National Organic Standards Board Meeting
October 15 & 17 (Comment webinars), and October 22 – 24, 2024 (NOSB meeting - Portland, OR)

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.

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National Organic Standards Board
Livestock Subcommittee Petitioned Material Proposal
Meloxicam
August 19, 2024

Summary of Petition:
In February 2024, the NOP received a petition to add meloxicam to the National List of synthetic substances allowed for use in organic livestock production 7 CFR 205.603.

Summary of Review:
Understanding the consistent need for high animal welfare standards, the Livestock Subcommittee (LS) promptly evaluated the petition for meloxicam. As it was presented in a format, not by manufacturers, but a wide swath of industry experts and stakeholders, the call for additional tools to alleviate animal pain in organic production was heard! Capitalizing on current expertise on the Livestock Subcommittee, LS allocated significant human capital to reviewing this petition while also upholding the standards of thorough, professional review.

Use:
Meloxicam is highly effective in treating acute pain from various veterinary procedures, including disbudding, debudding, dehorning, castration, or surgery, as well as managing chronic pain from conditions like lameness, arthritis, and other musculoskeletal issues. Meloxicam offers a prolonged therapeutic effect (half-life) within the animal's system, which often means a single dose is sufficient for acute cases, thereby enhancing the animal's welfare compared to other pain management drugs listed on the National List (NL). Available in oral tablet form with an extended half-life in tissues, meloxicam ensures longer intervals between treatments, making pain management easier and more efficient. This not only benefits the animal's well-being but also minimizes potential harm to the environment and the farm ecosystem.

Manufacture:
This petition is submitted by certified organic livestock producers and supporters who believe that adding meloxicam to the NL benefits organic producers, the livestock they care for, and the organic industry overall. No manufacturers were involved in or contributed to the creation of this petition. Consequently, the manufacturing information provided here is compiled from extensive online research, including sources such as the United States Food and Drug Administration (FDA), the United States National Institute of Health (NIH), the Chemistry Book, Merck Index, various scientific journals, and interviews. We cannot confirm that this information precisely describes the precursor and manufacturing process for any specific manufacturer of this generic drug.

Precursor substances
Benzothiazolo-3(2H)-one-1,1-dioxide and methyl chloroacetate.

Manufacturing process
Reaction of benzothiazolo-3(2H)-one-1,1-dioxide with methyl chloroacetate gives the methyl 2(3H)-acetate derivative, which is isomerized with sodium methoxide in toluene-tert-butanol yielding methyl 4-hydroxy-2H-1,2-benzothiazine-3-carboxylate-1,1-dioxide. Subsequent methylation with methyl iodide in methanol yields the 2-methyl compound. Finally, this compound is treated with 2-amino-5-methylthiazole in xylene. From: Ullmann's Encyclopedia of Industrial Chemistry. 6th ed. Vol 1: Federal Republic of Germany: Wiley-VCH Verlag GmbH & Co. 2003 to Present, p. V3 51 (2003). The FDA and NIH documents we were able to review regarding Meloxicam listed Benzothiazolo3(2H)-one-1,1-dioxide as a

precursor but a link to this substance was not provided, as it was to the other precursor and the intermediary substances in the manufacturing process.

Methyl chloroacetate (CAS 96-34-4)
According to Chemical Book, Methyl chloroacetate is prepared by esterification of chloroacetic acid with methanol. “Methanol and chloroacetic acid are uniformly mixed in a weight ratio of 0.366:1, heated with stirring, and the esterification reaction is carried out at 105-110 °C. In the reaction process, the ternary azeotrope of methyl chloroacetate, water and methanol is continuously steamed, layered through the ester separator, the separated methanol and water are returned to the reaction pot, and the separated crude ester is made of sodium carbonate. neutralize. The neutralized crude ester is firstly cut out the 130°C fraction by atmospheric distillation, and then subjected to vacuum distillation to collect the 65°C (8kPa) fraction, which is the finished product of methyl chloroacetate. The yield is about 96%.”

Excluded Methods
The manufacturing process of meloxicam is a chemical formulation and does not involve the potential use of excluded methods.

International Acceptance:

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed under veterinary supervision as per CGSB-32.311-2020, Table 5.3 Health Care products and production aids: Anti-inflammatories – Non-steroid anti-inflammatories such as ketoprofen. Preference shall be given to alternative products, such as those listed in Table 5.3, Botanical compounds; and Homeopathy and biotherapies.

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Allowed under veterinary supervision (EU) 2018/848 Annex II.1.5.2.2 states that “disease shall be treated immediately to avoid suffering to the animal. Chemically synthesized allopathic veterinary medicinal products, including antibiotics, may be used where necessary, under strict conditions and under the responsibility of a veterinarian, where the use of phytotherapeutic, homeopathic and other products is inappropriate. Where appropriate, restrictions with respect to courses of treatment and withdrawal periods shall be defined.”

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
While meloxicam is not specifically listed, the standard states that when veterinary drugs are used, the withholding period shall be twice the period of conventional standards.

International Federation of Organic Agriculture Movements (IFOAM)
While meloxicam is not specifically listed, the general principles state management practices should be directed to the well-being of animals, achieving maximum resistance against disease and preventing infections. Sick and injured animals must be given prompt and adequate treatment. Further, the standards note the well-being of the animals is the primary consideration in the choice of illness treatment. The use of conventional veterinary medicines is allowed when no other justifiable alternative is available. Withdrawal periods shall not be less than double of that required by legislation.

Japan Agricultural Standard (JAS) for Organic Production

While meloxicam is not specifically listed, the standard states that when veterinary drugs are used, the withholding period shall be twice the period of conventional standards.

Environmental Issues:

Environmental impact review of the National Library of Medicine, including the Hazardous Substances Data Bank (HSDB) revealed no generated environmental impact concerns from the manufacturing process, nor have any of the references noted in this petition suggested any such concerns. Additionally, the FDA rendered a decision through its review and approval process of meloxicam as an animal medication: "The agency has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required."

Ancillary Substances:

Meloxicam for oral use was patented in the US in 2005 but is now beyond its patent protection period. As the drug is produced and sold by various manufacturers in generic form, compiling a complete list of all possible ancillary substances, carriers, and excipients is impractical. Nevertheless, a typical list of excipients has been identified, and a link to this list is provided below. However, due to the numerous manufacturing sources, the list might not be exhaustive.

Carriers/excipients

The excipients include lactose monohydrate, microcrystalline cellulose, sodium citrate, crospovidone, povidone, colloidal anhydrous silica and magnesium stearate. (Meloxicam Aurobindo 7.5 mg and 15 mg, tablets Aurobindo Pharma B.V., the Netherlands. PUBLIC ASSESSMENT REPORT of the Medicines Evaluation Board in the Netherlands. 10 January 2013).

Subcommittee Review:

The subcommittee as a whole evaluated this material over the course of multiple meetings. Conducting a thorough review across all areas of consideration, the subcommittee found no concerns with this material and propose that it be added to the national list of approved synthetic materials.

Category 1: Classification

1. Substance is for: **_____Handling __X_ 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:

    b. If the substance is **non-agricultural**, is the substance **____Non-synthetic** or **__X__ Synthetic?**

    c. 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:

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)]
Meloxicam is a nonsteroidal anti-inflammatory drug (NSAID) pain relief anti-inflammatory medication. NSAID medications can result in adverse side effects such as indigestion, stomach ulcers, headaches, drowsiness, dizziness, and allergic reactions and in rare cases problems with the liver, kidney, or heart. Meloxicam combined with other NSAIDs, and possibly other related compounds could increase the risk of these adverse effects. In the case of organic livestock production these products would include aspirin or possibly natural remedies of Salicylates such as white willow bark.

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)]?
Doses greater than 5 times the therapeutic dose can result in toxicity. Chronic use in some animals may cause toxicity. Signs and symptoms of toxicity include "vomiting, abdominal pain, melena (black, tarry stool), and diarrhea." In the animal, after the drug has been administered, Meloxicam is metabolized to four biologically inactive metabolites and excreted in the feces and urine, suggesting that no untoward residual environmental concerns are likely to arise from this pathway.

3. Describe the probability of environmental contamination during manufacture, use, misuse or disposal of such substance? [§6518(m)(3)]
The environmental persistence is unlikely but in the rare case would be primarily from improperly disposed of product, as is true for most medications targeting human or animal use. After the drug has been administered to the animal, meloxicam is metabolized to four biologically inactive metabolites and excreted in the feces and urine. The consensus of available information is that with labeled use, no untoward impacts on the environment are to be expected.

4. Discuss the effect of the substance on human health. [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)].
Meloxicam is an approved drug for human use. It is available by prescription and not available over the counter. Meloxicam should be taken according to the recommendation of a patient's physician.

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)].
Meloxicam is metabolized to four biologically inactive metabolites and excreted in feces and urine. There are no known effects on soil organisms, crops, or livestock.

6. Are there any adverse impacts on biodiversity (§205.200)?
There are no reported adverse impacts on biodiversity. Meloxicam is an approved drug for humans and dogs. Meloxicam is a drug allowed for use in other livestock species in the US according to FDA regulations established under Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA).

<u>Category 3: Alternatives/Compatibility</u>
Below are the alternatives for pain management in livestock approved on the National List, or other natural remedies:

Flunixin (injectable and pour-on)
Flunixin injectable is approved only for intravenous use in cattle, and it can cause severe tissue reactions, leading to unpredictable drug withdrawal times or serious complications like abscesses and

clostridial infections. The pour-on version of Flunixin is easier to apply but requires careful handling to prevent absorption by the people administering it.

Aspirin (oral)
Aspirin, which is easy to give orally in pill form, is quickly metabolized in cattle, offering only up to six hours of pain relief per dose.

Other Remedies
Natural remedies, home remedies, and herbal tinctures often provide inconsistent and short-lived pain relief according to scientific studies. A 2022 study in the Journal of Dairy Science concluded that white willow bark is ineffective for pain relief in calves. Similarly, a 2021 study in Translational Animal Science found that herbal treatments given orally did not adequately manage acute pain in disbudded dairy calves and suggested that additional analgesics might be necessary.

Veterinarians are unlikely to use natural brand-name and home herbal tinctures, as they are not generally accepted as effective pain management methods under most dairy animal welfare programs.

Classification Motion:
Motion to classify meloxicam as synthetic
Motion by: Nate Powell-Palm
Seconded by: Kim Huseman
Yes: 5 No: 0 Abstain: 0 Recuse: 0 Absent: 0

National List Motion:
Motion to add meloxicam (CAS #-71125-38-7) at §205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.

> In accordance with approved labeling for organic livestock; Also, for use under 7 CFR part 205, the NOP requires:
>
> (i) Use by or on the lawful written order of a licensed veterinarian; and
>
> (ii) A meat withdrawal period of at least two-times that required by the FDA

Motion by: Kim Huseman
Seconded by: Nate Powell-Palm
Yes: 5 No: 0 Abstain: 0 Recuse: 0 Absent: 0

National Organic Standards Board
Livestock Subcommittee Proposal
DL-Methionine, DL-Methionine - hydroxy analog, DL-Methionine - Hydroxy analog calcium
Annotation Change
August 6, 2024

Summary of NOSB Activity:
Methionine is an essential sulfur-containing amino acid used in organic poultry rations. It was first allowed in organic poultry rations when its National List reference became effective on November 3, 2003. Since that time, methionine garnered scrutiny through NOSB reviews, petitions to amend annotations, and stakeholder comments. A full documentation of its NOSB and regulatory history can be found in the Petitioned Substances Index. Methionine is undergoing its five-year sunset review, and the Livestock Subcommittee (LS) is not recommending its removal, however, the LS is scrutinizing the current annotation and evaluating whether the impacts of this annotation on organic poultry flocks align with organic principles and the goals of encouraging natural alternatives.

Summary of Review:
At NOSB's Spring 2024 meeting in Milwaukee, WI, a majority of public commenters expressed the opinion that methionine remained necessary in organic poultry production and that natural alternatives were still not ready to replace methionine. A small minority of commenters recommended removal from the National List. The NOSB also posed the following question to stakeholders:

> *"Is the current restriction on methionine in organic poultry diets necessary? What would the impact be on poultry nutrition and feed formulations if methionine was allowed without any restrictions?"*

LS has discussed the merits of the current listing, and the comments from the Spring meeting, and we are proposing to amend the annotation for methionine to eliminate the inclusion limits based on poultry breed.

Effects of Current Annotation:
The current annotation on DL-methionine limits inclusion rates of the substance to 2 pounds per ton (2lbs/ton) of feed for laying hens, 2.5 pounds per ton (2.5lbs/ton) of feed for broiler chickens, and 3 pounds per ton (3lbs/ton) of feed for turkeys and all other poultry. The annotation also allows for this inclusion limit to be averaged over the lifetime of the flock, so that producers can feed more than the limit when necessary at certain times of the birds' lifecycles provided they are balanced with less than the limit at other times during the lifecycle. The goal of this "averaging" is to honor the caps on inclusion rate while recognizing that poultry need different amounts of methionine based on phase of life.

Requiring organic poultry producers to limit the amount of methionine in organic rations has a number of impacts:

1. **Increased reliance on soybean meal and high protein levels.** Since the limits on methionine in the current annotation are still below widely accepted minimum poultry nutrition requirements, organic producers must make up for that deficiency by increasing the amount of feed ingredients known to be high in methionine, like soybean meal. Impacts of this practice can include feeding crude protein at higher than ideal levels which can, in turn, increase ammonia concentrations in poultry housing and create manure management challenges.

2. **Higher mortality and morbidity.** Since the numerical limits for methionine are less than what poultry need for adequate nutrition, organic poultry feeds are often deficient in these essential amino acids. Acute methionine deficiency expresses itself in poultry with nervousness, feather picking, cannibalism, and sudden death. These symptoms are relieved, somewhat, by allowing producers to average methionine rates over the lifetime of the flock, but this approach is not always attainable to producers who have less visibility into their feed ration formulas. In addition, even with the ability to average over the lifetime of the flock, rations for broilers and turkeys for meat are often providing less methionine than is recommended by poultry nutritionists, which can impact these animals' muscle, organ, and feather development. Any impacts to these critical bodily systems in poultry can have negative affects on health and make poultry more susceptible to disease.
3. **Lower production.** A number of commenters at our Spring 2024 meeting noted that the limit on methionine can reduce productivity of laying hens by as much as 10%. NOSB concurs with poultry nutritionists who do not consider methionine to be a growth promoter or production stimulator, so we conclude that reduced production resulting from limiting methionine is likely due to inadequate nutrition. Eliminating limits on methionine would allow for more balanced nutrition, and poultry thriving on balanced rations will likely support increased productivity.

Allowing producers to average methionine inclusion rates over the lifetime of the flock eases the health impacts of strict methionine limits somewhat for some producers. A bird's metabolic demand for methionine ebbs and flows over its lifetime, and the current annotation recognizes this reality and provides a mechanism to accommodate it. Some producers can utilize this regulatory flexibility and are "making it work" for their flocks. Other producers, however, who do not have full control over each specific poultry ration throughout the lifetime of the flock may not be able to increase methionine when it is needed due to recordkeeping burdens or simply not knowing how much methionine is included in their purchased feed. One certifier commenting in the spring indicated that requiring producers to produce records to average methionine over the lifetime of the flock was burdensome to producers and inspectors.

Rationale for Removing Methionine Restrictions:
LS is proposing to amend the annotation for methionine to remove the inclusion rate limits. These limits can prevent producers from providing adequate nutrition to their flocks which has serious health impacts on organic poultry, does not align with our largest trading partners, Canada and the EU, and does not appear to have hastened the development of natural alternatives.

<u>Health Impacts</u>
The organic regulations require that organic producers provide livestock and poultry with *"…a feed ration sufficient to meet nutritional requirements of the animal, including vitamins, minerals, proteins and or amino acids, fatty acids, energy sources, and fiber (ruminants)."* [7 CFR 205.238(a)(2)].

It is clear to the LS based on public comments that the limits to methionine in the current annotation, even if allowed to be averaged over the lifetime of the flock, needlessly hamper organic producers' ability to meet this requirement of the organic regulation. Since most of the avian health impacts of a methionine deficient diet can be prevented with an adequate ration and a widespread acceptance that organic regulations should convey a baseline animal welfare guarantee, LS is prioritizing bird health in our recommendation to remove the inclusion rate limits on methionine.

International Regulation Harmonization

LS recognizes that Canada's organic regulations allow synthetic forms of both methionine and lysine for monogastric livestock (poultry, swine) when natural forms of amino acids derived through fermentation or organic sources (like fishmeal, insect meal, or brewer's yeast) do not meet amino acid requirements to produce a balanced feed.

We also acknowledge that while the European organic regulations specifically prohibit synthetic amino acids, their feed formulation regulation allows for a certain amount of non-organic feed to be included. Many rations compliant with EU organic regulations will rely on highly processed feed ingredients (like corn gluten meal) to supply the required amount of methionine necessary for proper bird health. These ingredients are typically not available to organic producers certified to the USDA standards because they require processing aids like strong synthetic acids that are not allowed in organic processing.

Both Canada and the EU recognize that methionine is essential in poultry production and allow producers the flexibility they need to feed their flocks balanced rations that promote healthy flocks. Eliminating the limits on methionine in organic poultry production certified under USDA organic regulations would align more with our trading partners, and as natural alternatives become more available, future boards could consider an approach similar to Canada's, which applies commercial availability as an incentive to choose natural substances, but ultimately allows farmers to provide balanced feeds when necessary.

Natural Alternatives

One of the justifications for limiting the amount of methionine in organic poultry rations is the assumption that the limitation itself would hasten the pace of development and adoption of a natural alternative to synthetic methionine. Methionine was first added to the National List in 2003, and since that time it has been annotated with either an expiration date or an arbitrary inclusion limit in organic poultry rations.

Over this period, the organic industry has explored various methionine alternatives; none of which have developed into feed ingredients that are widely available to producers, adequately address methionine needs in poultry rations, are acceptable feed ingredients to consumers, and are defined by the Association of American Feed Control Officials (AAFCO).

There appears to be promise in a number of methionine alternatives including insects, fish, and fermentation products, but none are ready for widespread adoption and scaling necessary for acceptance by producers. It does not appear as though the pressure put on the industry by either an expiration date annotation or a step-down limit on methionine inclusion in feed has had much effect on the pace at which the natural alternatives are developed.

As we recognize that limits on methionine do have negative effects on poultry health, we must question whether the limits are justified and effective in achieving the goal of moving towards organic and natural methionine alternatives.

Conclusion:

The Livestock Subcommittee is proposing to remove the annotation for DL-Methionine because these limits have a negative impact on organic poultry health. We understand the preference by many stakeholders to prioritize organic and natural alternatives to synthetic amino acids, however, we are not comfortable prioritizing this preference over bird health.

We also understand that annotations, making it harder to rely on a particular substance, can push producers to innovate and adopt alternatives, but it does not appear that annotations have significantly hastened the pace of alternative development in the case of methionine. Nor does it appear that a natural alternative is going to be available imminently to replace synthetic methionine. Therefore, we propose removing the annotation for methionine, thereby removing the limitation of methionine in organic poultry rations.

Subcommittee Vote:
Motion to amend the annotation of DL-Methionine on the National List at 7 CFR 205.603(d)(1) as follows:

§ 205.603(d) As feed additives.
(1) DL-Methionine, DL-Methionine—hydroxy analog, and DL-Methionine—hydroxy analog calcium (CAS #'s 59-51-8, 583-91-5, 4857-44-7, and 922-50-9)—for use only in organic poultry production ~~at the following pounds of synthetic 100 percent methionine per ton of feed in the diet, maximum rates as averaged per ton of feed over the life of the flock: Laying chickens—2 pounds; broiler chickens—2.5 pounds; turkeys and all other poultry—3 pounds.~~

Motion by: Nate Lewis
Seconded by: Kim Huseman
Yes: 4 No: 0 Abstain: 0 Recuse: 0 Absent: 1

National Organic Standards Board
Livestock Subcommittee
Iodine Annotation Change
June 4, 2024

Summary of Review:
The National Organic Standards Board (NOSB) acknowledges that iodine sanitizers remain necessary to livestock operations as a sanitizer for medical procedures as well as for topical use, particularly as a teat dip for dairy animals. The NOSB has also heard from numerous stakeholders that it is time to ensure that iodine products used on organic farms are free from nonylphenol ethoxylates (NPEs). The Livestock Subcommittee (LS) requested a limited scope technical report (TR) in 2024 to evaluate the availability of NPE-free iodine products and their suitability, the potential for NPEs contained in iodine products to contaminate organic products and the environment, and what detrimental effects may occur should NPEs enter the supply chain or be applied to soil.

At the NOSB's Spring 2024 meeting, the LS requested comments from stakeholders about a potential annotation change to prohibit NPEs in iodine products. Commenters generally expressed support for the phase-out of iodine formulas that contain NPEs. Environmental groups applauded the idea that organic farmers would lead the way in removal of these harmful substances from their organic system plans (OSPs). Certifiers and Materials Review Organizations (MROs) indicated that there are numerous formulations available on the market and approved for use in OSPs that do not contain NPEs. Organic dairy producers indicated support for the additional restriction, as it would better minimize impact to the environment while continuing to provide options for iodine products. Commenters suggested that the annotation prohibiting NPEs include language that clearly prohibits all alkylphenol ethoxylates. LS agrees with these commenters and is proposing an annotation change to prohibit alkylphenol ethoxylates.

Subcommittee Vote:
Motion to amend the listing for iodine at 205.603(a)(16) and 205.603(b)(4) as follows:

> Iodine<u>, must be produced without the use of alkylphenol ethoxylates.</u>

Motion by: Nate Lewis
Seconded by: Franklin Quarcoo
Yes: 4 No: 0 Abstain: 0 Recuse: 0 Absent: 1

Sunset 2026
Meeting 2 - Reviews
Livestock Substances § 205.603 & § 205.604
October 2024

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 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. Substances included in this document may also be viewed in the NOP's Petitioned Substances Index.

Request for Comments
Written comments should be submitted via Regulations.gov at www.regulations.gov on or before September 30, 2024, as explained in the meeting notice published in the Federal Register.

Public 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 Substances in Organic Production at § 205.603:
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 Substances in Organic Production at § 205.603:
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 at § 205.604, 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 Substances in Organic Production at § 205.604:
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 at § 205.604 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 September 30, 2024 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:

Atropine
Hydrogen peroxide
Iodine (a)(16)
Iodine (b)(4)
Magnesium sulfate
Fenbendazole
Moxidectin
Peroxyacetic/peracetic acid
Tolazoline
Xylazine

Oxalic acid dihydrate
DL-methionine
Trace minerals
Vitamins

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

None

Atropine

Reference: § 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.

(3) Atropine (CAS #-51-55-8)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires:

(i) Use by or on the lawful written order of a licensed veterinarian; and

(ii) A meat withdrawal period of at least 56 days after administering to livestock intended for slaughter; and a milk discard period of at least 12 days after administering to dairy animals.

Technical Report: 2002 TAP; 2019 TR

Petition(s): 2002

Past NOSB Actions: 05/2003 sunset recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)

Sunset Date: 9/12/2026

Subcommittee Review

Use

Atropine is a naturally occurring alkaloid (a nitrogen-containing molecule that is produced in plants and is physiologically active) produced by the plants in the nightshade family (EFSA 2008, Timberlake 2015). Atropine is primarily isolated from *Atropa belladonna* (also known as deadly nightshade) and is a component in both human and veterinary medicines for a range of treatments. Although, it is most widely used in both human and veterinary practices as a treatment for organophosphate poisoning. [2019 TR 35-39]

Atropine is currently allowed by the United States Department of Agriculture (USDA) organic regulations as a medical treatment for organic livestock production (7 CFR 205.603(a)). USDA organic regulations restrict atropine to "use by or on the lawful written or oral order of a licensed veterinarian," and it must be followed by "a meat withdrawal period of at least 56 days after administering to livestock intended for slaughter; and a milk discard period of at least 12 days after administering to dairy animals. [2019 TR 24-28]

Manufacture

Atropine is a naturally occurring alkaloid (a nitrogen-containing molecule that is produced in plants and is physiologically active) produced by plants in the nightshade family (EFSA 2008, Timberlake 2015). The primary source of atropine is accessed by extraction from *Atropa belladonna*, which yields the racemic mixture of (+)-hyoscyamine and (-)-hyoscyamine (atropine) (Figure 1). Atropine may also be synthesized in an acid-catalyzed esterification reaction in between tropine and tropic acid, although the primary source of atropine is from plant extracts (PubChem 174174, Karkee 1980, Merck 2001, USDA 2002, EFSA 2008). [2019 TR 51-56]

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

Allowed as a health care product and production aid. Botanical preparations (such as atropine, butorphanol, and other medicines from herbaceous plants) shall be used according to label specifications. Substances containing petroleum-derived formulants (such as propylene glycol) shall not be fed to livestock. (Table 5.3, Botanical compounds listing, CAN/CGSB-32.311-2020, page 26)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Not explicitly mentioned.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Not explicitly mentioned

International Federation of Organic Agriculture Movements (IFOAM)
Not explicitly mentioned

Japan Agricultural Standard (JAS) for Organic Production
Not explicitly mentioned

Ancillary Substances
None

Human Health and Environmental Issues
Atropine alkaloids are naturally produced by plants in the nightshade family, which exists exclusively (pre-extraction) as L-hyoscyamine (PubChem 174174, Bunke et al. 1996, Reist et al. 1997, EFSA 2008). Because L-hyoscyamine is the lone enantiomer that is biologically produced, atropine does not exist naturally, but rather is formed during the racemization. [2019 TR 343-347]

There are no reported studies on the persistence or concentration of atropine (neither D-hyoscyamine nor L-hyoscyamine) or the metabolized products tropine and tropic acid, although tropine has been identified as "readily biodegradable" (Sigma-Aldrich 2018b). [2019 TR 371-373]

Due to the limited application of atropine (for veterinary medicine, approved for use only when used or ordered by a veterinarian), and the small quantities administered (milligrams), atropine is unlikely to be a source of environmental contamination (Rinaldi and Himwich 1954, Chugh et al. 2005, Aardema et al. 2008, Eddleston et al. 2008, Kumar et al. 2010). Moreover, the L-hyoscyamine enantiomer is largely degraded to tropine and tropic acid prior to excretion, further reducing the likelihood of environmental persistence and concentration build-up (Sigma-Aldrich 2018b). [2019 TR 375-380]

The metabolism of atropine in humans is like that of most animal species. Atropine is both readily absorbed and distributed within the human body and readily excreted in urine (EMEA 1998, Williams et al. 2000, Aardema et al. 2008, EFSA 2008). Similar to the metabolic pathways in veterinary applications, humans also metabolize L-hyoscyamine (one enantiomer of the racemic atropine mixture) to tropine and tropic acid (Equation 2), which are excreted in urine along with the non-metabolized D-hyoscyamine enantiomer present in atropine (EMEA 1998, EFSA 2008). The short biological half-life of atropine (2-5 hours), and incorporation of the substance in human medical applications makes negative health effects from the approved usage of atropine unlikely (Williams et al. 2000, Aardema et al. 2008, Mayo Clinic 2017, MedlinePlus 2017). Moreover, atropine is approved for use only when used or ordered by a veterinarian coupled with the withdrawal restrictions placed on animals receiving atropine treatments, makes human health effects unlikely (Rinaldi and Himwich 1954, Chugh et al. 2005, Aardema et al. 2008, Eddleston et al. 2008, Kumar et al. 2010). [2019 TR 544-555]

Discussion
Both written and oral comments submitted at the Spring 2024 NOSB meeting were in support of relisting Atropine as essential product for use in organic animal production. One certifier stated that it did not have any livestock clients using products containing atropine. There were comments that emphasized the

importance of atropine for treating organophosphate poisoning, treatment of cardiac arrest, and its function as a bronchodilator. One commenter mentioned the negative effect of atropine on the vagal nerve thereby causing bloating if proper dosing of atropine was not ensured. Commenters generally referred to atropine as an emergency and potentially lifesaving drug that should be available to organic livestock producers. The withdrawal periods of 56 days for livestock intended for slaughter and 12-day milk discard period were mentioned as additional reasons for the strong endorsement among commenters. No commenters expressed opposition to relisting.

Justification for Vote
The Subcommittee finds atropine compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove atropine from the National List
Motion by: Franklin Quarcoo
Seconded by: Brian Caldwell
Yes: 0 No: 3 Abstain: 0 Recuse: 0 Absent: 2

Hydrogen peroxide

Reference: § 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.
(15) Hydrogen peroxide.
Technical Report: 1995 TAP (Crops); 2015 TR (Crops)
Petition(s): N/A
Past NOSB Actions: 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Historically, agricultural disinfectants containing hydrogen peroxide have been used for the disinfection of livestock housing surfaces and production equipment. Synthetic hydrogen peroxide is permitted for use in organic livestock production as a disinfectant, sanitizer, and medical treatment [7 CFR 205.603(a)]. It is also permitted for use in or on processed products labeled as “organic” or made with organic (specific ingredient or food group(s)) per 7 CFR 205.605(b), and for various uses in organic crop production per 7 CFR 205.601.

Manufacture
Commercially available hydrogen peroxide is industrially produced using the anthraquinone autoxidation (AO) process. The AO method involves initial catalytic reduction of an alkyl anthraquinone with hydrogen to form the corresponding hydroquinone. This is followed by the autoxidation of the hydroquinone in air to regenerate the anthraquinone and release hydrogen peroxide. The simplified overall reaction involves direct combination of gaseous hydrogen (H2) and oxygen (O2). Almost all modern production facilities manufacture commercial hydrogen peroxide solutions using large, strategically located anthraquinone autoxidation processes. [2015 TR 34-39]

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed as a health care product and production aid. Pharmaceutical grade hydrogen peroxide is allowed for external use as a disinfectant. Food-grade hydrogen peroxide is allowed for internal use (for example, added to livestock drinking water). (Table 5.3, CAN/CGSB-32.311-2020, page 27)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Not explicitly mentioned

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

International Federation of Organic Agriculture Movements (IFOAM) Norms
Allowed. (Appendix 5: Substances for Pest and Disease Control and Disinfection in Livestock Housing and Equipment, page 83)

Japan Agricultural Standard (JAS) for Organic Production
Allowed. (Appended Table 4: Chemicals for cleaning or disinfecting livestock or poultry house)

Ancillary Substances

Water is the primary inert ingredient in hydrogen peroxide formulations. Some product labels list salicylic, phosphoric acid, benzyl alcohol, acetic acid, citric acid, butoxy-propan-2-xyloxy- propan-2-ol [2015 TR 170-173]

Human Health and Environmental Issues

Hydrogen peroxide is inherently unstable due to the weak peroxide (O–O) bond. At typical pesticide concentrations, hydrogen peroxide is expected to degrade rapidly to water and oxygen (US EPA, 2007). [2015 Crops TR, lines 316-317]

When used as a fungicide, hydrogen peroxide is likely to contact soils under a variety of environmental conditions. Hydrogen peroxide degrades with an anaerobic (without oxygen) soil half-life of four hours in soils containing petroleum (US EPA, 2007). [2015 Crops TR, lines 320-322]

Since the substance has physical properties like those of water, hydrogen peroxide is unlikely to preferentially bind to soils when used in agricultural production (US EPA, 2007). [2015 Crops TR, lines 325-327]

Research data indicates that volatilization of the substance from moist soils and surface water is expected to be low (EC, 2003). [2015 Crops TR, lines 328-330]

When released to water, hydrogen peroxide should be rapidly consumed through biodegradation and photolysis. The half-life of hydrogen peroxide metabolism in water generally decreases with increasing size of the microbial populations in the receiving water. Consequently, hydrogen peroxide degradation half- lives in natural waters range from a few hours to several days. [2015 Crops TR, lines 331-334]

Hydrogen peroxide is not expected to bioaccumulate in aquatic organisms due to its low octanol-water partition coefficient (K_{ow}) of 0.032 (US EPA, 2007). [2015 Crops TR, lines 340-341]

Degradation of hydrogen peroxide released to the atmosphere is primarily a result of indirect photolysis reactions with smaller contributions from direct photolysis and chemical reaction with organic substances. [2015 Crops TR, lines 342-343]

Light, oxygen, ozone, hydrocarbons and free radicals in the atmosphere mediate hydrogen peroxide formation and release to the atmosphere, likely at a significantly greater rate than the agricultural uses of the substance (Goor, 2007; Eul, 2001). Considering the various atmospheric degradation pathways, the overall tropospheric half-life of hydrogen peroxide is estimated to be 10–24 hours (Goor, 2007; EC, 2003). [2015 Crops TR, lines 347-351]

Multiple EPA terrestrial effects characterizations have evaluated the toxicity of hydrogen peroxide and other "peroxy compounds" to mammals and birds. Studies submitted by the registrants indicate that hydrogen peroxide solutions used in pesticide products are corrosive to washed and unwashed eyes, as well as exposed skin (i.e., Toxicity Category I for eye and skin irritation). [2015 Crops TR, lines 355-358]

The EPA reported in 2009 the results of a skin sensitization study which suggests that Hydrogen peroxide is not likely to be a sensitizer to mammals. The compound is considered slightly toxic to practically non-toxic to birds on an acute oral basis. [2015 Crops TR, lines 363-371]

Hydrogen peroxide is an unstable inorganic compound and is expected to degrade rapidly to water and oxygen in the environment. The half-lives for aerobic and anaerobic degradation of hydrogen peroxide in various soils are between 1-7 hours. Hydrogen peroxide is mobile in soils but does not readily volatilize from moist soils and surface waters (EC, 2003; US EPA, 2007). When released to water, hydrogen peroxide is rapidly consumed through biodegradation and photolysis. The half-life for biodegradation of hydrogen peroxide in water generally ranges from minutes to several hours (Goor, 2007; US EPA, 2007). Light, oxygen, ozone, hydrocarbons, and free radicals contribute to hydrogen peroxide formation in the atmosphere, likely at significantly greater rates than the agricultural uses of the substance. The overall tropospheric half-life of hydrogen peroxide is estimated to be 10–24 hours (EC, 2003; Eul, 2001; Goor, 2007). Under typical use conditions, diluted and pure forms of hydrogen peroxide are reactive with transition metals (e.g., iron, copper, chromium) and organic materials (US EPA, 2007; ATSDR, 2014). [2015 Crops TR, lines 480-490]

Sensitivity of ecological receptors to hydrogen peroxide solutions range from insensitive to moderately sensitive. [2015 Crops TR]

- Hydrogen peroxide is considered slightly toxic to practically non-toxic to birds on an acute oral basis.
- Likewise, aquatic toxicity studies indicate that hydrogen peroxide is slightly toxic to aquatic invertebrates and practically non-toxic to fish on an acute exposure basis.
- In contrast to birds and aquatic animals, microorganisms are particularly sensitive to various concentrations of hydrogen peroxide.
    - The scientific literature and agricultural experience have demonstrated that hydrogen peroxide is toxic to pathogenic soil organisms, such as the downy mildew fungus *Pseudoperonospora cubensis* and pink rot of potato fungus *Phytophthora erythroseptica* (Kuepper, 2003; Al-Mughrabi, 2006).
    - Considering the oxidizing mode of action for hydrogen peroxide, it is likely that the substance is also toxic to beneficial soil organisms, including *Mycorrhizal* fungi and nitrogen-fixing bacteria.

- This non-target effect is most relevant for spray drift and soil drench scenarios and should not present a population-level concern for controlled hydrogen peroxide applications.

Environmental contamination is not expected when purified forms of hydrogen peroxide are released to the environment. [2015 Crops TR]

- At typical pesticide concentrations, hydrogen peroxide is expected to rapidly degrade to oxygen gas and water (US EPA, 2007).
- The toxic solvents and reagents used in the manufacture of hydrogen peroxide are removed prior to product formulation and, in many cases, are reused in subsequent synthetic reactions (Eul, 2001; Goor, 2007). As such, it is unlikely that these chemicals are readily introduced into the environment because of hydrogen peroxide production.

Hydrogen peroxide is generally considered safe for human exposure at **low doses.** Indeed, the US Food and Drug Administration (FDA) affirmed hydrogen peroxide as Generally Recognized as Safe (GRAS) when used as a direct food additive with certain limitations (see "Approved Legal Uses of the Substance" for details). [2015 Crops TR, lines 512-515]

Acute irritation and systemic toxicity are possible in humans exposed to moderate to high doses of hydrogen peroxide. Systemic effects of the substance generally result from the release of oxygen gas and water as the enzyme catalase decomposes available hydrogen peroxide. [2015 Crops TR, lines 515-517]

- Specifically, venous embolism (gas bubble in bloodstream) may occur when the amount of oxygen gas produced exceeds its blood solubility (ATSDR, 2014). Inhalation or ingestion of hydrogen peroxide at high concentrations may lead to seizures, cerebral embolism or even tissue death (infarction).

The most common symptoms reported were acute symptoms based on acute corrosion and irritation effects. The symptoms include eye irritation, skin burns, esophageal burns, nausea, dizziness, rash, and headaches. Inhalation effects include chest congestion, respiratory irritation, coughing of blood, tightness of chest and shortness of breath. Dermal effects include edema, erythema, skin burns, blistering, and swelling. These cases led to hospitalization in some cases. It is important to stress the following facts [2015 Crops TR, lines 536-543]:

- Hydrogen peroxide is unlikely to cause chronic toxicity in humans because it is rapidly decomposed in the body.
- The available toxicity and epidemiology studies provide no evidence of reproductive or developmental toxicity in experimental animals and humans (ATSDR, 2014).

On the other hand, hydrogen peroxide is a known mutagen and is associated with genotoxicity in mammalian and human cell lines (IARC, 1999; Driessens, 2009). In 2014, the International Agency for Research on Cancer (IARC) determined that there is *inadequate evidence* in humans and *limited evidence* in experimental animals for the carcinogenicity of hydrogen peroxide, classifying the substance as *Group 3 – Not classifiable as to its carcinogenicity to humans.* [2015 Crops TR, lines 549-553]

POSITIVE ATTRIBUTES/USES

- Moderate spills of hydrogen peroxide to marine and estuarine environments are unlikely to adversely affect the receiving water bodies. [2015 Crops TR, lines 417-418]
- On the contrary, a method describing the addition of hydrogen peroxide to natural waters as an oxidizing agent for oil spill remediation was published in patent literature (Hoag, 2014). [2015 Crops TR, lines 418-420]

- Hydrogen peroxide has been used to treat wastewater, and aids in the removal of soil contaminants, including creosote, polycyclic aromatic hydrocarbons (PAHs), and other inorganic and organic substances (Atagana, 2003; Conte, 2001; US EPA, 2007). [2015 Crops TR, lines 420-422]

Toxic substances used in the manufacture of hydrogen peroxide, including alkyl anthraquinones, aromatic solvents and transition metal catalysts (e.g., Raney nickel and palladium), are generally removed from hydrogen peroxide prior to formulation of commercial pesticide products. Further, certain fractions of these reagents, catalysts and solvents are often returned to the reactors for use in subsequent synthetic reactions (Goor, 2007; Eul, 2001). [2015 Crops TR, lines 423-429]

- Therefore, the chemicals used in the production of hydrogen peroxide should not be released to the environment when manufacturers adhere to standard operating procedures for safe handling and disposal of toxic substances.

Populations of beneficial soil fungi, such as *Mycorrhizal* fungi, and nitrogen-fixing bacteria may be negatively impacted by large-scale soil treatments of fungicides containing hydrogen peroxide. [2015 Crops TR, lines 456-458]

Overall, the available information suggests that large volumes of concentrated hydrogen peroxide solutions will adversely affect the viability and reproduction of non-target microorganisms, including beneficial soil fungi and nematodes. [2015 Crops TR, lines 472-474]

Discussion
During the Spring 2024 NOSB meeting, the Livestock Committee received comments in favor of relisting Hydrogen Peroxide and no comments against relisting. Some commenters mentioned the importance of hydrogen peroxide and the fact that it is a fairly common input in livestock production. Commenters listed their use in footbaths, to clean wounds, for cleaning to combat hard water as well as serving as ingredients in pre-dips. Some comments in support of relisting hydrogen peroxide focused on its minimal health and environmental concerns. Some proponents described hydrogen peroxide as a safer alternative to chlorine-based and other toxic sanitizers. The fact that the product breaks down quickly to oxygen and water which do not cause adverse residual effects was another positive factor that commenters listed for their support for relisting of Hydrogen peroxide. Additional comments include the fact that Hydrogen peroxide is relatively nontoxic in low concentrations. Some commenters talked stated that hydrogen peroxide may damage soil biota and exposure to its vapor may be harmful. Comments received were in support of relisting this product.

Justification for Vote
The Subcommittee finds hydrogen peroxide compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove hydrogen peroxide from the National List
Motion by: Franklin Quarcoo
Seconded by: Nate Powell-Palm
Yes: 0 No: 3 Abstain: 0 Recuse: 0 Absent: 2

Iodine §205.603(a)(16) and §205.603(b)(4)

Reference: § 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable. (16) Iodine.
§ 205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable. (4) Iodine.
Technical Report: 1994 TAP; 2015 TR; 2024 Limited Scope TR
Petition(s): N/A
Past NOSB Actions: 04/1995 meeting minutes and vote; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Iodine has excellent antimicrobial qualities and is widely used in organic livestock production as a topical treatment, disinfectant and antimicrobial, especially as a teat dip used both pre-milking and post- milking. Mastitis is a painful inflammation with infection. Antibiotic use is prohibited in organic agriculture so preventive healthcare is of critical importance. While a clean barn, clean milking parlor, and clean cows are a vital aspect of an organic milk production system, barns are not sterile environments and thus antimicrobial teat dips used in pre- and post-milking are vital preventive healthcare products. There are many teat dips available commercially. Iodine-based teat dips are the most commonly used in organic livestock production. Iodine can be in molecular form or iodophor form.

Typically, molecular iodine is “complexed” into a variety of iodophors where surfactants are mixed with molecular iodine to enhance water solubility and sequester the molecular iodine for extended release in disinfectant products. There may also be several other ingredients in iodine-based teat dips, some of which may be excipients.

Manufacture
Molecular iodine (I_2) production processes generally utilize raw materials containing iodine, including seaweeds, mineral deposits, and oil well or natural gas brines [2015 TR, lines 310-311]. Various chemical substances are added in the production of commercially available teat dip products. Many of the iodophors commonly used for disinfection in the dairy industry consist of iodine mixed with polymeric nonionic surfactants, such as the polyalkylene glycol and polyvinylpyrrolidone carriers. The nonylphenol ethoxylates (NPEs), polyoxyethylene nonylphenol (CAS# 9016-45-9) and ethoxylated nonylphenol (CAS# 26027-38-3), as well as polyvinylpyrrolidone (CAS# 9003-39-8) and other potential polymeric carriers are US EPA List 4 Inerts (US EPA, 2004a) when used in pesticides, including antimicrobial sanitizers. When used in animal drugs (*e.g.,* teat dips), these substances are considered excipients, and are subject to restrictions at section 205.603(f). This rule states that a given excipient may be used in the manufacture of drugs used to treat organic livestock when the excipient is: (1) identified as GRAS by FDA, (2) approved by FDA as a food additive, (3) included in the FDA review and approval of a New Animal Drug Application or New Drug Application, [2015 TR, lines 209-219] or (4) approved by APHIS for use in veterinary biologics.

Manufacturers commonly incorporate conditioners into iodine teat dip products to replace the protective oils that polymeric surfactants (*i.e.,* detergents) used as complexing agents remove from animal skin during treatment. Moisturizers such as glycerin and propylene are normally added at concentrations ranging from two to ten percent of the product formulation (Universal, 2011; Nickerson, 2001). Further, glycerin

produced through the hydrolysis of fats or oils is allowed as a livestock teat dip on the National List [7 CFR 205.603(a)(12)]. Lanolin may also be added to iodophor teat dip products as an emollient to replace natural oils lost from the affected skin of dairy cows (Nickerson, 2011) [2015 TR, lines 222-228].

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed as a topical disinfectant. Allowed iodine sources include potassium iodide and elemental iodine. If used as a cleaning agent, non-elemental iodine shall be used. Iodine shall not exceed 5% solution by volume (example: iodophors). Use shall be followed by a hot-water rinse (Table 5.3, CAN/CGSB-32.311-2020, page 27).

Substances such as alcohol, iodine, hydrogen peroxide, chlorine dioxide and ozone, can be used as disinfectants for a pre- or post-teat dip or udder wash if they are registered for this use by Canada's Food and Drug Regulations (Table 5.3, Teat dips and udder wash listing, CAN/CGSB-32.311-2020, page 29).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Not explicitly mentioned.

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

International Federation of Organic Agriculture Movements (IFOAM)
Allowed (Appendix 5: Substances for Pest and Disease Control and Disinfection in Livestock Housing and Equipment; iodine agent).

Japan Agricultural Standard (JAS) for Organic Production
Allowed. (Appended Table 4: Chemicals for cleaning or disinfecting livestock or poultry house).

Ancillary Substances

Excipients are almost always used in iodine sanitizing products, and the review of these substances is outlined above in manufacturing. One class of excipients, NPEs, has been identified as hazardous to the environment and potentially no longer necessary in manufacturing.

Human Health and Environmental Issues

A limited scope TR for iodine was requested for this sunset review of the substance. One of the questions explored by the TR was the impact that NPEs (an excipient used in combination with iodine) has on the environment and human health.

NPEs have long been known to be toxic to aquatic organisms, they bioaccumulate in plants, and they have been shown to exhibit estrogenic properties in human studies. Their use in cleaning and sanitizing products has slowly been phasing out. However, they remain in use in dairy iodine teat dips, and the residues of these substances can find their way into milk bulk tanks, equipment, and manure lagoons where they will likely be applied to the soil. The TR identifies iodine teat dips as the largest potential contributing source of NPEs on dairy operations.

Discussion

NOSB acknowledges that iodine sanitizers remain necessary to livestock operations as a sanitizer for medical procedures as well as for topical use, particularly as a teat dip for dairy animals. NOSB has also

heard from numerous stakeholders that it is time to ensure that iodine products used on organic farms are free from NPEs. A limited scope TR was conducted to evaluate the availability of NPE-free iodine products and their suitability, the potential for NPEs contained in iodine products to contaminate organic products and the environment, and what detrimental effects may occur should NPEs enter the supply chain or be applied to soil.

The Livestock Subcommittee believes iodine continues to meet National List criteria and should not be removed. The LS would like to consider an annotation to prohibit NPEs in iodine products used on organic livestock operations, and we have made a recommendation to that effect in a separate annotation change proposal document.

Questions to our Stakeholders

1. Based on the feedback received at previous reviews of iodine and the recently conducted limited scope TR of iodine, it appears that there is a significant supply of NPE-free iodine formulas for numerous types of iodine products, and a prohibition on NPE containing formulas would not have significant impact on the industry. Is this analysis correct? Are there specific types of iodine products where NPE-free formulas are not available?
2. For certifiers and MROs: Would an annotation restricting iodine formulas to those that are free of NPEs pose significant challenges to the review of iodine products in organic system plans?
3. What specific language should NOSB consider for a proposed annotation in order to fully restrict NPEs from iodine products used on organic livestock operations?

Commenters generally expressed support for the phase out of iodine formulas that contain NPEs. Environmental groups applauded the idea that organic farmers would lead the way in removal of these harmful substances from their system plans. Certifiers and Material Review Organizations (MROs) indicated that there are numerous formulations available on the market and approved for use in organic system plans (OSPs) that do not contain NPEs. Dairy producers indicated support for the additional restriction, as it would better support organic goals of minimizing impact to the environment while allowing options for iodine products. Commenters suggested that the annotation prohibiting NPEs include language that clearly prohibits all alkylphenol ethoxylates. The Subcommittee agrees with this and is proposing a proposal to amend the annotation in parallel with this sunset review.

Justification for Vote

The Subcommittee finds iodine compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote

Motion to remove iodine from § 205.603(a) and§ 205.603(b) of the National List
Motion by: Nate Lewis
Seconded by: Brian Caldwell
Yes: 0 No: 4 Abstain: 0 Recuse: 0 Absent: 1

Magnesium sulfate

Reference: § 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.
(19) Magnesium sulfate.
Technical Report: 1995 TAP; 2011 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Magnesium sulfate has a number of veterinary uses. It acts as an anticonvulsant, laxative, bronchodilator, electrolyte replacement aid with hypomagnesaemia, and may be used to treat cardiac arrhythmias. Specifically, in swine, magnesium sulfate is administered to treat malignant hypothermia. [2011 TR, lines 78-81]

Magnesium sulfate can be added to livestock feed to treat conditions stemming from a magnesium deficiency. Lactation tetany or grass tetany occurs when ruminants graze on grasses low in magnesium or suffer from a low level of magnesium in their diet. The condition is often realized after cases of sudden death in cattle. Clinical signs include convulsions and muscular spasms, and death may occur due to respiratory failure. If livestock are feeding on pastures with high potassium levels, which interfere with the uptake of magnesium by grasses, supplemental magnesium sulfate may be needed. [2011 TR, lines 83-89]

Magnesium capsules can be inserted into the rumen of livestock and after a one-week stabilization period, the capsule begins to release magnesium for up to 80 days. This capsule is recommended for use in high-risk or valuable animals. It is advised that, in addition to the capsule, the livestock be fed hay in order to increase absorption of the magnesium. If immediate treatment for magnesium deficiency is needed, magnesium sulfate can be administered intravenously. [2011 TR, lines 91-95]

A magnesium lick can also be provided for livestock to increase the amount of magnesium in the diet. Because magnesium sulfate is not palatable, molasses is added to the magnesium lick to encourage cattle‘s use. Licks are generally 80 percent molasses and 20 percent magnesium sulfate and are considered to be less reliable than supplementing feed with magnesium. [2011 TR, lines 97-100]

Magnesium sulfate, as Epsom salts, can be used to treat inflammation and abscesses in livestock. Soaking the affected area in a mixture containing Epsom salt and water can reduce signs of inflammation. [2011 TR, lines 102-104]

Manufacture
Magnesium sulfate can be obtained from naturally-occurring sources or manufactured by a chemical process. [2011 TR, lines 312-313]

Several mineral forms of magnesium sulfate are recovered from the ground. The magnesium sulfate generally found in nature is in the hydrated form (i.e., contains water). Specifically, magnesium sulfate

monohydrate and magnesium sulfate heptahydrate occur in nature as the minerals kieserite and epsomite, respectively (Kawamura and Rao, 2007). [2011 TR, lines 316-319]

The synthetic form of magnesium sulfate is produced by a chemical reaction in which magnesite ore (containing MgCO3), or magnesium hydroxide (Mg[OH]2) is ignited to produce magnesium oxide. Magnesium oxide is then reacted with sulfuric acid, producing magnesium sulfate. To produce a high grade of purity, the magnesium sulfate is re-crystallized and separated from the parent solution (Kawamura and Rao, 2007). [2011 TR, lines 321-325]

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed as an animal health care product and production aid; origin must be mined sources. Usage includes being a source of magnesium and sulphur. (Table 5.3, CAN/CGSB-32.311-2020, page 27)

Non-synthetic chelated or sulphated minerals are allowed for use as an animal health care product and production aid. Examples include oyster shell, calcium chloride and magnesium oxide. Synthetic nutrient minerals may be used if non-synthetic sources are not commercially available. Minerals from any source are allowed for medical use. (Table 5.3, CAN/CGSB-32.311-2020, page 28)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Allowed (Annex III, Part A(1), 2021/1165)

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

International Federation of Organic Agriculture Movements (IFOAM)
Not explicitly mentioned.

Japan Agricultural Standard (JAS) for Organic Production
Not explicitly mentioned.

Human Health and Environmental Issues
Magnesium and sulfur are ubiquitous in the natural environment. According to the 2011 TR, if used in accordance with 7 CFR 205.603, it is unlikely that magnesium sulfate will cause harm to the environment.

Magnesium sulfate is considered by the Food and Drug Administration (FDA) as generally recognized as safe (GRAS) when used as a nutrient or dietary supplement (21 CFR 184.1443). The Food and Nutrition Board, an organization established by the Institute of Medicine that provides guidance to the public and policy makers on nutrition and food sciences, has recommended that cereal grain products be fortified with magnesium in response to the potential risk of deficiency among significant segments of the population (FAQS, 2010). [2011 TR, lines 116-121]

Multiple products containing magnesium sulfate are approved by the FDA for medicinal use in humans. Magnesium sulfate can be administered via injection or can be orally ingested (U.S. FDA, 2010). In 2010, the FDA approved a product containing magnesium sulfate, which acts a colon cleanser in preparation for a colonoscopy (Braintree Laboratories, 2010). [2011 TR, lines 123-126]

If large quantities of magnesium sulfate are ingested by or injected into humans, blood electrolyte balance can be disturbed, resulting in circulatory collapse and death. However, this is far beyond the bounds of veterinary use.

Discussion
Written and verbal comments at the Spring 2024 meeting were unanimously in favor of relisting magnesium sulfate, with one commenter requesting that natural sources be used if available. This material has important veterinary uses and has little negative environmental or heath impact. Stakeholders were unaware of non-synthetic magnesium sulfate products.

Subcommittee Discussion
Magnesium sulfate satisfies the OFPA evaluation criteria, and the Livestock Subcommittee supports relisting.

Justification for Vote
The Subcommittee finds magnesium sulfate compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove magnesium sulfate from the National List
Motion by: Brian Caldwell
Seconded by: Nate Lewis
Yes: 0 No: 4 Abstain: 0 Recuse: 0 Absent: 1

Parasiticides, Fenbendazole

Reference: § 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.

(23) Parasiticides—prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock. Allowed for fiber bearing animals when used a minimum of 36 days prior to harvesting fleece or wool that is to be sold, labeled, or represented as organic.

(i) Fenbendazole (CAS #43210-67-9)— milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep, and other dairy species.

Technical Report: 1999 TAP (parasiticides: fenbendazole, ivermectin, levamisole); 2015 TR (parasiticides: fenbendazole, ivermectin, moxidectin); 2020 TR
Petition(s): 03/2007; 07/2019 (annotation change)
Past NOSB Actions: 05/2008 NOSB recommendation; 10/2015 sunset recommendation; 04/2016 recommendation – annotation change; 10/2019 sunset recommendation; 10/2020 NOSB recommendation to not amend listing
Recent Regulatory Background: Added to National List , effective May 16, 2012 (77 FR 28472); Renewed 03/15/2017 (82 FR 14420); Annotation change effective 01/28/2019 (83 FR 66559); Renewed 08/03/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use

In veterinary medicine the term parasiticide refers to anthelmintic drugs (medicines used to destroy parasitic worms) [2015 TR 148 - 150]. Anthelmintics are medications capable of causing the evacuation of parasitic intestinal worms. As veterinary drugs, parasiticides are articles intended for use in treatment or prevention of disease in animals (Section 201(g)(1)(B) & (C) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321(g)(1)(B) & 234 (C)]) [2015 TR 233-235]. The use of parasiticides in organic production is strictly confined to emergencies and the practice of returning livestock production to a healthy steady state does not include the routine use of parasiticides [2015 TR, lines 382-383]. Parasitism may be the weakest link in organic livestock production (Karreman, 2004). Outbreaks of disease due to nematode parasites can happen even in well managed herds. When changes in a production system occur as a result of land use, weather, or transient exposure of susceptible animals to parasites the natural imbalance favors parasite infestation. When unnoticed, undetected and without treatment parasite infestation can lead to disease and potentially death (Stockdale, 2008) [2015 TR 394-398].

The 2020 Technical Report discussed the use of fenbendazole in chickens, which was the subject of a 2019 petition to change the allowance on the National List. The 2020 TR summarized fenbendazole as follows:

> The target organisms of the parasiticide fenbendazole are the roundworms *Ascaridia galli* and *Heterakis gallinarum*. These nematodes, along with *Capillaria spp*., are recognized as the principal helminthic parasites of chickens, with *A. galli* by far the most common. The life cycles of both target nematodes are simple and direct, transmitted bird-to-bird via fecal droppings. Infected chickens are unthrifty, weak, and emaciated, and have weight loss proportional to the parasite burden. Young birds are particularly susceptible. Although mature hens are less susceptible, their egg productivity may drop, and death may occur in severe cases. Because chickens raised as broilers have a much shorter lifespan than laying hens, parasiticides are generally not required to treat them. Turkeys have a longer grow-out than broilers and are subject to additional helminthic parasite pressure, particularly the roundworm parasite *Ascardia dissimilis* [2020 TR 25-37].
>
> Fenbendazole is a benzimidazole veterinary anthelmintic – i.e., an antiparasitic drug (US NLM 2020). The mode of action works at the sub-cellular level, preventing cell division. Benzimidazoles bind to β-tubulin, inhibiting the cell's microtubule assembly responsible for intracellular transport and required for mitotic cellular division… The ultimate effect on nematodes is starvation caused by intestinal cell disruption and inhibition of nematode egg production. The late-stage (L5) larvae and adult stages of *A. galli* and *H. gallinarum* are susceptible. Efficacy studies reported that fenbendazole increased mortality of *A. galli* larvae and adult, but did not report any reduction in the number of viable parasite eggs [2020 TR 67-76].

Manufacture

The fenbendazole is manufactured using a condensation of o-phenylenediamine or o-nitroaniline with a carboxylic acid derivative. N-arylamide hydrochlorides can also be transformed to benzimidazoles with sodium hypochlorite and base. (Brown et al., 1961; Grenda et al., 1965; Loewe et al, 1976) [2015 TR Table 4].

Fenbendazole is approved as a New Animal Drug Application (NADA) by the U.S. Food and Drug Administration's Center for Veterinary Medicine (U.S. FDA CVM) … The FDA has established a tolerance of 1.8ppm fenbendazole in 93 eggs, using the predominant metabolite fenbendazole sulfone as a marker [21 CFR 556.275]. This effectively provides a maximum residue limit (MRL) of 2.4 ppm total fenbendazole, including its metabolites fenbendazole sulfone and oxfendazole. In addition to poultry, the FDA has

approved fenbendazole for use in cattle, swine, sheep, horses and turkeys, as well as zoo and wildlife animals [21 97 CFR 520.905, 21 CFR 558.258]. Fenbendazole is also approved for use as an anthelminthic for laying hens in the European Union (EMA 2011) and Canada (Health Canada 2020) [2020 TR 89-98].

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

5.2.2(b) Shall respect requirements set out in 6.6 of CAN/CGSB-32.310 with regard to the use of internal parasiticides. Parasiticides are prohibited on a routine basis. If there is a specific disease or health issue and natural methods are not effective, parasiticides may be used as long as there is a doubling of withdrawal times documented.

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

As per the 2015 TR - Parasiticides are prohibited on a routine basis. However, in the case of a sick animal requiring an immediate treatment, the use of chemically synthesized allopathic medicinal products is limited to a strict minimum. Doubling withdrawal periods after use of chemically synthesized allopathic medicinal products is suggested to guarantee the integrity of organic production for consumers. Because widespread animal diseases would seriously affect organic production, measures may be taken to ensure maintenance of farming or reestablishment of farming with nonorganic animals or non-organic for a limited period in the affected areas (2015 TR 461-467]

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

Parasiticides are prohibited on a routine basis. If there is a specific disease or health issue and natural methods are not effective, parasiticides may be used as long as there is a doubling of withdrawal times documented.

International Federation of Organic Agriculture Movements (IFOAM)

Parasiticides are prohibited on a routine basis. If there is a specific disease or health issue and natural methods are not effective, parasiticides may be used as long as there is a doubling of withdrawal times documented. IFOAM has an additional exception on the usage of parasiticides including a maximum of three courses of remedial treatments within 12 months, or one course of treatment if the productive lifecycle of the animal is less than one year

Japan Agricultural Standard (JAS) for Organic Production

Parasiticides are prohibited on a routine basis. If there is a specific disease or health issue and natural methods are not effective, parasiticides may be used as long as there is a doubling of withdrawal times documented.

Ancillary Substances

Excipients are identified in the 2015 Technical Report. No ancillary substances are identified.

Human Health and Environmental Issues

The risks associated with chemical treatment of parasites include (1) immediate non-target effects, (2) obligation for repeat treatments, (3) potential risk to domestic animals and human health, (4) target organism resistance to the treatment, (5) potential residue buildup and (6) potential food chain contamination (Rudd, 1985). [1999 TAP pgs. 6-7]. All FDA livestock approved parasiticides are synthetically produced substances shown by experimental and clinical studies to be safe for application to food animals. The excipients are usually United States Pharmacopoeia (USP) grade chemicals and also subject to FDA approval [2015 TR 379-381].

Discussion
Parasiticides are used in acute, emergency cases and should be administered under the care of a veterinarian across the spectrum of ruminant animals – sheep, goats, dairy, beef, etc. According to several organic focused dairy veterinarians, fecal samples should be sent to a lab to determine the parasite load and the farmer should accordingly develop a plan of action for the infected animal(s). Parasites are most common in young animals during the first grazing season. It is less common for adult animals to require treatment if good herd management practices are followed. It was noted that pasture height above six inches results in lower pest loads as the cows don't graze low enough to where the parasites are typically located. Additionally, it was anecdotally noted during Subcommittee discussion that calves allowed to nurse experience lower pest loads than calves that are bottle fed.
The Board recognizes that parasiticides are not a preventative measure for herd health; however, the ability to use these tools in acute cases provides the utmost care and exemplifies animal welfare best care practices.

Written comments for the Spring 2024 NOSB meeting were strongly in favor of relisting fenbendazole, as was the NOSB.

Justification for Vote
The Subcommittee finds fenbendazole compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove fenbendazole from the National List
Motion by: Nate Powell-Palm
Seconded by: Nate Lewis
Yes: 0 No: 5 Abstain: 0 Recuse: 0 Absent: 0

Parasiticides, Moxidectin

Reference: § 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.

(23) Parasiticides—prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock. Allowed for fiber bearing animals when used a minimum of 36 days prior to harvesting of fleece or wool that is to be sold, labeled, or represented as organic.

(ii) Moxidectin (CAS #113507-06-5)— milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep, and other dairy species.

Technical Report: 2003 TAP; 2015 TR (Parasiticides: Fenbendazole, Ivermectin, Moxidectin)
Petition(s): 2003
Past NOSB Actions: 05/2004 NOSB recommendation; 10/2015 sunset recommendation; 04/2016 NOSB recommendation - annotation change; 10/2019 sunset recommendation
Recent Regulatory Background: Added to National List , effective May 16, 2012 (77 FR 28472); Renewed 03/15/2017 82 FR 14420; Proposed rule 01/17/2018 (83 FR 2498); Annotation change 12/27/2018 (83 FR 66559); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review
Subcommittee review was brief; spring meeting was recapped with public comments and board dialogue. Full support from the subcommittee to relist this essential tool.

Use
In veterinary medicine the term parasiticide refers to anthelmintic drugs, although moxidectin is also effective against arthropod parasites [2015 TR, lines 148-149]. As veterinary drugs, parasiticides are articles intended for use in treatment or prevention of disease in animals (Section 201(g)(1)(B) & (C) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321(g)(1)(B) & 234 (C)]) [2015 TR, lines 233-235]. The use of moxidectin in organic production is strictly confined to emergencies and the practice of returning livestock production to a healthy steady state that does not include the routine use of parasiticides [2015 TR, lines 382-384]. Routine management of parasiticides should include proper grazing management (rotating pastures when the grass is less than 6" tall), herbal and natural remedies, and selective breed genetics.

Manufacture
Moxidectin, a derivative of nemadectin, is a chemically modified *Streptomyces cyanogriseus* fermentation product (Asato and France, 1990) [2015 TR, lines 224-225]. The synthesis of moxidectin involves protecting the 5-hydroxy group of nemadectin with p-nitrobenzoyl chloride to give the corresponding 5-O(p-nitrobenzoyl)- nemadectin, which is then oxidized to give a 5-O(p-nitrobenzoyl)-23-oxo- nemadectin derivative in a crystalline state. The 5-O(p-nitrobenzoyl)-23-oxo- nemadectin derivative is then reacted with methoxylamine to give the 23-(methyloxime)5-O(p-nitrobenzoyl)- nemadectin intermediate in a crystalline state. This intermediate is then deprotected in the presence of base to give the desired 23-(methyloxime)-nemadectin. These reactions take place in the presence of various organic solvents (U.S. Patent Number 4,988,824). [2003 TAP, page 2]

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Parasiticides are prohibited on a routine basis. If there is a specific disease or health issue and natural methods are not effective, parasiticides may be used as long as there is a doubling of withdrawal times documented.

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Parasiticides are prohibited on a routine basis. However, in the case of a sick animal requiring an immediate treatment, the use of chemically synthesized allopathic medicinal products is limited to a strict minimum. Doubling withdrawal periods after use of chemically synthesized allopathic medicinal products is suggested to guarantee the integrity of organic production for consumers. Because widespread animal diseases would seriously affect organic production, measures may be taken to ensure maintenance of farming or reestablishment of farming with nonorganic animals or non-organic for a limited period in the affected areas [2015 TR 461-467].

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Parasiticides are prohibited on a routine basis. If there is a specific disease or health issue and natural methods are not effective, parasiticides may be used as long as there is a doubling of withdrawal times documented.

International Federation of Organic Agriculture Movements (IFOAM)
Parasiticides are prohibited on a routine basis. If there is a specific disease or health issue and natural methods are not effective, parasiticides may be used as long as there is a doubling of withdrawal times

documented. IFOAM has an additional exception on the usage of parasiticides including a maximum of three courses of remedial treatments within 12 months, or one course of treatment if the productive lifecycle of the animal is less than one year.

Japan Agricultural Standard (JAS) for Organic Production
Parasiticides are prohibited on a routine basis. If there is a specific disease or health issue and natural methods are not effective, parasiticides may be used as long as there is a doubling of withdrawal times documented.

Ancillary Substances
Excipients are identified in the 2015 Technical Report. No ancillary substances are identified.

Human Health and Environmental Issues
The risks associated with chemical treatment of parasites include (1) immediate non-target effects, (2) obligation for repeat treatments, (3) potential risk to domestic animals and human health, (4) target organism resistance to the treatment, (5) potential residue buildup and (6) potential food chain contamination (Rudd, 1985). [1999 TAP pgs. 6-7]. Moxidectin is excreted in feces but is both microbially and photo-degraded in dung pats in the soil. It is the least toxic to dung beetles of the macrocyclic lactone anthelmintics. Moxidectin peaks in 2 days in feces after treatment and decreases to less than 10 ppb by 37 days after treatment. The half-life for degradation of moxidectin in the environment may be up to 130 days [2015 TR Table 5 and 575-577].

Discussion
During the Spring 2024 board meeting, public comment and board discussion were favorable for the relisting of moxidectin citing the need for organic livestock to uphold the highest standards for animal welfare. It was noted that creating robust organic system plans (OSPs) and maintaining accurate records are essential to monitoring the care of livestock. Although natural forms of pest management and prevention are encouraged, the use of parasiticides on the National List in acute, emergency cases should be allowed and administered under the care of a veterinarian across the spectrum of ruminant animals – sheep, goats, dairy, beef, etc.

According to several organic focused dairy veterinarians, fecal samples should be sent to a lab to determine the parasite load and the farmer should accordingly develop a plan of action for the infected animal(s). Parasites are most common in young animals during the first grazing season. It is less common for adult animals to require treatment if good herd management practices are followed. It was noted that herds who keep pasture height above 6” experience lower pest loads as the cows don’t graze low enough to where the parasites are typically located on the pasture plants. Additionally, it was anecdotally noted during discussion that calves allowed to nurse on their mother experience lower pest loads than calves that are bottle fed.

The Board recognizes that parasiticides are not a preventative measure for herd health; however, the ability to use these tools in acute cases provides the utmost care and exemplifies animal welfare best care practices.

History of Moxidectin
The NOSB recommended adding moxidectin to the National List in 2004 with the restriction that it only be allowed for use to control internal parasites. But NOSB October 2019 proposals and discussion documents Page 212 of 230 in the proposed rule published on July 17, 2006, USDA announced its decision that

moxidectin would not be proposed for inclusion on the National List because of its macrolide antibiotic classification.

Based upon the public comments received at the NOSB meeting July 17, 2006, the NOP verified the information supplied by commenters, and subsequently concurred that moxidectin does not function as an antibiotic when used as a parasiticide. In the Final Rule in 2012 NOP added moxidectin to National List.

Questions to our Stakeholders

1. How do certifiers mitigate consistent repeat use of parasiticides?
2. Are there suggestions to improve annotation?
3. Which age/class of animal do certifiers see their client's requesting approval for emergency parasiticide use?
4. How often do certifiers request fecal samples to confirm the parasite load in a herd prior to allowing an emergency treatment with parasiticides?

Justification for Vote

The Subcommittee finds moxidectin compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote

Motion to remove moxidectin from the National List
Motion by: Kim Huseman
Seconded by: Nate Lewis
Yes: 0 No: 5 Abstain: 0 Recuse: 0 Absent: 0

Peroxyacetic/peracetic acid

Reference: § 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.
(24) Peroxyacetic/peracetic acid (CAS #-79-21-0)—for sanitizing facility and processing equipment.
Technical Report: 2000 TAP; 2016 TR
Petition(s): 2008
Past NOSB Actions: 11/2000 NOSB recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use

Peracetic acid (PAA) is listed in the National List as allowed for use in organic livestock production for sanitizing facilities and processing equipment. This is consistent with the substance's primary use in the food industry as a bactericide and fungicide for sanitizing and disinfecting structures, equipment, and hard surfaces. 2016 Technical Report (TR) line 99 states, peracetic acid may be used in livestock production in dairies – milking parlors, dairy production and transfer facilities and equipment – as well as in poultry premises, hatcheries, livestock quarters, stables, stalls, pens, cages, and on feeding and watering equipment.

Beginning at 2016 TR line 288: The reason for the excellent and rapid antimicrobial effects of peracetic acid is its specific capability to penetrate the cell membrane. Once inside the cell, peracetic acid plays a role in denaturing proteins, disrupting cell wall permeability, and oxidizing sulfhydryl and sulfur bonds in enzymes and other proteins. PAA irreversibly disrupts enzyme systems, which destroys the microorganism. The end products of peracetic acid oxidation are acetic acid and water.

Manufacture
Solutions of peracetic acid used as sanitizers are created by combining aqueous mixtures of two substances: acetic acid (the acid in vinegar) and hydrogen peroxide. At cool temperatures, acetic acid and hydrogen peroxide react over a few days to form an equilibrium solution containing peracetic acid, acetic acid, and hydrogen peroxide. This equilibrium solution is the substance sold commercially as the sanitizer "peracetic acid."

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Not explicitly mentioned for livestock use.

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Allowed for cleaning and disinfection (Annex IV, Part D, 2021/ 1165).

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

International Federation of Organic Agriculture Movements (IFOAM)
Allowed. (Appendix 5: Substances for Pest and Disease Control and Disinfection in Livestock Housing and Equipment; peracetic acid, page 83).

Japan Agricultural Standard (JAS) for Organic Production
The Japanese Agricultural Standard for Organic Livestock Products, Table 4, lists "Agents for cleaning or disinfecting of housing for livestock." Included on this list are "Hydrogen Peroxide Solution" and "Cleaning agents and disinfectants for milking equipment, rooms and buildings." Peracetic acid is not specifically mentioned.

Ancillary Substances
Peracetic acid is a sanitizer regulated by the FDA and EPA, and a number of additional substances are allowed in peracetic acid formulations. These additional substances are necessary to stabilize the formulations and do not meet the NOSB's definition of an ancillary substance.

Human Health and Environmental Issues
Peracetic acid is considered an environmentally friendly substance, with very little potential to cause contamination due to its rapid breakdown into benign substances already present in the environment. It has, however, been reported that peracetic acid in the atmosphere can react with photochemically produced hydroxyl radicals (reaction half-life of approximately 9 days) (U.S. National Library of Medicine 2012), with a suggested role in contributing to acid rain.[2016 TR 544-547]

Both peracetic acid and hydrogen peroxide have been cited as potential contributors to acid rain. However, while peracetic acid and hydrogen peroxide can be involved in chemical reactions in the atmosphere that

ultimately lead to acid rain, the literature does not cite them as being a significant contributor to or source of acid rain.

[2016 TR lines 615-618] Peracetic acid has been found in some instances to have beneficial effects related to environmental contamination. One study reports peracetic acid to be effective in degrading toxic compounds benzo(a)pyrene and methylnaphthalene in lake sediments through oxidation of the parent compound.

Discussion
The importance of producers to have access to sanitizers in livestock operations cannot be understated. To maintain efficacy, producers must also have access to substances with multiple modes of action to prevent resistance to a single sanitizer. PAA functions as an effective sanitizer and poses little risk to human health or the environment. There is no new information available to the NOSB that would lead to recommending removal of this substance from the National List at 7 CFR 205.603(a).

Questions to our Stakeholders
None

Justification for Vote
The Subcommittee finds peracetic acid (PAA) compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove peracetic acid (PAA) from the National List
Motion by: Nate Lewis
Seconded by: Brian Caldwell
Yes: 0 No: 4 Abstain: 0 Recuse: 0 Absent: 1

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, and;
(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(s): 2002
Past NOSB Actions: 09/2002 NOSB recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 82 FR 14420; Proposed rule 01/17/2018 (83 FR 2498); Annotation change 12/27/2018 (83 FR 66559); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 10/30/2029

Subcommittee Review

Use
In organic livestock production, 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 and 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 [2019 TR 116-118].

Tolazoline is used only for veterinary applications, with no natural 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) [2019 TR 658-665].

Manufacture
Tolazoline is a synthetic substance 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 Allowed Substances List (CAN/CGSB 32.311-2020)
Although xylazine is listed in the CAN/CGSB-32.311-2015 — Organic production systems - permitted substances listed 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 explicitly mentioned.

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Tolazoline is not explicitly mentioned.

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

International Federation of Organic Agriculture Movements (IFOAM) Norms
Tolazoline is not explicitly mentioned.

Japan Agricultural Standard (JAS) for Organic Production
Tolazoline is not explicitly mentioned.

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

Neither xylazine nor tolazoline are listed by the EPA as an inert ingredient of toxicological concern [2019 TR 398]. There are no studies on tolazoline's environmental toxicity, persistence, or concentration.

Discussion
The Livestock Subcommittee (LS) finds that xylazine and tolazoline are critical tools for farmers and veterinarians. These two materials enable humane veterinary care. They are used together during both planned and emergency surgeries, sedating the animal to allow effective procedures. There are no equally effective synthetic or natural alternatives, and these two materials pose little environmental or health hazards. The subcommittee is reviewing xylazine and tolazoline together, updating their sunset schedule, as they are consistently used together.

Questions to our Stakeholders
None

Justification for Vote
The Subcommittee finds tolazoline compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal

Subcommittee Vote
Motion to remove tolazoline from the National List
Motion by: Nate Powell-Palm
Seconded by: Kim Huseman
Yes: 0 No: 5 Abstain: 0 Recuse: 0 Absent: 0

Xylazine

Reference: § 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.

(30) Xylazine (CAS #-7361-61-7)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires:

(i) Use by or on the lawful written order of a licensed veterinarian, and;

(ii) A meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals.

Technical Report: 2002 TAP (xylazine, tolazoline); 2019 TR (xylazine, tolazoline)
Petition(s): 2002
Past NOSB Actions: 09/2002 NOSB recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420) Proposed rule 01/17/2018 (83 FR 2498); Annotation change 12/27/2018 (83 FR 66559); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Xylazine is essential for use in veterinary surgical procedures for livestock, especially cattle.

Manufacture
Xylazine is synthesized by reacting 2,6-dimethylphenylisothiocyanate with 3-amino-1-propanol in a polar solvent (ether) to form a thiourea. Concentrated hydrochloric acid is added after the solvent is removed. Water is added to the cooled mixture, which is then filtered, and the filtrate is made basic to form a precipitate that is recrystallized as xylazine. Xylazine is used as a sedative, analgesic, and muscle relaxant in veterinary medicine. As a medical treatment, it can be administered intravenously, intramuscularly, subcutaneously, or orally, usually as a water-based injectable solution. Xylazine can also be found as a white crystalline powder. Xylazine sedative properties are due to its depressant mode of action on nervous system synaptic receptors. Sedation of animals is necessary for both planned medical procedures and emergency procedures to prevent the pain and suffering of animals as well as injury to the veterinarians performing the procedures. Xylazine is commonly used in conjunction with tolazoline, which is a reversal agent for sedatives such as xylazine. According to information posted on the FARAD (Food Animal Residue Avoidance Databank) website (http://www.farad.org/amduca-law.html), extra label use (i.e., off label use) of xylazine is permissible under the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) only if such use is by or on the lawful written or oral order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship. According to the FARAD Digest (published in JAVMA, Vol. 223, No. 9, Nov. 1, 2003), xylazine is used as a medical treatment in livestock intended for food production as well as in dairy cows.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed as a health care product and production aid (Table 5.3, Sedatives listing, CAN/CGSB-32.311-2020, page 28).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Not explicitly mentioned.

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

International Federation of Organic Agriculture Movements (IFOAM)
Not explicitly mentioned.

Japan Agricultural Standard (JAS) for Organic Production
Not explicitly mentioned.

Human Health and Environmental Issues
Xylazine is a substance with potent hypnotic and muscle-relaxation properties. The side effects of xylazine include significant cardiac arrythmias, which has resulted in its lack of approval for human medical applications (Green et al. 1981, EMEA 1999, Reyes et al. 2012). Due to the lack of approval for use in human medical applications, information on the mode of action and toxicity of xylazine is limited. [2019 TR 610-614]. Reported cases of xylazine in humans have shown physiological effects like those seen in veterinary applications (Samanta et al. 1990, JECFA 1998a). Upon absorption of xylazine, patients were difficult to rouse and showed signs of confusion (indicative of central nervous system and neuropathic depression) and expressed symptoms of bradycardia, hypotension (respiratory depression), and hyperglycemia (Gallanosa et al. 1981, Spoerke et al. 1986, Samanta et al. 1990). With regard to human carcinogenicity, no studies of direct effects have been published; however, the International Agency for Research on Cancer (IARC) has designated the xylazine metabolite, xylidine, as potentially carcinogenic to humans based on studies with

laboratory animals (NTP 1990, IARC 1993, JECFA 1998a). The lethal dosage of xylazine in humans is not well known and appears to vary dramatically between individuals (Spoerke et al. 1986, Ruiz-Colon et al. 2014). Fatal doses of xylazine recorded have been as low as 40 mg, while other individuals have survived exposure to levels as high as 2400 mg (Spoerke et al. 1986, Ruiz-Colon et al. 2014) [2019 TR 616-628].

Discussion
The Livestock Subcommittee (LS) finds that xylazine and tolazoline are critical tools for farmers and veterinarians. These two materials enable humane veterinary care. They used together during both planned and emergency surgeries, sedating the animal to allow effective procedures. There are no equally effective synthetic or natural alternatives, and these two materials pose little environmental or health hazards. The subcommittee is reviewing xylazine and tolazoline together, updating their sunset schedule, as they are consistently used together.

Questions to our Stakeholders
None

Justification for Vote
The Subcommittee finds xylazine compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal

Subcommittee Vote
Motion to remove xylazine from the National List
Motion by: Nate Powell-Palm
Seconded by: Kim Huseman
Yes: 0 No: 5 Abstain: 0 Recuse: 0 Absent: 0

Oxalic acid dihydrate

Reference: § 205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.
(8) Oxalic acid dihydrate—for use as a pesticide solely for apiculture.
Technical Report: 2018 TR
Petition(s): 2017
Past NOSB Actions: 04/2019 NOSB recommendation to add
Recent Regulatory Background: Added to NL 07/2021 (86 FR 33479)
Sunset Date: 7/26/2026

Subcommittee Review
As a varroa mite treatment, having oxalic acid dihydrate as a tool in the beekeeper toolbox is essential; subcommittee dialogue was brief but supportive of relisting.

Use
Oxalic acid is used as a parasiticide specifically for apiculture. Oxalic acid is currently labeled and approved by the EPA for use in beehives (Registration #91266-1). It is used both in the hive and during transport of honeybees in cages when sold as “bee packages”. It can be used in rotation with formic acid, currently on the National List, to control varroa mites and is a useful tool for beekeepers to manage honeybee parasites. Oxalic acid can be applied to a hive in two ways: In a sugar syrup to be trickled between frames, and as a vapor treatment. There are numerous types of equipment, both home-made and commercially available,

that provide the beekeeper the means of heating the oxalic acid and filling the hive with this vapor. In addition, oxalic acid is used to treat packaged bees before they are shipped to customers. Packaged bees with infestations of varroa mites have been a problem for beekeepers and the use of a sugar/oxalic acid syrup spray is a useful method to address this issue. Varroa mites, an invasive pest, are one of the many production problems affecting the livelihood of beekeepers. Numerous chemical varroa mite treatments have been used over the years in nonorganic operations. Many of these treatments are no longer effective due to the development of resistance by the varroa mite. Formic acid has been used for many years in honeybee hives, with no varroa mite resistance. It is considered unlikely that resistance will occur. Similar to formic acid, it is unlikely that varroa mites will develop resistance to oxalic acid.

The mode of action of this substance is not clearly understood, but it appears to be attributed to its acidity (pH near 0.9). Oxalic acid will cross the exoskeleton of the mites in a few hours of application and cause death. Oxalic acid vapor can enter the mite through the soft pads of its feet, enter the mite's blood stream and kill it. When mites parasitize and suck on the bee, it can kill the mite through this method as well. There is no clear research to determine if one or all of these are the main modes of action. Current research does indicate that the amount of oxalic acid typically applied to the honeybee hive is not toxic to the bees and is sufficient to kill varroa mites.

Manufacture
Oxalic acid is a dicarboxylic acid, which is in a crystalline form when solid, but loses this structure when dissolved in water. Commercial oxalic acid is produced through a variety of chemical reactions that include oxidation of carbohydrates or alkenes as well as synthesis from carbon monoxide and water. Oxalic acid crystals are produced through precipitation of the crystals from the mother liquor. Oxalic acid can also be produced through microbial fermentation of products such as citric acid, but these are not the typical method for commercial production.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
CAN/CGSB-32.310-2015 Clause 6.6.10: "The use of veterinary medicinal substances shall comply with the following: (a) if no alternative treatments or management practices exist, veterinary biologics, including vaccines, parasiticides or the therapeutic use of synthetic medications may be administered, provided that 408 such medications are permitted by this standard and Table 5.3 of CAN/CGSB-32.311 or are required by law."

Allowed as a health care product and production aid for mite control in honeybee colonies. (Table 5.3, CAN/CGSB-32.311-2020, page 28)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Allowed 2018/848 Annex 2, Part II 1.9.6.3 Health Care of Bees (e)
Formic acid, lactic acid, acetic acid and oxalic acid as well as menthol, thymol, eucalyptol or camphor may be used in cases of infestation with Varroa destructor."

OR 2021/1165 PART D Products referred to in Article 12(1) of this Regulation The following products or products containing the following active substances as listed in Annex VII to Regulation (EC) No 889/2008 cannot be used as biocidal products: — caustic soda; — caustic potash; — oxalic acid

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

Allowed for pest and disease control in beekeeping. (72, B. livestock & livestock products; page 17)

International Federation of Organic Agriculture Movements (IFOAM)
Allowed for pest and disease control in beekeeping. (5.8.7, page 52 and Appendix 5: Substances for Pest and Disease Control and Disinfection in Livestock Housing and Equipment, page 83)

Japan Agricultural Standard (JAS) for Organic Production
Japan does not have apiculture standards and oxalic acid is not present on their list of approved materials.

Ancillary Substances
None identified.

Human Health and Environmental Issues
Since it is an acid, it is considered hazardous in cases of skin contact, eye contact, ingestion, or inhalation. Handling instructions include use of protective equipment, such as long sleeves and pants, chemical resistant gloves, goggles, and a respirator.

There are no concerns of environmental contamination during manufacture or disposal. The amount used for honeybees is fairly small and does not add to concentrations of greenhouse gases in the atmosphere, and it would not have widespread negative impacts due to its biodegradability. Misuse of higher-than-recommended concentrations of oxalic acid could result in killing honeybees.

Discussion
In previous years' Board discussions, it was debated whether apiculture materials should be reviewed and approved only after there are NOP apiculture standards. It was noted that the NOP currently allows for organic honeybee products to be sold with the USDA organic seal, and honeybee products are certified organic by numerous NOP accredited certifiers. At the time, all Livestock Subcommittee members supported the implementation of the 2010 NOSB recommendation for organic apiculture standards. Beekeepers have expressed support in prior public comments noting some benefits over formic acid. During the Spring 2024 meeting, written comments and board discussion were limited but generally supportive of relisting.

Questions to our Stakeholders
What factors are weighed when determining to use sucrose octanoate esters, formic acid or oxalic acid dihydrate for varroa mite control?

Justification for Vote
The Subcommittee finds oxalic acid dihydrate compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove oxalic acid dihydrate from the National List
Motion by: Kim Huseman
Seconded by: Nate Lewis
Yes: 0 No: 5 Abstain: 0 Recuse: 0 Absent: 0

DL methionine

Reference: § 205.603(d) As feed additives.

(1) DL-Methionine, DL-Methionine—hydroxy analog, and DL-Methionine—hydroxy analog calcium (CAS #'s 59-51-8, 583-91-5, 4857-44-7, and 922-50-9)—for use only in organic poultry production at the following pounds of synthetic 100 percent methionine per ton of feed in the diet, maximum rates as averaged per ton of feed over the life of the flock: Laying chickens—2 pounds; broiler chickens—2.5 pounds; turkeys and all other poultry—3 pounds.

Technical Report: 2001 TAP; 2011 TR

Petition(s): 2005; 2007; 2009; 2011

Past NOSB Actions: 10/2001 NOSB recommendation; 03/2005 NOSB recommendation; 05/2008 NOSB recommendation; 04/2010 NOSB recommendation on Methionine annotation; 04/2010 NOSB recommendation on Methionine step-down annotation after October 2012; 04/2010 sunset recommendation; 08/2014 Organic poultry feed proposal; 04/2015 NOSB Formal recommendation to amend; 10/2015 sunset recommendation; 10/2019 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Proposed rule 01/17/2018 (83 FR 2498); Annotation change 12/27/2018 (83 FR 66559); Renewed 8/3/2021 (86 FR 41699)

Sunset Date: 9/12/2026

Subcommittee Review

Use

Methionine is an essential amino acid for poultry since it cannot be produced biologically by the birds and is necessary for proper cell development for the growing chicks and for proper feathering. The USDA organic standards require that all agricultural ingredients for livestock feed be certified organic, and prohibit feeding meat by-products to organic poultry. This restriction narrows the options for natural sources of methionine.

Manufacture

Methionine is a sulfur-containing amino acid. The 2011 Technical Report lists these various methods of manufacture:

1. L-methionine may be isolated from naturally-occurring sources, produced from genetically engineered organisms, or synthesized through many processes. While methionine has been produced by fermentation in the laboratory, racemic mixtures of D- and L-methionine (i.e., DL-methionine) are usually produced entirely by chemical methods (Araki and Ozeki, 1991) [2011 TR 238-240]. Most L-methionine is produced from synthetic DL- methionine, and DL-methionine can be produced in following ways:
    a. Reaction of acrolein with methyl mercaptan in the presence of a catalyst (Fong et al., 1981);
    b. Reaction of propylene, hydrogen sulfide, methane, and ammonia to make the intermediates acrolein, methylthiol, and hydrocyanic acid (DeGussa, 1995; 1996);
    c. Use of the Strecker synthesis method with α-methylthiopropionaldehyde as the aldehyde (Fong et 275 al., 1981); or
    d. Reaction of 3-methylmercaptopropionaldehyde with ammonia, hydrogen cyanide, and carbon dioxide in the presence of water in three reaction steps (Geiger et al., 1998) [2011 TR 242-248].
2. In general, L-methionine is produced from DL-methionine via optical resolution resulting in separation into the D- and Lenantiomers (Ajinomoto Corporation, 2012) or by acetylation of synthetic DL-methionine and subsequent enzymatic selective deacetylation of the N-acetylated L-

methionine (Usuda and Kurahashi, 2010). Because much of the DL-methionine supply is synthesized using chemical methods, the L methionine produced from it is also synthetic. While nonsynthetic L-methionine can be produced by fermentation, there are no commercial sources available that use this method (Kumar and Gomes, 2005) [2011 TR 479-480].

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

Allowed for use in feed, feed additives, and feed supplements. Organic sources, such as fishmeal, insect meal, brewer's yeast, potato protein, corn gluten and distillers' grains, shall be the first preference. When these organic sources does not meet amino acid requirements to produce a balanced feed, then:

a) amino acids derived from biological sources by biofermentation and extracted/isolated by hydrolysis, by physical, or other non-chemical means may be used;

b) when such forms of lysine and methionine are not commercially available for use in monogastrics feeding, all sources of lysine and methionine may be used.

This annotation will be reviewed at the next revision of the standard. (Table 5.2, Amino acids listing, CAN/CGSB-32.311-2020, page 23).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

The European Economic Community (EEC) Council Regulations state that "growth promoters and synthetic amino acids shall not be used" in animal feed in organic production.

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

Not explicitly mentioned.

International Federation of Organic Agriculture Movements (IFOAM)

Not allowed (3.2 Organic animal management does not use any of the following synthetic feed rations: amino acids (including isolates), page 16).

Japan Agricultural Standard (JAS) for Organic Production

Not explicitly mentioned.

Human Health and Environmental Issues

Synthetic methionine used as a nutritional supplement in livestock production can enter the environment through waste streams from its production, use, and disposal. Methionine has a relatively low vapor pressure, indicating that methionine present in soil or water is not likely to evaporate into air. Methionine is highly mobile in soil, and research has shown that most of the methionine in soil breaks down in about 16 days. Methionine can exist as a vapor or particulate in the air. Airborne methionine vapor will be degraded in the atmosphere with a half-life of about 7.5 hours. Methionine is also found naturally in water from metabolism of proteins. The potential for bioconcentration of methionine in aquatic organisms is considered low due to its high water solubility [2011 TR 729-286].

Discussion

The Livestock Subcommittee continues to see a need for synthetic DL-methionine in the organic poultry diet. Poultry are naturally omnivorous. Wild birds obtain sulfur containing essential amino acids (methionine and lysine) in their diet by eating insects, carrion, and other types of animal protein found in nature. Since USDA organic regulations prohibit the feeding of mammalian or poultry slaughter byproducts, the sulfur containing amino acids necessary for balanced poultry diets must come from other sources including agricultural products, nonsynthetic substances, and synthetic amino acids when permitted on the

National List at 205.603. Neglecting to supplement methionine in organic poultry diets results in serious health concerns including nervousness, feather picking, cannibalism and death. Organic poultry producers have struggled to find agricultural or nonsynthetic feed ingredients that adequately address methionine deficiencies without impacting bird health in other ways from overfeeding protein or introducing new feed ingredients that cause adverse health effects (e.g. Brazil nuts).

The feeding of synthetic methionine to organic poultry has been a contentious practice over the years, with some stakeholders opposed to any synthetic feed component. In contrast, comments from organic producers at the last review tended to strongly support the use of synthetic methionine under the current annotation. Commenters who identified as poultry producers all emphasized the essentiality of methionine to their operations. Specifically, commenters cited the animal welfare impact of methionine on their poultry including reduced pecking, improved feathering, and consistent, correct bird development. Research and innovation on this issue continues, but in the meantime the inclusion of DL-methionine on the National List appears warranted.

Questions to our Stakeholders

1. Is there a need for changes to the USDA organic regulations to align with either Canadian (unrestricted amino acid are allowed in organic feed) and/or EU (non-organic feeds containing methionine are allowed) organic regulations? If so, what changes to the USDA organic regulatory text should be made?

2. What other nutritional barriers to organic poultry production do producers face when formulating well balanced rations for all poultry in the organic sector?

3. Is the current restriction on methionine in organic poultry diets necessary? What would the impact be on poultry nutrition and feed formulations if methionine was allowed without any restrictions?

Justification for Vote
The Subcommittee finds DL-methionine compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove DL-methionine from the National List
Motion by: Nate Powell-Palm
Seconded by: Nate Lewis
Yes: 0 No: 5 Abstain: 0 Recuse: 0 Absent: 0

Trace minerals

Reference: § 205.603(d) As feed additives.
(2) Trace minerals, used for enrichment or fortification when FDA approved.
Technical Report: 2013 TR (aquatic trace minerals); 2019 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB recommendation; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 09/2014 subcommittee proposal - aquatic trace minerals; 10/2015 sunset recommendation; 10/2019 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Minerals are required in animal nutrition for their vital roles in various metabolic, enzymatic, and biochemical reactions in the animal body. Forages and grains are good sources of calcium and phosphorus, respectively. Minerals may be provided through the intake of plant matter feedstuffs and through synthetic supplements. Several factors directly or indirectly influence the levels of minerals in plants, including location, nature, and chemical composition of the soil; level of fertilization; and the presence of anti-nutritional factors that may reduce mineral bioavailability. Bioavailability is defined as the total proportion of the nutrient in a feedstuff that is available for use in normal body functions. As a result, the amounts of minerals for animals that depend on plants as feedstuffs will vary.

The dietary importance of each micro-mineral will depend on the animal species in question. When diet is insufficient to meet an animal's nutrient requirements, supplementation of minerals is typically done through inclusion in the diet either as an individual substance or as part of a trace mineral premix. NOP Guidance 5030 *Evaluating Allowed Ingredients and Sources of Vitamins and Minerals For Organic Livestock Feed* spells out in more detail which minerals are covered under this listing.

It should be noted that while it is beyond the scope of this sunset review to clarify which minerals are included in this listing, the Livestock Subcommittee acknowledges this listing also includes macro minerals. The 2019 TR addresses macro minerals that are included in animal diet, though not in great detail as they are outside the focus of trace minerals.

Manufacture
Because this is a broad categorical listing, manufacture varies. In most cases, biologically active forms of trace minerals cannot be obtained by mining, so many trace minerals used as feed additives are produced by chemical reactions resulting in inorganic forms of the mineral. More recently, organic forms have become available. This would include the various chelates and complex forms. One of the limiting factors to the use of chelated minerals has been high cost. At the time of the 2019 review, chelated minerals cost 10 to 15 times more per milligram of mineral supplied, compared to inorganic sources.

Descriptions of the common processes used to manufacture many of the trace minerals in use are included in the 2019 TR. This level of detail is not provided for the class of substances called metal amino acid chelates since the processes used to manufacture those materials are largely the same.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed for use in feed, feed additives, and feed supplements. Unprocessed rock dusts; ground animal or plant material (other than blood or bone meal); and seawater are preferred sources. Chelated and sulphated forms are allowed. If none of these sources are commercially available, other versions are allowed, except for forms containing or produced with EDTA or EDDHA. (Table 5.2, CAN/CGSB-32.311-2020, page 24)

Non-synthetic chelated or sulphated minerals are allowed for use as a health care product and production aid. Examples include oyster shell, calcium chloride and magnesium oxide. Synthetic nutrient minerals may

be used if non-synthetic sources are not commercially available. Minerals from any source are allowed for medical use. (Table 5.3, CAN/CGSB-32.311-2020, page 28)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Allowed for use as feed or in feed production (Annex III, Part B, 3(b), 2021/1165)

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Allowed when used in preference to veterinary drugs or antibiotics, needs to be recognized by the certification body or authority, and can only be used if they are of natural origin. In case of shortage of these substances, synthetic substances may be used.

International Federation of Organic Agriculture Movements (IFOAM)
Allowed. Animals may be fed vitamins, trace elements, and supplements from natural sources unless they are not available in sufficient quantity and/or quality.

Japan Agricultural Standard (JAS) for Organic Production
Allowed for therapeutic purposes and mineral supplementation.

Human Health and Environmental Issues
Based on information presented in the 2019 TR, the hazards associated with the use of the trace minerals are primarily associated with dust irritation of the skin and eyes.

When used as petitioned, trace minerals from unconsumed feed have the potential to be transferred to ground or surface waters. While trace minerals are essential dietary components for animal feeds, some are considered heavy metals with strong toxic potential. When included in animal feeds above required amounts, trace elements accumulate in urine and feces in low concentrations. In many cases, these may serve to increase deficient soil levels. The environmental risks of overly high micronutrient applications include impairment of plant production, accumulation in edible animal products, and contamination of the water supply. Concerns regarding specific minerals are included in the 2019 TR.

Discussion
The NOSB received 5 comments in spring 2024 supporting the relisting of trace minerals, and none opposed. They noted the essentiality of trace minerals to livestock health and welfare and their importance in offsetting seasonal variables in forage nutrition.

Some commenters noted organic production should not be dependent on synthetic nutrients and that the current annotation is not restrictive enough to prevent reliance on synthetic materials. These commenters recommend adding “when forage and available natural feeds are poor quality” to the annotation. However, according to the 2019 TR, forages alone do not always satisfy the mineral requirements of grazing cattle. Mineral deficiencies and imbalances in grazing ruminants have been reported in almost all regions of the world. The choice of forage crop; the part of the plant consumed, and the plant’s state of maturity; the soil type and condition; and climatic conditions and seasons when plant material is eaten/gathered are all factors in determining the level and availability of trace minerals in feeds, and thus the need for trace mineral supplements.

Justification for Vote
The Subcommittee finds trace minerals compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove trace minerals from the National List
Motion by: Brian Caldwell
Seconded by: Nate Powell-Palm
Yes: 0 No: 3 Abstain: 0 Recuse: 0 Absent: 2

Vitamins

Reference: § 205.603(d) As feed additives.
(3) Vitamins, used for enrichment or fortification when FDA approved.
Technical Report: 1995 TAP (Folic Acid); 2013 TR (aquaculture); 2015 TR; 2024 Limited Scope TR
Petition(s): 2012 (aquaculture)
Past NOSB Actions: 10/1995 NOSB recommendation; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290) ; Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
The National Organic Program (NOP) currently allows the use of vitamins as feed additives in organic livestock production under 7 CFR 205.603, "Synthetic Substances Allowed for Use in Organic Livestock Production" for enrichment or fortification when FDA approved in amounts needed for maintenance (7 CFR §205.237) and for adequate nutrition and health. Further, the USDA organic regulations require producers to meet certain standards for livestock health care practices. As part of this requirement, livestock feed rations must meet nutritional requirements, including vitamins, minerals, protein and/or amino acids, fatty acids, energy sources, and fiber (ruminants) (7 CFR 205.238(a)(2)).
The addition of vitamins directly or indirectly into animal food falls under the regulatory oversight of the U.S. Food and Drug Administration (FDA). According to FDA regulations, the addition of vitamins must be used according to the relevant food additive regulation, unless the substance is generally recognized as safe (GRAS) under 21 CFR 582/584 for that use pattern (FDA, 2014a) [2015 TR 234-236]. Vitamins may be added to mineral mixes and fed free choice or incorporated into rations.

Depending on the raw nutrients available, vitamins are combined in livestock feed rations of grains, beans, oilseeds, and other meals along with minerals and amino acids. There are 15 essential vitamins currently allowed for use in organic livestock production for fortification and enrichment: Vitamin A (vitamin A acetate), Vitamin B1 (thiamine hydrochloride), Vitamin B2 (riboflavin), Vitamin B3 (niacin, nicotinic acid), Vitamin B5 (calcium pantothenate), Vitamin B6 (pyridoxine hydrochloride), Vitamin B7 (biotin), Vitamin B12 (cyanocobalamin), Vitamin C (ascorbic acid), Choline chloride, Vitamin D3 (cholecalciferol), Vitamin E (α-Tocopherol acetate), and Inositol. The scope of vitamin compounds is reflective of vitamins defined as "required nutrients" by the National Research Council's (NRC's) Nutrient Requirements for cattle, sheep, swine and poultry. Dietary intake of these essential vitamins is essential for the health and well- being of all animals, including livestock. Most vitamins aid in the metabolism of proteins, carbohydrates, and fats while some vitamin compounds have important antioxidant properties. Common signs of vitamin deficiency include anorexia, poor growth, reduced feeding efficiency and, in some cases, mortality.

Manufacture
Individual vitamin compounds are normally produced on an industrial scale by chemical synthesis or partial synthesis. While chemical synthesis remains the dominant industrial production method for many vitamins, an increasing number of fermentation processes are being developed for vitamin production. Many recently developed fermentation methods for manufacturing vitamins utilize excluded methods. They use genetically engineered (GE) microorganisms, generating concerns over the use of these vitamin sources in organic food production. The Technical Review conducted in 2015 stated that fermentation production using genetic modification may be commonly used in production of vitamins A, B2, B5, B6, C, E, and B12. A new limited technical review was requested to update which vitamins are produced with excluded methods and the availability of other sources. The authors indicated that this was difficult because much of the information was proprietary and held by foreign companies outside the jurisdiction of US requirements. The new 2024 TR indicated that vitamins B2, B12, and C have a high probability of being produced with use of a GE microorganism, from a GE feedstock. In addition, vitamins B8 and E are likely made from a GE feedstock (corn and soybeans) with non-GE microbes.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Biological and mineral sources of all vitamins are allowed. Non-biological and non-mineral sources of vitamins B1, C (ascorbic acid) and E are allowed. (Table 4.2, CAN/CGSB-32.311-2020, page 21)

Allowed in feed, feed additives, and feed supplements as a concentrated mixture of minerals and vitamins, from organic sources if commercially available. Allowed for enrichment or fortification. Vitamin formulants that comply with Canadian regulations are accepted. Vitamins not compliant to 5.1.2 of CAN/CGSB-32.311 are allowed. (Table 5.2, Pre-mixes listing, CAN/CGSB-32.311-2020, page 25)

Allowed for use as a health care product and production aid. Vitamin formulants that comply with Canadian regulations are accepted. Vitamins not compliant to 5.1.2 of this standard are allowed. Orally, topically, or by injection. (Table 5.3, CAN/CGSB-32.311-2020, page 29)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Vitamins, pro-vitamins and chemically well-defined substances having similar effect allowed; agricultural derivatives preferred (Annex III, Part B, 3(a), 2021/1165)

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Vitamins or provitamins are allowed if they are of natural origin. In case of shortage of these substances or in exceptional circumstances, synthetics may be used. (page 13)

International Federation of Organic Agriculture Movements (IFOAM)
Allowed from natural sources unless they are not available in sufficient quantity and/or quality. (3.2-page 16; 5.5.6-page 48)

Japan Agricultural Standard (JAS) for Organic Production
Allowed for therapeutic purposes.

Human Health and Environmental Issues
In addition to being essential nutrients, vitamins are generally considered non-toxic and safe for livestock and human consumption at levels typically ingested through the diet and dietary supplements. When given

according to label directions, supplementation of animal feeds with vitamins is unlikely to result in excessive vitamin intake for humans.

No studies have been found indicating toxic effects of vitamins on soil-dwelling organisms. Strong acids and bases are used in the synthetic or extraction process of vitamin compounds. Improper use or disposal of these chemicals during the production of vitamins could affect both the pH and chemical composition of the soil, potentially resulting in physiological effects on soil organisms. Accidental release of chemical reagents during the production process may lead to ecological impairment.

Discussion

Public Comments

During the Spring 2024 NOSB review the Livestock Subcommittee received 5 comments in favor of relisting vitamins at §205.603, and none to delist. One said that only vitamins A, C, and D, when feeds are insufficient, should be relisted. Vitamins are widely used. B and K vitamins were not considered essential for ruminants [and are thus not commonly included in mineral mixes for these species]. B vitamins were considered essential for poultry. Certifiers commonly use affidavits to determine excluded method status.

Vitamins satisfy the OFPA evaluation criteria and the Livestock Subcommittee supports relisting. However, the use of excluded methods in the production of some vitamins, and the lack of transparency regarding production methods is problematic. The NOP has issued a guidance (NOP 5030, in 2013) and a "response to comments" document (NOP 5030-1) which include discussions of this issue.

- In NOP 5030 guidance document, NOP is clear that proteinated minerals produced with excluded methods are not allowed in organic livestock feed, however, it is silent on the review and approval of vitamins which may be produced using excluded methods.
- In NOP 5030-1 document, the NOP observes "a lack of technical review or specific recommendation from the National Organic Standards Board (NOSB) to clarify this issue regarding sources of livestock mineral and vitamins…."
- It further specifies that "FDA and AAFCO listed vitamins and minerals meet the specifications of the National List at § 205.603(d)(2) and § 205.603(d)(3)."
- Finally, NOP 5030-1 states, "The USDA organic regulations also prohibit use of excluded methods at § 205.105(e), and thus vitamins used in livestock feed should be reviewed for excluded methods."
- Currently, citing the absence of a clear directive in NOP 5030, the Accredited Certifiers Association Best Practice for GMO Vitamins in Livestock Feed vitamins states that the GMO status of AAFCO-listed vitamins used in certified organic livestock feed does not need to be verified.

Technical Reviews from 2015 and 2024 address this issue in depth and indicate that some FDA and AAFCO listed vitamins are highly likely to be produced with excluded methods.

Vitamins themselves are not GMO's. The NOP regulation states that to be sold as organic, the product must be produced and handled without the use of excluded methods (7 CFR 205.105(e)). This raises the question, if an animal was fed vitamins manufactured with GMO's, does that mean that the animal was produced using excluded methods?

We request advice from the organic community as to whether an annotation is needed, requiring that vitamins fed to livestock be produced without excluded methods. We recognize that this would entail additional work from certifiers and materials review organizations. Further, for the production of some synthetic vitamins such as vitamin C, it might be impossible to verify that excluded methods have not been used. If those synthetic vitamins are disallowed, organic livestock producers could be disadvantaged.

Questions to our Stakeholders

1. If an animal was fed vitamins manufactured with GMO's, does that mean that the animal was produced using excluded methods?
2. How far back in the manufacturing process of a vitamin would a certifier need to verify in order to conclude that the vitamin was produced without excluded methods?
3. How might an annotation be used to ensure that vitamins fed to livestock are produced without excluded methods?

Justification for Vote

The Subcommittee finds vitamins compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote

Motion to remove vitamins from the National List
Motion by: Brian Caldwell
Seconded by: Nate Lewis
Yes: 0 No: 4 Abstain: 0 Recuse: 0 Absent: 1

National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal
Carbon Dioxide
August 6, 2024

Summary of Petition:

Carbon dioxide (CO_2) was petitioned in 2020 to be added on the National List of Allowed and Prohibited Substances, for use as a plant or soil amendment at §205.601(j). The same petition requested the addition of carbon dioxide at §205.601(a) of the National List for use as an algicide, disinfectant, and sanitizer, including uses in irrigation systems, to acidify irrigation water. The petition heavily focused on the use as an algicide, disinfectant and sanitizer in irrigation systems, and did not provide enough information about the material as a plant or soil amendment. Under "the intended use or current use of the substance" the petitioner stated "Carbon dioxide is used in a water pH adjustment process. Dissolved carbon dioxide in water makes carbonic acid, which reduces water pH, therefore increasing H+ concentration and neutralizing bicarbonates. Water pH adjustment is common practice in agriculture. Irrigation water sources are usually alkaline and with bicarbonates above the maximum desired levels for proper irrigation water quality."

In 2022, the NOSB recommended the National Organic Program add carbon dioxide at §205.601(a) but requested a full-scope technical report (TR) to address the sections of the petition requesting the addition of carbon dioxide at §205.601(j), as a plant or soil amendment, before making a second recommendation.

The 2023 technical report outlined the specific use of the petitioned material as an atmospheric adjustment in indoor production. In the report, we find that ambient air contains 350-450 ppm CO_2, while the optimal concentration of CO_2 for plant growth in a greenhouse environment is 800-1000 ppm (Poudel & Dunn, 2017; Thomson et al., 2022; Wang et al., 2022). As plants grow, they metabolize CO_2 in the air of the greenhouse, depleting it to 100-250 ppm during peak CO_2 consumption. Venting the greenhouses to allow more atmospheric CO_2 in disrupts the temperature control. Natural turnover of air by venting may help to moderate CO_2 levels during warm months, but venting is usually not practical during colder periods or in colder regions, and supplementation is needed.

Subcommittee Review winter 2024:
Because there was not enough information in the petition about the importance or need for the substance to be listed as a crop or soil amendment, the Subcommittee has been hesitant to recommend its listing. The TR only listed its use as a plant or soil amendment in indoor production. The Subcommittee recognizes that this petition highlights the lack of clear standards pertaining to indoor and container production, which inhibits the NOSB from fully evaluating petitions for substances used in this type of production.

One member stated experience with the substance, noting that its use increases production potential, while another questioned its necessity, i.e., Is this material truly necessary for organic production or is it used as a booster like synthetic fertilizers or substance of high solubility? The Crops Subcommittee contacted organic greenhouse transplant and nursery producers and found that CO_2 was not needed nor supported for use. These producers were in the Southeast where average temperatures are warmer, and venting is less limited compared to colder climates. The Crops Subcommittee requested a greater explanation of the greenhouse gas effects of this material in its manufacture and use and how it ties to climate change.

Spring 2024 Public comments:
There were eight written comments for the spring 2024 Board meeting in Milwaukee. Four commenters supported the listing of synthetic carbon dioxide as a plant or soil amendment stating that it meets Organic Foods Production Act (OFPA) criteria, and four commenters opposed the listing. There was equally mixed support in oral comments, but no comments came from direct users of this material.

Spring 2024 NOSB Board meeting review:
Discussion at the spring meeting centered around the essentiality of this material. Other important discussions included the potential increase of carbon dioxide production. Would listing this material create a demand for supply that would justify the manufacturing of carbon dioxide? The lead stated that all synthetic CO_2 in the market is a by-product of other manufacturing processes. Given the mixed support, the proposal was sent back to Subcommittee for additional work, and so it could solicit additional feedback from stakeholders.

Subcommittee Review summer 2024:
A Board member with greenhouse production experience explained that heating the greenhouse with liquid propane created an amount of carbon dioxide, and instead of venting this by-product to the outside, it was vented into the production area to aid in raising carbon dioxide levels. This was done prior to OFPA and the organic standards. Without the petitioned listing, venting this by-product of carbon dioxide is not allowed in organic production.
According to the TR, there was a supply chain shortage of carbon dioxide in 2022. The shutdown of ethanol plants, contaminations in high-producing wells, and pandemic supply chain issues were attributed to the shortages (TR, 2023 lines 822-827). The recent shortage entertains the idea that the listing of carbon dioxide at §205.601(a) could lead to the increase in manufacturing processes to produce more carbon dioxide. In consideration of this concern the Subcommittee is proposing an annotation to restrict this substance to be sourced as a byproduct.

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 is the byproduct of many chemical and biological processes with fuel combustion and fermentation being the most prominent. The combustion of natural gas results in CO_2 and water vapor and CO_2 may be produced as a by-product of carbohydrate fermentation by yeast in the production of ethanol or alcoholic beverages (TR, 2023).

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?

CO_2 does not contain an active ingredient in any of the categories listed above. However, it is listed on 2004 EPA List 4A and was not revoked under NOP 5008, Guidance: Reassessed Inert Ingredients. As an insecticide, "carbon dioxide is exempted from the requirement of a tolerance when used after harvest in modified atmospheres for stored insect control on food commodities" per 40 CFR 180.1049 (TR, 2023).

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)]

At normal temperatures, CO_2 does not break down into simpler compounds, and it is not very reactive. While unlikely to be an issue in organic crop production, CO_2 can react with hydrogen gas to form carbon monoxide (CO). It can also react with ammonia to form ammonium carbamate, which when dehydrated then forms urea (TR, 2023).

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)]

According to the TR, higher concentrations of CO_2 can benefit plants, but soil composition, nutrient availability, plant species, and plant genetics all influence the response. The technical review referenced a study finding that plants in growth chambers showed symptoms of toxicity when subjected to 2000 ppm CO_2. It can also be toxic to microorganisms, and animals at significantly elevated levels. No information that specifically indicated that carbonate (CO_3^{2-}) or bicarbonate (HCO_{3-}) ions, formed from the dissolution of CO_2 in water, are toxic to plants.

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

CO_2 used in agriculture will largely be derived from fossil fuels, previously stored in the lithosphere, and will re-enter the carbon cycle temporarily persisting or concentrating in one of the three other major reservoirs: the terrestrial biosphere, the hydrosphere (oceanic reservoir), or atmosphere. Gaseous CO_2 is relatively stable in the atmosphere.

CO_2 plays an essential role in soil pH and aquatic environments because of the carbonic-acid system. In contact with water, a proportion of CO_2 dissolves until equilibrium is reached between CO_2, bicarbonate (HCO_{3-}), carbonate (CO_3^{2-}), and carbonic acid (H_2CO_3). A greater proportion of CO_2 shifts the equilibrium to the formation of carbonic acid resulting in lower pH (TR, 2023).

In the atmosphere, CO_2 absorbs longwave radiation coming from the earth's surface, causing warming known as "the greenhouse effect." Greenhouses usually have a CO_2-use efficiency of less than 60%, meaning that over 40% of the CO_2 that is added is released into the atmosphere without being ever incorporated into plant biomass.

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

According to the TR, CO_2 can be defined as a toxicant since it induces unconsciousness, respiratory

failure, inflammation, and sensory impairment. Instances of CO_2 poisoning are exceedingly rare events. The concentrations found in nature, in typical industrial settings, or used in greenhouses, are far lower than any of the concern levels listed above and are not a threat to human health. Adverse effects generally begin following exposure to 1% or greater CO_2, while background atmospheric levels are approximately 0.04% and enriched greenhouse atmospheres are approximately 0.1%. Confined areas like mines, silos, or fermentation chambers, for example, may be environments where CO_2 concentrations can surpass 1%, sometimes significantly. The current OSHA Permissible Exposure Limit (PEL) for 8-hour exposure to gaseous CO_2 is 5,000 ppm, or 0.5%.

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)]

Lowering the pH to 6.0-6.8 can improve the bioavailability of some nutrients, such as iron, zinc, boron, and manganese. Cation availability can also increase due to increased weathering of parent material and minerals, therefore affecting soil chemistry. In wet environments or where large amounts of irrigation are used, these effects can leach these available cations (TR, 2023).

At low concentrations (up to about 1200 ppm), CO_2 is generally safe and has low toxicity, and can have substantial beneficial effects to plants. However, at moderate concentrations (1200 ppm to several percent, depending on duration and tolerance of a given species, CO_2 can cause toxic effects in plants and animals. At high levels (>~50%), it can be toxic to microorganisms as well.

Decreasing water pH can increase the toxicity of copper for *Arenicola marina*, an aquatic segmented worm.

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

Applying CO_2 at higher than optimum levels could cause toxicity to a wide variety of organisms. This situation is unlikely, however, because it would also begin to exert negative growth effects on crops, thus defeating the purpose of its 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)]

There is no substitute for gaseous CO_2 in plant biology. It is an essential component of the photosynthesis process.

It is possible to produce CO_2 nonsynthetically using fermentation processes or extraction from natural CO_2 wells but the prevalence and availability of different CO_2 production streams is difficult to define, is determined by regional industry and transport infrastructure, and by the nature of the commodified raw chemical material market because many streams may be combined. Previous written comments have indicated that inadequate infrastructure and costly transport restricts the source of nonsynthetic carbon dioxide. The commentor also stated fermentation businesses were often using the $CO_2$for carbonating fermented beverages.

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

The Crops Subcommittee initially had questions regarding the greater explanation of the overall greenhouse gas effects of this material in its manufacturing and use, especially how it ties into climate change for this particular petitioned usage. CO_2 can be used for agriculture without adding harm to the environment. Because it is a byproduct of multiple manufacturing processes, the "production" of CO_2 is occurring regardless of its use in organic agriculture. If it weren't used, it would be released into the atmosphere. Although its use does not substantially reduce emissions because the CO_2 is only temporarily stored in the plant and then re-enters the carbon cycle. In reflection of this information the Crops Subcommittee proposes an annotation to restrict its use to byproduct sources.

Classification:
Carbon Dioxide is already on the national list and classified as synthetic.

National List Motion:
Motion to add carbon dioxide at §205.601(j) with the annotation: must be sourced as a byproduct.
Motion by: Logan Petrey
Seconded by: Jerry D'amore
Yes: 6 No: 2 Abstain: Recuse: Absent: 1

National Organic Standards Board
Crops Subcommittee
Compost Proposal
August 13, 2024

Introduction:

Compost and the process by which it is produced are defined in the organic regulations at §205.2 Terms Defined. Additionally, section 205.203(c) of the soil fertility and crop nutrient management practice standard outlines further requirements for processing and applying plant and animal materials under the organic regulations. The section emphasizes that an organic compost producer "must manage plant and animal materials to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances". The National List § 205.601 provides for one synthetic exception to plant and animal material composition of organic compost, with a listing for newspaper as a compost feedstock.

Certain types of compost and manure-based inputs commonly used in organic farming were not directly addressed in the rule, such that additional information and clarification was needed. Two different task forces were commissioned to make recommendations on compost, vermicompost, processed manures, and compost tea. In April 2002 the Compost Task Force Recommendation was presented to the NOSB and subsequently accepted as a recommendation to the NOP. In October 2004, a separate report and recommendation was presented to the NOSB by the Compost Tea Task Force. That document was also accepted by the NOSB, and the Crops Subcommittee (CS) was directed by the Board to determine the necessary work that needed to be done to clarify these documents to the public. In October 2006, the CS produced a document titled: Crops Subcommittee Recommendation for Guidance Use of Compost, Vermicompost, Processed Manure, and Compost teas, which was accepted by the NOSB. The NOP responded to those recommendations with guidance document NOP 5021 with the stated purpose of clarifying "allowed practices for composition, production, and use of compost and vermicompost in organic crop production". In December of 2016, the NOP published information regarding alternative compost methods in NOP 5034-1 Materials for Crop Production.

Given the efforts to address climate change through waste reduction and recycling, and to continuously improve and provide clarification of the organic standards, the NOSB and the Crops Subcommittee have been in discussions with the NOP regarding opportunities to update organic definitions and regulations regarding organic compost production. These discussions led to an official work agenda request to the NOP in September of 2023. Concurrently, in August of 2023, the Biodegradable Products Institute (BPI) submitted a petition for rulemaking directly to the United States Department of Agriculture (USDA), requesting that AMS change the definition of compost and add a definition of "compost feedstock" to the federal organic regulations at 205.2. Further, the petition seeks amendments to § 205.203. In October of 2023, the NOP issued a Memorandum to the National Organic Standards Board requesting a recommendation on the topic of compost in organic agriculture.

In the Spring of 2024, the Crops Subcommittee introduced a discussion document to provide a forum for the NOSB, NOP, and the stakeholder community to gain insight into the state of organic compost production. NOSB also hosted an expert panel on compost at the Spring 2024 meeting. This proposal responds to the information obtained from stakeholder engagement towards fulfilling the request by the NOSB to update compost references in regulations, while addressing the interest and concerns raised by BPI in a petition to the USDA to update compost definitions in organic regulations.

Background - Addressing concerns raised by the BPI Petition directly to the USDA:
The Crops Subcommittee and the full Board have clearly reinforced the Board's commitment to the organic process as it has worked since inception. The CS is not looking to disrupt long established organic processes by redefining foundational aspects of organic systems. Public comments from the compost industry were clear that the NOP regulations are working, and there is room for improvement, but defining compost feedstocks to include synthetic substances not on the National List or referring to a "de minimis " doctrine that has not been established in our definitions or regulations. Bypassing the NOSB process is a dangerous implementation of new procedures that circumvents our unique version of American democracy. The CS and the full Board have expressed a commitment to the process of evaluating synthetic inputs through the National List, technical reviews and full board engagement with stakeholder expertise via written and public comments. The process is predictable, and facilitates equitable engagement while providing a level of transparency to consumers upon which trust in the organic seal is founded. Moving the goalpost to meet the needs of an adjacent industry undermines the current practice of thorough evaluation of organic inputs via criteria established in regulations. The pressure to innovate climate change solutions to waste related challenges is a "politics of the moment" that appears to look towards the organic industry as a driver for acceptance to innovation in compostable waste. Nevertheless, the process USDA, NOSB, and the organic community has established for review of material inputs into organic systems that works and should not be jettisoned or circumvented.

The organic industry's approach to material review has matured and become more sophisticated in the past three decades following the passage of the Organic Foods Production Act. The NOP established in Guidance (NOP 5033) that natural substances that undergo chemical change resulting from a biological process remain natural. However, this precedent cannot be applied to synthetic substances that are subject to a chemical change that occurs through a biological process. In this case, substances that start as synthetic end as synthetic even if the chemical change was the result of a biological process. This principle applies to a compost feedstock that becomes part of the soil and plant life in organic cropping systems: the composting process, itself a biological process, does not magically transform synthetic substances into natural ones, and, as such, any feedstock used in the composting process should be either a natural or synthetic substance that has been added to the National List through a two-thirds vote by the NOSB and notice and comment rulemaking by NOP.

The petition from BPI asserts that the common practice of material review through the Subcommittee dissection of criteria to meet the National List allowance for allowed and prohibited substances is not necessary for compostable packaging. The petition states:

> *"This Petition seeks to have the materials and products that meet the American Society for Testing Materials ("ASTM") standards for compostability be designated as allowed compost feedstocks. The packaging materials that meet the ASTM compostability standard are presently allowed as food contact substances in packaging for organic food but anomalously are disallowed as a compost feedstock."*

The Crops Subcommittee is clear that the considerations taken into account when evaluating food contact substances in organic handling do not apply when evaluating inputs into organic cropping systems, even if those inputs may be food contact substances themselves. As a synthetic material, if compostable packaging is to be considered as a compost feedstock, the material is required to be evaluated and recommended for listing by a ⅔ vote of the NOSB and added to the National List by NOP through notice, comment, and rulemaking.

Additionally, the petition utilizes ASTM D6400-21, D6868-21, and D8610-21 as a means to objectively identify which synthetic substances should be allowed as compost feedstocks in organic compost. The CS acknowledges the utility of ASTM standards as a means to reliably review substances for adherence to a particular standard, and recognizes that ASTM standards are currently included in the organic regulations for substances on the National List:

7 CFR 205.2

Biodegradable biobased mulch film. A synthetic mulch film that meets the following criteria:

(1) Meets the compostability specifications of one of the following standards: ASTM D6400, ASTM D6868, EN 13432, EN 14995, or ISO 17088 (all incorporated by reference; see § 205.3);

(2) Demonstrates at least 90% biodegradation absolute or relative to microcrystalline cellulose in less than two years, in soil, according to one of the following test methods: ISO 17556 or ASTM D5988 (both incorporated by reference; see § 205.3); and

(3) Must be biobased with content determined using ASTM D6866 (incorporated by reference; see § 205.3).

Paper-based crop planting aid. A material that is comprised of at least 60% cellulose-based fiber by weight, including, but not limited to, pots, seed tape, and collars that are placed in or on the soil and later incorporated into the soil, excluding biodegradable mulch film. Up to 40% of the ingredients can be nonsynthetic, other permitted synthetic ingredients in § 205.601(j), or synthetic strengthening fibers, adhesives, or resins. Contains no less than 80% biobased content as verified by a qualified third-party assessment (e.g., laboratory test using ASTM D6866 or composition review by qualified personnel).

As required by OFPA and National List review criteria, NOSB's review of synthetic allowances on the National List must include information pertaining to the composition of allowed substances, not simply their fate in the environment. The ASTM standards for compostability do not provide composition assurances beyond indicating whether a substance is a plastic, a polymer liner or additive to paper and other substrates, or a fiber-based packaging material. Because of these limitations, the CS is declining to

include an amendment to the National List as part of this proposal, and instead, decoupled the National List matter of compostable plastics from this recommendation pertaining to definitions and practice standards. ASTM D6400-21, D6868-21, and D8410-21 standards for compostability require no more than 10% of the material to remain after 84 days in a controlled composting test. In public comments, the full Board heard the feedback from the composting industry that conditions are not consistent for this expectation to be met, nor do most commercial composting operations cure composting piles for that length of time. With respect, CS does not see the Petitioner's solutions to the problem of compostable plastics in organic compost as encompassing the evaluative depth of clarity required by organic regulatory processes.

Background - Addressing areas for follow up raised in Spring 2024 Discussion Document but not specifically addressed in this Proposal's Recommendation to the NOP:

In the Spring of 2024, the Crops Subcommittee asked stakeholders a series of questions regarding the current state of the compost industry and how practice/regulations relate to organic language and evaluation for allowance. During full Board discussion, members acknowledged concurrent work being done by the Compliance, Accreditation, and Certifications Subcommittee (CACS) around issues of residue testing and contamination issues facing organic producers. In that discussion, the Board acknowledged that questions around unavoidable residual environmental contamination (UREC), residue testing, and contamination should remain outside the scope of this proposal while CACS works on that particular issue. Public commenters were supportive of changes to the language in the definition and § 205.203, composting methods, time and temperature, C:N ratio, and the evaluation of synthetic compostable substances for inclusion on the National List following the typical process of evaluation by the Board. In this proposal we provide recommendations for changes to the definition and practice standard sections relating to compost. Recognizing that evaluation of synthetic compost feedstocks for inclusion on the National List requires gathering of additional technical information related to the substance's composition, fate in the environment, impacts to human health, and general use patterns, CS will place this body of work into a separate discussion document.

Compostable Polymers

At NOSB's Spring 2024 meeting in Milwaukee, WI, public commenters expressed strong and varied opinions about the appropriateness of including compostable polymers on the National List and allowing them in compost used on organic farms. In general, those wary of including these substances provided comments focused on two major areas of concern: 1. The potential for the compostable polymers, themselves, to contaminate soil and water; and 2. The overuse of single-use plastics, in general, and whether the allowance for compostable plastics in organic production would violate the National List criteria that requires all substances on the National List to be consistent with organic farming. Additionally, those commenters in support of allowing compostable polymers into compost used on organic farms cited these substances' role in meeting waste reduction goals, their uniformity and consistency in degradation during the composting process, and the strength of the organic market to drive innovation and adoption of food waste reduction in order to meet greenhouse gas emission reduction goals.

In light of the significant interest in reviewing suitability of compostable polymers for their inclusion in the National List as compost feedstocks, CS is moving forward with information gathering in order to inform its decision. Additionally, the CS is taking the following steps:

1. Ordering a Technical Review (TR) of resin formulated products and fiber-based products that meet ASTM D6400-21, D6868-21, or D8410-21 standards in order to inform the evaluation of whether these substances' chemical properties align with the tenets of organic production.

2. Hosting a conversation with organic stakeholders about composting as a driver of change towards sustainability, diverting food waste from the landfill and into composting operations, the role compostable polymers and other synthetic compost feedstocks play in meeting these waste reduction goals, and reducing polyethylene plastic and other contamination in compost currently used on organic farms.

CS is in discussion on how to frame a Technical Review on compostables, which we expect will support a more exhaustive review of these types of substances' fate in the environment and impacts on human health. We hope to solicit stakeholder comments to inform our evaluation of compostable polymers against National List criteria and whether the current allowance and annotation for newspaper as a synthetic compost feedstock remains relevant. Please continue to provide comments to the Subcommittee in order to inform ongoing work on the topic.

Subcommittee Review:
The Crops Subcommittee is grateful to the NOP for composing an expansive work agenda item for the NOSB around compost. Compost is foundational to the organic ethos. The partnership of a public engagement process, supported by industry expertise and technical review, towards recommendations that are then evaluated by the NOP for rulemaking is one of the least understood and most powerful forms of democracy in this country. We celebrate the USDA for receiving a petition around regulations and definitions and staying committed to the NOSB process. CS was also challenged upon learning that while a petition and a work agenda request had been introduced to the NOSB from the NOP around the compost definition, the NOP was concurrently working on a federal register notice to update the compost definition. The difficulty of working concurrently on organic issues has been avoided by great collaboration between the NOP and the NOSB in the past. The Subcommittee hopes this level of communication can be re-cultivated in future and is acknowledging the issue in this document due to the difficult nature of proposing new language while the regulations are in flux. For the purposes of this document, CS in this proposal recommends new language for the definition of 'compost' at 7 CFR 205.2 and for the composting requirements outlined at 7 CFR 205.203 with the understanding that the NOP will need to incorporate any recommendations made by NOSB into its rulemaking process already underway in the Market Development Rule for Mushrooms and Pet Food.

7 CFR 205.2 - Definitions

Currently, organic regulations define compost as:

205.2 Terms Defined

Compost. The product of a managed process through which microorganisms break down plant and animal materials into more available forms suitable for application to the soil. Compost must be produced through a process that combines plant and animal materials

1. *with an initial C:N ratio of between 25:1 and 40:1.*
2. *Producers using an in-vessel or static aerated pile system must maintain the composting materials at a temperature between 131 °F and 170 °F for 3 days.*
3. *Producers using a windrow system must maintain the composting materials at a temperature between 131 °F and 170 °F for 15 days, during which time, the materials must be turned a minimum of five times.*

The CS proposes the following new definition for compost:

Compost – the product of managed aerobic, biological decomposition of plant and/or animal materials, and/or permitted synthetic compost feedstocks at § 205.601(c). The product will have undergone mesophilic and thermophilic temperatures, which significantly reduce the viability of pathogens and weed seeds, and stabilize the carbon such that it is beneficial to plant growth.

The addition of the word "aerobic" stems from the consistent regulatory use of that term when defining compost. In 2015, the U.S. Food and Drug Administration (FDA) issued the final Produce Safety Rule as part of enacting the Food Safety Modernization Act (FSMA). This federal rule specifically describes two types of composting, both of which are required to maintain aerobic conditions. Public comments from the compost industry in the Spring of 2024 recommended organic regulations align with new language from the American Association of Plant and Food Control Officials (AAPFCO):

Compost – is the product manufactured through the controlled aerobic, biological decomposition of biodegradable materials. The product has undergone mesophilic and thermophilic temperatures, which significantly reduces the viability of pathogens and weed seeds, and stabilizes the carbon such that it is beneficial to plant growth. Compost is typically used as a soil amendment, but may also contribute plant nutrients

In the Fall of 2017, the NOSB passed a recommendation to the NOP regarding the exclusion of anaerobic digestate from a petition to amend §205.203(c), effectively eliminating that particular process from the compost umbrella as defined by organic regulations.

CS has included a reference to the National List in the definition for compost in order that producers, Material Review Organizations (MROs), certifiers, petitioners, adjacent industries, etc., can be clear in the understanding that CS is not taking a position on allowance of compostable packaging. CS is reinforcing the organic practice that all petitioned substances follow the same path for organic evaluation, through the National List process. Given organic language as it stands, how it is applied currently, and the considerations of public comments and industry feedback, CS sees the proposed definition as a balanced blend of regulatory frameworks around which organic regulations are situated and current science and practice of compost research, education and industry practices.

Updates to 7 CFR 205.203 - Soil fertility and crop nutrient management practice standard

Language at 7 CFR 205.203(c) describes composting methods, which are recognized to reduce pathogenicity sufficiently to allow for the application of manure composted by these means to organic crop fields without a 90-or-120 day preharvest interval.

Currently, organic regulations at 205.203(c)(2) state:

(c)(2) Composted plant and animal materials produced through a process that:

(i) Established an initial C:N ratio of between 25:1 and 40:1; and

(ii) Maintained a temperature of between 131 °F and 170 °F for 3 days using an in-vessel or static aerated pile system; or

(iii) Maintained a temperature of between 131 °F and 170 °F for 15 days using a windrow composting system, during which period, the materials must be turned a minimum of five times.

In the Spring 2024 Discussion Document, CS introduced 3 classifications of composting methods, followed by a request for comment on whether these categories accurately encompass the wide range of industry practices and how to situate time and temperature requirements that meet pathogen reduction standards for each method.

- *forced aeration compost/aerated static pile construction*
- *windrow/passively aerated composting systems*
- *contained and in-vessel composting method*

The time and temperature requirements embedded at § 205.203 are a reference to sanitation requirements for composting that arise out of U.S. Environmental Protection Agency (EPA) requirements for the treatment of wastewater biosolids. Composting is only one of the methods outlined in that system of oversight, but the requirements established at USEPA 40 CFR Part 503 are commonly referred to as "PFRP" - "Process to Further Reduce Pathogens". PFRP establishes the time and temperature requirements to reduce pathogens to an acceptably low level of risk for passing on disease or conditions that may negatively affect humans, plants or animals. The EPA rules are not a food safety standard but reference the treatment of sewage sludge.

Appendix B to Part 503—Pathogen Treatment Processes

B. Processes to Further Reduce Pathogens (PFRP)

1. Composting—Using either the within-vessel composting method or the static aerated pile composting method, the temperature of the sewage sludge is maintained at 55 degrees Celsius (131 F) or higher for three days.

Using the windrow composting method, the temperature of the sewage sludge is maintained at 55 degrees or higher for 15 days or longer. During the period when the compost is maintained at 55 degrees or higher, there shall be a minimum of five turnings of the windrow.

https://www.govinfo.gov/content/pkg/CFR-2018-title40-vol32/xml/CFR-2018-title40-vol32-part503.xml#seqnum503.14

As mentioned above, FSMA and the Produce Safety rule provide regulatory language to describe composting methods acceptable to FDA in mitigating risks from human pathogens found in biological soil amendments of animal origin (e.g. manure). In 21 CFR 112.54(b), the FDA has adopted the following composting standards into the "Standards for Growing, Harvesting, Packaging, and Holding of Produce for Human Consumption".

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=112.54

> 21 CFR 112.54(b) A scientifically valid controlled physical, chemical, or biological process, or a combination of scientifically valid controlled physical, chemical, and/or biological processes, that has been validated to satisfy the microbial standard in § 112.55(b) for *Salmonella* species and fecal coliforms. Examples of scientifically valid controlled biological (*e.g.,* composting) processes that meet the microbial standard in § 112.55(b) include:
>
> (1) Static composting that maintains aerobic (*i.e.,* oxygenated) conditions at a minimum of 131 °F (55 °C) for 3 consecutive days and is followed by adequate curing; and
>
> (2) Turned composting that maintains aerobic conditions at a minimum of 131 °F (55 °C) for 15 days (which do not have to be consecutive), with a minimum of five turnings, and is followed by adequate curing.

The CS finds it instructive that the FDA and EPA are aligned on systems for pathogen reduction that generally categorize composting systems as static aerated, within-in vessel or windrow composting methods and are seeking to align organic regulatory language with the federal frameworks within which Organic co-operates. Additionally, the CS is cognizant of the importance of NOP Guidance 5021 alignment with FDA language that codifies the notion that these methods are not an exhaustive list of acceptable composting methods. Title 21 of the FDA regulations are explicit in the emphasis that methods are acceptable when they demonstrate a scientifically valid, controlled physical, chemical or biological process or a combination of those methods that demonstrates the reduction of pathogens that has been validated to meet microbial standards for pathogens of concern. CS intends for the change in categories to provide end users with clarity around which category their process falls within, what are the process requirements for each specific category and emphasize that while other methods can be allowed, producers falling outside of the processes described herein should provide exhaustive evidence of compliance which demonstrates a scientifically valid, controlled process which has been validated to satisfy microbial standards for pathogen reduction and/or can include those listed in 5021:

> *Certified operations can also demonstrate compliance with the compost requirements by measuring temperature, time, moisture content, chemical composition, and biological activity. These measurements may include testing feedstock materials and compost for one or more characteristics including initial and final carbon to nitrogen ratios, stability (using ammonia/nitrate ratio, O2 demand, CO2 respiration rate, or other standard tests), pathogenic organisms, or contaminants.*

Public comments from the compost industry advocacy groups and research organizations were supportive of this recommended change in listing of composting methods. One written comment reflected support for the change noting “the updated language to be more inclusive to the wide range of commercial composting methods”. In another written comment, a material review organization supported the inclusion of specific composting methods, noting that it is extraneous to describe each possible method individually. A compost company supported the idea that narrow specifications should not be identified in regulations. In light of these comments, CS supports the new language with the understanding that NOP 5021 identifies alternative methods allowed in organic composting.

Contained and in-vessel composting methods are a grouping summarized by the Composting Handbook as “a diverse group of methods that confine the composting materials in whole or part within a building, container, or vessel” (Ed. Rynk, Robert, Black, Ginny, et al., pg. 271). The handbook discusses the difficulty of encompassing many of the methods as entirely contained or in-vessel, acknowledging that “containment is a common thread among this somewhat arbitrary grouping of methods” but that the commonality lies in that the structure of the compost making “rarely expose the composting process to the outdoors, and largely separates the composting materials (and their emissions) from the human composters overseeing the process” (pg. 271). The handbook lists some examples, including agitated bays/beds, turned vessels, aerated bays in halls, vertical silos, rotating drums, aerated tunnels/boxes, and moveable/modular aerated containers along with detailed explanations of the benefits of process isolation, separation and control. Each of these methods has variable requirements for how PFRP is met, including examples wherein the system of containment completes a first cycle of pathogen reduction and material is then moved to a windrow or forced aeration to complete the stabilization for finished compost. The Handbook notes that “in general, process control is more rigorous, often including monitoring of oxygen or carbon dioxide and moisture as well as temperature” (pg. 275). CS and public comments from the Spring meeting are in alignment that acknowledging in-vessel/container methods of composting in the regulation language is practical and applicable at review for allowance.

Given that the PFRP recommendations for two of the proposed categories are the same, CS is proposing to list contained/in vessel composting processes in the same category as mechanically forced aeration/aerated static pile composting processes in the same section of 205.203(c). The Composting Handbook describes the forced aeration/aerated static pile methods as using “fans to increase the airflow through the compost pile…[t]he increased airflow supports more efficient composting by limiting temperature rise, maintaining oxygen levels and by removing excess moisture, carbon dioxide and ammonia. The standard practice with forced aeration is to adjust the airflow rate to match the rate of biological heat generation” (pg. 200-201) in order to maintain compost temperatures above 131 °F.

Windrow composting relies on passive aeration and is a practice of “placing a mixture of organic feedstocks in long narrow piles called “windrows'' that are then agitated or “turned” on a regular basis” (Composting Handbook 171). CS is proposing to update the regulatory language around windrow composting in part, due to the confusion that can arise from the dynamics embedded in the 15day time and temperature requirement. Windrow composting systems must hold core temperatures above 131F and are required to repeat the conditions for 5 turnings in order that the entire mass of the compost windrow has the opportunity to sit in the core of the windrow at temperatures, reducing the presence of pathogens of concern throughout the pile. The Composting Handbook notes that: “Turning the

windrow five times ensures that all of the material in the windrow spends time within the hot core. In contrast, aerated static piles and in-vessel systems are considered to be large enough or well-insulated enough to experience high temperatures throughout" (pg. 85). CS discussed the merits of requiring 3 consecutive days at core temperatures with 5 turnings for a total of 15 non-consecutive days but is choosing to de-emphasize that part of the requirement due to the lack of clear research demonstrating that particular necessity to achieve Pathogen Reduction. The industry has noted that pathogen reduction is being achieved successfully with a 15 total day requirement. The Compost Handbook illuminates other considerations which are valuable to healthy compost making in windrow systems. In the chapter on managing windrows under the section titled "Timing and Frequency of Turning" (pg. 181-182), The Compost Handbook reflects:

> *"when and how often turning takes place is usually dictated by the goals and preferences of the composter. In practice, the number of turnings and time between turnings varies greatly among composters.....some composters prefer to turn almost daily and may turn a given pile up to 40 times in the cycle. At the other extreme, relatively large windrows are turned only 3 or 4 times over a period of four months or more. At some operations, windrows are turned opportunistically - when operators have time, the weather is good, or the wind is blowing away from sensitive areas."*

The Composting Handbook goes on to state:

"By monitoring the process conditions and the compost quality, operators learn the appropriate time intervals between turnings after gaining familiarity with the composting process and their feedstocks. At this point, turning often occurs at fixed time periods that accommodate the availability of labor and equipment.....the composting process affords a great deal of flexibility in this matter" CS emphasizes the importance of operator experience and the natural pathogen reduction tendency of a well managed aerobic composting process, along with the practical success the composters currently demonstrate in pathogen reduction. A regulatory reference to 3 consecutive days at core temps is not supported by external standards or extensive scientific research, and the CS acknowledges that level of regulatory specificity on windrow composting is not necessary and may create obstacles for windrow composters to meet the requirements. As pathogen reduction is being successfully achieved with 15 non-consecutive days and 5 turnings, CS has digested these dynamics and amended the language to reflect the reference which aligns with FSMA and EPA to produce regulatory/linguistic consistency.

CS wishes to reiterate support for the understanding conveyed in NOP Guidance 5021 that 205.203 is not an exhaustive list of allowed composting methods.

> *The NOP concurs with the NOSB that the examples provided in § 205.203(c)(1-3) is not a finite list of acceptable plant and animal materials for use in organic production. Site-specific variation in feedstock materials, management practices, and production requirements dictate that organic producers exercise flexibility in managing plant and animal materials on their operations.*

For composting methods listed which may be categorized as "other" methods, 5021 provides a clear path for compliance:

> *"production practices should be described in the operation's organic system plan (OSP). Certifying agents may allow the use of compost if they review the OSP and records and are*

assured that all requirements are met. Compost production records should include the type and source of all feedstock materials. When animal materials are used in compost production, the certified operation should maintain temperature monitoring logs, and document the practices used to achieve uniform elevated temperatures."

Additionally, NOP 5021 goes on to say

> *"Certified operations can also demonstrate compliance with the compost requirements by measuring temperature, time, moisture content, chemical composition, and biological activity. These measurements may include testing feedstock materials and compost for one or more characteristics* including initial and final carbon to nitrogen ratios, stability (using ammonia/nitrate ratio, O2 demand, CO2 respiration rate, or other standard tests), pathogenic organisms, or contaminants."

CS supports the use of an "other" category at material review for compost with the understanding that producers electing to be considered as such should provide exhaustive scientifically valid rationale for how the method satisfies microbial standards for pathogen reduction.

In regards to updating requirements for the C:N ratio – public comments from the compost industry acknowledged that C:N ratios are typically viewed by composters as a Best Management Practice (BMP) and should not be specifically prohibitive in regulation language. EPA and FDA regulatory language do not make reference to C:N ratios for establishing composting methods that meet requirements. Establishing initial C:N ratios requires the testing of what can be highly variable inputs/feedstocks, which is prohibitively expensive for compost makers and does not always result in a predictable C:N ratio in a finished compost product. Stakeholders noted that if the NOSB were to recommend a C:N ratio, it should be 20:1 – 60:1, which is more in line with current industry BMP. Additionally, stakeholders noted that a reference to final C:N ratios is a better path for demonstrating BMP throughout the composting process and is more useful to the end user. In discussion of the full Board in the Spring meeting and in Crops Subcommittee meetings, members expressed comfort with the idea of eliminating the C:N language or establishing a lower limit for finished compost. CS sees the potential for innovation in compost making as inevitable and supports alternative methods for allowance in organic compost making and does not at this time see the need to establish a lower limit for final C:N. Instead, we are proposing elimination of the C:N ratio requirement in the composting standards. In future, if producers/MROs/certifiers see concerns arise from eliminating this requirement, CS hopes they will bring the issue forward in the NOSB for full Board and stakeholder consideration.

In conclusion, the Crops Subcommittee has minimized the recommended changes to the language affecting organic compost production. We have heard from the community in public comments that our regulations are working well, and extensive change is not necessary and would be hugely disruptive. CS has considered the claims in BPI's petition to the USDA and put forth a rationale for continued use of the National List process for considering compostable packaging as an allowed compost feedstock. Adjustments to the compost definition and time and temperature requirements are a reflection of current compost industry best practices and regulatory frameworks, which have established reasonable expectations for reducing pathogens of concern in organic compost systems. CS will continue to collaborate with the CACS on issues of testing, UREC, and contamination while making technical review

requests for future discussion documents and proposals towards continuous improvement. We acknowledge that contamination of organic compost is an emerging issue and that it should be monitored closely and re-addressed through the NOSB process.

Proposal

Motion to amend 205.2 Terms Defined:

Compost – The product of managed aerobic, biological decomposition of plant and/or animal materials, and/or permitted synthetic compost feedstocks at § 205.601(c). The product will have undergone mesophilic and thermophilic temperatures, which significantly reduce the viability of pathogens and weed seeds, and stabilize the carbon such that it is beneficial to plant growth.

Vote in Crops Subcommittee:

Motion by: Mindee Jeffery
Seconded by: Amy Bruch
Yes: 8 No: Abstain: 0 Recuse: 0 Absent: 1

Motion to amend § 205.203(c) Soil fertility and crop nutrient management practice standard:

(2) Composted plant and animal materials and/or permitted synthetic compost feedstocks at § 205.601(c) produced through a process that:

(i) Maintains aerobic conditions at a minimum temperature at or above 131 F for 3 days using a contained/in-vessel process or a mechanically forced/aerated static pile process; or

(ii) Maintains aerobic conditions in a windrow process at or above 131 F for 15 days (which do not have to be consecutive), during which period, the materials must be turned a minimum of 5 times.

Vote in Crops Subcommittee

Motion by: Mindee Jeffery
Seconded by: Logan Petrey
Yes: 8 No: 0 Abstain: 0 Recuse: 0 Absent: 1

Appendix A – Redline of Proposed Changes Definitions and 205.203

§ 205.2 Terms Defined

Compost. The product of ~~a managed process through which microorganisms break down plant and animal materials into more available forms suitable for application to the soil. Compost must be produced through a process that combines plant and animal materials with an initial C:N ratio of between 25:1 and 40:1. Producers using an in-vessel or static aerated pile system must maintain the composting materials at a temperature between 131 °F and 170 °F for 3 days. Producers using a windrow system must maintain the composting materials at a temperature between 131 °F and 170 °F for 15 days, during which time, the materials must be turned a minimum of five times.~~ managed aerobic, biological decomposition of plant and/or animal materials, and/or permitted synthetic compost feedstocks at § 205.601(c). The product will have undergone mesophilic and thermophilic temperatures, which significantly reduce the viability of pathogens and weed seeds and stabilize the carbon such that it is beneficial to plant growth.

§ 205.203 Soil fertility and crop nutrient management practice standard

(c) (2) Composted plant and animal materials and/or permitted synthetic compost feedstocks at § 205.601(c) produced through a process that:

~~(i) Established an initial C:N ratio of between 25:1 and 40:1, and~~

~~(ii)~~ (i) Maintain~~ed a~~ aerobic conditions at a minimum temperature ~~of between~~ at or above 131 °F ~~and 170 °F~~ for 3 days using ~~an~~ a contained/in-vessel or mechanically forced/aerated static ~~aerated~~ pile ~~system~~ process; or

~~(iii)~~ (ii) Maintain~~ed~~ aerobic conditions in a windrow process at or above a temperature of ~~between~~ 131 °F ~~and 170 °F~~ for 15 days (which do not have to be consecutive), ~~using a windrow composting system,~~ during which period, the materials must be turned a minimum of five times.

National Organic Standards Board
Crops Subcommittee
Pear Ester Petition
August 6, 2024

Introduction:

In September 2023, the National Organic Program received a petition from Trece Incorporated requesting the addition of pear ester (i.e., Ethyl-2E,4Z-Decadienoate), a semiochemical material, to the National List as a synthetic allowed for use in crop production [§ 205.601]. Semiochemicals are bioactive molecules released by an organism to signal or provoke a behavioral or physiological response (Klassen et. al., 2023). Signaling may be between members of the same species or between two or more distinct species. Pheromones, kairomones and allomones are sub-categories of semiochemicals. Pear ester was previously allowed for use in organic crop production under the synthetic pheromone classification until its correct reclassification as a kairomone. Even though pheromones and kairomones are both semiochemicals, they differ in a couple of significant characteristics. Pheromones are volatile chemicals produced by a given species to communicate with other individuals of the same species to affect their behavior (EPA, 2011). A 2012 technical report on pheromones stated that they may signal dominance status, sexual receptivity, danger, and other information. Kairomones are chemical signals produced by plants or other organisms that are detected by a distinct species, often insects. They convey communication signals between two or more different species (Klassen et al., 2023). Detection of kairomones leads to a fitness benefit (to the receiving organism); these benefits include avoiding a predator or finding a suitable host plant. Pear ester was first isolated from ripe Bartlett pears (Jennings et al., 1964). The original experiments that identified pear ester as a kairomone used pear extracts (Light et al., 2001). Commercial pear essence contains about one-third pear ester by weight (Tucker et al., 2003). Pear ester used in commercial pest control formulations is produced by chemical synthesis (Light et al., 2017; Trécé, Inc., 2023; Tsubi et al., 1993). The high solubility of pear ester in lipid-like substances allows it to penetrate codling moth receptor structures with ease. Because of its volatility, pear ester dissipates quickly in the environment. Manufacturers encapsulate volatile components of spray formulations to limit volatilization and produce products that have a lasting effect (US EPA, 2013) [2024 TR 86-88].

The proper classification of pear ester as a kairomone instead of a pheromone rendered its continued use under the pheromone category in organic crop production, untenable (Trécé, Inc., 2023). This discussion document covers the petition to add pear ester, a kairomone, to the National List under 7 CFR 205.601 (synthetic material allowed in organic crop production). The petition is aimed at providing organic crop producers with pest management tools that were available to them prior to the reclassification of pear ester as a kairomone instead of a pheromone.

The current discussion document covers pertinent information from the 2024 technical report (TR) on the human, environmental, and ecological health, as well as the economic impact of the synthesis and application of pear ester in organic crop production.

Synthesis of Pear Ester

Pear ester is produced by a condensation reaction between two chemicals that are by-products of petroleum processing. The prevalent process for manufacturing pear ester is the condensation reaction between the eight-carbon allyl alcohol, oct-1-yn-3-ol (CAS No. 818-72-4), and triethylorthoacetate (CAS No 78-39-7). The condensation product is heated with propanoic acid as a catalyst, and the subsequent Johnson-Claisen rearrangement gives ethyl 2E, 4Z-decadienoate. It is a convenient one-step synthesis with good yields (Trécé, Inc., 2023; Tsubi et al., 1993).

Approved Legal Uses of Pear Ester:

Pear ester appears on the FDA list of Substances Added to Food (*formerly EAFUS*) for use as a flavoring agent or adjuvant food additive (US FDA, 2024). The EPA has registered pear ester formulations for pest management. This behavior-altering chemical (i.e., semiochemical) is particularly useful in the management of the codling moth, *Cydia pomonella* – an economically significant pest that principally affects apple, pear, and walnut crops (Trécé, Inc., 2023).

The codling moth has four life stages: adults, eggs, larvae, and pupae. The life cycle is synchronized with the weather by larval diapause, a form of hibernation. Larvae go into diapause in August and over winter in this form. In late winter, they pupate, and emerge as adults in the early spring (Quarles, 1997; Steiner, 1940; Van Leeuwen, 1940; Witzgall et al., 2008) [2024 TR 101-104]. Within a week after emergence from pupae as adults, mating is complete. Females lay up to 100-130 eggs, as isolated eggs, never as clusters, near developing fruit. Most of the reproductive activity associated with this first flight of adults is over by the end of April; there are a total of three flights each year in most areas (Quarles, 1997; Steiner, 1940; Van Leeuwen, 1940; Witzgall et al., 2008) [2024 TR 106-109]. The larvae damage fruit by chewing their way inside. Once inside, the fruit is unmarketable (Caprile & Vossen, 2011).

Pear Ester and Mating Disruption

Pear ester is used as part of codling moth mating disruption treatments. Although pheromones alone are used, pheromones combined with a simultaneous release of pear ester may be more effective (Light et al., 2017) (see also *Focus Question #1*) [2024 TR 151-153]. These mating disruption treatments can be applied in two ways: via plastic dispensers or as microencapsulated cover sprays (University of California Statewide Integrated Pest Management (IPM) Program, 2015). PVC dispensers have two reservoirs, one for the codling moth sex pheromone codlemone, (E, E)-8,10-dodecadien-1-ol (CAS No. 33956-49-9), and one for pear ester. Both materials passively diffuse from the dispensers into the air. There are standard dispensers and larger, “meso” dispensers that hold more active ingredient (Trécé, Inc., 2023) [2024 TR 111-112].

Mating disruption dispensers loaded both with codling moth sex pheromone and pear ester can be more effective for mating disruption than dispensers with pheromone alone (Light et al., 2017). Microencapsulated sprays of pear ester can also improve the effectiveness of mating disruption, make some insecticides more effective (Light et al., 2017), and can even prevent fruit damage as a standalone spray [2024 TR 161-167].

Pear Ester and Monitoring/Timing

Pear ester can be used as a lure in traps to monitor populations of codling moth in orchards (Light et al., 2001). Successful monitoring can then be used to determine the timing and set action thresholds for treatments (A. L. Knight & Light, 2005) [2024 TR 115-117].

Farmers and pest control professionals hang monitoring traps in orchards each year before mating populations of the codling moth emerge from their pupae. This helps to determine the "biofix point," which is the date of the first appearance of a codling moth in a monitoring trap. The biofix point is particularly important because mating disruption programs against the pest are not effective when commenced later than the first detection of the pest. Once mating disruption has started, monitoring traps with pheromone lures are no longer useful. At this point, the air is saturated with pheromones, and moths cannot find the traps. According to Integrated Pest Management experts, traps containing pear ester, and perhaps other kairomones, are essential to determine when to apply treatments (Caprile & Vossen, 2011; University of California Statewide IPM Program, 2015). Traps baited with pear ester lures can also be used for mass trapping, to remove egg-laying females from orchards (A. L. Knight et al., 2022). It is extremely important to note that unlike pheromone traps, monitoring traps containing kairomones such as pear ester make it possible for farmers and pest control professionals to check the effectiveness of mating disruption (A. Knight, 2010; A. Knight et al., 2014; A. L. Knight et al., 2019; Trécé, Inc., 2023). The kairomone improves codling moth monitoring, enhances mating disruption, disrupts egg laying, and confuses moth larvae and thereby make it harder for them to find, infest, and damage host fruits.

Monitoring to Determine Effectiveness of Mating Disruption

When used in combination with pheromones (e.g. codlemone) in mating disruption dispensers, or in microencapsulated sprays, pear ester can enhance the effectiveness of mating disruption (Light et al., 2017). The performance of mating disruption techniques can be evaluated in many ways. Monitoring traps baited with codlemone pheromone are used most often. The fewer moths trapped, the more effective the disruption. Elevated levels of the mating disruption pheromone make it difficult for males to locate the traps, resulting in trap shutdown. Monitoring traps baited with tethered females are also used (Stelinski et al., 2013). A more conclusive result is achieved by using monitoring traps baited with pear ester to catch females. The fewer mated females caught, the more effective the mating disruption (A. L. Knight, 2006). A practical measure is the amount of fruit damage. The less damage, the more effective the mating disruption. Of all the possible measurements of effectiveness, the easiest is trap shutdown, and the most important, from a grower standpoint, is the amount of fruit damage (Kovanci, 2015) [2024 TR 342-354-117].

Limitations of Mating Disruption

Even though mating disruption treatments release substantial amounts of pheromone, which make it harder for males to find females, its effectiveness is reduced by large initial codling moth populations. In situations of high population density, males can find females with visual cues. Farmers and pest control professionals sometimes use an insecticide treatment before starting a mating disruption program (Witzgall et al., 2008) to reduce population densities, thereby rendering mating disruption interventions more effective [2024 TR 358-362].

Immigration of already mated females from a nearby orchard can also overcome mating disruption treatments. This is because these females do not release pheromones to attract males for mating purposes. A buffer zone of 400 m and border sprays of insecticides help in limiting immigration of this insect pest (Rothschild, 1982) [2024 TR 364-366].

Sex pheromone treatments need to have uniform concentration throughout an orchard. If there are dead spots in the distribution, mating can occur in that area. There can also be problems with patchy codling moth distribution. Females prefer to lay eggs on trees that have the most fruit. When larvae pupate, males are already in the area waiting for females to emerge (Light et al., 2017; Witzgall et al., 2008) [2024 TR 368-371].

It is extremely important to note that mating disruption is not equivalent to mating prevention. According to Light et al. (2017), experiments have shown untreated apple orchards have 73-90% mated females, and orchards utilizing conventional pest controls have >77% mated females. When mating disruption treatments use pheromone only, 58-85% of females are mated, whereas mating disruption with combined pheromone and pear ester results in 64-71% mated females (Light et al., 2017) (see *Combinations of the Substance*) [2024 TR 375-377]. As stated earlier, mating disruption does not signify mating prevention. A simple delay in mating can reduce pest populations and fruit damage. A delay in female mating by more than two days results in significant reduction in population density because the female is older and lays fewer eggs. Fewer eggs results in less fruit damage (Jones et al., 2008). Witzgall et al. (2008) reports damage levels of 0.03 to 0.8% for California apple orchards using area-wide pheromone mating disruption.
Pear ester is a useful addition to IPM programs because it gives another layer of protection. If moths successfully mate and start laying eggs, pear ester confuses females that prefer to lay eggs near ripening fruit. This is because the insects identify ripening fruit partly using the pear essence (i.e., pear ester). Misplaced eggs lead to less fruit damage (Hughes et al., 2003). If eggs successfully hatch, larvae are also confused by pear ester and have trouble finding their way to fruit (Light & Beck, 2012) [2024 TR 385-389].

Human Health Impacts
Pear ester is a Generally Recognized as Safe (GRAS) food additive. In 2013, the EPA exempted it from the need to establish food tolerance for residues in or on food crops at 40 CFR 180.1323. The EPA concluded that, “there is a reasonable certainty that no harm will result to the U.S. population from aggregate exposures to ethyl-2E-4Z-decadienoate (pear ester)” (78 FR 53051, August 28, 2013). [2024 TR 889-892]. Pear ester has low acute toxicity to mammals, and the oral LD_{50} for rats is 4,027 mg/kg.[1] This number means pear ester is nearly non-toxic. Additionally, pear ester is an FDA approved food additive, and average human consumption in the U.S. is about 3 µg per day (US EPA, 2013). According to the EPA, pear ester also has low chronic toxicity, and is not a likely developmental toxicant, or a mutagen. It is not on the EPA list of carcinogens, or on the IARC carcinogen list. The EPA reported in 2013 that pear ester had not been evaluated for endocrine disruption [2024 TR 876-884].

The 2024 technical report on pear esters found no publications indicating harm to humans from pear ester or polyamide particulates. But according to the pear ester safety data sheet, pear ester may cause allergy or asthma symptoms or breathing difficulties if inhaled. Contact with skin or eyes may cause irritation. It must be noted that the food tolerance exemption provided by the EPA does not include an evaluation for occupational exposure. The maximum label amount is about 400 µg pear ester/day, which is well below the acute toxicity of 4027 mg/kg. Pear ester vapors are not likely a health problem for orchard workers [2024 TR 910-911].

Exposure to Polyamide Particulates

Sprays of about 30 g/ha decadienoic acid (DA) ethyl ester (i.e. pear ester), commercially known as DA MEC™, are applied to tree canopies with an air blast sprayer (Cidetrak, 2020). Even though exceedingly tiny amounts of DA MEC™ are used, the sprays contain a large number of small polyamide particles. Each tree canopy receives about five hundred million microencapsulated pear ester particles. There might be a respiratory hazard from inhaling the plastic microparticles when the spray is applied by air blast sprayer to individual trees. However, effects of exposure to the polyamide spherical capsules in the spray has not been evaluated by the EPA. Given the 4-hr re-entry restriction, the greatest acute risk is probably during spray applications with an airblast sprayer. But the DA MEC™ label does not require respiratory protection for workers (Cidetrak, 2020) [2024 TR 911-921]. It is important to note that the maximum 8-hr worst case chronic exposure would be about 0.0357 mg/m^3 or 36 µg/m^3. This exposure is below the U.S. 24-hr particulate standard of 150 µg/m^3 for PM 10 (89 FR 16202, May 6, 2024) [2024 TR 941-942].

Given the fact that sprayable microecapsulated pheromone particles can be washed out of tree canopies by wind, rain, and overhead irrigation sprays, pear esters are assumed/expected to meet the same fate.

Environmental and Ecological Health Impacts

The EPA did not require testing for bird, fish, and aquatic invertebrate toxicity because pear ester is expected to quickly disperse and degrade in the environment. However, the pear ester safety data sheet from Boudakian Research (Boudakian Research, 2023) states that pear ester is “very toxic to aquatic life with long lasting effects.” [2024 TR 650-653]. The substance is, however, exempt from testing for bird, fish, and aquatic invertebrate toxicity. According to the safety data sheet, pear ester is a marine toxicant and hazard (Boudakian Research, 2023) [2024 TR 862-865]. Environmental damage may be mitigated by the low application rate of 12 g DA MEC™/acre or 30 g/ha. That is about 0.27 mg DA MEC™/ft^2. That is a small amount, but each ml of the usual diluted field spray contains about 260,000 particles (Light & Beck, 2010). [2024 TR 864-865]. Once applied, microcapsules probably stay on the leaves until dislodged by wind and rain, which is the case for microencapsulated sprayable pheromones (A. L. Knight et al., 2004). When particles are dislodged by rain, they likely become part of runoff from an orchard (Trécé, Inc., 2023) [2024 TR 862-865]. Once the microencapsulated particles reach water, they might be ingested by fish or other aquatic creatures. No density information is given (Light & Beck, 2010), but likely the polyamide particles are less dense than water. The pear ester contained in the microparticles is an aquatic hazard (Boudakian Research, 2023) [2024 TR 869-870]. The 2024 technical report found no information on the environmental effects of pear ester polyamide microcapsules. There is no published

information of the effects of these particles on earthworms. If earthworms ingest them, birds would be exposed by eating earthworms. However, again, the amounts of pear ester involved are exceedingly small [2024 TR 865-867]. We found no information on whether the polyamide capsules are a hazard. The EPA did not require the product manufacturer to submit environmental toxicity tests of microencapsulated pear ester (US EPA, 2013) [2024 TR 872-874].

Economic Impacts

Available data and evidence show that pear ester exerts significant economic impacts on pear and apple growers. The impact is exerted through pear ester's documented direct impact on mass trapping, mating disruption, and proper timing of treatments (including pesticide applications), all of which impact the level of fruit damage. The improved effectiveness of traps and monitoring tools when pear ester is combined with pheromones is well documented. A 2015 study by Kovanci reported that more mated females (70%) were trapped with microencapsulated pear ester compared to microencapsulated pheromone DA MEC™ than with PH MEC (57.5%). There was a 54% reduction in late season pre-harvest fruit damage due to the use of microencapsulated pear ester alone, but reduction with microencapsulated pheromone or the combo was 72%. A 93% reduction in fruit damage was recorded by Ultra love volume (ULV) combo sprays. Combo sprays were more effective than sex pheromone alone in reducing fruit damage only with ULV applications (Kovanci, 2015). The author also reported that application of microencapsulated pear ester sprays alone can reduce fruit damage and increase larval mortality in apple and pear. Reduced fruit damage has direct economic impacts on producers of these fruits [2024 TR 413-420].

Performance of Alternatives

It is important to note that codling moth management performance of natural alternatives to synthetic pear ester tend to be enhanced when combined with the synthetic product. Products such as granulosis virus, Spinosad, BT products, and the use of degree day methods are employed against the codling moth. The performance of these alternatives is, however, enhanced by pear ester in monitoring traps to determine the biofix point and, thus, the correct and most effective timing of pesticide applications.

The NOSB has deemed the 2024 TR sufficient and has used the document as a basis for the current discussion document for use in the Fall 2024 meeting. Comments received so far on pear ester have been positive.

Subcommittee Next Steps

The Crops Subcommittee (CS) will continue its deliberations on pear ester through the presentation of a discussion document at the Fall 2024 NOSB meeting. A subsequent proposal will factor in public comments received. The CS will seek additional information on the reasons behind the EPA not requiring testing for fish and aquatic invertebrate toxicity given the fact that the safety data sheet for pear ester states that it is a marine toxicant and hazard (Boudakian Research, 2023).

Questions for Stakeholders

The CS has the following specific questions for stakeholders and, as always, welcomes any additional perspectives, solutions, and information related to inert ingredients used in organic pesticides.

1. Are there any human health and environmental concerns pertaining to pear ester that the CS needs to consider in its evaluation of the petition to add it to the National List?

Subcommittee Vote:
Motion to accept the discussion document on the petition to add pear ester to the National List as a Synthetic Substance Allowed in Pesticides for use in Organic Crop Production
Motion by: Franklin Quarcoo

Seconded by: Wood Turner
Yes: 8 No: 0 Abstain: 0 Recuse: 0 Absent: 1

Sunset 2026
Meeting 2 - Reviews
Crops Substances § 205.601 & § 205.602
October 2024

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 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. Substances included in this document may also be viewed in the NOP's Petitioned Substances Index.

Request for Comments
Written comments should be submitted via Regulations.gov at www.regulations.gov on or before September 30, 2024, as explained in the meeting notice published in the Federal Register.

Public 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 Substances in Organic Production at § 205.601:
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 Substances in Organic Production at § 205.601:
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 Support the Continued Prohibition of Substances in Organic Production at § 205.602:
If you provide comments supporting the prohibition of a substance at §205.602, 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 Do Not Support the Continued Prohibition of Substances in Organic Production at § 205.602:
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 at § 205.602 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 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 September 30, 2024 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:

Hydrogen peroxide (a)(4)
Hydrogen peroxide (i)(5)
Soaps, ammonium
Oils, horticultural (e)(7)
Oils, horticultural (i)(7)
Pheromones
Ferric phosphate
Potassium bicarbonate
Magnesium sulfate
Hydrogen chloride

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

Ash from manure burning
Sodium fluoaluminate

Hydrogen peroxide §205.601(a)(4) and §205.601(i)(5)

Reference: § 205.601(a) As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems. (4) Hydrogen peroxide. and
§ 205.601(i) As plant disease control (5) Hydrogen peroxide.
Technical Report(s): 1995 TAP; 2015 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation - deferred; 06/2006 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

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

Manufacture
According to the 2015 TR, commercially available hydrogen peroxide is industrially produced using the anthraquinone autoxidation (AO) process. The AO method involves initial catalytic reduction of an alkyl anthraquinone with hydrogen to form the corresponding hydroquinone. Subsequent autoxidation of the hydroquinone intermediate in air regenerates the anthraquinone with concomitant liberation of hydrogen peroxide. The simplified overall reaction involves direct combination of gaseous hydrogen (H2) and oxygen (O2): H2+ O2→H2O2

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
a) Allowed for use as a production aid. (Table 4.2, CAN/CGSB-32.311-2020, page 13)

Note: Crop production aids may be applied to the crop or soil, or used to control pests (including diseases, weeds, and insects). Examples include adjuvants, insect traps and plastic mulch, vertebrate animal pest management substances, plant disease and insect pest management substances.

i) Allowed for use as food-grade cleaners, disinfectants, and sanitizers without a mandatory removal event (Table 7.3, CAN/CGSB-32.311-2020, page 42)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
a) Not explicitly mentioned

i) Allowed (Annex I, Basic substances, 2021/1165)

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

i) Not explicitly mentioned

International Federation of Organic Agriculture Movements (IFOAM) Norms
a) Not explicitly mentioned for crop production. Hydrogen peroxide is allowed on the list for equipment cleanser and equipment disinfectants. (page 82)

i) Not explicitly mentioned

Japan Agricultural Standard (JAS) for Organic Production
a) Not explicitly mentioned

i) Not explicitly mentioned

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

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

Ancillary Substances
Other ingredients may include peroxyacetic acid (listed separately on the National List). The 2015 TR reports other potential materials present including caprylic acid and mono-and di-potassium salts of phosphorous acid, which is an oxidant stabilizer. Phosphorous acid is listed on the EPA Safer Choice list as a yellow triangle. (Yellow triangle - The chemical has met Safer Choice Criteria for its functional ingredient class, but has some hazard profile issues. Specifically, a chemical with this code is not associated with a low level of hazard concern for all human health and environmental endpoints. While it is a best-in-class chemical and among the safest available for a particular function, the function fulfilled by the chemical should be considered an area for safer chemistry innovation.)

Discussion
Hydrogen peroxide continues to receive strong support by the organic community and has been

consistently relisted on the National List. Oral and written comments submitted for the Spring 2019 NOSB meeting represent hundreds, if not thousands, of crop and livestock farmers and processors who uniformly support relisting this essential and relatively safe material. When used appropriately, hydrogen peroxide should not have adverse impacts on human health and the environment.

Most recently, it was supported by the prior Crops Subcommittee without dissent and was relisted by the full NOSB without dissent.

In this cycle, the substance has inspired limited discussion from the Crops Subcommittee. First and foremost, the subcommittee has acknowledged the importance of hydrogen peroxide as a sanitizer in the suite of materials available to support ongoing food safety expectations in the food system. As has been noted consistently by the NOSB, there is no dedicated review process in place to support a different level of evaluation of sanitizers currently allowed for use in organic and, as such, the Board is not eager to recommend removal of currently listed sanitizers.

The Subcommittee did discuss whether there might be unnecessary negative issues associated with the disposal of hydrogen peroxide after use. Most published guidance suggests that disposing of spent hydrogen peroxide into a drain is reasonable.

It was noted that the annotation for hydrogen peroxide differs from that of peracetic acid/peroxyacetic acid in that the reference does not specific use (specifically “for use in wash and/or rinse water according to FDA limitations. For use as a sanitizer on food contact surfaces”).

At the Spring 2024 NOSB meeting, the Board received eighteen written comments – unique to crop production applications – as well as some oral comments, all strongly in favor of relisting. The Board had no substantive discussion and is not proposing removal from the National List.

Justification for Vote
The Subcommittee finds hydrogen peroxide compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove hydrogen peroxide from the National List at §205.601(a)(4)
Motion by: Wood Turner
Seconded by: Amy Bruch
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

Motion to remove hydrogen peroxide from the National List at §205.601(i)(5)
Motion by: Wood Turner
Seconded by: Logan Petrey
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

Soaps, ammonium

Reference: § 205.601(d) As animal repellents—Soaps, ammonium—for use as a large animal repellant only, no contact with soil or edible portion of crop.
Technical Report: 1996 TAP; 2019 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Ammonium soaps are approved by the United States Department of Agriculture's (USDA) National Organic Program (NOP) for various crop production uses.

These uses are listed at 7 CFR 205.601 and include applications such as:

1. synthetic substances to act as algicides/demossers ((a)(7)),
2. herbicides ((b)(1)),
3. insecticides ((e)(8)), and
4. animal repellents (d), which is the specific focus of this sunset. Ammonium soaps are used as animal repellents to protect organically produced crops from unwanted browsing, primarily from deer and rabbits.

Manufacture
Ammonium soaps are manufactured by the hydrolysis of esters in fats (triglycerides) with an alkaline (base) source in a process called saponification. In this process, the base reacts with the fatty ester to break the ester linkages, forming a salt with the cation of the base and the carboxylate anion that remains at the end of the hydrolysis [2019 TR, lines 246-249]. Many fats may be used in saponification, including plant and animal fats. Because of the relative abundance of fats and their low cost, most soaps are produced by the saponification of natural fats.

Ammonium cations also exist in nature, play an essential role in the metabolic pathways of a range of organisms, and are a key component of the nitrogen cycle. Soaps, however, do not naturally exist in nature but are manufactured [2019 TR, lines 282-283].

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed for use as a large animal repellent. Direct contact with soil or edible portions of crops is prohibited. (page 20 and 45).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Not explicitly mentioned

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

Not explicitly mentioned

International Federation of Organic Agriculture Movements (IFOAM)
Not explicitly mentioned

Japan Agricultural Standard (JAS) for Organic Production
Not explicitly mentioned

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

Environment: Studies conducted by the EPA estimate that ammonium soaps will undergo rapid environmental degradation, primarily through microbial metabolism, yielding an environmental half-life of less than one day. It is interesting to note that the toxicological profile of the substance differs based on the environment in which it is located. They are regarded as having low toxicity to terrestrial organisms, with little impact on mammals and avian animals. They are, however, moderately toxic in aquatic environments. Ammonium soaps have been classified as "highly toxic" to crustaceans by the EPA. The EPA has placed them in Toxicity Category IV, the lowest available classification. Due to the potential toxicity to aquatic environments, ammonium soap repellent product labels stipulate, "This product may be hazardous to aquatic invertebrates. Do not apply to water bodies such as ponds or creeks [2019 TR, lines 318-322]."

Discussion
During the Spring 2024 NOSB meeting, the Board reviewed ammonium soaps. Many public comments supported relisting, and there were no comments supporting removal. However, there was one concern about drift potential. The Board discussed other means of pest prevention outside of ammonium soaps, including population control of animals, alteration of habitat, or physical barriers (fencing is widely acknowledged as the most effective means of preventing crop damage from unintended browsing). There are also natural (non-synthetic) substances that may be used in place of ammonium soaps. The discussion centered around using ammonium soaps in tandem with physical and mechanical controls.

Justification for Vote
The Subcommittee finds soaps, ammonium compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove ammonium soaps from the National List
Motion by: Amy Bruch
Seconded by: Nate Lewis
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

Oils, horticultural §205.601(e)(7)

Reference: § 205.601(e) As insecticides (including acaricides or mite control).
(7) Oils, horticultural—narrow range oils as dormant, suffocating, and summer oils.
Technical Report: 1995 TAP; 2019 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation – deferred; 06/2006 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Horticultural oils have widespread use in organic fruit and vegetable production. They can be used in nearly every season and may be used alone or in mixes that include other nutrient or pest control products. Oils may be used for control of multiple plant diseases as well as miticides and insecticides. According to the 2019 technical report (TR), oils have different modes of action on insects, mites and plant pathogens. They target multiple sites and not specific receptors and thus do not act like most synthetic insecticides. This action also helps to prevent resistance to their action. The multiple actions include smothering insect eggs by preventing atmospheric gas exchange, softening or disrupting insect cuticles, interfering with molting, as well as altering behaviors such as egg laying.

Horticultural oils may be called by many different names; however, the 2019 TR generally refers to them as petroleum-derived spray oils (PDSO's) or mineral oils. Their use has increased and has been refined over the last century. Recognition that different fractions of oils have higher efficacy for pest control and that the range of phytotoxic effects on the plant goes from none to high depending on the fraction used led to the selection of a narrow range of oils exhibiting the dual characteristics of being effective against pests and non-toxic to plants. They are often classified by boiling point, although modern terminology may refer to many other characteristics such as chain length and chemical structure (2019 TR).

Manufacture
Most PDSOs are produced from the extraction, distillation, and further refinement of petroleum. The 2019 TR describes in detail the potential processes by which crude petroleum may be transformed to a narrow range horticultural oil. In general, the crude petroleum may be converted chemically by either catalytic or thermal methods. Once the oils are converted to a certain fraction, additional chemical treatments are applied to the distillates to remove phytotoxic compounds, such as sulfur, while keeping compounds toxic to pests and diseases. Additionally, the 2019 TR states horticultural oils are often formulated with wetting agents or surfactants that allow them to be mixed and diluted with water. Most spray oils in the United States contain a non-ionic surfactant dissolved in the oil concentrate at a concentration of 0.35 percent for citrus use and 0.5 percent for deciduous use.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)Dormant and summer oils are contained in CAN/CGS- 32.311 Table 4.2. Dormant oils are "[f]or use as a dormant spray on wood plants. Shall not be used as a dust suppressant." Summer oils are limited for use "[o]n foliage, as suffocating or stylet oils." (Table 4.2, CAN/CGSB-32.311-2020, pages 10 & 21)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Paraffin oils may be used as plant protection products in organic production only when they are used in accordance with the uses, conditions and restrictions pursuant to Regulation (EC) No 1107/2009 and taking into account the additional restrictions, if any, in the right column of the table below (Annex I part 4, 2021/1165)

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Paraffin oil is a substance permitted for plant pest and disease control, with the limitation "Need recognized by certification body or authority" (Table 2, page 22)

International Federation of Organic Agriculture Movements (IFOAM)
Light mineral oils (paraffin) allowed for plant pest and disease control (Appendix 3, Section II, page 77).

Japan Agricultural Standard (JAS) for Organic Production
Mixed oil emulsion allowed (Appended Table 2: Agricultural chemicals)

Human Health and Environmental Issues
The exploration and extraction of petroleum has a number of environmental effects that include land use issues, spills, emissions, pipeline and infrastructure construction, among others. However, once the oil is refined and applied as a pest control material, the environmental impact of these oils decreases. The EPA exempts petroleum oils, or mineral oil, from the requirement of a tolerance when applied to growing crops [40 CFR 180.905]. The 2019 TR cites a number of studies that show that actual persistence in the field is highly variable and depends on many factors including temperature, precipitation, sunlight, how the oil is applied, and droplet size. Soil biota degrade these oils over time with the amount of time necessary for degradation dependent on many environmental factors. Various grasses and legumes may also be an effective means of removing petroleum hydrocarbons from the soil.

The effect of spray oils on non-target beneficial organisms varies based on the mobility of the organism, its stage of development, and its ability to reinvade after the oil application (2019 TR). The timing of the oil application may also alter the effects on beneficial organisms. For example, dormant applications of oil may be applied before beneficial organisms become active. Even where oil is applied repeatedly and in the non-dormant season, excellent biocontrol may still be achieved in organic systems. In general, non-dormant application rates are lower than dormant rates in order to prevent plant phytotoxicity. These lower rates may also limit the negative effects on biocontrol agents. Various studies have confirmed that the use of oils is compatible with integrated pest management systems (2019 TR).

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

Materials such as kaolin, botanical insecticides and plant-based oils may also be alternative to mineral oils. Kaolin may be effective in certain cases but does not have the spectrum of activity that oils do. Botanical insecticides may disrupt biocontrol programs. Other plant-based oils may be alternatives to petroleum-based oils. The 2019 TR notes a number of alternatives and cites one study that showed that castor, cottonseed, and linseed oils had comparable or better activity than petroleum oils against scales, but the

vegetable oils were also more phytotoxic to the plants. Some studies show that plant-based oils may be superior to PDSO's in pest controls, while others indicate lower efficacy.

Biopesticides may also have efficacy against target pests. These include a number of different fungi, bacteria and viruses such as codling moth granulosis virus, *Chromobacterium subtsuga,* and *Bacillus thuringiensis* (*Bt).* Oils may target a variety of pests while these various biopesticides either target a single pest species or a limited range of pest species. Additionally, these biocontrol agents may be applied at different timings than oils and may work better when used in conjunction with oils rather than as alternatives (2019 TR).

Previous sunset reviews included discussions around whether vegetable or fish oils could serve as a natural replacement for the horticultural oils. More commercial plant-derived or fish oil products appear on the market each year. These include products based on fish, castor, neem or soybean oils, as well as essential oils from plants like mint or thyme. Both vegetable and horticultural oils require the addition of emulsifiers to allow them to stay in suspension when added to water for application to the targeted crop.

In past sunset reviews there has been overwhelming support for the continued listing of this material. Many commenters noted the extensive benefits and need for these oils. Organic stakeholders provided a clear message that this material remains a necessary tool in organic crop production. It was also pointed out during public comment that these oils are allowed for use world-wide by most organic certifying bodies for use in organic crop production.

Written and oral comments for this review were overwhelmingly in support for the continued listing of this material. Many commenters noted the extensive benefits and need for these oils. Organic stakeholders provided a clear message that this material remains a necessary tool in organic crop production.

Questions to our Stakeholders
Farmers and researchers—Do you have experience with plant or fish oils that reflects on whether they can take the place of mineral oils in organic insect or mite management programs?

Justification for Vote
The Subcommittee finds horticultural oils compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove horticultural oils from the National List
Motion by: Brian Caldwell
Seconded by: Jerry D'Amore
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

Oils, horticultural §205.601(i)(7)

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

(7) Oils, horticultural, narrow range oils as dormant, suffocating, and summer oils.

Technical Report: 1995 TAP; 2019 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation - deferred; 06/2006 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Horticultural oils have widespread use in organic fruit and vegetable production. They can be used in nearly every season and may be used alone or in mixes that include other nutrient or pest control products. Oils may be used for control of multiple plant diseases as well as miticides and insecticides. According to the 2019 technical report (TR), oils have different modes of action on insects, mites and plant pathogens. They target multiple sites and not specific receptors and thus do not act like most synthetic insecticides. This action also helps to prevent resistance to their action. The multiple actions include smothering insect eggs by preventing atmospheric gas exchange, softening or disrupting insect cuticles, interfering with molting, as well as altering behaviors such as egg laying.

Horticultural oils may be called by many different names; however, the 2019 TR generally refers to them as petroleum-derived spray oils (PDSO's) or mineral oils. Their use has increased and has been refined over the last century. Recognition that different fractions of oils have higher efficacy for pest control and that the range of phytotoxic effects on the plant goes from none to high depending on the fraction used led to the selection of a narrow range of oils exhibiting the dual characteristics of being effective against pests and non-toxic to plants. They are often classified by boiling point, although modern terminology may refer to many other characteristics such as chain length and chemical structure (2019 TR).

Manufacture
Most PDSOs are produced from the extraction, distillation, and further refinement of petroleum. The 2019 TR describes in detail the potential processes by which crude petroleum may be transformed to a narrow range horticultural oil. In general, the crude petroleum may be converted chemically by either catalytic or thermal methods. Once the oils are converted to a certain fraction, additional chemical treatments are applied to the distillates to remove phytotoxic compounds, such as sulfur, while keeping compounds toxic to pests and diseases. Additionally, the 2019 TR states horticultural oils are often formulated with wetting agents or surfactants that allow them to be mixed and diluted with water. Most spray oils in the United States contain a non-ionic surfactant dissolved in the oil concentrate at a concentration of 0.35 percent for citrus use and 0.5 percent for deciduous use.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Dormant and summer oils are contained in CAN/CGS- 32.311 Table 4.2. Dormant oils are "[f]or use as a dormant spray on wood plants. Shall not be used as a dust suppressant." Summer oils are limited for use "[o]n foliage, as suffocating or stylet oils." (Table 4.2, CAN/CGSB-32.311-2020, pages 10 & 21)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Paraffin oils may be used as plant protection products in organic production only when they are used in accordance with the uses, conditions and restrictions pursuant to Regulation (EC) No 1107/2009 and taking into account the additional restrictions, if any, in the right column of the table below (Annex I part 4, 2021/1165)

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Table 2 of the Codex Alimentarius Commission's Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods lists "Paraffin oil" as a substance permitted for plant pest and

disease control, with the limitation “Need recognized by certification body or authority” (FAO/WHO Joint Standards Programme 1999).

International Federation of Organic Agriculture Movements (IFOAM)
The IFOAM—Organics International standards Appendix 3 permits the use of “light mineral oils (paraffin)” without annotation for plant pest and disease control (IFOAM 2014).

Japan Agricultural Standard (JAS) for Organic Production
The Japanese Agricultural Standard for Organic Plants, Table 2 allows mixed oil emulsion, petroleum oil aerosol, and petroleum oil emulsion for plant pest and disease control without annotation (Japan MAFF 2000).

Human Health and Environmental Issues
The exploration and extraction of petroleum has a number of environmental effects that include land use issues, spills, emissions, pipeline and infrastructure construction, among others. However, once the oil is refined and applied as a pest control material, the environmental impact of these oils decreases. The EPA exempts petroleum oils, or mineral oil, from the requirement of a tolerance when applied to growing crops [40 CFR 180.905]. The 2019 TR cites a number of studies that show that actual persistence in the field is highly variable and depends on many factors including temperature, precipitation, sunlight, how the oil is applied, and droplet size. Soil biota degrade these oils over time with the amount of time necessary for degradation dependent on many environmental factors. Various grasses and legumes may also be an effective means of removing petroleum hydrocarbons from the soil.

The effect of spray oils on non-target beneficial organisms varies based on the mobility of the organism, its stage of development, and its ability to reinvade after the oil application (2019 TR). The timing of the oil application may also alter the effects on beneficial organisms. For example, dormant applications of oil may be applied before beneficial organisms become active. Even where oil is applied repeatedly and in the non-dormant season, excellent biocontrol may still be achieved in organic systems. In general, non-dormant application rates are lower than dormant rates in order to prevent plant phytotoxicity. These lower rates may also limit the negative effects on biocontrol agents. Various studies have confirmed that the use of oils is compatible with integrated pest management systems (2019 TR).

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

Previous sunset reviews included discussions around whether vegetable or fish oils could serve as a natural replacement for the horticultural oils. More commercial plant-derived or fish oil products appear on the market each year. These include products based on fish, castor, neem or soybean oils, as well as essential oils from plants like mint or thyme. Both vegetable and horticultural oils require the addition of emulsifiers to allow them to stay in suspension when added to water for application to the targeted crop.

Plant-based oils may be viable alternatives to mineral oils. Some studies show that plant-based oils may give good disease control, while others indicate lower efficacy and/or the potential for phyotoxicity. However, farmer experience indicates that some plant-based oils may not be phytotoxic. More research on plant-based oils needs to be done to clarify which oils are effective against which pathogens, and whether phytotoxicity is an issue in those cases. Approved biopesticides may also have efficacy for target diseases; they may be more selective and thus less versatile than PDSOs.

Written and oral comments for this review were overwhelmingly in support for the continued listing of this material. Many commenters noted the extensive benefits and need for these oils. Organic stakeholders provided a clear message that this material remains a necessary tool in organic crop production.

Questions to our Stakeholders
Farmers and researchers—Do you have experience with plant or fish oils that reflects on whether they can take the place of mineral oils in organic disease management programs?

Justification for Vote
The Subcommittee finds horticultural oils compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove horticultural oils from the National List
Motion by: Brian Caldwell
Seconded by: Jerry D'Amore
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

Pheromones

Reference: § 205.601(f) As insect management. Pheromones.
Technical Report: 1995 TAP; 2012 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
The EPA defines pheromones as volatile chemicals produced by a given species to communicate with other individuals of the same species to affect their behavior. Synthetic versions of natural pheromones are employed in insect pest management.

There are various types of pheromones which elicit various behavioral responses; these include pheromones that

(a) signal dominance status,
(b) sex pheromones that indicate sexual receptivity,
(c) alarm pheromones which signal danger,
(d) aggregation pheromones that bring organisms of the same species together for feeding or reproduction purposes, and
(e) trail pheromones that communicate directions to food resources and provide information for movement or relocation of colonies.

Both non-synthetic and synthetic pheromones are used in pest management. They perform this function by eliciting behavioral changes in the target pest to achieve crop protection goals.

There are three major uses of pheromones in pest management.

(a) They serve as traps and lures for determining the incidence and population density of insects in an area. The lures are often held in polyethylene or rubber, which facilitates a slow release of the pheromone. This method is used to conduct mass trapping of male insects thereby reducing pest populations by reducing the availability of males for mating purposes.

(b) Pheromones are also used in attract and kill systems, which are a mixture of pheromones and insecticides. The pheromones serve to attract the target pests, which are then exposed to lethal doses of the insecticide in the mixture. The use of pheromones as attractants in such mixtures reduces the quantity of insecticides required to achieve effective management of target insects. Attract and kill systems have been employed effectively in the management of the boll weevil and grape root borer moth.

(c) Pheromones are also used to disrupt mating in target pests. This involves saturating an area with synthetic pheromones, making it difficult for males of the target pest to locate receptive females for mating purposes. This mating disruption is either competitive or non-competitive. The competitive disruption refers to males of target insects following a plume of non-synthetic pheromone released by a dispenser instead of natural pheromone blends released by actual females in the population. Non-competitive mating disruption involves the release of an unnatural blend of synthetic pheromones, which masks the natural pheromones released by females of target insects, thereby making it difficult for males to orient themselves correctly to locate female insects for mating purposes.

Manufacture

Even though natural pheromones can be obtained from female insects, commercial pheromones are synthetic products involving chemical processes that are unique to the various pheromones.

1. Pheromones are made of specific esters obtained from reactions between an oxoacid with a compound such as an alcohol or phenol that contains a hydroxyl group.
2. Pheromones are also synthesized by condensing an acid with an alcohol.

Methods of pheromone synthesis include

- derivation from natural products such as insect pheromones,
- chemical or biochemical processes, and
- enantiomer separation.

Moth pheromones are usually made up of hydrocarbon chains that are about 10 to 18 carbons in length with 1 to 3 double bonds with an acetate, alcohol, or aldehyde at the terminal end. Many pheromone products are formulated as mixtures with inert ingredients. Pheromone formulations may also contain antioxidants and ultra-violet stabilizers to protect the pheromones from rapid degradation.

Pheromones are dispensed in various ways. These include

- Passive dispensers which refer to materials that release pheromones via volatilization instead of spraying resulting in the concentration of pheromones in a limited area. The idea behind the use of pheromones is to draw insect pests away from crops.

1. PASSIVE DISPENSERS INCLUDE
   a) polymer spirals,

b) ropes, and
c) tubes.

The problem with such passive dispensers is that the release of pheromones is dependent on ambient temperature, which is also dependent on time of day. More pheromones tend to be released during the day, which does not coincide with the nocturnal activity of moths.

2. RETRIEVABLE POLYMERIC DISPENSERS

These are dispensers that are constructed in sizes that render them easily recognizable and retrievable. These dispensers are not in contact with crops.

- Microencapsulated pheromones (MEC) refer to very small droplets of pheromones held within polymer capsules that determine the rate of their release.
    - MECs are designed to be small enough so they can be applied in water medium inside sprayers used in conventional application of pesticides.
    - Polymer capsules prevent the registration of sprayable pheromones for use in organic fruit production.
- Hollow fibers represent another method of dispensing pheromones. These dispensers consist of impermeable short tubes that are sealed at one end and filled with pheromones. These dispensers release a burst of pheromones shortly after installation, after which emission becomes fairly constant.

3. HIGH EMISSION DISPENSERS

These are dispensers that deliver larger quantities of pheromones, thereby reducing the number of dispensers needed to cover large areas; their use also results in reduction of labor costs.

It is important to note that 7 CFR 205.601 does not allow the use of List 3 inerts (i.e., inerts with unknown toxicity) with active dispensers.

There are other methods of dispensing pheromones such as

- the Specialized Pheromone Lure Application Technology (SPLAT^{TM}), which is a propriety formulation of biologically inert materials that are used to control the release of semiochemicals including pheromones with or without pesticides.

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
All sources allowed for pest control; use in pheromone traps or passive dispensers. (Tables 4.2 & 8.2, CAN/CGSB-32.311-2020, page 17 and 45)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Allowed (1.10.3, 2018/848 & Annex I, Table 4, 2021/1165)

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Allowed in traps. (pages 19 and 23)

International Federation of Organic Agriculture Movements (IFOAM)
Allowed in traps and dispensers only. (Appendix 3: Crop Protectants and Growth Regulators, page 78)

Japan Agricultural Standard (JAS) for Organic Production
Allowed. Limit use to chemical agents with an insect pheromone action as the active ingredient, except when used on plant products for the purpose of controlling pests and diseases. (Appended Table 10: Chemical agents & Appended Table 2: Agricultural chemicals)

Ancillary Substances
Many pheromone products are formulated as mixtures with inert ingredients. Pheromone formulations may also contain antioxidants and ultra-violet stabilizers to protect the pheromones from rapid degradation. It is important to note that the specific composition of pheromones formulated with inert constituents is not declared to the public because it is considered confidential business information.

It is important to note that 7 CFR 205.601 does not allow the use of List 3 inerts (i.e., inerts with unknown toxicity) with active dispensers.

Human Health and Environmental Issues
Inert ingredients used in pheromone formulations include compounds that are potentially linked to asthma, cancer, and endocrine disruption. The fact that dispensers serve as physical barriers to exposure to these chemicals makes the risk or level of exposure to terrestrial and aquatic organisms low. This is particularly so when dispensers are placed away from water sources.

Microencapsulated pheromones may have negative impacts on human health; this includes respiratory irritation caused by inhalation of particles. Such effects are due to the size of the microencapsulated products and not specifically due to the pheromone chemicals.

Based on observed toxicity in animal testing and expected low exposure to humans, no risk to human health is expected from the use of synthetic and non-synthetic insect pheromones. The 2012 TR states that no effects on human health are reported for any of the pheromone products registered with the EPA. The EPA in 2011 affirmed that no adverse effects had been reported from the use of synthetic pheromones.

Material Safety Data Sheets pertaining to skin and eye irritation from pheromones are based on exposure to very high concentrations of the undiluted active ingredient. It must be noted that, in the case of passive dispensers, the pheromone is enclosed and diluted within a plastic tube and allowed to dissipate into the atmosphere at low concentrations.

An Environmental Impact Report (EIR) by the California Department of Food and Agriculture in 2009 covered the impact of three mating disruption application methods, namely:
(a) twist-ties,
(b) ground applications of a thick pheromone-containing matrix applied to trees and utility poles, as well as
(c) aerial applications.

The EIR found that none of these application methods had significant unavoidable impacts.

Twist ties
- were found to have no impact on beneficial insects and agriculture,
- no potential for exceedance of toxicity reference values for non-target invertebrates and pollinators, and
- no impact associated with terrestrial wildlife, fish, or human health due to accidental spills.

Ground and aerial applications

- had less than significant potential impacts on the afore-listed categories.

Aerial application

- poses some ecological risks compared to dispenser methods.
- Non-target organisms, such as honeybees, may be coated with viscous material while in flight or these might be picked from sprayed plant surfaces.
- Aerial application methods may also result in disposal of pheromones into small streams, which could potentially impact aquatic organisms.

Evaluation of aerial and ground application methods, however, revealed that the risk to aquatic systems was slightly higher for twist-ties or ground application methods compared to aerial methods.

The California Department of Food and Agriculture also reported that the fate and transport properties of pheromones formulations applied aerially renders them unlikely for a significant amount of pheromone to deposit into an aquatic system.

Discussion

Both written and oral comments at the Spring 2024 meeting were in favor of relisting pheromones. Comments were similar to those made during the sunset review in 2019. Comments were in favor of relisting pheromones due to their widespread use, insect specificity, use in monitoring populations, and benign nature. Some of the comments during the 2024 Spring meeting did support relisting, with the caveat that the pheromones are (a) identical to or substantially similar to natural pheromones, (b) in passive dispensers, (c) without added toxicants, and (d) used with only approved inert ingredients.

Questions to our Stakeholders

Is there an interest in knowing more about the inert ingredients that are used in formulating pheromone products? How much information would be considered acceptable given proprietary information rights of pesticide manufacturers?

Justification for Vote

The Subcommittee finds pheromones compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote

Motion to remove pheromones from the National List
Motion by: Franklin Quarcoo
Seconded by: Brian Caldwell
Yes: 0 No: 5 Abstain: 0 Recuse: 0 Absent: 4

Ferric phosphate

Reference: § 205.601(h) As slug or snail bait.
(1) Ferric phosphate (CAS #s 10045-86-0).
Technical Report: 2004 TAP; 2010 TR; 2012 Supplemental TR; 2024 Limited Scope TR
Petition(s): 05/2003 , Supplemental Information 02/2005, Petition to remove: 07/2009
Past NOSB Actions: 03/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2012 recommendation on petition to remove from National List; 04/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Added to National List 09/11/06 (71 FR 53299); Renewed 08/03/2011 (76 FR 46595); Renewed 09/12/16 (81 FR 8821); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

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

Manufacture
Ferric phosphate is present naturally in the soil; however, to achieve concentrations toxic to molluscs, ferric phosphate must be supplemented through applications, most often with ferric phosphate formulated with a chelating agent. To produce ferric phosphate synthetically, an aqueous iron sulfate solution is mixed with an aqueous disodium phosphate solution in a stainless steel boiler. The mixture is heated to 50-70°C in order to precipitate ferric phosphate. The precipitate is filtered from the solution, washed with distilled water, and dried with hot air. The baited pellets contain approximately 1% by mass of ferric phosphate with the remainder of the pellet comprised of a chelating agent and carbohydrate inerts.

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed as a molluscicide for slug and snail control. Use in a manner that runoff into water bodies is prevented. Contact with crops is prohibited. (Table 4.2, CAN/CGSB-32.311-2020, page 11)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Allowed (Annex I, 2. Low risk active substances, 2021/1165)

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Allowed as a molluscicide. (Table 2 Substances for Plant Pest and Disease Control; Iron phosphates, page 23)

International Federation of Organic Agriculture Movements (IFOAM)
Allowed for use as a molluscicide. (Appendix 3: Crop Protectants and Growth Regulators, page 78)
Japan Agricultural Standard (JAS) for Organic Production
Allowed. (Appended Table 2: Agricultural chemicals; Ferric phosphate granules)

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

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

Discussion
The 2012 technical review addressed a series of concerns about the biological activity of ferric phosphate, both in terms of its effectiveness in suppressing slugs and snails as well as its non-target effects on the ecology and abundance of soil dwelling organisms. Because the commercial formulations of ferric phosphate always include a chelating agent, the NOSB was concerned about the effects of the formulated products. The 2012 TR indicated that without the chelating agent, ferric phosphate did not provide sufficient or consistent suppression of slugs and snails. In fact, the efficacy was so low that it is hard to see why it would be used for slug and snail suppression without the chelating agent. The TR then asked about the risks of ferric phosphate and its associated chelating agents to soil organisms and water quality. Here, the existing data was scant. Three studies published between 2006 and 2009 indicated responses ranging from non-significant to highly significant adverse effects of chelated ferric phosphate on a range of non-target species.

The Subcommittee recognizes the efficacy of ferric phosphate is inextricably linked with the formulation; when formulated with a chelating agent, ferric phosphate effectively suppresses slugs and snails. Unfortunately, the non-target effects on other soil organisms increases as well.

In 2019, the NOSB received considerable public comment on ferric phosphate, learning that it is seen as an integral part of vegetable and fruit pest management and is widely used for slug and snail management in organic systems. At that time, there were no alternative commercial organic products for suppression of slugs and snails. However, products using sulfur as the active ingredient are now approved for this purpose.

A new technical review on ferric phosphate was requested. which focused on the following questions:

1. Is there new information about the effects of EDTA or other chelating agents on the toxicity of ferric phosphate to non-target organisms, including earthworms and dogs?
2. Are there ferric phosphate products that don't include chelating agents?
3. Do sulfur-based slug management products provide an effective alternative to ferric phosphate? Do they also include chelating agents?
4. When used in ferric phosphate products, does EDTA chelate heavy metals in soils? Are there studies that show the combination of ferric phosphate + EDTA (chelator) cause toxic effects in soil microorganisms, including earthworms, or plants?

The 2024 TR indicated that new studies had been done since 2012; these studies allayed concerns regarding the toxicity of ferric phosphate products (which include chelating agents) to earthworms. The TR

reported that field use rates of these products had only minor, temporary effects on various earthworm species. Toxicity to dogs was temporary and non-lethal, and resulted from dogs eating bait directly from containers or during or immediately after application. Symptoms included vomiting, lethargy, and diarrhea.

Studies with sulfur-based slug management products showed efficacy ranged from similar to slightly less effective compared to ferric-based products. It is unknown whether they also contain chelating agents. Similarly, information is not available about the existence of ferric phosphate slug management products that do not contain chelating agents. However, it is unlikely these products exist since their efficacy would be very low.

At field use rates, the effects of the chelating agents in ferric phosphate products on levels of heavy metals in the soil are very small. Research rates in relevant studies showing effects were hundreds of times higher than label use rates.

Justification for Vote
Based on this information, the Subcommittee finds ferric phosphate compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove ferric phosphate from the National List
Motion by: Brian Caldwell
Seconded by: Nate Lewis
Yes: 0 No: 8 Abstain: 0 Recuse: 0 Absent: 1

Potassium bicarbonate

Reference: § 205.601(i) As plant disease control.
(9) Potassium bicarbonate.
Technical Report: 1999 TAP; 2015 TR
Petition(s): N/A
Past NOSB Actions: 10/1999 NOSB meeting minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Potassium bicarbonate is a useful plant disease control material best suited for powdery mildew diseases and early blight control and has proven to be an important tool for a wide range of organically produced crops. Potassium bicarbonate is used to control *Alternaria* in cucurbits and Cole crops; anthracnose in cucurbits, blueberries, grapes, spinach, and strawberries; black dot root rot and early blight in potatoes; sooty blotch and powdery mildew in apples; downy mildew in cucurbits, Cole crops, grapes, and lettuce; and gray mold in beans, lettuce and strawberries. (For a complete list of uses please see lines 70 through 87 in the 2015 limited scope TR).

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

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

Allowed for pest and disease control for crops grown in greenhouses, other structures, and other crops (Table 4.2, CAN/CGSB-32.311-2020, page 19).

Allowed on organic product contact surfaces as food-grade cleaners, disinfectants, and sanitizers without a mandatory removal event (Table 7.3, CAN/CGSB-32.311-2020, page 42).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Allowed for the production and conservation of organic grapevine products (Annex V, Part D, 2021/1165).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Allowed – listed as potassium hydrogen carbonate (Table 2, Section II, page 23).

International Federation of Organic Agriculture Movements (IFOAM)
Allowed (Appendix 3: Crop Protectants and Growth Regulators, page 77).

Japan Agricultural Standard (JAS) for Organic Production
Allowed (Appended Table 2: Agricultural chemicals; Potassium hydrogen carbonate aqueous solution).

Human Health and Environmental Issues
When the National Organic Program added potassium bicarbonate to the National List in April 2001, this substance was described as, " a least toxic, agronomically desirable material, with greater efficacy for controlling powdery mildew or late blight than does the currently available organic options." The original 1999 Technical Advisory Report (TAP) stated that there is "no carcinogenicity" and that "no effects of over exposure were documented."

The U.S. Food and Drug Administration (FDA) has declared potassium bicarbonate to be Generally Recognized as Safe (GRAS).

The U.S. Environmental Protection Agency (EPA) states that potassium bicarbonate is a naturally occurring compound that is not expected to have adverse effects on humans or the environment when used as a fungicide. The EPA further states that potassium bicarbonate is ubiquitous in nature, naturally present in human food and required for normal function in human, plant, and environmental systems.

Discussion
The 1999 TAP review found potassium bicarbonate to be compatible with organic crop production. It also found this material to be safer and more environmentally friendly than many of the alternatives.

During the 2015 sunset review, a limited scope technical report (TR) was requested. This TR focused almost exclusively on two questions: 1) Describe all natural (non-synthetic) substances or products which may be used in place of potassium bicarbonate and provide a list of allowed substances that may be used in place of potassium bicarbonate, and 2) Describe any alternative practices that would make potassium

bicarbonate unnecessary. *Bacillus amyliquifaciens* strain D747, *Bacillus subtilis*, *Bacillus pumilis*, gibberellic acid, *Streptomyces griseovirdis, Streptomyces lydicus*, *Gliocladium catenulatum,* and extracts of giant knotweed are all listed as natural alternatives for numerous plant diseases across many crops. Bordeaux mix, kaolin, lime sulfur, sulfur, hydrogen dioxide, and neem extracts are also suggested as alternatives. The TR also deals with a variety of cultural and mechanical practices as methods of disease prevention. Further clarification was sought in 2015 from stakeholders using potassium bicarbonate to help understand under what conditions the alternatives might be used. The organic producers responded that, while alternative materials and/or practices exist, potassium bicarbonate remains essential for their specific production practices.

This 2023 Sunset Review for potassium bicarbonate, as presented during the 2024 Spring Meeting in Milwaukee, generated about 23 written and oral comments during the public comment periods. Most of the comments were in favor of keeping potassium bicarbonate on the National List, with one commenter questioning its classification. Many of the stakeholder responses addressed the two questions asked under "Questions to our Stakeholders (see below). The general comments, plus those comments in direct response to the two questions, continue to support the necessity of potassium bicarbonate as a plant disease control material.

Questions to our Stakeholders
As "necessity" appears to be a key question, we are asking the same two questions of our stakeholders as presented in the previous two sunset reviews:

1. Have you used any of the many alternative materials to potassium bicarbonate on your farm, and did they provide the desired results for disease control?
2. Is potassium bicarbonate still needed in your organic farming operations? If so, why?

Justification for Vote
The Subcommittee finds potassium bicarbonate compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove potassium bicarbonate from the National List
Motion by: Jerry D'Amore
Seconded by: Wood Turner
Yes: 0 No: 5 Abstain: 0 Recuse: 0 Absent: 4

Magnesium sulfate

Reference: § 205.601(j) As a plant or soil amendment.
(6) Magnesium sulfate—allowed with a documented soil deficiency.
Technical Report: 1995 TAP; 2011 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use

Magnesium sulfate has a wide variety of uses including agricultural, food processing, personal care products, and medicine. In crop production, it serves as a soil amendment for addressing magnesium deficiency or to improve the uptake of nitrogen and phosphorous [2011 TR, line 56, Epsom Salt Council, 2009]. It may be used in combination with non-synthetic or synthetic crop fertilizers. Magnesium sulfate..." *…helps seeds to germinate, increases the production of chlorophyll, and aids in the production of flowers" [*[2011 TR, lines 203-204]. The high solubility of the compound makes it highly suitable for adding magnesium to the soil. It is a common addition to growth media in potted plants [2011 TR, lines 54-55].

> "In food processing, magnesium sulfate is used as a flavor enhancer in bottled water and as a firming agent in soybean curd. Magnesium sulfate is also used as a nutrient, primarily in salt-replacer products, dietary supplements, carbonated diet soft drink beverages, sports drinks, and enhanced (fortified) water beverages. It is used as in fermentation and malting aid in ale, beer, and other malt beverages (Kawamura and Rao, 2007) [2011 TR, lines 65-69].
>
> "Magnesium sulfate has many human medicinal uses. Injections of magnesium sulfate can be used as an anticonvulsant… Magnesium sulfate injections can help lower the blood pressure of pregnant females suffering from preeclampsia… Asthma attacks can be treated with magnesium sulfate… Magnesium sulfate can act as a laxative (Adnani, 2010)… Epsom salt, a common form of magnesium sulfate, is…used to relieve muscle aches and pains as well as to reduce itching and inflammation… It is commonly added to bath water and used by individuals suffering from joint pains (Epsom Salt Council, 2009) [2011 TR, lines 71-80]
> "Magnesium sulfate also has a number of veterinary uses. It acts as a… laxative, bronchodilator, electrolyte replacement aid with hypomagnesaemia, and may be used to treat cardiac arrhythmias. Specifically in swine, magnesium sulfate is administered to treat malignant hypothermia (Dodman, 2010) [2011 TR, lines 71-80]

Magnesium sulfate can be added to livestock feed to treat magnesium deficiency [2011 TR, line 61]

The National List permits the use of magnesium sulfate in organic crop production at §205.601(j)(6) with a documented soil deficiency.

Manufacture

Magnesium sulfate can be obtained from naturally occurring sources or chemically synthesized. Magnesium sulfate exists in nature as epsomite (magnesium sulfate heptahydrate) and kieserite (magnesium sulfate monohydrate). [2011 TR lines 262-266, 278-284]

The synthetic form of magnesium sulfate is produced by a two-step chemical reaction. The first step involves the ignition of magnesite ore (containing magnesium carbonate) or magnesium hydroxide (obtained from seawater) to produce magnesium oxide, which is then reacted with sulfuric acid to produce magnesium sulfate. Recrystallization and separation of the resulting crystals from the parent solution results in magnesium sulfate with a high grade of purity. [2011 TR, lines 262-266, 286-290.]

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

Allowed when soil and plant deficiencies are documented by visual symptoms, by testing of soil or plant

tissue, or when the need for a preventative application is documented. (Table 4.2, Magnesium listing, CAN/CGSB-32.311-2020, page 14)

Allowed as a food additive ingredient. (Table 6.3, CAN/CGSB-32.311-2020, page 33)

Allowed as food-grade cleaners, disinfectants, and sanitizers without a mandatory removal event. (Table 7.3, CAN/CGSB-32.311-2020. page 42)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Natural origin allowed. (Annex II, 2021/1165)

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Allowed for use in soil fertilizing and conditioning. (Table 1, page 20)

International Federation of Organic Agriculture Movements (IFOAM)
Allowed regardless of soil deficiency documentation. (Appendix 2: Fertilizers and Soil Conditioners, page 76)

Japan Agricultural Standard (JAS) for Organic Production
Allowed regardless of soil deficiency documentation. (Appended Table 1: Fertilizers and soil improvement substances; Natural substances or substances derived from natural sources which have not undergone any chemical treatment)

Ancillary Substances
Varies based on the chemical properties of the synthetic or non-synthetic fertilizers that may be combined with magnesium sulfate for application as a soil amendment.

Human Health and Environmental Issues

> "…accumulation of magnesium ions in body fluids can cause toxic effects, including heart changes, cyanosis, and flaccid paralysis (Gilman and Goodman, 1980)' [2011 TR, lines 412-413]

Reduction and eventual disappearance of tendon reflexes as well as heart block and respiratory paralysis are outcomes of the elevation of magnesium in blood plasma to levels that exceed the threshold level of 4 mEq/liter and approach 10 mEq/liter (HOSPIRA, 2004) [2011 TR, lines 338-340].

Administration of an excessive dose of magnesium sulfate in the treatment of preeclampsia results in toxic effects in neonates that include hypotension, flushing, sweating, flaccid paralysis, circulatory collapse, depression of cardiac function, and reflexes. Vasodilation from low doses of magnesium results in symptoms such as flushing and sweating, while higher doses of the compound results in circulatory collapse. [2011 TR, lines 415-421.] It is important to note that agricultural uses of the compound are not likely to result in such exposures.

> "If used in accordance with 7 CFR 205.601, it is unlikely that magnesium sulfate will cause harm to the environment.
>
> Magnesium exists in the atmosphere as a particulate as is not likely to be released following most manufacturing processes. The substance is removed from the atmosphere by wet and dry deposition.

> The physicochemical properties of magnesium sulfate make it an unlikely cause of contamination to the aquatic environment. Magnesium sulfate is considered highly soluble in water and also very mobile.
>
> Magnesium is not likely to volatize in soil due to its ionic properties. Magnesium sulfate also undergoes ion exchange with calcium, which allows for its removal in sediments… [Available data] indicates that magnesium ions are weakly sorbed on river sediments." [2011 TR, lines 391-403],

Discussion
Both written and oral public comments at the Spring 2024 meeting were in favor of relisting magnesium sulfate with documented soil deficiency. One written comment paraphrastically stated that biologically active soils should not be deficient in magnesium. The comment listed unbalancing of soil nutrients as one of the disadvantages of adding magnesium sulfate to the soil. The comment authors stated that even langbeinite and dolomite (which are nonsynthetic forms of magnesium) add potassium and calcium, respectively, to the soil that may not be needed. The authors stated that foliar application of magnesium was not an acceptable general practice even though it provides plants with a crucial macronutrient. The commenting organization considers the application of magnesium sulfate to be acceptable only under limited conditions, which must be stated in an annotation. The comment authors stated that synthetic plant nutrients should not be taking the place of organic soil-building practices, which are highly recommended for enriching soils with magnesium.

Questions to our Stakeholders
None

Justification for Vote
The Subcommittee finds magnesium sulfate compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove magnesium sulfate from the National List
Motion by: Franklin Quarcoo
Seconded by: Jerry D'Amore
Yes: 0 No: 8 Abstain: 0 Recuse: 0 Absent: 1

Hydrogen chloride

Reference: § 205.601(n) Seed preparations. Hydrogen chloride (CAS # 7647-01-0)—for delinting cotton seed for planting.
Technical Report: 2003 TAP, 2014 Limited Scope TR; 2024 Limited Scope TR pending
Petition(s): 2002
Past NOSB Actions: 05/2004 NOSB recommendation for National List; 11/2009 sunset recommendation; 4/2015 recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Added to National List 09/11/06 (71 FR 53299); Renewed 08/03/2011 (76 FR 46595)

Renewed 09/12/16 (81 FR 8821); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Hydrogen chloride is used in the process of delinting cotton seeds. Hydrogen is vaporized and then sprayed on cotton seeds after the ginning process. The gas mixes with the moisture in the seeds, resulting in acidic conditions, which the seeds are subjected. The lint on the seeds become weakened by the acid and is more readily buffed off before planting occurs [2003 TAP].

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

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Not Explicitly Mentioned

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Not explicitly mentioned for crop production. Allowed in the preparation of foodstuffs of animal origin for gelatine production (Annex V, Section A2, 2021/1165)

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Not Explicitly Mentioned

International Federation of Organic Agriculture Movements (IFOAM)
Not Explicitly Mentioned

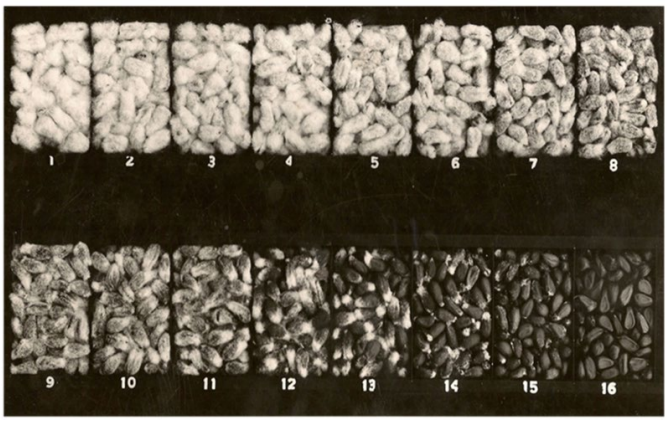
Japan Agricultural Standard (JAS) for Organic Production
Not Explicitly Mentioned

Human Health and Environmental Issues
Human Health –Hydrogen chloride will only exist in the air if transported through an aerosol or as a soot particle deposit. Hydrogen chloride exposure normally will not affect those vital organs furthest from the point of contact in the body; however, a major side effect is local irritation. Inhalation causes coughing, inflammation, pain, and edema of the upper respiratory tract, while eye contact may induce vision reduction or blindness. . Hydrogen chloride concentrations of 35 ppm or greater can cause throat irritation after short-term exposure. Hydrochloric acid, the aqueous form of hydrogen chloride when it is dissolved in water, is not considered a carcinogenic substance to humans. However, hydrochloric acid is very corrosive, and, if contacted with the skin, irritation and burns may occur [2003 TAP].

Environmental Issues - If exposed to the environment, hydrochloric acid will neutralize carbonate-based soil components. Large hydrochloric acid spills can be neutralized with lime or diluted alkaline solutions of soda ash. The EPA 1985 emission inventory indicates that less than one percent of hydrogen chloride emissions come from production practices, while nearly 89 percent of all emissions come from coal combustion [2003 TAP].

Discussion
During the Spring 2024 NOSB meeting, the board reviewed the substance, its history, the 2024 limited-scope TR that focused on alternatives, and public comments. Hydrogen chloride was petitioned in 2002 to be added to the National List, and it was added in 2004. In prior reviews, hydrogen chloride was deemed the only available solution for organic farmers needing to delint cotton seed.

Similar to past NOSB meetings, the discussion at the 2024 Spring NOSB meeting focused on natural alternatives and additional practices. The 2023 NOSB Crops Subcommittee requested a limited scope TR to review updates in innovation for natural or alternative practices that are at a commercial scale. No non-synthetic substances are available as alternatives to synthetic acids for cotton seed delinting. However, the 2024 limited scope TR provided insight into alternative practices that could be used to delint cotton outside of chemical means involving acid, which includes mechanical delinting, flaming, or breeding fuzzless seeds. Also discussed was the USDA cotton research group in Texas, which had successfully built a commercial-scale mechanical delinter. However, up to the date of writing this report, there has been no industrial partner ready to manufacture it.



(TR – Figure 2): Variable degrees of cotton seed delinting. Fully delinted seed (16) is likely achieved using acid delinting (Anonymous author, source: https://file.scirp.org/Html/13-2600348_20046.htm).

At the Spring 2024 meeting, the Board discussed public comments, including three comments in support of relisting. The Board reviewed NOP 5029 and NOP5029-1. NOP 5029-1 states, “We have also clarified that substances used in producing nonorganic seed or non-organic planting stock do not require review. This includes substances that may be used in post-harvest handling and cleaning of non-organic seed and planting stock that do not remain on the seed when it is planted.” Based on 5029-1, farmers can use the preferred delinting acid, sulfurous acid, for delinting cotton since the seed planted in the US is not certified organic due to the small marketplace.

Although progress has been made, viable alternatives to hydrogen chloride are not yet available. A key challenge is the small size of the U.S. organic production market, which does not economically incentivize companies to develop organic-specific technologies. The Crops subcommittee discussion centered around maintaining the listing, as it would be critical when organic cotton seed is available.

Justification for Vote
The Subcommittee finds hydrogen chloride compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove hydrogen chloride from the National List
Motion by: Amy Bruch
Seconded by: Wood Turner
Yes: 0 No: 8 Abstain: 0 Recuse: 0 Absent: 1

Ash from manure burning

Reference: § 205.602 Nonsynthetics prohibited
(a) Ash from manure burning.
Technical Report: 2021 TR (Biochar)
Petition(s): 2014; 2019 annotation change
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 4/2016 NOSB formal recommendation; 10/2019 sunset recommendation; 10/2021 recommendation to not annotate
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Ash from manure burning can be used as a soil amendment, used to address soil remediation, and to sequester carbon. Burning the manure would lessen the volume of material (manure) transported to a field for fertilizer and to recover some of the nutrients in a more concentrated form (phosphorus, calcium, potassium, and magnesium). The ash can then be used as a fertility input that is high in these nutrients. This ash from manure has also been touted as a feed ingredient for livestock. The NOP organic standards do not allow re-feeding of manure to organic livestock.

Manufacture
Manure can be thermally decomposed through combustion and pyrolysis to produce ash. The NOP articulated a position that pyrolysis is not its own unique mode of processing but in fact should be viewed as analogous to burning or combustion, and thus a source of ash [NOP 5033-1, section 4.8].

According to the 2021 TR, nearly all biochar is produced during the thermochemical degradation of biomass in the absence of oxygen from animal and plant feedstocks including: shells, sugarcane bagasse, coconut husks, cotton, crop remnants, grain remnants, grass residues, wood chips, tree back, organic waste, animal bedding, livestock manure, poultry litter, sewage sludge, paper sludge, and municipal waste.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Ash from plant and animal sources is allowed. However, ash from burning manure or from burning minerals, coloured paper, plastics or other non-biological substances is prohibited. (Table 4.2, Ash listing, CAN/CGSB-32.311-2020, page 4)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Not explicitly mentioned

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Not explicitly mentioned

International Federation of Organic Agriculture Movements (IFOAM)
Not explicitly mentioned

Japan Agricultural Standard (JAS) for Organic Production
Not explicitly mentioned

Ancillary Substances
None identified

Human Health and Environmental Issues
There do not appear to be any documented human health impacts from the petitioned substance.
The 2021 TR states that biochar can help decontaminate soil from pesticides and heavy metals but can also harbor toxins such as polycyclic aromatic hydrocarbons (PAH), which are typically formed using high-temperature production methods and heavy metals that are typically carried over from the feedstock.

Discussion
Ash from manure burning is a non-synthetic material present on the prohibited list for crop production. Since the carbon present in manure is considered valuable for soil building, it's destruction during burning would not be consistent with foundational organic production principle.

In 2016, the Board denied a petition to add the following annotation: "except where the combustion reaction does not involve the use of synthetic additives and is controlled to separate and preserve nutrients," stating that:

"Utilizing burning as a method to recycle millions of pounds of excess poultry manure inadvertently supports the business of Concentrated Animal Feeding Operations (CAFOs) by creating an organic industry demand for ash. Utilizing ash from manure burning in order to assist CAFOs in their reduction of environmental and human health contamination is not a compelling argument for consideration for addition to the National List."

In 2021, the Board denied the petition to annotate 205.602(a) to "(a) Ash from manure burning – unless derived as part of the production of biochar from pyrolysis of cow manure," stating that:

"While pyrolysis may be different from burning, the NOP has issued guidance (NOP Guidance 5033, 2016) stating that pyrolysis may be treated as equivalent to burning or combustion. Public comments were mixed as to whether the annotation should be changed; however, more comments supported maintaining the current annotation. Additionally, the NOSB found that while biochar may have many benefits, there are allowed alternative methods for producing biochar from other materials. Manures may be used in organic agriculture without conversion to biochar, thus a majority of the NOSB considered the use of biochar from animal manures not essential to organic agriculture and not meriting an annotation change."

One subcommittee member stated that there is not an excess supply of manures in the agricultural industry and burning off the material to handle the supply is not necessary. The market for manure is currently competitive.

All written comments were in support for relisting Ash from manure burning as a prohibited material. During the full board meeting, there was no further discussion about this material.

Questions to our Stakeholders
None

Justification for Vote
The Subcommittee finds ash from manure burning compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove ash from manure burning from the National List
Motion by: Logan Petrey
Seconded by: Jerry D'amore
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

Sodium fluoaluminate (mined)

Reference: § 205.602 Nonsynthetics prohibited
(g) Sodium fluoaluminate (mined).
Technical Report: none
Petition(s): 2002 Cryolite
Past NOSB Actions: 05/1996 NOSB meeting minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use:
According to the Environmental Protection Agency (EPA) fact sheet from 1996, "Cryolite is an insecticide used on many fruits, vegetables and ornamental crops to protect against leaf eating pests. Currently, the predominant uses are on grapes, potatoes, and citrus. Cryolite is formulated as dusts, wettable powders, and water dispersible granulars and can be applied by ground or air equipment. Multiple applications at high rates are typical. The highest single application rate is 30 lbs./acre on citrus and ornamentals; the highest seasonal rate from multiple applications is 154 lbs./acre on lettuce."

Sodium fluoaluminate (Na_3AlF_6)—also known as "sodium fluoroaluminate," "aluminum sodium fluoride," "trisodium hexafluoroaluminate," and "cryolite"— is used as a solvent for bauxite in the electrolytic production of aluminum and has various other metallurgical applications, and it is used in the glass and enamel industries, in bonded abrasives as a filler, and in the manufacture of insecticides.

Manufacture
Sodium fluoaluminate is a colorless to white halide mineral. Cryolite is a naturally occurring mineral that is also synthetically produced. It occurs in a large deposit at Ivigtut, Greenland, and in small amounts in Spain, Colorado, U.S., and elsewhere.

International

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Not explicitly mentioned

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Not explicitly mentioned

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

International Federation of Organic Agriculture Movements (IFOAM) Norms
Not explicitly mentioned

Japan Agricultural Standard (JAS) for Organic Production
Not explicitly mentioned

Environmental Issues

According to an EPA memorandum dated March 16, 2011, on the subject of "Cryolite. Human Health Assessment Scoping Document in Support of Registration Review," the toxicity of sodium fluoaluminate/cryolite is caused by the release of fluoride into the environment due to the dissociation of cryolite into fluoride. The EPA memorandum cited above references a number of animal toxicological studies on this substance. other studies about fluoride toxicity are also referenced; since fluoride enters the environment in multiple ways—including fluoridated water— it can have a cumulative adverse impact on health.

Discussion

During previous sunset reviews, the NOSB found that sodium fluoaluminate was not compliant with OFPA criteria and recommended this material remain as a prohibited substance on the National List. Given the toxicity associated with fluoride pollution in the environment and the multiple sources of such pollution, continued prohibition of the use of this substance in organic production is the current climate of the Crops Subcommittee.

At the Spring 2024 meeting, the NOSB and stakeholders supported the continued listing of sodium fluoaluminate as a prohibited substance. All written public comments received in this round supported the continued listing of this material as a prohibited substance. Comments cited issues of public health and the availability of effective alternatives. Commenters noted organic growers have not reported a need for this material.

Questions for stakeholders

Is there any new research or relevant information in the marketplace that should be considered in conjunction with OFPA criteria and the long-standing prohibition on using sodium fluoaluminate in organic production?

Justification for Vote

The Subcommittee finds sodium fluoaluminate non-compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is proposing to maintain its prohibition.

Subcommittee Vote
Motion to remove sodium fluoaluminate from the National List
Motion by: Mindee Jeffery
Seconded by: Amy Bruch
Yes: 0 No: 8 Abstain: 0 Recuse: 0 Absent: 1

National Organic Standards Board
Certification, Accreditation, Compliance Subcommittee (CACS)
Climate-Induced Farming Risk and Crop Insurance Proposal
July 18, 2024

Intro & Background:
Farming is both a rewarding and humbling profession in part because there are only a few variables within one's control, and mother nature is not one of them. The scientific literature recognizes organic farming as being climate-smart. It includes building soil organic matter, improving soil water-holding capacity, and eliminating the need for pesticides, synthetic fertilizers, and herbicides. Despite these attributes, major climate events such as hailstorms, tornadoes, floods, and droughts pose existential risks to all producers, conventional and organic. Inclement climatic events can devastate organic producers; therefore, sufficient crop insurance options are needed.

Additionally, the USDA's Transition to Organic Partnership Program (TOPP), climate-smart farming methods, and climate change-induced risk underlines the need to enhance support for transition and organic producers managing climatic risk on their farms. The primary mechanism for climatic risk support involves improving the existing crop insurance policy tools offered to organic producers.

Requirements from other entities are another driver for offering organic producers adequate and meaningful crop insurance offerings. Many financial institutions require organic producers to have adequate coverage before lending annual operating lines of credit. Additionally, the government requires producers to purchase crop insurance with the most recent Emergency Relief Program (ERP) facilitated by the Farm Service Agency (FSA) office. As the ERP landing page notes, "Producers who receive ERP payments must purchase crop insurance or Noninsured Crop Disaster Assistance Program (NAP) coverage for the next two available crop years." For an organic producer with diverse crop rotations, coverage for all crops is usually challenging through RMA channels, and producers then have to research and acquire NAP coverage from the FSA office, which, as the name states, for "non-insured crop disasters" offers a low-level coverage and generally, education on the specificities is low.

The NOSB has worked to identify barriers to farmers' transition to organic farming and the further retention of existing organic producers. Through robust rounds of public comment, we have heard repeatedly that crop insurance is one program that has an outsized potential to help farmers mitigate the climatic risk of both transitioning to organic and staying organic once they've been certified. Focusing on crop insurance is essential for the organic farming community. It was further echoed by public comments, including one stakeholder stating, "We encourage RMA, NOP, and the NOSB to continue to work with organic stakeholders to develop further new crop insurance tools that serve the needs of diversified organic growers (and transition-to-organic producers) and a system that recognizes the robust and extended rotation both during transition and as organic producers, rather than penalizing them through the Annual Production History system."

The Director of the Product Administration & Standards Division of the USDA's Risk Management Agency (RMA) gave a presentation on crop insurance at the Fall 2023 NOSB meeting in Providence, RI. Her presentation described the crop insurance landscape across the United States and how the agency works diligently to make better insurance products available to more producers.

Progress:
The CACS celebrates the progress RMA has made to improve access to crop insurance for organic producers. RMA has attempted to understand how organic farming works and to build better programs

for organic farmers. Indeed, several CACS members remarked on how much progress has been made in the past ten years. Recently, a new round of improvements for organic and specialty crop growers was announced through the Expanding Options for Specialty and Organic Growers Final Rule. RMA Administrator Marcia Bunger stated, "Expanding our coverage options gives producers more opportunities to manage their risks."

See below for some progress highlights:

- **Enterprise and Optional Units:**
  - Allow EUs by organic farming practice for alfalfa seed, almonds, apples, avocado (California), cabbage, canola, citrus (Arizona, California and Texas), coarse grains, cotton, ELS cotton, dry beans, dry peas, figs, fresh market tomatoes, forage production, grass seed, macadamia nuts, millet, mint, mustard, pears, potatoes (northern, central, and southern), processing tomatoes, prunes, safflower, small grains, sunflower seed, and walnuts.
  - Expand OUs by organic practice to all remaining crops where OUs are available, and the organic practice is insurable.

- Reduce coverage penalties on perennial specialty crop producers and producers of intensively managed crops, such as alfalfa, when they move to row crop production. This allows for a seamless transition without losing crop insurance coverage.

- **Good Farming Practices (GFP):** Streamline and shorten the FCIC GFP reconsideration process by closing the administrative file following FCIC's initial GFP determination.

- **Double Cropping and Annual Forage:** Clarify that a producer must prove an insurance history for the annual forage crop and meet the current double cropping requirements to receive a full prevented planting payment.

RMA will release new **Organic Practice Guidelines** to producers for the 2025 crop year. These guidelines will assist producers with reporting planted or perennial acreage insured under a certified organic or transitional practice.

Notable improvements RMA has already implemented:
RMA introduced a contract price addendum that allows transitioning and organic producers to submit their contracts in advance to obtain a higher price for crop coverage.

1. The RMA Agent Finder Web Page connects farmers interested in the Whole Farm Revenue/Microfarm Program with agents experienced in writing those policies.
2. Pasture, Forage, Rangeland (PRF) now has organic forage, allowing for more suitable organic coverage.

Continuous Improvement Still Needed:
Through public comments and various farmer and crop insurance agent interviews, we have heard that while significant progress has been made, there is still work to be done to level the playing field for organic producers. At a minimum, by offering risk management options that do not *disincentivize* the transition from conventional production to organic, the opportunity to participate in the organic marketplace will expand to more producers. Additionally, those certified producers will benefit from more robust, equitable risk management options. Further refining organic crop insurance options will help address the farming communities' concerns. A public commenter shared, "When a farmer changes

from one form of production to another (conventional→organic), even if one is very experienced and has an established track record of good management, one is treated like a beginning farmer in the RMA system. This is likely an inaccurate risk prediction, given the experience and track record, and it also systematically disadvantages farmers entering transition and organic production."

Because the organic marketplace is unique, organic farmers frequently face different risks than their conventional counterparts. The following list includes overarching opportunities that organic producers and agents mentioned in public comments and various interviews regarding improving crop insurance to help organic producers, both row crops and produce, mitigate risk.

Opportunities for Improvement:

1. **Quality Factor Consideration During Loss Adjustment:** Because of the dynamic food market that corresponds to a more diverse cropping rotation, organic producers raise crops that, to meet the market demand, must meet high-quality specifications. Because they are unique and not readily substitutable into the conventional commodity supply chain, these crops may only have a secondary market, like feed, if they meet the specifications. For this reason, if a farmer does not experience a yield loss but rather a quality loss due to a climatic event, it can be as economically devastating as a complete yield wipeout. With the recently published rule for crop insurance, quality adjustment coverage expansion did occur, i.e., sunburned damaged walnuts to be eligible for indemnity payments. Additional expansion for other organic and specialty crops is critical. Regarding row crops, an example to review is when raising blue corn; if a farmer does not have a yield loss but a quality loss, they will not be able to sell into the food market. They also cannot sell into the organic feed market as their blue corn may discolor chicken eggs. Their corn cannot be sold in the conventional market because of its color. Therefore, with no quality coverage, the farmer raising this otherwise in-demand-for-food crop will be left with only the option to compost it—a complete loss with no coverage even though yields were "fine." *Note: specific loss adjusting standards for quality are available for some specialty crops, including produce crops.

2. **T-Yields:** Transitional yields (T-yields) are county-level actuarial numbers on which insurance providers base a policy guarantee when a farmer cannot provide previous production data. By resetting the T-yield at the start of the transition, producers' coverage is generally decreased compared to conventional counterparts. Note: T-yield, coverage level, and price are the main factors determining loss payout. Building history within organics takes many years due to robust crop rotations. The organic producers and others in the organic community overwhelmingly expressed the need for RMA to re-look at the actuarial process regarding t-yields and how they are assigned to transition and organic producers. Several ideas were discussed amongst the community, including, at a minimum, allowing for the yield history acquired during the transition to carry on through organic farming since the farming "practice would be the same" instead of restarting the clock-building yield history. Additionally, stakeholders saw value in a more customized approach for t-yields that could be offered to allow a portion of the conventional yield history (an index applied to a producer's conventional approved production history, APH) to be associated with the assigned t-yield during transition and organic. Lastly discussed, if the base assigned t-yield values could not be changed or customized per operation, another idea that the organic community could be interested in would be a potential "buy up" coverage above the 85% level offered (similar to options available for production hail or pasture, range, forage (PRF) policies.

3. **In Field Adjusting Speed for Organics:** Whether you plant organic blueberries or organic corn, The time frame for adjusters to review a loss and visit a crop in-field can be the difference between an organic farmer saving the crop after weather damage (currently, adjusters are to see a field 7-13 days after a climatic event). For example, if a producer has a hail event before organic crops have time to canopy, the producer will experience a burst of weed pressure within one day of the hail event. Because of the potential delay in receiving a visit from an adjuster, the farmer is not allowed to get in the field and address the weeds mechanically without risking losing coverage for the crop. All organic crops need specific "in-field" adjusting standards for organic producers.

4. **Organic Crop Insurance Specialist Finder:** Organic crop insurance requires additional expertise to help farmers maximally. Modeled after the newly created agent finder for Whole Farm Revenue Protection/Micro Farm Landing Page hosted by RMA, it would be an excellent service to organic producers for RMA to create a similar landing page for adjusters and insurance agents who have specific knowledge of organic policies and are interested in working with organic farmers. There are many excellent crop insurance agents and crop adjusters around the country. Still, a farmer's ability to find them is relative to their network in the organic farming world. It is a distinct disadvantage to producers new to organic or farmers outside of organic agricultural hot spots.

5. **Ensuring Crop Insurance works for more organic farmers:** The design of crop insurance policies should be examined to ensure that they meet the needs of all organic farmers. Many organic producers who could benefit from existing programs still need to be aware of organic crop insurance option offerings. Many excellent, high-yielding farmers are not participating in organic crop insurance programs. By making more farmers aware of the programs, a larger pool with more diverse operators will help stabilize the loss ratio for organics.

NOTE: As shown above, opportunities 1 and 3 would benefit from having a distinct section in the RMA's loss adjustment manual specifically for organic production.

Other challenges that producers and agents mentioned include:

1. Now that RMA has adopted enterprise units through organic practice, the next step would be to allow different coverage levels through organic practice. For example, RMA allows different coverage levels for irrigated and non-irrigated land. Let farmers choose different coverage levels for conventional, transitional, and organic acreage.
2. There must be a clear path to providing feedback for Launching the Good Farming Practices Updated Handbook, especially for calibrating NRCS and RMA regarding no-till organic practices and relay cropping.
3. Whole Farm Revenue Program (WFRP): Agents cite the program's complexity (a 50-75 page application) and lower agent compensation compared to other insurance as a disincentive for writing those policies.
4. The time required to develop yield history on new crops insured under written agreements can slow their adoption, which, in turn, disincentives producers from diversifying their rotation.
5. Producer awareness and understanding of RMA's current policies and programs are inconsistent across the country.
6. The "Transition System Plan" or "Transition Producer Plan" is new, and producers transitioning to organic may not have sufficient help understanding its role in obtaining coverage. The idea is

good; however, it needs additional simplification as the amount of work required to complete it resembles a complete Organic System Plan.

7. Required planting dates can conflict with diverse crop rotations, including the incorporation of cover crops. This needs to be examined on a regional basis.
8. However, outside of climatic events, organic producers mentioned the threats posed by volatile, unknown point-of-source drift events such as dicamba.

Closing:

Organic producers take on significant costs and burdens; it's essential for crop insurance solutions for organic producers to be equitable to those available to conventional farmers, so farmers don't need to choose between being certified organic and having sufficient risk coverage.

The organic community appreciates the progress in improving crop insurance options and quality for organic producers. However, this document highlights more actions that would narrow the gap between conventional and organic crop insurance options and avoid disincentivizing the transition to organic, farm diversification, and climate-smart practices, including:

1. Updating the loss adjusting manual to include more specific quality adjusting standards and in-field adjusting standards relevant to organic producers
2. Improving the actuarial assignment of t-yields
3. Identifying organic literate agents who can help producers navigate the system.

Finally, RMA should continue to monitor the use of crop insurance by organic and transitioning producers and continuously improve access to and quality of relevant insurance policies for these producers.

Subcommittee Vote:

Motion to accept the Climate-Induced Farming Risk and Crop Insurance proposal
Motion by: Amy Bruch
Seconded by: Nate Powell-Palm
Yes: 8 No: Abstain: 0 Absent: 0 Recuse: 0

Appendix

The three significant weather events described below highlight why better coverage is necessary for organic producers to stay on the land.

Montana Diversified Farm Hailstorm:

In the spring of 2023, a well-known organic vegetable farm in Montana experienced a devastating loss due to a hailstorm. This farm has been certified organic for 19 years. It is a model of the potential for organic: They raise vegetables, rotate perennial legumes, produce compost, and have integrated pasture into their rotation using their certified organic goats, which they also milk and make certified organic cheese. This operator has adopted every climate-smart practice possible, and they have a thriving business.

On June 8th, 2023, this operator suffered a devastating loss from a hailstorm. According to their public account of the event, the storm brought in massive amounts of hail and 4-5+ inches of rain within an hour. It decimated most of their vegetable crops that supply the community with fresh vegetables. Anything that wasn't covered with a row cover was shredded. After the storm, a river ran through the field, unlike anything they'd ever seen. Some spots on the field had 4 inches of hail where it had piled up. Many vegetables were ready to be harvested and sent to the CSA members, farmer's markets, local restaurants, and grocery stores. The beautiful fields were gone.

This operator did not have adequate crop insurance coverage and needed to resort to a GoFundMe campaign to recover from the losses. These operators need improved insurance product options to keep them whole when they have devastating losses due to extreme weather.

Minnesota / Iowa Area Flooding:

In the spring of 2024, it was extremely and abnormally wet in northwest Iowa and Southwestern Minnesota, with some daily rainfalls exceeding 10+ inches. Continuous rainy conditions persisted, causing many rivers to exceed their banks and devastating flooding attributed to 100-year storms, which seem to come more frequently. The flooding caused tens of thousands of acres of conventional and organic farmland to be underwater, killing the planted crops. By the time the floods subsided, and the land dried out, it was mid-July and too late to plant additional crops for the season.

Nebraska Hailstorm:

Thirdly, on August 14th, 2017, a large storm rolled through Nebraska that had high straight-line winds (exceeding 80 mph) that destroyed grain bins, upended pivots, and snapped many corn plants to the ground, jagged golf-ball hailed trailed the wind, which pummeled everything else that was left standing. The organic producer's white corn crop was on track to exceed the t-yield assigned to the field. The corn was at the tender sweet corn stage, and quality and yield losses on corn left standing were high. Even with over 50% of the corn plants gone (broke off below the ear), this corn field outperformed the t-yield established. Since a yield loss was not triggered, then a quality loss wasn't assessed either, leaving the producer that several hours before the storm hit thinking they would have an excellent harvest to assess if crop inputs would even be covered by the damaged crop as there was not any insurance money to be received due to the low floor set by the t-yields assigned even though 50% of the crop was damaged.

National Organic Standards Board
Certification, Accreditation, and Compliance Subcommittee
Residue Testing for a Global Supply Chain Discussion Document
July 9, 2024

Note: The Certification, Accreditation, and Compliance Subcommittee (CACS) is working on many fronts regarding residue testing. This document discusses several topics, including updates to Guidance Documents NOP 2610, NOP 2611, NOP 2611-1, and NOP 2613.

Executive Summary of Changes to Existing Guidance Documents:
This table outlines the changes proposed to each of the current guidance documents in the National Organic Program (NOP) Program Handbook, which are discussed in more detail throughout this discussion document. Also summarized are recommendations for additional guidance documents.

NOP 2610 – Sample Procedures for Residue Sampling	•Sampling Equipment •Inspector Training and Competencies •Duplicate Sampling and Sample Retention •Chain of Custody Integrity •Sample Collection Diversity & Sample Amounts •Time is of the essence •Specific Redline Corrections
NOP 2611 – Laboratory Selection Criteria	•Expand Testing Guidance •Specific Redline Corrections
NOP 2611-1 – Prohibited Pesticides for NOP Residue Testing	•Information Layout •Regional and Crop Specific Information •Expand What to Test •Test for Metabolites •Companion Testing •Update Frequently
NOP 2613 – Responding to Results	•Detection without Tolerance Level •Dehydrated, Extracted, or Concentrated •Above EPA Tolerance / FDA Action Level •Specific Redline Corrections
Additional Guidance Documents	•Residue Sampling Decision Tree •Residue Sampling of Non-Crop and Non-Harvested Crop Products •Validation and Verification Guidance for 205.273(d) •Additional Instruction Considerations

Introduction:
The Certification, Accreditation, & Compliance Subcommittee (CACS) presented discussion documents at the Fall 2023 and Spring 2024 NOSB meetings on Residue Testing for a Global Supply Chain (RTGSC). Many commenters supported continuous improvement in testing to ensure integrity, considering the size of the organic marketplace and the program's global reach.

Residue testing is an essential tool for ensuring compliance with organic regulations. Residue testing does not substitute for the certification process and verification of compliance through an organic system plan review and annual inspection. However, it can support this process with objective results related to the presence of prohibited substances or the use of excluded methods.

The RTGSC series aims to work with the community to provide a recommendation that ensures testing remains a relevant and effective tool for compliance verification in the organic global supply. At the Fall 2023 NOSB meeting, a commenter wrote, “An updated and more rigorous testing program will augment the ability for both certifiers and certified operations to verify compliance, deter fraud, and prevent contaminated/fraudulent products from entering organic supply chains.”

Foundational Focus and Timing:
Foundational work is needed first. Therefore, the CACS aims to update the foundational elements in the respective related guidance and instruction documents with this document. As one commenter stated, “...ensure there can be clarity and consistency in the testing and response practices.”

During the spring 2024 NOSB meeting, the CACS asked the community for feedback on modernizing the guidance documents corresponding to residue testing. The common theme was that the guidance scope needed to encompass prohibited substances beyond residues of pesticides (e.g., synthetic solvents, heavy metals, and other prohibited substances) in addition to expanding guidance to address samples beyond the harvested crop / raw ag commodity (e.g., soil, water, plant tissue, livestock products, processed products, etc.). Also, there was a consensus that pesticide residue tests must be expanded based on known domestic and international risks (e.g., herbicides and fumigants) and common farming practices for the region based on agronomics. A public commenter from the certifying community noted, “Broadening the list to include solvents, fumigants (particularly those used at the borders), conventional fertilizers, herbicides, and other prohibited substances used in conventional food production would give us more useful tools without increasing the burden of testing.”

Updates to the guidance documents on these topics are necessary to support the work of certifiers and their inspectors, who collect samples and analyze results. The guidance documents must provide certifiers and inspectors with the resources and information to collect samples confidently, ensure the appropriate type of test is ordered, and consistently respond when samples test positive for prohibited substances.

The goal is to aid the NOP in updating guidance documents so residue sampling can remain a critical verification tool in the certification process. We also encourage the organic community, certifiers, scientists, farmers, inspectors, and NOP to share experiences of potential threats and determine best

practices through testing to verify the integrity and authenticity of organic products. Below is a summary of public comments and NOSB analysis related to the various guidance documents on residue sampling.

Proposed Updates to NOP Guidance

Sampling Procedures for Residue Sampling (NOP 2610)

1. NOP 2610's primary focus is to outline sampling procedures. NOSB requests that the below-mentioned updates be incorporated into revised instructions for sampling procedures for residue testing.

    a. **Sampling Equipment**
        i. Sampling equipment can pose a risk of contamination of sampled products. To create a consistent sampling regime across all certifiers globally, NOP should update this guidance with a list of minimum equipment and inspector competencies required to take a sample; specific tests have different requirements.
            1. Equipment: Shipping cooler, ice packs, gloves, bags, sample collection reports, grain probe (for sampling grain bins), other specialized sampling tools, and proper cleaning methodology.

    b. **Inspector Training and Competencies**
        i. Competencies: What training do all inspectors need to qualify to consistently take samples on organic operations?
            1. This training should also be developed for more complicated sampling demands on higher-risk operations.
                a. I.e., Imports, investigations, etc.
        ii. Note: Coupling sampling and annual inspections can compress inspectors into a rushed sampling procedure.

    c. **Duplicate Sampling and Sample Retention**
        i. When sample results are positive for residues, many quality assurance programs retain a duplicate sample to retest. However, it is not currently best practice to take a duplicate sample when inspectors take samples per §205.670. NOP 2610 could be updated to outline when this action is relevant and what steps inspectors should take to ensure the validity of results from duplicate samples.
            1. We need to determine how and where these duplicates are retained.

d. **Chain of Custody Integrity**

i. A residue sample chain of custody is essential in obtaining actionable sample results. If there is any breakdown in this chain of custody, the validity of the results can be questioned, and certifiers may not be able to take action if a positive outcome is found. The current guidance outlines the best practices for sealing bags, tamper-evident tape, and ensuring that shipping labels demonstrate a chain of custody. However, the updated guidance could include instructions for adequately identifying samples, ensuring integrity, and documenting the chain of custody. A clear set of procedures would assist certifiers with their staff training and potentially develop agreements with 3rd parties other than inspectors to conduct residue sampling activities.

e. **Sample Collection Diversity and Sample Amounts**

i. NOP 2610 clearly describes the sample size necessary for obtaining valid pesticide residue results based on the commodity type. It provides some narrative guidance on what part of the plant should be sampled if sampling occurs in the field or how to document a composite sample if several samples from different bulk containers are used to create a single composite sample. However, the instructions must clarify how samples are collected in various situations and include pre-collection preparatory information such as purging or best practices for avoiding sample site contamination. For example, collecting a grain sample in the field would dramatically differ from collecting a grain sample in a bulk ship. As we look to expand the handbook documents beyond prohibited pesticides, the guidance should include specific processes for collecting samples in inspectors' various situations. Hence, inspectors and certifiers have the confidence to take samples in many situations. At a minimum, NOSB would like to see specific sampling procedures for the following commodities and situations:

1. Produce in the field.
2. Produce in packed boxes.
3. Grain and oilseed in the field
4. Grain and oilseed in storage (bins, tanks, covered piles)
5. Grain and oilseed in transit (rail cars, containers, bulk ships)
6. Liquid processed products
    a. Oils
    b. Juice and other extracts
    c. Milk
7. Herbs and spices
8. Non-crop and non-harvested crop samples (soil, water, tissue, inputs, seeds)
9. All other crops appropriate to their condition

f. **Time is of the Essence**
    i. Sample collection and preparation must be thorough and expedient to minimize sample decay, pesticide losses, and contamination of products entering the chain of commerce.
        1. Include best practices for sample holding and timeframes for submission.

g. **Specific Redline Corrections:**
    i. **Update section 4.4**: Certifiers are called upon to record the variety of a crop and the brand name. However, circumstances may arise in which this information is unavailable to the individual collecting the sample. We recommend changing to "recording information when available."
    ii. Evaluate that reference material is current and that reference links are functional.
        1. Codex Alimentarius Commission links are broken in the reference section.
        2. Reference links should be expanded to reflect best practices in sampling.

Laboratory Selection Criteria (NOP 2611)

1. NOP 2611 primarily focuses on ensuring the laboratories used for residue analysis are accredited to conduct multi-residue pesticide screens. As NOP expands guidance related to testing for other types of pesticides and prohibited substances, the laboratories conducting these analyses must be competent and consistent. Therefore, NOSB requests that additional specific requirements for laboratory selection accompany any additional types of tests described in handbook updates.

    a. **Expand Testing Guidance:**
        i. Identify labs that can test for specific risks across all organic scopes: crops, livestock, wild crops, and handlers.
            1. Crops Scope—Guidance is needed for laboratory selection to include prohibited materials in inputs, synthetic herbicides, fertilizers, and other substances prohibited in organic production.
                a. Additional items to test outside pesticide residue must be included.
                    i. For example, testing oilseed meal for prohibited synthetic solvents requires laboratory competencies in oil chemistry, and certifiers will need to determine if the laboratories they currently use for multi-residue pesticide screens have the necessary competency and accreditation to conduct these additional tests.
            2. Identify Current best practices for a broader set of needed test methods, matrices, and sample methodologies.

a. Testing within the agricultural and food industry is routine and well-researched.
    i. Benchmarks with ISO, GAFTA, FOSFA International, Regulation EC No 619/201, and other respected institutions may be consulted as resources to help inform what type of lab accreditation and testing methods are needed across the NOP Scopes.
    ii. Benchmark with the USDA / AMS laboratories that conduct PDP testing for quality control and verification of procedures.

b. Specific Redline Corrections:

i. **Expand Scope and Rename Document:** The Title of 2611 focuses solely on pesticide residue testing, and the instruction concentrates mainly on the QueEChERS (**Q**uick, **E**asy, **C**heap, **E**ffective, **R**ugged, **S**afe) method. With the recommended scope expansion changes suggested above, the title of this document will need to change to reflect the updated content.
    1. The QueEChERS, method is an analytical approach that vastly simplifies the analysis of multiple pesticide residues in fruit, vegetables, cereals, and processed products.

ii. **Update Section 4.1:** revise the language from "should" to "must" in the last paragraph, which states, "If certifying agents suspect a prohibited substance was used that is not included on the NOP "target" list, they should initiate sampling/testing and investigation."
    1. If testing is not conducted, an explanation as to why a test was conducted should occur.

iii. **Update Section 4.2.1:** revise the Laboratory Selection Criteria to require "a current copy of the lab's accreditation certificate on file" versus the need to have "lab accreditation certificates attached to each lab test."

iv. **Update Section 4.2.2**: revise the language from "certifiers should maintain the lab's current proficiency test and resolution of corrective action" instead of relying on these documents to "be available from the laboratory."

Note: Industry and regulatory collaboration must exist to ensure the current methodology is approved promptly.

Prohibited Pesticides for NOP Residue Testing (NOP 2611-1)

1. NOP 2611-1 provides certifiers with a list of prohibited pesticides commonly included in multi-residue pesticide screens. The list offers a baseline multi-residue screen so that certifiers implementing pesticide residue sampling as a compliance tool request the most comprehensive list of substances possible from the laboratory. However, this guidance document must be expanded to reflect the breadth of prohibited substance residue testing conducted by certifiers. NOSB received substantial comments from stakeholders with suggestions for additional substances that could be tested for and types of tests that could be performed.

   Stakeholders would like to see this guidance become more practical. NOSB believes updating the structure to include specific testing methodologies for particular substances and the rationale for electing a specific test will accomplish this need. Also, indicating the connection between chemical name, pesticide function, and the registered crop could assist certifiers with investigations. Therefore, NOSB would like NOP to consider the following tips in revising this guidance document to be more beneficial for certifiers engaged in broader residue sampling activities.

   a. **Information Layout:**
      i. Example 1 below includes the type of test first and the specific substances second.

Test Type	**Specific Analyte Tested**
Multi-residue pesticide screen (ex. QuEChERS)	1-Naphthol, 3-hydroxy carbofuran, 5-Hydroxythiabendazole, Acephate, Acetamiprid…etc.
Single Analyte Herbicide Screen	Glyphosate, 2,4-D, Dicamba
Residual Solvent Panel	Hexane, Acetone, Methanol, etc.
Heavy Metals	Cadmium, Arsenic, Lead, …etc.

      ii. Example 2 below also considers adding best practices or rationale for electing a particular type of residue screen:

Test Type	**Specific Analyte Tested**	**Rationale for Selecting Test**
Multi-residue pesticide screen (ex. QuEChERS)	1-Naphthol, 3-hydroxy carbofuran, 5-Hydroxythiabendazole, Acephate, Acetamiprid…etc.	Choose this screen when testing the efficacy of buffers on specialty crops grown near conventional production.

		When ordering and designing multi-residue screens, consider the product's origin. Tests should focus on the pesticides typically used in the country of origin.
Single Analyte Herbicide Screen	Glyphosate (with AMPA and Glyphosine), 2,4-D, Dicamba	Choose this screen when inspectors observe herbicides or when sampling a crop (e.g., wheat) where herbicides are routinely used but other pesticides are not. Note: this is not a panel screen
Residual Solvent Panel	Hexane, Acetone, Methanol, Di-Chloroethane, etc.	Choose this screen when sampling oilseed meals in transit or at handling facilities. Consider adding the fat content percentage to provide insight into whether the seed meal was expeller- or solvent-extracted.

b. **Regional and Crop-Specific Information:** Understanding the region and what pesticides or processing aids are commonly used on conventional farms can provide insight into what to test for to identify the presence of residues. Some pesticides are illegal in the U.S. but still permitted in certain countries. One stakeholder mentioned, "We recommend using pesticide use data to develop a list of prohibited substances that are the most likely to be used for a specific crop in a production region."
c. **Expand What to Test:** Currently, the target list found in 2611-1, also referred to in the industry as the "NOP panel," lists fewer residues than a standard or EU panel. One commenter mentioned, "We believe that the list of prohibited substances provided is incomplete, and including it as guidance could lead to the mistaken impression that it is comprehensive. Analyses should be based on the most likely pesticides found on the crop in the region where it is grown."

i. A multi-residue single-panel screen is suitable for use in some scenarios; however, the target list is limited, and pesticides often do not appear on the crop's harvested portion.
    1. Foliar and soil tests are valuable; for example, if a producer sprays corn with fungicide before the ear has set, the grain may not contain the fungicide.
ii. The NOP is expanding guidance on the types of tests that certifiers can perform to address broader contamination and fraud concerns.
iii. For example, solvents are ubiquitous in conventional production. Consider testing organic soybean meal for solvents. Guidance for testing livestock products (milk, eggs, fiber), livestock tissue, processed products, agricultural inputs, etc. needs to be considered
iv. Expand target list (NOP Panel) to include other prohibited substances, including glyphosate, 2, 4-D, dicamba, co-formulants, adjuvants, antibiotics (specifically streptomycin, oxytetracycline, and natamycin), GMOs, livestock drugs (hormones, antibiotics, or synthetics), etc., keeping continuous improvement in mind and updating the suggested list at a frequency similar to the PDP program updates.

d. **Testing for Metabolites:** Testing for metabolites can also have value. One commenter stated, "The metabolites aminomethylphosphonic acid (AMPA) and glyphosine should also be included. These degradants are more likely to persist in the soil and would be strong evidence that glyphosate had been applied recently on a given field."
e. **Companion Tests:** As the table states above when examining a solvent test to identify the illegal use of a processing aid for soybean processing into soybean meal, a fat % test could provide an additional indication of fraud.
f. **Update Frequently:** A list can be helpful for reference; however, it must be reviewed at a set frequency to ensure that it is current for domestic and international substances.

Note: Several commenters mentioned the power of a multi-screen residue test and its limitations. One commenter stated, "The QuEChERS method and variations on it have several advantages in conjunction with multi-residue analytical methods; it is not necessarily the best approach in every case nor the sole approach that should be utilized."

A commenter stated, "The prescriptive nature of this list creates an overtly focused emphasis on screening for pesticides instead of testing for any or all likely present prohibited substances. Testing needs to be targeted to the likely risk to a specific type of operation or the potential contamination observed on site."

Responding to Results (NOP 2613)

NOP 2613 provides excellent guidance to certifiers when responding to results from multi-residue pesticide screens on raw agricultural commodities. It does not support the needs of certifiers when faced with positive results for pesticides not registered for the crop on which it is found, for other prohibited substances that are not pesticides (e.g., solvents or heavy metals), or for residues of any kind found in dehydrated, extracted or concentrated plant material. We expand on the issues and propose some solutions below:

1. NOP 2613 only outlines how to respond to positive results of pesticide residues. It does not provide direction on responding to positive results of other prohibited substances. NOSB acknowledges that the current regulations only exclude organic sale provisions when residues are detected above the FDA action level or above 5% of the EPA tolerance. However, certifiers need a roadmap for responding to positive results from tests for residual prohibited solvents, heavy metals, and other prohibited substance screens. Without a roadmap for responding to positive results, there will likely be hesitancy in collecting samples for non-pesticide residue sampling, and it will be challenging to ensure consistency among certifiers in responding to these results.
    a. **Detection without Tolerance Level:** When detected pesticides are not registered for the crop on which they are found at any level above 0.01 ppm, the guidance indicates that certifiers should exclude the crop from the organic marketplace and alert the appropriate authorities, including the EPA and FDA. This approach assumes that any detection of a prohibited pesticide when there is no established tolerance indicates that the product no longer qualifies for organic status and that there is a human health and safety concern.
        i. **Minor Crops:** However, this situation can occur when testing minor crops for which tolerances have yet to be established for many pesticides (e.g., aronia berries and Jerusalem artichokes). Therefore, NOP should develop alternative corrective action approaches or tolerance levels when residues of pesticides not registered for the crop are detected on “minor crops” (EPA defines minor crops as crops grown on fewer than 300,000 acres).
        ii. **Non-Food Crops:** Criteria should also be developed to determine tolerance levels for non-food crops, such as cotton seed meal
            1. Resource Examples for Creating Paths Forward
                a. EPA has established tolerances for the edible portion of the crop.
        iii. **Drift or Inadvertent Contamination:** Guidance is needed to determine drift or inadvertent contamination events versus fraudulent activities
            1. Resource Examples for Creating Paths Forward
                a. Review EPA Tolerances for Indirect or Inadvertent Residues
                b. Limits could be determined by levels of that material that might be used in conventional products.
                    i. Generally, if it is drift or inadvertent contamination, the residue levels should be about a tenth of what would be found in a conventional product.

b. **Dehydrated, Extracted, or Concentrated Organic Products:** When sampling dehydrated, extracted, or concentrated organic products, positive results can be amplified and misconstrue the raw agricultural commodity's contamination level. For example, a fresh hop sample may indicate no pesticide residue detection. However, that same hop sample dehydrated and concentrated may reveal positive results. EPA tolerance is established for various agricultural commodities, typically specific to the form (e.g., fresh, dried, etc.). However, this system only sometimes supports taking action on a positive sample result. NOSB recommends NOP develop a specific section in NOP 2613 related to responding to positive results for dehydrated, extracted, or concentrated products.
    i. Resource Examples for Creating Paths Forward
        1. United States Pharmacopeia (USP) 561 has limits for botanical/supplements / concentrated products.
        2. The European Union uses a factor to convert fresh to concentrated.
c. **Above EPA Tolerance / FDA Action Level:** Guidance should be explicit regarding how certifiers should exclude products from the organic marketplace and how other agencies should be alerted when residues are detected above the EPA tolerance / FDA action level.
d. **Specific Redline Corrections**
    i. Update 5.3.2.b to clarify if it should also include detections "at or above" the FDA action level
    ii. Update 5.3.3. am to clarify if it should also include detections "at or above" 0.01 parts per million
    iii. Update 5.3.3 to clarify how to respond to positive results for materials that are not pesticides.

Suggestions for New Guidance Documents:

1. The discussion around residue testing as a compliance verification tool has identified some gaps in guidance. In the sections above, we provided suggestions for improving the existing guidance. Below, we give some ideas and context for new guidance documents that could assist certifiers in deploying residue testing more effectively in the organic marketplace.

2. We welcome additional stakeholder comments on additional aspects that should be included in guidance on residue sampling of prohibited residues in organic operations.

    a. **Residue Sampling Decision Tree**

i. Overall, stakeholders commented that it would be tremendously helpful to certifiers if NOP developed a decision tree that could assist certifiers in determining when to sample, what to sample, where to sample, what types of tests to run, and how to respond to positive results from each situation. Guidance might not capture the nuance of every situation, but having a decision tree could support certifiers in understanding how to apply residue testing in a supply chain most effectively. We welcome stakeholder comments on how such a decision tree would be organized and how it could be presented to be readily understood and integrated into certifiers' residue sampling programs.

1. Three samples from our stakeholder community are found in the appendix.
    a. Risk-Based Decision Tree
        i. Critical Aspect of Selecting the Product to Sample
            1. high-value crops, large shipments, country of origin, market footprint, and split or parallel production are target areas for testing.
        ii. Multi-ingredient processed products
        iii. Residue Test Result Decision Tree based on Current Instruction
        iv. Notice of Detection and Next Steps Decision Tree

b. **Residue Sampling of Non-Crop and Non-Harvested Crop Products in organic operations**

i. Certifiers need to sample inputs, such as soil, water, tissue, etc. This guidance should encompass the following relevant areas:

1. Proper sampling techniques and testing methodology
2. Unavoidable Residual Environmental Contamination
3. Enforcement of positive results

c. Validation and Verification Guidance for 205.273(d)

i. The Strengthening Organic Enforcement rule now requires importers to have a prohibited substance prevention plan. For certifiers to validate and verify the efficacy of these plans, they must have some guidance related to how residue testing can support these validation and verification efforts. We welcome stakeholder comments on essential elements to guide validating and verifying importers' prohibited substance prevention plans.

d. Additional Instruction Considerations

i. Residue Sampling and Testing Instructions for all scopes: Handling, Livestock, Crops
ii. Residue Sampling for Multi-Ingredient Products / Finished Products
iii. Initiation Sequencing for a Stop Sale Action.
    1. Fraud has resulted in significant quantities of contaminated or illegitimate products being placed into the stream of commerce.

In addition to guidance document updates, other comments from the public centered around:

1. **Collecting and Aggregating Positive Test Result Information:** Testing results must be aggregated and disseminated to certifiers. Some commenters pointed to a unified reporting format and a centralized point for posting positive residue test information. This would help transparency and inform the certifier's risk assessments and decisions on what to sample.
2. **Costs as a barrier to testing:** Extensive testing, companion testing, duplicate testing, etc., can be cost-prohibitive or ultimately impact certification fees.
    a. Some solutions provided included certifiers who could collectively approach ISO-accredited labs to request a group discount for cost savings.
3. **Working Group:** Several members of the stakeholder community mentioned the value of a cross-functional working group consisting of inspectors, certifiers, laboratory personnel, and specialists in the field to identify and outline the industry's best practices and certifier policy for sampling and testing specific to the matrix sample and the test required.
4. **Appropriate Compensation**: Although out of the NOSB scope, several stakeholders mentioned testing can be expensive. It is essential to ensure that costs are not a limiting factor in leveraging testing as a tool.

Conclusion:
Testing, as a tool, has played a crucial role in the organic program since the implementation of the Strengthening Organic Enforcement (SOE) Rule. It not only assists certifiers in validating compliance but also provides the ability to rapidly detect evidence of commingling/contamination in operations deemed to be high risk, thereby enhancing the program's proactive nature.

Modern-day threats do not just come from pesticide residues. A one-size-fits-all test is only sometimes the correct tool for the job. Threats can also come from fumigants and conventional processing aids, such as solvents.

In the spirit of continuous improvement, CACS believes that a full review of existing guidance and regulations regarding prohibited substance residue testing protects the integrity, unlocks the power to assist in compliance verification, and helps create consistent enforcement decisions. We appreciate all stakeholder comments as we look to make recommendations for final updates to residue testing instruction documents at the NOSB Spring 2025 Meeting.

Questions:

The CACS has an extensive series of questions to inform continued discussion regarding the regulations surrounding testing.

A. Guidance Document Questions

1. **NOP 2610 -**
    a. What training do all inspectors need to take to qualify to take samples on an operation?
    b. To increase bandwidth, should certifiers outsource sampling to a third party?
    c. What additional changes or corrections would you recommend?
2. **NOP 2611 -**
    a. What additional changes or corrections would you recommend?
3. **NOP 2611-1 -**
    a. What additional changes or corrections would you recommend?
    b. What is the best method to ensure the target list of prohibited substances provided is updated, maintains relevancy, and isn't restrictive?
4. **NOP 2613 -**
    a. How should a certifier select a reference EPA tolerance when the commodity or group is not listed with an established tolerance?
    b. How should a certifier review metabolite detection?
    c. What should a certifier do when results come from third-party operations with unknown sampling methodology?
    d. How should a certifier interpret samples of a multi-ingredient product or a tested lot composed of several lots from suppliers?
    e. What should a certifier do with multiple tests for a single lot, but the test results conflict?
    f. How should a certifier interpret and respond to results from foliage versus commodity tests?
    g. How should a certifier address tests conducted outside the U.S. for materials not on the "NOP panel" multi-residue screen panel?
    h. How can instruction be improved to supply guidelines for prohibited material applications before harvest (intentional and unintentional) since EPA and FDA tolerances are established based on the consumption of the harvested commodity and what existing tools and resources are needed or available to inform the scenarios below:
        i. Identify what might have been applied when concerns exist so that appropriate testing can be conducted

ii. Evaluate the concentration of the material on commodities that aren't at the harvest stage so investigations can determine whether an application intentionally or unintentionally occurred.
iii. Determine whether crop or field status should or should not be impacted

i. What additional changes or corrections would you recommend?

5. Suggestions for new guidance docs

a. What essential elements guide validating and verifying importers' prohibited substance prevention plans?
b. How should a decision tree be organized, and how could it be presented to be readily understood and integrated into certifiers' residue sampling programs?
c. What additional guidance documents should be created to assist in residue testing

B. How to Enhance Testings' Effectiveness Questions

1. Given the limited number of samples, how can certifiers maximize the information gathered? Specifically, how can certifiers coordinate and strategize to take samples that represent the most significant risk to the organic supply chain?

2. How can certifiers see testing as a solid tool to detect and react to fraudulent activities? What would change about the program for certifiers to elevate how they test?

3. What technical assistance is needed for certifiers to leverage testing to initiate adverse action?

4. What training resources are needed to prepare inspectors to be sufficiently proficient in sampling so the test results cannot be challenged based on testing protocol?

5. Does testing 5% of operations annually provide a sufficient survey of the organic supply chain to deter fraudulent actors? If cost were not a factor, what is the best testing rate to understand the entire supply chain and the risks for contamination?

C. 7 CFR 205.671 - Exclusion from organic sale

Background: The Organic Foods Production Act at 7 USC 6511(c)(2)(A-B) outlines the authority conveyed to the Secretary for "removal of the organic label" should a prohibited substance be detected on an organic agricultural product. It is determined that the residue is either "the result of an intentional application of a prohibited substance or present at levels greater than unavoidable residual environmental contamination as prescribed by the Secretary…in consultation with the appropriate environmental regulatory agencies." It appears that Congress intended the Secretary to establish exclusions from organic sale mechanisms for intentional applications of prohibited substances and unintentional contamination detections when levels exceeded UREC levels. It did not limit the authority to only pesticides regulated by EPA or FDA. CACS recognizes that the initial regulation, 205.671, focused on pesticides, as the respective regulatory agencies established thresholds to draw. However, as the

organic marketplace matures and our compliance verification mechanisms become more sophisticated, it necessitates a review of the regulations that enable certifiers to take direct action in excluding contaminated organic products from the marketplace.

It is in this light that CACS asks the following questions of stakeholders:

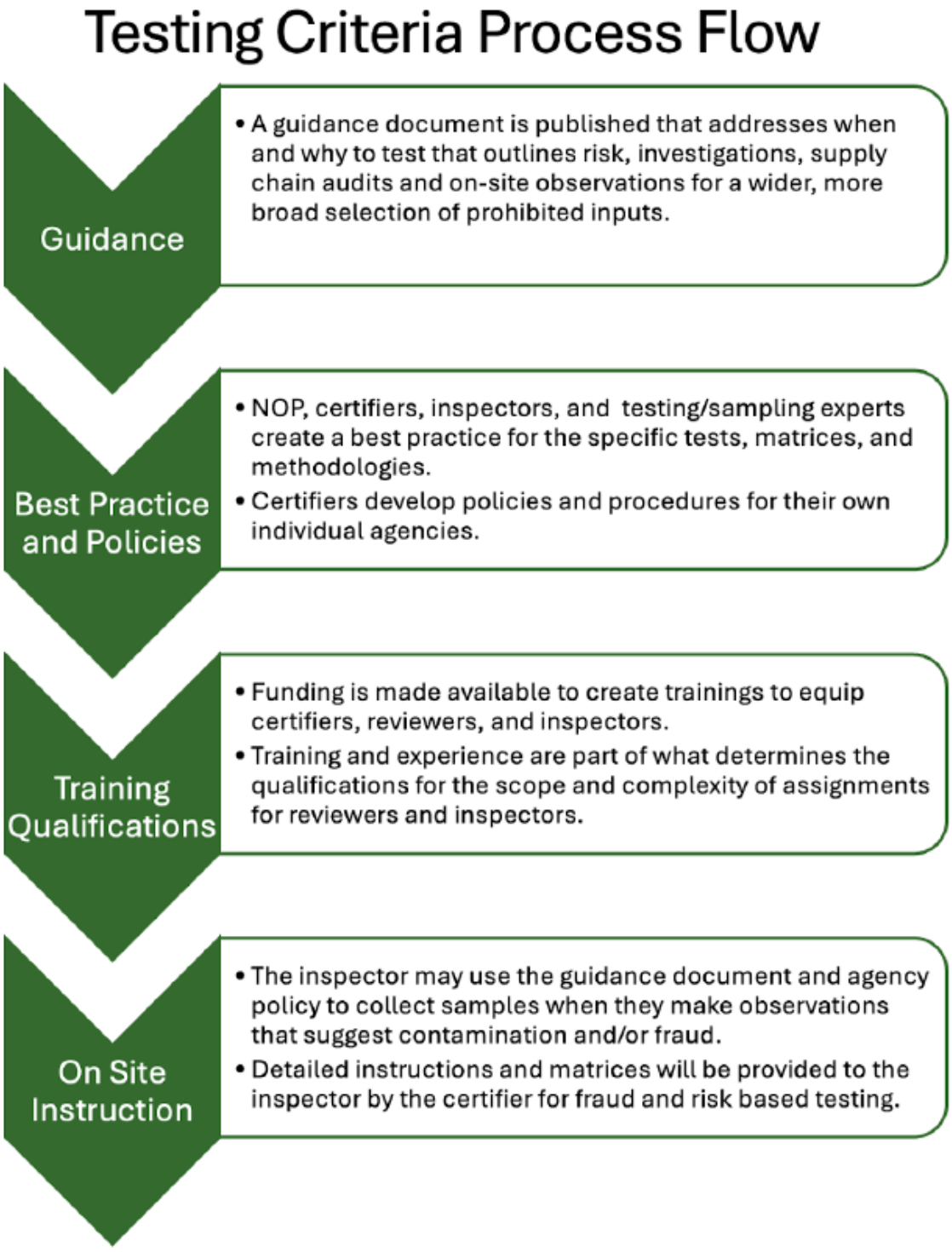
1. Should certifiers have more flexibility/cause to exclude organic products from the marketplace? Detection of what types of prohibited substances warrant exclusion from the market? How should NOP establish thresholds for substances that do not have tolerances or action levels determined by other regulatory agencies? Please provide comments on the following hypothetical situations and present your own experiences.
    a. Positive residues of EPA-registered pesticides detected on immature crops (e.g., corn plant before tasseling) through tissue testing rather than testing of the crop itself. In these cases, since the crop is not what was tested but is the only part of the plant for which an EPA tolerance is established, certifiers do not have the authority to exclude the crop from the organic marketplace without a subsequent test of the crop.
    b. Positive residues of prohibited substances that are not pesticides (e.g., hexane in soybean meal). When prohibited substances other than pesticides are detected, the current regulation has no regulatory mechanism to exclude that product from the organic marketplace.
    c. Positive tests of non-harvested crop products. Should certifiers have the authority to exclude products from the organic marketplace when residues are detected in the soil, water, inputs, tissues, etc., but not the organic products themselves?

2. How can we strengthen partnerships with other agencies to improve our ability to exclude contaminated products from the organic marketplace?

Subcommittee Vote:
Motion to accept the discussion document on Residue Testing for a Global Supply Chain
Motion by: Amy Bruch
Seconded by: Nate Lewis
Yes: 6 No: 0 Abstain: 2 Recuse: 0 Absent: 0

Appendix - Decision Tree Framework Ideas from Stakeholders

Decision Tree Example #1: Risk-Based Decision Tree



Decision Tree Example #2: Residue Test Result Decision Tree Based on Current Instruction

A. Residue Detected
    a. No
        i. Notify the certified operation of the test results and indicate that the product may be sold as organic.
    b. Yes
        i. Residues Detected at less than 0.01 ppm
            1. Notify the certified operation of the test results and indicate that the product may be sold as organic. Asses Why the residue is present and follow up with the operation as appropriate
        ii. Residues Detected at or above 0.01 ppm
            1. EPA tolerance is established
                a. Yes
                    i. If residue is detected at or below 5% of the EPA tolerance
                        1. Notify the certified operation of the test results. Assess why the residue is present. If appropriate, consider a notice of noncompliance for the following violations: 205.202(b), 205.202(c), 205.272. If residues are not a result of the application of prohibited pesticides, the product may be sold as organic.
                    ii. If residue is detected above 5% of the EPA tolerance but not above the EPA tolerance level
                        1. Immediately Notify the certified operation of the test results and indicate that the product may not be sold as organic. Assess why the residue is present. Issue a notice of noncompliance for the violation of 7 CFR 205.671. Additional violations may include a notice of noncompliance for the following violations: 205.202(b), 205.202(c), 205.272.
                    iii. If residue is detected above the EPA tolerance level
                        1. Immediately notify the certified operation of the test results and indicate that the product may not be sold as organic. Immediately report the violation to the appropriate agency as described in section 5.3.4 of NOP 2613. Assess why the residue is present. Issue a notice of noncompliance for the violation of 7 CFR 205.671. Additional violations may include a notice of noncompliance for the following violations: 205.202(b), 205.202(c), 205.272.
                b. No
                    i. FDA Action Level Exists?
                        1. Yes
                            a. If residue is detected below the FDA action level
                                i. Notify the certified operation of the test results. Assess why the residue is present. If appropriate, consider a notice of noncompliance for the

following violations: 205.202(b), 205.202(c), 205.272. If residues are not a result of the intentional or direct application of prohibited pesticides, the product may be sold as organic.

b. If residue is detected at the FDA action level
    i. • (needs defined as requested above)
c. If residue is detected above the FDA action level
    i. Immediately notify the certified operation of the test results and that the product may not be sold as organic. The FDA or a foreign equivalent may provide guidance on addressing these products. Immediately report the violation to the appropriate agency as described in section 5.3.4 of NOP 2613. Assess why the residue is present. If appropriate, consider a notice of noncompliance for the following violations: 205.202(b), 205.202(c), 205.272

2. No
    a. If residue is detected at 0.01ppm
        i. (needs to be defined as requested above)
    b. If testing detects a residue of prohibited pesticides above 0.01ppm
        i. Immediately notify the certified operation of the test results and indicate that the product may not be sold as organic. Immediately report the violation to the appropriate agency as described in section 5.3.4 of NOP 2613. If appropriate, consider a notice of noncompliance for the following violations: 205.202(b), 205.202(c), 205.272.

Example #3 Decision Tree: Notice of Detection and Next Steps Decision Tree

1. Receive a notice of detection.
2. Verify lab results, methods, date of test, and authorized signature to determine how actionable the residue testing may be
3. Review the material and brand name association products, comparing the affected crop type.
4. Confirm if the crop is allowed in organic production
5. Confirm the EPA tolerance level and the amount of detected material
6. Initiate a trace to determine the grower, ranch, lot, facility, and shipping locations
7. Place the product on hold as applicable
8. Review the grower application records to determine the source and whether the material is permitted in the affected crop.

National Organic Standards Board
Certification, Accreditation, Compliance Subcommittee
Risk-based Certification Discussion Document
August 6, 2024

Discussion:

Overview of Risk-based Oversight and Risk Assessment of Certified Operations

Risk-based oversight as a model for decision-making and compliance prevention strategy is an approach used by certified operations and certifiers in organic certification. As the organic supply chain and businesses engaged in the organic industry get more complex, organic certification is becoming less "one size fits all". It is becoming more important for organizations to use a risk-based approach in order to optimize their activities (i.e. focus their attention on the areas of highest risk to their organization). Certified operations and certifiers can both apply risk-based oversight to themselves and their activities; or as an evaluation process to determine the risk of another organization they do business with. This could be a certified operation evaluating a supplier or a certifier evaluating one of their certified operations.

Additionally, the Strengthening Organic Enforcement (SOE) final rule now codifies that certifiers must evaluate and identify high risk operations and products. Specifically, §205.504(b)(7), requires that certifiers develop policies and procedures in order to perform supply chain traceability audits (SCTA) on operations identified as high risk. Supply chain traceability audits may be smaller in scale (e.g. cross check of a smaller number of transactions between two entities). This is often referred to by certifiers as a routine SCTA. SCTAs may also be conducted as part of an investigation. The scope and scale of this type of SCTA may be expanded to cover more transactions or to go further up or down along the supply chain.

The concept of risk-based certification or decision-making frameworks has been in existence within the organic certification process for some time. Organic inspectors and reviewers proficient in risk-based decision making are more effective and efficient in their work than inspectors and reviewers that are challenged by this concept. Many certifiers have been evaluating the risk of their certified operations for years but for others, evaluating risk is new. Due to SOE as well as the continued pressure on staffing resources within the organic certification community, risk-based oversight and the evaluation of risk is taking a more prominent place in organization's strategies. And while there are some resources, this document aims to determine if these resources are effective or if additional resources are required for certified operations and certifiers to fully adopt and become proficient at risk-based oversight.

These different components of risk evaluation have different purposes and objectives.

Risk-based Oversight and Evaluation Activity	Purpose/Objective
Certifier Performing Risk Evaluation Process on Itself and its Own Activities	• Be proactive and not reactive to addressing potential risks • Develop controls, policies and procedures for the areas of the organization with the most risk
Certifier Performing Risk Evaluation Process on Operations it Certifies per §205.504(b)(7)	• Comply with accreditation requirements (§§ 205.504(b)(7) and 205.501(a)(21)) • Increase oversight of operations identified as high risk in order to identify operations that are engaged in fraudulent activities
Certifier utilizing a risk-based oversight approach	• Incorporates the risk evaluation of oneself and the operations it certifies to set organizational strategies and annual work plans to maximize resources and streamline processes
Certified Operation Performing Risk Evaluation Process on Itself and its Own Activities	• Be proactive and not reactive to addressing potential risks • Develop controls, policies and procedures for the areas of the organization with the most risk
Certified Operation Performing Risk Evaluation Process on Operations it does business with	• Comply with certification requirements (organic fraud prevention plan in 205.201(a)(3)) • Increase oversight of operations doing business with order to avoid doing business with operations that are engaged in fraudulent activities
Certified Operation utilizing a risk-based decision-making approach	• Incorporates the risk evaluation of oneself and the operations it does business with to set organizational strategies and ensure longevity of business due to maximizing organic integrity within one's business and who one does business with

Overview of Current Resources

As previously stated, §205.504(b)(7) requires that certifiers submit to the NOP a copy of the criteria they will use to identify high-risk operations and agricultural products for supply chain traceability audits; and procedures to conduct risk-based supply chain traceability audits, as required in §205.501(a)(21); and procedures to report credible evidence of organic fraud to the Administrator. In addition, per §205.201(a)(3), a certified operation must include in their organic system plan a description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented. This must include a description of the monitoring practices and procedures to verify suppliers in the supply chain and organic status of agricultural products received, and to prevent organic fraud, as appropriate to the certified operation's activities, scope, and complexity. In order for an operation to successfully create an organic fraud prevention plan they need to evaluate the risks and vulnerabilities their operation is subject to. Again, fraud risk is important however, there are other risks that an operation should be

evaluating and mitigating against in order to maintain organic integrity and compliance on their operation.

Beyond the regulatory text, there are some resources that are focused on the topic of risk-based oversight as it specifically pertains to the organic certification industry.

First, we can look to the preamble to the SOE Final Rule which includes the following criteria as potential risk criteria (to be used to evaluate a certified operation's risk):

- Products for which there is a relatively high demand, low supply, and high organic premium;
- Products which may be subject to treatment with prohibited substances after production;
- Unpackaged products which are not enclosed in final retail containers;
- Products with multiple handlers in the supply chain;
- Products from a supplier that lacks a record of compliance;
- A sudden increase in the available supply of an organic product or commodity;
- Operations which change certifying agents frequently; and
- Operations which are certified by more than one certifying agent.

In addition, the Accredited Certifiers Association (ACA) has a few best practice documents:

1. ACA Best Practice for Risk Assessment and Follow-up *(November 2019)*
2. ACA Best Practice for Certifier-to-Certifier Information Sharing and Supply Chain Traceability Audits (SCTA) *(April 2024)*
3. ACA SCTA Risk Score Card Template (*April 2024)*
4. ACA SCTA Info Request Form (*April 2024)*

The first document was published in November 2019 as a tool to "help assure sensible allocation of resources and should increase the likelihood of uncovering fraudulent activity or other non-compliant actions that jeopardize the integrity of the organic label." This best practice document breaks out risk criteria by scope (e.g. all scopes/general, crops, livestock, handling) and includes criteria such as compliance history, split or parallel production and complexity of the operation, just to name a few. This best practice document is available to ACA members only.

Subsequently, due to SOE and as part of the cooperative agreement between the ACA and NOP, the ACA developed the latter three documents. These are available to the public through a request to ACA staff. ACA members may access when logged into their member portal.

The SCTA Risk Score Card is the 2.0 version of the previous 2019 version. It includes similar criteria as the 2019 version. In addition, it breaks the risk evaluation into two parts: general risk of an operation and risk criteria related to fraud that would make the operation a good candidate for a SCTA.

Certifiers are not required to use these criteria to comply with §205.504(b)(7).

The Organic Integrity Learning Center is another great resource for certifiers and certified operations. There are a few courses that address the concept of risk:

1. NOP-230: Risk-based Oversight. This course is largely focused on fraud as a risk. However, it does provide an overview that would help an organization apply the risk-based oversight to other risks (other than fraud).
2. NOP-100: Organic Fraud and the Criminal Mind. This course is aimed at providing insight into how fraudsters think so that operations can help deter fraud.

3. NOP-110: Preventing the Organic Fraud Opportunity. This course provides an in-depth review of the fundamental supply chain risk management concepts that can reduce the organic fraud opportunity

Overview of potential issues/gaps

Risk-based oversight was brought up several times during the spring 2024 NOSB meeting in regard to not overburdening smaller, low risk farm operations by the SOE rulemaking. This concept also continues to be a priority of many certifiers that are looking to focus their time and efforts on the certification activities/operations that present the greatest threat to organic integrity due to limited resources (e.g. staff time).

In evaluating the above identified resources, it appears the following could be potential gaps and opportunities for continued improvement:

1. **Definitions:** The topic of risk is multi-faceted and includes an approach (risk-based oversight) as well as two risk evaluation concepts (risk of fraud and risk maintaining organic integrity). Due to this it may be valuable to codify some definitions to assure that the term risk is being used uniformly. Within the OILC courses there are several terms that are defined:
    a. Risk-based oversight
    b. Risk management
    c. Risk
    d. Vulnerability

2. **Evaluation Criteria:** As previously stated, certifiers must establish criteria to evaluate and identify high-risk operations and agricultural products for supply chain traceability audits. Resources exist currently for certifiers to evaluate an operation's risk of fraud (making them a good candidate for an SCTA) as well as an operation's more general organic compliance risk. Risk criteria are not specified in the regulations so there isn't a consistent set of criteria used by all certifiers. Additionally, there currently isn't a defined mechanism for how industry can provide information and data to NOP and certifiers outside of the complaint process which doesn't apply in all situations. Industry may have more general information regarding commodities from certain countries or regions that should be evaluated as risks. Developing a pathway to engage with industry to proactively obtain this information, along with developing processes by which certifiers can evaluate their risk criteria and add and remove criteria. How can we take an agile approach to risk criteria so that we are considering acute risks?

3. **Risk-based decision-making framework:** The idea of risk-based oversight is more of a best practice. In the OILC course NOP-230 it is stated that when risks stemming from vulnerabilities (e.g. financial stressors, limited staff or resources, supply chain changes, regulatory updates, human error, and negligence) are not addressed it can lead to the following:

    a. For certifiers:
        i. Loss of business
        ii. Increases in costly mediation and settlement agreements
        iii. Suspension or revocation of noncompliant operations
        iv. NOP enforcement action
        v. Loss of accreditation

b. For certified operations:
   i. Product recalls
   ii. Fraudulent organic sales
   iii. Loss of organic integrity
   iv. Suspension or revocation of organic certification

In addition, CACS believes that loss of certified operations following the rules (e.g. voluntary surrender) may occur when other certified operations do not address their vulnerabilities.

It just makes good business sense to evaluate risk and vulnerabilities to one's business. Also, the likelihood of addressing all the risks simultaneously does not seem feasible, especially when a business is navigating finite resources (e.g. money and staff time). Therefore, implementing a risk-based approach to identify the highest compliance risks to one's organization and prioritizing the mitigation strategy again just makes good business sense. In organic certification, certifiers can and should use this approach to prioritize and target high-risk operations and activities. However, this is a skill. Some people are naturally better at this type of decision making but it certainly can be learned. There isn't currently in the resources identified above a preferred framework that businesses should use when utilizing a risk-based oversight approach. Obviously, each business's risk factors will be different and how they choose to prioritize them and mitigate against them will be different. In organic certification, is a shared or consistent risk-based decision-making framework important so that certifiers are utilizing the same model on themselves and on the operations, they certify in order to arrive at similar decisions on where and how to spend their time (i.e. prioritizing certification oversight on operations that present greater risk)?

4. **"One size fits all (most)" Certification:** As continuously stated throughout this document, with the advancement of the organic industry we've seemingly outgrown the "one size fits all (most)" model. A low-risk operation's certification process should likely not be the "same" as a higher risk operation. In some ways, it can be easier to fall back to this way of thinking as it takes some of the decision making out of it. It is easier for certifiers to have one organic system plan with the same questions and leave it up to the operation to determine if it applies to them and based on their activities how complex their answer needs to be. It is easier for inspectors to do the same number of audits (for example) on all types of operations versus needing to decide on the number of audits to conduct based on the risk of an operation. It is easier for review staff to answer the same set of questions in evaluating an inspection report and making a final certification decision. Certifiers are likely also concerned with ensuring they are meeting accreditation requirements. Certifiers may feel they are at risk of a noncompliance if they are taking a risk-based approach and are streamlining the certification process in certain ways for low-risk operations.

   However, the easefulness created for certifiers in continuing this "one size fits all (most)" certification is resulting in an additional burden to lower risk operations.

   This is part of how a certifier could be using risk-based oversight. Meaning that if a certifier was using a risk-based oversight approach the result could be that certification requirements look different for lower-risk operations than higher risk operations, such as reduced paperwork, reduced audits, reduced inspection time and/or focus areas, recalibration of focus on areas of an operation where the likelihood of fraud to be detected increases (e.g. yield and sales verification). Some certifiers are likely already doing this; however, it is likely that many are not. Certifiers may need to consider where they are applying resources and adjust accordingly. It is

likely that certifiers don't have a full enough picture of an operation and its risk until after an Organic System Plan (OSP) is submitted. One way to reduce burden is to reduce paperwork. However, in order to do so a certifier would need to have an idea of the operations potential risk prior to the submission of its OSP, which means frontloading resources. The idea is that in the end the resource burden is less on operations and certifier staff later in the certification process. Again, these are new concepts for some so understanding the possibilities for compliant ways to reduce the burden on low-risk operations that are not too resource-heavy on certifiers will help certifiers feel comfortable in adopting this approach.

Conclusion:

Risk evaluation is an important tool and is now required by certifiers to evaluate high risk operations and by certified operations in the form of an organic fraud prevention plan. Risk evaluation is a factor in risk-based oversight or decision making. The result of which is spending more time on higher risk areas of an operation or on higher risk operations and less time on lower risk activities of an operation or lower risk operations.

While these concepts are not new, there seems to be a renewed focus on them due to SOE and continued limitation on resources. The board seeks to understand what resources are serving the organic community well and what additional resources exist so that we may continue to grow the organic sector while maintaining a high level of organic integrity and reducing fraud.

Questions to stakeholders:

1. How does your organization define risk?
    a. Would it be valuable for the definitions listed above (Risk-based oversight, Risk management, Risk, Vulnerability) to be included at §205.2 Terms Defined?
    b. Are there other definitions that would be beneficial to include at §205.2 Terms Defined besides those listed above? Is it important that all certifiers use the same risk criteria to evaluate certifier operations? Why or why not?
2. What other resources (e.g. trainings, models, certifications/credentialing program) are currently available that would help an organization become more proficient at risk-based oversight and/or risk evaluation?
3. What are the unintended consequences that could arise from using a risk-based oversight approach?
4. What other ways are there to reduce burdens on low-risk operations?
5. How can the community provide information to NOP and/or certifiers on acute risks?
6. Certifiers:
    a. Have you adopted or base your risk assessment criteria on the ACA Best Practices documents?
    b. When operations are identified as low risk, what actions are you taking to streamline and make these operations' certification less burdensome?

Subcommittee Vote:

Motion to accept the discussion document on risk-based certification
Motion by: Kyla Smith
Second by: Nate Lewis
Yes: 7 No: 0 Abstain: 0 Recuse: 0 Absent: 1

National Organic Standards Board
Certification, Accreditation, Compliance Subcommittee (CACS)
Consistency in Organic Seed Use Discussion Document
August 6, 2024

Summary:
The **Certification, Accreditation, Compliance Subcommittee (**CACS) seeks to understand the current state of organic seed use, potential tools for increasing the amount and variety of organic seed that is commercially available, and methods for strengthening enforcement of the existing commercial availability requirements.

Background:
Organic producers are generally required to use organically grown seeds (7 USC § 6508(a); 7 CFR § 205.204). Nonorganically produced, untreated seeds may only be used "when an equivalent organically produced variety is not commercially available" (7 CFR § 205.204(a)(1)). In August 2005 and November 2008, the NOSB made recommendations on implementation of the commercial availability requirement, and in 2013, the NOP issued Guidance 5029, which outlines procedures for verifying compliance with the commercial availability requirement. The relevant statutory, regulatory, and guidance text is attached as Appendix A. The NOSB made additional recommendations for rulemaking and strengthening Guidance 5029 in 2018 and 2019, respectively. The 2018 and 2019 recommendations are summarized in Appendix B.

During the recent public comment hearings in Spring 2024 organic stakeholders reported concern about the state of organic seed use. Research supports the public comments regarding low levels of organic seed use, that the commercial availability requirement is inconsistently enforced, and the organic seed market is stagnating in the face of uncertain demand. The 2022 State of Organic Seed presents reported organic seed use for 2011, 2016, and 2022, which shows that the percent of acres planted with organic seed has been roughly unchanged over the years. The one exception is that the share of acreage planted with organic vegetable seed increased between 2011 and 2016. Research examining organic seed use found that some organic food manufacturers require that their suppliers use specific varieties of ingredients, for which organic seeds are not available.

In the European Union (EU), pursuant to regulation EC No 2018/848, use of non-organic seed will be phased out completely by January 1, 2037. Member states have formed national seed expert panels that are currently developing lists (annexes) that identify seeds that are partially or fully commercially available as organic. Nonorganic seeds cannot be used in place of seed varieties identified as fully commercially available as organic. Organic seed supplier information is available in national organic seed databases.

Discussion & Questions:
The need for NOP action on the 2018 and 2019 recommendations is still strong, and additional actions may also be necessary to spur use of organic seed and growth of the organic seed market in the United States. The NOSB seeks stakeholder input on the following questions, to guide next steps:

1. Is there still support for the 2018 and 2019 recommendations?
2. How burdensome is it for producers to demonstrate compliance with the commercial availability requirement for seed?

3. In general, how available is organic seed, and is untreated seed significantly easier to find than organic seed?
4. Are there some crops for which organic seed is available? Are there any crops for which lack of organic seed supply is notable?
5. Is current organic seed research meeting industry needs? Which crops/varieties are the most promising avenues for organic seed research?
6. How can the NOP address the handler role in seed choice, beyond the updates to Guidance 5029 that the NOSB previously recommended? Should the regulations be amended to apply the commercial availability requirements in 7 CFR § 205.204 to handling operations? Should handler Organic System Plans address seed choice? If so, how?
7. What additional information do certifiers and inspectors need to effectively enforce the commercial availability requirement (i.e. how would a certifier or inspector know that an organic option is available and must be used)?
8. How could the NOP (or other entity) make information about commercial availability available publicly? What additional factors could be used to determine that a seed must be used? How could the EU's seed expert panel model inform the U.S. approach?
9. Who could/should build/maintain a U.S. commercial availability database for seed? What attributes should be listed/made available?

Subcommittee Vote:

Motion to accept the discussion document on Consistency in Organic Seed Use
Motion by: Carolyn Dimitri
Seconded by: Jerry D'Amore
Yes: 7 No: 0 Abstain: 0 Recuse: 0 Absent: 1

Appendix A: Relevant Statutory, Regulatory, and Guidance Provisions

- 7 USC § 6508. Prohibited crop production practices and materials
  (a) Seed, seedlings and planting practices
  For a farm to be certified under this chapter, producers on such farm shall not apply materials to, or engage in practices on, seeds or seedlings that are contrary to, or inconsistent with, the applicable organic certification program.

- 7 CFR § 205.2 Terms Defined.
  Commercially available. The ability to obtain a production input in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic production or handling, as determined by the certifying agent in the course of reviewing the organic plan.

- 7 CFR § 205.204 Seeds and planting stock practice standard.
  (a) The producer must use organically grown seeds, annual seedlings, and planting stock: Except, That,
  (1) Nonorganically produced, untreated seeds and planting stock may be used to produce an organic crop when an equivalent organically produced variety is not commercially available: Except, That, organically produced seed must be used for the production of edible sprouts;
  (2) Nonorganically produced seeds and planting stock that have been treated with a substance included on the National List of synthetic substances allowed for use in organic crop production may be used to produce an organic crop when an equivalent organically produced or untreated variety is not commercially available;
  (3) Nonorganically produced annual seedlings may be used to produce an organic crop when a temporary variance has been granted in accordance with § 205.290(a)(2);
  (4) Nonorganically produced planting stock to be used to produce a perennial crop may be sold, labeled, or represented as organically produced only after the planting stock has been maintained under a system of organic management for a period of no less than 1 year; and
  (5) Seeds, annual seedlings, and planting stock treated with prohibited substances may be used to produce an organic crop when the application of the materials is a requirement of Federal or State phytosanitary regulations.

- Guidance 5029 § 4.1.2. …
  a. … For the purposes of this [commercial availability] exception, an "equivalent variety" is a variety of the same "type" (e.g. head lettuce types versus leaf lettuce types) or has similar agronomic or marketing characteristics needed to meet site-specific requirements for an operation. These characteristics may include, but are not limited to number of days until harvest; color, flavor, moisture, chemical, or nutrient profiles of the variety of the harvested crop; vigor or yield of harvested crop; regional adaptation, disease and pest resistance, or the plant's utility in a crop rotation.
  b. Price cannot be a consideration for determination of commercial availability.

- Guidance 5029 § 4.1.3 The following considerations could be acceptable to justify use of non-organic seeds and planting stock as not commercially available. These considerations must be described by the operation in their organic system plan (OSP), pursuant to § 205.201(a)(2), and approved by the certifying agent.

a. Form Considerations: Examples of forms may include, but are not limited to, treated or non-treated seeds or planting stock, use of pelleted seed, or use of bare root nursery stock or container plants.
b. Quality Considerations: Examples may include, but are not limited to, germination rate of the seed; presence of weed seeds in the seed mix; shelf life and stability of the seeds; and disease and pest resistance.
c. Quantity Considerations: Producers may provide evidence that quantities are not available in sufficiently large or small amounts given the scale of the operation.

- Guidance 5029 § 4.2 Recordkeeping for Organic Producers
  4.2.1 The following records should be maintained by organic producers:
  a. A list of all seed and planting stock, indicating any non-organic seeds or stock used, and the justification for their use including lack of equivalent variety, form, quality or quantity considerations. Records describing on-farm trials of organic seed and planting stock can be used to demonstrate lack of equivalent varieties for site specific conditions.
  b. The search and procurement methods used to source organic seed and planting stock varieties, including:
  1. Evidence of efforts made to source organic seed, including documentation of contact with three or more seed or planting stock sources to ascertain the availability of equivalent organic seed or planting stock. Sources should include companies that offer organic seeds and planting stock.
  2. Records may include, but are not limited to: letters, faxes, email correspondence, and phone logs from seed suppliers and companies; seed catalogs; searches of organic seed databases; receipts; receiving documents, invoices, and inventory control documents.

- Guidance 5029 § 4.4 Role of Certifying Agents
  4.4.1 Certifying agents must verify the procedures that certified operations utilize to obtain and plant organic varieties suitable for their operations as part of their annual review of the OSP.
  …
  4.4.3 Certifying agents shall verify the commercial availability requirements on an annual basis, in their review of the OSP, pursuant to § 205.402(a)(1).
  4.4.4 Certifying agents should review an operation's progress in obtaining organic seeds, planting stock and transplants by comparing current source information to previous years.

Appendix B: Summary of NOSB's 2018 & 2019 Recommendations

October 2018 Rulemaking Recommendation:

To amend the 7 CFR § 205.204, Organic seed and planting stock practice standard as follows **(in bold):**

(a) The producer must use organically grown seeds, annual seedlings, and planting stock: Except, That,

(1) Nonorganically produced, untreated seeds and planting stock may be used to produce an organic crop when an equivalent organically produced variety is not commercially available: Except, That, organically produced seed must be used for the production of edible sprouts;

(i) Improvement in searching, sourcing, and use of organic seed/planting stock must be demonstrated every year with the goal of using only organic seed and planting stock.

October 2018 & April 2019 Guidance Recommendations:

4.1.2 Certified operations may use non-organic seed and planting stock only if equivalent organically-produced varieties of organic seeds and planting stock are not commercially available, **and the conventional replacement variety can be documented as being produced without the use of excluded methods.**

4.1.2

c. On-farm variety trials of organic seed/planting stock may be used by producers to evaluate and document organic variety/cultivar equivalency to the nonorganic item in use. If trials are not performed, the producer can use catalog or website seed descriptions, to document there are no organic seeds that have equivalent characteristics to the nonorganic seed in use.

4.1.2

d. Documentation of on-farm trials or seed characteristic searches can be provided at the annual inspection. This documentation can include which seed characteristics are desired, and be based upon the varietal benefits of the current nonorganic seed/planting stock in use. The varietal characteristics discovered during the on-farm trail, of both the nonorganic seed/planting stock and the organic seed/planting stock trialed, can be tracked in a simple table or spreadsheet detailing the specific characteristics sought, and whether or not the various varieties grown contained those characteristics.

4.1.6 Use of non-organic planting stock to produce organic crops is subject to commercial availability as per § 205.204.(a)(1). If planting stock is from a non-organic source and is used to produce perennial crops, then that planting stock may be sold, labeled or represented as organic planting stock or an organic vegetative crop only after 12 months of organic management §205.204 (a)(4). STRIKE THIS SECTION

4.2.1 The following records should be maintained by organic producers:

a. A list of all seed and planting stock, indicating any non-organic seeds or stock used, and the justification for their use including lack of equivalent variety, form, quality or quantity considerations. Records describing on-farm trials, **or other descriptions illustrating seed characteristics,** can be used to demonstrate lack of equivalent seed or planting stock varieties/cultivars for site specific conditions.

b. The search and procurement methods used to source organic seed and planting stock varieties, including:

1. Evidence of efforts made to source organic seed and planting stock varieties **should include but is not limited to:**

i. Documentation of contact with at least three or more seed or planting stock sources to ascertain the availability of equivalent organic seed or planting stock, including

date, variety requested, quantity of seed, as well as if the seed is available organically, or was out-of-stock.

ii. Improved timeliness of seed/planting stock ordering by documenting the date(s) of orders. Earlier ordering can result in a greater chance of organic seed/planting stock availability. For larger orders, suppliers need to be given sufficient lead time to provide the quality, quantity and variety/cultivar within the timeframe needed by the organic producer.

iii. Work with seed/planting stock suppliers that provide a quick response of organic availability, to enable the producer to request seed, in a timely manner, of other suppliers if organic seed was not available from the first supplier.

iv. Demonstrate an increase in the percentage of organic seed/planting stock used over time by the operation.

v. Search suppliers that are known to carry organic varieties or cultivars of the type they seek.

vi. Discuss and document their desire to purchase equivalent organic varieties or cultivars with their current nonorganic suppliers.

vii. Failure to demonstrate improvement in sourcing organic seed/planting stock over time may result in additional seed/planting stock sources being required or additional steps taken to procure organic seed/planting stock, by the organic certifier.

4.2.1 b. 2. (no changes)

4.2.1 (b) 3. If seed/planting stock is sourced or mandated by the buyer of a contracted organic crop, the producer must obtain sourcing information and documentation from the contracted buyer. The buyer's attempts to source organic seed/planting stock then becomes part of the producer's Organic System Plan. Such documentation could include:

i. The handler's organic search documents there are no organic equivalents in quality, quantity or function, to the nonorganic seed/planting stock they require.

ii. The handler has discussed the development of an equivalent organic seed/planting stock source with their nonorganic seed supplier, as well as with organic seed breeders.

iii. The handler seeks out organic growers, either those that are contracted to grow organic crops from that nonorganic seed/planting stock source, or known organic growers who are experienced in seed/planting stock production, to trial production of an organic equivalent variety/cultivar.

iv. The handler clearly documents that mandating use of nonorganic seed/planting stock is not solely based upon the possibly higher monetary cost of an organic equivalent variety.

v. The handler can be required to illustrate they have performed the items required of producers in 4.2.1 (b), where the certifier feels this is appropriate, in order to achieve the goal of full compliance in the use of only organic seed/planting stock.

4.4.4 Certifying agents should review an operation's progress in obtaining organic seeds, planting stock and transplants by comparing current source information to previous years

a. If sufficient progress is not demonstrated a certifying agent may ask for a corrective action plan and require additional seed sources be researched, encourage variety trials, or require additional steps to procure organic seed.
b. Non-compliances should be issued for repeated lack of progress in sourcing and using commercially available organic seed/planting stock over time. Judgment of a noncompliance can include, but is not limited to:

1. The certifier's communication detailing commercially availability organic seed/planting stock and continued non-use by the farmer
2. Organic seed searches that do not include suppliers who carry organic seed/planting stock of that specific crop.
3. The producer's lack of on-farm seed trials, or reference to descriptions, for judging equivalency between nonorganic seed and organic seed.
4. When producer returns to nonorganic seed/planting stock use, if the organic equivalent seed/planting stock was not documented as having a significant yield, market or other loss.

4.4.5 Certifying agents should review the prevention measures taken to avoid contamination for seed of crops grown by the organic operator, at-risk of GMO contamination.

National Organic Standards Board
Materials Subcommittee
2024 Research Priorities Proposal
August 13, 2024

Executive Summary

Overall: The National Organic Standards Board (NOSB) presents an annual list of research priorities for organic food and agriculture, a process originally established by the Board in 2012. 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. As part of this year's process, the Livestock, Crops, and Handling Subcommittees have made an effort to categorize and differentiate highest priority topics from ongoing topics.

LIVESTOCK

Top priorities for organic livestock research

Elucidate the barriers to increased organic pork production and markets.

Develop balanced organic livestock rations that incorporate high percentages of diverse, regionally adapted grain crops to complement corn and soybeans and allow farmers to realize more marketing opportunities for a robust crop rotation.

Ongoing organic livestock research topics

Evaluate ways to prevent and manage parasites in all species of livestock, in each region. This includes determining the efficacy of natural parasiticides and methodologies, including but not limited to, nutritional programs, use of herbs, essential oils, homeopathic remedies, diatomaceous earth, pasture rotation, pasture species, mixed species grazing, and utilizing the genetic pool within and between breeds.

Evaluate natural alternatives to DL-Methionine in a system approach for organic poultry feed program.

Develop a dairy program to address climate change mitigation strategies where production capabilities are not hindered, and effective forage rotations are maximized.

CROPS

Top priorities for organic crop research

The extent and impact of plastic use in organic crop production, and how organic producers can lead in reducing it and aligning with consumer concerns.

Side-by-side trials of approved organic pesticide products, both synthetic and natural, and cultural methods, in multiple regions, with a request for collaboration with the IR4 project.

Alternatives to eliminate usage and remediation strategies to mitigate contaminated areas for Per- and Polyfluoroalkyl (PFAS) substances.

Assessing the extent, economic impact and compensation mechanisms of GMO contamination and prohibited pesticide drift, such as from Dicamba, on organic crops.

Conduct whole farm ecosystem service assessments to determine the economic, social, and environmental impact of farming systems choices

Ongoing organic crop research topics

Inputs

Examination of decomposition rates, the effects of residues on soil biology, and the factors that affect the breakdown of biodegradable bio-based mulch film.

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.

Holistic soil research to quantify soil biology

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

Comprehensive review of positive and negative impacts of copper product use in pest management.

Contaminants

Investigate contaminated inputs from non-organic sources, including from compost approved for use on organic farms.

Systems

Conduct whole farm ecosystem service assessments to determine the economic, social, and environmental impact of farming systems choices.

Elucidate practices that reduce greenhouse gas emissions and that contribute to farming systems' resilience in the face of climate change.

Factors impacting organic crop nutrition, and organic/conventional nutrition comparisons.

Organic no-till and low-till practices for diverse climates, crops, and soil types.

Develop cover cropping practices that come closer to meeting the annual fertility demands of commonly grown organic crops.

More research, extension, and education are needed to fully understand the relationship between on-farm biodiversity and pathogen presence and abundance.

Strategies for the prevention, management, and control of problem insects, diseases, and weeds in light of a changing climate, and how to anticipate or predict new pest problems. Systems-based approaches are emphasized.

FOOD HANDLING AND PROCESSING
(prioritized order within categories; categories not ordered by priority)

Improving methods and practices for organic handling and processing

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.

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.

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.

Expanding market opportunities for organic products – e.g., consumer expectations, products based on rotational crops, etc.

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.

Alternatives to conventional celery powder for curing organic meat.

Consumer food product development research for crops integral to organic farming systems (e.g., rotational crops).

Complete (or full) materials review

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.

MATERIALS/GMO

Outcome of genetically engineered (GMO/GE) material in organic compost.

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.

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.

Techniques for preventing adventitious presence of GE material in organic crops, and evaluation of the effectiveness of current prevention strategies.

Testing for fraud by developing and implementing new technologies and practices.

GENERAL

Examination of the factors influencing access to organically produced foods.

Production and yield barriers to transitioning to organic production to help growers successfully complete the transition.

National Organic Standards Board
Materials Subcommittee
2024 Research Priorities Discussion Document
August 13, 2024

INTRODUCTION

The National Organic Standards Board (NOSB) presents an annual list of research priorities for organic food and agriculture based on a process originally established by the Board in 2012. The NOSB's Livestock, Crops, Handling, and Materials/GMO Subcommittees proposed an updated set of priorities at the Fall 2023 Board meeting. The Board requests input from stakeholders on the 2024 research priorities and will review those comments for the Fall 2024 proposal. As part of this year's process, the Livestock, Crops, and Handling Subcommittee have made an effort to categorize and differentiate highest priority topics from ongoing topics.

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. We especially encourage university researchers to non-intrusively study working organic farms.

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

LIVESTOCK

Top priorities for organic livestock research

Elucidate the barriers to increased organic pork production and markets. Production of organic pork has lagged behind chickens, eggs, and dairy. We request holistic investigations into what the barriers are, including, but not limited to markets, pricing, input costs, processing facilities, and production constraints such as lack of hardy breeds and housing/humane standards. Competition from non-organic pasture-raised, local, and other production claims should be included, as should evaluation of methods to avoid the need for farrowing crates.

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.

Ongoing organic livestock research topics

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, 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 over time? 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? An area of particular concern is control of *A. galli* and *H. gallinarum* in laying and replacement chickens.

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 regard to NOP regulations §205.237(5) (b) which prohibits organic operations from feeding mammalian or poultry slaughter by-products to mammals or poultry, "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[1] 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:

A. Evaluation of the merits and safety of natural alternative sources of methionine such as herbal methionine, high methionine corn, and corn gluten meal, potato meal, fishmeal, animal by-products, and other non-plant materials including insect protein in organic poultry production systems. Additional research on the more promising alternatives to bring them into commercial production is also encouraged;

B. 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;

C. Management practices impacting the flock's demand for methionine should be included, such as flock management practices, access to pasture, and pasture management; and

D. 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.

The fruition of these types of research topics could take years to achieve; however, an aggressive and/or heightened research focus could lead to findings that can positively impact the organic poultry industry and the organic brand.

Develop a dairy program to address climate change mitigation strategies where production 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.

[1]*The National Organic Standards Board is committed to the phase-out of synthetic methionine for organic poultry production and encourages aggressive industry and independent research on natural alternative sources of methionine, breeding poultry that perform well on less methionine, and management practices for improved poultry animal welfare.*

CROPS

Top priorities for organic crop research

The extent and impact of plastic use in organic crop production

Both consumers and producers are concerned about the use of plastics in organic agriculture. The Crops subcommittee is requesting research and information on the following:

- Statistics on current use (acreage and quantity) of crop production plastics, including mulches, drip tape, containers, row covers, tarps, high tunnels, greenhouses, etc.
- What is the turnover and fate of these plastics? This information is needed for the US and major production areas such as Mexico, Spain, Chile, Holland, Canada, etc.

- What are the effects of breakdown products, airborne releases, and microplastics on soil organisms and crop plants?
- What are the economics of alternatives?
- If approved biodegradable biobased mulch films are developed, how many organic farmers would switch to them, and what would impact overall plastic usage?
- Can longer-term mulches such as landscape fabric reduce overall plastic use if allowed to remain in place over several years?
- What are the best first steps to reduce plastic use in organic production?

Efficacy Comparisons of Inputs and Practices for Organic Production

Organic farmers need to have information from side-by-side trials between 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.

Per- and Polyfluoroalkyl (PFAS): Alternatives to eliminate usage and remediation strategies to mitigate contaminated areas

Background: There is a need for increased research examining PFAS substances. PFAS is a broad term that contains thousands of chemicals used in consumer, commercial, and industrial products. There is evidence that PFAS substances, also known as “forever chemicals,” contaminate farmland, water, food, consumer goods, and more. PFAS substances can negatively impact human health and animal health in direct and indirect ways over time. Many researchers and scientists are looking into matters related to PFAS substances.

The NOSB is requesting additional research on the following:

- To find safe and eco-friendly alternatives so PFAS substances can be eliminated in the production of consumer, commercial, and industrial products to prevent any future contamination.
- To quantify the impact of PFAS substances on the environment, including agricultural land and water, and human and animal health.
- To identify tools to identify, measure, and remediate PFAS contamination that has already occurred in the environment and on organic and non-organic farmland.

- To identify viable programs for addressing the financial and emotional costs of land that must be removed from production due to PFAS contamination.

Assessing the economic impact of GMO contamination on organic crops

Background: Genetically Engineered Crops and Organic Crops can exist in adjacent fields. There are many risks, including cross-pollination, that are mitigated as best as possible by the growers involved, but much to the expense of the organic producer. Organic growers use borders, at a minimum of thirty feet, off-set planting timeframes to avoid cross-pollination (causing organic crops to be planted sometimes at undesirable times) and change cropping rotations, all to mitigate risk. In addition, dicamba drift from sources further away can damage crops.

Research is needed on the following:

- The total cost of GMO contamination on organic farms for the full range of crops with GMO varieties (including lesser-studied crops like apples, canola, summer squash, sweet corn, etc.). This would include recommended buffer requirements, recommended planting delays windows, testing costs, a variety of pollen receptivity restrictions, loss of sales, etc.
- Are USDA coexistence provisions adequate?
- Drifting chemicals can be considered "chemical trespassing." Could pollen contamination be considered trespassing as well? Are there avenues for compensation for organic crops damaged or with reduced sale value due to contamination from other farms?

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?

Ongoing organic crop research topics

<u>Inputs</u>

Biodegradable Bio-based Mulch Film

Biodegradable mulch film was recommended in 2012 for addition to the National List by the NOSB but it did not specify a required percentage of biologically derived (i.e., bio-based) content. The NOP regulations require 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. Data from Europe, where BBMF mulches are allowed for organic production, may be particularly useful.

• 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?

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.

Holistic Soil Research to Quantify Soil Biology

Organic farmers are presented with many alternative ways of assessing the health of their soil and its biological components. Which assessments give the most accurate and useful information to help farmers best manage soil over the short and long term?

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 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.

Comprehensive Review of Copper

Systems research that identifies disease resistant material and biological controls that can reduce the use of copper-based compounds where possible. Use of copper has documented negative effects on human and ecosystem health. Continued strong efforts need to be made to reduce the reliance on copper in organic production.

- Develop alternative formulations of materials containing copper so that the amount of elemental copper is reduced.
- Develop biological agents that work on diseases that copper is now used on.
- Research on tadpole shrimp and algae control in rice and whether sodium carbonate peroxyhydrate or other materials are suitable copper alternatives in an aquatic environment.
- Research on movement and fate of applied copper in aquatic and field environments.
- Establish available and total copper threshold levels above which soil organisms are harmed, for different regions and soil types.
- Breeding plants that are resistant to the diseases that copper controls.

Contaminants

Investigate contaminated inputs from non-organic sources

In addition to PFAS and GMO drift, there are many other sources of contamination that can negatively impact organic farms and crops. Examples would be contaminants in manures and other fertilizers, irrigation water, etc. Research to identify these and whether they are avoidable needs to be ongoing.

Systems

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?

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 several 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. Life cycle analysis of organic inputs and practices is critical. In particular, work is needed on comparing soil-based and soil-less systems, as well as the effects of farm scale on greenhouse emissions.

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 with 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.

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.

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. Further, there need to be more programs to breed seeds for cover crops.

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.

Management of Problem Insects, Diseases, and Weeds

There is a large pool of research on the control of insects, diseases, and weeds using organic methods. Many controls use a systems approach and are quite effective. However, some arthropod pests including new invasive species, are problematic, and in several cases the organic control options are very limited or nonexistent. The organic community needs more information on their biology, life cycle weak points, and natural enemies to implement targeted and systemic management.

Examples are:

- spotted wing drosophila
- brown marmorated stinkbug
- Spotted lanternfly
- Swede midge

- Leek moth
- Corn rootworm beetle (northern and western)
- Cutworms (army, western bean, etc.)
- and others

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 and biological controls that limit the use of copper-based compounds and other fungicides 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.
- 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.
- Evaluate plant nutritional strategies to lessen disease impacts.

Further research into certain diseases in vegetables (including but not limited to early blight, late blight, downy mildews, etc.), fruits (including, but not limited to, apple scab, fire blight, peach leaf curl, little cherry disease, X-disease, grape botrytis, etc.), and soilborne or other disease affecting organic crops that require mitigations such as approved fungicides or the increased use of copper.

Weed management is one of the greatest challenges to successful organic crop production. Development of integrated organic management strategies that effectively control weeds in specific cropping systems without excessive tillage continues to be a top research priority for organic producers. For instance, Canadian thistle, pigweed (including invasive palmer amaranth and water hemp), wild sunflower, giant ragweed, cocklebur, and other perennial weeds can be very difficult to control in reduced tillage systems.

Research into new technologies such as electroshock weeders, interrow mowers, camera-guided cultivators, laser-weeders incorporating AI (artificial intelligence) and robotics, propane flamers, etc. is critical to success in field crops, whereas tarping, solarization, and a new generation of hand tools have great potential in small- to medium-scale vegetable crops. For large scale vegetables as well as row-crop producers, strip tillage and compatible weed management tools including row cleaners, finger weeders, and high residue cultivators can combine reduced tillage and cover crops into one practice set.

Future cropping systems will utilize multiple elements of soil, crop, arthropod, disease, and weed management. The integration of tools such as weed-suppressive cover crops and rotations, livestock

grazing, flaming, beneficial insect habitat, intercropping, etc. into annual and perennial cropping systems needs more research.

FOOD HANDLING AND PROCESSING

(prioritized order within categories (underlined); categories not ordered by priority)

<u>Improving methods and practices for organic handling and processing</u>

Sanitizers: Effective alternatives of sanitizers, effect on occupational human health and environment, effectiveness of rotational use strategies with the sanitizers currently on the NL

- 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 and should also include sanitizers such as quaternary ammonia compounds, or QACs.)
- 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? That includes 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?

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.

- *[intentionally does not include further detail]*

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.

- *[intentionally does not include further detail]*

<u>Expanding market opportunities for organic products – e.g., consumer expectations, products based on rotational crops, etc.</u>

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 and/or analysis of the barriers to organic production via laboratory testing, sensory evaluation, and/or market analysis

- In review of substances on the National List at 205.605 and 205.606 during the sunset process questions related to essentiality and commercial availability of organically produced substances, and if supplies are lacking knowledge of the barriers to organic production, are often the focus of the review by the Handling Subcommittee and of stakeholder comments. There are often commenters that blanketly state that all items should be removed from 205.606 - inferring that there should be the ability to produce all of these substances organically. Therefore, it would be beneficial to comprehensively understand the current status of essentiality of these substances and if organic alternatives exist; and if not what the barriers are that prevent a vibrant organic market for these substances.

Alternatives to conventional celery powder for curing organic meat.

- Celery powder is used in a variety of processed meat product (hot dogs, bacon, ham, corned beef, pastrami, pepperoni, salami, etc.) to provide "cured" meat attributes without using prohibited nitrites (note: products must still be labeled "uncured"). Celery powder is naturally high in nitrates that are converted to nitrites during fermentation by a lactic acid culture. It has proven difficult to produce celery powder under organic production practices with sufficient levels of nitrates for cured meat applications. Are there growing practices or regions that could produce celery under organic conditions that would yield a crop with sufficient nitrate content for cured meat applications? Are there agriculturally derived substances (other than celery) that could be produced under organic production practices that provide nitrate levels sufficient for cured meat product applications of comparable quality?

Consumer food product development research for crops integral to organic farming systems (e.g., rotational crops).

- *[intentionally does not include further detail]*

<u>Complete (or full) materials review</u>

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.

- The topic of ancillary substances contained in substances on 205.605 and 205.606 and how the NOSB should review them has been a topic of discussion since 2013 but has not reached a full resolution. The current process is to review individually during the petition or sunset review process. However, as noted by stakeholder comments this has the potential to result in different decisions due to the gap in time, available information and/or persons responsible for conducting the review being different. It would be beneficial to analyze and compare different strategies for conducting ancillary substance review in a more comprehensive manner as opposed to the current individual review process that includes a cost/benefit analysis of each proposed review strategy.

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:

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?

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.

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.

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.

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.

Improving our understanding of the (1) potential threats and (2) costs to the organic sector that result from the use of excluded methods. First, identify the set of potential threats the use of excluded methods presents to organic businesses (farms and handlers). The potential threats include crop damage and cross contamination, but we recognize there might be others not yet identified. Second, estimate the costs the threats present to organic farms and organic handlers.

GENERAL

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.

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 proposal on the 2024 NOSB Research Priorities
Motion by: Wood Turner
Seconded by: Kyla Smith
Yes: 7 No: 0 Abstain: 0 Recuse: 0 Absent: 1

Approved by Franklin Quarcoo, Materials Subcommittee Chair, to transmit to NOSB, August 14, 2024

National Organic Standards Board
Materials Subcommittee
Inert Ingredients in Organic Pesticide Products Proposal
August 13, 2024

Introduction:

The National Organic Program (NOP) issued a memo to National Organic Standards Board (NOSB) on June 23, 2023 requesting the NOSB provide a recommendation related to inert ingredients used in pesticide products allowed in organic production. The memo provides a history of the inerts issue, describes four options NOP is considering for the future regulation of inert ingredients, and provides a synthesis of the public comments received on NOP's Advance Notice of Proposed Rulemaking (ANPR) published September 2, 2022. The four options as described by NOP are as follows:

- Allow inert ingredients in EPA-registered pesticides without further review. This would be the easiest to implement and an effective way to evaluate products for compliance. This option would require stakeholders to actively engage in EPA rulemaking and may delegate some control of inert ingredients in organic production to the EPA.

- Reference a subset of EPA regulations (e.g., inerts exempt from the requirement of a tolerance) for allowed inert ingredients. This could be combined with an initial list of prohibited inert ingredients. Further prohibitions or allowances may be added through the petition process. This option maintains much of the simplicity of allowing all EPA registered pesticides while allowing more control. Specifically, it allows stakeholders to submit petitions to prohibit or allow certain inert ingredients as more research is published.

- Develop a single, external list of allowed inert ingredients. The National List would reference this list for allowed inert ingredients. This would function similarly to the current system of referencing EPA List 3 and List 4. This option reduces the sunset burden but is inflexible, like the current reliance on EPA List 3 and List 4. The initial list could be developed from EPA List 3 and List 4, but it is unclear how and by whom this list would be maintained or updated, and how it would fit within the regulatory framework of the National List.

- List allowed inert ingredients individually on the National List in the organic regulations. While the NOSB may be able to initially review these inert ingredients in groups to recommend adding them to the National List, they would need individual sunset reviews every five years. This could nearly double the Board's sunset workload.

NOSB received numerous comments on the topic of inert ingredients at its Fall 2023 and Spring 2023 meetings; the general themes of the comments are summarized below:

- There are two options that garner the most support: 1. To list each inert ingredient allowed for use in organic pesticide formulations on the National List individually; and 2. To reference a subset of EPA regulations in combination with an initial list of prohibited inert ingredients.
- There is consensus that inert ingredients allowed in minimum risk ("25(b)") pesticides and inert ingredients allowed in pheromone type pesticides should be allowed in organic production.
- There is little interest from stakeholders in allowing all inert ingredients permitted in EPA pesticides in organic pesticide formulations, as this would delegate too much of the regulatory authority away from NOSB and NOP.
- Several stakeholders pointed out that the number of inert ingredients currently in use is a relatively small subset of those permitted, and should be the starting point for handling this issue. Material Review Organizations (MRO's) can disclose the inerts in formulations they approve, without revealing confidential information about specific products.

Subcommittee Resources:
The Materials' Subcommittee (MS) has worked with NOP staff to provide the resources needed to continue evaluating the viability of these options, which we describe in additional detail:

- Inert substances spreadsheet - in collaboration with Board members, NOP staff have developed a spreadsheet of the three hundred inert substances currently in use in organic pesticide formulas (according to public comments from MROs), descriptions of these substances' functions in formulas and general chemical classifications, and any current EPA inert ingredient regulations that list these substances. The spreadsheet also includes all of the substances currently allowed as inert ingredients, which have been allowed in pesticide products as part of EPA's ongoing inert ingredient review and approval process.
- Guest speaker - The MS has had the pleasure of hosting two calls with experts in the field of pesticide formulation and registration. Evisabel Craig and Kerry Leifer from EPA provided an overview of EPA's inert ingredient review and approval process, and Karen Warkentien and Scott Tann-Lamberti, both from companies that formulate pesticides and produce inert ingredients, provided the MS with an overview of the considerations taken into account when formulating different types of pesticides and how the pesticide industry has adapted to EPA's current regulatory framework governing approval of inert ingredients in pesticide products.

Below is a list of viable options that the MS has identified in response to the National Organic Program's request. It must be emphasized that the NOSB deems it extremely important to avoid the current dependence on an outdated and/or static substance list.

Two Viable Options
The MS has concluded through its own review and discussion, input from stakeholders through the public comment, and guest speakers, that there are two viable options to review inert ingredients in organic pesticide products:

1. List inert ingredients individually on the National List. Starting with the list of substances currently in use in organic pesticide formulas, NOP should move forward with rulemaking listing all of these substances individually. With the status-quo preserved in the National List with individual listings, additions and removals can be petitioned by the public as needed, and NOSB can propose additions and removals during the sunset cycle. MS acknowledges this option expands the National List substantially and adds to the sunset review burden for future boards, however, this option also focuses the individual review of inert substances used in organic pesticides away from EPA and towards NOSB and NOP, which aligns with many public commenters' opinions.

2. Allow substances defined and allowed by EPA as "inert ingredients" (40 CFR 152.3 & 7 CFR 205.2) with restrictions and prohibitions. Starting with inert ingredients that have been reviewed and approved by EPA for inclusion in pesticide formulas, MS recommends further restricting this group by only allowing those which are allowed in formulations that are exempt from the requirement of tolerance. MS also proposes an initial list of prohibitions that include alkylphenol ethoxylate substances and per- and polyfluoroalkyl substances.

Sunset Review

Both options will require sunset review every five years as mandated by the Organic Foods Production Act (OFPA). While the two options may present different sunset review burdens, future boards will benefit from NOSB providing a road map for this review. As such, the MS will continue to work on developing a sunset review process for both options, so future boards are supported in their ongoing work. We hope this work can parallel the rulemaking process at NOP so that there is a sunset review road map for whatever option NOP ultimately decides to enact.

Further Discussion:

Option 1: List Individually or individually by group

National List Criteria

Substances to be added to the national must satisfy the following criteria:

1. The input is necessary or essential because of the unavailability of natural or organic alternatives
2. The input is not harmful to human health or the environment; and
3. The input is consistent with organic principles.

Pros / Cons

This option aligns fully with National List requirements. It is not dependent on external lists that may change without notice over time, giving confidence to pesticide manufacturers. Inerts that are nonsynthetic are not part of the National List and can be used in organic pesticide formulations. Manufacturers must document their nonsynthetic status as part of the material review process.

Our current listing of inerts in use in approved organic pesticides indicates 227 synthetic substances. All of these substances will need to be reviewed on a staggered 5-year basis. We suggest they be placed into groups based on chemical types and use:

- Alkylphenols
- Polymers
- Emulsifiers and surfactants
- Solvents
- Minerals, pH adjusters, physical effects
- Preservatives
- Coloring agents
- Other

This grouping approach should not impact how a substance can be used in a pesticide formulation, but, rather, provides a framework to add efficiency to the sunset review process. For example, if a substance functions as either a surfactant or a solvent, it can be used for either purpose regardless of whether its sunset review is done within the surfactant group or the solvent group. This process is manageable and gives pesticide manufacturers the opportunity to provide input to the NOSB during the sunset review process. If a substance is voted by the NOSB to be removed from the National List, there is time during rulemaking for further input and reformulation.

This process is transparent and allows the NOSB to apply NOP standards to inerts, which go beyond the requirements of the EPA for approval. It strengthens the integrity of the process and allows for innovation since substances not on the National List can be petitioned for inclusion.

Sunset Considerations

We suggest staggering the reviews of these groups over a 5-year period, with those that may have problematic items being reviewed earlier. For instance, the alkylphenol group or some members of the emulsifiers and surfactant group may be removed from the list after initial review. We expect the first sunset review of each group to be most difficult, requiring research assistance from the NOSB food technologist. Subsequent reviews may require less work.

Option 2: EPA List with restrictions and prohibitions

National List Criteria

Substances to be added to the National List must satisfy the following criteria:

1. The input is necessary or essential because of the unavailability of natural or organic alternatives
2. The input is not harmful to human health or the environment; and
3. The input is consistent with organic principles.

    a. Inert ingredients are necessary components of organic pesticide formulations. Depending on the chemical and physical characteristics of approved active ingredients, the target pest, and application method, synthetic inert ingredients are necessary in

order to make pesticide formulations effective. It is impossible to evaluate the necessity of each individual inert ingredient within a particular pesticide formulation, as these formulations are confidential and protected by the disclosure laws included in the Federal Insecticide, Fungicide, and Rodenticide Act.

b. EPA currently evaluates all inert ingredients used in pesticide formulations and either determines that the individual compounds are allowed in pesticide formulations that are exempt from tolerance or establishes limits for individual compounds used in pesticide formulas. NOSB is proposing to only allow the inert ingredients that are permitted to be included in pesticide formulas exempt from the requirement of a tolerance because these are the substances that EPA has determined to be not harmful to human health or the environment. We have also proposed an exception to this general rule for alkyl-phenol ethoxylates, as new science has shown this class of compounds to have negative environmental impacts and should not be allowed in organic pesticide formulas.
c. Consistency with organic principles is a challenging National List criteria to apply to an opaque set of compounds and formulas. However, we acknowledge that forever chemicals such as per- and polyfluoroalkyl substances (PFAS) are not consistent with organic principles and should not be included in organic pesticide formulas regardless of use pattern or potential to cause harm to human health or the environment. Therefore, we propose an additional exception to the allowance for inert ingredients to prohibit this class of substances.

The intention behind this option is to allow all inert ingredients allowed in pesticide formulas exempt from tolerance, with exceptions. The two exceptions proposed at this time are alkyl-phenol ethoxylates and PFAS for reasons explained above. We chose to use language in the recommendation around exemptions from tolerance rather than specific regulatory references in order to ensure this baseline remains evergreen should EPA update its categorization of inert ingredients again. However, currently, the inert ingredients that meet this minimum threshold are included in the following federal references:

- 40 CFR 180.910 (Crops)
- 40 CFR 180.920 (Crops)
- 40 CFR 180.930 (Livestock)
- 40 CFR 180.940 (Post-Harvest Antimicrobials)
- 40 CFR 180.950 (Minimum Risk Pesticides)
- 40 CFR 180.960 (Polymers for Passive Pheromone Dispensers)

Pros / Cons

The option to align with EPA's list of inert ingredients with exceptions will significantly reduce the burden on NOSB to conduct lengthy sunset reviews of each substance potentially used in pesticide formulas. It will allow NOSB to focus on prohibiting problematic substances as they arise during the sunset review process. This option also does not rely on MROs disclosing substances actually in use in organic pesticide formulas, which is privileged information and may not be available to NOSB in future sunset cycles. It also ensures that, at a bare minimum, only inert substances allowed in tolerance-exempt pesticides will be allowed in organic pesticide formulas. It also allows pesticide manufacturers to reformulate organic pesticides with the

industry's best and least toxic materials immediately rather than to wait for the petition and addition of individual compounds to the National List.

The efficiency gained by aligning with EPA does come with tradeoffs, however. NOSB will not evaluate and vote on each individual inert ingredient allowed in organic pesticide formulas, and some stakeholders will view this unfavorably. There is also a concern related to the potential difficulty in adding to the list of exceptions in the future as new science reveals additional substances that should not be permitted in organic pesticide formulas.

Sunset Review Considerations
Regardless of which option ultimately becomes part of the National List, NOSB will be obligated to conduct sunset reviews of the listings. Should the EPA list-with-exceptions become the regulation, NOSB will have to evaluate whether these substances continue to meet National List Criteria or if additional prohibitions should be proposed. In order to support this work, the NOSB is committed to developing an inerts sunset "roadmap" regardless of which option is adopted. For this option, a starting place for future NOSB sunset reviews could be to compare current allowances and exceptions with the European Union's banned co-formulants list (Annex III to Regulation (EC) No 1107/2009). Many of the substances on this list are prohibited with the proposed exceptions (APEs and PFAS) in this proposal.

Subcommittee Vote:

Motion to accept this proposal, which proposes two viable listing motion options for NOP to consider in rulemaking related to synthetic inert ingredients used in organic pesticide products.

Motion to add [individual substances identified in Appendix A] at 205.601(m)

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

~~(1) EPA List 4 Inerts of Minimal Concern~~
~~(2) EPA List 3 Inerts of unknown toxicity for use only in passive pheromone dispensers~~
(1) 1,2,3-Octadecenoate (CAS 9007-48-1)
(2) 12-Hydroxystearic acid-polyethylene glycol copolymer (CAS 70142-34-6)
(3) …

Motion to add [individual substances identified in Appendix A] at 205.603(e)

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

~~(1) EPA List 4 Inerts of Minimal Concern~~
~~(2) EPA List 3 Inerts of unknown toxicity for use only in passive pheromone dispensers~~
(1) 1,2,3-Octadecenoate (CAS 9007-48-1)
(2) 12-Hydroxystearic acid-polyethylene glycol copolymer (CAS 70142-34-6)
(3) …

OR

Motion to amend 205.601(m)

(m) ~~As S~~Synthetic inert ingredients as classified by the Environmental Protection Agency (EPA) and exempted from the requirement of a tolerance, for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances, except for:

~~(1) EPA List 4-Inerts of Minimal Concern~~

~~(2) EPA List 3-Inerts of unknown toxicity-for use only in passive pheromone dispensers~~

(1) Alkylphenol ethoxylate substances

(2) Per- and polyfluoroalkyl substances

Motion to amend 205.603(e)

(e) ~~As S~~Synthetic inert ingredients as classified by the Environmental Protection Agency (EPA) and exempted from the requirement of a tolerance, for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances, except for:

~~(1) EPA List 4-Inerts of Minimal Concern~~

~~(2) EPA List 3-Inerts of unknown toxicity-for use only in passive pheromone dispensers~~

(1) Alkylphenol ethoxylate substances

(2) Per- and polyfluoroalkyl substances

Motion by: Nate Lewis
Seconded by: Brian Caldwell
Yes: 7 No: 0 Abstain: 0 Recuse: 0 Absent: 1

APPENDIX A:
See Regulations.gov - docket # AMS-NOP-24-0023 - under "Supporting & Related Material" for Excel Spreadsheet

National Organic Standards Board
Materials Subcommittee Discussion Document
Induced Mutagenesis
August 13, 2024

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. 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. The 2016 TBD list included TILLING, Induced Mutagenesis (IM), Haploid Doubling Technology, Transposons, and Cell Fusion. In several comment opportunities since 2016, organic stakeholders, including seed breeders, have urged the NOSB to resolve the status of methods on the TBD list.

Induced Mutagenesis, Transposons, and Cell Fusion using in vitro nucleic acid techniques were determined to be excluded methods in 2019, but those techniques, in the absence of recombinant DNA techniques, remained on the TBD list. In 2022, cell fusion and protoplast fusion were determined to be excluded methods only when donor and recipient cells are not within the same taxonomic plant families and/or when derived using techniques of recombinant DNA technology. This discussion document addresses Induced Mutagenesis (IM) methods used without in vitro recombinant DNA technology.

Goals of this document

The focus of this document is the production of plant varieties using IM.
The Materials' Subcommittee suggests different decisions and rationales regarding the status of IM, and request that stakeholders respond with their opinions and guidance.

Definitions

Under current National Organic Program regulations, 7 CFR 205.2 Terms defined **excluded methods** is defined 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.
It is important to note that this definition refers to ***means*** not possible under natural conditions, not ***results*** not possible under natural conditions.

The NOSB previously recommended the use of the following definition of **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; 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.

In this document, we will use these additional definitions:
A **mutation** is an alteration in the nucleic acid sequence of the genome of an organism, virus, or extrachromosomal DNA.
Mutagenesis is a process by which the genetic information of an organism is changed by the production of a mutation. Mutagenesis may occur spontaneously in nature, or as a result of exposure to mutagens. In nature mutagenesis can lead to cancer and various heritable diseases, and it is also a driving force of evolution.
A **mutagen** is a chemical or physical mutation-causing agent which results in an increased rate of mutations in an organism's genetic code.
Induced mutagenesis is an increased rate of mutations caused by mutagens used in plant, microbe, or animal breeding.

Discussion
Mutations arise as a result of induced changes in the base sequence of DNA. Spontaneous mutations result from a biological process, or from mutagenic agents present in the environment (i.e. cosmic rays, heat, starvation) that change the structure of DNA. That mutation can be an atypical recombination, an atypical segregation, a removal of an amino group from an amino acid, or serious damage to the DNA caused by the breaking of covalent bonds that release nucleic acid components guanine or adenine from DNA. Induced mutations are the result of human interference and can be accomplished through physical agents, such as ultraviolet light, x-rays, heat, irradiation and/or chemical agents (i.e. mustard gas, ethylene amine, and others).
IM techniques were developed beginning in the 1930's. Before the development of direct manipulation of DNA, the use of mutagens was a source of many new mutations for plant and microbe breeding. Hundreds of plant varieties and microbe strains were developed using IM. "Records maintained by the joint FAO/IAEA Division in Vienna show that 2965 crop cultivars, with one or more useful traits obtained from induced mutations, were released worldwide during the [period from 1971 to 2011]" (Sikora et al 2011). IM plant varieties include rice, wheat, cotton, many flowers, grapefruit, pears, tomatoes, and more.

A Technical Review (TR) on Induced Mutagenesis was requested in 2023 and finalized in 2024. Much of this discussion is based on information in that TR. According to the TR, IM is not considered to be recombinant DNA or GMO technology. However, the criteria for excluded methods goes further. According to the NOP definition of excluded methods, they must meet three criteria. They must:
1. be methods used to genetically modify organisms or influence their growth and development

2. use means that are not possible under natural conditions or processes
3. use means that are not considered compatible with organic production

IM methods produce heritable genetic changes, so #1 is met.
For #2, exposure of seed or tissue to high levels of natural mutagens such as colchicine is possible in nature, but extremely unlikely. Typical mutagens used in IM are various forms of concentrated radiation and highly toxic synthetic chemicals including ethyl methanesulfonate (EMS), sodium azide (Az) and methylnitrosourea (MNU). Thus, IM uses means not possible under natural conditions. IM is also not included in the definition of Traditional or Classical breeding methods.
#3--Concerns about IM plant varieties as a general class involve the level of genetic damage they have sustained and how appropriate they are for use in organic farming systems. IM techniques almost invariably involve highly toxic chemical agents or radiation. "All three chemical mutagens are, as can be expected, strongly carcinogenic and should be handled with extreme care" (Sikora et al 2011). These mutagens create widespread genetic damage in the treated tissue (usually seeds). Poorly understood cellular mechanisms repair some or most of this damage, though many seeds are not viable. Those that are, can be grown out and crossed with healthy plants of existing varieties from the same species to start the process of creating a new, desired variety with a novel trait. In general, because of the destructive nature of the process, these new traits involve the deletion of genes, though sometimes a new trait that was previously suppressed can be expressed such as in red grapefruit.
The highly toxic chemicals or radiation used in IM are not allowed for direct use on organic farms or handling operations. Disposal of the chemicals and sources of radiation involve significant environmental risk. However, somewhat similar chemicals (though not radioactive materials) may be used in the production of organic inputs such as pesticides or processing chemicals. A critical difference here is that in the case of IM, living seed or tissues are exposed to them. One exception is in the de-linting of cotton seeds. Cotton seeds may be treated with strong hydrochloric acid for this purpose and used on organic farms. However, in general living seed or tissues used in organic production may not be treated with toxic chemicals or radiation.
The rates of mutation occurrence in IM are very high. On the order of a thousand times more mutations than normal results from the IM process. Spontaneous mutation rates per cell division across the full genome of plants listed in the TR vary from 4×10^{-3} to 567. In contrast, the range following IM was from 63 to 666,000.
In general, a group of seeds is considered "saturated" with mutations when 25-50% of treated seeds die from the mutagenesis treatment (Ke et al 2000).
Many of the survivors may have impaired function, however, desired mutations may be identified in some, and those genes may be introgressed into fully functional varieties via repeated backcrossing. Many, but not all of the damaged genes are removed this way. Backcrossing over a period of years can get rid of unwanted mutations, however some unknown background mutations can remain in the plant undetected even after many generations of selection (ZKBS, 2018).
According to the TR (lines 1863-1864), there is no specific number of backcrosses used to eliminate unwanted mutations. If an original IM plant had 1000x the normal level of mutations and each backcrossing event "cleaned up" 50% of them (Graham et al. 2020), then after 7 backcrosses the new progeny would still have about 8x the normal level. Hidden or apparently minor genetic damage could

be present in IM-derived varieties, and that these may not be fully able to fulfill their role in a healthy agro ecosystem. Thus, they would not be fully compatible with organic production.
It appears that IM meets the definition of an excluded method.
However, there has been history of the wide/safe use of induced mutagenesis in in the US and Europe in various crops like rice, wheat, tomato, soybean, and barley (Wieczorek and Wright, 2012; European Union, 2018). Furthermore, it has been documented that organic growers in the US currently use cultivars developed using induced mutagenesis (National Research Council, 2004). Researchers claim that gamma ray induced mutagenesis could potentially generate new plant varieties with desirable traits, contributing to crop improvement, agricultural sustainability, global food security while helping to mitigate existing climate change issues.
Although it is true that plant breeding is a continuous process with traits being passed down to subsequent generations through cross pollination, it would be difficult to know the extent to which traits (e.g. color, yields, drought, pest/disease tolerance etc.) altered by induced mutagenesis would be present in progeny varieties. Due to the unpredictable behavior of mutagenetic process, undesirable traits/genes may be expressed with the subsequent application of traditional breeding methods to IM varieties.
The decision to accept or exclude the induced mutagenesis breeding method therefore could, on one hand, limit the range of varieties available to organic farmers and on the other hand, contradict organic standards while compromising the integrity of organic products (Nawaz et al. 2020). We wish to honor organic agriculture's core values (ecology, health, fairness, and care) and request input from affected stakeholders including scientists, policy makers, non-breeders, consumers, and farmers to ensure transparency with information sharing.
The effects of IM varieties on crop yield, quality, the environment, and health need to be considered. If approved, comparative field trials with non-IM varieties under organic management could shed more light on this (Ntsomboh et al. 2023).
If IM is classed as an excluded method, the question arises as to whether and how the many plant varieties produced using it can be identified. The TR and other articles provide starting points for this. We request guidance on how this could be reasonably accomplished. Would it be necessary to make a list of prohibited varieties? Note that other new varieties using CRISPR and other excluded methods may require such a list as well, since they may not be readily identified as GMO's.
Another option would be to focus only on varieties introduced after the decision is made. Perhaps only new varieties produced using IM would be prohibited, since prohibiting older varieties produced using IM could be disruptive to the production and markets of many crops. Would it be advisable to "grandfather" such older varieties for use, perhaps prohibiting them for use in future crosses along with any new IM varieties? For instance, could it be argued that they are acceptable, having been sufficiently "cleaned up" of undesirable hidden mutations via many backcrosses with healthy partners?
These are difficult problems. We welcome input from all stakeholders on how best to move forward.

Questions for stakeholders

1. Should induced mutagenesis be classed as an excluded method? On what basis?
2. If IM is determined to be an excluded method, how should varieties produced using it be handled?

a. Should all varieties with IM heritage be disallowed for organic production? How would this be managed?
b. Should varieties with IM background currently in use be allowed, and IM be prohibited from use in plant breeding going forward?

3. Should varieties with IM be allowed, perhaps on the basis that IM is compatible with organic production because subsequent backcrossing sufficiently reduces any negative features it may introduce?

Subcommittee Vote:

Motion to accept the discussion document on excluded methods/Induced mutagenesis
Motion by: Franklin Quarcoo
Seconded by: Logan Petrey
Yes: 7 No: 0 Abstain: 0 Recuse: 0 Absent: 1

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National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
Potassium Phosphate(s)
August 9 2024

Summary of Petition [link]:

Potassium phosphate is currently allowed on the National List of Allowed and Prohibited Substances (the National List) portion of the USDA organic regulations in 7 CFR 205.605(b)(28) with the following annotation: *For use only in agricultural products labeled "made with organic (specific ingredients or food group(s)),"* prohibited in agricultural products labeled "organic."

The petitioner asks: (1) to remove the restriction that potassium phosphate can only be used in products labeled 'made with organic ingredients' and (2) to change "potassium phosphate" to "potassium phosphates," which would allow new types of potassium phosphate (*e.g.,* diphosphates and triphosphates) in organic food products

The petitioner states the current views on phosphates are outdated. This petition argues that removing the restriction on use would:

1. Make it possible for potassium phosphate(s) to replace sodium phosphate in organic food, thereby lowering sodium content of processed foods. This is in response to FDA's proposed rule to permit the replacement of salt completely or partially with potassium phosphate.
2. Align organic with the Food Safety and Inspection Service (FSIS) "safe and suitable" use of potassium phosphates for meat and poultry products.
3. Not have a negative impact on human health, as newly published research suggests.

Context:

The Organic Foods Production Act of 1990 (OFPA) (7 U.S.C. chapter 94) establishes criteria [in §§6518(m)(1) – (7)] the Board must consider when evaluating a substance for inclusion on the National List. Section 6518(m)(6), specifically, requires the Board to consider the availability of alternative practices and substances. Several potential alternative substances allowed for use in organic handling are identified in Table 1, shown as Appendix 1.

Furthermore, in addition to the review criteria in §6518(m), §6517(c)(1)(A) prohibits allowing substances in organic production that are harmful to human health. One method for evaluating substances against this requirement is to check if the U.S. Food and Drug Administration (FDA) determined the substance is "generally recognized as safe" for human consumption, also referred to as GRAS (21 CFR part 182).[1] One form of potassium phosphate, dipotassium phosphate, is listed in FDA regulations as GRAS (21 CFR 182.6285); other forms of potassium phosphate may be allowed as food additives. There were no GRAS Notices found for potassium phosphate, but a GRAS Notice was found for a related substance, sodium potassium hexametaphosphate (GRN No. 316).[2] Reports were found for potassium phosphate monobasic, potassium phosphate dibasic, and potassium phosphate tribasic in the GRAS Substances Database (SCOGS).[3]

[1] Generally Recognized as Safe (GRAS). *FDA*. www.fda.gov/food/food-ingredients-packaging/generally-recognized-safe-gras.
[2] GRAS Notices. *FDA*. https://www.cfsanappsexternal.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices.
[3] SCOGS Reports. *FDA*. https://www.cfsanappsexternal.fda.gov/scripts/fdcc/index.cfm?set=SCOGS.

Summary of Review and Discussion:

This substance has been examined multiple times by the NOSB, as it is already on the National List for use, albeit in a restricted fashion. A 2016 discussion document, titled "Cumulative impact of phosphates in organic food" discussed phosphates in general. A 2016 Technical Report provided current information on phosphates. The NOSB voted to leave potassium phosphate on the list, with the annotation, in 2021.

Given that the substance has already been classified and is already on the list, the NOSB's response to the petition focuses only on the request to change the annotation and to change the listing to potassium phosphates. We first examine whether there are sufficient changes in the scientific evidence since the 2016 discussion document.

New scientific research

The petitioner's addendum dated May 2024 included a peer reviewed journal article reporting research that was funded by the petitioner; furthermore, the following disclosure is included on the publication:

> We acknowledge the support and coordination of Berit Dockter; Scientific and Regulatory Affairs Manager of the International Food Additives Council on managing project details.

Fulgoni, K., Fulgoni III, V.L. and Wallace, T.C., 2022. Association of total, added, and natural phosphorus intakes with biomarkers of health Status and mortality in healthy adults in the United States. Nutrients, 14(9), p.1738.

In this paper, Fulgoni et al. attempt to separate health impacts of natural and added phosphorous using The Center for Disease Control's National Health and Nutrition Examination Survey (NHANES) data in tandem with industry supplied data on phosphorous content of foods. The authors refer to the current understanding of phosphorous: "*Elevated serum phosphate levels, otherwise known as hyperphosphatemia, have been associated with changes in health status, of note detrimental effects on cardiovascular and renal health." (quote from abstract).* Their work has two results relevant to this petition: (1) no 'meaningful' association between phosphorous and mortality was identified and (2) naturally occurring phosphorous intake was found to be negatively associated with the risk of increased blood pressure.

The Subcommittee discussion centered on the following:

1. FDA's designation of GRAS applies only to dipotassium phosphate, with no other potassium phosphate salts deemed GRAS.

2. As shown in Appendix A, many materials already on the National List are available for the uses mentioned in the petition.

3. The findings of the search of the peer reviewed literature targeted recent publications (see Appendix B for select list). The literature search revealed that the health concerns remain unchanged. The publications we identified mentioned: the likelihood that dietary exposure to phosphates is underestimated; the typical person is exposed to more than twice the recommended amount; and impacts on brain, cardiovascular, kidneys, bone health, and overall

mortality. Thus, the bulk of the evidence still points to health concerns about dietary exposure to phosphate(s) in general.

4. The paper submitted by the petitioner – funded and managed by the petitioner – appears to be the lone paper we were able to locate that finds no significant relationship between phosphorous intake and negative health outcomes (including the papers that cite this work).

5. The subcommittee finds that the body of research finding no health impacts is not sufficiently robust and is still outweighed by the vast amount of the research that finds negative health impacts of phosphorous. Thus, the health concerns raised in the 2016 NOSB Discussion Document remain relevant.

Classification Motion:
Potassium phosphate has already been classified as synthetic.

National List Motion:
Motion to remove the annotation restricting the use of potassium phosphate to 'made with organic ingredients' and to add an "s" to phosphate at 205.605(b)
Motion by: Carolyn Dimitri
Seconded by: Jerry D'Amore
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

Appendix A: Other products on the National List that are alternatives to potassium phosphate, by use

Table 1: Potassium phosphate alternatives on the National List. Organized by potassium phosphate petitioned functions.

Potassium phosphate petitioned use	National List (7 CFR 205.605 and/or 205.606) alternative substance
As a **pH buffer**, to adjust the pH	Calcium chloride[4] Calcium citrate[5] Calcium hydroxide[6] Citric acid[5] Glucono delta-lactone[7] Lactic acid[4,5] Phosphoric acid[6] Potassium carbonate[6] Potassium chloride[6] Potassium citrate[5] Potassium hydroxide[7] Potassium lactate[7] Sodium citrate[5] Sodium hydroxide[8] Sodium lactate[7] Sodium phosphates[9] Tartaric acid[4]
In processed cheese products, both for pH buffering and also to interact with milk proteins to promote emulsification (**emulsifier**)	Agar-agar[7] Alginates[6] Calcium citrate[5] Carrageenan[7] Gellan gum[6] Glycerides[6] Lecithin[6] Magnesium stearate[6] Phosphoric acid[6] Potassium citrate[5] Sodium acid pyrophosphate[5] Sodium citrate[5] Sodium phosphates[9] Tamarind seed gum[6] Tartaric acid[7] Tragacanth gum[6] Xanthan gum[6]

[4] Chen, B.Y., A.S. Grandison, and M.J. Lewis. "Comparison of Heat Stability of Goat Milk Subjected to Ultra-High Temperature and in-Container Sterilization." *Journal of Dairy Science*. 95, no. 3 (March 1, 2012): 1057–63. https://doi.org/10.3168/jds.2011-4367.
[5] Spring 2024 Handling Sunset Review, www.ams.usda.gov/sites/default/files/media/HS2026SunsetRvwMtg1RqstPublicCmmnt2024.pdf
[6] Fall 2023 Handling Sunset Review, www.ams.usda.gov/sites/default/files/media/HS2025SunsetRvwMtg2_0.pdf
[7] Fall 2021 Handling Sunset Review, www.ams.usda.gov/sites/default/files/media/HS2023SunsetRvwFinalRec.pdf
[8] Fall 2020 Handling Sunset Review, www.ams.usda.gov/sites/default/files/media/HS2022SunsetRecs_webpost.pdf
[9] Fall 2022 Handling Sunset Review, www.ams.usda.gov/sites/default/files/media/HS2024SunsetRvwFinalReviews.pdf

Potassium phosphate petitioned use	National List (7 CFR 205.605 and/or 205.606) alternative substance
In casein-based coffee creamers, to stabilize the protein layer and thus prevent syneresis and curdling of the protein when added to hot, acidic coffee or tea (use a **gelling agent** to prevent syneresis)	Agar-agar[7] Calcium carbonate[6] Carob bean gum[6] Carrageenan[7] Gelatin[5] Guar gum[6] Gum arabic[6] Locust bean gum[6] Tamarind seed gum[6] Gellan gum[6] Pectin[9]
As a nutrient and buffer in fermentation operations (**ferment**)	Calcium carbonate[7] Magnesium sulfate[5] Microorganisms[5] Potassium citrate[5] Sodium hydroxide[7] Yeast[5]
As a **sequestrant** in meat and poultry products to decrease the amount of cooked-out juices (**chelate**)	Calcium citrate[5] Calcium phosphate (monobasic)[8] Citric acid[5,8] Glucono delta-lactone[7] Potassium citrate[5] Sodium acid pyrophosphate[5] Sodium phosphates[9] Tartaric acid[7]
As a **mineral** supplement in foods and beverages to provide **potassium** fortification	Potassium carbonate[6] Potassium chloride[6] Potassium citrate Potassium hydroxide[5,7] Potassium iodide[5] Tartaric acid (to make potassium salts)[7]
As a partial substitute for sodium chloride or in combination with sodium phosphates to reduce sodium content in food products (**sodium** or **salt**)	Calcium phosphate (monobasic and dibasic)[8] Potassium carbonate[6] Potassium chloride[6] Potassium citrate[5]

Potassium phosphate petitioned use	National List (7 CFR 205.605 and/or 205.606) alternative substance
In ice cream and frozen desserts as a protein **stabilizer** (**stabilization**) [and/or] To promote heat stability (acting as a **chaperone**) for whey proteins during thermal processing to prevent destabilization during processing and aggregation of the protein (**stability, stabilization,** or **stabilizer** in dairy)	Alginates[6] Calcium carbonate[6] Carob bean gum[6] Enzymes[5] Gellan gum[6] Glycerides[6] Guar gum[6] Gum arabic[6] Locust bean gum[6] Potassium acid tartrate[9] Potassium chloride[6] Sodium acid pyrophosphate[5] Sodium carbonate[9] Sodium citrate[5] Sodium phosphates[9] Tamarind seed gum[6] Xanthan gum[6]
To promote **stabilization** for Indirect Ultra High Temperature (UHT) pasteurized dairy products.	Calcium phosphate[8]
Aid **emulsification** in Indirect UHT pasteurized dairy products.	Lecithin[6]
Assists in **removing excess calcium** and/or **adjust the pH** in Indirect UHT pasteurized dairy products.[4,10]	Calcium citrate[5] Potassium citrate[5] Sodium citrate[5]
To promote **stabilization of proteins** and **prevent product separation** in Indirect UHT pasteurized dairy products.	Sodium phosphates[9]

Appendix B: Select readings identified in literature search

Bird, R.P. and Eskin, N.M., 2021. The emerging role of phosphorus in human health. In *Advances in food and Nutrition Research* (Vol. 96, pp. 27-88). Academic Press.

- The intake of phosphorus by the general population world-wide is almost double the amount required to maintain health. This increase is attributed to the incorporation of phosphate containing food additives in processed foods purchased by consumers. The role of phosphorus and its polymers in the renal and cardiovascular system as well as on brain health appear to be important and promising future research directions.

[10] *UHT milk is heated to high temperatures to destroy pathogens, which allows this milk to be shelf-stable without refrigeration. However, there can be some unwanted effects in UHT milk that results from this heat. One type of unwanted effect is sediment formation from calcium ions. Stabilizing salts, like potassium phosphate, are added to remove calcium ions from UHT milk.*

Brown, R.B., Bigelow, P., Dubin, J.A. and Mielke, J.G., 2023. High dietary phosphorus is associated with increased breast cancer risk in a US Cohort of middle-aged women. *Nutrients*, *15*(17), p.3735.

Calvo, M.S. and Uribarri, J., 2017. Phosphorus in the modern food supply: underestimation of exposure. *Clinical aspects of natural and added phosphorus in foods*, pp.47-76.

- Problematic for chronic kidney disease

Chazelas, E., Deschasaux, M., Srour, B., Kesse-Guyot, E., Julia, C., Alles, B., Druesne-Pecollo, N., Galan, P., Hercberg, S., Latino-Martel, P. and Esseddik, Y., 2020. Food additives: distribution and co-occurrence in 126,000 food products of the French market. *Scientific reports*, *10*(1), p.3980.

- Describes phosphates as having suspected health effects

Deng, C.Y., Ke, X.P. and Guo, X.G., 2024. Dietary calcium, phosphorus, and potassium intake associated with erectile dysfunction in the National Health and Nutrition Examination Survey (NHANES) 2001 to 2004. *Plos one*, *19*(2), p.e0297129.

Ma, J., Li, P., Jiang, Y., Yang, X., Luo, Y., Tao, L., Guo, X. and Gao, B., 2024. The Association between Dietary Nutrient Intake and Acceleration of Aging: Evidence from NHANES. *Nutrients*, *16*(11), p.1635.

Rubio-Aliaga, I. and Krapf, R., 2022. Phosphate intake, hyperphosphatemia, and kidney function. *Pflügers Archiv-European Journal of Physiology*, *474*(8), pp.935-947.

- High dietary phosphate intake and hyperphosphatemia are progression factors for declining kidney function and are associated with higher cardiovascular disease and mortality risk. This is best established for pre-existing chronic kidney disease, but epidemiological and experimental data strongly suggest that this holds true for subjects with normal renal function as well.
- An important proportion of the population is consuming regularly twice the amount of phosphate recommended. Studies indicate that this high phosphate consumption may lead to higher incidence of kidney disease and associated risks such as cardiovascular disease and bone disorders and a higher mortality rate.

National Organic Standards Board
Handling Subcommittee
L-Malic Acid Reclassification Proposal
July 16, 2024

Summary of Issue.
Reclassification of L-Malic Acid has been on the National Organic Standards Board (NOSB's) work agenda for a number of years, and the Handling Subcommittee (HS) is attempting to resolve the ongoing classification issue at this sunset review of L-Malic Acid. The sunset review can be found in a separate document. This proposal focuses squarely on classification of L-Malic Acid and whether it should be listed at 7 CFR 205.605(a) or 7 CFR 205.605(b).

L-malic acid occurs naturally in many fruits and vegetables, including apples and cherries, and can be obtained by enzymatic conversion of fumaric acid and by fermentation of glucose and other carbohydrates. It is not economical to extract L-malic acid from natural foodstuffs such as apple juice. In the first round of the sunset review, in Spring 2019, a number of commenters questioned whether commercially available L-malic acid comes from nonsynthetic sources, as this listing restricts. Commenters noted that while supporting documentation may state L-malic acid is produced naturally via enzymatic fermentation, this statement refers only to the second half of the process. Industrial quantities of L-malic acid are made using biological processes, with the major industrial process to produce L-malic acid being a two-step procedure:

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

More detailed information on the two-step process can be found in Appendix A of the 2019 Technical Report.

There are two options for obtaining the fumaric acid in the first step in this process: 1) The fumaric acid precursor is obtained through the fermentation of carbohydrates (i.e., *Rhizopus spp*.) or, 2) The fumaric acid precursor is obtained as a synthetic product from maleic acid of petroleum origin. Commercial quantities of nonsynthetic L-malic acid may also be produced using a one-step fermentation process through biological methods such as microbial fermentation using *Aureobasidium pullulans* and *Penicillium vitacola*, though it is not believed that this process is occurring on a scale that would accommodate the needs of the current market. The major commercial source of L-malic acid is enzymatic conversion of synthetic fumaric acid to L-malic acid by immobilized microbes (Chibata et al. 1983; Chi et al. 2016a; Dai et al. 2018). If the malic acid produced by this method is synthetic, most, if not all, of the L-malic acid on the market will also be synthetic (Goldberg et al. 2006; Chibata et al. 1983; Engel et al. 2008; Chi et al. 2016a; Dai et al. 2018).[All citations from 2019 TR]

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

L-malic acid can also be produced by microbes in a one-step fermentation process fueled by glucose or other carbohydrates. Reaction conditions are adjusted to cause overproduction of L-malic acid, which is an essential product of microbe metabolism. While this production process is possible, it is not clear how much is produced and whether it will be able to produce sufficient quantities to supply handlers currently relying on the L-malic acid produced by the synthetic process.

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

Discussion
The ongoing discussion around L-malic acid is not whether it is essential to organic handling or if it has detrimental effects on the environment or human health. In fact, there is broad agreement that it is essential, particularly to juice manufacturers, and there is no evidence to suggest that it does not meet National List criteria. However, as the organic material review process has become more refined and the production methods of L-malic acid has changed, we now see that much of the L-malic acid used in organic processing is "synthetic" while L-malic acid is currently listed at 7 CFR 205.605(a) as a "nonsynthetic" substance.

Previous Handling Subcommittees have suggested relisting L-malic acid at §205.605(b) as a "synthetic" substance to accurately reflect the predominant production method, and to ensure that the classifications inherent to the National List of nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" are consistent with NOP material classification guidance.

This Subcommittee agrees with the previous Board and suggests adding L-malic acid to §205.605(b) to reflect that most L-malic acid used in organic food processing is synthetic in origin. However, the Subcommittee has declined to recommend L-malic acid be removed from §205.605(a), as there may be nonsynthetic forms of L-malic acid in use, and should commercial quantities of nonsynthetic L-malic acid become available, organic processors may show a preference for a nonsynthetic option.

The NOSB did not receive any comments at the Spring 2024 meeting that quantified the amount of nonsynthetic L-malic acid currently in use, but commenters confirmed that most of what is currently in use would be classified as 'synthetic.' There were numerous opinions regarding how 'synthetic' L-malic acid should be considered or added to the National List. Some commenters preferred adding L-malic at §205.605(b) and keeping the nonsynthetic listing at §205.605(a). Some commenters preferred removing L-malic from §205.605(a) and requiring a petition to add it at §205.605(b). There appears to be general consensus that the substance currently in use by organic processors is classified as 'synthetic' and its allowance should be reflected by inclusion at §205.605(b). However, there is disagreement about whether the nonsynthetic listing should remain or if NOSB should recommend addition at §205.605(b) as part of the L-malic acid classification work agenda item or if a petition should be required for the reclassification.

The HS does not see any justification for removal of L-malic acid during this sunset review and views the classification as a critical revision that must be made. However, the classification of L-malic acid used by organic processors (e.g. synthetic or nonsynthetic) does not impact the substance's compatibility with National List criteria, and L-malic acid should remain on the National List. At this sunset review, the HS proposes an additional classification and listing motion, so the National List accurately reflects the classification of the substance in use in organic processing. These motions are not contingent in any way

on the motion to remove L-malic as part of the OFPA mandated sunset review process, but they are discussed in the HS sunset recommendation for clarity and ease of reference. The HS believes that L-malic should remain at §205.605(a) to clarify that nonsynthetic forms of this substance remain allowed in organic processing. Should, in future sunset reviews, new information raise clear concerns about either the nonsynthetic or synthetic form of the substance, the NOSB will have the option to remove it with a decisive vote.

Classification Motion:
Motion to classify L-malic acid produced by fermentation of fumaric acid as synthetic
Motion by: Nate Lewis
Second by: Kyla Smith
Yes: 9 No: 0 Abstain: 0 Recuse: 0 Absent: 0

National List Motion:
Motion to add L-malic acid at 205.605(b)
Motion by: Nate Lewis
Second by: Kim Huseman
Yes: 9 No: 0 Abstain: 0 Recuse: 0 Absent: 0

National Organic Standards Board
Crops Subcommittee
Petitioned Material Discussion Document
Ethylene
August 6, 2024

Summary of Petition
The National Organic Standards Board (NOSB) received a petition to expand use of ethylene gas to include sprouting inhibition on organic potatoes and onions. The petitioner is a manufacturer of equipment that generates ethylene gas onsite through the catalytic conversion of ethyl alcohol. Ethylene is currently allowed at 7 CFR 205.605(b) for use in postharvest ripening of tropical fruit and degreening of citrus.

Summary of Review:
The Handling Subcommittee (HS) has ordered a limited scope technical review (TR) to evaluate any human health or environmental concerns related to the use of ethylene, specifically when used to inhibit sprouting of potatoes or onions. We anticipate receiving this TR in sufficient time to inform a proposal for the Spring 2025 meeting. The HS has also interviewed organic potato and onion growers to gauge interest in use of the substance. One organic potato grower indicated that the nonsynthetic sprout inhibitor currently allowed, clove oil, has limited effectiveness and can cause significant irritation to workers applying it. One organic onion grower expressed interest in the use of ethylene if it reduced the percentage of onions that must be culled when packing. As we await the technical review, we welcome any feedback from stakeholders on the use of ethylene as a sprout inhibitor in organic potatoes and onions.

Questions:

1. Ethylene has the potential to extend storage life and reduce culls in organic potatoes and onions. Should HS consider this substance any differently than it does for ripening tropical fruit because in the petitioned use it would be inhibiting growth rather than encouraging it?
2. It appears that clove oil is currently in use to inhibit sprouting in organic potatoes, but it may be less effective and cause health risks for workers. How should HS consider petitioned synthetic substances which may pose less of a human health concern than natural alternatives?
3. If the HS recommends an annotation change to ethylene to permit its use as a sprout inhibitor, should HS consider any additional revisions to the annotation related to ripening of tropical fruit or degreening citrus for these allowed uses to be more clear?

Subcommittee Vote:
Motion to accept the discussion document on ethylene petitioned for use as sprout inhibitor on organic potatoes and onions.
Motion by: Nate Lewis
Second by: Kyla Smith
Yes: 7 No: 0 Abstain: 0 Recuse: 0 Absent: 2

Sunset 2026
Meeting 2 - Reviews
Handling Substances § 205.605(a), § 205.605(b), § 205.606
October 2024

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 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. Substances included in this document may also be viewed in the NOP's Petitioned Substances Index.

Request for Comments

Written comments should be submitted via Regulations.gov at www.regulations.gov on or before September 30, 2024, as explained in the meeting notice published in the Federal Register.

Public 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 Substances in Organic Production at § 205.605(a), § 205.605(b), and/or § 205.606:

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 Substances in Organic Production at § 205.605(a), § 205.605(b), and/or § 205.606:

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.

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.

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

Written public comments will be accepted through September 30, 2024 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)).’’:

Acids - Citric
Acids - Lactic
Calcium chloride
Enzymes
L-Malic acid
Magnesium sulfate
Microorganisms
Perlite
Potassium iodide
Pullulan
Yeast

§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)).’’:

Activated charcoal

Ascorbic acid
Calcium citrate
Collagen gel
Ferrous sulfate
Hydrogen peroxide
Nutrient vitamins and minerals
Peracetic acid/Peroxyacetic acid
Potassium citrate
Potassium phosphate
Sodium acid pyrophosphate
Sodium citrate
Tocopherols

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

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

Acids Citric

Reference: § 205.605(a) Nonsynthetics allowed
(1) Acids (Citric – produced by microbial fermentation of carbohydrate substances; and Lactic).
Technical Report: 1995 TAP - Citric; 2015 TR - Citric; 1995 TAP - Lactic; 2015 TR - Lactic; 2023 Limited Scope TR (Citric acid and salts)
Petition(s): N/A
Past NOSB Actions: 04/1995 recommendation; 11/2005 sunset recommendation; 03/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

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

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

NOSB requested a limited scope TR for citric acid in preparation for this sunset review. The limited scope TR focused on the microorganisms used in the fermentation process to manufacture citric acid and what potential there is for these microorganisms to have been produced through excluded methods as defined by the NOP regulations. Based on available information, most citric acid manufacturers use wild type fungal strains or strains that are products of classical induced mutagenesis. The use of microorganisms developed using excluded methods appears to remain at an experimental phase and is not commercially available.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed in feed. Preference should be given to bacterial or enzymatic additives derived from bacteria, fungi, plants, and food by-products (such as molasses and whey). The following acids may be used: lactic, propionic, and formic. (Table 5.2, Hay or silage preservation products listing, CAN/CGSB-32.311-2020 page 24)

Allowed as food additives. (Table 6.3, CAN/CGSB-32.311-2020, page 30)

Allowed as processing aids from fruit and vegetable products or produced by microbial fermentation of carbohydrate substances. (Table 6.5, Citric acid listing, CAN/CGSB-32.311-2020, page 38)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Citric acid is allowed in plant & animal products as a processing aid. Lactic acid is allowed in the brine of cheese products (Annex V, Part A, Section A2, 2021/1165)

Both lactic and citric acids are allowed in animal and plant products as additives. (Annex V, Part A, Section A1, 2021/1165)

Both lactic and citric acids are allowed for the regulation of pH in primary yeast production. (Annex V, Part C, 2021/1165)

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Citric acid is allowed in the following foods of plant origin: Fruits and vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera, seaweeds, and nuts and seeds).

Citric acid is allowed in the following foods of animal origin: fats and oils essentially free from water, egg and egg products, and as a coagulation agent for specific cheese products and for cooked eggs. (Table 3 - page 24)

Lactic acid is allowed in the following foods of plant origin: Fermented vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes and aloe vera) and seaweed products. Not allowed in fermented soybean products.

Allowed in the following foods of animal origin: Dairy products and analogues. Not allowed in edible casings. (Table 3 - page 24)

International Federation of Organic Agriculture Movements (IFOAM)
The IFOAM NORMS for Organic Production and Processing allow citric acid as an additive and a processing and post-harvest handling aid in Appendix 4, Table 1.

Citric acid is allowed in equipment cleaners and disinfectants (Appendix 4, Table 2).

Japan Agricultural Standard (JAS) for Organic Production
Allowed as an additive. Limited to the use as a pH control agent or in processed vegetable products or processed fruit products. (Appended Table 1)

Ancillary Substances
Citric acid is commercially supplied as a pure compound and otherwise does not contain ancillary substances.

Human Health and Environmental Issues
Although it is a weak acid, exposure to pure citric acid may cause coughing, shortness of breath, and skin irritation. The fermentation process does produce by-products including oxalic acid. Citric acid will degrade

to produce non-toxic and non-persistent environmental products. The potential health hazard of citric acid is moderate based on systemic toxicity (EPA 2007). EPA listed citric acid as List 4A (minimal risk inert) in their 2004 list and currently list citric acid at 40 CFR 180.950(e) as a tolerance exempt inert ingredient.

Discussion
Citric acid remains an essential ingredient for organic food processors, and NOSB does not have any new information to suggest that citric acid should be removed from the National List at 7 CFR 205.605(a). NOSB requested a limited scope TR to evaluate the potential for microorganisms used in the fermentation process of citric acid manufacturing to be products of excluded methods. The TR indicated that the use of genetically modified microorganisms remains only in experimental phase in the production of citric acid, and it listed numerous suppliers of citric acid that utilize either wild type fungal strains or strains that are the product of classical induced mutagenesis. This indicates that there is ample supply of citric acid that complies with the prohibition on excluded methods in organic food.

There were numerous commenters who provided insight into the issue of whether a commercial availability requirement was appropriate for citric acid at this point. While conceptually, most commenters expressed a preference for an organic option and indicated that there is some organic citric acid available in the marketplace, it was also noted that the organic supply fails to meet the current demand. Discussion occurred regarding the impact a commercial availability clause for citric acid would have on the organic industry, and it appears as though it would create additional recordkeeping burden without having a significant impact on use of organic citric acid. Therefore, at this sunset review, NOSB does not recommend adding an annotation to citric acid requiring organic forms when commercially available. However, it is important to regularly revisit the potential for an organic version of any National List item to replace the non-organic version, and the use of a commercial availability annotation should be considered in that review.

Questions to our Stakeholders
There are now numerous suppliers of certified organic citric acid. Should NOSB consider recommending the addition of an annotation to citric acid requiring processors to use an organic version of citric acid when commercially available?

Justification for Vote
The Subcommittee finds citric acid compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote:
Motion to remove citric acid from the National List
Motion by: Nate Lewis
Seconded by: Kyla Smith
Yes: 0 No: 9 Abstain: 0 Recuse: 0 Absent: 0

Acids Lactic

Reference: § 205.605(a) Nonsynthetics allowed
(1) Acids (Citric – produced by microbial fermentation of carbohydrate substances; and Lactic).
Technical Report: 1995 TAP - Citric; 2015 TR - Citric; 1995 TAP – Lactic; 2015 TR - Lactic; 2023 Limited Scope TR (Citric acid and salts)
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 03/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Lactic acid is widely used in almost every segment of the food industry, where it carries out a wide range of functions. The major use of lactic acid is in food and food-related applications, which in the U.S. accounts for approximately 85% of the demand. It is found naturally in milk, meat, and beer but is normally associated with sour milk. Lactic acid controls the growth of bacteria including listeria (NOSB Fall Meeting Transcript 2015 pp. 263). The other uses are non-food industrial applications. Lactic acid occurs naturally in many food products. It has been in use as an acidulant and pH regulator for many years. It regulates microflora in food and has been found to be very effective against certain types of microorganisms, giving it pronounced efficacy as a preservative (Vijayakumar, Aravindan and Viruthagiri 2008). Other uses include mixing with sodium, potassium, and distilled water to form intravenous fluids commonly used after blood loss. It is sometimes used in the pharmaceutical industry to adjust acidity. Lactic acid appears on the National List, 7 CFR Part 205.605(a), as a non-synthetic material without further annotation.
Common uses include, but are not limited to:

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

Manufacture
First isolated in 1780 from sour milk, lactic acid can be produced both naturally and synthetically. It can be produced in either a solid, water-soluble state, or a colorless liquid state. Lactic acid is produced on an industrial scale through carbohydrate fermentation performed by lactic acid bacteria converting simple carbohydrates such as glucose, sucrose, or galactose to lactic acid. A secondary manufacturing process involves chemical synthesis of adding hydrogen cyanide to acetaldehyde, an organic chemical compound found in coffee, bread, ripe fruit, coal, or crude oil. This process only exists today in Japan. There is also a group of microbes known broadly as Lactic Acid Bacteria which produce lactic acid as a result of carbohydrate fermentation.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed in feed. Preference should be given to bacterial or enzymatic additives derived from bacteria, fungi, plants, and food by-products (such as molasses and whey). The following acids may be used: lactic, propionic, and formic. (Table 5.2, Hay or silage preservation products listing, CAN/CGSB-32.311-2020 page 24)

Allowed as food additives. (Table 6.3, CAN/CGSB-32.311-2020, page 30)

Allowed as processing aids from fruit and vegetable products or produced by microbial fermentation of carbohydrate substances. (Table 6.5, Citric acid listing, CAN/CGSB-32.311-2020, page 38)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Citric acid is allowed in plant & animal products as a processing aid. Lactic acid is allowed in the brine of cheese products (Annex V, Part A, Section A2, 2021/1165)

Both lactic and citric acids are allowed in animal and plant products as additives. (Annex V, Part A, Section A1, 2021/1165)

Both lactic and citric acids are allowed for the regulation of pH in primary yeast production. (Annex V, Part C, 2021/1165)

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Citric acid is allowed in the following foods of plant origin: Fruits and vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera, seaweeds, and nuts and seeds).

Citric acid is allowed in the following foods of animal origin: fats and oils essentially free from water, egg and egg products, and as a coagulation agent for specific cheese products and for cooked eggs. (Table 3 - page 24)

Lactic acid is allowed in the following foods of plant origin: Fermented vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes and aloe vera) and seaweed products. Not allowed in fermented soybean products.
Allowed in the following foods of animal origin: Dairy products and analogues. Not allowed in edible casings. (Table 3 - page 24)

International Federation of Organic Agriculture Movements (IFOAM)
The IFOAM NORMS for Organic Production and Processing allow citric acid as an additive and a processing and post-harvest handling aid in Appendix 4, Table 1.

Citric acid is allowed in equipment cleaners and disinfectants (Appendix 4, Table 2).

Japan Agricultural Standard (JAS) for Organic Production
Allowed as an additive. Limited to the use as a pH control agent or in processed vegetable products or processed fruit products. (Appended Table 1)

Ancillary Substances
None

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

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

Lactic acid is one of the most widely distributed acids and preservatives in nature. It is produced naturally by humans, animals, and microorganisms. Lactic acid is an acidulate that is a natural organic acid present in milk, meat and beer, but is normally associated with sour milk. It occurs naturally in two isomers (D) and (L). (D) is harmful to humans so (L) is the preferred isomer for food and pharmaceuticals. It functions as a flavor agent, preservative and acidity adjuster in foods.

There is no known organic alternative to lactic acid.

Questions to our Stakeholders
None

Justification for Vote
The Subcommittee finds lactic acid compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote:
Motion to remove lactic acid from the National List
Motion by: Nate Lewis
Seconded by: Kyla Smith
Yes: 0 No: 9 Abstain: 0 Recuse: 0 Absent: 0

Calcium chloride

Reference: § 205.605(a) Nonsynthetics allowed
(7) Calcium chloride.
Technical Report: 1995 TAP, 2024 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 03/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Calcium chloride is used in a wide variety of food processing applications including the following, as listed in the Table 3 in the 2024 TR:

- Firming agent (fish, mushrooms, processed whole and cut vegetables)
- Flavor enhancer (beer, canned breadnut seeds, cucumber pickles, processed meat products)
- Nutrient supplement (dairy products, nutrition beverages, tofu)
- pH control agent (beer)
- Processing aid (bakery products, beer, cheese, tofu)
- Stabilizer and thickener (fruit jams and jellies)
- Synergist in combination with sodium alginate (dressings, fruit snacks, sauces, soups)
- Tenderizer/texturizer (beef, chicken, goose, lamb, rabbit)

Manufacture
According to the 2024 TR, calcium chloride can be produced from three different sources/processes:

- From natural brines
- Reaction of calcium hydroxide with ammonium chloride (Solvay ammonia-soda process)
- Reaction of hydrochloric acid with calcium carbonate

The TR also mentioned a fourth method claimed by TETRA Technologies, as a byproduct of the manufacturing of magnesium oxide. The TR authors couldn't find details on this process or mention of it elsewhere. [2024 TR 487-494]

Calcium chloride derived from brines are nonsynthetic in many cases. However sometimes depending on the brine process, classification becomes more complicated. The starting material is a natural brine solution that is pumped out from underground salt beds and calcium chloride is what is left when other materials are extracted from the brine. When calcium chloride uses evaporation for the extraction, it is effectively unchanged (more concentrated and some ions are removed). This process is nonsynthetic. However, sometimes other chemicals are added such as calcium hydroxide or slaked dolime. These substances are processing aids added to remove other substances and they may leave residues of calcium and chloride in the final calcium chloride product and would be indistinguishable from their natural counterparts. [2024 TR 496-628]

Calcium chloride may also be commercially obtained as a byproduct in the ammonia-soda (Solvay) process (synthetic). Soda ash can also be produced in other ways, such as through the chlor-alkali process or by utilizing an ore called "trona". According to the TR, trona is rare in the EU, so almost all of the soda ash

produced in the EU utilizes the Solvay process. However, trona is plentiful in the US and since that process is cheaper, very little soda ash is produced from the Solvay process in the US. Therefore, when calcium chloride is sourced from the US, the likelihood that it is processed using the Solvay process is quite low. [2024 TR 630-676]

Lastly, calcium carbonate can be produced from the reaction of hydrochloric acid with calcium carbonate, which is a process that renders the calcium chloride synthetic. However, the TR states that it is unclear how relevant this process is for current industrial production. [2024 TR 678-697]

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed as food additives in milk products; fat products; soybean products; and fruits and vegetables. (Table 6.3, CAN/CGSB-32.311-2020, page 30)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Allowed as a coagulation agent in dairy products. (Annex V, Part A, Section A1, 2021/1165)

Allowed as a coagulation agent in products of plant origin & sausages based on meat. (Annex V, Part A, Section A2, 2021/1165)

Allowed as a processing aid for the production of primary yeast. (Annex V, Part C, 2021/1165)

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Allowed in the following plant origin products: fruits and vegetables (including mushrooms, seaweeds, and nuts and seeds) and soybean products (excluding seasonings, condiments and fermented soybean products).

Allowed in the following animal origin products: Dairy products and analogues. Not allowed in processed meat, poultry, poultry and game products, edible casings. (Table 3 - page 28). Allowed as a firming/coagulation agent in cheese making. (Table 4 - pages 30-31)

International Federation of Organic Agriculture Movements (IFOAM)
Allowed as an as additive and processing/post-harvest handling aid. (Appendix 4 - Table 1 - page 80)

Japan Agricultural Standard (JAS) for Organic Production
Allowed as an additive. Limited to the use as a coagulant in processed products of plant origin/cheesemaking, or in edible oils or fats, processed vegetable products, processed fruit products, products containing beans, dairy products, or processed meat products. (Appended Table 1)

Ancillary Substances
None

Human Health and Environmental Issues
Environment: The 2024 TR indicated that calcium chloride, at the concentrations used for food commodities, is unlikely to negatively affect the environment when disposed, as it dissociates into calcium and chloride ions that can easily be taken up and metabolized by plants (at low concentrations). However, it was noted that calcium chloride can be toxic to plants and animals at high concentrations.

As with all mined substances on the National List, the biggest impact to the environment is caused by the manufacturing of calcium chloride. Calcium chloride utilizes similar extraction and recovery techniques used by the oil and gas industry. [2024 TR 944-1105]

Human Health: GRAS. When used in concentrations utilized in food products the 2024 TR stated that calcium chloride is unlikely to have a negative effect on human health as it readily dissociates into calcium and chloride ions which are both essential body constituents in all animal species.

The 2024 TR also stated that although rare, in certain circumstances, calcium chloride may cause soft tissue necrosis. [2024 TR 1110-1133]

Discussion
The Handling Subcommittee received the draft TR on January 22, 2024. It was reviewed and the Subcommittee had additional questions regarding the manufacturing process when calcium chloride is produced from soda ash derived from trona ore, as well as commercial availability of calcium chloride manufactured by the various processes. The Subcommittee received a revised TR on March 19, 2024 and deemed it sufficient.

The Subcommittee discussed the wide use of calcium chloride. The TR authors found no evidence of a single substance offering the versatility of calcium chloride that is also non-synthetic. [2024 TR 1166-1290]

The 2024 TR mentions the following alternatives by function:

- Anti-microbial agents: carbon dioxide and ozone
- Firming agent: ozone and other sources of calcium such as calcium sulfate, calcium citrate and monocalcium phosphate
- Coagulants: calcium phosphate, calcium sulfate and magnesium sulfate
- Curing/pickling: other salts such as sodium chloride, calcium hydroxide, magnesium chloride and potassium chloride
- Nutrient supplement: calcium carbonate, calcium citrate, calcium hydroxide, and calcium phosphate
- pH control in brewing: calcium sulfate
- Tenderizer/texturizer: sodium chloride, lactic acid

The Subcommittee discussed the various ways to manufacture calcium chloride, some of which are nonsynthetic and some synthetic, as noted in the 2024 TR. Calcium chloride is currently listed at §205.605(a), so only the nonsynthetic forms are allowed. The TR noted that some methods used to extract calcium chloride from the natural brine use chemicals as processing aids. According to the TR when evaluating the classification of this manufacturing process using the decision tree, this extraction process falls into a gray area. The Subcommittee determined that use of these chemicals as processing aids would result in a nonsynthetic classification as the calcium chloride did not undergo a chemical change (it is still calcium chloride) and the additional calcium or chloride ions that may still be present were not added with the intent of providing a technical effect. [2024 TR 476-782]

As part of the Spring 2024 agenda and review of this substance, about a dozen comments were submitted. All were in favor of relisting or didn't state their opposition. The Subcommittee posed questions related to the types of calcium chloride being used (synthetic vs. non-synthetic) and what types of documentation certifiers are obtaining to confirm the manufacturing process of calcium chloride is nonsynthetic. Some commenters responded stating that indeed the calcium chloride they are using is nonsynthetic. Certifiers commented stated that classification is confirmed through the receipt of processing descriptions and/or

attestations from the manufacturer. Two commenters stated that the HS should investigate the presence of calcium bromide and consider an annotation as applicable. Additionally, one commenter stated that since some processes for manufacturing calcium chloride result in a synthetic product, it should be annotated to ensure only calcium chloride from a nonsynthetic process is used. However, this seems redundant since it is listed on the nonsynthetics allowed part of the National List and the appears adequate based on responses from certifiers.

The Board seemed in alignment with both the Subcommittee's and commenter's position to relist calcium chloride, as no additional discussion was had during the Spring 2024 board meeting.

Based on the information provided in the TR and comments received at the spring meeting, the Handling Subcommittee is proposing that calcium chloride remain on the National List due to its essentiality, lack of alternatives and limited negative impact on the environment and human health.

Justification for Vote
The Subcommittee finds calcium chloride compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote:
Motion to remove calcium chloride from the National List
Motion by: Kyla Smith
Seconded by: Allison Johnson
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

Enzymes

Reference: § 205.605(a) Nonsynthetics allowed
(11) Enzymes—must be derived from edible, nontoxic plants, nonpathogenic fungi, or nonpathogenic bacteria.
Technical Report: 1995 TAP (bacterial); 1996 TAP (plant); 1996 TAP (microbial); 2003 TAP (enzymes: plant, fungal); 2011 TR; 2015 TR; 2024 Limited Scope TR (enzymes, microorganisms, yeast)
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 10/1999 recommendation (plant, fungal): 11/2005 sunset recommendation; 04/2011 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Enzymes are naturally occurring proteins that act as highly efficient catalysts in biochemical reactions. Enzymes are produced by all living organisms; however, the 2024 Limited Scope TR only focuses on enzymes produced by microorganisms (including fungi). In some cases, enzymes are produced by microorganisms that are developed using excluded methods, which was the focus of the 2023 Limited Scope TR.

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

Manufacture

According to the 2023 draft TR, "Food-grade enzymes are typically produced in pure culture fermentation using "Current Good Manufacturing Practices" for food. Almost all fermentation processes used to produce enzymes are aerobic. Most industrial producers of food-grade enzymes use aerobic submerged fermentation or liquid fermentation (LF). Fungi produce approximately 50% of the enzymes used globally, bacteria produce 35%, and the remaining 15% are produced from non-fermentation organisms like plants and animals."

Some examples of different sources of food-grade enzymes include:

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

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

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

Fermentation produced chymosin (FPC) rennet is derived from genetically modified organisms and is not allowed in organic processing. The 2023 TR takes an intensive look at the excluded methods used to produce enzymes (such as using genetically modified organisms) and found that there is currently no capacity for regulators to determine the origin of an enzyme sample once it has been produced (Draft TR 2023 976-983).

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

Allowed as food additives. The following sources of enzymes are allowed: a) any preparations of enzymes normally used in food processing derived from edible, non-toxic plants, non-pathogenic fungi or non-pathogenic bacteria; b) derived from animals—shall be organic if commercially available: rennet; catalase from bovine liver; animal lipase; pancreatin; pepsin; and trypsin. Animal-derived enzymes shall be free of Specified Risk Material (SRM); and c) egg white lysozyme. (Table 6.3, CAN/CGSB-32.311-2020, page 31)

Allowed as processing aids. The following sources of enzymes are allowed: a) any preparations of enzymes normally used in food processing derived from edible, non-toxic plants, non-pathogenic fungi or non-pathogenic bacteria; b) animal-derived—shall be organic if commercially available: rennet; catalase from bovine liver; animal lipase; pancreatin; pepsin; and trypsin. Animal-derived enzymes shall be free of Specified Risk Material (SRM); c) egg white lysozyme. (Table 6.5, CAN/CGSB-32.311-2020, page 39)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

Allowed (Annex II, Part IV, 2.2.2 (a), 2018/848)

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

Allowed. Enzymes derived from genetic engineering organisms is prohibited. (Table 3-3.4, page 29 & 31)

International Federation of Organic Agriculture Movements (IFOAM)
Allowed if derived from naturally occurring organisms. Genetically engineered microorganisms and their products are prohibited. Nonorganic forms are allowed in organic products only if there are no organic sources. (7.2.5 - page 58 & 72)

Japan Agricultural Standard (JAS) for Organic Production
Allowed as an additive. (Appended Table 1)
Ancillary Substances
Ancillary substances are explained in the 2015 Technical Report:

"Enzyme products used in food processing may be single ingredient, stand-alone preparations of the enzyme, or formulated with other ingredients (OMRI, 2015). In many cases the enzyme product which results from a fermentation process is not effective in food applications without further formulation (Whitehurst & Van Oort , 2009). Enzyme preparations therefore commonly contain other substances, not only as incidental secondary metabolites and residual growth media from the enzyme production, but also intentionally added ingredients which function as diluents, preservatives, stabilizers, antioxidants, etc. (FDA, 2010). These additives must be generally recognized as safe (GRAS), or be FDA approved food additives for this use (FDA, 2014)."
To prevent the loss of enzyme activity, ancillary substances, such as stabilizers, are added. This is especially true for liquid enzyme preparations due to the destabilizing effect of water. Stabilizers are also used to combat the degradation of enzyme structures due to autolysis or proteolysis.
To control microbial contamination of enzyme preparations, preservatives are added. The development of alternatives to preservatives (plant extracts, peptides, compounds from herbs and spices) is increasing but there are microbial resistance challenges and the need for continued research. Currently it is unknown if natural preservatives are being used in any enzyme formulations.
The following additional ancillary substances were identified through public comment during the last sunset review:
Anti-caking & anti-stick agents: calcium stearate, magnesium silicate/talc, magnesium sulfate, sodium aluminosilicate.
Carriers and fillers: calcium phosphate, calcium acetate, calcium carbonate, calcium chloride, calcium sulfate, dextrin, dried glucose syrup, ethyl alcohol, glucose, glycol, lactic acid, maltose, mannitol, mineral oil, palm oil, propylene, purity gum (starch), saccharose, sorbitol, soy flour, soy oil, sunflower oil, trehalose, vegetable oil.
Preservatives: alpha (hops) extract, benzoic acids and their salts, calcium propionate, citric acid, potassium chloride, potassium phosphate, sodium acetate, sodium chloride, sodium propionate, sodium sulfate, sorbic acid and its salts, stearic acid, tannic acid, trisodium citrate, zinc sulfate.
Stabilizers: betaine (trimethylglycine), glucose, glycerol, sodium chloride, sodium phytate, sorbitol, sucrose.
pH control, buffers: acetic acid, citric acid anhydrous, sodium citrate, sodium phosphate, trisodium citrate.
Public comment submitted during the Spring 2019 NOSB meeting suggest adding several other ancillary substances to this list:
Anti-Caking & Anti-Stick Agents: manganese sulphate, magnesium sulphate, microcrystalline cellulose powder
Carriers and Fillers: corn gluten, corn steep powder, dextrose, lactose, propylene glycol, soya flour, soya oil, soyatone, sucrose.
Preservatives: propyl p-Hydroxybenzoate, sodium metabisulfite, sodium nitrate.
Stabilizers: calcium lactate, ethylene diamine tetra acetic acid, glycerin, sodium alginate.
pH control, Buffers: adipic acid, di potassium phosphate (K_2HPO_4), diammonium phosphate, disodium phosphate (Na_2HPO_4), hydrochloric acid, mono potassium phosphate (KH_2PO_4), tri ammonium citrate.

Human Health and Environmental Issues
The 2011 TR did not find the manufacture or use of enzymes to be harmful to the environment or biodiversity. Enzymes are used in small amounts, are biodegradable, and the release of enzymes into the environment is not an environmental concern.

The 2011 TR did not find significant effects upon human health. Enzymes can remain active after they are digested and, as proteins, cause allergic reactions in sensitive individuals. FDA reports it is not aware of any allergic reactions associate with the ingestion of food containing enzymes commonly used in food processing (TR 2011 752- 758).
The 2023 Limited Scope TR does not add any information about human health or environmental issues, beyond those which would be of concern should excluded methods be used.

Discussion
During the 2015 sunset review, a variety of organizations and manufacturers commented in support of keeping enzymes on the National List. There were no commenters opposed. One organization suggested that enzymes be classified as synthetic unless annotated to define those that have not undergone synthetic chemical change.

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

Stakeholder Comments Informing the Spring 2024 Meeting in Milwaukee: There were about 16 total stakeholder comments, both written and oral, with the majority being written. All, but one comment, were in favor of keeping enzymes on the National List. One commenting entity stated that they and their members would be willing to participate in a fermentation panel.

The presentation of the enzyme sunset document (among other sunsets) at the Spring 2024 NOSB meeting in Milwaukee generated considerable board discussion mostly regarding fermentation and excluded methods. This discussion provided details regarding certifiers process which includes the use of a risk-based approach for assessing the compliance of 205.605(a) inputs. This approach is described in the ACA Best Practice for Common Material Review Issues[1] which provides further information regarding classification verification and prohibitions of the use of excluded methods.

The new 2023 Limited Scope TR brings up a variety of new questions relevant to the use of excluded methods in the production of this material. As it was noted in several stakeholder comments this 2023 Limited Scope TR was first made available to the public shortly before the public comment period closed. We are therefore leaving the following “Questions to our Stakeholders” open for comment for the coming Fall 2024 session in Portland.

Questions to our Stakeholders
1. For manufacturers: describe how you ensure no excluded methods are used when including enzymes into your organic formulation.

[1] ACA Best Practice for Common Material Review Issues V4.4, January 2024 (ACA Materials Working Group)

2. For certifiers: describe how you ensure organic processors' compliance with the prohibition on excluded methods in organic products when enzymes are used in the formulation.
3. Are there ancillary substances that should be prohibited for use, due to concerns about excluded methods?

Justification for Vote
The Subcommittee finds enzymes compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote:
Motion to remove enzymes from the National List
Motion by: Jerry D'Amore
Seconded by: Kyla Smith
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

L Malic acid

Reference: § 205.605(a) Nonsynthetics allowed
(16) L-Malic acid (CAS # 97-67-6).
Technical Report: 2003 TR; 2019 TR
Petition(s): 2002
Past NOSB Actions: 05/2003 sunset recommendation; 11/2009 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Added to National List 09/11/06 (71 FR 53299)
Renewed 08/03/2011 (76 FR 46595); Renewed 09/12/16 (81 FR 8821); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Malic acid exists in D-, L-, and racemic DL-forms, which is a mixture of equal parts of D- and L-. L-malic acid is the form listed at §205.605(a), while the D- and DL-forms are not approved for use in organic production. L-malic acid is used as a flavor enhancer, flavoring agent, adjuvant, and pH control agent in a variety of foods. The 2002 malic acid petition also notes it is used in dry mix beverages, carbonated beverages, bakery products, fruit juices, candies, gelatins, desserts, frozen specialties, and tea as a flavor enhancer and food acidulant, and that malic acid provides greater tartness and better taste retention than other major food acids. Malic acid has a smooth, persistent sourness and can be blended with other organic acids, sugars, sweeteners, and flavors. It also intensifies and extends the impact of flavors, allowing producers to reduce the amount of added flavoring. U.S. Food and Drug Administration (FDA) lists L-malic acid as a Generally Recognized as Safe (GRAS) food additive as a pH control agent, flavor enhancer, flavoring agent, and adjuvant in all food types except for baby food. The listing also includes maximum good manufacturing practice (GMP) levels for various applications (21 CFR 184.1069; U.S. FDA 2018).

Manufacture
L-malic acid occurs naturally in many fruits and vegetables, including apples and cherries, and can be obtained by enzymatic conversion of fumaric acid and by fermentation of glucose and other carbohydrates. It is not economical to extract L-malic acid from natural foodstuffs such as apple juice. In the first round of the Spring 2019 sunset review, a number of commenters questioned whether commercially available L-

malic acid comes from nonsynthetic sources, as this listing restricts. Commenters noted that while supporting documentation may state L-malic acid is produced naturally via enzymatic fermentation, this statement refers to only the second half of the process. Industrial quantities of L-malic acid are made using biological processes, with the major industrial process to produce L-malic acid being a two-step procedure:

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

More detailed information on the two-step process can be found in Appendix A of the 2019 Technical Report.

There are two options for obtaining the fumaric acid in the first step in this process: 1) The fumaric acid precursor is obtained through the fermentation of carbohydrates (i.e., *Rhizopus spp*.) or, 2) The fumaric acid precursor is obtained as a synthetic product from maleic acid of petroleum origin. Commercial quantities of nonsynthetic L-malic acid may also be produced using a one-step fermentation process through biological methods such as microbial fermentation using *Aureobasidium pullulans* and *Penicillium vitacola*, though it is not believed that this process is occurring on a scale that would accommodate the needs of the current market. The major commercial source of L-malic acid is enzymatic conversion of synthetic fumaric acid to L-malic acid by immobilized microbes (Chibata et al. 1983; Chi et al. 2016a; Dai et al. 2018). If the malic acid produced by this method is synthetic, most, if not all, of the L-malic acid on the market will also be synthetic (Goldberg et al. 2006; Chibata et al. 1983; Engel et al. 2008; Chi et al. 2016a; Dai et al. 2018).[All citations from 2019 TR]

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

L-malic acid can also be produced by microbes in a one-step fermentation process fueled by glucose or other carbohydrates. Reaction conditions are adjusted to cause overproduction of L-malic acid, which is an essential product of microbe metabolism. While this production process is possible, it is not clear how much is produced and whether it will be able to produce sufficient quantities to supply handlers currently relying on the L-malic acid produced by the synthetic process.

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

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

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed as ingredients classified as food additives: listed as malic acid (Table 6.3, CAN/CGSB-32.311-2020, page 33).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 & 2021/1165
Malic acid is allowed in products of plant origin (Annex V, Part A, Section A1, 2021/1165).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
In Table 3 of "Annex 2: "Permitted substances for production of organic foods," malic acid (INS no. 296) is a permitted food additive listed without conditions (Codex 2013). L-malic acid is not explicitly mentioned; DL-malic acid is allowed.

International Federation of Organic Agriculture Movements (IFOAM)
L-malic acid (INS no. 296) is listed on page 79 in Appendix 4, "Table 1: List of approved additives and processing/post-harvest handling aids." L-malic acid is listed both as a food additive and post-harvest handling aid without restrictions (IFOAM 2014).

Japan Agricultural Standard (JAS) for Organic Production
On page 6, "Appended Table 1-1, Additives," DL-malic acid (INS no. 296) is an approved food additive limited to use in processed foods of plant origin (JAS 2022). L-malic acid is not explicitly mentioned.

Ancillary Substances

The 2019 TR does not describe any ancillary substances in L-malic acid.

Human Health and Environmental Issues

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

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

Discussion

The ongoing discussion around L-malic acid is not whether it is essential to organic handling or if it has detrimental effects on the environment or human health. In fact, there is broad agreement that it is essential, particularly to juice manufacturers, and there is no evidence to suggest that it does not meet National List criteria. However, as the organic material review process has become more refined and the production methods of L-malic acid has changed, we now see that much of the L-malic acid used in organic

processing is “synthetic” while L-malic acid is currently listed at 7 CFR 205.605(a) as a “nonsynthetic” substance.

Previous Handling Subcommittees have suggested relisting L-malic acid on §205.605(b) as a “synthetic” substance to accurately reflect the predominant production method, and to ensure that the classifications inherent to the National List of nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” are consistent with NOP material classification guidance.

This Subcommittee agrees with the previous thinking of the Board and would like to suggest adding L-malic acid to §205.605(b) to reflect that most L-malic acid used in organic food processing is synthetic in origin. However, the Subcommittee also questions whether L-malic acid should be removed from §205.605(a), as there may be nonsynthetic forms of L-malic acid in use, and should commercial quantities of nonsynthetic L-malic acid become available, organic processors may show a preference for a nonsynthetic option.

Questions to our Stakeholders

1. Do any organic products contain nonsynthetic forms of L-malic acid?
2. Should L-malic acid should be reclassified as a synthetic substance and added to §205.605(b)?
3. If L-malic acid is added to §205.605(b), should its nonsynthetic listing be removed from §205.605(a)?

NOSB did not receive comments that quantified the amount of nonsynthetic L-malic acid currently in use, but comments related to this substance’s use in organic products confirmed that most of what is currently in use would be classified as ‘synthetic.’ There were numerous opinions regarding how ‘synthetic’ L-malic acid should be considered or added to the National List. Some commenters preferred adding L-malic to 205.605(b) and keeping the nonsynthetic listing at § 205.605(a). Some commenters preferred removing L-malic from 205.605(a) and requiring a petition to add at § 205.605(b). There appears to be general consensus that the substance currently in use by organic processors is classified as ‘synthetic’ and its allowance should be reflected by inclusion at § 205.605(b). However, there is disagreement about whether the nonsynthetic listing should remain or if NOSB should recommend addition at § 205.605(b) as part of the L-malic acid classification work agenda item or if a petition should be required for the reclassification.

HS does not see any justification for removal of L-malic acid and views the classification as a critical revision that must be made. However, the classification of L-malic acid used by organic processors (i.e., synthetic or nonsynthetic) does not impact the substance’s compatibility with National List criteria, and L-malic acid should remain on the National List. At this sunset review, HS proposes an additional classification and listing motion, so the National List accurately reflects the classification of the substance in use in organic processing. HS makes these recommendations in a separate proposal related to the classification of L-Malic acid. These motions are not contingent in any way on the motion to remove L-malic as part of the OFPA mandated regular sunset review process. HS believes that L-malic should remain at § 205.605(a) to clarify that nonsynthetic forms of this substance remain allowed in organic processing. Should, in future sunset reviews, new information raise clear concerns about either the nonsynthetic or synthetic form of the substance, NOSB will have the ability to remove it with a decisive vote.

Justification for Vote

The Subcommittee finds L-malic acid compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote:
Motion to remove L-malic acid from the National List
Motion by: Nate Lewis
Seconded by: Kyla Smith
Yes: 0 No: 9 Abstain: 0 Recuse: 0 Absent: 0

Magnesium sulfate

Reference: § 205.605(a) Nonsynthetics allowed
(18) Magnesium sulfate, nonsynthetic sources only.
Technical Report: 1995 TAP; 2011 TR; 2024 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2011 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Magnesium sulfate is Generally Recognized as Safe (GRAS) and has a wide variety of uses in food processing and personal care products. It is used as a firming agent, and sometimes combined with other coagulators, in the production of tofu. Magnesium sulfate is also used as a nutrient in salt-replacer products, dietary supplements, carbonated beverages, sports drinks, and fortified water beverages, and as a fermentation and malting aid in beer, ale, and other malt beverages. In addition, magnesium sulfate has a variety of human medicine applications. Epson salts are a common form of magnesium sulfate.

Manufacture
Both nonsynthetic and synthetic forms of magnesium sulfate exist. The nonsynthetic forms are from naturally occurring salt deposits or rocks, with isolation from open-pit mines or salt ponds. Various levels of hydration create different crystalline structures that impact commercial viability, and manufacturers control humidity and temperature to isolate useful forms of magnesium sulfate. Magnesium sulfate can also be manufactured synthetically through the chemical reaction of magnesium containing materials and sulfuric acid.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed as food additive. (Table 6.3, CAN/CGSB-32.311-2020, page 33)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 & 2021/1165
Not addressed

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

International Federation of Organic Agriculture Movements (IFOAM)
Not addressed

Japan Agricultural Standard (JAS) for Organic Production
Not addressed

Ancillary Substances
None identified.

Human Health and Environmental Issues
Magnesium sulfate is primarily extracted from salt lakes in the northern part of the Tibet Autonomous Region and Qaidam Basin of the Qinghai Province using large-scale open-pit mining, which results in heavy damage to surface vegetation, as well as water and air pollution from equipment. There is limited information available about mining magnesium sulfate, specifically, relative to other magnesium materials.

Use of magnesium sulfate in food processing does not appear to cause significant health or environmental issues, particularly relative to industrial uses.

Discussion
There are alternatives to magnesium sulfate for at least some applications, including tofu and beer production, but they may change the properties of the finished product.

In public comments, just a few operations reported using magnesium sulfate as a yeast nutrient and for water adjustment. No commenters provided information about alternatives.

Justification for Vote
The Subcommittee finds magnesium sulfate compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote:
Motion to remove magnesium sulfate from the National List
Motion by: Allison Johnson
Seconded by: Jerry D'Amore
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 3

Microorganisms

Reference: § 205.605(a) Nonsynthetics allowed
(19) Microorganisms—any food grade bacteria, fungi, and other microorganism.
Technical Report: 2003 TAP; 2014 TR; 2024 Limited Scope TR (enzymes, microorganisms, yeast)
Petition(s): 2002 petition
Past NOSB Actions: 05/2003 minutes and vote; 11/2009 sunset recommendation; 04/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Added to National List with annotation 09/11/06 (71 FR 53299)
Renewed 08/03/2011 (76 FR 46595); Renewed 09/12/16 (81 FR 8821); Renewed 8/3/2021 (86 FR 41699)
Sunset Date 9/12/2026

Subcommittee Review

Use
Microorganisms are organisms that are so small they can only be viewed with a microscope, broadly encompassing bacteria, fungi, viruses and other single-celled organisms. The microorganisms used in organic handling include bacteria, yeasts and viruses, but yeasts are reviewed separately as their applications are broad. Microorganisms are used as probiotics, for fermentation, and bacteriophages are used for food safety. Microorganisms are used by organic processors to make many well-known products including yogurts, miso, soy sauce and sake. The use of these microorganisms can increase the digestibility of products, create different flavors and textures, and provide potential health benefits to the consumer. Additionally, bacteriophages can work to decrease harmful food organisms and increase the safety of processed foods.

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

The 2024 Limited Scope TR stated that there is no direct evidence that microorganisms other than yeast were produced by excluded methods, but there were cases in which no methods were disclosed. It went on to say that for microorganisms created through solid state fermentation, many are genetically modified using recombinant DNA technology. Any microorganism that is genetically modified is not permitted in organic food.

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed in feed. If organic sources of yeast are not commercially available, non-organic yeast sources shall be used. (Table 5.2, Microorganisms and yeasts listing, CAN/CGSB-32.311-2020, page 24)

Allowed as ingredients not classified as food additives. Microbial preparations may contain substrates derived from agricultural or biological substances such as milk, lactose, soy, agar, etc. May also contain allowed carriers (see Table 6.3 & 6.4 Carriers). Starter and dairy cultures and other preparations of microorganisms normally used in product processing are allowed. (Table 6.4, CAN/CGSB-32.311-2020, page 36)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Allowed (Annex I, 3. Micro-organisms, 2021/1165)

Rules for the production of processed feed and food.
For the purpose of Article 19(2)(b) of Regulation (EC) No 834/2007, only the following substances can be used in the processing of organic food, with the exception of wine:

(a) substances listed in Annex VIII to this Regulation;

(b) preparations of micro-organisms and enzymes normally used in food processing.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Allowed. Micro-organisms that are genetically engineered/modified are prohibited. (Table 3 - 3.4 - pages 29 & 31)

International Federation of Organic Agriculture Movements (IFOAM)
Allowed if derived from naturally occurring organisms. Genetically engineered microorganisms and their products prohibited. Nonorganic forms are allowed in organic products only if there are no organic sources. (7.2.5 - pages 58 & 72)

Japan Agricultural Standard (JAS) for Organic Production
JAS does not specifically mention microorganisms as an ingredient or additive to organic food.

Ancillary Substances
Ancillary substances may be present in microorganism cultures. Ancillary substances for microorganisms primarily include the growth media used to produce the microorganism, and fillers or carriers to bring the microorganisms to purchasers in a stable and predictable form. According to the 2024 Limited Scope TR, "growth media can be as simple as a single feedstock and water, or may be comprised of as many as 40 different components." These components may include corn steep liquor, molasses and horse manure extract. Additional preservatives or anti-caking agents are used with some species.

The 2024 Limited Scope TR includes the following table of allowed ancillary substances in organic microbial preparations.

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

Potential concerns have been raised about ancillary substances used in cultures and their compatibility with organic handling standards. It is unclear, for example, whether the corn used to make the starches and liquors mentioned above is required to be organic. Functional foods may contain a combination of probiotic culture with a prebiotic substrate that favors its growth (2014 TR). The use of ancillary substances has not prevented the relisting and general support for microorganisms. In general, they have not been implicated

in negative health effects, but are something that should be continually monitored. Additionally, as with all organic materials, any culture that is genetically modified is disallowed.

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

The 2024 Limited Scope TR did not bring up additional concerns for human health or the environment, beyond those that would occur through the use of excluded methods.

Discussion
In general, microorganisms are essential to the production of many organic foods, and they are widely used in the industry. A question could be posed regarding whether yeast should be grouped with other microorganisms, as they certainly fall within the classification of microorganisms. The definition is critical for microorganisms in use currently, and can be used to determine whether additional organisms, such as unicellular algae, should be considered microorganisms.

This discussion could be taken a step further to determine whether the products of microorganisms, substances such as citric acid, malic acid, and others, could also be grouped under the umbrella of microorganisms. As the primary concern for most of these microbial products is whether the microorganisms used to produce them were genetically modified, the broader guidelines may apply. These comments do not suggest that microorganisms should be delisted, but rather that additional attention needs to be paid to this particular listing and the definitions associated with it.

Stakeholder comments informing the Spring 2024 meeting in Milwaukee: There were about 19 total stakeholder comments, both oral and written, with the majority being written. All but two of the comments provided were in favor of keeping microorganisms on the National List with several pointing out that the 2024 limited scope TR was unavailable during much of the comment period. Many of the commenters gave detailed and informative answers to the “Questions for our Stakeholders” shown below.

The presentation of the microorganism Sunset document (among other sunsets) at the Spring 2024 board meeting in Milwaukee generated considerable board discussion mostly regarding fermentation and excluded methods. This discussion provided details regarding certifiers’ process, which includes the use of a risk-based approach for assessing the compliance of 205.605(a) inputs. This approach is described in the ACA Best Practice for Common Material Review Issues[2] which provides further information regarding classification verification and prohibitions of the use of excluded methods.

The new 2024 Limited Scope TR brings up a variety of new questions relevant to the use of excluded methods in the production of this material. As it was noted in several stakeholder comments, this 2024

[2] ACA Best Practice for Common Material Review Issues V4.4, January 2024 (ACA Materials Working Group)

Limited Scope TR was first made available to the public shortly before the public comment period closed. We are therefore leaving the following "Questions to our Stakeholders" open for comment for the Fall 2024 session in Portland.

Questions to our Stakeholders

1. For manufacturers: describe how you ensure no excluded methods are used when including microorganisms in your organic formulation.
2. For certifiers: describe how you ensure organic processors' compliance with the prohibition on excluded methods in organic products when microorganisms are used in the formulation.
3. Are there any ancillary substances that should be prohibited due to the potential for excluded methods?

Justification for Vote

The Subcommittee finds microorganisms compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote:

Motion to remove microorganisms from the National List
Motion by: Jerry D'Amore
Seconded by: Carolyn Dimitri
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

Perlite

Reference: § 205.605(a) Nonsynthetics allowed
(22) Perlite—for use only as a filter aid in food processing.
Technical Report: 1996 TAP; 2024 TR
Petition(s): N/A
Past NOSB Actions: 09/1996 NOSB minutes and vote; 11/2005 sunset recommendation; 03/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use

Perlite is used as a filter aid in food processing, such as in the filtration of juices, beer, wine, and vegetable oils. It is a budget-friendly, inorganic adsorbent in filter aids. Filter aids may be applied either as precoat on the filter material and/or as body feed in the liquid. In practice, a combination of the two approaches is the most common. Examples of successful perlite use in organic operations include removing yeast aflatoxins from milk and impurities in beer.

Manufacture

Perlite is produced from glassy volcanic rock raw materials and is formed naturally from the hydration of obsidian or pitchstone; it is sourced primarily from open mines in the U.S., Greece, Turkey and China. The raw materials are mechanically crushed. The high-water content of the mineral causes it to expand up to 20

times its original volume when exposed to temperatures of 760-1100°C. The process involves heating granulated perlite ore until it becomes molten glass.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed as a filtering aid. (Table 6.5, CAN/CGSB-32.311-2020, page 39)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 & 2021/1165
Perlite is allowed as a processing aid in products of plant origin and gelatine. (Annex V, Part A, Section A2, 2021/1165)

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Allowed as a processing aid for the preparation of products of agricultural origin. (Table 4, page 30)

International Federation of Organic Agriculture Movements (IFOAM)
Allowed as a processing/post-harvest handling aid. (Appendix 4, Table 1, page 81)

Japan Agricultural Standard (JAS) for Organic Production
Appended Table 1-1, Additives (Organic processed foods other than organic alcohol beverages); Appended Table 1-2 Additives (Organic alcohol beverages). In organic foods other than organic alcohol beverages: limited to the use in processed products of plant origin. In organic alcohol beverages: no restrictions

Ancillary Substances
None Identified

Human Health and Environmental Issues
Few studies have evaluated the environmental effects of perlite manufacturing on the environment. There is some concern with the potential human health hazard of inhalation of fine silica dust when using this material. Personal protective equipment such as a dust mask can minimize this risk.

Discussion
Public comments and discussion at the Spring 2024 meeting were brief and overall supportive to relist. Technical report was received after the deadline for the spring meeting , but it was reviewed prior to subcommittee vote. Technical report was used to expand the details of the sunset write up, but no substantive changes were made to alter the course of the review.

Justification for Vote
The Subcommittee finds perlite when used as a filtering aid to be compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote:
Motion to remove perlite from the National List
Motion by: Kim Huseman
Seconded by: Nate Lewis
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 3

Potassium iodide

Reference: § 205.605(a) Nonsynthetics allowed
(24) Potassium iodide.
Technical Report: 1995 TAP; 2011 TR; 2023 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2011 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Potassium iodide is used as a form of iodine in trace mineral supplements. Iodine is an essential component of the thyroid hormones that regulate basal metabolism. Iodine deficiency causes thyroid enlargement (goiter), mental retardation that can be severe (cretinism in 10% of the population), and hypothyroidism. The developing brain is the most sensitive organ; iodine deficiency reduces IQ by 13.5 points [2011 TR 356-359]. Iodization of salt eliminated new cases of cretinism in Switzerland. According to FDA, potassium iodide may be used as a food additive in the following functions:

- A nutrient in table salt as a source of iodine.
- A dietary supplement for human consumption and in animal feeds.
- A sanitizing agent for food processing equipment. [2011 TR 35-38].

Manufacture
Potassium iodide can be refined non-synthetically from sea water and in salt deposits. It can be produced synthetically by reacting hydriodic acid with potassium bicarbonate or by electrolysis of hydriodic acid and potassium bicarbonate or, industrially, by treating potassium hydroxide with iodine. [21 CFR 184.1634] [2011 TR 200-201].

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed as ingredients not classified as food additives. Use when legally required or allowed (Table 6.4, CAN/CGSB-32.311-2020, page 36).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 & 2021/1165
Allowed for use as feed or in feed production (Annex III, Part B, 3(b), 2021/1165). Not explicitly mentioned for use in/on processed products.

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

International Federation of Organic Agriculture Movements (IFOAM)
Not explicitly mentioned.

Japan Agricultural Standard (JAS) for Organic Production
Not explicitly mentioned.

Ancillary Substances
No identified.

Human Health and Environmental Issues
Potassium iodide may be added to food as a nutrient/nutritional supplement for human consumption or to animal feeds. Iodine (in the form of iodide) is a necessary human nutrient that is required for proper functioning of the human endocrine system, specifically synthesis of thyroid hormones—thyroxine (T4) and triiodothyronine (T3) [2011 TR 352-354]. It is well-documented that pre-existing nutritional deficiency of iodine in the diet can perturb levels of thyroid hormones which cause a spectrum of disorders that include in increasing order of severity, goiter and hypothyroidism, mental retardation, and cretinism. There are no indications of special sensitivity of infants or children resulting from exposure to iodine. Therefore, the Food Quality Protection Act (FQPA) Safety Factor has been removed (i.e., reduced to 1x) for iodine [2011 TR 396-397].

Based on a review of the available toxicology data, the U.S. Environmental Protection Agency (EPA) has concluded that iodine and iodophor complexes are of very low toxicity by the oral, dermal, and inhalation routes of exposure. Acute and chronic risks to non-target birds, aquatic invertebrates, and fish are highly unlikely [2011 TR 345-346].

Discussion
Potassium iodide is an important material that helps prevent a range of health issues caused by iodine deficiencies. In previous sunset reviews the NOSB asked questions to stakeholders regarding the use of this substance as a sanitizer, but no feedback was received. Stakeholders favored keeping this listing in addition to the current Nutrient Vitamin and Mineral listing. The NOSB has unanimously supported relisting potassium iodide at each sunset date.

Written comments were all in support for relisting potassium iodide. One commentor supported listing this material as a synthetic. There were no oral comments for the 2024 spring meeting. There was little to no discussion at the full board meeting.

Questions to our Stakeholders
None.

Justification for Vote
The Subcommittee finds potassium iodide compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove potassium iodide from the National List
Motion by: Logan Petrey
Seconded by: Dilip Nandwani
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

Pullulan

Reference: § 205.605(a) Nonsynthetics allowed
(25) Pullulan—for use only in tablets and capsules for dietary supplements labeled "made with organic (specified ingredients or food group(s)).
Technical Report: 2018 TR
Petition: 2004; 2018
Past NOSB Actions: 04/2019 recommendation to add
Recent Regulatory Background: Added to National List effective 07/26/2021 (86 FR 33479)
Sunset Date: 7/26/2026

Subcommittee Review

Use
According to the U.S. Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER), pullulan is a "product used for tablet coating, as an excipient to aid tableting processes, in the production of edible films, and as an alternative to gelatin in capsule production" (FDA 2014). The unique film-forming property of pullulan enables the production of clear capsules and coatings for dietary supplements [2018 TR 72-75].

In addition to the petitioned use of pullulan as an ingredient in tablets and capsules for dietary supplements, edible pullulan films are used to extend the shelf life of various foods. These films prevent moisture loss and reduce surface exposure to oxygen and spoilage bacteria in intact berries, Brussels sprouts, baby carrots, nuts, fresh eggs, intact apples, and cut fruits such as apple slices [2018 TR 88-94].

Manufacture
All pullulan is created by microbial fermentation. The microorganism is usually the black, yeast-like fungus *A. pullulans*, although other species from this genus of black fungus—such as *A. fermentans* and *A. melanogenum*—have also been shown to produce pullulan. Nitrogen is provided in the growth medium in the form of inorganic nitrogen sources such as ammonium salts, nitrates, and biological sources such as glutamate, peptone, yeast extract, and corn steep liquor. Essential nutrient minerals are provided as phosphates, magnesium salts, and the sulfates of iron, manganese, and zinc [2018 TR 219-225].

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Not explicitly mentioned.

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Not explicitly mentioned.

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

International Federation of Organic Agriculture Movements (IFOAM)
Not explicitly mentioned.

Japan Agricultural Standard (JAS) for Organic Production
Not explicitly mentioned.

Ancillary Substances
None

Human Health and Environmental Issues
No adverse effects on human health and environmental issues were mentioned in the 2018 technical report.

Discussion
The NOSB asked stakeholders whether organic, agricultural pullulan is commercially available. One commenter stated that there is a company that is manufacturing organic pullulan, but it is not yet producing at the scale necessary to consider it commercially available. It is possible that by the next sunset review, that threshold could be met.

Justification for Vote
The Subcommittee finds pullulan compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote:
Motion to remove pullulan from the National List
Motion by: Dilip Nandwani
Seconded by: Allison Johnson
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

Yeast

Reference: § 205.605(a) Nonsynthetics allowed

> (30) Yeast—When used as food or a fermentation agent in products labeled as "organic," yeast must be organic if its end use is for human consumption; nonorganic yeast may be used when organic yeast is not commercially available. Growth on petrochemical substrate and sulfite waste liquor is prohibited. For smoked yeast, nonsynthetic smoke flavoring process must be documented.

Technical Report: 1995 TAP (smoked yeast); 1995 TAP (baker's yeast); 1995 TAP (autolysate); 1995 TAP (brewers); 2014 TR; 2024 Limited Scope TR (enzymes, microorganisms, yeast)
Petition(s): 2006 Petition; 2010 Petition Supplement; 2010 Petition memo
Past NOSB Actions: 10/1995 sunset recommendation; 11/2005 sunset recommendation; 3/2007 NOSB committee recommendation; 10/2010 NOSB recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290): Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Yeast is widely used and has been for centuries. Yeast is a microorganism that is commonly used for fermentation, baking, food flavors, adding nutritional value and providing health benefits. Yeasts are in kingdom Fungi and are single celled eukaryotic organisms. They utilize organic materials for energy by releasing enzymes that digest organic matter or by absorbing simple molecules directly through their cell

walls. Yeasts differ from other fungi, such as molds and mushrooms, in that they exist as individual cells rather than forming hyphae that interconnect with other cells.

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

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

Manufacture

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

The 2023 Limited Scope TR made it clear that yeast may be genetically modified, primarily within brewing and fermentation applications. Yeast manufacturers are increasingly using tools like CRISPR to edit genes and add desirable traits from wild strains [2023 TR 499-504]. These genetically modified yeast would be prohibited under current NOP regulations.

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

Allowed as ingredients classified as food additives. If organic sources of yeast are not commercially available, these alternative sources of yeast may be used: a) autolysate; b) bakers' (may contain lecithin, as listed in Table 6.3); c) brewers'; d) nutritional; and e) torula. Growth on petrochemical substrate and sulphite waste liquor is prohibited. Yeast may be smoked or smoke-flavoured. When smoked, the smoke shall come from concentrated, condensed smoke from wood without additional ingredients (unless listed in

Tables 6.3, 6.4 or 6.5). (Table 5.2, CAN/CGSB-32.311-2020, page 35)

Allowed as ingredients not classified as food additives: If organic sources of yeast are not commercially available, these alternative sources of yeast may be used: a) autolysate; b) bakers' (may contain lecithin, as listed in Table 6.3); c) brewers'; d) nutritional; and e) torula. Growth on petrochemical substrate and sulphite waste liquor is prohibited. Yeast may be smoked or smoke-flavoured. When smoked, the smoke shall come from concentrated, condensed smoke from wood without additional ingredients (unless listed in Tables 6.3, 6.4 or 6.5). (page 37)
European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Allowed (Annex II, Part VII, 2021/1165)

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Not explicitly mentioned; may be considered a micro-organism, which is allowed. Micro-organisms that are genetically engineered/modified are prohibited. (Table 3 - 3.4 - page 29 and 31)

International Federation of Organic Agriculture Movements (IFOAM)
Allowed if derived from naturally occurring organisms. Genetically engineered microorganisms and their products are prohibited. Cultures that are prepared or multiplied in house shall comply with the requirements for the organic production of microorganisms. Nonorganic forms are allowed in organic products only if there are no organic sources. (7.2.5 - page 58 and 72).

Japan Agricultural Standard (JAS) for Organic Production
JAS does not specifically mention yeast as an additive or ingredient to organic food.

Ancillary Substances
During the 2015 sunset review, the following Functional Classes were reviewed for ancillary substances in yeasts: Antioxidants, preservatives, emulsifiers, defoaming agents, and substrate that may remain in the final product. It was suggested that starch be added to this list during that review. One substance, BHT, was questioned as problematic for exposure.

According to the 2014 TR, there are a few yeast species that are formulated with no ancillary substances; however, many commercially available yeasts are formulated with other ingredients. These substances, such as ascorbic acid, may be listed on the National List. However, other ancillary ingredients not appearing on the National List are routinely combined with yeast on a commercial scale. These may be water, emulsifiers, and cutting oils. The compounds used for emulsifiers are enumerated in the TR (2014 TR) and that extensive list should be referred to for specific details of ancillary substances in yeast products.

The 2023 Limited Scope TR indicates that for yeast to be certified as organic, the inputs such as molasses or corn steep liquor must also be organic and no synthetic substance that is not on the National List may be included [2023 TR 1255-1261].

Human Health and Environmental Issues
It should be noted that while yeast itself is often considered of minimal risk to both the environment and in human use, there can be negative environmental impacts from the manufacturing processes used to create yeast formulations. Appropriate mitigation strategies for these impacts, such as the emissions of acetaldehyde and ethanol, exist and when appropriately used minimize environmental impact (2014 TR). The 2023 Limited Scope TR did not provide additional information on the potential impacts to human

health or environmental issues, aside from those that could potentially occur through the use of excluded methods.

Discussion
Public comment from the Spring and Fall 2019 meetings was overwhelmingly in favor of relisting of yeasts as annotated. Commenters noted that since yeast is commonly not available in organic form necessary for certain flavors, yeasts are not always available in the quantities needed, and that organic yeast quality can vary, the annotation and listing should remain as is. It isn't currently clear how to determine whether a non-organic form of yeast may be used in an organic product.
Stakeholder Comments Informing the Spring 2024 meeting in Milwaukee: There were about 13 total stakeholder comments, both written and oral, with the majority being written. All comments were in favor of keeping yeast on the National List. Much like comments made in 2019, some commenters expressed concern that organic yeast is not consistently commercially available. One commenter noted that ancillary substance used in the formation process could be problematic.

The presentation of the yeast sunset document (among other sunsets) at the Spring 2024 board meeting in Milwaukee generated considerable board discussion mostly regarding fermentation and excluded methods. This discussion provided details regarding certifiers process which includes the use of a risk-based approach for assessing the compliance of 205.605(a) inputs. This approach is described in the ACA Best Practice for Common Material Review Issues[3] which provides further information regarding classification verification and prohibitions of the use of excluded methods.

The new 2023 Limited Scope TR brings up a few new questions relevant to the use of excluded methods in the production of this material. As it was noted in several stakeholder comments, this 2023 Limited Scope TR was first made available to the pubic shortly before the public comment period closed. We are therefore leaving the following "Questions to Our Stakeholders" open for comment for the coming Fall 2024 session in Portland.

Questions to our Stakeholders
1. For manufacturers: describe how you ensure no excluded methods are used when including yeast into your organic formulation.
2. For certifiers: describe how you ensure organic processors' compliance with the prohibition on excluded methods in organic products when yeast is used in the formulation.
3. Are there ancillary substances that should be prohibited for use, due to concerns about excluded methods?

Justification for Vote
The Subcommittee finds yeast compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote:
Motion to remove yeast from the National List
Motion by: Jerry D'Amore
Seconded by: Dilip Nandwani
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

[3] ACA Best Practice for Common Material Review Issues V4.4, January 2024 (ACA Materials Working Group)

Activated charcoal

Reference: § 205.605(b) Synthetics allowed

(2) Activated charcoal (CAS #s 7440-44-0; 64365-11-3)—only from vegetative sources; for use only as a filtering aid.

Technical Report: 2002 TAP; 2024 TR

Petition(s): 2002 petition

Past NOSB Actions: 09/2002 sunset recommendation; 11/2009 sunset recommendation; 04/2015 sunset recommendation; 10/2019 sunset recommendation

Regulatory Background: Added to National List with annotation 9/11/06 (71 FR 53299); Renewed 8/03/2011 (76 FR 46595); Renewed 09/12/16 (81 FR 8821); Renewed 8/3/2021 (86 FR 41699)

Sunset Date: 9/12/2026

Subcommittee Review

The Subcommittee had a brief discussion of the 2024 technical review (TR) and the Spring 2024 public comments. The Subcommittee members were all in support of relisting.

Use

Activated charcoal is used in processing for mechanical filtration involving the physical separation of suspended solids from a liquid passing through carbon arrayed as a porous media in a column or bed [2002 TR, lines 142-143]. This type of filtration is used as a taste and odor-removing agent and purification agent in water and food. Activated carbon has a very large surface area and pore volume that gives it its unique adsorption capacity [2002 TR, lines 57-58].

Manufacture

Activated charcoal of vegetative origin can be made from a large variety of sources such as hardwoods, grain hulls, corn cobs and nut shells [2024 TR, lines 59-60]. The material undergoes pyrolysis at a very high heat, and may be chemically activated using acids (acetic acid), bases (potassium hydroxide and sodium hydroxide), or through exposure to oxygenated gas or steam [2024 TR, lines 328-334].

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)

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

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165

Lists activated carbon for the preparation of foodstuffs of plant and animal origin.

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

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

International Federation of Organic Agriculture Movements (IFOAM)

IFOAM Norms Appendix 4 – Table 1 lists activated carbon as allowed for use as a processing and postharvest handling aid. Synthetic forms are allowed if organic or natural sources are not commercially available. May be used as a processing or a post-harvest handling aid.

Japan Agricultural Standard (JAS) for Organic Production
Appended Table 1-1, Additives (Organic processed foods other than organic alcohol); Appended Table 1-2, Additives (Organic alcohol beverages). Limits the use of active carbon for processed foods of plant origin and also beverages.

Ancillary Substances
None identified.

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

Discussion
The new 2024 TR was received during subcommittee review. There were a handful of public comments in support of activated charcoal remaining on the National list; the question posed to stakeholders was not addressed in comments or during board discussion.

Questions to our Stakeholders
Are there any industry changes that would challenge the current listing for activated charcoal?

Justification for Vote
The Subcommittee finds activated charcoal compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove activated charcoal from the National List
Motion by: Kim Huseman
Seconded by: Jerry D'Amore
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 3

Ascorbic acid

Reference: § 205.605(b) Synthetics allowed
(6) Ascorbic acid.
Technical Report: 1995 TAP; 2019 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Ascorbic acid is used as a dietary supplement and nutrient, flavor ingredient, used in meat and meat containing products, curing and pickling, in flour to improve baking quality, as an antioxidant in fats and oils, and a wide variety of other food processing uses. It is also used in frozen and precut fruits as an antioxidant. Industrially produced L-ascorbic acid is widely used in the feed, food, and pharmaceutical sector as a nutritional supplement and preservative, making use of its antioxidative properties. Ascorbic acid is often added to processed foods for nutritional purposes and is one of the most common sources of Vitamin C, which provides many important biological functions. Several animals, including humans, a variety of primates and guinea pigs have lost the ability to produce ascorbic acid and must obtain this essential vitamin through their diets. As it is water soluble, and cannot be stored in the body, it must be consumed daily. However, its addition as a nutritional fortifier also provides preservative properties. The preservative nature of the compound is derived from its reducing nature, through which it reacts with oxidized species (including radicals and molecular oxygen) to prevent enzymatic browning and food spoilage. Ascorbic acid is GRAS as a chemical preservative (21 CFR 182.3013), a dietary supplement (21 CFR 182.5013), and nutrient (21 CFR 182.8013) when used in accordance with Good Manufacturing Practices. The FDA has identified ascorbic acid as a required nutrient in infant formula (21 CFR 107.100).

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

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed as ingredients classified as food additives. (Table 6.3, CAN/CGSB-32.311-2020, page 30)

Allowed as processing aid, specifically anti-browning agents prior to the extraction or concentration of fruit or vegetable juice. (Table 6.5, CAN/CGSB-32.311-2020, page 38)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Allowed in products of plant origin & meat products. (Annex V, Part A, Section A1, 2021/1165)

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Allowed in food of plant origin, provided natural sources are not available. Allowed in the following foods of animal origin, provided natural sources are not available: processed meat, poultry, game products, poultry and edible casings. (Table 3 - page 24)

International Federation of Organic Agriculture Movements (IFOAM)
Allowed as an as additive. (Appendix 4 - Table 1 - page 79)

Japan Agricultural Standard (JAS) for Organic Production
Allowed as an additive. Limited to the use in processed products of plant origin. (Appended Table 1)

Ancillary Substances
No discussion of ancillary substances in the 2019 TR.

Human Health and Environmental Issues
The 2019 Technical Report found no published studies on the persistence or impacts to biodiversity of ascorbic acid. Given the natural prevalence of the substance in plants and animals, the incorporation of ascorbic acid in the handling/processing of organic food products is unlikely to provide any significant increase to environmental levels of the substance.

Discussion
Ascorbic acid is a vital nutrient necessary for humans and other primates. Humans cannot synthesize Vitamin C and must rely on dietary intake. Modern production techniques rely on fermentation of glucose, but addition of synthetic acids in the process render the final ascorbic acid product a "synthetic" substance according to NOP 5033-1. Previous sunset reviews of the substance asked whether excluded methods are used in the production of ascorbic acid, and the 2019 TR indicates that the microorganisms used in its manufacture are not the product of excluded methods.

Some stakeholders have identified ascorbic acid's use as a preservative incompatible with the requirements in organic handling, however, other stakeholders report it remains essential for numerous functions in food including protein processing in cheese, color stabilization in fruit juice, and as an antioxidant and vitamin C source. The Subcommittee notes that evaluation criteria at 7 CFR 205.600(b) restricting a material's use as a preservative or its use to recreate or improve flavors, colors, textures, or nutritive value lost during processing is limited to processing aids and adjuvants.

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

At the Spring 2024 meeting, one commenter indicated the use of organic cherry powder as an alternative to ascorbic acid in some preserved meat products, but this alternative is not feasible in other types of products due to off flavors. Some commenters supported removal of ascorbic acid due to the availability of natural and organic alternatives, but did not provide evidence to support these statements. Public comments indicated that ascorbic acid remains widely used and compatible with National List Criteria.

Questions to our Stakeholders
Do stakeholders have any experience with natural or organic alternatives to ascorbic acid for some or all of its uses in organic handling?

Justification for Vote
The Subcommittee finds ascorbic acid compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote:
Motion to remove ascorbic acid from the National List
Motion by: Nate Lewis
Seconded by: Jerry D'Amore
Yes: 0 No: 9 Abstain: 0 Recuse: 0 Absent: 0

Calcium citrate

Reference: § 205.605(b) Synthetics allowed
(7) Calcium citrate.
Technical Report: 1995 TAP; 2015 TR; 2023 Limited Scope Technical Report (pdf) (citric acid and salts)
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 4/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Calcium citrate is used as an ingredient in dietary supplements, where it provides calcium. It is also used as a nutrient; sequestrant; buffer; antioxidant; firming agent; acidity regulator in jams and jellies, soft drinks and wines; raising agent; an emulsifying salt; to improve the baking properties of flours; a stabilizer; to remove scale from boilers, evaporators and other processing equipment; to wash equipment to remove off flavors; in cosmetic and personal care items; and as a water softener.

Calcium citrate may be added to foods to supplement calcium per FDA nutrition guidelines, although there are other calcium sources for supplementation purposes including calcium carbonate, calcium oxide, calcium sulfate, etc., all of which are permitted per a separate listing on §205.605(b) as Nutrient Vitamins and Minerals.

Manufacture
Citric acid is a naturally-produced, non-volatile organic acid with a long history of use in food processing. The 2015 TR considered production of citric acid by microbial fermentation with *Aspergillus niger* or *Candida* yeasts from carbohydrate sources but includes additional information regarding production from plant sources.

Note that the process that creates citric acid is fermentation of carbohydrates. In terms of concern about excluded methods, the 2015 TR indicates that the organisms underlying the fermentation process are considered 'classical mutants,' and further notes that the prohibition on excluded methods in food by the European countries suggests the underlying citric acid is unlikely to include carbohydrates that have manipulated genes.

The citrate salts – calcium citrate, potassium citrate and sodium citrate – are all derived from citric acid. The citrate salts are produced by chemical reaction with citric acid and the hydroxide or carbonate of the respective salt (calcium, sodium or potassium).

Calcium citrate is the calcium salt of citric acid. It is prepared by neutralizing citric acid with calcium hydroxide or calcium carbonate and subsequent crystallization. It is most commonly found in the tetrahydrate form.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed as food additives (Table 6.3, CAN/CGSB-32.311-2020, page 30).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Allowed as a food additive and processing aid in products of plant origin (Annex V, Part A, A1, 2021/1165).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Calcium citrate is allowed in food of plant origin and dairy products/analogues. Not allowed in fats, oils, and fat emulsions (page 25).

International Federation of Organic Agriculture Movements (IFOAM)
Allowed as an additive (Appendix 4 - Table 1 - page 79).

Japan Agricultural Standard (JAS) for Organic Production
Not explicitly mentioned.

Ancillary Substances
None.

Human Health and Environmental Issues
There are no expected significant human health impacts or remarkable environmental issues, according to the 2015 TR.

Discussion
The bulk of the discussion about this product addresses the production process for citric acid.

The nine public comments made prior to the Spring 2024 meeting were largely supportive of relisting; one commenter mentioned it was especially useful when trying to avoid sulfates. Another cautioned about the ensuring that nanoparticles are not intentionally added.

The Board had no comments.

Justification for Vote
The Subcommittee finds calcium citrate compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote:
Motion to remove calcium citrate from the National List
Motion by: Carolyn Dimitri
Seconded by: Nate Lewis
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 3

Collagen gel

Reference: § 205.605(b) Synthetics allowed
(13) Collagen gel—as casing, may be used only when organic collagen gel is not commercially available.
Technical Report: 2019 TR
Petition(s): 2018 (for addition at 205.606)
Past NOSB Actions: 04/2019 Recommendation to add
Recent Regulatory Background: Added to NL 07/26/2021 (86 FR 33479)
Sunset Date: 7/26/2026

Subcommittee Review
Subcommittee discussion was centered around commercial availability of organic collagen gel and what criteria would need to be met to be deemed 'commercially available'. A board member encouraged wild marine materials be allowed as certified organic; it could then be a potential source of organic collagen gel.

Use
Collagen gel acts as an edible film used to produce meat products (e.g. sausage) as an alternative to casings which is listed under §205.606(b). The collagen casing protects the meat product from oxidation and discoloration by acting as a semipermeable membrane for gases, moisture, and other solvents. The casing also provides a more desirable bite and texture to meat products as well as aids in additional flavorings to the product (Savic and Savic 2002, Han and Gennadios 2005, Harper et al. 287 2012, Ioi 2013, Marousek et al. 2015). Collagen gel is a more affordable, efficient, and sanitary means of manufacturing meat products and increases opportunities to produce a larger variety of organic meat products. It allows production of single-species products that can meet the needs and preferences of different consumer populations.

Manufacture
Collagen is a natural animal protein found in skin, bones, muscle, and connective tissues that is isolated from mostly bovine and porcine sources at USDA inspected facilities following all pertinent regulations. The animal-based collagen source is partially hydrolyzed through enzymatic, thermal, or acid treatment from meat processing byproducts to cleave the protein. Once cleaved, the collagen extract is decalcified and ground to uniformity within the collagen fibers. The collagen fibers are then swollen with an acid treatment before the extrusion process.
According to the TR, collagen gel is comprised of 3.0–4.5% collagen, < 3% cellulose, and 95.5-97% water. Collagen is a naturally occurring protein that is abundant in the connective tissue, bones, blood vessels, skin, and muscles of animals (Kim and Mendis 2006, Sahithi et al. 2013, Oechsle et al. 2014, Marousek et al. 2015). The unique structural properties of collagen's triple helix provide the desirable qualities of high-tensile strength and flexibility important to edible film casings (Oechsle et al. 2014, Oechsle et al. 2017).

Cellulose is currently approved for use as a synthetic substance "in regenerative casings [extruded collagen casing that is dried prior to use], as an anti-caking agent (non-chlorine bleached) and filtering aid," and for processed products labeled "organic or made with organic," at 7 CFR 205.605.

Marine collagen is rarely used. Dark coloration and odor have been difficult to overcome. Isolating collagen from marine sources are based on processing fish by-products. Sources are not well defined and may vary from bones and skins to include viscera and heads [2019 TR 99-102]. At the time of the technical review, marine sources of collagen remained largely in research state.

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Collagen is listed in the Canadian General Standards Board Permitted Substances List (CAN/CGSB-32.311-2015) in Table 6.4 as allowed for "ingredients not classified as food additives" in the form of "collagen casings." Collagen casings are required to "be derived from animal sources," and "if derived from cattle, shall be guaranteed free of specified risk materials." Moreover, collagen casings are permitted to include "other ingredients (such as, but not limited to cellulose, calcium coatings, glycerin, etc.) added to collagen casings during their manufacture, which remain in the collagen casing."

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Not explicitly mentioned

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Not explicitly mentioned

International Federation of Organic Agriculture Movements (IFOAM)
Not explicitly mentioned

Japan Agricultural Standard (JAS) for Organic Production
Not explicitly mentioned

Ancillary Substances

Cellulose powder, derived from plant sources, is an inert substance in collagen gel. Cellulose's functionality is, however, critical once collagen gel has been coextruded into an enrobed extruded sausage. Cellulose adds permeability to the sausage's skin, allowing for the release of the meat emulsion's oil and fats during the sausage's cooking process. In finished collagen gel, cellulose is present in the range of 2 – 5%, depending on targeted product characteristics.

Human Health and Environmental Issues

Collagen gel has no known toxicities and breaks down into its constituent amino acids upon digestion. It has no environmental persistence and use of collagen gel is unlikely to have any additional adverse impact on the environment.

Discussion

Collagen gel, added to the National List in 2021, has provided more options for edible films and thus created a bigger market for organically produced meat; it is consistent with current regulations.

Collagen gel is GRAS (Generally Recognized as Safe) for use in meat products.

Questions to our Stakeholders

1. Is there a method of production for nonsynthetic collagen gel?
2. Are organic livestock by-products commercially available for organic collagen gel production?
3. Have advancements been made with testing the viability of marine sourced collagen gel?

Justification for Vote
The Subcommittee finds collagen gel compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote:
Motion to remove collagen gel from the National List
Motion by: Kim Huseman
Seconded by: Allison Johnson
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 3

Ferrous sulfate

Reference: § 205.605(b) Synthetics allowed
(15) Ferrous sulfate—for iron enrichment or fortification of foods when required by regulation or recommended (independent organization).
Technical Report: 1995 TAP; 2015 TR (Nutrient Vitamins and Minerals)
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Renewed 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Ferrous sulfate is commonly added to flours and cereal products to make an optional enriched claim and often found in baked products and infant snacks (oat cereal, teething biscuits, etc.).

Manufacture
Ferrous sulfate is made by reacting sulfuric acid with iron.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Ferrous sulphate is allowed for use if legally required and may be used, on a voluntary basis, if legally allowed. (Table 6.4, Vitamins and mineral nutrients listing, CAN/CGSB-32.311-2020, page 37)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 & 2021/1165
Not explicitly mentioned.

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

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

Japan Agricultural Standard (JAS) for Organic Production
Not explicitly mentioned.

Ancillary Substances
The 2015 TR for nutrient vitamins and minerals notes that ferrous sulfate is sometimes encapsulated to prevent the iron from catalyzing oxidation reactions that lead to rancidity, color and taste changes, or other undesirable effects. It is usually encapsulated in hydrogenated vegetable fat, with lecithin as an optional ingredient.

Human Health and Environmental Issues
Iron is an essential component of hemoglobin, enzymes involved in energy metabolism, and other enzymes. Hemoglobin transports oxygen to body tissues.

Iron deficiency leads to anemia, poor work performance and endurance, persistent cognitive and developmental impairment, increased maternal perinatal mortality and a greater rate of premature labor and delivery, and depressed immune function.

However, excess dietary iron can also cause health problems. Accidental overdose of ferrous sulfate drops is the most common cause of poisoning deaths in children in the U.S. Chronic excess consumption can cause constipation, nausea, vomiting, iron accumulation in the liver, higher cancer risk, and hemochromatosis.

Ferrous sulfate may also be hazardous in cases of skin contact (irritant), eye contact (irritant), ingestion, or inhalation. Possibly hazardous short term biodegradation products are not likely. However, long term biodegradation products may arise. The products of biodegradation are less toxic than the product itself.

The 2015 TR does not include information on environmental concerns for ferrous sulfate.

Discussion
There has been past discussion about whether ferrous sulfate is encompassed within the nutrient vitamins and minerals listing or needs to be listed separately. The NOSB recommended identical annotations for ferrous sulfate and nutrient vitamins and minerals in 1995, but they were ultimately listed with different annotations. The nutrient vitamins and minerals annotation is broader and would encompass ferrous sulfate and potentially allow other uses. However, because of the risks of excess iron consumption, it is unlikely that it would be added to products outside the uses currently allowed under the ferrous sulfate annotation.

Several public comments supported keeping ferrous sulfate on the National List.

Justification for Vote
The Subcommittee finds ferrous sulfate compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote:
Motion to remove ferrous sulfate from the National List
Motion by: Allison Johnson
Seconded by: Kim Huseman
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 3

Hydrogen peroxide

Reference: § 205.605(b) Synthetics allowed
(17) Hydrogen peroxide.
Technical Report: 2015 TR (Crops)
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Hydrogen peroxide (CAS# 7722-84-1) is a very simple molecule with a formula of H2O2. It is a weak acid but also a strong oxidizer which makes it an effective microbial pesticide for organic handling purposes. It is used as a disinfectant and sanitizer and also for post-harvest treatment of produce. USDA organic regulations currently allow the use of hydrogen peroxide in organic crop production under 7 CFR §205.601(a) as an algicide, disinfectant and sanitizer, and under 7 CFR 205.601(i) for plant disease control as a fungicide. Hydrogen peroxide is also permitted for use in organic livestock production as a disinfectant, sanitizer and medical treatment (7 CFR 205.603(a)). Lastly, synthetic hydrogen peroxide may be used as an ingredient in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).” (7 CFR 205.605(b)).

Manufacture
According to the 2015 TR, commercially available hydrogen peroxide is industrially produced using the anthraquinone autoxidation (AO) process. The AO method involves initial catalytic reduction of an alkyl anthraquinone with hydrogen to form the corresponding hydroquinone. Subsequent autoxidation of the hydroquinone intermediate in air regenerates the anthraquinone with concomitant liberation of hydrogen peroxide. The simplified overall reaction involves direct combination of gaseous hydrogen (H2) and oxygen (O2): $H2+ O2 \rightarrow H2O2$

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Permitted for many uses including as food-grade cleaners, disinfectants and sanitizers that are allowed without mandatory removal of residues; cleaners, disinfectants and sanitizers allowed on food contact surfaces including equipment, provided that substances are removed from food contact surfaces prior to organic production; and as a food-grade processing aid for bleaching proteins and starches.

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Allowed as a processing aid for gelatine. (Annex V, Part A, Section A2, 2021/1165)

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

International Federation of Organic Agriculture Movements (IFOAM) Norms
Allowed as an equipment cleanser and disinfectant. (Appendix 4 - Table 2- page 82).

Japan Agricultural Standard (JAS) for Organic Production
Not explicitly mentioned.

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

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

Ancillary Substances
Other ingredients may include peroxyacetic acid (listed separately on the National List). The TR reports other potential materials present including caprylic acid and mono-and di-potassium salts of phosphorous acid, which is an oxidant stabilizer. Phosphorous acid is listed on the EPA Safer Choice list as a yellow triangle. (Yellow triangle - The chemical has met Safer Choice Criteria for its functional ingredient class, but has some hazard profile issues. Specifically, a chemical with this code is not associated with a low level of hazard concern for all human health and environmental endpoints. (See Safer Choice Criteria). While it is a best-in-class chemical and among the safest available for a particular function, the function fulfilled by the chemical should be considered an area for safer chemistry innovation.)

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

During the previous sunset cycle, it was supported by the prior Handling Subcommittee without dissent and

was relisted by the full NOSB without dissent.
The Subcommittee previously asked stakeholders to weigh in on whether hydrogen peroxide is an effective alternative to other more problematic sanitizers and whether certifiers allow it to be used in direct contact with products. The Subcommittee did not hear significant comments in direct response to these questions, although it welcomes responses to these legacy questions at any time.

Discussion during this sunset cycle at the subcommittee level has focused on the need to understand disposal factors for this substance, the essentiality of this material in the overall rotation of allowed sanitizers, and whether it has specific value in one sector or another. Questions emerged about the fact the annotation on this substance differs from that on peracetic acid (another sanitizer) and why that might be. At the Spring 2024 NOSB meeting, the Board received thirteen total written comments and some oral comments, all strongly in favor of relisting. The Board had no substantive discussion and is not proposing removal from the National List.

Justification for Vote
The Subcommittee finds hydrogen peroxide compliant with the Organic Foods Production Act (OFPA) and is not proposing removal.

Subcommittee Vote
Motion to remove hydrogen peroxide from 205.605(b) of the National List
Motion by: Wood Turner
Seconded by: Jerry D'Amore
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

Nutrient vitamins and minerals

Reference: § 205.605(b) Synthetics allowed
(20) Nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines For Foods.
Technical Report: 1995 TAP - Minerals; 1995 TAP - Vitamins; 2015 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 03/2011 Handling Subcommittee Proposal; 04/2011 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
This listing allows nutrient vitamins and minerals to be added to organic food in accordance with 21 CFR 104.20, which is the U.S. Food and Drug Administration's (FDA) fortification policy. That policy lays out principles intended to serve as a model for the rational addition of nutrients to food and promote a balanced and nutritious food supply, while avoiding over- or under- fortification of consumer diets. It outlines situations in which it may be appropriate to add nutrients to food, including certain situations

where needed to correct a dietary insufficiency recognized by the scientific community to exist and known to result in nutritional deficiency; to restore nutrients lost in storage, handling, or processing; to avoid nutritional inferiority of a food that replaces a traditional food; as well as where required by regulation. It states that FDA does not encourage indiscriminate addition of nutrients to foods, nor does it consider it appropriate to fortify fresh produce; meat, poultry, or fish products; sugars; or snack foods such as candies or carbonated beverages. Manufacturers are urged to use these principles to design fortified foods.

The 2015 TR breaks this umbrella listing into five categories: fat-soluble vitamins (Vitamins A, D, E, K, carotenoids), water-soluble vitamins (Vitamins C, B1, B2, B6, B12, niacin, folate, pantothenic acid, biotin, choline, inositol), trace mineral elements (chromium, copper, iodine, iron, manganese, molybdenum, selenium, zinc), major minerals in bone (calcium, phosphorus, magnesium, fluorine), and major electrolyte minerals (potassium, sodium, chloride).

Manufacture
Because this listing encompasses a wide range of substances with nutritional value, the processes used to create them also vary widely. Vitamins can be extracted from food, synthesized, produced via fermentation, or some combination of these methods. Of note, fermentation methods may involve genetically engineered microorganisms. Minerals are pulled from the environment, including brines, salt deposits, and mineral ores.

International Acceptance
In addition to the categorical listings described below, all international standards also individually list some substances that may be considered vitamins and minerals (i.e. ascorbic acid or calcium carbonate).

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Vitamins and mineral nutrients are allowed as ingredients not classified as food additives in three situations:

1. Shall be used if legally required (e.g., fluid milk, white flour, infant formula, meal replacement, etc.).
2. The following non-dairy substitute products may be fortified on a voluntary basis, if legally permitted: plant-based beverages, products that resemble cheese, and butter substitutes.
3. Ferrous sulphate shall be used if legally required and may be used, on a voluntary basis, if legally permitted.

European Economic Community (EEC) Council Regulation, EC No. 2018/848 & 2021/1165
Vitamins are allowed in the processing of food if their use is legally required. (Annex II, Part IV, 2.2.2 (f), 2018/848)

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Vitamins and minerals are allowed if their use is legally required in the food products in which they are incorporated. (3.5, page 29)

International Federation of Organic Agriculture Movements (IFOAM)
Minerals (including trace elements), vitamins, essential fatty, amino acids, and other isolated nutrients allowed when their use is legally required or strongly recommended in the food products in which they are incorporated. (Processing and Handling, page 19)

Japan Agricultural Standard (JAS) for Organic Production
Not explicitly mentioned.

Ancillary Substances
The 2015 TR states that ancillary substances are used to limit oxidation and promote even distribution of fat-soluble vitamins. Substances used to limit oxidation may include tocopherols, fat-soluble ascorbic acid (ascorbyl palmitate), carotenoids (e.g., beta carotene), and GRAS synthetic chemical antioxidants (BHT, BHA, PG, and TBHQ). Fat-soluble vitamin materials usually can be obtained free of BHT, BHA, PG, and TBHQ. Emulsifiers like lecithin are used to disperse fat-soluble vitamins in baby formula, and microencapsulation in starch, gums, gelatin, casein, and a wide range of other GRAS substances help with dispersion in other foods. Encapsulation is also used to protect and disperse water-soluble vitamins and minerals in substances including fats, waxes, and cellulose. Many, but not all, of these substances are included on the National List.

Human Health and Environmental Issues
The 2015 TR does not identify significant human or environmental issues connected with this categorical listing.

Discussion
The NOSB's original 1995 recommendation for the nutrient vitamins and minerals listing included this annotation: "Accepted for use in organic foods for enrichment or fortification when required by regulation or recommended by an independent professional organization," but the final rule published in 2000 (65 FR 13512) included the current annotation, which references FDA's fortification policy.

The Board and NOP have considered various proposals to change this listing to align more closely with the NOSB's original recommendation, to specifically address concerns about fortification of infant formula, and to consider nutrients that may fall in gray areas. According to the Board's 2019 sunset recommendation, in 2011 the Handling Subcommittee proposed to change the annotation at sunset but received approximately 2000 comments against it. The Subcommittee withdrew the proposal prior to the April 2011 NOSB meeting, and the NOSB supported relisting with the existing annotation for the 2012 sunset review. The NOSB also recommended listing certain nutrients (DHA, ARA), but not some amino acids and antioxidants.

Several subsequent actions were considered, but nothing further appears to have progressed after the current listing was retained in the 2021 sunset, in alignment with the Board's 2019 recommendation. Specifically, no action has been taken to:

- Act on the 2016 Handling Subcommittee discussion document, which outlined several options for annotation changes.
- Finalize or withdraw the January 12, 2012 Proposed Rule (77 FR 1979), which would have changed the listing to: "Vitamins and minerals. For food- vitamins and minerals identified as essential in 21 CFR 101.9. For infant formula-vitamins and minerals as required by 21 CFR 107.100 or §107.10." NOP published an Interim Rule on September 27, 2012 (77 FR 59287), effective October 21, 2012, which renewed the current listing until completion of the Proposed Rule.

It appears that there has not previously been sufficient public demand, regulatory challenge, or consensus to carry through with changes to this listing. The current reference to 21 CFR 104.20 in the annotation essentially commits the use of nutrient vitamins and minerals to an organic food manufacturer's discretion, within the principles the FDA has set out.

Public comments generally supported relisting nutrient vitamins and minerals, but demonstrated that there is still confusion about the annotation and what materials may be allowed under it. One certifier reported following the proposed rule from January 2012 that was never finalized, and another certifier reported following the current rule with the existing annotation (but also noted that they receive limited fortification

requests). A certifier noted that they do not review ancillary substances for nutrient vitamins and minerals and requested that the NOSB review ancillaries in the sunset process and identify them as allowed or prohibited. Several commenters noted that algal DHA is used in milk to add omega 3 fatty acids; the inclusion or exclusion of that material from the current listing remains unclear, and DHA has not been added to the National List individually.

The Board discussed various options for moving forward and clarifying this annotation, including proposing adoption of the annotation from the January 2012 proposed rule that was not finalized. The Board noted that certain vitamins and minerals required for fortification effectively cannot be removed by sunset, because they are legally required in certain food products, and considered the potential for recommending that those materials move to another place in the NOP regulations that is not subject to the sunset process. The Board also considered retaining the current listing with the explicit option to exclude materials by annotation.

Justification for Vote
The Subcommittee finds nutrient vitamins and minerals compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote:
Motion to remove nutrient vitamins and minerals from the National List
Motion by: Allison Johnson
Seconded by: Nate Lewis
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 3

Peracetic acid/Peroxyacetic acid

Reference: § 205.605(b) Synthetics allowed
(22) Peracetic acid/Peroxyacetic acid (CAS # 79-21-0)—for use in wash and/or rinse water according to FDA limitations. For use as a sanitizer on food contact surfaces.
Technical Report: 2000 TAP; 2016 TR
Petition(s): 2008 Petition (Crops)
Past NOSB Actions: 11/2000 recommendation (Periacetic [sic] acid p. 467); 04/2004 resolution (periacetic [sic] acid p. 2740); 11/2009 sunset recommendation; 04/2015 sunset recommendation; 10/2019 sunset recommendation.
Recent Regulatory Background: Added to National List with annotation 9/11/2006 (71 FR 53299); Renewed 8/03/2011 (76 FR 46595); Renewed 09/12/2016 (81 FR 8821); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Peracetic acid (CAS # 79-21-0) is currently allowed for use in organic handling in wash water and rinse water, including during post-harvest handling, to disinfect organically produced agricultural products, such as fruits and vegetables, according to FDA limitations. It is also used to sanitize food contact surfaces, including dairy-processing equipment, food-processing equipment, and utensils. It is an important sanitizer used in organic handling.

Peracetic acid/peroxyacetic acid was added to §205.605(b) on September 12, 2006 It is also on the National List at §205.601 and §205.603 for use in crops and livestock, respectively. Peracetic acid disinfects by oxidizing the outer cell membrane of vegetative bacterial cells, bacterial spores, endospores, yeast, and mold spores, making it an effective sanitizer against many microorganisms [2016 TR, lines 265-267]. The end products of peracetic acid oxidation are acetic acid and water.

Manufacture

According to the 2016 technical report (TR), solutions of peracetic acid used as sanitizers are created by combining aqueous mixtures of two substances: acetic acid (the acid in vinegar) and hydrogen peroxide. At cool temperatures, acetic acid and hydrogen peroxide react over a few days to form an equilibrium solution containing peracetic acid, acetic acid, and hydrogen peroxide. The equilibrium solution is the substance sold commercially as the sanitizer "peracetic acid." Solutions of peracetic acid, hydrogen peroxide, acetic acid and water are produced by reacting glacial acetic acid with hydrogen peroxide, often in the presence of a catalyst such as a mineral acid (e.g., sulfuric acid) [2016 TR, lines 451-458]. Commercial grades are available in concentrations ranging from about 0.3 to 40% by weight. A peracetic acid solution can also be generated in situ by dissolving an activator and a persalt in water or on site by adding sodium hydroxide to triacetin and hydrogen peroxide [2016 TR, lines 53-62].

International Acceptance

Canadian General Standards Board Permitted Substances List

Not explicitly mentioned for processed products. On food and plants, peracetic acid may be used in wash or rinse water and on food contact surfaces. (Table 7.3, page 42)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 & 2021/1165

Allowed for cleaning and disinfection. (Annex IV, Part D, 2021/ 1165)

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

Not explicitly mentioned for processed products.

International Federation of Organic Agriculture Movements (IFOAM) Norms

Allowed as an equipment cleanser and disinfectant. (Appendix 4, Table 2, page 82)

Japan Agricultural Standard (JAS) for Organic Production

Not explicitly mentioned.

Environmental Issues

Peracetic acid likely has no significant environmental impacts. Like other oxidative sanitizers (i.e., chlorine compounds), concentrated solutions of peracetic acid are strong irritants to the skin, eyes, mucous membranes, and respiratory system. As reviewed in the TR, when using fully diluted sanitizing solutions, no special eye, hand, skin, or respiratory protective equipment is normally required [2016 TR, lines 647-651]. No risk through dietary exposure is anticipated. All uses of this material should be consistent with FDA, USDA, and EPA labels and regulations and utilize personal protective equipment as needed.

Ancillary Substances

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

Discussion
Peracetic acid has been relisted each time it was reviewed during the sunset review process. There has been strong support for continued availability of this material. Oral and written comments submitted for the Spring 2019 NOSB meeting represent hundreds, if not thousands, of crop and livestock farmers and processors who uniformly support relisting this essential and relatively safe material. In particular, many processors identified the need for a "no-rinse" material as essential for treating equipment and other food contact surfaces. Overall, this material is considered effective and offers a less toxic profile compared to several other sanitizing materials, including many chlorine compounds. The 2016 TR does not offer new evidence of unacceptable adverse impacts on human health or the environment.

During the last review, use of a synthetic stabilizer such as 1-hydroxyethylidene-1,1- diphosphonic acid (HEDP) or 2,6- pyridinedicarboxylic (dipicolinic) acid to slow the rate of oxidation or decomposition were judged to be "inerts" for EPA registration as an antimicrobial and not subject to review as an ancillary substance. However, comments submitted for the Spring 2019 NOSB Meeting stated that dipicolinic acid is a former List 3 inert, is not allowed in products used in organic production, and identifies additional inert materials that warrant review. Only products with allowable inert ingredients should be used.

During the previous sunset cycle, the Handling Subcommittee supported relisting without dissent and this substance was recommended for relisting by the full NOSB without dissent.

Discussion during this sunset cycle at the Subcommittee level has focused on the need to understand disposal factors for this substance, the essentiality of this material in the overall rotation of allowed sanitizers, whether it has specific value in one sector or another, and how stakeholders might become more open to using sanitizers like peracetic acid that are less corrosive without losing efficacy. Questions emerged about the fact that the annotation on this substance differs from that on hydrogen peroxide (another sanitizer) and why that might be. At the Spring 2024 NOSB meeting, the Board received seventeen total written comments and some oral statements, all strongly in favor of relisting. The Board had no substantive discussion and is not proposing removal from the National List.

Questions to Stakeholders

1. Are certifiers looking at ancillary substances in peracetic acid? Are there always ancillary substances that should be considered with respect to peracetic acid?

Justification for Vote
The Subcommittee finds peracetic acid compliant with the Organic Foods Production Act (OFPA) and is not proposing removal.

Subcommittee Vote
Motion to remove peracetic acid from 205.605(b) of the National List
Motion by: Wood Turner
Seconded by: Dilip Nandwani
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

Potassium citrate

Reference: § 205.605(b) Synthetics allowed
(25) Potassium citrate.
Technical Report: 1995 TAP; 2015 TR; 2023 Limited Scope Technical Report (pdf) (citric acid and salts)
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Potassium and sodium citrate are used as ingredients where they function as acidulants, pH controls, flavoring agents, sequestrants, and buffering or emulsifying agents. Potassium citrate is used to replace sodium citrate whenever a low sodium content is desired. The three citrates are also used as dispersants in flavor or color additives, and to wash processing equipment to remove off flavors.

Potassium citrate is commonly used in biscuits, baby food, soup mixes, soft drinks, and fermented meat.

Manufacture
Citric acid is a naturally-produced, non-volatile organic acid with a long history of use in food processing. The 2015 TR considered production of citric acid by microbial fermentation with *Aspergillus niger* or *Candida* yeasts from carbohydrate sources but includes additional information regarding production from plant sources.

Note that the process that creates citric acid is fermentation of carbohydrates. In terms of concern about excluded methods, the 2015 TR indicates that the organisms underlying the fermentation process are considered 'classical mutants,' and further notes that the prohibition on excluded methods in food by the European countries suggests the underlying citric acid is unlikely to include carbohydrates that have manipulated genes.

The citrate salts – calcium citrate, potassium citrate and sodium citrate – are all derived from citric acid. The citrate salts are produced by chemical reaction with citric acid and the hydroxide or carbonate of the respective salt (calcium, sodium or potassium).

Potassium citrate is the potassium salt of citric acid. It is prepared by neutralizing citric acid with potassium hydroxide or potassium carbonate and subsequent crystallization. It is most commonly found in the monohydrate form.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed as food additives (Table 6.3, CAN/CGSB-32.311-2020, page 33).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Not explicitly mentioned.

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

International Federation of Organic Agriculture Movements (IFOAM)
Allowed as an additive (Appendix 4 – Table 1 – page 79).

Japan Agricultural Standard (JAS) for Organic Production
Not explicitly mentioned.

Ancillary Substances
None

Human Health and Environmental Issues
There are no expected significant human health impacts or remarkable environmental issues, according to the 2015 TR.

Discussion
The bulk of the discussion about this product addresses the production process for citric acid.

The nine public comments made prior to the Spring 2024 meeting were largely supportive of relisting; concern was raised about fermentation for citric acid, which this product is derived from.

The Board had no comments.

Justification for Vote
The Subcommittee finds potassium citrate compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove potassium citrate from the National List
Motion by: Carolyn Dimitri
Seconded by: Kim Huseman
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 3

Potassium phosphate

Reference: § 205.605(b) Synthetics allowed
(28) Potassium phosphate—for use only in agricultural products labeled "made with organic (specific ingredients or food group(s))," prohibited in agricultural products labeled "organic".
Technical Report: 1995 TAP; 2016 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Potassium phosphate can be used as for pH control in milk and dairy products, to make acidified milk products, and in milk protein stabilization. Potassium phosphate interacts with milk proteins, such as casein, to function as emulsifiers that prevent the separation of fat and water in cheese, and to stabilize milk and cheese by chelating (sequestering) calcium [2016 TR, lines 191-193].

Potassium phosphate can also be used as a nutritional additive as a source of potassium, as a nutrient in yeast, and in prepared meat applications and liquid eggs. The 1995 Technical Advisory Panel report (TAP) included a recommendation to list this material as an approved synthetic in products labeled "organic," but was only approved for use in "made with" products.

Manufacture
The 1995 TAP noted potassium phosphates are isolated from brines or salt deposits. However, the 2016 technical report (TR) explained that all of the orthophosphate derivatives of potassium can be generated by the neutralization of phosphoric acid with potassium hydroxide. Phosphoric acid is produced by treating phosphate rock (tricalcium phosphate) with sulfuric acid, forming phosphoric acid and calcium sulfate. Potassium hydroxide is obtained commercially from the electrolysis of potassium chloride solution in the presence of a porous diaphragm [2016 TR, Table 5].

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed as ingredients classified as food additives. For use in products whose contents are ≥ 70% and < 95% organic ingredients. (Table 6.3, CAN/CGSB-32.311-2020, page 33)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Not explicitly mentioned

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Not explicitly mentioned

https://www.ifoam.bio/our-work/how/standards-certification/organic-guarantee-system/ifoam-normsInternational Federation of Organic Agriculture Movements (IFOAM)
Not explicitly mentioned

Japan Agricultural Standard (JAS) for Organic Production
Not explicitly mentioned

Ancillary Substances
Not identified

Human Health and Environmental Issues
During the last sunset review, commenters noted a concern with the use of phosphates in the production of processed foods and that phosphorus may not appear on the nutritional panel, making it difficult to be informed about total phosphorous intake– although they would appear on the ingredient list. There were concerns raised about the cumulative health impacts of phosphorous additives in food and, in 2015, the NOSB requested a technical review and work agenda item to study this issue further. According to the 2016

TR, since most dairy foods naturally contain substantial amounts of both sodium and phosphorus from milk, the small incremental amount of sodium and phosphorus contributed by a sodium phosphate stabilizer may exempt sodium phosphate from the requirement to be declared as an ingredient on the label; this would not be allowed in hypoallergenic foods and infant foods [2016 TR, lines 135-139]. The TR indicates that small amounts of sodium phosphates may not cause human health problems, but long-term cumulative impacts are not fully understood.

Discussion
Concerns were based on peer reviewed research indicating that the cumulative effects of phosphates as a group contribute to renal damage and failure, osteoporosis, and heart failure. Sodium phosphate was reviewed in 2017 and the NOSB concluded that no single phosphate food additive or ingredient can be implicated as an isolated risk factor. Concerns arise from the increase in cumulative use of phosphates and possible health effects on the general population.

There were no oral comments about this material for the Spring 2024 NOSB meeting. All written comments supported relisting potassium phosphate. The Subcommittee asked stakeholders for information regarding human health concerns with phosphates. No new data was presented; however, there is a pending petition to remove the restriction that potassium phosphate can only be used in products labeled 'made with organic' ingredients and to change "potassium phosphate" to "potassium phosphates," which would allow new types of potassium phosphates (*e.g.,* diphosphates and triphosphates) in organic food products.
Questions to our Stakeholders
None

Justification for Vote
The Subcommittee finds potassium phosphate compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600, however, the group has concerns about effects of cumulative use of phosphates on human health.

Subcommittee Vote:
Motion to remove potassium phosphate from the National List
Motion by: Logan Petrey
Seconded b: Kyla Smith
Yes: 3 No: 4 Abstain: 0 Recuse: 0 Absent: 2

Sodium acid pyrophosphate

Reference: § 205.605(b) Synthetics allowed
(30) Sodium acid pyrophosphate (CAS # 7758-16-9)—for use only as a leavening agent.
Technical Report: 2001 TAP (Sodium Phosphates); 2010 TR; 2016 TR
Petition(s): 2002; 2007 (Petition for expanded use)
Past NOSB Actions: 05/2003 recommendation; 11/2009 sunset recommendation; 04/2011 recommendation; 10/2019 sunset recommendation
Regulatory Background: Added to National List 09/12/06 (71 FR 53299); Renewed 8/03/2011 (76 FR 46595); Renewed 09/12/16 (81 FR 8821); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
The 2010 Technical Report (TR) indicates that sodium acid pyrophosphate is used in conventional foods as a chemical leavening agent in baked goods; a sequestrant (chelating agent) to maintain the appearance of cooked and uncooked fruits and vegetables, particularly processed potatoes; an emulsifying agent and stabilizer in cheeses and related products; an inhibitor of struvite formation in canned tuna; and a curing accelerator in processed meat and poultry products [2010 TR, lines 36-40]. The NOP regulations at 7 CFR 205.605(b) limit the use of sodium acid pyrophosphate in organic foods to use only as a leavening agent. Sodium acid pyrophosphate is used as a component of chemical leavening agents (baking powder).

In some meat- and poultry-containing processed foods, sodium acid pyrophosphate is used to accelerate color fixing or to preserve color during storage of cured pork and beef cuts, cured poultry, and cured comminuted poultry and meat food products. However, in organic foods, sodium acid pyrophosphate is permitted solely for leavening, so this color-fixing use is not permitted.

Manufacture
Sodium carbonate is reacted with phosphoric acid to form monosodium phosphate, followed by heating the monosodium carbonate to 220°C to form sodium acid pyrophosphate. It is expressed by the formula $Na_2H_2P_2O_7$ and is composed of 20.72% Na, 0.91% H, 27.91% P, and 50.46% O. Sodium is isolated from brines or salt deposits. Phosphorous is isolated from phosphate rock. Food-grade phosphates are formed by reacting purified phosphoric acid with sodium, potassium, or calcium hydroxides.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed in ingredients classified as food additives. For use as a leavening agent. (Table 6.3, CAN/CGSB-32.311-2020, page 34)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Not explicitly mentioned

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Not explicitly mentioned

https://www.ifoam.bio/our-work/how/standards-certification/organic-guarantee-system/ifoam-normsInternational Federation of Organic Agriculture Movements (IFOAM)
Not explicitly mentioned

Japan Agricultural Standard (JAS) for Organic Production
Not explicitly mentioned

Ancillary Substances
None identified

Human Health and Environmental Issues
The 2016 TR on phosphates includes extensive discussion on the impact of phosphorous on the human diet, with particular focus on health effects of phosphorous provided by phosphate additives versus natural phosphorous in foods. Added phosphorous, as is found in sodium acid pyrophosphate, is immediately and

completely bioavailable upon consumption, whereas “food” phosphorous is much less available. High blood-phosphate levels are associated with kidney and vascular disease. A sufficiently high intake of calcium appears to counteract some of the ill effects of excess dietary phosphorus, but leads to an increased requirement for magnesium. Due to the restrictions on phosphate use in organic foods, it would be expected that basing a diet on organic foods would reduce phosphorus intake.

Discussion
Yeast is a natural leavener, but results in a different physical texture and requires more time than chemically-leavened foods. Chemical leavening is used instead of yeast for products where fermentation flavors would be undesirable or where the batter lacks the elastic structure to hold gas bubbles for more than a few minutes, such as muffins, pancakes and cookies.

Many manufacturers provided comments during the 2019 sunset review about the essentiality of sodium acid pyrophosphate because it is the only chemical leavening agent available.

There were no oral comments about this material for the Spring 2024 NOSB meeting. All written comments supported the relisting of sodium acid pyrophosphate. The Subcommittee asked stakeholders for information regarding human health concerns. No new data was presented. There was little to no discussion during the full board meeting.

Questions to our Stakeholders
None

Justification for Vote
The Subcommittee finds sodium acid pyrophosphate compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote:
Motion to remove sodium acid pyrophosphate from the National List
Motion by: Logan Petrey
Seconded by: Kyla Smith
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

Sodium citrate

Reference: § 205.605(b) Synthetics allowed
(31) Sodium citrate.
Technical Report: 1995 TAP; 2015 TR; 2023 Limited Scope Technical Report (pdf) (citric acid and salts)
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Potassium and sodium citrate are used as ingredients where they function as acidulants, pH controls, flavoring agents, sequestrants, and buffering or emulsifying agents. Potassium citrate is used to replace sodium citrate whenever a low sodium content is desired. These materials are also used as dispersants in flavor or color additives, and to wash processing equipment to remove off flavors.

Sodium citrate is used as an emulsifier in dairy products to keep fats from separating, and in cheese making where it allows the cheeses to melt without becoming greasy.

Sodium citrate is chiefly used as a food additive, usually for flavoring or as a preservative. Sodium citrate gives club soda both its sour and salty flavors. It is common in lemon-lime soft drinks, and it is partly what causes them to have their sour taste. Additionally, it is used in jams, jellies, meat products, baby foods, and milk powder.

Manufacture
Citric acid is a naturally-produced, non-volatile organic acid with a long history of use in food processing. The 2015 TR considered production of citric acid by microbial fermentation with *Aspergillus niger* or *Candida* yeasts from carbohydrate sources but includes additional information regarding production from plant sources.

Note that the process that creates citric acid is fermentation of carbohydrates. In terms of concern about excluded methods, the 2015 TR indicates that the organisms underlying the fermentation process are considered 'classical mutants,' and further notes that the prohibition on excluded methods in food by the European countries suggests the underlying citric acid is unlikely to include carbohydrates that have manipulated genes.

The citrate salts – calcium citrate, potassium citrate and sodium citrate – are all derived from citric acid. The citrate salts are produced by chemical reaction with citric acid and the hydroxide or carbonate of the respective salt (calcium, sodium or potassium).

Sodium citrate is the sodium salt of citric acid. It is prepared by neutralizing citric acid with sodium hydroxide or sodium carbonate and subsequent crystallization. It is most commonly found in the anhydrous or dihydrate forms.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed as food additives (Table 6.3, CAN/CGSB-32.311-2020, page 34).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Allowed as a food additive and processing aid in products of plant and animal origin (Annex V, Part A, A1, 2021/1165).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Sodium Dihydrogen Citrate is not allowed in food of plant origin. Allowed in milks/cream, dairy-based drinks, unripened cheese, and yogurt as a stabilizer only. Allowed in processed cheese as an emulsifier only.

Allowed in whey and whey products; excluding whey cheeses; processed meat; poultry, and game products; and egg white products (page 25).

International Federation of Organic Agriculture Movements (IFOAM)
Allowed as an additive (Appendix 4 - Table 1 - page 79).

Japan Agricultural Standard (JAS) for Organic Production
Sodium citrate is allowed, but limited to use for dairy products, or for albumen and sausage as low temperature pasteurization.

Ancillary Substances
None

Human Health and Environmental Issues
There are no expected significant human health impacts or remarkable environmental issues, according to the 2015 TR.

Discussion
The bulk of the discussion about this product addresses the production process for citric acid.

Twelve written comments prior to the 2024 public meeting were supportive of relisting, and one commenter mentioned this product was a good alternative to phosphates, and for this reason should remain on the list.
The Board members did not say much about this material.

Justification for Vote
The Subcommittee finds sodium citrate compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove sodium citrate from the National List
Motion by: Carolyn Dimitri
Seconded by: Jerry D'Amore
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 3

Tocopherols

Reference: § 205.605(b) Synthetics allowed
(36) Tocopherols—derived from vegetable oil when rosemary extracts are not a suitable alternative.
Technical Report: 1995 TAP; 2015 Limited Scope TR; 2024 Limited Scope TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2011 sunset recommendation; 10/2015 sunset recommendation; 09/2016 Handling Subcommittee proposal to add listing; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

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

Manufacture
Tocopherols are a group of lipophilic phenolic antioxidants that occur naturally in a variety of plant species.

The main sources of tocopherols are plant derivatives (such as various ground meals) and, more commonly, the deodorized distilled sludge (DD) obtained from conventional vegetable oil refining. Soybean oil deodorized distillate is the primary source of tocopherols due to soybean oil's low cost, although corn and rapeseed oil are also sometimes used. Table 2 in the 2024 TR summarizes the source materials and the extraction method commonly used.

As described in the 2024 TR, tocopherols are separated from the other compounds in the oil distillate by multiple extraction and refining steps. These steps can include solvent extraction, pressurized liquid extraction, extraction using matrix solid phase dispersion, superficial fluid extraction, ultrasonic assisted extraction or molecular distillation.

Being that there are several source materials and several manufacturing processes, it is not possible to categorically state that tocopherols are nonsynthetic or synthetic. Table 3 from the 2024 TR summarizes the classification of tocopherols as nonsynthetic or synthetic.

The total tocopherol content of the resulting product is usually 30 - 80%. Liquid forms of mixed tocopherols are commercially available diluted in vegetable oils and are also available as mixtures with rosemary extracts, ascorbyl palmitate/ascorbic acid, lecithin and/or citric acid. Powdered forms of tocopherols are produced by spray-drying the liquid tocopherol oils onto a carrier or mixture of carriers.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed as ingredients classified as food additives. Tocopherols may be derived from vegetable oil when rosemary extract is not a suitable alternative. (Table 6.3, CAN/CGSB-32.311-2020, page 34)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Allowed as an antioxidant in products of plant & animal origin. (Annex V, Part A, Section A1, 2021/1165)

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Natural tocopherols allowed. (Table 3 - page 24)

International Federation of Organic Agriculture Movements (IFOAM)
Allowed as a processing/post-harvest handling aid if from a natural source. (Appendix 4 - Table 1 - page 79)

Japan Agricultural Standard (JAS) for Organic Production

Allowed as an additive when used in products of livestock origin. Limited to the use in processed meat. (Appended Table 1)

Ancillary Substances
The following ancillaries were listed in the 2015 TR: sunflower oil, soybean oil, gum acacia, sterols, squalene, monodiglycerides, calcium carbonate, silica, rice maltodextrin, organic sunflower oil, tapioca starch. The 2015 TR also listed "unknown" in the ancillary column for several tocopherol products. [2015 TR, Table 1]

Human Health and Environmental Issues
Environment: Tocopherols are abundant in plant tissues and therefore are naturally abundant in the environment. Potential contamination could result from the manufacturing process of tocopherols if organic solvents and other chemicals are used. If these are released into the environment through waste streams, then environmental contamination could occur. The 2015 TR found no sources that discussed the possible persistence of tocopherols in the environment nor that concentrations of tocopherols or its breakdown products were present in the environment. [2015 TR 476-486]

Human Health: GRAS. It is unlikely that the use of tocopherols as an antioxidant in foods is harmful to human health. Tocopherols are a natural part of the human diet, with a large portion coming from naturally present in vegetable oils [2015 TR 507-509]

Discussion
During previous reviews, the Board has consistently relisted tocopherols due to their wide use in many processed foods even though stakeholders have been divided about relisting.

Those in favor stated that tocopherols are critically essential to maintaining food safety, preventing rancidity, and providing nutrients to their products, and that rosemary oil imparted off flavors or fragrances to their products that were not acceptable to consumers.

Those opposed stated that the material's primary use is as a preservative and therefore inconsistent with organic production, along with the assertion that non-synthetic tocopherols are commercially available and should be used instead of synthetic.

At the Fall 2019 meeting, the 2017 decision by the Handling Subcommittee to not move forward with an annotation change was reiterated, noting that if there were sufficient commercial availability of tocopherols in another form that members of the public were encouraged to submit a petition.

The Handling Subcommittee requested a limited scope TR to address the following: update to evaluation questions 1, 2, 3 and 13 to clarify the different manufacturing process of non-synthetic and synthetic tocopherols, as well as the commercial availability of the different forms (non-synthetic vs. synthetic).

As part of the Spring 2024 agenda and review of this substance, about a dozen comments were submitted. All were in favor of relisting or didn't state their opposition. Some commenters did report that they don't use rosemary because of the flavor it imparts in their product. We had some commenters again ask us to investigate the availability of natural tocopherols.

The 2024 TR provides updated information regarding the manufacturing of tocopherols. As stated above in the manufacturing section there are several sources of tocopherols with varying extraction methods, resulting in the classification as nonsynthetic or synthetic.

Also, the TR included several spice extracts that could be used to prevent lipid oxidation. It would seem that these would have a similar issue as the rosemary extract – in that operations would not want to use them since they would impart potentially unwanted flavor.

While it does appear that tocopherols are available in nonsynthetic form (as well as one certified organic tocopherol product), it is unclear if the predominant source currently in use is nonsynthetic or synthetic. It is still the view of the Subcommittee that if there is an adequate and suitable supply of tocopherols that a petition should be submitted for the addition of tocopherols at §205.605(a) or §205.606, and the removal from §205.605(b).

Questions to our Stakeholders

1. Are organic tocopherols commercially available?
2. Is there an adequate and suitable supply of non-synthetic tocopherols to meet commercial needs?

Justification for Vote
The Subcommittee finds tocopherols compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove tocopherols from the National List
Motion by: Kyla Smith
Seconded by: Dilip Nandwani
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

Celery powder

Reference: § 205.606 Nonorganic agriculturals allowed
(c) Celery powder
Technical Report: N/A
Petition(s): 2007 Petition
Past NOSB Actions: 03/2007 NOSB recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Celery powder serves a dual purpose in the formulation of meat products. In addition to flavor, its primary function is as a natural source of nitrate which cures meat without relying on synthetic nitrates and nitrites and has been used in this application for millennia. There are other vegetables and minerals which contain natural nitrates including beets, spinach and sea salt. Although each has its benefits and challenges, none is an ideal substitute for natural celery powder in quality, form and function.

In the organic sector, celery powder is used in a variety of processed meat products (hot dogs, bacon, ham, corned beef, pastrami, pepperoni, salami, etc.) to provide “cured” meat attributes without using prohibited

nitrites. Celery powder is naturally high in nitrates that are converted to nitrites during fermentation by a lactic acid culture. Celery powder and the presence of nitrate and nitrites protects against spoilage (as an antioxidant) and also reduces risk from food borne pathogens, including clostridium botulinum, which produces botulin toxin. Celery powder is used in place of synthetic chemical nitrate and nitrite which are not currently permitted in U.S. organic agriculture. Although functionally similar to the use of synthetic nitrate and nitrite, meat products processed with celery powder must be labeled "uncured."

Manufacture
Celery is cleaned, macerated, physically separated (liquid/solid), and the liquid is concentrated by evaporation, then heated and vacuum dried. According to the original 2007 petition, 0.2-0.5% celery powder and 0.01-0.5% of lactic acid starter culture are used to convert the nitrates to nitrite and thus create the curing agent. According to the Kerry Inc. patent (https://patentimages.storage.googleapis.com/1b/75/a5/082eb2538620f2/US20080305213A1.pdf), "the curing agent can further comprise additional components, including but not limited to, yeast extract, protein hydrolyzates, amino acids, vitamins, minerals, and carbohydrates. Prior to the conversion of nitrate to nitrite, the pH and salt content of the plant material can be adjusted with the addition of a suitable acid, base, salt, or combination thereof. The plant material can be subjected to additional processing steps prior to conversion of nitrate to nitrite. Such processing steps can include, but are not limited to, heat treatment, filter sterilization, or a process which reduces the initial microbial load." Celery powder is typically standardized to a specific nitrite content. See discussion below for more information about source material.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed as food additives: Extracts, juice, or cultured powder of celery or chard are allowed. Shall be organic if commercially available. (Table 6.3, Meat curing agents listing, CAN/CGSB-32.311-2020, page 33)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Not explicitly mentioned, although sodium nitrate (an alternative to celery powder) is allowed.

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

International Federation of Organic Agriculture Movements (IFOAM) Norms
Not explicitly mentioned

Japan Agricultural Standard (JAS) for Organic Production
Not explicitly mentioned.

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

powder would pose similar risks. Nitrates in food may provide some health benefits. For example, formation of nitrous oxide may result in lowered blood pressure and better cardiovascular function.

Ancillary Substances
Possibly materials listed in the patent and 2007 petition: “including but not limited to, yeast extract, protein hydrolyzates, amino acids, vitamins, minerals, and carbohydrates.”

Discussion
In the organic sector, celery powder is used in a variety of processed meat products (hot dogs, bacon, ham, corned beef, pastrami, pepperoni, salami, etc.) to provide “cured” meat attributes without using prohibited nitrites. Celery powder is naturally high in nitrates that are converted to nitrites during fermentation by a lactic acid culture.

Concerns were raised about the direct dependence on a conventionally grown agricultural product in organic trade and concomitant impacts on human health and the environment. Particular concerns have been raised about the possibility of enhanced use of nitrate fertilizers to “supercharge” the product used for celery powder manufacture.

In lieu of a technical report, a celery powder expert panel was convened for the April 2019 NOSB meeting. Experts spoke to key questions addressing nitrate safety, organic celery powder production, processing and manufacture of celery powder, progress toward organically sources celery or other substrates that could be used process organic meats, and the scale of the organic processed meat industry.

Overall, trade and industry members of the organic community supported relisting of celery powder at §205.606, with the caveat that more research is needed to produce a viable organic alternative. Given the importance of the organic processed meat industry, public and NOSB comments encouraged the USDA to fund additional research to develop organic alternatives to conventionally produced celery powder. It continues to be included in the Handling Subcommittee annual research priorities (most recently on the approved proposal from the Fall 2023 NOSB meeting).

Celery powder was relisted by the NOSB in 2017 on a split vote (9-5). It was recommended by the Handing Subcommittee for relisting in 2019 with no dissent and relisted by the full board with one member in dissent.

Discussion during the current sunset cycle on this substance has focused on questions of ancillary substance review, fermentation, and an interest in understanding environmental impacts from conventional celery production. At the Spring 2024 NOSB meeting, the board received twelve unique written comments. Most of the comments supported continued relisting, asserting the essentiality of the material in key applications. Certifiers attested to substantial use among clients. Others, representing non-profits, retailers, and coalitions, urged strongly for the material’s removal from the National List, largely on the grounds of potential human health impacts from nitrate and nitrite exposure some suggested was similar to or even exceeding conventional cured meats. Board discussion was substantive and largely focused on positive research (supported by significant grants informed by ongoing NOSB Research Priorities) from the University of Wisconsin-Madison about effective organic curing sources – including Swiss chard -- that currently would not meet the needs of the entire organic meat industry but are likely to within a few short years.

Questions to our Stakeholders

1. Is there stakeholder concern about ongoing non-specified ancillary substances used in this material?
2. Is organic supply commercially available for this material? What are the barriers to organic production?
3. Is the organic version of the same caliber as the nonorganic?
4. Are stakeholders comfortable with the state of emerging research around alternatives?

Justification for Vote

The Subcommittee finds celery powder compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote

Motion to remove celery powder from the National List
Motion by: Wood Turner
Seconded by: Jerry D'Amore
Yes: 2 No: 7 Abstain: 0 Recuse: 0 Absent: 0

Fish oil

Reference: § 205.606 Nonorganic agriculturals allowed

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

Technical Report: 2015 TR
Petition(s): 2007
Past NOSB Actions: 03/2007 recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Added to NL 6/21/2007 (72 FR 35137); Renewed 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use

Fish oil is currently included on the National List as a nonorganically produced ingredient allowed in or on processed products labeled as "organic" when the substance is not commercially available in organic form (7 CFR 205.606). FDA GRAS notices (GRNs) exist for several variations of the term fish oil.

- fish oil concentrate (GRN 105)
- fish oil (GRN 138)
- fish oil (predominantly sardine and anchovy); tuna oil (GRN 193)

Fish oil is used in organic processing and handling as an ingredient to increase the content of omega-3 fatty acids—primarily, eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA)—in foods to benefit human health by contributing to healthy brain development and reducing risks of cardiovascular disease, diabetes, inflammation, atherosclerosis. Fish oil is used in a variety of food products, including breads, pies, cereals, yogurt, cheese products, frozen dairy products, meat products, cookies, crackers, snack foods, condiments, sauces, and soup mixes. [2015 TR 19-25]

Fish oil is also used in aquaculture as a feed supplement for farmed fish (Naylor et al., 2001). The farmed fish are fed fish oil because their diets are typically deficient in plants and animals that lead to the inherent production of fish oil (Naylor et al., 2001). [2015 TR 148-150]

In addition to aquaculture—estimated to use about 81% of the fish oil produced worldwide—fish oil is used in feed for livestock such as pigs, cattle, poultry, and sheep. Industrial applications of fish oil include paint production, leather making, and biodiesel manufacture. Historically, fish oil was used as lamp oil, among other uses (Rizliya and Mendis, 2014). [2015 TR 155-158]

Manufacture

Fish oil is produced from fish byproducts or from fish that are caught specifically for the purpose of making fish oil (Kim and Venkatesan, 2014). Between 20 and 80 kilograms of fish oil can be extracted per ton of fish waste (Karadeniz and Kim, 2014). The steps for fish oil extraction are-

- Once the raw fish or fish parts are obtained, they are cooked in steam at 100 °C in a process called wet reduction (U.S. EPA, 1995; Kim and Venkatesan, 2014). The cooked material is then strained and sent to a press, where liquid, including the oil, is pressed from the cooked fish (U.S. EPA, 1995). The oil is decanted from the pressing liquid, and separation is accomplished using a centrifuge (U.S. EPA, 1995; Kim and Venkatesan, 2014). The oil may be further washed with hot water in a process called polishing (U.S.EPA, 1995). The oil is stored in tanks until it is used for its commercial purpose as a food ingredient or supplement, and any remaining fish solids or fish solubles from the process are dried and used as fish meal (Kim and Venkatesan, 2014). At this point in the process, the only additions to the fish oil are water, heat, and pressure. The waste streams from this process include emissions of volatile organic compounds (VOCs) hydrogen sulfide and trimethylamine and wastewater. VOC emissions result during both the pre- of fish solids and fish solubles into fish meal (U.S. EPA, 1995). [2015 TR 283-296]

Fish oil may be further processed by hardening, which is performed to further purify the oil (U.S. EPA, 1995). [2015 TR 304-305]

Further extraction and purification of the oil can be performed by selective hydrolysis, followed by filtration, neutralization with sodium hydroxide, removal of oxidized oil by clay, and deodorization using steam distillation (EPAX Norway, undated; U.S. FDA, 2002). [2015 TR 311-313]

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Not explicitly mentioned.

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Fish oil is allowed in feed for carnivorous aquaculture animals (EC No 2018/848, General requirements, 3.1.3.3, page 76).

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

International Federation of Organic Agriculture Movements (IFOAM)
Not explicitly mentioned.

Japan Agricultural Standard (JAS) for Organic Production

Not explicitly mentioned.

Ancillary Substances
None.

Human Health and Environmental Issues
The 2015 TR notes that although there are potential human health benefits of consuming fish oil, including reduced risk of various cardiovascular and digestive diseases, there are also risks; fish oil consumption may increase exposure to mercury and other contaminants that may interfere with early brain development and may increase risk of bleeding. A laboratory analysis of 31 fish oil supplements found that every product contained measurable amounts of mercury, PCBs might also be present in fish oil. Dioxins and furans are hazardous environmental compounds that may also be found in fish and fish oil.

The environmental impacts of fishing are severe. The number of collapsed fish stocks has increased exponentially since the 1950s and demands on fisheries may overburden the current supply of fish. Exploitation of fisheries is also the largest contributor to marine extinctions, above habitat loss, climate change, invasive species, pollution, and disease. Aquaculture is the largest use of fish oil worldwide.

Discussion
In Fall 2021, the Board unanimously recommended an amendment to the annotation on fish oil restricting sources to fishing by-products only and to fishing industries that meet third-party sustainability standards:

> §205.606 (e) Fish oil (Fatty acid CAS #'s: 10417-94-4, and 25167-62-8) - stabilized with organic ingredients or only with ingredients on the National List, §§205.605 and 205.606. Sourced from fishing industry by-product only and certified as sustainable against a third-party certification that is International Social and Environmental Accreditation and Labeling (ISEAL) Code Compliant or Global Seafood Sustainability Initiative (GSSI) recognized.

The recommendation is now listed as "Closed" in the NOSB Recommendations Library, with the note "AMS does not plan to act on this recommendation at this time." At the Fall 2023 NOSB meeting, the NOP indicated that they would not be moving forward with that recommendation, or related recommendations from the Crops and Materials subcommittees, in part due to the complexity of identifying appropriate third-party sustainability standards.

Some commenters continued to note that moving forward with the organic aquaculture standard and developing an organic production standard for wild caught fish would facilitate the production of certified organic fish oil and could alleviate concerns about overfishing and toxic contaminants present in fish oil.

The Handling Subcommittee discussed fish oil extraction, the manufacturing process, and environmental issues. The Subcommittee understands the challenges with referencing third-party standards in NOP regulations, but also remains concerned about the environmental impacts of overfishing. As described above, the Canadian and European Union organic standards for aquaculture both allow fish oil to be used in aquaculture, with limitations that promote sustainability. The Canadian annotation, which references the FAO Code of Conduct for Responsible Fisheries, appears relatively simple and appropriate to implement in the United States. In the meantime, fish oil remains an essential ingredient in organic products, and its use in processed organic products has a small impact on fisheries, relative to its use in aquaculture. The Subcommittee does not recommend removing it at this time.

Questions to our Stakeholders

1. Should the Board consider updating the 2021 recommendation to align the fish oil annotation with the Canadian annotation for fish oil used in aquaculture?
2. Should NOSB prioritize completing a recommendation for wild seafood standards, pursuant to OFPA, 7 U.S.C. section 6506(c)?

Justification for Vote

The Subcommittee finds fish oil compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote

Motion to remove fish oil from the National List
Motion by: Dilip Nandwani
Seconded by: Jerry D'Amore
Yes: 0 No: 6 Abstain: 1 Recuse: 0 Absent: 2

Gelatin

Reference: § 205.606 Nonorganic agriculturals allowed
(h) Gelatin (CAS # 9000-70-8).
Technical Report: 2002 TAP; 2019 TR gelatin, collagen gel, and casings
Petition(s): 2001; 2002 (addition as ingredient (capsules); 2007 Petition (addition to 205.606)
Past NOSB Actions: 05/2002 NOSB recommendation; 05/2007 recommendation to add; 04/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 09/12/2026

Subcommittee Review

The NOSB had a brief discussion of public comments and the Spring 2024 review, and the Board members were all in support of relisting.

Use

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

Manufacture

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

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed as ingredients classified as food additives: shall be organic if commercially available. Gelatine may be sourced from plants or animals. If derived from cattle, gelatine shall be guaranteed free of Specified Risk Material (SRM). (Table 6.3, CAN/CGSB-32.311-2020, page 32)

Allowed as processing aids: shall be from organic sources if commercially available. Allowed sources are plants and animals. Animal gelatine may be used in preparations of canned meat or as a gelling agent for gummed candy. If derived from cattle, gelatine shall be guaranteed free of Specified Risk Material (SRM). (Table 6.5, CAN/CGSB-32.311-2020, page 39)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Allowed in products of plant origin. (Annex V, Part A, Section A2, 2021/1165)

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Allowed as a processing aid for the preparation of products of agricultural origin. (Table 4 - page 30)

International Federation of Organic Agriculture Movements (IFOAM)
Allowed as a processing/post-harvest handling aid. (Appendix 4 - Table 1 - page 80)

Japan Agricultural Standard (JAS) for Organic Production
Additive allowed. Limited to the use in processed products of plant origin. (Appended Table 1)

Ancillary Substances

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

Human Health and Environmental Issues

There have been no published studies on the impact of gelatin on human health. Gelatin has been widely incorporated into a range of industries, including food and medicine, and is widely regarded as biocompatible and biodegradable. It is not anticipated to have a negative impact on human health or have a negative impact on the environment or biodiversity.

Discussion

The 2019 TR did not contain new information indicating that organic gelatin would be commercially available in the near future. In 2021 the Handling Subcommittee hoped that at the next sunset review, the barriers to production of organic gelatin will no longer be present.

Gelatin has been granted GRAS status by the FDA for “substances migrating from cotton and cotton fabrics used in dry food packaging,” at 21 CFR 182.70. Moreover, gelatin is generally recognized as safe (GRAS) when used “to clarify juice or wine,” at 27 CFR 24.246.

Questions to our Stakeholders

1. Is there sufficient commercially available organic gelatin?
2. What gaps persist that necessitate gelatin to be on the national list?

Justification for Vote
The Subcommittee finds gelatin compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove gelatin from the National List
Motion by: Kim Huseman
Seconded by: Carolyn Dimitri
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 3

Orange pulp, dried

Reference: § 205.606 Nonorganic agriculturals allowed
(m) Orange pulp, dried.
Technical Report: N/A
Petition(s): 2008 Petition
Past NOSB Actions: 11/2008 NOSB recommendation for addition to the National List; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Added to NL effective 03/15/2012 (77 FR 8089); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Dried orange pulp is used as a moisture retention agent and fat substitute in baked goods, pastas, salad dressing, confectionary, processed cheese spreads, beverages, meat products and frozen foods. Dried orange pulp is used in rates up to 5 percent depending on use but is self-limiting after that point due to loss of desirable eating qualities.

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

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Not listed.

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Not listed.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Not listed individually as non-organic agricultural commodities allowed. However, CODEX allows for up to 5% non-organic content.

International Federation of Organic Agriculture Movements (IFOAM)
Not listed individually as non-organic agricultural commodities allowed. However, IFOAM allows for up to 5% non-organic content.

Japan Agricultural Standard (JAS) for Organic Production
Not listed individually as non-organic agricultural commodities allowed. However, JAS allows for up to 5% non-organic content.

Ancillary Substances
No ancillary substances are indicated.

Human Health and Environmental Issues
The only noted concern pertaining to orange pulp is the use of conventional pesticides in conventional orange production that may negatively impact the environment and potentially leave residue in the final product of orange pulp, dried.

Discussion
During the Spring 2019 review, the Handling Subcommittee voted to remove this item from the National List because orange pulp, dried, does not seem to be necessary for or consistent with organic handling (failing OFPA criteria at 7 U.S.C. 6517(c)(ii)–(iii)), and alternatives exist (failing OFPA criteria at § 6518(m)(6)). There were no comments that supported its use, nor any known organic products that include it as an ingredient. However, orange peel and orange pulp were listed as ingredients in organic products. It was noted that this listing also has a patent which may limit its use in organic products. Additionally, during the in-person Fall 2019 NOSB meeting, the petitioner for this substance provided verbal comment, and stated that they wished to continue the listing. They indicated that they have customers who wish to continue the use of this nonorganic product in their organically labeled foods. The petitioner also clarified the supply of organic oranges is located about an hour too far away from their processing facility to use their patented process and make their dried orange pulp.

While numerous NOSB members felt that the use of dried orange pulp is very small, and in the future, the distance issues and other barriers may be overcome, a decisive vote to remove it from §205.606 was not reached, therefore the motion to remove orange pulp from §205.606 failed (7/5).

As part of the Spring 2024 agenda and review of this substance eight comments were submitted. While two were generally supportive of relisting, most were opposed or didn't state their opinion. Those that didn't state their opinion were mostly certifiers that were reporting numbers of operations that use this substance. Of the certifiers that commented it was reported that only two operations were using this substance. The Subcommittee posed questions related to the supply of organic orange pulp and what organic products would no longer be able to be produced if orange pulp, dried were to be removed from the National List. The sufficient and adequate supply is still a question. However, based on the certifiers that reported (which we acknowledge is only a subset) it appears that this substance isn't in wide use. Perhaps that is due to operations switching to using an organic form of this substance.

A search in September 2023 of the Organic Integrity Database for the following products yielded the below results:

- orange pulp, dried = 0 results
- dried orange pulp = 0 results
- orange pulp = 6 results
- orange powder = 29 results

After the Spring 2024 board meeting additional research determined that FiberStar, the original petitioner is now certified, and offers an organic citrus fiber. Based on that information along with comments received during the Spring 2024 meeting most of which were either in favor of removal or were certifiers that reported limited use, the Handling Subcommittee is proposing to remove orange pulp, dried from the National List.

Justification for Vote
The Subcommittee proposes removal of orange pulp, dried from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600: lack of essentiality due to the presence of organic forms of orange pulp, dried.

Subcommittee Vote
Motion to remove orange pulp, dried from the National List
Motion by: Kyla Smith
Seconded by: Allison Johnson
Yes: 5 No: 2 Abstain: 0 Recuse: 0 Absent: 2

Seaweed, Pacific kombu

Reference: § 205.606 Nonorganic agriculturals allowed
(q) Seaweed, Pacific kombu.
Technical Report: 2016 TR (Marine Plants & Algae)
Petition(s): 2007 Petition
Past NOSB Actions: 05/2008 NOSB recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Added to NL effective 03/15/12 (77 FR 8089); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 09/12/2026

Subcommittee Review
At §205.606 (d)(3), (n), (v) and (z), four substances from marine plants and algae are specifically identified as nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as ''organic'' when the specific product is not commercially available in "organic" form: (d)(3) beta-carotene extract color, derived from algae (CAS #1393– 59 63–1), not produced using synthetic solvents and carrier systems or any artificial preservative; (n) Kelp used only as a thickener and dietary supplement; (v) Pacific kombu; and (z) Wakame seaweed (*Undaria pinnatifida*) [2016 TR 55-61]

Use
Seaweed is used as food, in cosmetics and fertilizers, processed to extract thickening agents, and as an additive to animal feed (FAO, 2014). Increasing demand over the last fifty years outstripped the ability to supply the market from natural (wild) stocks. Cultivation industries now produce more than 90 percent of the markets' demand. Some commercial organizations have been promoting seaweed for restaurant and domestic use, with some success. An informal market exists among coastal dwellers in some developing countries where there has been a tradition of using fresh seaweeds as vegetables and in salads (FAO, 2012). [2016 TR 193-195]

Kombu, produced from hundreds of hectares of brown seaweed, *Laminaria japonica* that is grown on suspended ropes in the ocean.

Seaweeds as a source of hydrocolloids dates back to 1658, when the gelling properties of agar that is extracted with hot water from a red seaweed were first discovered in Japan. Extracts of Irish moss, another red seaweed, contain carrageenan and were popular as thickening agents in the nineteenth century. [2016 TR 217-219]

Seaweed meal, used an additive to animal feed, has been produced in Norway, where its production was pioneered in the 1960s. It is made from brown seaweeds that are collected, dried and milled.

Cosmetic products, such as creams and lotions, sometimes show on their labels that the contents include "marine extract", "extract of alga", "seaweed extract" or similar. Usually this means that one of the hydrocolloids extracted from seaweed has been added. 2016 TR 252-254]

Manufacture

Kelps are seaweed and recognized as Kombu in Japan and various kinds of food made from Kombu, one of the most important of the marine vegetable preparations. The seaweeds used in the manufacture of Kombu are coarse, broad-fronded members of the kelp family (Laminariaceae), and until *Laminaria japonica* was introduced. Other kelps utilized in Kombu manufacture are *Arthrothamnus bifidus* and *kurilensis, Alaria fistulosa* (Smith, 1904). [2016 TR 858-866] The gathering of kelp begins in July and ends in October and is engaged in by many fishermen. The fishermen go to the kelp grounds in open boats, each boat with one to three men and a complement of hooks with which the kelp is torn or twisted from its strong attachment on the rocky bottom. The hooks are of various patterns; some are attached to long wooden handles, and some are weighted and dragged on the bottom by means of ropes while the boats are under way (Smith, 1904). [2016 TR 868-872]

Uses of the Argentinian seaweeds have expanded to new markets for human consumption, nutraceuticals, and cosmetics including the fucoidan industries. Local farmers directly sell the seaweeds to the processing companies or companies with concessions which directly employ their own workers for harvesting during the year and contracted divers in the summer. The National Center of Patagonia (CENPAT) guarantees that the harvesting methods are performed in a sustainable way. Regulations for the management of brown seaweeds and marine concessions are particularly well developed, and the supply in brown seaweed to the alginate industry is well managed and organized (Rebours et al., 2014). [2016 TR 889-892]

An Icelandic company whose products include rockweed (*Acophyllum nodosum*) and kelp (*Laminaria digitata*). Mechanical harvesting uses specialized equipment and takes place between April and October. As with other areas where *Ascophyllum nodosum* and *Laminaria digitata* are harvested commercially, ecological concerns about changes in species diversity resulting from harvesting have been noted (Ingolfsson, 2010). [2016 TR 893-897]

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Seaweed and seaweed products are allowed in crop production (Table 4.2, page 19). Seaweed meal is allowed as feed, feed additives, and feed supplements (Table 5.2, page 25).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Not explicitly mentioned.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Seaweeds and seaweed products are allowed for use in soil fertilizing and conditioning (Table 1, page 19). Seaweed, seaweed meal, seaweed extracts, sea salts, and salty water are allowed for plant pest and disease control (Table 2, page 22).

International Federation of Organic Agriculture Movements (IFOAM)
Seaweed and seaweed products allowed as fertilizers and soil conditioners if obtained by physical processes, extraction with water or potassium hydroxide solutions when the minimum amount of solvent necessary for extraction is used, and fermentation (Appendix 2, page 75).

Japan Agricultural Standard (JAS) for Organic Production
Not explicitly mentioned.

Ancillary Substances
None.

Human Health and Environmental Issues
No known impact on human health impact and environmental issues, per 2016 TR.

Discussion
Public comment from the previous sunset review indicated that the two seaweed materials be reviewed within the broader context of marine materials. At that time, commenters suggested that as part of the review, the NOSB should consider the addition of an annotation related to harvest restrictions and risk-based testing for toxic materials, using a decision tree to identify harvesting areas where testing would need to be performed. At the Fall 2023 meeting, the NOP stated that it will not take action on the NOSB's Fall 2020 recommendations on other marine materials, in light of the "technical complexity of marine environments."

At the Spring 2024 NOSB meeting a stakeholder commented on environmental concerns of harvesting seaweeds. In 2020 an NOSB member wrote an extensive proposal on the sustainable harvest of seaweed for use in organic products: https://www.ams.usda.gov/sites/default/files /media/MSMarine MaterialsRec_webpost.pdf. The health of our oceans, the fish, plants and other species is an important topic and organic seaweed must meet the highest standard of sustainability and protection of the resource. Once it is over-harvested or severely damaged through poor practices, it is very difficult or even impossible to bring back to health. Seaweed is important for the health of the oceans, not only for food, but also as habitat for fish and other creatures, and most harvesting practices do have a negative impact on these non-target species. The organic label must not represent the degradation of an important worldwide resource and ecosystem.

The Handling Subcommittee discussed seaweed extraction, the manufacturing process, and environmental issues. The Subcommittee understands the challenges with referencing third-party standards in NOP regulations, but also remains concerned about the environmental impacts of harvesting seaweeds. Based on the comments received and board discussion, the Handling Subcommittee is recommending that Pacific Kombu seaweed remain on the National List.

Justification for Vote
The Subcommittee finds Pacific kombu seaweed compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove Pacific kombu seaweed from the National List
Motion by: Dilip Nandwani
Seconded by: Kim Huseman
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

Wakame seaweed

Reference: § 205.606 Nonorganic agriculturals allowed
(t) Wakame seaweed (*Undaria pinnatifida*).
Technical Report: 2016 TR (Marine Plants & Algae)
Petition(s): 2007 Petition
Past NOSB Actions: 04/2007 NOSB recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Seaweed is used as food, in cosmetics and fertilizers, processed to extract thickening agents, and as an additive to animal feed (FAO, 2014). As the world has internationalized, seaweed consumption as food including wakame, has expanded from China, Japan and Korea to the entire world. Farming seaweed on lines in the ocean has expanded globally for production of alginates, carrageenans, other chemicals and the edible seaweed varieties, as management of harvest of wild seaweed forests continues throughout the world (Hunter, 1975). [2016 TR 379-383] Increasing demand over the last fifty years outstripped the ability to supply the market from natural (wild) stocks. Cultivation industries now produce more than 90 percent of the markets' demand. Some commercial organizations have been promoting seaweed for restaurant and domestic use, with some success. [2016 TR 192-193]

Seaweed meal, used an additive to animal feed, has been produced in Norway, where its production was pioneered in the 1960s. It is made from brown seaweeds that are collected, dried and milled. Cosmetic products, such as creams and lotions, sometimes show on their labels that the contents include "marine extract", "extract of alga", "seaweed extract" or similar. Usually this means that one of the hydrocolloids extracted from seaweed has been added.

Whole algae incorporated into food and food additives has been used to develop healthier and more nutritious foods particularly because there is a technical advantage in the use of algae as natural ingredients in food reformulation for healthy foods and beverages. Wakame (*Undaria pinnatifida*) a widely consumed brown algae contains high levels of dietary fiber and minerals. [2016 TR 505-508]

Manufacture
The edible seaweed wakame is produced by drying *Undaria pinnatifida* and is generally regarded as safe (FDA GRN No. 565 — 21 CFR 184.1120). The Republic of Korea grows three different species, and about 50 percent of this is for wakame, produced from a different brown seaweed, *Undaria pinnatifida*, grown in a similar fashion to *Laminaria* in China.

Undaria pinnatifida (wakame) and *Saccharina latissima* (sugar kombu) are two of the most valuable seaweeds in northern Spain due to their high demand and economic value. On a commercial basis along the Atlantic coast of Europe, particularly in northern Spain, water movement is a key factor controlling the production and quality of kelp. *U. pinnatifida* is best cultured at more exposed sites rather than at sheltered sites, whereas both sheltered and exposed sites are suitable for *S. latissima* cultivation; hanging rope culture is best in sheltered areas, while horizontal rope culture is better suited for exposed locations. The fixed-pole anchor system for raft culture has been used successfully in exposed open-ocean sites as an alternative to the traditional system with concrete blocks; outplanting dates for the *U. pinnatifida* and *S. latissima* on the Atlantic coast of southern Europe are from October to November and from November to December, respectively. Harvesting is conducted from March to April and from April to May for these two outplanting seasons, respectively. Seawater temperature and seawater nitrogen concentration are the main determinants of the start and end of culture in the sea for both species. *S. latissima* is more economically and environmentally advantageous 1057 than *U. pinnatifida* (Peteiro et al., 2016). [2016 TR 1046-1057]

In Argentina, the National Center of Patagonia (CENPAT) guarantees that the harvesting methods are performed in a sustainable way. Regulations for the management of brown seaweeds and marine concessions are particularly well developed, and the supply in brown seaweed to the alginate industry is well managed and organized (Rebours et al., 2014). [2016 TR 889-892]

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Seaweed and seaweed products are allowed in crop production (Table 4.2, page 19). Seaweed meal is allowed as feed, feed additives, and feed supplements (Table 5.2, page 25).

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International Federation of Organic Agriculture Movements (IFOAM)
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Japan Agricultural Standard (JAS) for Organic Production
Not explicitly mentioned.

Ancillary Substances

None.

Human Health and Environmental Issues

No known impact on human health impact and environmental issues, per 2016 TR.

Discussion
Public comment indicated that the two seaweed materials be reviewed within the broader context of Marine Materials. At that time, commenters suggested that as part of the review, the NOSB should consider the addition of an annotation related to harvest restrictions and risk-based testing for toxic materials, using a decision tree to identify harvesting areas where testing would need to be performed.

At the Spring 2024 NOSB meeting a stakeholder commented on environmental concerns of harvesting seaweeds. In 2020 an NOSB member wrote an extensive proposal on the sustainable harvest of seaweed for use in organic products. https://www.ams.usda.gov/sites/default/files /media/MSMarine MaterialsRec_webpost.pdf. The health of our oceans, the fish, plants and other species is an important topic and organic seaweed must meet the highest standard of sustainability and protection of the resource. Once it is over-harvested or severely damaged through poor practices, it is very difficult or even impossible to bring back to health. Seaweed is important for the health of the oceans, not only for food, but also as habitat for fish and other creatures, and most harvesting practices do have a negative impact on these non-target species. The organic label must not represent the degradation of an important worldwide resource and ecosystem.

The Handling Subcommittee discussed seaweed extraction, the manufacturing process, and environmental issues. The Subcommittee understands the challenges with referencing third-party standards in NOP regulations, but also remains concerned about the environmental impacts of harvesting seaweeds. Based on the comments received and board discussion, the Handling Subcommittee is recommending that wakame seaweed remain on the National List.

Justification for Vote
The Subcommittee finds wakame seaweed compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote
Motion to remove wakame seaweed from the National List
Motion by: Dilip Nandwani
Seconded by: Kim Huseman
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2