (JAS) for Organic Production
Limited to the use for disinfecting meat and poultry at slaughter, or washing eggs.

Environmental Issues
While the manufacture and use of acidified sodium chlorite solutions have resulted in releases to the environment, the risk of environmental contamination from released acidified sodium chlorite is minimal. Certain manufacturing facilities have reported releases of chlorine dioxide, a portion of which was generated through reaction of chlorite with a strong acid, to air, water, and soil (ATSDR, 2004) (2013 TR, 360 - 362). Strong acids (e.g., hydrochloric acid) and bases (sodium hydroxide) are used in the commercial production of sodium chlorite, and their release due to improper handling/disposal could lead to serious environmental impairments. Likewise, the release of strong oxidizing agents in large quantities may lead to ecotoxicity in both terrestrial and aquatic environments. This is true of both the chemical feedstocks (e.g., hydrogen peroxide) used in the manufacture of acidified sodium chlorite precursors and the chemicals in acidified sodium chlorite solutions (i.e., chlorous acid, chlorine dioxide, chlorite). Regarding the former, several lower reactivity sulfur-containing and carbonaceous substances have been evaluated for the conversion of chlorine dioxide to sodium chlorite.

The acid used to acidify sodium chlorite is natural citric acid, which is stated in the petition. However, there is no information in the petition regarding how the natural citric acid is manufactured.

Discussion
In the 2017 sunset review, public comment regarding acidified sodium chlorite was mixed. Those in support stated that this is an essential tool in the fight against food borne pathogens. Those opposed to relisting stated that the NOSB should do a comprehensive review of sanitizers. The NOSB believes a review of that scope is beyond that of the sunset review process. Based on the Subcommittee review and public comment, the NOSB finds acidified sodium chlorite compliant with OFPA criteria, and does not recommend removal from the National List.

Questions to our Stakeholders
- Is the substance essential for organic food production?
- Since the material was last reviewed, have additional commercially available alternatives emerged?

The Handling Subcommittee encourages current users of acidified sodium chlorite to provide detailed comments describing the situations in which it is the most appropriate or effective antimicrobial for a given application.

Carbon dioxide

Reference: §205.605(b) *Synthetics allowed:*
Carbon dioxide.
Technical Report: 1995 TAP; 2006 TAP.
Petition: 2005.
Past NOSB Actions: 10/1995 minutes and vote; 2007 recommendation; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset review; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)

Subcommittee Review

Use

Carbon dioxide is used in modified atmosphere packaging, modified atmospheric storage, the freezing of foods, beverage carbonation, as an extracting agent, and for pest control in grain and produce storage.

Manufacture
It is available in limited supplies from underground wells and as a byproduct of various manufacturing processes. All of the processes require purification of the carbon dioxide before being used in food processing and handling.

International Acceptance
Canadian General Standards Board Permitted Substances List
Carbonation of wine or mead is prohibited.
Allowed for controlled atmosphere storage and for storage pest control.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Listed as an allowable processing aid for ingredients of agricultural origin from organic production.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
Allowed as a pest control method in storage facilities, and as a processing aid.

International Federation of Organic Agriculture Movements (IFOAM) Norms
Approved as processing and post-harvest handling aid (e.g., for flavoring agents).
Approved as an additive.

Japan Agricultural Standard (JAS) for Organic Production
Approved for use a fumigant in storage facilities.

Environmental Issues
According to the 2006 TAP report, the production of carbon dioxide is a byproduct of environmentally damaging processes via air pollution, solid waste streams, and drilling underground wells.

Carbon dioxide is a greenhouse gas and its use in organic food production means there may be a delayed release to the atmosphere in some cases.

Discussion

This product is on the FDA list of generally recognized as safe products. The EPA allows carbon dioxide as a pesticide as a fumigant, insecticide, and rodenticide.

In the previous sunset review, there was no substantive discussion about this material. No public comment supported delisting. There was support for its continued use by food manufacturers and associations.

Questions to our Stakeholders
1. Is carbon dioxide essential for organic food production?
2. Since the material was last reviewed, have additional commercially available alternatives emerged?

Sodium phosphates

Reference: §205.605(b) *Synthetics allowed:*
Sodium phosphates—for use only in dairy foods.
Technical Report: 2001 TAP; 2016 TR (phosphates).
Petition: 2001.
Past NOSB Actions: 10/1995 minutes and vote; 10/2001 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset review; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)

Subcommittee Review

Use
Sodium phosphates are salts used as pH control agents and buffers, acidulants, sequestrants, texturizers, and nutrients in organic dairy products. They act as stabilizers in milk and as emulsifiers in cheese. Disodium phosphate can be used as a processing agent in heavy whipping cream, where it binds to milk minerals to prevent the milk from coating the equipment during processing. Sodium phosphates are used in some organic milk products, such as half-and-half and heavy whipping cream, to stabilize the milk protein and to ensure the products do not separate or lose protein prior to consumer use.

Sodium phosphates are generally recognized as safe (GRAS) across multiple regulatory entities.

Manufacture
Finely ground, mined phosphate rock is mixed with sulfuric acid to form phosphoric acid. It is then reacted with sodium hydroxide to form sodium phosphate. There is a purification step in each reaction to remove substances like arsenic and fluorine.

International Acceptance
Canadian General Standards Board Permitted Substances List
Permitted for dairy use only.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Not listed.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
Not listed.

International Federation of Organic Agriculture Movements (IFOAM) Norms
Not listed.

Japan Agricultural Standard (JAS) for Organic Production
Not listed.

Environmental Issues
Phosphates, including sodium phosphates, can pollute water bodies and lead to eutrophication and there have been global efforts to remove phosphates from detergents. That said, there is no widespread concern about adverse impacts of these substances in food uses (specifically dairy) on the environment.

Also, since sodium phosphates derive from the mining of phosphate rock, there are environmental impacts associated with the manufacture.

Discussion
Public comment regarding sodium phosphates has historically been mixed. During the previous sunset review, stakeholders in support of the material's use in organics stated that sodium phosphate is essential in organic cheese products, including liquid and powdered forms, specifically as an emulsifier and stabilizer for shelf stable cheese products. Opposing stakeholders have expressed concern about potential human health impacts (the 2016 technical report was inconclusive) and material essentiality. Prior subcommittee review concluded that since there are four phosphates on the National List at § 205.605(b), no single phosphate food additive or ingredient can be implicated for inordinate and isolated risk. Some studies have indicated that high levels of phosphate consumption can accelerate aging and vascular damage, although sodium phosphate itself also has use among athletes for performance enhancement.

Questions to our Stakeholders
1. How essential are sodium phosphates to your operations or the operations of your stakeholders? Are there other natural substances or synthetic substances on the National List that could perform the same essential functions as sodium phosphates?
2. Do you have any new and compelling evidence that health impacts from sodium phosphates are significant?

Casings

Reference: §205.606(b) Casings, from processed intestines.
Technical Report: N/A
Petition: 2006
Past NOSB Actions: 4/2007 recommendation; 10/2010 sunset recommendation; 10/2015 sunset review.
Recent Regulatory Background: Added to National List on 06/21/2007 (72 FR 35137); Sunset renewal notice 03/21/2017 (82 FR 14420); Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset Date: 10/30/2024

Subcommittee Review

Use
The intestines of beef, lamb, and pork are used to make natural casings for sausage. The alternative material for casings is synthetic cellulose or synthetic collagen.

Casings have not received GRAS status, according to the 2019 TR.

Manufacture
Intestines are washed in pure water with no chemicals, and salted in NaCl salt and water. No other ingredients or processing aids are used. The animal intestines used may be from organic or nonorganic animals. Slaughterhouses do not separate certified organic and non-organic offal.

International Standards
Canadian General Standards Board Permitted Substances List
Collagen casings are allowed for poultry sausages

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

Environmental Issues
There are no published reports of heavy metals and other contaminants present in formulations of collagen gel and casings. According to the TR, there are no published studies on environmental impacts of casings, but "the manufacture of collagen may result in reductions to livestock and fish wastes".

Discussion
Since 2007, all casings sunset reviews have considered limitations on the availability of casings produced from organically raised livestock and agreed that a §205.606 listing is appropriate. Echoing comments in 2015 and earlier, comments on casings submitted to the Spring 2017 meeting also raised concerns about the limited availability of organically produced casing material. Comments were in favor of retaining use of non-organically produced casings as an option for production of organic sausage meat. Concerns were raised about the need to incentivize production of organic casings but that was viewed as a long-term effort.

There was strong public support for the continued use of casings at the last review. Some commenters encouraged the industry to examine the barriers to the availability of organic casings and raised the concern about the need to incentivize production of organic casings.

Questions to our Stakeholders
1. How much potential is there for a certified organic casings market?
2. Is separation at the slaughterhouse still a barrier to the availability of certified organic supply?

Pectin

Reference: 205.606(p) Pectin (non-amidated forms only).
Technical Report: 1995 TAP; 2009 TR; 2010 TR (supplemental); 2015 Limited Scope TR.
Petition: 2005 (low methoxy).
Past NOSB Actions: 4/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 recommendation; 10/2015 sunset review; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset date: 10/30/2024

Subcommittee Review

Use
Pectin is extracted from citrus and pome fruits but so far there is no organic supply of extracted pectin. It is used as a gelling agent in jams, preserves, fillings and other products. It is a desirable ingredient in organic food because it allows food to gel with less sugar than would be used without it. The excess sugar has the potential for more negative human health effects than pectin.

Manufacture
The most common production of non-amidated pectin is the treatment of pectin containing byproducts (pome fruit cores, citrus peels) with acidified water. Insoluble materials are filtered and removed, and the pectin is precipitated out with alcohol.

International Standards
[Canadian General Standards Board Permitted Substances List]
Compliant with the Canadian organic standards (both high and low methoxy allowed)

[European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008]
Pectin allowed in all products but meat-based products

[Japan Agricultural Standard (JAS) for Organic Production]
Pectin allowed in all products but meat-based products

[International Federation of Organic Agriculture Movements (IFOAM).]
Unmodified forms only

Environmental Issues
According to the most recent TR, the FDA "suggest that the petitioned substance is not harmful to human health or the environment. Since the manufacture of pectin is a by-product of the fruit juice industry, its production therefore serves to reduce the waste streams generated from the making of fruit juices."
Ancillary Substances
Ancillary substances used in pectin include sugar and dextrose for standardizing products, and trisodium citrate (or other salt buffers described in the 2015 TR).
Discussion
In previous Sunset reviews, public comments submitted by organic manufacturers, trade associations, material suppliers and certifiers detailed extensively pectin's use and necessity in organic production. One comment noted organic pectin was listed in the Organic Integrity Database but also noted these products use it as a dietary supplement not as a gelling agent. Comments from a trade association representing the pectin industry spoke to constraints in commercializing organic pectin due to commingled raw material supplies and the current unavailability of organic pectin. A comment from an interest group stated pectin should be limited to high methoxyl pectin (HMP), extracted from citrus peel and apple pomace, and wanted an evaluation to take into consideration the use of pesticides in the production of the non-organic raw materials.

There was strong public support for the continued use of pectin. Previous Board discussion noted the desire for the development of an organic pectin and discussed how this production could be incentivized but also noted the lack of commercial availability.

Questions to Stakeholders:
1. Has an organic source of pectin become commercially available?

Potassium acid tartrate

Reference: §205.606(q) Potassium acid tartrate.
Technical Report: 1995 TAP; 2017 TR.
Petition: N/A
Past NOSB Actions: 10/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset review; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420); Classification changed from non-agricultural to agricultural 5/30/2019 (84 FR 18133).
Sunset Date: 5/30/2024

Subcommittee Review

Use
Potassium acid tartrate is a by-product of wine making. It is commonly known as Cream of Tartar. It is used in baked goods, a component of baking powder, for stabilizing egg whites or other food uses, pH control, and as an antimicrobial agent (2017 TR). A detailed discussion of the historical documents relevant to potassium acid tartrate is provided in the 2017 TR.

Potassium acid tartrate was previously allowed under the National Organic Program (NOP) regulations at 7 CFR 205.605(b) as a "nonagricultural, synthetic substance for use as an ingredient in or on processed products labeled "organic" or "made with organic (specified ingredients or food group(s))." However, during the 2017 sunset review, a number of commenters noted that it should be listed at § 205.606 as a non-organically produced agricultural substance. The NOSB agreed with this assessment and passed a recommendation for the change of listing. That recommendation underwent subsequent rulemaking and potassium acid tartrate is now listed under § 205.606.

Manufacture
During the winemaking process, sediments form that must be removed to produce a clear wine. "Lees" is the name of the sediment consisting of dead yeast cells, grape pulp, seed, and other grape matter that accumulates during fermentation. "Argol" and "tartar" are synonyms used to describe the crust that builds up in wine vats and casks. Argol is defined as crude potassium hydrogen tartrate, deposited as a crust on the sides of wine vats. Tartar is defined as a substance consisting essentially of cream of tartar that is derived from the juice of grapes and deposited in wine casks together with yeast and other suspended matter as a pale or dark reddish crust or sediment. Tartar consists of about 80% potassium acid tartrate. Potassium acid tartrate is only slightly soluble in cold water but highly soluble in hot water (6.1g/100 mL at 100°C). Extracting wine lees with hot water dissolves the potassium acid tartrate. When the filtered extraction solution is cooled, potassium acid tartrate precipitates as very pure crystals (>99.5% pure). No other reagents or solvents are involved in the extraction.(TR 2017, 58-69).

GRAS: Potassium acid tartrate is Generally Recognized as Safe (GRAS) (TR 2017, 350).

Ancillary Substances
There are no ancillary substances associated with the listed substance.

International Use
According to the 2017 TR, international guidance and regulations include the use of potassium acid tartrate (INS 336i) in organic processing and are generally consistent with the limited uses described by FDA at 21 CFR 184.1077(c). The European-focused regulations and guidance – CODEX, IFOAM and the EU – additionally include potassium tartrate (dipotassium tartrate) (INS 336ii) as an allowed potassium tartrate.

Canadian General Standards Board Permitted Substances List
Potassium acid tartrate ($KC_4H_5O_6$) is a permitted processing substance listed in Table 6.3, ingredients classified as food additives, with the following annotation: "If the non-synthetic form is not commercially available, the synthetic form is permitted."

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Consistent with the Codex guidelines, the European Community regulation permits the use of the potassium tartrates (i.e., both potassium acid tartrate E 336i and dipotassium tartrate E 336ii) in processing organic foods of plant origin (EC No. 889/2008 Annex VIII, Section A Food Additives).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
The Codex organic guidelines permit the use of potassium acid tartrate (INS 336i) and dipotassium tartrate (INS 336ii) in plant foods, specifically confectionary, flours and starches, and cakes, but not in animal foods.

International Federation of Organic Agriculture Movements (IFOAM) Norms
The IFOAM Norms, Appendix 4, Table 1, permit the use of INS 336 (i.e., both potassium acid tartrate E 336i and dipotassium tartrate E 336ii) as an additive and as a processing and post-harvest handling aid, without limitation.

Japan Agricultural Standard (JAS) for Organic Production
Article 4, Table 1, Food Additives permits the food additive INS 336i, potassium acid tartrate, for limited use for grain processed foods or confectionary only.

Environmental Issues
Since potassium acid tartrate is a byproduct of the winemaking process, the environmental issues are limited to those associated with the production of conventional grapes. There are increasing quantities of organically produced grapes and wines available.

Discussion
Public commenters overwhelming supported relisting of this substance during the public sunset review process in 2017. As with several of the products derived from wine making, there is a question of commercial availability, and when the quantity of organic supply could meet the needs of the marketplace and this substance could be delisted. It is difficult to develop organic supply while non-organic tartrate is in the marketplace, thus making it hard to determine when there could be, or is, sufficient supply to meet the organic market needs.

Questions to our Stakeholders
1. Is there adequate supply of organically produced potassium acid tartrate to meet commercial needs?

National Organic Standards Board
Materials/GMO Subcommittee
Excluded Methods Determinations Proposal Spring 2022
February 8, 2022

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 "To Be Determined (TBD) list" of technologies needing further review to determine if they should be classified as excluded methods or not; this proposal continues the work established in 2016. The organic community, as well as the NOSB, has voiced a consistent, unanimous stance that direct manipulation of genes through in vitro nucleic acid techniques should be considered as excluded methods.

Cell Fusion is listed specifically in the regulations under (7 CFR 205.2) under terms defined as an excluded method. In 2013, Policy Memo 13-1 clarified cell and protoplast fusion as mimicking natural phenomenon with the limiting factor of [use when the original cells are within the same taxonomic plant family. In the October 2021 NOSB meeting, the Board put forth a discussion document to clarify whether cell and protoplast fusion are excluded methods when the techniques are employed within taxonomic plant families. Note that in recent years, protoplast fusion is the scientifically preferred term for cell fusion as used in plant breeding. This document will continue to distinguish them as is necessary for the purpose of clarity.

Goals of this proposal/document

At the October 2021 NOSB meeting, a discussion document was presented for public comment for the two items covered in this proposal: cell fusion and protoplast fusion. This proposal addresses these two items which have remained on the TBD list, despite cell fusion's appearance in terms defined, and the clarification in Policy Memo 13-1. This Proposal seeks to clarify the position of cell and protoplast fusion, taking into consideration all previous NOSB work on the topic and current public comments.

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 emerging technologies do or do not meet our current definitions. We may need to incorporate additional criteria to evaluate new and unique technologies as they become commercially available as potential inputs to organic supply chains.

The NOSB is aware that specific laboratory tests may not be available to detect the presence of excluded methods in organic systems and will continue to emphasize the power of this process based, systems approach to evaluating agriculture and food processing. Until such a time as higher regulatory authorities provide organic systems with definitions and transparency of methodologies organic systems view as prohibited, the Materials Subcommittee will continue to evaluate, define, and assist organic stakeholders in determining the presence of excluded methods in organic systems as they emerge.

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 (7 CFR 205.2 Terms defined) 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.

The NOSB previously recommended the use of the following definitions to determine whether or not a method should be/is excluded.

Genetic engineering (GE) – A set of techniques from modern biotechnology (such as altered and/or recombinant DNA and RNA) by which the genetic material of plants, animals, organisms, cells, and other biological units are altered and recombined.

Genetically Modified Organism (GMO) – A plant, animal, or organism that is from genetic engineering as defined here. This term will also apply to products and derivatives from genetically engineered sources. (Modified slightly from IFOAM Position)

Modern Biotechnology – (i) in vitro nucleic acid techniques, including recombinant DNA and direct injection of nucleic acid into cells or organelles, or (ii) fusion of cells beyond the taxonomic family, that overcomes natural, physiological reproductive or recombination barriers, and that are not techniques used in traditional breeding and selection. (From Codex Alimentarius)

Synthetic Biology – A further development and new dimension of modern biotechnology that combines science, technology, and engineering to facilitate and accelerate the design, redesign, manufacture and/or modification of genetic materials, living organisms and biological systems. (Operational Definition developed by the Ad Hoc Technical Expert Group on Synthetic Biology of the UN Convention on Biological Diversity)

Non-GMO – The term used to describe or label a product that was produced without any of the excluded methods defined in the organic regulations and corresponding NOP policy. The term "non-GMO" is consistent with process-based standards of the NOP where preventive practices and procedures are in place to prevent GMO contamination while recognizing the possibility of inadvertent presence.

Classical/Traditional plant breeding – Classical (also known as traditional) plant breeding relies on phenotypic selection, field-based testing, and statistical methods for developing varieties or identifying superior individuals from a population, rather than on techniques of modern biotechnology. The steps to conduct breeding include the following: generation of genetic variability in plant populations for traits of interest through controlled crossing (or starting with genetically diverse populations), phenotypic selection among genetically distinct individuals for traits of interest, and stabilization of selected individuals to form a unique and recognizable cultivar. Classical plant breeding does not exclude the use of genetic or genomic information to more accurately assess phenotypes, however the emphasis must be on whole plant selection.

Criteria

Below are the criteria listed in the 2016, 2017, 2018 and 2019 NOSB recommendations to determine if methods should be excluded.

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.

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; it can have unintended consequences.

Method and synonyms	**Types**	**Excluded Methods**	**Criteria Applied**	**Notes**
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; it 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.
Induced Mutagenesis		YES	1	Developed through in vitro nucleic acid techniques does not include mutagenesis developed through exposure to UV light, chemicals, irradiation, or other stress-causing activities.
Cell and Protoplast Fusion	donor and/or recipient cells are outside taxonomic plant family; and/or recombinant DNA technology is employed	YES	Terms Defined 205.2	See NOP Policy Memo 13-1.

Methods Allowed:

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.
Embryo transfer, or embryo rescue, in animals		NO		*Use of hormones not allowed in recipient animals.
Transposons		NO		Developed through environmental stress, such as heat, drought, or cold.
Cell and Protoplast Fusion	Recipient and/or donor cells are within the same taxonomic plant family; must be achieved without recombinant DNA technology	NO		NOP Policy Memo 13-1; Definition of Modern Biotechnology

TBD list:

Terminology

Method and synonyms	Types	Excluded Methods	Criteria Used	Notes
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 detect DHT with tests.
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

Under the NOP organic regulation, cell fusion is, by definition, an excluded method at §205.2. In 2013, NOP Policy Memo 13-1 provided further context for the use of cell fusion which included protoplast fusion. Both were deemed by the Policy Memo to be excluded methods except when either technique was employed within taxonomic plant families. The Policy Memo defends this assertion that this limited use mimics natural phenomena and is therefore allowed. In response to the 2021 Discussion document on this subject, a stakeholder provided historical context that indicates the NOSB's support for the Policy memo:

"At the time the policy memo 13-1 came out, the NOSB was just starting to work on Excluded methods and there was a lot of controversy over the memo. That has since died down, and the definition of "Modern Biotechnology" that was adopted in the 2016 recommendation essentially codifies the approach in that memo by citing the international definitions that allow it within plant families."

Furthermore, in February 2013, the NOSB Discussion Document on Excluded Methods Terminology references the Policy Memo explaining "that cell fusion techniques are considered an 'excluded method' when the donor cells/protoplasts do not fall within the same taxonomic family. Cell fusion is also an 'excluded method' when the donor or recipient organism is derived using techniques of recombinant DNA technology and techniques involving the direct introduction into the organism of hereditary materials prepared outside of the organism."

As the NOSB continued its work around issues of Excluded Methods, both cell fusion and protoplast fusion were included on a list of techniques that needed consideration for allowance/prohibition (see Appendix for NOSB Proposal and Discussion Document April 2016). The TBD list included cell fusion with the note column giving the explanation "[s]ubject of an NOP memo in 2013. The Crops Subcommittee will continue to explore the issue." Protoplast fusion was included in the TBD list with the note "[t]here are many ways to achieve protoplast fusion, and until the criteria about cell wall integrity are discussed and developed, these technologies cannot yet be evaluated."

In the Fall 2021 Discussion Document preceding this proposal, stakeholders were asked if additional criteria for excluded methods determinations are necessary before work on the remaining terms can be addressed as indicated in the TBD list notes. Stakeholders were also asked if Policy Memo 13-1 is complete and being applied consistently in organic systems. These questions were intended to establish whether the conversation around cell and protoplast fusion is complete or if more discussion is needed.

In response, except for consistent suggestions for an edit to the language of the first criteria for scientific accuracy, stakeholders expressed overwhelming support for the criteria developed for evaluating Excluded Methods as they stand. One commenter captured the tone of many with the following assertion:

"We do not support or see a need for additional criteria for excluded methods determinations at this time. It is imperative to the integrity of the NOSB's process that the same criteria be applied to all methods that have been reviewed and those still under review by the NOSB…….[i]t is important to first recognize that cell fusion is already clearly listed as an excluded method per the regulatory definition (7 CFR 205.2). What the NOP Policy Memo 13-1 deems an allowable method is cell fusion and protoplast fusion within taxonomic plant families. "Cell fusion and protoplast fusion within the same taxonomic family" should be moved to the list of methods determined to NOT be excluded. This is consistent with Policy Memo 13-1 and clarifies that this method – again, when employed within taxonomic families – is viewed as traditional plant breeding and not genetic engineering."

Stakeholders were consistent in response to the Policy Memo 13-1, asserting that the regulatory definition in conjunction with the Policy memo provide necessary clarity. The subcommittee appreciates that public comments were united and practical. One commenter reflected:

"….organic plant breeders, organic seed companies, organic growers, and organic certifiers find Policy Memo 13-1 remains an important touchstone for guiding their decisions. Upholding Policy Memo 13-1 is essential to the success of organic operations, especially when considering the extensive use of cell fusion and protoplast fusion within taxonomic plant families"

Additionally, an organic seed producer provided the following:

"…Policy Memo 13-1 adequately defines the instances under which cell fusion and protoplast fusion can be used in organic and ties the logic directly to the first sentence of the Regulatory definition of an 'excluded method' wherein methods which could be achieved in nature are compatible with organic production; also, the third sentence of the definition wherein traditional breeding and hybridization are listed allowable.

*We would prefer that these methods be moved to the *Excluded Methods -NO - List with a note that 'Except when used outside of taxonomic plant families'. If kept on the Excluded Methods -YES -list, with the note 'Except when employed within taxonomic plant families' we would then prefer that the above mentioned (*) of NO list also be honored in order to clearly define and underscore that certain usages of cell fusion and protoplast fusion, in cases within taxonomic plant families, are acceptable for on farm use.*

For the sake of discussion, we would further raise the idea of updating the Guidance table on Excluded Methods to be renamed Allowed Methods or similar positive prose."

The Materials Subcommittee did not see the need to address issues of phasing out the use of either cell or protoplast fusion at this time, for these specific techniques. The policy memo was established in 2013 and public comment expressed overwhelming support for the forward motion of this proposal as a validation of long-standing NOP Policy and the will of previous NOSB decision making on excluded methods.

Subcommittee Vote:
Motion to accept the proposal on excluded methods determinations for cell and protoplast fusion.
The NOSB recommends the NOP develop a formal Guidance document to include the above Definitions, Criteria, Excluded and Allowed Methods tables as developed by previous Board Proposals in 2016, with the addition of the following:

1. Cell Fusion
    - The NOSB recommends the NOP add Cell Fusion to the table of Excluded Methods when the donor and the recipient cells are outside taxonomic plant families and/or when either is derived using techniques of recombinant DNA technology; with notes on the exception for use when donor and recipient cells are within the same taxonomic plant families.
    - The NOSB recommends that Cell Fusion be added to the table of Allowed Methods with notes limiting the use to when the donor and recipient cells are within taxonomic plant families, and neither are derived from techniques of recombinant DNA technology.
2. Protoplast Fusion
    - The NOSB recommends the NOP add Protoplast Fusion to the table of Excluded Methods, when either the donor or the recipient cells are outside taxonomic plant families and/or when either is derived using techniques of recombinant DNA technology; with notes on the exception for use when donor and/or recipient cells are within the same taxonomic plant families.
    - The NOSB recommends that Protoplast Fusion be added to the table of Allowed Methods with notes limiting the use to when the donor and recipient cells are within

taxonomic plant families, and neither are derived from techniques of recombinant DNA technology.

Subcommittee Vote:
Motion by: Mindee Jeffery
Second: Logan Petrey
Yes: 5 No: 0 Absent: 1 Abstain: 0 Recuse: 0

Approved by Wood Turner, Materials Subcommittee Chair, to transmit to NOSB February 15, 2022.

National Organic Standards Board
Materials Subcommittee Petitioned Material Discussion Document
Distilled Tall Oil
February 8, 2022

Relevant Background on the Distilled Tall Oil Petition

A petitioner has submitted documentation (August 24, 2020; May 13, 2021; November 22, 2021) to the National Organic Program (NOP) requesting the use of distilled tall oil (DTO) at 7 CFR §205.601(m) and 7 CFR §205.603(e) as a synthetic substance permitted in organic agriculture. Per the petition, the intended use of DTO – a viscous yellow to amber-brown liquid insoluble in water -- in organic crop and livestock production is as an inert ingredient and as an adjuvant for use as a solvent, sticker, anti-leaching agent, and time-release agent in pesticides. The petitioner asserts that DTO offers a range of benefits to organic production, including but not limited to improved performance, employee and environmental health and safety, and reduced re-treatment intervals.

A previous petition submitted in 2008 was denied by the National Organic Standards Board (NOSB) in October 2010. The principal focus of the technical report on that petition and the NOSB's subsequent review appears to have been on crude tall oil (CTO) and DTO as being structurally and functionally one in the same. The current petitioner has sought to draw an essential distinction between the two substances in how they are constituted, applied, and ultimately incorporated by and into the environment.

Another important issue to consider with this petition is that the intended use of DTO is as an inert or adjuvant ingredient, not an active ingredient and specifically not an active insecticide/pesticide. The petitioned use as an inert ingredient is to augment the functionality and sequestration of other approved substances in organic crop and livestock production. Both the prior technical report and NOSB review and the current technical report have dedicated significant analysis on the substance as an *active* ingredient, which may not be appropriate for this petition. This petition coincides with the NOP's review of EPA List 3 and List 4 inerts.

Given its application to both crop production and livestock production, the petition was assigned to the NOSB's Materials Subcommittee for review and over the course of the Subcommittee's review, questions have emerged for which a broader discussion with stakeholders is sought.

Distinction between Distilled Tall Oil and Crude Tall Oil

The Materials Subcommittee found the petition sufficient for evaluation and requested an updated technical report, specifically seeking differentiation between CTO and DTO. Neither CTO nor DTO have a history of use in organic but have long been used in conventional agriculture. Neither substance appears on any international lists of substances permitted in organic.

Both CTO and DTO are derived from Kraft pulping – in alkaline conditions -- of coniferous trees and are comprised of fatty acids, rosin acids, and – most minimally -- neutrals [or unsaponifiable (non-soaping) compounds]. While the two substances are identified by a common Chemical Abstracts Service (CAS) number, they are differentiated by the degree to which each final substance is refined or purified. In DTO, the final substance is purified to the extent of having reduced rosin acids and neutrals compared to

CTO. This results in a final substance with a higher percentage of fatty acids. The technical report also provided references indicating that CTO and DTO may differ in the species of conifer from which they are sourced and the context within which pulping of the source material occurs in order to derive the black liquor that becomes the key feedstock for both substances. One cited source from 1992 suggested that the majority of all tall oil in the United States is distilled, not crude.

DTO is made when tall oil soap is isolated from the black liquor that results from pulping. When combined with sulfuric acid, the tall oil soap forms CTO. When it is further refined, it becomes DTO.

Inert versus Active

Since the petition only contemplates the use of DTO as an inert or adjuvant ingredient in pesticide application, this review is limited in its scope to the appropriateness of the substance as petitioned, not as an active pesticide ingredient. It should be noted that this is the first time since February 2011 that a petition has been brought before the NOSB for a substance that the petitioner considers an inert.

While DTO can be an active pesticide (whereby soft-bodied insects are suffocated upon contact with the substance), it is petitioned here as an inert or adjuvant (auxiliary) substance needed to dissolve active ingredients. That said, the technical report asserts that “inert” by no means implies “nontoxicity” or that it does not have insecticidal functionality. These considerations may be a function of the way that EPA classifies and manages inerts. It is important to note that DTO does appear on the EPA’s List 3, inerts of unknown toxicity. Tall oil (broadly) appears on EPA List 3, inerts of unknown toxicity, but does not – nor does DTO -- appear on List 4, inert ingredients of minimal risk. The implications for these listings are relevant to the NOSB’s continued vigilance on the issue of inerts and the reliance on obsolete lists under the jurisdiction of other agencies. The use of List 3 materials in organic production is annotated to limit their use to "use only in passive pheromone dispensers.” Until the references to List 3 and 4 materials is changed, those lists define the way that inert materials are reviewed. However, this petition asks that DTO be reviewed independently from its listing on List 3 and be specifically placed on the National List as an allowed synthetic for organic production. When used as an inert, DTO would be combined with active ingredients in pesticides.

While the technical report suggests that the inert use of DTO still manifests insecticidal results (which should be a significant consideration relative to its use in organic production), the petitioner has since responded that the use of the substance as an inert is intended to produce the effects of an insecticide. The petitioner has submitted additional information since the drafting of this discussion document, and it should be available in the public comment docket on Regulations.gov prior to the Spring 2022 meeting That said, application rates for the substance as outlined in the petition more closely suggest active function than the rates that would be expected of an inert. The Subcommittee has discussed the challenges of effectively reviewing this substance as an inert when application rates more clearly resemble those of active-functioning ingredients and is looking at this discussion document as an opportunity for discovery to receive information from stakeholders on the science of inert evaluation.

The technical report articulates alternatives to DTO that may not be relevant to this petition, as they seem to be alternatives to its active (not inert) use, i.e., nets and other physical barriers to reduce pest impacts as well as mechanical removal of insects. Presumably DTO as an inert would simply be augmenting the time-release and related functionality of allowed substances and products. The technical report also alludes to weed removal, seasonal cropping, and crop rotations as means of avoiding DTO’s application as an active pesticide ingredient (i.e., insect suffocant).

Further, the Materials Subcommittee acknowledges that the NOP has an [Advance Notice of Proposed Rulemaking (ANPR)] in process, in an attempt to address the obsolete EPA List 3 and EPA List 4 references in the organic regulations.. The ANPR is happening concurrently with this petition and could establish precedent for how the National List addresses inerts moving forward.

Other Considerations

The insolubility of DTO in water – its inherent hydrophobia – appears to decrease the solubility of the pesticides of which it is a part and helps to prevent both leaching of pesticides into groundwater and leaching of micronutrients from topsoil. This sequestration role of DTO appears to be one of its main functional benefits.

Although perhaps not relevant to this petition, DTO appears in a number of food packaging applications and is generally regarded as safe (GRAS) by the Food and Drug Administration.

Questions to our Stakeholders

1. Does distilled tall oil as an inert ingredient provide functionality that could be beneficial to organic producers? Could that vary between usage in crop production versus livestock production?

2. As the petitioner suggests, are there no other, or few other, time-release agents available for use in organic production?

3. The regulation wherein the EPA classifies DTO as a List 3 inert is obsolete; however, according to the technical report, the rate of application for the substance as outlined in the petition could function more like an active pesticide, not an inert or adjuvant. Does the projected rate of application contribute to the substance functioning as an inert or active ingredient? Should the NOSB develop an annotation limiting the application rate of inerts and adjuvants so as to ensure they function as such and not as an active ingredients or pesticides?

4. Can DTO as an inert function as an active insecticide, making it fall outside the scope of this petition?

Subcommittee Vote:
Motion to accept the discussion document on Distilled Tall Oil
Motion by: Wood Turner
Seconded by: Mindee Jeffery
Yes: 6   No: 0   Abstain: 0   Absent: 0   Recuse: 0

Approved by Wood Turner, Materials Subcommittee Chair, to transmit to NOSB, February 11, 2022

USDA National Organic Standards Board
Research Priorities Discussion Document
Spring 2022
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. Determine the efficiency of natural parasiticides and methodologies, including but not limited to, nutritional programs, use of herbs, essential oils, homeopathic remedies, diatomaceous earth, and the genetic pool of laying hens in controlling *A. galli* and *H. gallinarum* in laying and replacement chickens intended to become hens.
2. Evaluate natural alternatives to DL-Methionine in a system approach for organic poultry feed program.
3. Evaluate ways to prevent and manage parasites in livestock, examining breeds, geographical differences, alternative treatments, and pasture species.
4. Develop a dairy program to address climate change mitigation strategies where milking capabilities are not hindered and effective forage rotations are maximized.
5. Develop balanced organic livestock rations that incorporate high percentages of diverse, regionally adapted grain crops to reduce the reliance on corn and soybeans and allow farmers to realize more marketing opportunities for a robust crop rotation.

Crops

1. Examination of decomposition rates, the effects of residues on soil biology, and the factors that affect the breakdown of biodegradable bio-based 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 (including specific considerations related to copper use in organic rice production) 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 and weeds.
8. Factors impacting organic crop nutrition, and organic/conventional nutrition comparisons.
9. Side-by-side trials of approved organic inputs, both synthetic and natural, and cultural methods, with a request for collaboration with the IR4 project.
10. Impartial evaluation of microbial inoculants, soil conditioners, and other amendments is needed as there is little objective evidence upon which to assess their contribution to soil health.
11. More research, extension, and education are needed to fully understand the relationship between on-farm biodiversity and pathogen presence and abundance.
12. Elucidate practices that reduce greenhouse gas emissions and that contribute to farming systems resilience in the face of climate change.

Food Handling and Processing

1. Sanitizers: Effective alternatives of sanitizers, effect on occupational human health and environment, effectiveness of rotational use strategies with the sanitizers currently on the National List
2. Effect of various types of food packaging on organic products, including suitable alternatives to BPA (Bisphenol-A) for linings of cans used for various products, plastic use, antimicrobial nanoparticle surface coatings of packaging.
3. Research on the creation of an overarching ancillary ingredient review process for materials used in processing and handling vs reviewing ancillaries as part of the petition or sunset review process, including cost/benefit of each process.
4. Alternatives to conventional celery powder for curing organic meat.
5. Research on best practices for identifying potential vectors of heavy metal contamination in organic systems, including strategies for effective testing in soils, water, organic processing, etc. that could lead to the identification and prevention of heavy metals transgression in organic systems.
6. Evaluation of the essentiality of 205.605(a), 205.605(b), and 205.606 substances and the suitability of organic alternatives in applicable food formulations via laboratory testing, sensory evaluation, and/or market analysis.

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 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 Discussion Document
2022 Research Priorities
Spring 2022

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 proposed an updated set of priorities at the Fall 2021 board meeting. The Board requests input from stakeholders on the 2022 research priorities and will review those comments for the Fall 2022 proposal.

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 reflect the existing need more accurately for new knowledge.

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.

The NOSB encourages integrated, whole farm research into the following areas:

Livestock

1. Efficiency of Natural Parasiticides and Methodologies – Nutritional programs, use of herbs, essential oils, homeopathic remedies, Diatomaceous Earth, and the genetic pool of laying hens in controlling *A. galli* and *H. gallinarum* in laying and replacement chickens intended to become hens – among other interventions – may be helpful in ensuring flock health. Ongoing research into the usefulness and viability of such innovations is consistent with NOSB action.

2. 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; (3) assessment of management practices for improving existing organic poultry welfare under different conditions; and (4) and with the European Union as a case study, assess how it is that EU farmers manage the methionine needs of their flocks in the absence of synthetic methionine use. 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.

3. 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, bird and 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, diatomaceous earth, or other treatments that have been proven to work overtime? What are the parasite-resistant breeds? Are there plant species in pastures, hayfields, 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?

4. Develop a dairy program to address climate change mitigation strategies where milking capabilities are not hindered and effective forage rotations are maximized. - To further acknowledge the central role the certified organic industry will play in the fight against climate change, an opportunity exists to both empower the economic resilience of organic dairy farmers while harnessing the soil building potential of diverse perennial and annual forages, we encourage the research community to dedicate resources to the following need:

A. Identify an index of dairy cattle genetics to which producers could breed their existing herds and achieve a minimum of 12,000 lbs. of milk production per year on 100% forage diets. In considering the genetics selected, also identify animals bred for longevity as the more lactations on a cow, the more spread out the fixed costs of raising her as a heifer becomes.

B. To assist dairy farmers in having the tools to consider a forage-based rotation for their herds, research and identify crop rotations that have three functions: produce high quality forage, maximize soil building, and result in the most profitable outcome for the dairy producer.

5. Develop balanced organic livestock rations that incorporate high percentages of diverse, regionally adapted grain crops to reduce the reliance on corn and soybeans and allow farmers to realize more marketing opportunities for a robust crop rotation. - The US organic livestock demand and consumption of organic corn and soybean meal in feed rations exceeds US production. To help encourage farmers to utilize robust crop rotation programs that are specific to their geographical region, give livestock producers more product availability/flexibility of ingredients, and reduce the dependence on corn and beans, there needs to be proven equitable rations in all livestock segments that include alternative energy and protein sources

Crops

1. Biodegradable Bio-based Mulch Film - Biodegradable mulch was recently approved by the NOSB but did not specify a required percentage of biologically derived (i.e., bio-based) content. In 2015, NOP issued a Policy Memo that states that certifiers and material organizations should review biodegradable mulch film products to verify that all (100%) of the polymer feedstocks are bio-based. This requirement makes bio-based mulches unavailable to organic producers because petroleum-based polymers are present 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 are important to develop more clarity on mulch films and possibly develop an additional annotation to address producer needs for biodegradable mulch films even if petroleum-based polymers are used:

- 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 or breakdown products of these mulches that do not fully decompose? Do any of these mulches 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? What are the environmental fates of micro- and nano-plastic fragments resulting from biodegradable mulch film degradation, and what hazards do they present to organisms that they interact with on the way to that fate?
- 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 - How do organic systems impact ecosystem service provisioning, both on-farm and off-farm through the materials and inputs sourced and used for production? For example, life-cycle analysis of environmental costs and benefits of inputs used for organic production, such as manure, seaweed, and fish-based soil amendments, would be beneficial. Additionally, what is the impact of diversified and agroecologically designed organic farming systems on biodiversity and ecosystem services within the farm and in its surroundings? 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 and Minimum Tillage - Organic no-till 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.

Farmers are employing several different approaches to organic no-till. Some are using a roller-crimper to terminate cover crops for in-place mulching. They then transplant or seed directly into the cover crop mulch. Others are utilizing polyethylene sheets (silage tarps) to prepare land for no-till planting. This approach often involves termination of a cover crop, as with the roller-crimper systems, but seemingly as often, or more frequently, is utilized to prepare fallow ground (for stale seed bedding, termination of crop residue and subsequent incorporation via soil fauna), or in conjunction with large applications of compost or other sources of organic matter.

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 potential pest 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 mulching system on weed, pest, and disease management, as well as soil fertility?
- What are the biodiversity benefits to living and/or killed mulches, and how does this contribute to pest, weed, and disease management?
- Do these systems 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?
- Research is needed on seeds, specifically for good cold germination, rapid emergence and establishment, seedling vigor, nutrient uptake efficiency, and overall weed competitiveness to crop cultivar development goals for organic conservation tillage systems.
- How can reduced tillage weed management be improved, including development of new tools and techniques that provide greater weed control for less soil disturbance?

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** - 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 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 primarily on cover crops to meet production needs, particularly for horticultural crops. At present, there is inadequate data on the nutrient benefits of different cover crop mixes and how those benefits vary according to species mix, mowing practices, tillage regimes, subsequent planting time of the cash crops, and importantly the preceding practices that define the legacy of individual fields.

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.
- Research on scum and algae control in rice and whether sodium carbonate peroxyhydrate or other materials are suitable alternatives in an aquatic environment.
- Soil management and crop cultivar development for enhanced beneficial crop-root microbe partnerships that protect organic crops from soil borne and foliar pathogens.
- Alternatives to antibiotics (tetracycline and streptomycin) for fire blight control, particularly in pears and apples.

Specifically related to organic rice production and the ongoing concern about copper usage related to that crop (although not exclusive to it), more research is needed on disease management that:

1) supports a systems-based approach to reduce the needs of copper materials;
2) addresses a breeding component for disease resistance (where copper is used);
3) addresses alternate formulations to help reduce elemental copper;
4) speaks to developing biological agents to (hopefully) displace copper with a softer alternative;
5) evaluate plant nutritional strategies to lessen disease impacts.

6. Identify Barriers and Develop Protocols for Organic Nursery Stock Production
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. Research has shown that application of the correct ectomycorrhizal inoculants to roots can substantially (50% or more) enhance establishment and early growth of woody perennial horticultural crops. How can fine tuning the use of mycorrhizal inoculants to make organic nursery stock production easier and more profitable, thereby helping to close the demand/supply gap? Research centered on development of practical organic methods for the nursery industry to implement is needed, including:

- Disease and insect control materials that are allowed under organic standards and may be accepted under specific phytosanitary regulatory requirements.

- New materials for controlling pests addressed by phytosanitary rules that show promise of compatibility with National List review criteria.
- Alternative protocols for phytosanitary certification of nursery stock that are based on outcomes (such as testing or inspection) rather than requirements for use of synthetic materials during production.

7. Management and Control of Invasive Insects and Weeds - 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 currently 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.

Weeds pose one of the greatest barriers to successful organic crop production. Invasive weeds include exotic species that aggressively displace both crops and native plant species, as well as creeping perennial species (exotic or native) that are difficult to control without repeated, intensive tillage. The NOP standards require certified organic producers to use tillage and cultivation practices that maintain or improve soil conditions. Development of integrated, organic management strategies that effectively control invasive weeds without excessive tillage continues to emerge as a top research priority for organic producers.

8. Nutritional Value of Organic Crops - How do organic soil health and fertility practices—crop rotations, cover crops, compost and other organic or natural mineral amendments, etc. — affect the nutritional value or "nutrient density" of organically produced 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.

9. Side-by-Side Efficacy Comparisons Between National List Allowed and Petitioned Synthetic Inputs Versus Non-synthetic Alternative Inputs or Practices - 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. It should be noted that growers commonly rely on a mix of cultural practices and both non-synthetic materials and materials from the National List to produce crops of marketable quality and sufficient yield for profitability; it is understood that such studies would serve as a starting point and would form part of the comprehensive material review process.

10. Evaluation of Microbial Inoculants, Soil Conditioners, and Other Amendments – Vendors of organic amendments now offer a large and growing array of microbial inoculants, organic soil conditioners, and other materials claimed to improve soil health, crop vigor and quality, and combat weeds, pests, and diseases. There is an urgent need for impartial evaluation of these materials to help producers decide which products to use and to avoid unnecessary expenditures on products that are unlikely to yield benefits.

11. Pathogen Prevention - Third-party food safety auditors believe that some biodiversity-maintenance strategies employed by organic farmers may increase the risk for introduction of human pathogens on the field. While some research has been conducted disproving this hypothesis, more research, extension, and education are needed to fully understand the relationship between on-farm biodiversity and food safety – and this research must be communicated to third-party food safety auditors and incorporated into their audits.

12. Climate Change (Reducing Greenhouse Emissions and Sequestering Carbon) - A growing body of research demonstrates that organic farming can help prevent anthropomorphic climate change, and some strategies employed by organic farming can also help with resilience to current climate challenges such as drought and flooding. Although a number of researchers are examining this issue, additional work is needed to pinpoint specific strategies that organic farmers can take to reduce greenhouse gas emissions and respond to current climate challenges threatening the future of our food security.

Handling

1. Chlorine Materials and Alternatives - 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. Chlorine materials are also acutely toxic to workers. New sanitizers and disinfectants are regularly petitioned to the NOSB for addition to the National List. 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 use in wash tanks, including information about the amount of time of exposure, would help inform understanding of human exposure to chlorine and health risks. Are residues from produce washing 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?
- Can research projects that emphasize and reinforce collaboration between researchers, agencies that regulate sanitizers and food safety, and NOP be designed with the goal of developing an alternative process for evaluating sanitizers and sanitation practices for use by organic operations?
- Is there a measurable transfer of sanitizer residue to organic food following the sanitization of food contact surfaces? If residues are not found, is it even necessary for the National List to regulate surface/environmental sanitizers? (This topic should not be limited to only National List materials, but should also include sanitizers such as quaternary ammonia compounds.)
- What amount of sanitizer/disinfectant remains on the surface of various organic products after a processing or packing step that includes direct treatment with a sanitizer? What about from a water bath containing water treated with a sanitizer?
- Could the development of robust, post-harvest handling standards better identify which sanitation, disinfectant, or treatment practices have an impact on organic integrity? Could expanded handling standards assist in regulating and enforcing the use of sanitizers instead of, or in addition to, the National List?
- Could restructuring the National List to separate sanitizers from ingredients and processing aids create a pathway to development of an alternative set of evaluation criteria for sanitizers?
- What would the impact on handlers and processors be if any one of the sanitizers were removed from the National List?

2. 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), issues which are currently being addressed through a comprehensive stream of work on Excluded Methods. The following research priorities are among the areas that the Excluded Methods work continues to elevate:

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** - Develop then implement methods of assessing the genetic integrity of crops at risk 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 accept the discussion document on the 2022 NOSB Research Priorities
Motion by: Wood Turner
Seconded by: Kim Huseman
Yes: 5 No: 0 Abstain: 0 Absent: 1 Recuse: 0

Approved by Wood Turner, Materials Subcommittee Chair, to transmit to NOSB, February 11, 2022

National Organic Standards Board
Crops Subcommittee Proposal
Highly Soluble Nitrogen Fertilizers
January 18, 2022

Note: References are made to the 2020 Technical Report (TR) throughout this document. It is intended that the citation of the TR inherently includes the citations of the references contained within the TR. When the TR is quoted, the citations noted in the text of the TR have been removed for clarity – for a complete list of references, please refer to the TR.

References to ammonia or ammonium are specifically intended to include both unless stated explicitly that it is only one or the other.

Use

Highly soluble nitrogen sources such as sodium nitrate, guano, and the recently reviewed ammonia extracts are used as nitrogen sources to produce a wide range of annual and perennial crops. Of these materials, sodium nitrate and guano have historically been used for organic agriculture. Sodium nitrate is on the prohibited section of the National List but is annotated to allow use to no more than 20% of crop needs. Other organic materials such as protein hydrolysates, feather meals, blood meals, and liquid fish fertilizers also provide rapid nitrogen availability to crops. A primary difference in these materials is that they are mostly protein or amino acid-based compared to materials containing primarily ammonia or nitrates. Thus, these biologically derived products require soil conversion from amino acids or proteins to ammonia and nitrates before they are plant available.

More recently, non-synthetic processes to produce highly soluble fertilizers have been developed. The recent NOSB vote to prohibit ammonia extracts is an example of when a new material, meeting the organic definition of naturally derived, enters the organic marketplace without a review process as to whether the material complies with OFPA criteria. Future processes will likely be developed for new, highly soluble nitrogen fertilizers. Therefore, it is critical that restrictions on the use of these materials occur before they can be reviewed and become widely used. If, after review, the NOSB determines that the use of a particular material falls within organic production standards, that material could be exempted from any restriction on the National List and allowed for use.

Nitrogen is often a major limitation to crop yields and is biologically vital as a macronutrient. It contributes to plant growth by forming amino acids, serves as the building block for proteins, and improves photosynthetic efficiency (2020 TR). However, as was determined with ammonia extracts, the use of highly soluble nitrogen fertilizers may not be compatible with organic production. In the past, the NOSB and those responsible for developing the USDA organic guidelines have restricted or prohibited materials of high solubility. These materials include calcium chloride, potassium chloride, sodium nitrate, and, more recently, ammonia extracts. In the preamble to the publication of the NOP Final Rule on December 21, 2000, NOP discusses how it decided to agree with the NOSB recommendation and to put specific regulation of substances of high solubility into the annotations for each of these materials where they appear on the National List of Allowed and Prohibited Substances. NOP goes on to say, "Based on the recommendation of the NOSB, the final rule would prohibit the use of these materials [substances of high solubility], unless the NOSB developed recommendations on conditions for their use and the Secretary added them to the National List." At the time, the discussion was about mined substances of high solubility because there were not concentrated, highly soluble plant nutrient materials other than mined sources available at that time. However, the same rationale would apply to newly developed nitrogen fertilizers of high solubility.

Manufacture

While the Haber-Bosch process is the primary method for making nitrogen fertilizers, it is not relevant to organic processing and use. More recently, several methods have been developed to produce ammonia products non-synthetically (2020 TR). Given recent developments in novel technologies, it seems likely that other non-synthetic nitrogen fertilizers could be developed similarly to ammonia extracts. Other historically used organic materials such as sodium nitrate and guano are mined from naturally occurring deposits. Protein and amino acid-based materials such as hydrolysates, fish emulsions, feather meal, and blood meal are produced from by-products of other manufacturing processes. They are allowed for use in organic production.

International

While highly soluble nitrogen products are not addressed as a group, sodium nitrate is not allowed in Canadian production, and crops grown with sodium nitrate may not be exported to Canada. While it is unknown, comments received at the Spring and Fall 2021 NOSB meetings voiced concerns that the use of ammonia extracts or other new highly soluble nitrogen materials in the United States might also be rejected by other countries for exported products.

Summary of Review

The reviews of non-protein/amino acid highly soluble nitrogen materials have resulted in a wide variety of public comments and perspectives. These comments were often focused on reviews of sodium nitrate and ammonia extracts. These perspectives ranged from issues with soil health and environmental concerns and the use of multiple sources of highly soluble nitrogen fertilizers (HSN fertilizers). Comments were submitted that argued for both pros and cons on each issue.

In general, the comments from long-time organic organizations and growers tended to favor limiting HSN fertilizers based on the organic principles of enhancing soil biological processes rather than applying a nutrient that is immediately available to the plant. They also noted the low carbon to nitrogen ratios and the high solubility of these materials could cause environmental issues.

Proponents cite the need for immediately available nitrogen sources as a bridge for when unusual events cause nitrogen deficits to crops, and soil processes have not had a chance to recharge the available nitrogen. They also note that using these materials can help prevent nitrogen loss since they could allow better targeting of nitrogen applications to specific crop needs.

As noted previously, several materials are already in the organic marketplace. These materials have been approved by OMRI and other material review organizations, although with the caveat that non-synthetic, liquid fertilizers that have a nitrogen analysis greater than 3 percent must comply with additional recordkeeping and inspection requirements following NOP Guidance on the Approval of Liquid Fertilizers for Use in Organic Production (NOP 5012). Non-synthetic fertilizers that test above 3 percent ammoniacal nitrogen are considered at higher risk for violating the soil fertility and crop nutrient management practice standards at 205.203. OMRI attaches a note that "this product contains highly soluble nitrogen and must be applied in a manner that does not contribute to the contamination of crops, soil or water. Its use must be part of an organic system plan that maintains or improves the natural resources of the operation, including soil and water quality, and comply with crop nutrient and soil fertility requirements." The NOSB determined at the Fall 2021 meeting that ammonia extracts did not meet the criteria for use in an organic system plan and subsequently voted to prohibit ammonia extracts in organic production.

Furthermore, the Board and other stakeholders expressed concerns that new, non-synthetic HSN fertilizers that fall outside the definitions of ammonia extracts could be developed in the future. Those materials would have no limit to their use unless a petition to restrict or prohibit them was submitted to the NOSB and the NOSB voted to restrict their use.. The use of new non-synthetic fertilizers might have similar issues to ammonia extracts with regard to compatibility with organic systems. Thus, the NOSB proposes that limitations be put on any HSN fertilizer until the NOSB can review it, and if so desired, a developer of a new HSN fertilizer could petition the NOSB to remove the restriction. Manufacturers would also know of potential limitations before investing in novel production methods for these fertilizers.

Soil Health

The Organic Foods Production Act (OFPA) through regulations at § 205.203(a) requires that a producer must select and implement tillage and cultivation practices that maintain or improve the physical, chemical, and biological condition of the soil and minimize soil erosion. At §§ 205.203(c) and (d), OFPA states that the producer must manage plant and animal materials or crop nutrients and soil fertility to maintain or improve soil organic matter content.

At the Fall 2020, and Spring and Fall 2021 NOSB meetings, many commenters noted that the use of HSN fertilizers runs counter to the organic principles outlined in the regulations by directly applying plant nutrients rather than applying nutrients that improve the biological condition of the soil. Inherently, the annotation added to high nitrogen (N) ammonia/ammonium-containing-products notes that "this product contains highly soluble nitrogen and must be applied in a manner that does not contribute to the contamination of crops, soil or water. Its use must be part of an organic system plan that maintains or improves the natural resources of the operation, including soil and water quality, and comply with crop nutrient and soil fertility requirements." This annotation would not be added unless there was a risk that the materials do not contribute to the stated OFPA criteria. For example, several commenters testifying in favor of ammonia extracts at the 2020 and 2021 NOSB meetings reinforced this by stating that these ammonia extracts should not be used alone – they must be used with other soil building practices to comply with OFPA.

An example of a comment that refers to basic tenets of organic agriculture and prior OFPA and NOSB actions was submitted at the Spring 2020 meeting:

> In contrast to the reductionism of "conventional" chemical-intensive agriculture, the origins of organic agriculture are in holistic and ecological thinking. Historically, perhaps the most important principle of organic production is the "Law of Return," which, together with the foundational philosophy "Feed the soil, not the plant," and the promotion of biodiversity, provide the ecological basis for organic production. Together these three principles describe a production system that mimics natural systems—the Law of Return. In an organic system, residues are returned to the soil by tillage, composting, or mulching. While most organic growers depend on some off-site inputs, most of the fertility in a soil-based system comes from practices that recycle organic matter produced on-site. The cycling of organic matter and on-site production of nutrients—as from nitrogen-fixing bacteria and microorganisms that make nutrients in native mineral soil fractions available to plants—is essential to organic production. The Law of Return is not about feeding plants but about conserving the biodiversity of the soil-plant-animal ecological community. The Law of Return says that we must return to the soil

what we take from the soil. Non-crop organic matter is returned directly or through composting plant materials or manures. To the extent that the cash crop removes nutrients, they must be replaced by cover crops, crop rotation, animal manures, or additions of off-site materials when necessary. Feed the soil, not the plant.

The dictum to "Feed the soil, not the plant" reminds us that the soil is a living superorganism that supports plant life as part of an ecological community. We do not feed soil organisms in isolation to process nutrients for crop plants; we feed the soil to support a healthy soil ecology, which is the basis of terrestrial life.

Biodiversity. Finally, biological diversity is important to the health of natural ecosystems and agro-ecosystems. Biodiversity promotes balance, which protects farms from damaging insects and disease outbreaks. It supports the health of the soil through the progression of the seasons and stresses associated with weather and farming. It supports our health by offering a diversity of foods. Ultimately, holistically healthy, genuinely organic farms produce healthy plants that require far fewer applications of insecticides and fungicides (even if approved for organic production).

The principle of feeding the soil rather than the crop. OFPA §6513(b) requires that organic operations establish a plan designed to "foster soil fertility, primarily through the management of the organic content of the soil through proper tillage, crop rotation, and manuring." **Substances of high solubility, i.e., those materials that provide nutrients directly to the plant because they are quickly taken up into the plant from the soil solution, are counter to foundational organic principles, so they have always been restricted.** Such materials are listed in §205.602—non-synthetic substances prohibited for use in Organic Crop Production or the "prohibited naturals" section of the National List:

1) Calcium chloride is limited to treating a physiological disorder;
2) Potassium chloride must be used in a manner that minimizes chloride accumulation in the soil and;
3) Sodium nitrate is restricted to no more than 20% of the crop's total nitrogen requirement.

The organic regulations limit substances of high solubility. In the preamble to the publication of the NOP Final Rule on December 21, 2000, NOP discusses how it decided to agree with the NOSB recommendation and to put specific regulation of substances of high solubility into the annotations for each of these materials where they appear on the National List of Allowed and Prohibited Substances. NOP goes on to say, "Based on the recommendation of the NOSB, the final rule would prohibit the use of these materials [substances of high solubility], unless the NOSB developed recommendations on conditions for their use and the Secretary added them to the National List." At the time, the discussion was about mined substances of high solubility because there were no concentrated, highly soluble plant nutrient materials other than mined sources available at that time. New materials of high solubility should be prohibited or restricted.

The current motion to restrict the use of highly soluble nitrogen fertilizers follows this recommendation to prohibit or limit the uses of highly soluble materials unless the NOSB develops recommendations and conditions for their use. The motion would prevent the widespread use of new, non-synthetic fertilizers while also allowing for the potential of restricted use of these materials in critical situations. Some of those situations were outlined in the ammonia extract proposal. These include times when abnormal weather events cause temporary nitrogen deficiencies or limited situations where the release rate of appropriately applied organic inputs does not meet crop needs.

Studies show that long-term organic fertilizer inputs enrich carbon-related soil functions. Manure additions can strongly influence the formation, storage, and cycling of soil organic carbon and nitrogen and soil microecology (Sharif, Thompson, et al., 2021; Ozlu, Sandhu, et al., 2019). Living organisms' total amounts (weights) vary in different cropping systems. In general, soil organisms are more abundant and diverse in systems with complex rotations that return more diverse crop residues and use other organic materials such as cover crops, animal manures, and composts. When crops are rotated regularly, fewer parasites, diseases, weeds, and insect problems occur than when the same crop is grown year after year (Magdoff and Van Es, 2021). These biotic links can also positively influence the ability of plants to resist insect pests. Plants grown in a balanced nutrient system are less likely to be attacked by pests than plants with readily available nitrogen added (Phelan, Mason, et al., 1995).

The NOSB received comments that HSN fertilizers may increase the mineralization rate in soils and thus be beneficial. This could be true in a short time frame, but this accelerated mineralization rate could come at the cost of long-term soil carbon resources. Wang, Juliang, et al., 2018, found that long-term application of N-fertilizers causes an abundance of bacterial groups responsible for the denitrification process, which causes the turnover of nitrogen to increase and results in more significant nitrogen loss over time. Essentially, adding more nitrogen fertilizer results in long-term nitrogen loss while altering other soil components, like decreasing soil pH and C: N ratio. When soil carbon and nitrogen are reduced in response to the application of chemical fertilizers, the beneficial enzymatic activity of the soil also decreases (Ozlu, Sandhu, et al., 2019). Another study concluded:

> Annual nitrate leaching was 4.4–5.6 times higher in conventional plots than in organic plots, with the integrated plots in between. This study demonstrates that organic and integrated fertilization practices support more active and efficient denitrifier communities, shift the balance of N2 emissions and nitrate losses, and reduce environmentally damaging nitrate losses. Although this study specifically examines a perennial orchard system, the ecological and biogeochemical processes we evaluated are present in all agro-ecosystems. The reductions in nitrate loss in this study could also be achievable in other studies cropping systems (Kramer, Reganold, et al., 2006).

Organic systems include cover cropping and interplanting and varied crops and the addition of manures and composts. This mix of fertility sources is used to mitigate issues of nutrient excesses.

> Incorporating **crop residues and compost** [emphasis added] provides a potential long-term alternative to ammonia extract and other nitrogen fertilizers. Nitrogen content in compost is slowly released through mineralization processes in the soil, primarily facilitated by its metabolism by microorganisms in the soil. Unlike ammonia extract, the use of compost also contributes to soil organic matter and available carbon, phosphorous, and micronutrients, as well as soil microorganism populations and activities. The incorporation of compost into the agro-ecosystem has been reported to improve soil characteristics, specifically water holding capacity and cation exchange capacity (CEC). Increased soil CEC allows it to more effectively retain cations, including ammonium ions and metal cations required as micronutrients (e.g., iron [Fe], copper [Cu], zinc [Zn]) (2020 TR)

Public comments and scientific research publications demonstrate that much more research regarding the use of these materials and the soil health, plant health, and biological interactions need to be conducted. There is conflicting information from conventional soils and very little research conducted on organic soils. For example, a study on tomatoes in California (Bowles, Hollander, et al., 2015) found that the complex plant and microbial processes that affect nitrogen cycling are affected by the ecology of each farm and between fields within a farm. Most research-oriented toward nitrogen cycling occurs at research stations with fixed factors and limited soil variations; there has been little research about how nitrogen cycling happens on working organic farms. The study detailed how organic tomato farms can achieve high yields even though tests showed relatively low nitrogen availability. They attributed this to the possibility that the nitrogen cycling was tightly coupled with tomato plant needs. While tests showed low nitrogen with respect to conventional standards, the sustained release curve of the nitrogen in those plots met plant needs. They concluded that new indicators of N availability are needed that consider active C and N processes in organic systems. This is another indicator that our lack of understanding of nutrient processes and needs in organic systems makes conclusions about the need for fast-acting nitrogen applications problematic.

These factors make reaching a conclusion difficult. In the absence of consistent research showing overwhelming benefits from the high applications of HSN fertilizers, and with the requirement to fulfill OFPA criteria, the use of these compounds raises questions regarding soil health and the maintenance or improvement of soil organic matter. There are effective organic systems that pay close attention to nitrogen needs using multiple approaches to fertility that include the basics of crop rotations and applications of manures and composts. By paying attention, these systems do not result in large build-ups of phosphorous or excessive loss of nitrogen to the environment. There are arguments for the limited use of allowed HSN fertilizers in emergency situations or when soil availability of nitrogen is limited. However, there are strong arguments that the use of these materials should be limited. The ecosystem managed to maintain or increase soil organic matter does not include reliance on a highly soluble fertilizer.

While organic regulations require an organic soil fertility plan to maintain or improve soil organic matter (205.203), the interpretation of this requirement can be complicated for certifiers to enforce. Does growing the same crop for several years, followed by a different crop, and then back to the first crop conform to this requirement? What level of highly soluble, low carbon to nitrogen ratio materials can be used before they are too much and do not comply with OFPA. Given the wide range of organic soil fertility options available, it can be challenging to have a notice of non-compliance from a certifier be enforceable. A prohibition with an annotation allowing restricted use of HSN fertilizers would give certifiers an additional tool to interpret growing practices that comply or do not comply with OFPA.

The restriction of the use of sodium nitrate to 20% of crop needs from the beginning of the National Organic Program limits the potential for overuse of that form of highly soluble nitrogen fertilizers. The prior vote of the NOSB to completely prohibit ammonia extracts illustrates the concern the organic community has for using these highly soluble nitrogen fertilizers. One comment received at the Spring 2020 meeting demonstrates the slippery slope of using these types of fertilizers, including ammonia extracts:

> Fertilizing through drip irrigation systems allows for precise placement and timing of the fertilizer for optimum crop production. Drip irrigation has become a major method of irrigating crops, especially in California. The growth in drip irrigation is driven by drought, over-draft of aquifers, and the need for more precise fertilization… The type of crops irrigated with drip irrigation include all kinds of vegetables, tree fruit, strawberries, cane berries, and tomatoes. Many of these crops, such as tree fruit and berries, are only irrigated using drip irrigation systems. These crops often have very long cropping cycles making it impossible to apply

> nutrients by a method other than through the drip irrigation system. Any fertilizing material added to drip irrigation water must have little to no solids, with most of the nutrients in a soluble form. Two major liquid nitrogen products are made with liquid fish (fish solubles, fish protein, fish emulsion, hydrolyzed fish) and corn steep liquor. These ingredients contain high levels of insoluble material, which cause costly plugging of drip irrigation lines.

This illustrates a system that utilizes a large amount of highly soluble fertilizer for the fertility program. At what point does the use of highly soluble nitrogen fertilizers cross the line to being the primary source of nitrogen, with other soil organic building practices being a minor part of the fertility program?

Sodium nitrate is approved for organic use with a limitation of use to 20% of crop nitrogen needs. Sodium nitrate is a non-synthetic alternative to bioavailable nitrogen for plants. Unlike other naturally derived substances that must undergo mineralization to be plant available, sodium nitrate acts more like conventional fertilizers. The 2020 TR cites several sources that demonstrate the benefits of materials that need to undergo mineralization as opposed to those that are immediately available and states:

> Many substances derived from natural products are allowed as organic fertilizers, including fish meal, liquid fish residues, feather meal, bird or bat guano, alfalfa meal, soybean meal, bone meal, kelp, seaweed, blood meal, and meat meal. Like crop residues and compost, organic fertilizers require additional mineralization processes and provide a slow release of nitrogen, which is primarily present in complex molecules. Like crop residues and compost, organic fertilizers also contribute to increased soil organic matter, CEC capacity, and other nutrients and micronutrients. Unlike nitrogen fertilizers used in conventional agriculture, organic fertilizers have been reported to have minimal negative to long-term positive effects.

There is the potential to use multiple sources of low C: N ratio high bioavailability fertilizers to replace basic soil fertility methods such as crop rotation, intercropping, and appropriate manure and compost use. Traditional organic materials, with the exceptions of sodium nitrate and guano, have a C: N ratio above 3:1:

Material	C: N ratio range
Sodium nitrate	0.02: 1
Sea bird guano	1.2 - 3.3: 1
Blood meal	3.1 - 3.8: 1
Fish powder	3.4 - 4.0: 1
Feather meal	3.5 - 3.8:1
Bone meal	3.6: 1
Liquid food-based fertilizer	4.6-5.2: 1
Liquid fish emulsion	5.2: 1
Cottonseed	5.5: 1
Poultry litters	8-12: 1
Composts	10.7 - 99.3:1
Soil	10-12
Clover and alfalfa (early)	13
Alfalfa meal	15.9: 1
Dairy manure (low bedding)	17
Alfalfa hay	20
Green rye	36
Corn stover	60

Wheat, oat, or rye straw	80
Oak leaves	90
Fresh sawdust	400
Newspaper	600

Sources: Cassity-Duffey, Cabrera, et al., 2020; Hartz and Johnstone, 2006; Lazicki, Geisseler, et al., 2020; Magdoff and Van Es, 2021.

Ammonia extracts have C: N ratios below 3:1 as compared to other liquid products:

Type of product	**Ammonia-N (%)**	**Total N (%)**	**Ammonia-N/Total N (%)**	**C: N**
manure tea	0.003 - 0.42	0.09 - 0.71	3.3 - 59.2	17:1
restricted ammonia product	4.2 – 7.47	5.78 – 8.23	51.0 – 99.6	2:1
liquid fish fertilizer	0.4 - 0.95	3.96 – 5.25	7.6 – 20.7	3.35
anaerobic digestate	0.048 - 0.68	0.28 – 2.21	2.2 – 43.2	1.25 - 5.48

Source: OMRI

Any amendment applied over 40:1 can cause temporary plant nitrogen deficits since nitrogen must be taken from surrounding soil to break down these materials. Conversely, amendments with lower C: N ratios can contribute available nitrogen to the system (Magdoff and Van Es, 2021).

As written by one public commenter (Spring, 2021):

> The prohibition of synthetic nitrogen fertilizers manufactured through the Haber-Bosch process is a longstanding and fundamental prohibition in organic agriculture. The proliferation of these fossil-fuel-based synthetic fertilizers in conventional agriculture was a primary motivator of the modern organic agricultural movement. The principles of organic (as described in the 2001 NOSB Recommendation) seek to achieve agricultural and environmental goals through the "use of cultural, biological, and mechanical methods, as opposed to using synthetic materials to fulfill specific functions within the system." Therefore, substances that mimic synthetic nitrogen fertilizers' chemistry and functionality can be considered equally incompatible with traditional organic principles.

Another commenter stated:

> Highly soluble sources of nitrogen cannot be addressed in a vacuum, and we cannot look at one material at a time. We must take a broader approach to limiting highly soluble sources of nitrogen as a whole. To evaluate and list each individually, even with a restriction, is a slippery slope and raises the concern of "stacking." [Question #4 of the Spring 2020 Discussion document] asks: "Should the use of natural ammonia extract be limited to a certain percent of nitrogen use in crops (similar to the Chilean nitrate restriction)?" With this approach, producers could potentially "stack" highly soluble sources of nitrogen, using 20% of the crop's needs from Chilean nitrate, 20% of the crop's needs from another source, and 20% of the crop's needs from yet another source.

Products that are immediately plant bioavailable mimic conventional nitrogen sources. Products that require additional mineralization, such as protein sources, require soil biotic transformation to be bioavailable to plants. While not perfect, organic products with greater than a 3:1 C: N ratio fit into the category of materials that require soil biotic transformation. Non-synthetic products below a 3:1 ratio tend to be those that are immediately plant available.

Public comments received during the Fall 2021 NOSB meeting raised several concerns regarding the motion to restrict nitrogen fertilizers with a C: N ratio of 3:1 or less, including those individual components of a blended fertilizer formulation, to a cumulative total use of 20% of crop needs.
As always, stakeholder insights are a welcome part of NOSB decision-making. A number of certifiers submitted comments at the Fall 2021 meeting supporting the motion as written. However, others had concerns and asked for further vetting of the motion. The following address specific comments raised by stakeholders.

Clarifying which nitrogen materials might be covered – the proposal initially read "Nitrogen products." Since this could cover any material with nitrogen incorporated in it, the phrasing has been changed to read "Nitrogen fertilizers." This specifies materials used to fertilize crops rather than any nitrogen compound and follows the definition of fertilizers listed in the organic regulations.

Clarification as to how fertilizer blends are evaluated – Some commenters suggested that the final product's overall C: N ratio is used rather than looking at individual components of a blend. While this would simplify the evaluation, it would sidestep the intention of the motion. For example, a high carbon source could be mixed with an HSN composed entirely of nitrate to bring the blend above the required 3:1 ratio. However, that blend would still be mainly composed of a nitrogen fertilizer that is immediately plant available. Carbon would be added to the soil, but the nitrogen component would bypass important nitrogen cycling soil processes described previously. While some fertilizers include some nitrate or ammonia (such as liquid fish), the preponderance of nitrogen is not ammonia or nitrate (see chart previously cited). Likewise, to support soil biological processes, a blended fertilizer should contain components that include soil biological processes for nitrogen release.

To determine the amount of nitrogen in a blend that would be included in the restriction, the percentage of the nitrogen in a multi-component product (blend) that is below the 3:1 ratio can be calculated.

In order to know what percent of the nitrogen in a blend counts toward the 3:1 restriction, a manufacturer could either provide the percent of the nitrogen in the blend that is restricted on the label (without disclosing what that material is) or a Material Review Organization could list that on the product certificate. As a last resort, if neither of those listings is available, the grower could call the manufacturer for that information. This would be similar to the soluble and insoluble nitrogen sub-analysis that is already present on fertilizer labels, i.e., 3% N from ingredients below 3:1 C: N. If a grower uses multiple fertility sources, they will total all the N application from restricted materials and make sure the total is less than 20% of the crop needs.

If manufacturers won't disclose the information, one certifier notes:

> When people say manufacturers won't disclose, with pesticide materials it is the same way. If you won't tell us, we won't approve it. Besides, saying 20% of a blend is below 3:1 doesn't say anything about what the actual materials are that make up that 20%. Things can still be confidential. I think many of these materials will go through an MRO anyhow and they can just list the C: N ratio on their listing, or at least whether it is above or below 3:1. And, it may push

people to use less of these highly soluble materials since it will be very transparent as to what they use.

The process to identify the total nitrogen in a blend that is restricted is as follows:

1. What is the source of the material?
2. Does the HSN Fertilizer contain multiple components (blend)?
    a. NOTE: Make sure to determine the source of all the material(s) within a product
3. What is the C:N ratio of the components(s)?
4. Does any of the components(s) of the fertilizer fall below the 3:1 C: N ratio
    a. If no, then the fertilizer (and its respective components) has no restrictions
    b. If yes, then component(s) of the fertilizer needs to be analyzed, and a nitrogen calculation needs to be conducted to quantify pounds of N from a restricted source.
5. Obtain the %nitrogen of the product and the %nitrogen that is restricted from the material(s) that fertilizer product is composed of from the manufacturer, MRO, product certificate, or product label
6. Based on the overall Nitrogen composition – determine how many pounds of N would be restricted from the known concentration of HSN that is restricted due to falling below the 3:1 ratio in relation to the entire product
7. Identify what 20% of crop needs are and ensure that restricted material(s) fall below that level.

An example:

- If a product containing multiple components (a blend) contains a material that would be restricted (below a 3:1 ratio) and that material provides 50% of the nitrogen in the overall product, then 50% of the amount of nitrogen in the fertilizer would fall under the HSN fertilizer restriction.

- If the blended product was an 8-0-0 and a producer applied 100 lbs., then 8 lbs. of actual N would be applied to the crop.

- Since 50% of the nitrogen in the blended product falls under the restriction, therefore in this example, 4 lbs. of the actual N being applied would count towards the overall limit of 20% of crop needs.

- If the total crop need is 80 lbs. of nitrogen, then up to 16 lbs. of that N could come from a restricted material(s) (20%*80lbs = 16lbs).

- If the blend is the only fertilizer applied, then up to 400 lbs. of the blend could be used.

Additional Examples:

Example Fertilizer	Source	Blend?	C:N ratio	Contains restricted material?	Total %N of product (provided by manufacturer)	%N from restricted N material (provided by manufacturer or MRO)	%N in total product restricted (total N x % of total N restricted)	Amount restricted N per 100 lb of product applied	Crop N need lb/ac	20% of crop N need lbs/ac	Total lbs of actual product use allowed (assuming only this product applied)
A	sodium nitrate	No	0.2:1	Yes	16	100	16	16	100	20	125
									150	30	188
									200	40	250
B	fish emulsion	No	5:1	No	4.5	0	0	0	no restriction on use	-	-
C	poultry litter	No	10:1	No	5	0	0	0	no restriction on use	-	-
D	poultry litter	Yes	10:1	Yes	10	50	5	5	100	20	400
	sodium nitrate		0.2:1						150	30	600
									200	40	800
E	poultry litter	Yes	10:1	Yes	13	30	3.9	3.9	100	20	513
	feather meal		3.6:1						150	30	769
	sodium nitrate		0.2:1						200	40	1026

Determination of total crop nitrogen needs – this approach is consistent with the sodium nitrate listing. The limitation of use to 20% of total crop needs parallels the sodium nitrate wording. It prevents conflicting interpretations of how this listing and the sodium nitrate listing would apply to each other. Certifiers also evaluated the 20% of total crop needs for sodium nitrate for twelve years before that listing became technically incorrect. While several certifiers have stated that they had difficulty with those calculations, they were still enforced. Guidelines could be developed with crop needs that all certifiers could use. If a producer argued that the figure was too low, they could present soil analyses, production data, or other means to support their higher crop needs.

Crop nitrogen needs are widely available from university extension publications on a state and regional basis. For example, the University of Georgia College of Agricultural Sciences has a publication available on the internet showing N crop needs: http://aesl.ces.uga.edu/publications/soil/cropsheets.pdf It shows canola as needing 135-175 lbs. of nitrogen per year. Thus, up to 27- 35 lbs. (actual N) of fertilizer below a 3:1 C: N ratio could be applied per year.

Recommendations:

Recommended pH:	6.0. If the pH is less than 6.0, see Lime Table C.
Nitrogen:	135-175 pounds nitrogen (N) per acre. Rate will depend upon cropping system.
Magnesium:	If soil test Mg level is low and lime is recommended, use dolomitic limestone; if soil test Mg is low and lime is not recommended, apply 25 pounds of Mg/Acre. Coastal Plain: Low: 0 - 60 lbs/acre; Medium: 61 - 120 lbs/acre; High: >120 lbs/acre Piedmont: Low: 0 - 120 lbs/acre; Medium: 121 - 240 lbs/acre; High: >240 lbs/acre
Other:	See sulfur (S) and boron (B) recommendations below.

Fact Sheet:

*For canola following a non-legume crop, apply 160 to 175 pounds nitrogen (N) per acre. Following a legume crop, apply 135 to 150 pounds nitrogen per acre. Apply 40 to 50 pounds of the recommended nitrogen per acre in the fall and the remainder in early February prior to crop bolt (rapid stem elongation).

The Supplemental Technical Report on sodium nitrate (2011) includes an example chart with nitrogen requirements for select organic crops in the Midwestern United States:

Table 1: Per Acre Applications of Nitrogen Required for Select Crops Grown on Organic Farms in the Midwestern United States

Crop	**Amount of N Required lbs./acre)**	**Maximum NOP Allowed 20% of Requirement (lbs./acre)**	**Projected Amount of Chilean Nitrate 16-0-0**1 **(lbs./acre)**
Winter wheat	80-100	16-20	100-130
Spring wheat	80-100	16-20	100-130
Oats, barley, spelt	60-80	12-16	75-100
Corn	120-150	24-30	150-180
Sweet corn	80-100	16-20	100-130
Pasture-grass	100-120	20-24	120-150
Soybean	8-15	1.5-3	10-20
Alfalfa-low OM soil	8-10	1.5-2	10-12
Cotton	50-75	10-15	60-100
Peanuts	80-120	16-20	100-130
Potatoes	180-200	36-40	225-250
Cole Crops	150-175	24-35	150-200
Green Beans	60-80	12-16	75-100
Cucurbit	100-150	20-30	120-180
Onions, Leeks, Garlic	100-150	20-30	120-180
Tomatoes	100-150	20-30	120-180
Carrots	100-150	16-20	120-180

Finally, a common source of crop nitrogen needs is those listed in soil analyses. Recommendations from labs doing those soil tests are a readily available reference source of accepted crop needs.

Traditional organic fertilizers that might be affected by the 3:1 ratio – Stakeholders raised concerns that several organic fertilizers traditionally used by producers might fall just below the 3:1 ratio. As noted in the table previously listed, feather, bone, and blood meals are above the 3:1 ratio but are very close. Certifiers or material review organizations could develop a list of unrestricted, allowed materials, such as these, that could be referenced so that they would not need to be continually reanalyzed. Several commenters suggested developing a closed list of materials that would fall below the 3:1 ratio and specifically state they could not be used. However, one concern is that new, not identified materials will be introduced. The purpose of this motion is to limit the use of new, novel nitrogen sources. Specifically stating what materials would be limited by this proposal would not limit new, currently unidentified products. If, for example, manufacturers develop products that are not covered under the specifics of the ammonia extract prohibition, this motion would limit the use of those products falling outside those definitions. A manufacturer could submit a petition for unrestricted use if they wanted their product to be exempt from this restriction. While creating a closed list of products below a 3:1 ratio would defeat the purpose of this motion, making a list of what known materials (feather meal, bone meals) are recognized as being **above** the 3:1 ratio might be useful.

Clarification of why the C: N ratio is used rather than total fertilizer N or percentage of ammonia/nitrate to total N – existing fertilizers commonly used in organic production have widely varying amounts of ammonia/nitrate to total N ratios. Given this range, it is difficult to determine where a material would be acceptable in terms of ammonia/nitrate to total N ratio. The motion could read that, materials with greater than 50% of ammonia/nitrate compared to total N would be restricted. But then there would be an incentive to make a material that included only 49% of these HSN fertilizers. In addition, fertilizers that contain proteins require soil mineralization to become plant available. These materials inherently contain carbon to form proteins. Using a C: N ratio addresses the need to have carbon-based materials applied to soil to promote the soil biology and transformation processes rather than only applying plant-available nitrogen fertilizers composed of nitrate or ammonia.

Clarification on listing – Several commenters raised the question of whether § 205.203(f) is the correct place to put this motion. Ultimately, where this motion would be listed would be determined by the NOP. This motion intends that this limitation of HSN fertilizers apply to all crop producers, regardless of production system. This is similar to how synthetic materials added to the National List are allowed for all crop producers. Thus, the motion could be placed at § 205.602, similar to the prohibition on sodium nitrate or the suggested listing of ammonia extracts. Materials with a C: N ratio below 3:1 would be prohibited, but with an annotation allowing up to 20% of crop needs, similar to sodium nitrate. The listing could also be placed in the practice standards at § 205.105 or § 205.203(e) – "the producer must not use." This would be like the practice standard of prohibiting the use of sewage sludge or materials that contain synthetic substances not included on the National List. The final placing of the listing by the NOP should ensure that it applies equally to all producers of food crops like the materials placed at § 205.602 or § 205.105. Other motions approved by the NOSB and passed through rulemaking have had similar intent in uniform applicability.

Category 1: Classification

1. For CROP use: Is the substance **X Non-synthetic** or **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.

Highly soluble nitrogen fertilizers can be manufactured using non-synthetic processes, as demonstrated by the development of ammonia extracts. The development of ammonia extract could not be anticipated at the time of the National Organic Program's adoption. Similarly, it is likely that there will be the development of additional, non-synthetic HSN fertilizers through novel manufacturing processes.

1. 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?

Highly soluble nitrogen fertilizers do not include any of the above materials.

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)]

To the extent that the application of highly soluble nitrogen fertilizers can affect soil pH and/or other microbial processes, other nutrients may or may not be released based on the soil pH effects.

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

Highly soluble nitrogen materials may have short lifetimes in the environment, typically ranging from hours to days based on environmental conditions. The short environmental lifetimes are due to the bioavailability of nitrogen in these compounds, which are readily incorporated into amino acids and other biologically important molecules.

Furthermore, the TR states that the high-water solubility of ammonia, ammonium, and nitrate ions makes them conducive to leaching into water ecosystems. While aquatic microorganisms can metabolize these compounds, if they are overabundant, eutrophication can occur, and ammonia and ammonium can be toxic to aquatic life. Algal blooms can be caused by the influx of high concentrations of nitrogen nutrients. Algal blooms can reduce oxygen concentrations and result in hypoxic and anoxic environments.

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

The production of highly soluble nitrogen materials could result in the release of nitrogen into the environment. This is expected due to the inability of processes to capture 100% of the nitrogen content of feedstocks. The efficiency of capture depends on the processes used (2020 TR).

The release of these compounds into the atmosphere can contribute to the degradation of air quality and visibility due to the formation of aerosols. Additionally, the primary issue of environmental contamination is the over-application of nitrogen products and their subsequent leaching into non-agricultural environments. Dramatic losses of 20-80% have been noted. (2020 TR).

Finally, the disposal/use of the feedstock material that may be used to produce these compounds will depend on the processes. Depending on the use of that feedstock, there are potential environmental issues with that remaining material. Comments have focused on issues with phosphorous increases and issues when using manures/composts. This same problem could be an issue when a feedstock is disposed of after removing nitrogen.

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

The 2020 TR refers to several human health effects from highly soluble nitrogen materials such as ammonia. Ammonium is a positive ion, and its impact on human health depends on the remaining negative portions of the ionic compound. Ammonium ions play a critical role in the Krebs cycle.

Ammonia is classified as a respiratory irritant – long-term exposure to gaseous ammonia can result in bronchial or pulmonary inflammation. Repeated exposure can lead to pulmonary fibrosis. Direct inhalation or ingestion can cause esophageal burns.

5. Discuss any effects the substance may have on biological and chemical interactions in the agro ecosystem, 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 2020 TR states: Highly soluble nitrogen compounds can readily migrate from the applied soil system into the atmosphere and marine environments. When these materials remain in their applied soils, they can also induce changes to the local environment. For example, the acidity of ammonium ions is recognized as a cause of soil acidification, reducing the soil pH. These pH changes result in changes to the solubility and bioavailability of other nutrients, affecting crops and soil organisms. Changes in soil pH may also negatively impact the viability of soil organisms, including earthworms and various microbial populations. High soil concentrations of inorganic nitrogen sources have been shown to slow the natural nitrogen fixation processes of plants. This shift in natural nitrogen production reduces the natural efficiency of the soil, making it more reliant on continued nitrogen inputs.

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

The use of HSN fertilizers can alter nitrogen uptake rates and alter plant nutrient production. Studies by Phelan, Mason, et al., 1995, demonstrate that these altered plant nutrient production cycles can lead to increased susceptibility to pests.

Other studies show that long-term organic fertilizer inputs enrich carbon-related soil functions. Manure additions can strongly influence the formation, storage, and cycling of soil organic carbon and nitrogen and soil microecology (Sharaf, Thompson, et al., 2021; Ozlu, Sandhu, et al., 2019). Living organisms' total amounts (weights) vary in different cropping systems. In general, soil organisms are more abundant and diverse in systems with complex rotations that return more diverse crop residues and use other organic materials such as cover crops, animal manures, and composts. When crops are rotated regularly, fewer parasite, disease, weed, and insect problems occur than when the same crop is grown year after year. (Magdoff and Van Es, 2021)

Several public comments noted that the use of HSN fertilizers could increase the rate of mineralization in soils and thus be beneficial. In a short timeframe, this could be true, but this accelerated rate of mineralization could come at the cost of long-term soil carbon resources. Wang, Juliang, et al., 2018, found that long-term application of N-fertilizers causes an abundance of bacterial groups responsible for the denitrification process, which causes the turnover of nitrogen to increase and results in more significant nitrogen loss over time. Essentially, adding more nitrogen fertilizer results in long-term nitrogen loss while altering other soil components, like decreasing soil pH and C: N ratio. When soil carbon and nitrogen are reduced in response to the application of chemical fertilizers, the beneficial enzymatic activity of the soil also decreases (Ozlu, Sandhu, et al., 2019). Another study concluded:

> Annual nitrate leaching was 4.4–5.6 times higher in conventional plots than in organic plots, with the integrated plots in between. This study demonstrates that organic and integrated

fertilization practices support more active and efficient denitrifier communities, shift the balance of N2 emissions and nitrate losses, and reduce environmentally damaging nitrate losses. Although this study specifically examines a perennial orchard system, the ecological and biogeochemical processes we evaluated are present in all agro-ecosystems, and the reductions in nitrate loss in this study could also be achievable in other cropping systems (Kramer, Reganold, et al., 2006).

The TR states that incorporating crop residues and compost provides a potential long-term alternative to HSN fertilizers. Nitrogen content in compost is slowly released through mineralization processes in the soil, primarily facilitated by its metabolism by microorganisms in the soil. Unlike ammonia extract, the use of compost also contributes to soil organic matter and available carbon, phosphorous, and micronutrients, as well as soil microorganism populations and activities.

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)]

The following statements are taken from the 2020 TR.

There are many natural soil amendments that can deliver nitrogen for crops. Manure is a source of nitrogen compounds, including ammonia, ammonium ions, and urea, which are biological waste compounds. However, manure has a relatively low level of biologically available nitrogen compared to HSN fertilizers. The biologically available forms of nitrogen in manures may also lead to similar issues with nutrient leaching as ammonia extract, potentially polluting surrounding water systems and leading to atmospheric ammonia emissions. Manure from both organic and conventional livestock is permitted for use in the production of organic crops. However, the availability of manure may be limited regionally due to the continued segregation of crop and animal agricultural production.

In addition to manure, crop residues and compost may be added as a source of bioavailable nitrogen. This includes the direct integration and composting of manure and other organic agricultural wastes. These feedstocks' high protein and amino acid content allow for their conversion to ammonia and ammonium compounds through anaerobic digestion and metabolism by soil microorganisms. When composts do not include manures, they are generally low in nitrogen-containing compounds (2020 TR).

Incorporating crop residues and compost provides a potential long-term alternative to ammonia extract and other nitrogen fertilizers. Nitrogen content in compost is slowly released through mineralization processes in the soil, primarily facilitated by its metabolism by microorganisms in the soil. Unlike ammonia extract, the use of compost also contributes to soil organic matter and available carbon, phosphorous, and micronutrients, as well as soil microorganism populations and activities. The incorporation of compost into the agro-ecosystem has been reported to improve soil characteristics, specifically water holding capacity and cation exchange capacity (CEC). Increased soil CEC allows it to retain cations more effectively, including ammonium ions and metal cations required as micronutrients (e.g., iron [Fe], copper [Cu], zinc [Zn]) (2020 TR).

Many other substances derived from natural products are allowed as organic fertilizers. These include fish meal, liquid fish residues, feather meal, bird or bat guano, alfalfa meal, bone meal, kelp, seaweed, and meat meal. These materials may be more readily available to crops due to their lower C: N ratio, but all require mineralization to be plant bioavailable. The mineralization is required due to the nitrogen available in these materials being present as more complex molecules and proteins. These materials provide a slower N release than ammonia extracts. They also contribute to increased soil organic matter, CEC capacity, and other nutrients and micronutrients. Unlike conventional fertilizers, organic fertilizers have been reported to have minimal negative to long-term positive effects on soil health (2020 TR).

Crop rotation and intercropping are traditional methods to ensure soil health. They can be especially effective if legumes are included in the rotations. Legumes can fix nitrogen from the atmosphere by converting atmospheric dinitrogen into bioavailable nitrogen. Legumes and other nitrogen-fixing plants produce higher quantities of bioavailable nitrogen when there are low soil concentrations of ammonia and ammonium. Intercropping offers the potential of direct input of bioavailable nitrogen from legumes to other crops by growing them alongside each other. Intercropping has been shown to increase crop yields, and these yields have been shown to be less dependent on nutrient inputs compared to monocropping systems. Cover cropping also promotes increased organic matter, increased CEC properties, and prevents soil erosion. However, cover crops use can be limited by regional climates and require adequate soil temperatures to grow between agricultural seasons (2020 TR).

2. In balancing the responses to the criteria above, is the substance compatible with a system of sustainable agriculture?

To evaluate compatibility, the Subcommittee review includes answers to the following 12 questions as noted in the NOSB Policy and Procedures Manual.

- **Does the substance promote plant and animal health by enhancing the soil's physical, chemical, or biological properties**?

During the discussion and public comment period regarding ammonia extracts at the 2020 and 2021 NOSB meetings, commenters indicated that ammonia extracts must be used with other soil-building practices to comply with OFPA criteria. These comments would suggest that the use of ammonium extracts alone does not enhance the soil's biological properties. For example:

> The Petition ignores that the use of any fertilizer, including presently approved ammonia extracts, can only be applied under a holistic certified organic system plan.

This is a complex issue, and commenters provided a range of responses that either indicated that these extracts would harm soil biological properties or that they would enhance these properties.

Diverse soil fertility practices can increase soil biological activity, as noted by one comment:

> The impact of soil carbon on soil biological response was more closely related to the inputs of carbon due to crop rotations than fertilizer practice (Geisseler, 2014). These complexities have been explored by Hijbeeks et al. (2017) when they compared soil and crop responses to organic and inorganic fertilizers on a range of crops from long-term experiments across Europe. Their results showed no significant effect of the organic inputs on crop yield with the effects from organic additions dependent upon the clay content, climate, and the soil organic matter at the beginning of the experiment, as shown from their results (Fig. 4). These findings are consistent with those from Lori et al. (2017) in their meta-analysis of 56 experiments across the world. They found organic systems exhibited 32-84% greater microbial biomass carbon, microbial

biomass nitrogen, total phospholipid fatty acids, dehydrogenase, urease, and protease activities than conventional systems. When they used subgroup analyses, they found that crop rotation, inclusion of legumes in the rotation, along with the organic inputs were all significant factors affecting the soil microbial size and activity.

There were few comments comparing the environmental effects of any type of HSN Fertilizer to an organic system using manures, composts, crop rotations, cover crops, and interplanting. Several commenters wrote that this is an area where research is limited, and effects may largely be unknown.

Given that the comments and citations supporting these materials only be used in conjunction with other carbon contributing soil practices and that some research indicates their negative effects on soil biology, a conservative approach to this answer is that the use of HSN fertilizers does not positively contribute to plant health over the long term.

- **Does use of the substance encourage and enhance preventative techniques, including cultural and biological methods for the management of crop, livestock, and/or handling operations?**

Commenters have argued that the limited use of HSN fertilizers in situations where nitrogen might be limited due to unusual weather events or cold soils could “prime” the soil system to increase biological activity or bridge short-term nitrogen deficits. But these situations do not meet the criteria of the wording “encourage and enhance preventative techniques” since they would be a response in an unusual situation when other techniques have failed. Others have noted that if soils are wet or cold during planting time, this points to the inefficiency of the mycorrhizal fungi or the root system itself. Nitrogen is not generally needed in large amounts early on, and it is actually phosphorus that is needed. If mycorrhizal fungi are not active due to weather, they cannot process the needed phosphorus to assist early plant germination. There can be a phosphorus deficit in the plants when cold/wet soils occur, even in excess phosphorus soils. From the viewpoint of conventional farmers, a true starter fertilizer is 10-34-0, indicating more phosphorus is needed early on to charge the soil for the plant “pop-up” than nitrogen itself. This same issue goes for organic soil.

Additionally, HSN fertilizers inherently contain a very low C: N ratio. In the past, the NOSB had prohibited materials sourced from agricultural waste when the carbon value of the original source material was not retained in the final product. The prohibition of ash from manure burning is an example where the carbon from the manures is removed by burning, and the value of the materials for restoring soil organic matter is destroyed. These precedents may lead to the conclusion that all HSN’s that are separated from their carbon source should be prohibited, similar to the vote by the NOSB to prohibit ammonia extracts. However, at this time, this motion mimics the annotation for sodium nitrate, allowing very limited use of an HSN.

- **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?**

Arguments are made both ways as to whether applications of HSN fertilizers and their ready availability to plants reduce their leaching potential (since only the amounts needed can be applied) or whether they bypass soil systems that tie up and release soil nitrogen dynamically (those systems only have a small proportion of nitrogen available to leach). The timing of nitrogen application can be controlled with HSN fertilizers, and they can be applied in quantities that the crop needs at that point. This could lead to a better match of nitrogen added to the nitrogen required by the crop. However, there is also evidence that dynamic soil systems that release and then reabsorb nitrogen can supply crop needs while minimizing free nitrogen (Bowles, Hollander, et al., 2015). The free nitrogen would be limited and, thus, leaching potential reduced.

One researcher (Phelan, Mason, et al., 1995) has conducted studies showing that plants are more resistant to insect damage when organic fertilizers are used instead of readily available mineral materials. Thus, the use of HSN fertilizers can disrupt biological controls since they are readily available.

- **Does use of the substance have a positive influence on the health, natural behavior, and welfare of livestock?**

  N/A

- **Does the substance satisfy expectations of organic consumers regarding the authenticity and integrity of organic products?**

While the answer to this question is not referenced in the TR or other research reports, one public commenter noted that:

> Objections to the compatibility of these substances with organic principles are serious enough to potentially lead to fragmentation of the organic market. Some companies have indicated they may be prepared to establish private standards that exclude products produced with this input from their supply chain. This indicates that the substance could fail to align with the 2004 NOSB Recommendation, which asks NOSB to consider whether the substance would "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?**

This is a complex question. Some commenters argue that the potential for yield increases, precision application of nitrogen, and reduction of environmental contamination from excess nitrogen or phosphorous from composts and manures will increase the long-term viability of organic farms.

Others argue that using HSN fertilizers will degrade soil biological systems and interfere with biological processes important to plant and soil health. Using these materials may increase short-term yield but not promote long-term soil carbon building. Thus, long-term resiliency and viability may be hurt by using these materials.

Using OFPA and deploying a total systems approach is necessary. Precision technology independent of nitrogen sources should be adopted by organic farmers interested in increasing their yields and applying the right nutrients in the right places. Excess nitrogen or phosphorus applications need to be regulated through soil samples, removal rates, etc., and should not be an issue if the total systems approach is applied. Also, if there are nutrient management problems on a particular soil, avoiding solving them and bypassing them with a material that mimics conventional materials should not be permitted in an organic system. At a minimum, HSN fertilizers should be listed as a restriction on the OMRI certificate. They cannot be applied if work has not been done to remediate excess phosphorus or calcium build-up in soils due to over applications in prior years.

- **Is there evidence that the substance is mined, manufactured, or produced through reliance on child labor or violations of applicable national labor regulations?**

There is no evidence that these materials violate 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?**

N/A

- **Is the use of the substance consistent with other substances historically allowed or disallowed in organic production and handling?**

This is a proposal to limit the use of non-synthetic nitrogen materials. Other materials currently used in organic production (liquid fish, soy protein hydrolysate, blood meal, sodium nitrate) are similar in use. Still, all outside of sodium nitrate is protein-based, requiring some mineralization before impact to plants. Of these, only sodium nitrate has significant nitrogen in an immediately plant usable form. Sodium nitrate is annotated on the National List to a limit of not more than 20% of crop needs. When this restriction was applied, sodium nitrate was one of the very few highly soluble nitrogen materials available, and it was naturally mined and not manufactured. However, it should be noted that a previous NOSB voted to prohibit the use of sodium nitrate due to concerns of salt build-up and similar concerns regarding soil biology effects. This motion mirrored restrictions on sodium nitrate when it was one of the few non-synthetic forms of highly soluble nitrogen.

In general, natural substances allowed in organic production are made up of complex chemical structures, including lignans, proteins, carbon, nitrogen, and other minerals and materials. As noted above, different behavior in the soil of HSN fertilizers may be beneficial or detrimental. These differences may be exhibited by the differing C: N ratio between these materials and other organic inputs. Except for sodium nitrate, most other traditional non-synthetic organic fertilizers have ratios of at least 3:1 and often greater. The low C: N ratio of HSN fertilizers would be expected to cause different soil effects than those materials with higher carbon amounts.

Proponents of HSN fertilizers argue that they are similar to other substances allowed and are only more immediately available. When used in moderate quantities, they enhance soil biology and can cause soil and plant ecosystems to be more productive.

Opponents argue that HSN fertilizers bypass and short circuit soil biological processes and do not enhance long-term carbon build-up in the soil. Their low C: N ratio is contrary to the original intent of the organic regulations in that soil fertility methods should promote long-term soil health and ecosystem stability.

- **Would approval of the substance be consistent with international organic regulations and guidelines, including Codex?**

The use of sodium nitrate for products exported to Canada is prohibited. Inconsistencies between international certifiers reduce export market potential and create additional confusion with countries with substantially different standards that the United States receives imports from.

- **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?**

Given the conflicting information regarding the use of HSN fertilizers, it seems prudent to limit the usage of extracts. As with the debate regarding ammonia extracts, adequate research demonstrating that these high-nitrogen, carbon-limited materials comply with OFPA criteria for maintaining and increasing soil organic matter is very limited. As noted above, arguments can be made that these materials have a positive or negative effect. Given that there is no clear answer and adverse effects on soil health have been documented, an abundance of caution warrants a limitation on using HSN fertilizers. Since future innovations in the non-synthetic production of HSN fertilizers are possible, a limit on the cumulative use of HSN fertilizers in organic agriculture is prudent. If future research conclusively demonstrates that these materials comply with the OFPA criteria to maintain and build soil organic matter, a petition could be submitted to remove the limitation.

Furthermore, an abundance of caution warrants a close look at the use of low (below 3:1) C: N ratio materials, such as ammonia extracts, for organic fertility. The NOSB has set precedents to the limitation of these types of materials. Sodium nitrate is limited to 20% of crop needs. Other highly soluble, non-nitrogen materials are also limited by annotation. It was noted in public comments that:

> An abundance of caution warrants a close look at the use of low (below 3:1) C: N ratio materials. The NOP and NOSB have previously discussed the need to limit materials of high solubility. Furthermore, the recent vote by the NOSB to prohibit ammonia extracts is another example of the concern over the use of these types of low C: N ratio materials.
>
> In the preamble to the publication of the NOP Final Rule on December 21, 2000, NOP discusses how it decided to agree with the NOSB recommendation and to put specific regulation of substances of high solubility into the annotations for each of these materials where they appear on the National List of Allowed and Prohibited Substances. NOP goes on to say, "Based on the recommendation of the NOSB, the final rule would prohibit use of these materials [substances of high solubility], unless the NOSB developed recommendations on conditions for their use and the Secretary added them to the National List." At the time, the discussion was about mined substances of high solubility because there were no concentrated, highly soluble plant nutrient materials other than mined sources available at that time.

This long-time concern for using highly soluble plant nutrients and the “an abundance of caution” criteria is important for this proposal. Concerning this motion, several options are open to the NOSB. The first is to reject the motion altogether and allow the unlimited use of non-synthetic HSN fertilizers (except for the 20% limitation on sodium nitrate). The second is to annotate the use of each of these materials to some maximum percent of crop needs, like sodium nitrate. The third is to limit the cumulative total use of these materials to some maximum percent of crop needs.

If an annotation to limit the use of a single material were to be put in place, the potential exists for sodium nitrate, and another allowed HSN to both be used up to each of their maximum allowed rates. This stacked rate would allow for higher applications than either alone. The combined use would put the burden on certifiers to identify whether the total use of these highly soluble products violated the OFPA criteria to maintain or build soil organic matter. It is likely that different certifiers would have different interpretations and that notices of non-compliance would be challenging to enforce.

Additionally, the effectiveness of a prohibition or limitation is dependent on an exact definition of materials already prohibited or limited. If new products are developed that fall outside those definitions, a future petition would have to be submitted to determine if they should or should not be allowed. This could create additional workloads and a perpetual cycle of review for each new product produced. It would seem prudent to set an additional limitation for materials that might fall outside the current definitions and other highly soluble nitrogen materials.

A limitation restricting the total use of highly soluble nitrogen fertilizers would prevent the "stacking" of multiple highly soluble fertilizer types. With the proposed motion, to restrict nitrogen fertilizers with a C: N ratio of 3:1 or less, including those individual components of a blended fertilizer formulation, to a cumulative total use of 20% of crop needs, The NOSB should not have to continually be concerned about the introduction of novel non-synthetic nitrogen materials before a petition is submitted to restrict them. Manufacturers of these new HSN fertilizers would know that there is a limitation on an HSN fertilizer before resources are invested in the process. A manufacturer could also submit a petition to remove any restriction applied to their product.

A public commenter noted:

> Sodium nitrate was prohibited in part for this same rationale. As stated by NOSB in a past review to justify its recommendation to prohibit, the "use and dependence on sodium nitrate also can tend for producers to put off the need for strong soil-building practices, consistent with §205.203 since it behaves similarly to conventional synthetic nitrogen fertilizers." This is evidence that the substance could fail to align with the 2004 NOSB Recommendation which asks NOSB to consider whether "use of the substance is consistent with other substances historically allowed or disallowed in organic production and handling." Highly soluble sources of nitrogen cannot be addressed in a vacuum, and we cannot look at one material at a time. We must take a broader approach to limiting highly soluble sources of nitrogen as a whole. If each material must be evaluated and listed individually, the evaluation process could be endless. Additionally, there would be the possibility of stacking HSN fertilizers, thus bypassing any restrictions on individual HSN fertilizers.

- **Does use of the substance have a positive impact on biodiversity**?

There are arguments that HSN fertilizers enhance soil biological processes, while others say that these materials either do not impact or decrease biodiversity. A proponent of the use of ammonia extracts cited Jerry Hatfield in that:

> Bio-based fertilizers have been shown to increase the characteristics related to soil health, e.g., organic matter, soil aggregates, enhanced biological activity, increased nutrient cycling because they stimulate biological activity through a balanced carbon: nitrogen (C: N) ratio

Contrarily, regarding ammonia extracts, the 2020 TR states:

> While bioavailable nitrogen is also important for the function of microorganisms, high concentrations of ammonia and ammonium compounds result in changes to the native soil communities. These changes vary based on the initial soil communities and may result in either an increase or decrease in total population. However, while there are cases of population growth in some communities, the application of nitrogen fertilizers is associated with decreases in the diversity of these microbial communities.

Given the conflicting information regarding biodiversity impacts, it would be difficult to state unequivocally that the use of HSN fertilizers positively impacts biodiversity. While there is a chance that these materials increase diversity, there is also a very likely chance that they decrease biodiversity. As noted during the debate that eventually led to an NOSB vote to prohibit ammonia extracts, there are situations where the very limited use of highly soluble nitrogen fertilizer may be warranted. The current use of sodium nitrate or guano meets these situations. However, a limitation on the use of these materials and the use of any future HSN fertilizers prevents the potential stacking or overuse of these materials. In addition to the prohibition on ammonia extracts, this motion will limit the use of any new novel highly soluble nitrogen materials until their compliance with OFPA criteria can be evaluated through the petition process.

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Sharaf, H., Thompson, A. A., Williams, M. A., et al.; 2021; Functional change in bacterial communities to fertilizer and rootstock; Soil Science Society of America Journal, July/August, 85:4, p. 1105-1121.

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Subcommittee Vote:

National List Motion
Motion to add at § 205.105: nitrogen fertilizers with a C: N ratio of 3:1 or less, including those individual components of a blended fertilizer formulation, are limited unless use is restricted to a cumulative total use of 20% of crop needs.
Motion by: Amy Bruch
Seconded by: Brian Caldwell
Yes: 7 No: 1 Abstain: 0 Absent: 0 Recuse: 0

National Organic Standards Board
Crops Subcommittee Petitioned Material Proposal
Carbon Dioxide
January 18, 2022

Summary of Petition:
The NOSB received a petition requesting the addition of synthetic carbon dioxide at §205.601 Synthetic substances allowed for use in organic crop production as (a) algicide, disinfectants, and sanitizer, including irrigation system cleaning systems and (j) As plant or soil amendments.

Carbon dioxide is currently allowed for use as an ingredient in organic labeled processed food products: §205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).” (b) Synthetic allowed: - Carbon dioxide.

This petition requests the allowance of carbon dioxide in organic crop production.

Subcommittee Review:
Carbon dioxide is understood to be a material with inherently low risk and is approved as a processing aid. Because carbon dioxide is a synthetic material, the Subcommittee discussions focused on the need and benefits of using carbon dioxide over other allowed alternatives?

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.

   Carbon dioxide (empirical formula CO2, CAS Reg. No. 124-38-9) occurs as a colorless, odorless, noncombustible gas at normal temperatures and pressures. The solid form, dry ice, sublimates under atmospheric pressure at a temperature of −78.5 °C.

   Carbon dioxide is prepared as a byproduct of the manufacture of lime during the “burning” of limestone, from the combustion of carbonaceous material, from fermentation processes, and from gases found in certain natural springs and wells.

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?

   Carbon dioxide falls under the category of production aid.

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)]

   Carbon dioxide is already allowed as an organic processing substance. It occurs naturally in the atmosphere, has little chemical interactions with other substances, and has no apparent negative effect on 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)]

   The action to dissolve carbon dioxide (CO_2) in water (H_2O) makes carbonic acid (H_2CO_3): $H_20 + CO_2 \rightarrow H_2CO_3$. Carbonic acid is dissociated in water to: $HCO_3^- + H^+$. This hydrogen lowers water pH. This is a common, naturally occurring reaction in the soil ecosystem from CO_2 in the atmosphere. In soils with high pH, applying water with a reduced pH can increase nutrient availability and increase plant health. Additionally, the activity of carbon dioxide in water can help prevent clogging of irrigation systems by algae and other plant contaminants.

   CO_2 can also be used for pest control in storage areas, however, that is not the subject of this petition.

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

   As a basic component of the atmosphere, carbon dioxide has a high environmental persistence. This is not a negative, except to the overarching concern of global warming. At the rates occurring in the atmosphere, it is completely non-toxic and is exempt from having a lethal dose. The water pH adjustment process can be manually controlled, as well as automatically controlled, by adding a pH probe and controller that adjusts the carbon dioxide (CO_2) injection to maintain target pH values in the water. Water cannot drop below pH 5.0 when carbonic acid (dissolved CO_2) is used in the acidification process. This characteristic makes the use of carbonic acid the safer and most secure process for water pH adjustment when compared to alternatives.

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

   Suffocation can occur in pure carbon dioxide but is due to the lack of oxygen not toxicity of carbon dioxide. There are no other direct effects of human health from the substance.

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 use of dissolved carbon dioxide to reduce water pH is an acidifying method that occurs naturally, i.e., atmospheric carbon dioxide from biological processes enters water through equilibrium. It dissolves in water, including water in soil solution, to form carbonic acid. Carbonic acid breaks down into carbon dioxide.

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

   Carbon dioxide is a greenhouse gas and can contribute to climate change. Its increase in the atmosphere has altered the biodiversity in many ecosystems. However, the use of this product in accordance with the petition will not add to the increase of carbon dioxide. The petitioned use is for carbon dioxide produced as a byproduct of other processes. The carbon dioxide would be released to the atmosphere regardless of the petitioned use.

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)]

   Alternatives used in organic production to lower pH levels in irrigation water are sulfur "burners" and citric acid. Because water pH cannot drop below 5.0 when carbon dioxide is used as an acidifier, this method may be considered more secure as a pH adjustment compared to alternatives.

   Sulfur burners create sulfurous acid by dissolving the fumes of burning sulfur in irrigation water. Sulfur is an odorless, tasteless, light-yellow solid usually sold in blocks or pellets. Sulfurous acid is slightly irritating to the skin, and strongly irritating to the eyes of rabbits. Under acidic conditions, sulfurous acid may liberate sulfur dioxide, which is known to induce respiratory irritation in humans.

   Citric acid is a non-synthetic 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. Citric acid has GRAS status (generally recognized as safe) by the FDA.

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

   Because carbon dioxide is approved as an organic processing substance, is already being produced, and its listing at § 205.601 would be considered a recycling process, the Crops Subcommittee finds it compatible with a system of sustainable agriculture.

Subcommittee Vote:

Classification Motion:
Motion to classify carbon dioxide as synthetic
Motion by: Logan Petrey
Seconded by: Rick Greenwood
Yes: 8 No: 0 Abstain: 0 Absent: 0 Recuse: 0

National List Motion:
Motion to add carbon dioxide at §205.601(a) algicide, disinfectants, and sanitizer, including irrigation system cleaning systems
Motion by: Logan Petrey
Seconded by: Rick Greenwood
Yes: 7 No: 0 Abstain: 1 Absent: 0 Recuse: 0

National List Motion:
Motion to add carbon dioxide at §205.601(j) As plant or soil amendments.
Motion by: Logan Petrey
Seconded by: Steve Ela
Yes: 7 No: 1 Abstain: 0 Absent: 0 Recuse: 0

Sunset 2024
Meeting 1 - Request for Public Comment
Crops Substances § 205.601 & § 205.602
April 2022

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 which must be reviewed by the NOSB and renewed by the USDA before their sunset dates. This document provides the substance's current status on the National List, annotation, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, this is noted in this list. To see if any new technical report is available, please check for updates under the substance name in the Petitioned Substances Database.

Request for Comments
While the NOSB will not complete its review and any recommendations on these substances until the Fall 2022 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the Spring 2022 public meeting. Comments should be provided via Regulations.gov at www.regulations.gov on or before April 1, 2022, as explained in the meeting notice published in the Federal Register.

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

Public comments should clearly indicate the commentor's position on the allowance or prohibition of substances on the National List and explain the reasons for the position. Public comments should focus on providing relevant new information about a substance since its last NOSB review. Such information could include research or data that may support a change in the NOSB's determination for a substance (*e.g.*, scientific, environmental, manufacturing, industry impact information, etc.). Public comment should also address the continuing need for a substance or whether the substance is no longer needed or in demand.

For Comments that Support the Continued Use of §205.601 Substances in Organic Production:
If you provide comments supporting the allowance of a substance at §205.601, you should provide information demonstrating that the substance is:

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

For Comments that Do Not Support the Continued Use of §205.601 Substances in Organic Production:
If you provide comments that do not support a substance at §205.601, you should provide reasons why the use of the substance should no longer be allowed in organic production. Specifically, comments that support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:

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

For Comments that <u>Support</u> the Continued Prohibition of §205.602 Substances in Organic Production:
If you provide comments supporting the prohibition of a substance on the §205.602 section of the National List, you should provide information demonstrating that the substance is:

1. harmful to human health or the environment; and
2. inconsistent with organic crop production.

For Comments that <u>Do Not Support</u> the Continued Prohibition of §205.602 Substances in Organic Production:
If you provide comments that do not support the prohibition of a substance at §205.602, you should provide reasons why the use of the substance should no longer be prohibited in organic production. Specifically, comments that support the removal of a substance from the §205.602 section of the National List should provide <u>new</u> information since its last NOSB review to demonstrate that the substance is:

1. not harmful to human health or the environment; and/or
2. consistent with organic crop production.

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

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

Your comments should address whether any alternatives have a function and effect equivalent to or better than the allowed substance, and whether you want the substance to be allowed or removed from the National List. Assertions about alternative substances, except for those alternatives that already appear on the National List, should, if possible, include the name and address of the manufacturer of the alternative. Further, your comments should include a copy or the specific source of any supportive literature, which could include: product or practice descriptions, performance and test data, reference standards, names and addresses of organic operations who have used the alternative under similar conditions and the date of use, and an itemized comparison of the function and effect of the proposed alternative(s) with substance under review.

Written public comments will be accepted through April 1, 2022, via [www.regulations.gov.](http://www.regulations.gov) Comments received after that date may not be reviewed by the NOSB before the meeting.

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

- Herbicides, soap-based
- Biodegradable biobased mulch film
- Boric acid
- Sticky traps/barriers
- Elemental sulfur (h)(2)
- Coppers, fixed
- Copper sulfate (i)(3)
- Polyoxin D zinc salt
- Humic acids
- Micronutrients:
    - Soluble boron products
    - Sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt
- Vitamins B_1, C, E
- Squid byproducts

§205.602 Sunsets: Nonsynthetic substances prohibited for use in organic crop production:

- Lead salts
- Tobacco dust (nicotine sulfate)

Herbicides, soap-based

Reference: §205.601(b) As herbicides, weed barriers, as applicable.

(1) Herbicides, soap-based—for use in farmstead maintenance (roadways, ditches, right of ways, building perimeters) and ornamental crops.

Technical Report: 1996 TAP; 2015 TR.

Petition: N/A

Past NOSB Actions: Actions: 1996 recommendation; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 11/2017 sunset recommendation.

Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)

Sunset date: 10/30/2024

Subcommittee Review

Use

As herbicides, soap-based herbicides are used as weed barriers, for use in farmstead maintenance (roadways, ditches, right of ways, building perimeters) and ornamental crops as a last resort.

Manufacture

Soap-based herbicides are potassium salts of fatty acids and are produced through saponification, where aqueous potassium hydroxide is added to fatty acids commonly found in animal fats and plant oils. Ammonium salts of fatty acids, such as ammonium nonanoate, are produced through room temperature reaction of aqueous ammonia or ammonium hydroxide with fatty acids.

International Acceptance

Canadian General Standards Board Permitted Substances List

The Canadian Organic Production Systems Permitted Substances List provides several use patterns for soaps in organic crop and livestock production, as well as organic processing

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

European organic regulations allow the use of soap salts in crop and livestock production as insecticides and disinfecting agents but are not mentioned for use as herbicides.

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

The use of soaps in organic productions is an allowed synthetic substance for plant pest and disease control but no mention of specific use as an herbicide.

International Federation of Organic Agriculture Movements (IFOAM) Norms

A number of uses of soaps are listed for organic crop production and disinfection but no mention of specific use as an herbicide.

Japan Agricultural Standard (JAS) for Organic Production

Soaps can be used for control of pests in organic crop production. No mention of specific use as an herbicide.

Environmental Issues

Potassium and sodium salts of fatty acids decompose rapidly and do not persist in the environment. They need to be sprayed directly on the target plant and thus, environmental contamination is not expected. Studies have not shown any negative interactions with other chemicals used for organic farming.

Discussion
In 2017, the NOSB received several comments in favor of keeping soap-based herbicides on the National List. Comments indicated that although soap-based herbicides are sometimes only marginally effective, they are a safe alternative, and some farmers rely on them for weed control on farmsteads, roadways, and other places they are approved for use. There were no comments in favor of removing soap-based herbicides.
The subcommittee discussed soap-based herbicides and considers them to be benign to the environment and human health,

Questions to our Stakeholders
None

Biodegradable biobased mulch film

Reference: §205.601(b) As herbicides, weed barriers, as applicable. (2) Mulches.
(iii) Biodegradable biobased mulch film as defined in §205.2. Must be produced without organisms or feedstock derived from excluded methods.
Technical Report: 2012 TR; 2015 Report; NOP Policy Memorandum 15-1; 2016 Supplemental TR.
Petition: 2012.
Past NOSB Actions: Actions: 10/2012 recommendation; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset date: 10/30/2024

Subcommittee Review

Use
Biodegradable biobased mulch film (BBMF) is used to suppress weeds, conserve water, and facilitate production of row crops. Some commenters have noted that having a degradable plastic mulch is likely to be more environmentally friendly than using landfills for the non-degradable plastic mulches. The requirement for 100% biobased feedstocks to manufacture the film is articulated in the preamble of the final rule that added Biodegradable biobased mulch film to the National List. Past commenters have acknowledged that there are currently very few options (other than difficult to use paper mulch) for 100% BBMF but have generally felt this listing should remain despite the fact that no 100% BBMF is available (see below). At the Fall 2021 NOSB meeting, the Board voted to allow 80% BBMF (https://www.ams.usda.gov/sites/default/files/media/NOSBFall2017ProposalsDDTOC.pdf).

As noted in numerous public comments on past documents relating to BBMF, the current listing allowing the use of these films is impractical. No biobased films meet the 100% annotation and are unlikely to meet this criterion in the near future. There is also broad consensus among the Board and stakeholders that the use of allowed polyethylene mulch has serious negative environmental impacts. After input from stakeholders on the practicality and environmental impacts from biodegradable mulch, the Board passed a proposal modifying the annotation for BBMF. While there are no currently available products that meet the modified criteria, commenters noted that it is possible that materials meeting the proposed annotation could be available in the near future. The use of BBMF that meets this proposed annotation would alleviate the environmental impact of disposal of non-recyclable polyethylene mulch. The proposed language, “When greater than 80% biodegradable biobased mulch films become commercially available, producers are required to use them, given that they are of the appropriate quality, quantity, and form”, also reflects the Boards intent to ensure that famers must use BBMF with biobased content greater than 80% when these materials become commercially available.

The timing of this sunset review predates the rulemaking process to implement the annotation allowing 80% BBMF. The Crops Subcommittee has voted to relist BBMF at §205.601(b) As herbicides, weed barriers, as applicable. (2) Mulches. (iii) Biodegradable biobased mulch film as defined in §205.2. Must be produced without organisms or feedstock derived from excluded methods until the annotations is implemented.

Manufacture
BBMF is a synthetic plastic material manufactured from polymers using plant-based carbon sources.

International Acceptance
Canadian General Standards Board Permitted Substances List
Plastic mulches: non-biodegradable and semi-biodegradable materials shall not be incorporated into the soil or left in the field to decompose. Use of polyvinyl chloride as plastic mulch or row cover is prohibited. Biodegradable mulches: 100% of biodegradable mulch films shall be derived from bio-based sources. Biodegradable polymers and Carbon Black from GE or petroleum sources are not permitted.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Mulches are not specifically addressed in EEC. Under plant protection it states that all plant production techniques used shall prevent or minimize any contribution to the contamination of the environment.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
No reference in CODEX on biodegradable mulch.

International Federation of Organic Agriculture Movements (IFOAM) Norms
Under 4.5.1, mulches are permitted as a pest management practice under and 4.5.2 references appendix 3 as an approved list including "mulch" as a barrier. 4.6.3 states "for synthetic structure coverings, mulches, fleeces, insect netting and silage wrapping, only products based on polyethylene and polypropylene, or other polycarbonates are permitted. These shall be removed from the soil after use and shall not be burned on the farmland."

Japan Agricultural Standard (JAS) for Organic Production
Mulches are permitted for the control of noxious animals and plants in fields or cultivation sites. Mulches derived from used papers (those without chemically synthesized materials added in production) or plastic mulches (those intended to be removed after use). There is no listing of biodegradable mulches.

Environmental Issues
Concerns about BBMF have been extensively discussed in prior documents including discussion documents, reports, and proposals for the annotation change. Concerns have been raised about incomplete degradation and migration of partially decomposed particles into the environment.

Discussion
There have been numerous public comments requesting the NOSB work with the NOP to allow a BBMF that contains unique polymers. Some noted that having a degradable plastic mulch is likely more environmentally friendly than using landfills for the non-degradable plastic mulches. Past commenters also acknowledged that there are currently very few options (other than

difficult to use paper mulch) for 100% BBMF but felt the listing should remain despite the fact that 100% BBMF is not available. As noted above, at the Fall 2021 NOSB meeting, the Board voted to allow 80% BBMF (https://www.ams.usda.gov/sites/default/files/media/NOSBFall2017ProposalsDDTOC.pdf).

Questions to our Stakeholders
Is there new information on the availability of 100% BBMF?

Boric acid

Reference: §205.601(e) As insecticides (including acaricides or mite control).
(3) Boric acid - structural pest control, no direct contact with organic food or crops.
Technical Report: 1995 TAP.
Petition: N/A
Past NOSB Actions: 04/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset date: 10/30/2024

Subcommittee Review

Use
As an insecticide, boric acid is odorless. It attacks insect nervous and metabolic systems. It can also dehydrate insects and be abrasive to insect exoskeletons. It has been used as an insecticide since 1948 and is common in household insecticides.
As a structural pest control tool, it is used as a bait which insects ingest and return to their colonies. As a result, it can eliminate entire pest colonies.
This material is often used in packing sheds and other facilities. Many times, it is used as a powder introduced into cracks and crevices, and is essential for controlling ants and roaches.
It has a number of industrial and medical uses and is often used as an amendment in boron-deficient soils.

Manufacture
Boric acid is a white powder that is soluble in boiling water. It is a mined substance, occurring naturally in areas of high volcanic activity, and its primary source is the Mojave Desert of Nevada and California. It also occurs in plants, is prevalent in most fruits, and appears in rocks and soil.

Boric acid produced through the manufacturing process includes a broad range of formulations in concentrations from 1-100% in liquids (solutions, emulsifiable concentrates), granules, wettable powders, dusts, pellets, tablets, and baits.

International Acceptance
Canadian General Standards Board Permitted Substances List
The Canadian Organic Production Systems Permitted Substances List includes boric acid for structural pest control.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
European organic regulations do not reference boric acid.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
CODEX regulations do not reference boric acid.

International Federation of Organic Agriculture Movements (IFOAM) Norms
IFOAM regulations do not reference boric acid.

Japan Agricultural Standard (JAS) for Organic Production
JAS regulations allow boric acid for pest control for plants.

Environmental Issues
Boric acid is generally regarded as safe (GRAS) and of low toxicity, although it can be an eye, skin, and respiratory and nasal irritant. Ingestion by humans or pets can cause gastrointestinal distress. Long-term exposure can affect the kidneys, although it is not generally considered to be carcinogenic. There is no evidence it can be an endocrine disruptor or can create reproductive toxicity in humans (although birds may experience some reduced growth rates after ingestion). Several species of fish have been tested for impacts from boric acid, and the World Health Organization determined very low sensitivity to the material in those species. It has low toxicity to bees.

Boric acid is mined from the environment in deserts where sensitive habitats and species may exist. Boric acid is released into the environment due its wide range of applications, including borate salt laundry products, power generation, chemical manufacturing, copper smelters, rockets, mining operations, and the manufacture of glass, fiberglass, porcelain enamel, ceramic glazes, metal alloys and fire retardants.

Discussion
Boric acid, derived from the mineral borax/borate salts, is a weak acid that has long been considered a "least-toxic" pesticide because it is non-volatile when placed in bait or gel formulations and therefore eliminates risk of direct exposure. It is essentially hydrated boron.

At the Fall 2015 NOSB meeting, the Crops Subcommittee proposed to remove boric acid from §205.601(e) on the basis of not fully meeting all sub-components of OFPA criteria, particularly criteria of Impacts on Humans and the Environment, Essentiality, and Compatibility & Consistency. The motion to remove failed after receiving 1 "Yes" and 13 "No" votes. While boric acid does not fully meet the OFPA criteria of Impacts on Humans and the Environment, Essentiality, and Compatibility & Consistency, the alternatives often have equally challenging issues.

In 2017, there was no new information provided from the stakeholder community through public comment during subcommittee review and prior to full consideration before the NOSB in-person vote. There was also no support for removing boric acid from the National List. Neither the Subcommittee nor the full board recommended its removal from the National List.

The Crops Subcommittee discussed the use of this material and noted it is both common and useful in these applications.

Questions to our Stakeholders:
None

Sticky traps/barriers

Reference: §205.601(e) As insecticides (including acaricides or mite control).
(9) Sticky traps/barriers.
Technical Report: 1995 TAP.
Petition: N/A
Past NOSB Actions: 10/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset date: 10/30/2024

Subcommittee Review

Use
Pest control and monitoring. Also used with traps as a production aid.

Manufacture
This listing covers a wide range of traps and coatings made with a number of different materials, including coated paper, coated plastic, and brushed on sticky chemicals applied directly to plants. Some sticky traps are made with petroleum wax or linear hydrocarbons.

International Acceptance
None noticed

Environmental Issues
Sticky traps are used in limited quantities in confined areas such as traps or tree trunks, and have limited mobility, making it unlikely to have environmental impacts.

Discussion
There was broad support for relisting sticky traps/barriers from farmers, certifiers, and trade organizations the last time sticky traps came up for sunset review. Based on the previous Subcommittee review and public comment, the NOSB found sticky traps/barriers compliant with OFPA criteria, and did not recommend removal from the National List.
Sticky traps do not come into contact with food.

Questions to our Stakeholders
None

Elemental sulfur (h)(2)

Reference: §205.601(h) As slug or snail bait.
(2) Elemental sulfur.
Technical Report: 1995 TAP; 2018 TR.
Petition: 2017.
Past NOSB Actions: 04/2018 recommendation.
Recent Regulatory Background: Added to National List on 11/22/2019 (84 FR 56673).
Sunset Date: 11/22/2024

Subcommittee Review

Use

When used to manage slugs and snails, sulfur is formulated with attractants plus other "inert" ingredients and extruded into pellets. These are broadcast or hand-applied near crops needing protection. For this purpose, a 1% sulfur formulation is used at a labeled rate of up to 44 lbs. per acre, with an actual elemental sulfur application rate of up to 0.44 lbs. per acre. This is much lower than labeled rates for sulfur when used as a fungicide in formulations of 80% or 90% elemental sulfur.

Manufacture

Elemental sulfur can come either from a natural mined source, or may be produced as a by-product from natural gas or petroleum operations and refinery processes. The latter appears to be the source of most elemental sulfur currently being used. Because the sulfur is chemically extracted from fossil-fuel feedstock, it is considered synthetic.

International Acceptance

Canadian General Standards Board Permitted Substances List

The Canadian General Standards Board (CGSB) includes elemental sulfur from either mined and reclaimed sources as permitted substances for organic production systems (CAN/CGSB-32.311-2015) for use as a soil amendment and as a foliar application. The CGSB also permits the use of sulfur for the control of external parasites and sulfur smoke bombs in conjunction with other methods used for rodent control when a pest control program is temporarily overwhelmed.

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

The European Economic Community (EEC) Council Regulation (EEC No 2092/91) and carried over by Article 16(3)(c) of Regulation No 834/2007, permits the use of sulfur as a fungicide, acaricide, and repellent in organic food production.

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

The Codex Alimentarius Commission's "Guidelines for the Production, Processing, Labelling, and Marketing of Organically Produced Foods" (GL 32-1999) lists elemental sulfur as an allowed substance for pest and disease control.

International Federation of Organic Agriculture Movements (IFOAM) Norms

The International Federation of Organic Agriculture Movement's (IFOAM) lists sulfur as an approved substance for pest and disease control, for use as fertilizer/soil conditioner, and for use as a crop protectant and growth regulator.

Japan Agricultural Standard (JAS) for Organic Production

The Japan Agricultural Standard (JAS) for Organic Production (Notification No. 1605 of 2005) permits the use of sulfur as a fertilizer or soil improvement substance, and as a substance for plant pest and disease control.

Environmental Issues

When used as a fungicide with several applications per season, sulfur can lower soil pH over time, and have negative effects on beneficial mite populations. However, rates in use for slug and snail management are much lower and would not be expected to have those effects.

Discussion

Sulfur for use as a slug or snail bait was added to the National List at §205.601(h) in 2019. This is its first sunset review. Its 2017 petition includes studies showing that a sulfur slug bait product is somewhat more effective than other products approved for this use in organic production.

Other synthetic products commonly used by organic farmers to kill slugs use the active ingredient ferric phosphate. It is invariably combined with a synergist, the chelator EDTA, which is an inert ingredient on the defunct EPA list 4. The EDTA + ferric phosphate combination has been implicated in harm to earthworms in soil and also pet dogs due to enhanced iron toxicity. In 2012 these products were petitioned for removal from the National List at § 205.601(h) for this reason, but the NOSB motion to remove failed. At that time, the NOSB Recommendation indicated that there were no commercial alternatives to ferric phosphate. In 2018, the listing for ferric phosphate was renewed on the National List.

In light of questions about the toxicity of ferric phosphate and the availability of relatively new sulfur alternatives, organic farmers may consider the sulfur products to be desirable. The label of one sulfur-based slug bait product states that it can be used around pets and wildlife when used as directed. The label shows 1% sulfur and 99% inert ingredients, which include iron. It is not known whether this product also contains EDTA.

At labeled rates, sulfur used for this purpose is thought to have little or no negative environmental impacts, even if applied multiple times per season. However, other components of a product's formulation are unknown and may have negative effects.

Questions to our Stakeholders

1. Are there cultural practices that can make slug and snail baits unnecessary?
2. Is it necessary to have sulfur-based products for slug management in addition to ferric phosphate?

Coppers, fixed

Reference: §205.601(i) As plant disease control.

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

Technical Report: 1995 TAP; 2011 TR.

Petition: N/A

Past NOSB Actions: 10/1995 minutes and vote; 11/2005 sunset recommendation; 4/2011 sunset recommendation; 10/2015 sunset recommendation; 11/2017 sunset recommendation.

Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)

Sunset date: 10/30/2024

Subcommittee Review

Use

Coppers, fixed was reviewed and approved for continued use during the October 2015 NOSB meeting. Coppers were considered to be an important tool for organic producers as part of a comprehensive approach to disease management in many crops. For example, copper products became an integrated part of fire blight control in pome fruits after antibiotics were removed from the National List. While some copper minerals and compounds occur in nature, products for agriculture are made from by-products of processing copper ores and are considered synthetic. Copper is on the list of exemptions for synthetic materials in OFPA at § 6517(c)(1)(B)(i). Copper sulfate is also undergoing sunset review, and the Crops Subcommittee submitted a separate review.

Manufacture
Fixed coppers, such as copper hydroxide, are formed by treating copper sulfate with another compound (in this case sodium hydroxide). In another example, copper carbonate is formed by treating copper sulfate with sodium carbonate.

International Acceptance
Canadian General Standards Board Permitted Substances List

- Permitted for use as a wood preservative, fungicide on fruit and vegetables or for disease control.
- Shall be used with caution to prevent excessive copper accumulation in the soil. Copper buildup in soil may prohibit future use.
- Visible residue of copper products on harvested crops is prohibited.

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

- The EEC states that, "it is appropriate to restrict the use of plant protection products containing copper compounds to a maximum application rate of 28 kg/ha of copper over a period of 7 years (i.e., on average 4 kg/ha/year) in order to minimize the potential accumulation in soil and the exposure for not target organisms, while taking into account agro-climatic conditions occurring periodically in Member States leading to an increase of the fungal pressure. When authorizing products Member States should pay attention to certain issues and strive for the minimization of application rates."

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

- Copper in the form of copper hydroxide, copper oxychloride, (tribasic) copper sulfate, cuprous oxide, Bordeaux mixture and Burgundy mixture are listed in Annex 2 (Permitted substances for the production of organic foods), Table 2 (Substances for plant pest and disease control) of —Guidelines for the production, processing, labeling and marketing of organically produced foods‖ (CODEX-GL 32, 1999).

International Federation of Organic Agriculture Movements (IFOAM) Norms

- Copper is only mentioned as a soil amendment and trace soil nutrient under IFOAM.

Japan Agricultural Standard (JAS) for Organic Production

- While the document refers to 'copper powder" repeatedly, only copper sulfate is specifically mentioned. Copper sulfate is only permitted in organic agriculture as a fungicidal spray.

Environmental issues
Run-off from treated fields can contain high levels of copper. Copper is readily dissolved and suspended in the water and is lethal to fish and other aquatic organisms at fairly low concentrations. In the soil, it tends to concentrate heavily in the topsoil and leads to copper resistant fungal strains over time, as well as altering the soil microbiota and killing soil-dwelling animals such as earthworms. Copper toxicity in the soil can reduce the growth and nutrient value of crop plants, as well as damage the integrity of root systems (Van Assche and Clijsters, 1990). Because it accumulates in the soil over time and eventually results in poor plant outcomes, its use as a sustainable practice must be questioned.

Discussion
Copper products are difficult substances to evaluate, as there appears to be broad consensus throughout the US, EU, and Canada that they are hazardous to both human health and the environment. Despite this, their use period has been extended in all three jurisdictions. There doesn't yet appear to be a viable organic alternative for copper in certain applications, including in the lucrative organic wine industry. Banning the use of coppers entirely could eliminate organic wine production, as there are no other widely available and effective tools for controlling downy mildew. While there is not yet a broadly accepted alternative to copper compounds for controlling downy mildew, research has pointed to plant extracts from yucca and salvia, as well as another fungus, *Trichoderma harzianum*, as a possible means of biological control (Dagostin et al., 2011). However, some organic vineyards have also withdrawn from the organic label in order to allow for use of copper alternatives in their vineyards, citing toxic copper build-up in the soil. One way to mitigate this issue would be to implement regular soil testing in organic vineyards and mandate soil remediation once a toxic threshold is approached.

One method to remove toxic copper levels from the soil of vineyards uses plants and bacteria to pull the heavy metal from the soil (Mackie et al, 2012). Phytoremediation with mustard (*Brassica juncea*) can help remove toxic Cu levels from the soil (Ariyakanon and Winaipanich, 2006). There appears to be varying tolerance of crops to copper levels in the soil, suggesting that copper-tolerant crops could be rotated into place after a period of copper intensive cropping. While this would clearly not work for long-lived perennial crops like grapes, annual crops such as potatoes and melons might benefit from this type of crop rotation.

2017 NOSB Review:
Copper sulfate and fixed coppers used for plant disease control (§205.601(i)(2) and §205.601(i)(3)) were reviewed in 2015 ahead of the 2017 sunset date. . There was strong public support for relisting of copper materials. Although there was some discussion regarding the annotation, the final public comment was that the current annotation is adequate. Given the extensive use and documented need for copper sprays, the NOSB found coppers, fixed, compliant with OFPA criteria, and did not recommend removal from the National List. At the 2017 sunset review, the Board voted unanimously to not remove coppers from the National List.

2022 NOSB Review:
Overview: Distinguishing between copper sulfate and fixed coppers seems redundant as they are used in a similar manner and are reviewed in the same TRs. In the scientific literature, they are grouped as CBACs (copper-based antimicrobial compounds). Copper sulfate contains more "free" copper ions vs. "fixed" and is therefore often combined with lime to bind the copper ions. The free copper ions contribute to its solubility in water and its higher uptake by plants.

Main Considerations in 2022 Review

- Copper compounds readily dissolve in water and are highly toxic to many aquatic organisms. They disperse quickly in water.

- Copper compounds bind to soil and tend to accumulate significantly in clay soils and with increasing soil pH. Soils with pH over 6.5 are particularly susceptible to metal toxicity from repeated application.
- Copper compounds can damage the plants they are applied to, as well as impact the appearance and taste of the crop.
- Widespread use of copper compounds has led to the evolution of copper-resistant disease varietals.
- There is a well-studied link between dysfunctional copper metabolism and Alzheimer's disease. Recent research finds a link between the epidemic of Alzheimer's disease and the agricultural use of copper for disease management in plants.
- Foliar spray of copper mixtures has long been recognized to impact lung and liver function in agricultural workers.

In December 2021, the Crops Subcommittee discussed the need for an updated technical report. Not only has ten years passed since the previous report was written, but there are new concerns regarding human and environmental health.

The Crops Subcommittee requested a new technical report during its December 7 call. The Subcommittee requested that the new technical report highlight five areas that should be expanded and updated with the latest research: human health concerns, soil health and microbiota, application rates and accumulation in the soil, copper in the aquatic environment, and alternatives to copper-based products. We also ask that the future TR use consistent units of measurement when discussing rates of application and copper concentrations.

Questions to our Stakeholders

1. Are there organic alternatives to copper products that are more suitable for use in disease control?
2. Are there viable practices that can be used *in situ* to offset the toxic build-up of copper in soil and water?

References

1. Ariyakanon N, Winaipanich B (2006) Phytoremediation of copper contaminated soil by *Brassica juncea* (L.) Czern and *Bidens alba* (L.) DC. var. *radiate*. J Sci Res Chula Univ 31(1):49–56
2. Dagostin S, Schärer H, Pertot I, Tamm, L (2011). Are there alternatives to copper for controlling grapevine downy mildew in organic viticulture? Crop Protection. 30(7):776-788.
3. Mackie KA, Müller T, Kandeler E (2012) Remediation of copper in vineyards—a mini review. Environmental Pollution 167:16–26.
4. Van Assche F, Clijsters H (1990) Effects of metals on enzyme activity in plants. Plant Cell Environ. 13:195-206.

Copper sulfate (i)(3)

Reference: §205.601(i) As plant disease control.

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

Technical Report: 1995 TAP; 2011 TR.
Petition: N/A
Past NOSB Actions: 10/1995 minutes and vote; 11/2005 sunset recommendation; 4/2011 sunset recommendation; 10/2015 sunset recommendation; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset date: 10/30/2024

Subcommittee Review

Use
Copper sulfate was reviewed and approved for continued use during the October 2015 NOSB meeting. Coppers were considered to be an important tool for organic producers as part of a comprehensive approach to disease management in many crops. For example, copper products became an integrated part of fire blight control in pome fruits after antibiotics were removed from the National List. While some copper minerals and compounds occur in nature, products for agriculture are made from by-products of processing copper ores and are considered synthetic. Copper is on the list of exemptions for synthetic materials in OFPA at § 6517(c)(1)(B)(i). Fixed coppers is also undergoing sunset review, and the Crops Subcommittee has submitted a separate review.

Manufacture
Copper sulfate is manufactured by treating copper ore with concentrated sulfuric acid. It is also known as copper vitriol. In order to enhance its fungicidal properties, it is mixed with calcium hydroxide to produce a "Bordeaux mixture" which is sprayed on crops for disease control.

International Acceptance
Canadian General Standards Board Permitted Substances List

- Permitted for use as a wood preservative, fungicide on fruit and vegetables or for disease control.
- Shall be used with caution to prevent excessive copper accumulation in the soil. Copper buildup in soil may prohibit future use.
  Visible residue of copper products on harvested crops is prohibited.

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

- The EEC states that, "it is appropriate to restrict the use of plant protection products containing copper compounds to a maximum application rate of 28 kg/ha of copper over a period of 7 years (i.e., on average 4 kg/ha/year) in order to minimize the potential accumulation in soil and the exposure for not target organisms, while taking into account agro-climatic conditions occurring periodically in Member States leading to an increase of the fungal pressure. When authorizing products Member States should pay attention to certain issues and strive for the minimization of application rates."

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

- Copper in the form of copper hydroxide, copper oxychloride, (tribasic) copper sulfate, cuprous oxide, Bordeaux mixture and Burgundy mixture are listed in Annex 2 (Permitted substances for the production of organic foods), Table 2 (Substances for plant pest and disease control) of ―Guidelines for the production, processing, labeling and marketing of organically produced foods‖ (CODEX-GL 32, 1999).

International Federation of Organic Agriculture Movements (IFOAM) Norms
Copper is only mentioned as a soil amendment and trace soil nutrient under IFOAM.

Japan Agricultural Standard (JAS) for Organic Production
Copper sulfate is only permitted in organic agriculture as a fungicidal spray.

Environmental Issues
Run-off from treated fields can contain high levels of copper. Copper is readily dissolved and suspended in the water and is lethal to fish and other aquatic organisms at fairly low concentrations. In the soil, it tends to concentrate heavily in the topsoil and leads to copper resistant fungal strains over time, as well as altering the soil microbiota and killing soil-dwelling animals such as earthworms. Copper toxicity in the soil can reduce the growth and nutrient value of crop plants, as well as damage the integrity of root systems (Van Assche and Clijsters, 1990). Because it accumulates in the soil over time and eventually results in poor plant outcomes, its use as a sustainable practice may be questioned.

Copper sulfate has been shown to be toxic to bees, particularly in tropical environments. At sub-lethal levels, the heavy metal also changes behavior and movement ability. Despite this, there are multiple statements on the National Pesticide Information Center (NPIC) and in US Environmental Protection Agency Office of Pesticide Programs documents stating that copper sulfate is virtually non-toxic to bees. This is an important point to clarify. The role that bees play in the pollination of commercial crops globally should make this a concern to farmers and the general public alike.

Copper sulfate has been classified as a human carcinogen by the European Chemicals Agency (ECHA), with specific concern for renal cancers (Buzio et al, 2002). Chronic exposure to fungicidal sprays elevated the risk of renal cancers by almost 3 times. While copper binds to soils readily, copper contamination of drinking water sources would also be a concern.

Discussion
Copper sulfate is a difficult substance to evaluate, as there appears to be broad consensus throughout the US, EU, and Canada that it is hazardous to both human health and the environment. Despite this, its use period has been extended in all three jurisdictions, as there isn't yet a viable organic alternative for copper in certain applications, including in the lucrative organic wine industry. Banning the use of copper sulfate entirely could eliminate organic wine production, as there are no other widely available and effective tools for controlling downy mildew. While there is not yet a broadly accepted alternative to copper sulfate for controlling downy mildew, research has pointed to plant extracts from yucca and salvia, as well as another fungus, *Trichoderma harzianum*, as a possible means of biological control (Dagostin et al., 2011). However, some organic vineyards have also withdrawn from the organic label in order to allow for use of copper alternatives in their vineyards, citing toxic copper build-up in the soil. One way to mitigate this issue would be to implement regular soil testing in organic vineyards and mandate soil remediation once a toxic threshold is approached.

One method to remove toxic copper levels from the soil of vineyards uses plants and bacteria to pull the heavy metal from the soil (Mackie et al, 2012). Phytoremediation with mustard (*Brassica juncea*) can help remove toxic Cu levels from the soil (Ariyakanon and Winaipanich, 2006). There appears to be varying tolerance of crops to copper levels in the soil, suggesting that copper-tolerant crops could be rotated into place after a period of copper sulfate intensive cropping. While this would clearly not work for long-lived perennial crops like grapes, annual crops such as potatoes and melons might benefit from this type of crop rotation.

2017 NOSB Review

Copper sulfate and fixed coppers used for plant disease control (§205.601(i)(2) and §205.601(i)(3)) were reviewed in 2015 ahead of the 2017 sunset date. There was strong public support for relisting of copper materials. The NOSB made a motion to remove copper sulfate from the National List. The motion to remove failed after receiving 2 "Yes" and 12 "No" votes. - Although there was some discussion regarding the annotation, the final public comment was that the current annotation is adequate. Given the extensive use and documented need for copper sprays, the NOSB found copper sulfate compliant with OFPA criteria, and did not recommend removal from the National List.

2022 NOSB Review

Overview: Distinguishing between copper sulfate and fixed coppers seems redundant as they are used in a similar manner and are reviewed in the same TRs. In the scientific literature, they are grouped as CBACs (copper-based antimicrobial compounds). Copper sulfate contains more "free" copper ions vs. "fixed" and is therefore often combined with lime to bind the copper ions. The free copper ions contribute to its solubility in water and its higher uptake by plants.

Main Considerations in 2022 Review

- Copper compounds readily dissolve in water and are highly toxic to many aquatic organisms. They disperse quickly in water.
- Copper compounds bind to soil and tend to accumulate significantly in clay soils and with increasing soil pH. Soils with pH over 6.5 are particularly susceptible to metal toxicity from repeated application.
- Copper compounds can damage the plants they are applied to, as well as impact the appearance and taste of the crop.
- Widespread use of copper compounds has led to the evolution of copper-resistant disease varietals.
- There is a well-studied link between dysfunctional copper metabolism and Alzheimer's disease. Recent research finds a link between the epidemic of Alzheimer's disease and the agricultural use of copper for disease management in plants.
- Foliar spray of copper mixtures has long been recognized to impact lung and liver function in agricultural workers.

In December 2021, the Crops Subcommittee discussed the need for an updated technical report. Not only has ten years passed since the previous report was written, but there are also new concerns regarding human and environmental health.

The Crops Subcommittee requested a new technical report during its December 7 call. The Subcommittee requested that the new technical report highlight five areas that should be expanded and updated with the latest research; human health concerns, soil health and microbiota, application rates and accumulation in the soil, copper in the aquatic environment, and alternatives to copper-based products. We also ask that the future TR use consistent units of measurement when discussing rates of application and copper concentrations.

Questions to our Stakeholders

1. Are there organic alternatives to copper sulfate that are more suitable for use as a fungicide?
2. Are there viable practices that can be used *in situ* to offset the toxic build-up of copper in soil and water?

References

1. Ariyakanon N, Winaipanich B (2006) Phytoremediation of copper contaminated soil by *Brassica juncea* (L.) Czern and *Bidens alba* (L.) DC. var. *radiate*. J Sci Res Chula Univ 31(1):49–56
2. Buzio L, Tondel M, De Palma G, et al. (2002) Occupational risk factors for renal cell cancer. An Italian case-control study. La Medicina del Lavoro. 93(4):303-309.
3. Dagostin S, Schärer H, Pertot I, Tamm, L (2011). Are there alternatives to copper for controlling grapevine downy mildew in organic viticulture? Crop Protection. 30(7):776-788.
4. Mackie KA, Müller T, Kandeler E (2012) Remediation of copper in vineyards—a mini review. Environmental Pollution 167:16–26.
5. Van Assche F, Clijsters H (1990) Effects of metals on enzyme activity in plants. Plant Cell Environ. 13:195-206.

Polyoxin D zinc salt

Reference: §205.601(i) As plant disease control.
(11) Polyoxin D zinc salt.
Technical Report: 2012 TR; 2017 Limited Scope TR.
Petition: 2016 (Addendum #1, #2, #3).
Past NOSB Actions: 04/2018 recommendation.
Recent Regulatory Background: Added to National List on 11/22/2019 (84 FR 56673).
Sunset Date: 11/22/2024

Subcommittee Review

Use
Polyoxin D zinc salt is used as an agricultural fungicide. It has a locally systemic function, meaning that it is absorbed into surface plant tissues. It currently appears on the National List as plant disease control at 7 CFR 205.601(i). Few fungicides used in organic production are systemic, and polyoxin D zinc salt products may have greater efficacy against some plant disease organisms.

Manufacture
Polyoxin D is produced by controlled fermentation of the naturally occurring (non-GMO) soil microorganism *Streptomyces cacaoi* var. asoensis. While polyoxin D might be considered a nonsynthetic product, its chemical conversion to a zinc salt makes it synthetic. The zinc salt makes this product more useful by lessening its high water-solubility, thereby preventing the product from washing off the application area too quickly.

International Acceptance
Polyoxin D zinc salt does not appear on any of the following lists.

Canadian General Standards Board Permitted Substances List

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

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

International Federation of Organic Agriculture Movements (IFOAM) Norms

Japan Agricultural Standard (JAS) for Organic Production

Environmental Issues
The 2017 Technical Review (TR) states that polyoxin D zinc salt rapidly degrades on plant surfaces, in approximately 2-3 days, and has a half-life of 16 days in soil. The 2018 NOSB review concluded there was low environmental risk, and further that there is no concern during the manufacture, use, or disposal of polyoxin D zinc salt other than that this product should not be used nearby to, or in, water since it is moderately toxic to aquatic invertebrates and fish. The 2021 TR concurs and states "Based on the results [of numerous studies cited], polyoxin D zinc salt is presumed to carry very low environmental risk and because polyoxin D zinc salt is formed through fermentation, it is considered to be less toxic to the environment than a fungicide that was chemically manufactured such as copper, sulfur or petroleum distillates."

Polyoxin D zinc salt has a unique, non-toxic mode of action. No other active ingredient registered for use in North America has the same mode of action (FRAC Code 19). As described in the 2012 petition (page 18): "The active portion of polyoxin D zinc salt is polyoxin D which is produced by a microorganism that is naturally occurring in the soil. Polyoxin D inhibits the growth of phytopathogenic fungal cell wall chitin by competitively inhibiting chitin synthetase. Without chitin, susceptible fungi are unable to continue growing and infecting plant cells. Polyoxin D zinc salt does not kill the fungi; it simply stops the fungal growth. The action of Polyoxin D is highly specific; it does not affect bacteria, viruses, or mammals."

In response to NOSB questions of toxicity to beneficial soil fungi, honeybees, or ladybird beetles, the petitioner commissioned their own studies and found no negative effects of polyoxin D zinc salt on any of these organisms. If directly mixed with products used by organic producers containing living beneficial fungi, the fungi could be rendered ineffective.

Human Health Issues
The 2017 TR of polyoxin D zinc salt states there is very low acute toxicity to humans by oral, dermal, or inhalation routes, and it did not demonstrate mutagenic potential. There are warnings on the label about possible skin and eye irritation effects. Polyoxin D Zinc Salt is poorly absorbed with the vast majority of the product (>90%) being excreted unchanged, directly in the feces. Polyoxin D zinc salt has been in use as an antifungal agent for over 40 years in Japan on rice, without any notable, consistent, adverse human reactions being recorded. It has been approved in the USA and Mexico on food crops for over 5 and 3 years, respectively and for non-food crops in the USA for over 16 years. The direct risk to humans is considered to be extremely low.

A separate issue relates to how its agricultural use could affect anti-fungal medicines in human health. Considerable research has focused on polyoxins as less-toxic alternatives to currently available therapeutic antifungal medications in humans. These studies have led to mostly unsuccessful results, and polyoxins are not used clinically at the present time. - Polyoxin D has thus far been ineffective in therapeutic exploratory studies for potential human use against fungi, except at very high concentrations. It has shown some efficacy against yeasts, but is considered unlikely to be used as a human medicine. Thus, human pathogen resistance to polyoxin D would have little or no medical impact.

It is possible that from polyoxin D use in agriculture, cross-resistance could develop to related antibiotics such as Nikkomycin Z, currently being tested as a human anti-fungal medicine. In order for such resistance to develop, polyoxin D would need to be used widely. A human fungal pathogen would need to acquire the resistance to polyoxin D, either from direct exposure or via transfer from other resistant organisms. Finally, the pathogen's resistance to polyoxin D would need to confer resistance to the to-be-developed new medicine. This seems to be a highly unlikely chain of events.

Discussion
Based on its efficacy, low environmental impact, and low risk to human health, the Crops Subcommittee recommends renewing polyoxin D zinc salt at §205.601(i) As plant disease control.

Questions to our Stakeholders
1. Is there a concern that cross-resistance to polyoxin D could negatively affect human health?
2. Is Polyoxin D zinc salt an effective fungicide?

Humic acids

Reference: §205.601(j) As plant or soil amendments.
3) Humic acids-naturally occurring deposits, water and alkali extracts only.
Technical Report: 1996 TAP; 2006 TR; 2012 TR (oxidized lignite/humic acid derivatives).
Petition: N/A
Past NOSB Actions: 09/1996 minutes and vote; 4/2006 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset date: 10/30/2024

Subcommittee Review

Use
Humic acids can be soil-applied or foliar applied depending on the specific product. Humic acid affects soil fertility by making micronutrients more readily available to plants rather than contributing additional nutrients to the soil. According to the 2006 TR, humic substances can chelate (bind) soil nutrients, improve nutrient uptake, reduce the need for nitrogen fertilizer, remove toxins from soils, stimulate soil biological activity, solubilize minerals, improve soil structure, and improve water holding capacity.

Manufacture
According to the 2006 TR , humic substances (which include humic acids) naturally constitute a significant fraction of the organic matter in the soil and are formed through the process known as "humification." Humification is the natural conversion of organic matter into humic substances by microorganisms in the soil (Mayhew, 2004).

Commercially available humic acids are derived from leonardite, lignite, or coal. Extracts from non-synthetic humates by hydrolysis using synthetic or non-synthetic alkaline materials are permitted, including the use of sodium, potassium, or ammonium hydroxide. The TR states the process begins with separating organic matter from the inorganic matrix of sand, silt, and clay. Next, a sodium hydroxide solution creates a liquid solution (Weber, undated). The extracted liquid solution is incompatible with acids because it is very alkaline, in the range of 8 to 12 pH (Mayhew, 2004). Alkali extraction can also be conducted using potassium hydroxide, a typical alkali used by manufacturers to extract humic acid from leonardite.

International Acceptance

Canadian General Standards Board Permitted Substances List

The Canadian standards state: permitted if mined; produced through microbial activity; extracted by physical processes; or with: a) Table 4.2 Extractants; or b) potassium hydroxide—potassium hydroxide levels used in the extraction process shall not exceed the amount required for extraction. Levels (mg/kg) of arsenic, cadmium, chromium, lead and mercury shall not exceed the limits (category C1) specified in Guidelines for the Beneficial Use of Fertilizing Residuals. Shall not cause a build-up of heavy metals or micronutrients in soil.

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

Humic acid derivatives and oxidized lignite do not appear on Annex I, Fertilizers, soil conditioners and nutrients referred to in Article 3(1) and Article 6d(2) (EC, 2008). The EU requires all substances used as a fertilizer, soil conditioner or nutrient in organic production in the EU appear on that Annex (EC, 2007). However, humic acids do appear on Annex VII, Products for Cleaning and Disinfection (EC, 2008).

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

No information was identified at the listed site.

International Federation of Organic Agriculture Movements (IFOAM) Norms

Humic acid derivatives do not appear on Appendix 2: Fertilizers and Soil Conditioners. However, the use of humic acids are covered under a derogation found in §4.4.6, which reads: "Mineral fertilizers shall be applied in the form in which they are naturally composed and extracted and shall not be rendered more soluble by chemical treatment, other than addition of water and mixing with other naturally occurring, permitted inputs.

Japan Agricultural Standard (JAS) for Organic Production

The Japanese Agricultural Standard for Organic Production does not include humic acid derivatives or oxidized lignite on Table 1, Fertilizers and Soil Improvement Substances (JMAFF, 2012).

Environmental Issues

Humic acids themselves are not known to cause environmental issues. The TR states that there is no information available from EPA to suggest that environmental contamination results from their manufacture, use, misuse, or disposal. Improper disposal of acids or bases used in the extraction process could be a source of environmental contamination. The mining of lignite/leonardite or other source materials has environmental impacts.

Questions to our Stakeholders

None

Micronutrients: soluble boron products

Reference: §205.601(j) As plant or soil amendments. (7) Micronutrients—not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Micronutrient deficiency must be documented by soil or tissue testing or other documented and verifiable method as approved by the certifying agent.

(i) Soluble boron products.

Technical Report: 2010 TR (Micronutrients).

Petition: N/A

Past NOSB Actions: 04/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset

recommendation; 10/2015 sunset recommendation; 10/2015 micronutrient annotation change; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 1/28/2019 (83 FR 66559)
Sunset Date: 01/28/2024

Subcommittee Review

Use
Soluble boron is a crop micronutrient that can be soil-applied or applied foliarly. According to the technical review (TR), when compared to the other recognized plant micronutrients, boron deficiency is the most common. Every year, boron deficiency is responsible for significant crop losses, whether in volume or quality.

Soluble boron products have appeared on the National List for use as micronutrients since it was first published in 2000.

Manufacture
The TR states that all soluble boron products are derived from mined borate mineral deposits. Borate minerals can be extracted by surface mining or solution mining (Garrett, 1998).

Borax/borate salts
Refined sodium borate salts are typically produced by crushing solid borate ores and dissolving in the water alongside trona (a double salt of sodium carbonate and sodium bicarbonate), or supersaturating brine with carbon dioxide in the case of solution mining (Office of Energy Efficiency and Renewable Energy, 2002; Smith, 2000). Insoluble waste materials are filtered out of the liquor, and disodium tetraborate pentahydrate and decahydrate are selectively crystallized by temperature control and vacuum crystallization, followed by centrifugation and drying (Smith, 2000). To prevent crystallization water loss and caking, disodium tetraborate decahydrate crystals are sometimes washed with a boric acid solution that coats the crystals with a thin layer of the pentahydrate variety (Smith, 2000).

High purity borax can also be produced in a reaction between boric acid and hot sodium hydroxide (Smith, 2000). Various dehydration and rehydration methods can be utilized to selectively produce the different hydration states of disodium tetraborate (Smith, 2000). Boric acid reactions with sodium hydroxide can also be used to produce disodium octaborate tetrahydrate (Kutcel, 2001).

Boric acid
In the United States, boric acid is typically prepared by reacting naturally occurring solid sodium borate minerals with strong mineral acids like sulfuric acid (Smith, 2000). This results in a concentrated solution of boric acid and sodium sulfates, after which the boric acid is crystallized by evaporation.

International Acceptance
Canadian General Standards Board Permitted Substances List
The Canadian Organic Standards permit soluble boron products at CAN/CGSB 32.311-2020 Table 4.2, column 1, entry for Boron. Borate (boric acid), sodium tetraborate (borax and anhydrous), and sodium octaborate are permitted only when one of the following has been established:

- soil and plant deficiencies are documented by visual symptoms
- testing of soil or plant tissue demonstrates the need
- the need for a preventative application can be documented (CGSB, 2020)

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Several boron substances are allowed for soil management and fertilization by the European Union organic regulations. EC Regulation No. 889/2008 Article 3 permits the use of substances appearing in Annex I when the nutritional needs of plants cannot be met by certain preventative measures (European Parliament, Council of the European Union, 2008). Annex I permits the use of boric acid, sodium borate, calcium borate, and boron ethanolamine (European Parliament, Council of the European Union, 2003).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
The Codex guidelines include "Trace elements (e.g., boron, copper, iron, manganese, molybdenum, zinc)" in Table 1, substances for use in soil fertilizing and conditioning (FAO 2007).

International Federation of Organic Agriculture Movements (IFOAM) Norms
Boric acid, sodium borate, calcium borate, and "borethanolamin" (presumably referring to boron ethanolamine) of mineral origin are permitted as fertilizers and soil conditioners in the IFOAM NORMS, where soil or plant nutrient deficiency can be documented by soil or tissue testing or diagnosed by an independent expert. Chloride and nitrate forms are prohibited, as are micronutrients used as defoliants, herbicides, or desiccants (IFOAM Organics International, 2019).

Japan Agricultural Standard (JAS) for Organic Production
Trace elements (manganese, boron, iron, copper, zinc, molybdenum, and chlorine) are permitted by the Japanese Agricultural Standard for Organic Plants as fertilizers and soil improvement substances if a crop cannot grow normally because of a micronutrient shortage (MAFF, 2017).

Environmental Issues
Mining the original base material could cause an environmental impact. In addition, the TR states that sulfuric acid is used as a reactant to make boric acid from colemanite, and calcium sulfate is sometimes produced as a by-product. This results in a significant waste stream and can have environmental consequences related to the build-up of industrial waste. Wastewater discharge is also a source of boron pollution since boron appears in some soaps and washing chemicals

Discussion
The Crops Subcommittee reviewed soluble boron products and the role they can play in crop development. Also reviewed were the ways that organic producers demonstrate deficiency.

Questions to our Stakeholders
None

Micronutrients: sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt

Reference: §205.601(j) As plant or soil amendments. (7) Micronutrients—not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Micronutrient deficiency must be documented by soil or tissue testing or other documented and verifiable method as approved by the certifying agent.

> (ii) Sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt.

Technical Report: 2010 TR (Micronutrients).
Petition: N/A
Past NOSB Actions: 04/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset

recommendation; 10/2015 annotation change recommendation; 10/2015 sunset recommendation; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 1/28/2019 (83 FR 66559)
Sunset Date: 01/28/2024

Subcommittee Review

Use
Micronutrients are essential for plant growth and are used across all types of crop production, but are typically required in very small quantities. Although some forms of micronutrients are found naturally in the soil, many producers find deficiencies of some or all of the micronutrients on the National List. These deficiencies can be a limiting factor in water and macro-nutrient uptake, and can result in limited growth and vitality of crops.

Manufacture
Plant micronutrients at this listing are made up of both compounds and natural minerals. After physical processing such as breaking and grinding, these natural minerals might be used as micronutrients in agriculture. Many commercial micronutrients are manufactured as by-products or intermediate products of metal mining and processing industries.

International Acceptance
Canadian General Standards Board Permitted Substances List
The Canadian Organic Production Systems Permitted Substances List permits micronutrients with a similar annotation to the USDA.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
European organic regulations do not reference micronutrients.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
CODEX does not reference micronutrients.

International Federation of Organic Agriculture Movements (IFOAM) Norms
Micronutrient use is restricted to cases where soil/plant nutrient deficiency is documented by soil or tissue testing or diagnosed by an independent expert. Micronutrients in either chloride or nitrate forms are prohibited. Micronutrients may not be used as a defoliant, herbicide, or desiccant.

Japan Agricultural Standard (JAS) for Organic Production
JAS does not reference micronutrients.

Environmental Issues
Simple inorganic compounds such as Co, Cu, Fe, Mn, Mo, Se, and Zn, are found naturally in soil. Applied micronutrients are not expected to be significantly different from naturally occurring compounds in terms of concentration and physiological activity, when the applied under set limits. Micronutrients are “heavy metals”, but the annotation prevents contamination by restricting its use to correct a deficiency.

Discussion
The Crops Subcommittee supports renewing micronutrients.

Questions to our Stakeholders:
None

Vitamins C, E

Reference: §205.601(j) As plant or soil amendments.
(9) Vitamins C, and E.
Technical Report: 1995 TAP; 2015 TR.
Petition: N/A
Past NOSB Actions: 10/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 11/2017 sunset recommendation (relist C and E, remove B_1).
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset date: 10/30/2024

Subcommittee Review

Use
Vitamins, including synthetically derived C (ascorbic acid) and E (tocopherols), are generally considered non-toxic essential nutrients for terrestrial and aquatic organisms. Vitamins C and E are used to promote both growth and yields and to protect plants from oxidative stress due to salinity. During the previous sunset review (11/2017), vitamin B1 (thiamine) – which had been previously paired with the other two vitamins on the National List – was recommended for removal from the list on the basis that foliar and soil applications of the material did not stimulate root growth in transplanted crops. Rulemaking to remove B1 is in progress.

A TR was completed on these materials in 2015. It did, however, lack practical information regarding the use of Vitamins C and E, and thus relied on peer-reviewed scientific literature.

Manufacture
Although Vitamins C and E are naturally occurring in commonly consumed foods, they are typically derived for commercial use from laboratory processes.

International Acceptance
Canadian General Standards Board Permitted Substances List
Vitamin C is listed for crop production; Vitamin E is not.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Neither substance is listed.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
Neither substance is listed.

International Federation of Organic Agriculture Movements (IFOAM) Norms
Neither substance is listed.

Japan Agricultural Standard (JAS) for Organic Production
Neither substance is listed.

Environmental Issues
It is unclear whether there are particular environmental concerns regarding the manufacture and use of Vitamins C and E for these purposes.

Discussion
The subcommittee had a general discussion of the historical review of these substances, including the recommendation to remove vitamin B1 from this listing. Notably, the vitamin B1 removal is in rulemaking and slated for near-term completion.

Questions to our Stakeholders
1. Do vitamins C and E provide essential functions in organic crop production?

Squid byproducts

Reference: §205.601(j) As plant or soil amendments.
(10) Squid byproducts—from food waste processing only. Can be pH adjusted with sulfuric, citric, or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5.
Technical Report: 2016 TR.
Petition: 2015 (Amendment #1).
Past NOSB Actions: 04/2016 recommendation.
Recent Regulatory Background: Added to National List on 01/28/2019 (83 FR 66559).
Sunset Date: 01/28/2024

Subcommittee Review

Background
Squid are invertebrates classified into the phylum Mollusca, class Cephalopoda and order Loligo (later renamed Doryteuthis). There are an estimated 300 squid species known throughout the world. Common to the northeastern Atlantic coast is the longfin squid, species *Doryteuthis (Loligo) pealli*. Common to the US west coast is the market squid, species *Doryteuthis (Loligo) opalescens*. The use of squid and squid byproducts in agriculture dates back to the 1800's when much of the product was shipped from California market squid fisheries to Asian countries for consumption and fertilizer applications.

Use
Squid and squid byproducts are the starting ingredients in the production of enzymatically produced hydrolysates with N-P-K values ranging from 2-2-2 to 3.3-7.3-2 or more. Seafood derived hydrolysates, including squid and squid byproducts, have been used both as foliar sprays and soil amendments for propagating cranberries, cherries, and apples.

Manufacture
Squid byproducts make up 52% of the total body weight and include the squid ink, pen, skin, milt, liver, and viscera, which are typically discarded as waste. In general, squid byproducts are chopped, heated, digested with natural enzymes, and stabilized with an acid such as phosphoric, sulfuric, or citric acid to prevent

microbial growth.

International Acceptance

Canadian General Standards Board Permitted Substances List

The Canadian Organic Standard allows for the use of fish products; in Canadian fisheries, the definition of fish includes marine invertebrates such as squid.

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

The EU Organic Standard allows the use of molluscan (squid) products from sustainable fisheries and may be used in organic production of feeds for non- herbivores; squid products are not explicitly authorized for use in organic production.

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

CODEX does not reference squid byproducts.

International Federation of Organic Agriculture Movements (IFOAM) Norms

IFOAM permits the use of fish and shell products and food processing of animal origin.

Japan Agricultural Standard (JAS) for Organic Production

The Japanese Organic Standard permits the use of food industry byproducts of fish origin if they are derived from natural sources; mollusks (squid) are included in Japanese fisheries.

Environmental Issues

Squid are commercially harvested using nets directly above spawning grounds during mating season primarily for calamari. Fisherman target spawning squid because they die shortly after reproduction. There are two main squid fisheries in the US including along the Atlantic coast for long-finned squid and along the Pacific coast for market squid. The US Pacific squid fishery is managed by the California Department of Fish and Game, the National Oceanographic and Atmospheric Administration (NOAA) Fisheries, and the Pacific Fishery Management Council. Atlantic squid are managed in federal waters by NOAA Fisheries in conjunction with the Mid-Atlantic Fishery Management Council. Management includes seasonal catch limits, timed fishery closures, administration of permit issuance, and limitations on using lights to attract squid to ensure uninterrupted spawning.

Discussion

The manufacturing and use of squid byproducts has little to no environmental impact or human health concerns and provides organic growers with another nitrogen source.

Questions to our Stakeholders

None

Lead salts

Reference: §205.602(d) Lead salts.
Technical Report: N/A
Petition: N/A
Past NOSB Actions: 04/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 11/2017 sunset recommendation.

Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset date: 10/30/2024

Subcommittee Review

Use
Lead salts are used as both pesticides and herbicides.

Manufacture
Lead salts are usually produced using the following reaction, which leads to formation of the desired product as a solid precipitate:

$$Pb(NO_3)_2 + H_3AsO_4 \rightarrow PbHAsO_4 + 2\ HNO_3$$

International Acceptance
None found

Environmental Issues
Lead poisoning can cause a number of adverse human health effects but is particularly detrimental to the neurological development of children. Lead accumulates in soils, so it is important to avoid soil applications of materials containing lead, whether the lead is in synthetic materials or naturally occurring (nonsynthetic) lead salts. Notably, the CDC has found that there is no safe level of lead exposure and in 2021 lowered the reference level from 5 ug/dl to 3.5 ug/dl.

Discussion
Public comments received in previous sunset reviews were and are in favor of keeping lead salts on the list of nonsynthetic substances prohibited for use in organic crop production.

The NOSB Crops Subcommittee also supports keeping lead salts in its prohibited status on the National List and will vote on the proposal at the Fall 2022 meeting.

Questions to our Stakeholders
None

Tobacco dust (nicotine sulfate)

Reference: §205.602(j) Tobacco dust (nicotine sulfate).
Technical Report: N/A
Petition: N/A
Past NOSB Actions: 04/1995 minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 11/2017 sunset recommendation.
Recent Regulatory Background: Sunset renewal notice effective 3/15/2017 (82 FR 14420). Sunset renewal notice effective 10/30/2019 (84 FR 53577)
Sunset date: 10/30/2024

Subcommittee Review

Use
Nicotine is a natural insecticide produced as a secondary metabolite in tobacco. Tobacco dust can be used in agriculture for pest control.

Manufacture
Tobacco dust is a by-product of agro-industrial waste from the commercial processing of tobacco products. It was noted during a previous review that tobacco dust is no longer commercially available as a crop pest control product, however it could still be homemade by mixing tobacco with water.

International Acceptance
Canadian General Standards Board Permitted Substances List
There is no reference to tobacco dust.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
There is no reference to tobacco dust.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
There is no reference to tobacco dust.

International Federation of Organic Agriculture Movements (IFOAM) Norms
There is no reference to tobacco dust.

Japan Agricultural Standard (JAS) for Organic Production
There is no reference to tobacco dust.

Environmental Issues
Present on the Occupational Safety and Health Administration Hazardous Substance list and regulated by the Environmental Protection Agency (EPA) as a pesticide.

Discussion
According to the previous NOSB Review: Tobacco dust (nicotine sulfate), has been present on the National List as a prohibited substance since the inception of the USDA organic regulations. Due to the negative human health effects caused by this material, it has been relisted as a prohibited nonsynthetic on the National List at every sunset with no objections from the public or from the NOSB. It is present on the Hazardous Substance list and regulated by OSHA and the EPA as well as other agencies.

Previous public comments indicated that certifiers, businesses, and public interest organizations agree that tobacco dust should remain listed as a prohibited nonsynthetic. The Crops Subcommittee supports keeping tobacco dust on the National List at §205.602.

Questions to our Stakeholders
None

National Organic Standards Board
Policy Development Subcommittee Proposal
Policy and Procedures Manual (PPM) Revision
January 19, 2022

Introduction and Background

The Policy and Procedures Manual (PPM) was established to assist the National Organic Standards Board (NOSB) in the implementation of its duties under OFPA. It contains operating procedures and policies for the NOSB. During the period since the last revision (October 2019), 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.

Summary Table of Changes

Section/Page	Changes (red highlight indicates additions, strikethrough indicates deletions)
VIII. E Page 33	Made minor clerical changes for clarity. Added a sentence requiring written commenters to refrain from personal attacks. Removed a redundant header "Oral Comments".

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.~~ Individuals are encouraged to submit written comments and may also present oral comment at either a pre-meeting electronic webinar or at the in-person NOSB meeting.

Comments 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.

Commenters shall refrain from including personal attacks or remarks that might impugn the character of any individual.

Oral Comments
~~Oral comments:~~ Individuals may present oral comment at either a pre-meeting electronic webinar or at the in-person NOSB meeting. ~~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.

Motion to accept the proposal on the PPM update to the public comment process
Motion by: Mindee Jeffery
Seconded by: Jerry D'Amore
Yes: 3 No: 0 Abstain: 0 Absent: 0 Recuse: 0