Sunset 2025
Meeting 2 - Reviews
Livestock Substances § 205.603 & § 205.604
October 2023

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. If a new technical report has been requested for a substance, it is noted in this list. Substances included in this document may also be viewed in the NOP's Petitioned Substances Index.

Request for Comments

Written public comments will be accepted through September 28, 2023 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

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 §205.603 Substances in Organic Production:

If you provide comments supporting the allowance of a substance at §205.603, you should provide information demonstrating that the substance is:

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

For Comments that Do Not Support the Continued Use of §205.603 Substances in Organic Production:
If you provide comments that do not support a substance at §205.603, you should provide reasons why the use of the substance should no longer be allowed in organic production. Specifically, comments that support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:

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

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

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

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

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

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

1. Alternative management practices or natural substances that would eliminate the need for the specific substance;
2. Other substances that are on the National List that are better alternatives, which could eliminate the need for this specific substance; and/or
3. 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 28, 2023 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:

- Alcohols: Ethanol
- Alcohols: Isopropanol
- Aspirin
- Biologics—Vaccines
- Electrolytes
- Glycerin
- Phosphoric acid
- Lime, hydrated
- Mineral oil

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

- None

Alcohols: Ethanol

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.
(1) Alcohols. (i) Ethanol - disinfectant and sanitizer only, prohibited as a feed additive.
Technical Report: 1995 TAP; 2014 TR
Petition(s): N/A
Past NOSB Actions: 11/1995 NOSB minutes and vote (pg. 23); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
The following is from the 2014 Technical Report (TR), line 118-123:

> "The United States Environmental Protection Agency (US EPA) regulates all non-food applications of ethanol, including its use as a pesticide and plant growth regulator. According to the Reregistration Eligibility Decision (RED) for Aliphatic Alcohols, ethanol and isopropanol were registered in the US as early as 1948 as active ingredients in indoor disinfectants (US EPA, 1995). Approximately 48 ethanol products were registered for use as hard surface treatment disinfectants, sanitizers and mildewcides as of 2012 (US EPA, 2012a). Ethanol is also the active ingredient in certain plant growth regulator products."

Manufacture:
The following is from the 2014 TR, line 43-48:

> "Both fermentation and chemical synthesis procedures are used in the commercial production of ethanol for the preparation of disinfectant solutions, spirits, and industrial fuel sources. A variety of methods are available for the fermentative production of ethanol from carbon sources such as starch, sugar and cellulose using natural and genetically engineered strains of yeast or bacteria (Merck, 2006; Logsdon, 2004). Ethanol can also be produced synthetically through the direct or indirect hydration of ethylene ($H_2C{=}CH_2$), and as a by-product of certain industrial operations."

International Acceptance:
Canadian General Standards Board Permitted Substances List
The following is from the 2014 TR, line 204:

> "Canadian organic production standards permit the use of ethanol for a number of agricultural applications."

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
The following is from the 2014 TR, line 222-223:

> "Alcohols, presumably including ethanol, may be used for cleaning and disinfecting livestock building installations and utensils…"

[CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)]
The following is from the 2014 TR, line 215-216:

> "Ethanol is allowed… when mechanical, physical and biological methods are inadequate for pest control."

[International Federation of Organic Agriculture Movements (IFOAM)]
The following is from the 2014 TR, line 242-243:

> "…synthetic ethanol is an approved additive and processing/post-harvest handling aid when organic and natural sources are not available."

[Japan Agricultural Standard (JAS) for Organic Production]
The following is from the 2014 TR, line 229-231:

> "…ethanol may be used in the processing, cleaning, storage, packaging, and other post-harvest processes when physical or methods using naturally derived substances are insufficient."

Environmental Issues:
The following is from the 2014 TR, line 586-594:

> "Aside from accidental spills, the risk of environmental contamination from released ethanol is minimal. The release of strong acids and bases used in the production of ethanol due to improper handling/disposal could lead to serious environmental impairments and ecotoxicity in both terrestrial and aquatic environments. However, no incidents involving the release of these chemical feedstocks from ethanol production facilities have been reported. Further, lesser amounts of ethanol are constantly released to the environment from animal wastes, plants, insects, forest fires, and microbes without causing environmental impairment (HSDB, 2012). It is therefore unlikely that large-scale spills and associated environmental contamination will occur under the allowed use of ethanol as a sanitizer and disinfectant in organic livestock production."

Discussion:
The Subcommittee highlighted the fact that to maintain efficacy, producers need a range of sanitizers so as to not have any one sanitizer lose its efficacy. Additionally, the benign manufacturing process of this material further confirms it as being aligned with OFPA.

Questions to our Stakeholders:
None.

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

Subcommittee Vote:
Motion to remove alcohols: ethanol from the National List
Motion by: Nate Powell-Palm
Seconded by: Brian Caldwell
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 0

Alcohols: Isopropanol

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.
(1) Alcohols. (ii) Isopropanol-disinfectant only.
Technical Report: 1995 TAP; 2014 TR
Petition(s): N/A
Past NOSB Actions: 11/1995 NOSB minutes and vote (pg. 23); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
The following is from the 2014 Technical Report (TR), line 54-63:

> "Isopropanol is used for a variety of industrial and consumer purposes, ranging from chemical and solvent applications to medical and consumer usage... Agricultural uses of isopropanol include the disinfection of production tools and surfaces and topical antisepsis during medical treatments. Livestock producers may use alcohol (i.e., isopropanol and/or ethanol) solutions for sanitizing and disinfecting surfaces (e.g., production implements, troughs, and floor drains) and during medical treatments as a topical disinfectant (Jacob, 2013; Dvorak, 2008)."

Manufacture:
2014 TR, line 37-44:

> "Chemical synthetic procedures are used in the commercial production of isopropanol that is used in the preparation of consumer-use disinfectants, industrial solvents, and specialty chemicals. Specifically, indirect and direct methods for the hydration of petroleum-derived propylene are the two primary commercial processes to produce isopropanol. In addition, smaller amounts of industrial isopropanol are generated through the hydration of acetone over transition-metal catalysts (Papa, 2011; Merck, 2006). A variety of methods are also available for the fermentative production of isopropanol from carbon sources, such as starch, sugar, and cellulose, using genetically engineered yeast and bacteria (Papa, 2011)."

International Acceptance:
Canadian General Standards Board Permitted Substances List
2014 TR, line 195-196:

> "Canadian organic production standards permit the use of isopropanol for a number of agricultural applications."

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
\Isopropanol is not an allowed synthetic substance for organic production within the European Union. However, Commission Regulation (EC) No 889/2008 provides rules for two different uses of ethanol in organic production in European Union member states. Alcohol, likely referring to ethanol alone, may be used for cleaning and disinfecting livestock building installations and utensils under Annex VII of the

regulations. In addition, Annex VIII stipulates the use of ethanol (not isopropanol) in Section B—Processing aids and other products, which may be used in the processing of ingredients of agricultural origin from organic production. This regulation specifically allows the use of ethanol as a solvent in the preparation of foodstuff of both plant and animal origin..

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
The Codex Guidelines do not provide any allowable uses for isopropanol in the production or processing of organically produced foods. However, ethanol is allowed under Annex 2 (table 2) of the Guidelines when mechanical, physical and biological methods are inadequate for pest control. Further, the Guidelines require that an organic certification body or authority recognize the need for any pest control treatments using ethanol. Ethanol is also listed as an allowed processing aid "which may be used for the preparation of products of agricultural origin." Specifically, ethanol may be used as a solvent in these preparatory operations (Codex, 2013)..

International Federation of Organic Agriculture Movements (IFOAM)
2014 TR, line 239-241:

> "…isopropanol is an approved synthetic equipment cleaner and equipment disinfectant. Isopropanol is also an allowed synthetic substance for pest and disease control and disinfection in livestock housing (IFOAM, 2012)."

Japan Agricultural Standard (JAS) for Organic Production
Japanese organic standards do not directly permit the use of isopropanol for any purpose in organic production or processing. In contrast, ethanol is allowed for use in several areas of organic production/processing. In lieu of information related to the use of isopropanol, technical information for ethanol is compiled in the following paragraph. __According to the Japanese standards for organic plant production, ethanol may be used in the processing, cleaning, storage, packaging and other post-harvest processes when physical or methods utilizing biological function are insufficient. The specific crop uses of ethanol are for (1) controlling noxious animals and plants, and (2) quality preservation and improvement (JMAFF, 2005a). Likewise, ethanol may also be used in the manufacturing, processing, packaging, storage and other processes associated with organic livestock feed when physical or methods utilizing biological function are insufficient for disease and pest control (JMAFF, 2005b). Similar provisions exist for the use of ethanol in the slaughter, dressing, selection, processing, cleaning, storage, packaging and other processes associated with organic livestock products. "Alcohols" are listed as allowed cleaning and disinfection agents for livestock housing; however, it is unclear whether isopropanol is allowed under this listing (JMAFF, 2005c). It should be noted that ethanol use is not permitted for the purpose of pest control for plants and agricultural products. For processed foods, ethanol may be used as an additive in the processing of meat products only (JMAFF, 2005d).

Environmental Issues:
2014 TR, line 362-364:

> "Although isopropanol is a volatile organic compound and potentially contributes to the formation of ozone and photochemical smog, large-scale releases of isopropanol under the prescribed use pattern in organic crop production are unlikely."

2014 TR, line 366-367:

> "Isopropanol may enter the environment because of its manufacture in addition to its solvent and chemical intermediate uses."

2014 TR, line 413-415:

> "According to US EPA, isopropanol is slightly toxic (Category III) to practically non-toxic (Category IV) based on acute oral and inhalation toxicity tests as well as primary eye and dermal irritation studies (EPA, 410 1995)."

Discussion:
The Subcommittee highlighted the fact that to maintain efficacy, producers need a range of sanitizers so as to not have any one sanitizer lose its efficacy. Additionally, the benign manufacturing process of isopropanol further confirms it as being aligned with OFPA.

Questions to our Stakeholders:
None.

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

Subcommittee Vote:
Motion to remove alcohols: isopropanol from the National List
Motion by: Nate Powell-Palm
Seconded by: Kim Huseman
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 0

Aspirin

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.
(2) Aspirin-approved for health care use to reduce inflammation.
Technical Report: 1994 TAP; 2017 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote (pg. 347-348); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review
There was no additional discussion aside from the review of Spring 2023 meeting comments.

Use:
The following information and data was taken from the 2017 TR.

Aspirin is considered a pain reliever and fever reducer in the over-the counter, tentative final monograph for Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter

Human Use by the U.S. Food and Drug Administration (FDA) (53 Federal Register 46204, Nov. 16, 1988 and 21 CFR 343). Aspirin is included under 21 CFR 343.12 and 343.13 for the prevention of cardiovascular events and the treatment of rheumatologic disorders. Aspirin is also listed at 7 CFR 205.603 as a synthetic substance allowed for the use in organic livestock production and is approved for health care use to reduce inflammation. Its half life is short in cattle, and it is not as beneficial in reducing pain as Flunixin. However, aspirin is usually given orally, which makes it easier and more usable for farmers in an emergency. Additionally, Flunixin must be administered under written orders of a licensed veterinarian, and it has a restriction annotation for a withdrawal time. A second pain medication approved for pain relief in organic livestock is Butorphanol (7 CFR 205.603(a)(5) and 21 CFR 522.246). Butorphanol is a synthetic opioid partial agonist analgesic; however, it also must be administered under a veterinarian's written orders, and it too is restricted by annotation to a withdrawal time. Aspirin inhibits the biosynthesis of certain hormone-like substances called prostaglandins, which accounts for most of its clinical effects. Depending on where in the body these prostaglandins are produced, they may trigger pain, inflammation, fever, or blood clotting. Following absorption, aspirin is hydrolyzed to salicylic acid, which is the active metabolite for its major clinical effects. Aspirin also inhibits platelet aggregation by irreversibly inhibiting prostaglandin cyclooxygenase.

Manufacture:
The most prevalent method of synthesizing aspirin is via esterification. Salicylic acid is treated with acetic anhydride, an acid derivative, causing a quantitative chemical reaction that turns salicylic acid's hydroxyl group into an ester group (R-OH → R-OCOCH3; Figure 2). This process yields aspirin and acetic acid, which are considered byproducts of this reaction. Small amounts of sulfuric acid (and occasionally phosphoric acid) are almost always used as a catalyst. The chemical feedstocks for synthesizing aspirin are also manufactured through a chemical process. Salicylic acid is produced commercially via the Kolbe-Schmitt process. Here, phenol and sodium hydroxide react to make sodium phenoxide. The phenoxide comes into contact with CO2 to form sodium salicylate. The salicylate is acidified to give salicylic acid. The acid is usually crystallized from an aqueous solution to give a technical grade 99.5% salicylic acid product. For a pharmaceutical grade product, salicylic acid is further purified by sublimation. The commercial process for acetic anhydride was developed by Wacker Chemie in 1922 and uses a chemical reaction between acetic acid and ethenone at a low temperature and pressure.

International Acceptance:
Canadian General Standards Board Permitted Substances List
The Canadian General Standards Board includes aspirin as a permitted substance for organic production 82 systems under CAN/CGSB-32.311-2015 for pain mitigation and inflammation reduction in livestock 83 84 Aspirin was not found to be listed under any other international standard for organic livestock production.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Aspirin was not found to be listed.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Aspirin was not found to be listed under CODEX for organic livestock production.

International Federation of Organic Agriculture Movements (IFOAM)
Aspirin was not found to be listed under IFOAM for organic livestock production.

Japan Agricultural Standard (JAS) for Organic Production
Aspirin was not found to be listed under JAS for organic livestock production.

Environmental Issues:
Due to the rapid biodegradation/hydrolysis of aspirin and its active metabolite, salicylic acid, and the effectiveness of sewage treatment, there are no known reports of aspirin causing appreciable harm to surface or groundwater, soil, or agro-ecosystems. The background levels present in drinking water would result in the average exposure of approximately 0.05% of a typical daily dose over an average 70-year lifetime in humans. There is some evidence that acetylsalicylic acid (and/or active metabolites) can be toxic to aquatic invertebrates; however, current research into the impact of aspirin and pharmaceuticals in wastewater and aquatic ecosystems is not sufficient for definite conclusions.

Discussion:
Aspirin is important to the humane treatment of organic animals and is commonly used to reduce inflammation. It is the only real-time responsive form for inflammation and fever management available. There are other products that are available but do not offer the same type of timely response to ensure animal health and wellbeing. This is also a proven remedy and is critical in organic livestock production.

This material satisfies the OFPA evaluation criteria.

Questions to our Stakeholders:
None

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

Subcommittee Vote:
Motion to remove aspirin from the National List
Motion by: Kim Huseman
Seconded by: Brian Caldwell
Yes: 0 No: 5 Abstain: 0 Recuse: 0 Absent: 1

Biologics Vaccines

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.
(4) Biologics - Vaccines.
Technical Report: 2014 TR2011 TR (GMO vaccines); 2014 TR (§205.611 aquaculture)
Petition(s): 2012 (§205.611 aquaculture)
Past NOSB Actions: 11/1995 NOSB minutes and vote (pg. 3-4); 11/2005 NOSB sunset recommendation; 11/2009 NOSB recommendation (§205.105 excluded methods); 10/2010 NOSB sunset recommendation; 10/2014 NOSB recommendation (§205.105 excluded methods); 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation; 10/2019 NOSB recommendation (§205.105 excluded methods)
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290);

Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
The Organic Foods Production Act (OFPA) specifically allows vaccines to be used in the absence of illness, while prohibiting all other medications from this use (7 U.S.C. 6509(d)(1)(C)). Vaccination against bacterial or viral infections is a cost-effective and efficient method of lessening animal suffering and disease. A vaccine contains, or produces in the vaccinated individual, an antigen that stimulates an immune response and enables protection from the disease and/or future infection. In the case of a disease outbreak, administration of vaccines may be required by government agencies.

Manufacture:
Vaccines are produced through a variety of methods that use natural pathogens, parts of pathogens, or genetically modified organisms grown in a culture (yeast, bacteria or cell), separation and purification of the vaccine, and addition of other materials that may enhance the efficacy or stability of the vaccine. In mRNA vaccines, the final production of the antigen occurs in cells of the vaccinated person or animal via the action of introduced modified mRNA.

International Acceptance:
Canadian General Standards Board Permitted Substances List
It appears that GMO vaccines are allowed in organic agriculture in Canada if other vaccines are not commercially available or are ineffective (CAN/CGSB-32.311-2020 table 5.3).

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
EU standards (EU 2018/848) do not explicitly discuss GMO vaccines. GMOs are not allowed.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
2011 Technical Report (TR), which focuses on GMO vaccines, says this in lines 153-158:

> According to the Codex Alimentarius Commission's guidelines for organic agriculture, *"where specific disease or health problems occur, or may occur, and no alternative permitted treatment or management practice exists, or, in cases required by law, vaccination of livestock, the use of parasiticides, or therapeutic use of veterinary drugs are permitted."* The standards do not clarify whether vaccines should be free of GMO organisms; however, it is noted in the guidelines that anything contained in animal feed must be from non-biotechnology-derived sources (Codex Alimentarius Commission, 1999).

International Federation of Organic Agriculture Movements (IFOAM) Norms
2011 TR, line 164-167 says:

> According to the International Federation of Organic Agriculture Movements (IFOAM) draft 2010 standards, while *"the deliberate use or negligent introduction of genetically engineered organisms or their derivatives is prohibited"* for animals, seeds, fertilizers, and other materials, IFOAM makes an exception for vaccines (IFOAM, 2010).

Japan Agricultural Standard (JAS) for Organic Production

2011 TR, line 169-171 says:

> Recombinant technology is generally prohibited in the production of livestock products under the Japan Agricultural Standard (JAS) for Organic Production; however, a discussion of vaccines derived with GMO organisms is not provided (JMAFF, 2005).

Environmental Issues:
The Subcommittee has structured this sunset review of Biologics-Vaccines based on the substance evaluation criteria in the OFPA (7 U.S.C. 6518). 7 U.S.C. 6518 (National Organic Standards Board) paragraph "m" (Evaluation) lists seven items that the Board shall consider when evaluating National List substances. The Subcommittee pulled responses to items 1-6 from the 2011 TR. The Subcommittee response to item 7 is based on the NOSB 2019 formal recommendation to the NOP.

§6518(m)(1) the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems.

> The 2011 TR, lines 261-265, indicates:
> Vaccine additives may interact with other additives/adjuvants; however, reactions are limited due to the generally small amounts of chemical constituents present in vaccines. Furthermore, preservative/adjuvant combinations such as thimerosal [a mercury-based preservative] and aluminum salts are common, and generally any vaccines causing adverse reactions would not be allowed on the market unless risks were mitigated (Roth and Henderson, 2001).

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

> The 2011 TR, lines 236-243, indicates:
> All vaccines (conventional and GMO) can be shed in the animal's feces and other secretions, although not all animals will shed vaccine DNA. This shed DNA could potentially infect other animals and spread the virus or bacteria in the environment. However, … vaccines cannot survive in the environment for long periods of time. Vaccines contain aluminum salts and other chemical adjuvants or additives; however, it is unclear if these substances are released in high quantities or whether they may impact the environment. Moreover, for both conventional and GMO vaccines, regulatory authorities consider additives when licensing them, establishing residue limits and withdrawal periods (required time between vaccination and slaughtering or milking) when necessary (OIE, 2010).

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

> The 2011 TR, lines 248-255, indicates:
> Although accidental spills may occur during vaccination and some environmental contamination may occur during proper use (e.g., in coarse spray vaccine administration),… extensive contamination of the environment with vaccine organisms is not anticipated due to low rates of shedding and the low survival rate of many pathogens in the environment (CFIA 2007 and 2008a). If manufacturers/livestock farmers do not correctly dispose of unused or expired vaccine materials, there is a potential for contamination of the environment with vaccine additives such as mercury-containing thimerosal (MDH, 2011). The impact of this contamination would depend on the specific circumstances of the manufacturing process or disposal.

§6518(m)(4) the effect of the substance on human health.

> The 2011 TR, lines 307-323, indicates:

Regulators have noted that farmers or vaccine applicators could become infected during care of vaccinated animals that shed viral or bacterial organisms (CFIA, 2007 and 2008a). However, many of the diseases for which food animals are vaccinated cannot reproduce in either the target animal or humans (CFIA, 2007 and 2008a). For example, the vector for the porcine circovirus vaccine is Baculovirus, which is an insect virus not associated with disease in humans or animals. Risk assessments for GMO vaccines conducted by the Canadian Food Inspection Agency (CFIA) predicted that human health effects in workers would be minimal, as long as handlers took the necessary safety precautions to protect themselves (e.g., safety equipment such as gloves).

Some regulators and scientists have questioned whether the meat from GMO vaccinated animals may be harmful to humans who consume it (CFIA, 2006; Traavik, 1999). This issue is examined before licensure of a GMO vaccine. For example, the risk assessment report from the CFIA (2006) indicates that the Salmonella typhurium vaccine (live culture GMO vaccine) has a low health risk to humans exposed through spills or shedding by vaccinated animals. The vaccine strain is entirely eliminated before the broiler chickens are sold, so salmonella exposure to humans consuming vaccinated animals is unlikely. If any viral DNA is left in meat from vaccinated animals, it is expected to be broken down in the human gastrointestinal tract, thus, health problems are not anticipated from consumption (CFIA, 2010).

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

The 2011 TR, lines 283-290, indicates:

GMO vaccines are meant to improve immunity to disease in vaccinated livestock animals…. All vaccines, including GMO vaccines, can cause unwanted side effects in vaccinated animals including swelling and irritation at the site of injection, fever, coughing (after nasal administration), respiratory distress, and reduced fertility (Morton, 2007). However, there is no difference in these symptoms between GMO and traditional vaccines, and all vaccines are evaluated for side effects by manufacturers.

§6518(m)(6) the alternatives to using the substance in terms of practices or other available materials.

The 2011 TR, lines 340-346, indicates:

Homeopathic remedies may be used to supplement or replace vaccines. For example, nosodes are a homeopathic remedy made from a pathological product (e.g., blood, saliva, or diseased tissue) that are administered orally (ECCH, 2008). Nosodes act similarly to vaccines by facilitating natural resistance mechanisms and increasing the cure rate of existing infections in animals. However, some studies have indicated that nosodes are not highly efficacious in preventing disease (McCroy and Barlow, in Morris and Keilty, 2006). Nosodes may be more effective if combined with conventional vaccines or if other homeopathic remedies are used. Natural herbal supplements like dandelion and chicory may also be used, but these are usually used to treat infection once it occurs, rather than to prevent infection (Morris and Keilty, 2006).

The 2011 TR, lines 423-431, also indicates:

According to the European Council for Classical Homeopathy (ECCH), nosodes are "homeopathic remedies of biological origin that are derived from pathologically modified organs or parts of organs that are of human or animal origin, or from cultured micro-organisms that have been killed, or from products of the decomposition of animal organs, or from body liquids containing pathogens or pathological products" (ECCH, 2008). Nosodes act similarly to vaccines by facilitating natural resistance mechanisms and increasing the cure rate of existing infections in animals. Nosodes have been used to treat bovine mastitis, or inflammation of the mammary glands, in dairy cows. This condition is usually caused by bacteria entering the udder. Vaccines have been shown to be ineffective in preventing most cases of mastitis.

Finally, the 2011 TR, lines 441-451, indicates:
A study by Werner et al. (2010) found no difference between the cure rates of homeopathic treatments versus antibiotic treatments (allowed in conventional livestock only) for mild to moderate mastitis at the end of a 56-day treatment period. However, authors reported that the homeopathic remedy significantly increased the cure rate compared to placebo treatments…. Despite the improvements compared to placebo-treated animals, authors noted that both homeopathic and antibiotic treatments had a relatively low cure rate, suggesting low efficacy for these two treatments Werner et al., 2010).

§6518(m)(7) its compatibility with a system of sustainable agriculture.

The NOSB recognizes that vaccines play an important role in a sustainable agriculture system, from animal health to farm financial viability. The 2019 NOSB recommendation states the following:
"The [NOSB] recognizes the importance vaccines play in the prevention of livestock disease. When an organic livestock producer loses one or more of their animals, there is the loss of the animal's production capability, as well as a loss of time and resources associated with the breeding and selection that resulted in that specific animal. Breeding and selection often take years or even decades. When an animal is lost, all of those years of breeding and their unique genetics are also lost. The use of vaccines as a preventative can protect this long-term investment in genetic improvement, and vaccines remain an important tool in the organic livestock producer's toolbox to protect the investments that producers have in individual animals as well as their herds or flocks."

Discussion

The Livestock Subcommittee recognizes that use of vaccines can be critical to the success of organic livestock farms. Two areas in the organic regulations address use of vaccines; one on the National List of Allowed and Prohibited substances at §205.603(a)(4), and one in the section that details excluded methods at §206.105 (e). In 2019, the NOSB issued a formal recommendation to the NOP. In this, the NOSB recommended that the NOP change the USDA organic regulations at §205.105(e), from:

(e) Excluded methods, except for vaccines: *Provided,* That, the vaccines are approved in accordance with §205.600(a).

to:

(e) Excluded methods, except for vaccines: Provided, That, **vaccines produced through excluded methods may be used when an equivalent vaccine not produced through excluded methods is not commercially available.**

The 2019 NOSB recommendation also included proposed instructions on how to determine whether a vaccine was produced with excluded methods. The recommendation included a list of vaccines produced with and without excluded methods (from the 2011 TR), that the NOSB asked the NOP and stakeholders to use and update. As of the writing of this subcommittee sunset review for the October 2023 NOSB meeting, the 2019 NOSB recommendation has not been adopted by the NOP and the NOSB Recommendations Library (July 2023 version) indicates that this recommendation is "On Hold".

For Spring 2023 stakeholder comments, the Livestock Subcommittee posed several specific questions:

1. What are the most up to date organic regulations on GMO vaccines in other countries?
2. Are there concerns about components of vaccines besides the active ingredients?
3. Are certifiers interpreting the provisions at §205.603(a)(4) and § 205.105(e) consistently, even though the 2019 NOSB recommendation has not been officially adopted?
4. Is the wording in italics below an acceptable interpretation of § 205.105(e)?

This sunset review encompasses the entire class of synthetic livestock vaccines, including those made with excluded methods. The NOSB encourages the NOP to adopt the 2019 recommendation. In the meantime, our interpretation is that this listing fulfills the requirement at §206.105 (e) for all livestock vaccines.

The Subcommittee received one answer to #1, saying that to their knowledge, all vaccines are allowed in Canada and the EU and #2, that other components are present in minute quantities. Responses to #3 and #4 indicated that in practice, certifiers follow the italicized approach above. One consumer group opposes that interpretation, saying that since no vaccines have been individually reviewed, no GMO vaccines should be allowed. One farmer organization opposes the implementation of the 2019 recommendations because they felt that it would present practical difficulties and be a barrier to farmers. Eight other stakeholders supported the implementation of the 2019 recommendations.

In spite of important concerns over non-active ingredients and the GMO status of many livestock vaccines, the Livestock Subcommittee feels that the need for effective vaccines is critical for livestock production. Since the 2019 recommendations have not been implemented at this time, the Livestock Subcommittee has adopted the following interpretation:

> This sunset review encompasses the entire class of synthetic livestock vaccines, including those made with excluded methods. The Livestock Subcommittee encourages the NOP to adopt the 2019 NOSB recommendation. In the meantime, our interpretation is that this listing fulfills the requirement at §206.105 (e) for all livestock vaccines.

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

Subcommittee Vote
Motion to remove biologics - vaccines from the National List
Motion by: Brian Caldwell
Seconded by: Amy Bruch
Yes: 0 No: 4 Abstain: 0 Recuse: 0 Absent: 2

Electrolytes

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.
(11) Electrolytes - without antibiotics.
Technical Report: 1995 TAP; 2015 TR
Petition(s): N/A
Past NOSB Actions: 11/1995 NOSB minutes and vote (pg. 23); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review
Electrolytes are more properly called "veterinary electrolyte formulations”. They are mixtures of multiple synthetic ingredients used to restore ionic balance, especially in oral rehydration solutions to correct dehydration and in oral and injectable formulations for correction of milk fever. Key electrolyte ingredients include calcium, potassium, magnesium, and sodium salts plus phosphates, dextrose and other additives.

Use:
Electrolytes are considered animal drugs by the FDA, and in USDA organic production they may only be used when preventative practices are inadequate to prevent illness and may not be given in absence of illness. Electrolytes are used to restore ionic balance, treating a variety of metabolic conditions such as hypocalcemia, scours, milk fever, dehydration, mastitis, ketosis, acidosis and more. Electrolyte balance is essential to maintain normal physiology and health of livestock. When there is an imbalance of cations such as sodium, potassium, calcium or magnesium, either too low or high, the health and life of the animal is at risk. Stages of life, environmental stresses, stages of production such as birthing an animal, are all conditions that can throw the electrolyte balance off and would necessitate the use of electrolytes to restore health and well-being to the animal.

Manufacture:
Electrolytes are produced through industrial processes, fermentation, or may be mined. The major component of electrolyte formulations are salts and would have a variety of carriers or other ingredients (i.e., excipients) that enhance their properties, such as dextrose, citric acid, glucose, glycine, and more. The 2015 Technical Report (TR) has a detailed description of the various manufacturing processes.

International Acceptance:
Canadian General Standards Board Permitted Substances List
In Canada, the Permitted Substances List for Organic Animal Production allows electrolytes as part of Table 5.3 ‘Health Care Products and Production Aids.’ Calcium borogluconate is specifically permitted as a treatment for milk fever. ‘Electrolytes without antibiotics’ are permitted, and electrolyte solutions ‘with no added active ingredients’ are permitted (Canadian Standards 2011).

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

Electrolytes are not specifically mentioned. However, under Health Care, Section 22 “where specific disease or health problems occur, or may occur, and no alternative permitted treatment or management practice exists, or, in cases required by law, vaccination of livestock, the use of parasiticides, or therapeutic use of veterinary drugs are permitted.” However, veterinary drugs are not permitted to be used for preventive purposes (Codex 2001).

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Electrolytes are not mentioned specifically in 834/2007. However, Article 14 Section 1 (e) (ii) states “chemically synthesised allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions” (EU EEC 2007).

In 889/2008 many of the electrolyte salts are permitted as feed additives. The list is in Annex V, Feed Materials of Mineral Origin (EU EEC 2008).

Japan Agricultural Standard (JAS) for Organic Production
The Japanese Agricultural Standard (JAS) for Organic Production originally considered only crops and processing (JAS 2005). Later revisions included livestock. A summary in 2007 mentions that organic livestock must be fed organic feed, have exercise and access to pasture, and must not be fed antibiotics or GMOs. Electrolytes for organic animal production were not mentioned; therefore, it is unknown whether they are specifically allowed or prohibited (JAS 2007).

International Federation of Organic Agriculture Movements (IFOAM)
In the IFOAM NORMS for organic production and processing version 2012, electrolytes are not specifically mentioned for organic animal production. In Section III (5) on Animal Husbandry, only natural sources are permitted for vitamins, trace elements, and supplements. Use of synthetic allopathic veterinary drugs or antibiotics will cause the animal to lose its organic status (IFOAM 2012). But many of the electrolyte substances are mentioned in Appendix 4 as additives and processing aids.

Environmental Issues:
Environmental impacts are thought to be low. Since electrolytes are usually added to correct deficiencies, concentrations in the environment due to excretion would be no more than a normal untreated animal with normal electrolyte balances. Also, usually only a small number of animals are treated at a time. Production of electrolytes does have environmental effects, but quantities used for this purpose are relatively small.

Discussion:
There was agreement among all Spring 2023 written commenters to retain electrolytes on the National List, with no changes to the annotation. One commenter requested that the allowed uses be specified, but this is accomplished via the listing at 205.603(a) As disinfectants, sanitizers, and medical treatments as applicable. Electrolytes are used regularly and found to be essential by a large number of organic livestock producers. Environmental and consumer groups supported electrolytes, as well as companies that market organic livestock products.

Questions to our Stakeholders:
None.

Justification for Vote:

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

Subcommittee Vote:
Motion to remove electrolytes from the National List
Motion by: Brian Caldwell
Seconded by: Kim Huseman
Yes: 0 No: 4 Abstain: 0 Recuse: 0 Absent: 2

Glycerin

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.
(14) Glycerin - allowed as a livestock teat dip, must be produced through the hydrolysis of fats or oils.
Technical Report: 2010 TAP
Petition(s): N/A
Past NOSB Actions: 10/1999 NOSB minutes and vote (pg. 441); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Technical correction (changed to "glycerine") published 12/12/2007 (72 FR 70479); Sunset renewal notice published 06/06/2012 (77 FR 33290); Technical correction (changed back to "glycerin") published 02/05/2015 (80 FR 6429); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
Glycerin has over 1,000 uses; however, its use in organic livestock is limited to an ingredient in teat dips (§205.603(a)(11)). As an ingredient in teat dips, glycerin prevents teat irritation and improves skin conditioning. Glycerin does have some germicidal activity (Fox et al., 1990) [2010 TAP p. 1].

Manufacture:
Glycerin is a byproduct of the soap manufacturing process. The oldest method of manufacture is by hydrolysis of natural fats and oils (either animal or vegetable): heat, steam, and pressure "split" the glycerin from the oil. The glycerin is concentrated in multistage evaporators and refined. Purification is achieved through either an ion exchange process or a distillation system, but it can also be produced synthetically from propylene.

If only heat, steam or pressure is used to split the ester bonds to liberate free glycerol from fat (i.e., triglycerides), then this is a hydrolysis reaction catalyzed by physical forces and is compatible with organic criteria. However, if glycerol is formed by the chemical reaction of sodium hydroxide, then glycerol is produced by a chemically catalyzed hydrolysis reaction and may be considered synthetic [2010 TAP pgs. 1, 3].

International Acceptance:

Canadian General Standards Board Permitted Substances List
Glycerin or other synthetics used as a teat dip are not addressed, but it does not appear to be prohibited.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Glycerin or other synthetics used as a teat dip are not addressed, but it does not appear to be prohibited.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Glycerin or other synthetics used as a teat dip are not addressed, but it does not appear to be prohibited.

International Federation of Organic Agriculture Movements (IFOAM)
Glycerin or other synthetics used as a teat dip are not addressed, but it does not appear to be prohibited.

Japan Agricultural Standard (JAS) for Organic Production
Glycerin or other synthetics used as a teat dip are not addressed, but it does not appear to be prohibited.

Environmental Issues:
Glycerin breaks down to glucose, which in turn readily breaks down in the environment to carbon dioxide (CO_2) and water (H_2O); there are no concerns with persistence or toxicity in the environment [2010 TAP pg. 2].

Discussion:
Spring 2023 comments were supportive of relisting glycerin. A few commentors noted that manufacturer documentation can validate hydrolysis process.

Natural alternatives include castor oil and vegetable oils. There are some management tools for controlling mastitis, which include wiping debris from the teats, massaging the teat to loosen debris and stimulate milk letdown, wiping off the teat dip using individual cloths or paper towels, and applying the milking unit without air admission. None of the management tools seem to be effective alone. Glycerin falls under section 6517(1)(B)(i) of the OFPA code that describes livestock medicines.

Questions to our Stakeholders:
None

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

Subcommittee Vote:
Motion to remove glycerin from the National List
Motion by: Kim Huseman
Seconded by: Amy Bruch
Yes: 0 No: 4 Abstain: 0 Recuse: 0 Absent: 2

Phosphoric acid

Reference: 205.603(a) As disinfectants, sanitizer, and medical treatments as applicable.
(25) Phosphoric acid - allowed as an equipment cleaner, *Provided*, That, no direct contact with organically managed livestock or land occurs.
Technical Report: 1999 TAP (pg. 25-34); 2003 TAP (pg. 21-24); 2021 TR (handling); 2023 Limited Scope TR
Petition(s): N/A
Past NOSB Actions: 10/1999 NOSB minutes and vote (pg. 441); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
Phosphoric acid (H_3PO_4) has many uses. As a cleaner, it is generally used to remove rust and mineral deposits found on metal equipment such as boilers and steam-producing equipment. In dairy operations, it is used to remove calcium and phosphate salt deposits from processing equipment. Phosphoric acid is a hazardous substance.

From the 2023 Limited Scope Technical Report (TR), line 63-66:

> "In livestock facilities, phosphoric acid is used in Clean-In-Place (CIP) and non-CIP systems[2] to remove encrusted surface matter and mineral scale found on metal equipment. The chemical reaction of the acid with minerals found in deposits makes them water soluble and thus easier to remove. For cleaning purposes, phosphoric acid is often combined with a surfactant, usually a detergent….
>
> [2] Clean-in-Place refers to cleaning the interior surfaces of pipes and equipment without dismantling them first. NonCIP would involve at least some dismantling of the equipment before cleaning."

From the 2023 Limited Scope TR, line 70-73:

> "Phosphoric acid is sometimes used to remove resistant biofilms, colonies of microorganisms that attach to a surface and are protected by a self-generated protective film of polysaccharides (Muhammad et al., 2020). Surfaces covered with mineral scale are particularly susceptible to biofilm attachment. It is important to note that when the mineral scale is dislodged, the biofilm is also dislodged."

Manufacture:
There are two ways to create phosphoric acid (2003 Technical Advisory Panel (TAP), pg. 21).

1. Wet Process – Mined phosphate ore is treated with sulfuric acid, and the resulting phosphoric acid is separated from the calcium sulfate crystals produced. Many ore impurities exist; therefore, they can be further purified to obtain technical or food-grade phosphoric acid.

2. Thermal (furnace process) – Pure phosphorus is burned in excess air, and the resulting phosphorus pentoxide is then hydrated, cooled, and the acid mist is collected. It is considered purer than phosphoric acid achieved via the wet process and is considerably more expensive.

International Acceptance:

Canadian General Standards Board Permitted Substances List

2021 TR for Handling, line 349-351:

> "Phosphoric acid is… listed as a "cleaner, disinfectant and sanitizer permitted on organic product contact surfaces for which a removal event is mandatory [for use] on dairy equipment." "

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

2021 TR for Handling, line 358:

> Phosphoric acid is not listed in EC No. 834/2007 or EC No. 889/2008.

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

2021 TR for Handling, line 358:

> "Phosphoric acid is not listed in the CODEX."

International Federation of Organic Agriculture Movements (IFOAM)

2021 TR for Handling, line 365-367:

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

Japan Agricultural Standard (JAS) for Organic Production

2021 TR for Handling, line 361:

> "Phosphoric acid is not listed in the JAS."

Environmental Issues:

The 2021 TR (handling) indicates that if stored, used, and disposed of properly, phosphoric acid utilized as a cleaning agent for livestock equipment and facilities will not interact very much with the agroecosystem nor come into direct contact with livestock. The acid will dilute quickly in the environment, and there are no toxicity issues directly from its breakdown products.

Effects on Human Health – The exact dangers depend on the solution's concentration strength, with higher concentrations presenting greater hazards. Phosphoric acid, at 85 wt. % is considered a corrosive chemical solution that can cause, through skin exposure and inhalation, severe skin burns, permanent eye damage, sore throat, shortness of breath, and even death.

Discussion:

The Subcommittee conducted a thorough discussion of phosphoric acid and reviewed extensive public comments at the Spring 2023 Board meeting. Public comments indicated consensus in relisting, as phosphoric acid is used extensively to remove deposits on equipment, such as milk lines and bulk tanks, that cannot be removed with other detergents and acids. The Board reviewed concerns from stakeholders regarding the need for clarity on several fronts, including the following:

1. **Rinse or No Rinse:** Clarity is needed regarding phosphoric acid's classification as a sanitizer or a cleaner. Use as a cleaner requires a rinse post-use. The Board discussed the legal requirement to not rinse phosphoric acid, per the United States Public Health Service/Food and Drug Administration (USPHS/FDA) Grade "A" Pasteurized Milk Ordinance (PMO).
2. **Downstream equipment**: Clarity is needed surrounding the bulk tank, located downstream of the milking system equipment, about whether it is included in this scope. If the bulk tank does get rinsed, can the rinsate, that is combined with manure, be applied onto farm fields?
3. **Livestock and Handling:** Stakeholders believe that the livestock listing for phosphoric acid is clearer than the handling listing, and requested that the handling listing (§205.605) be updated to mimic the listing in livestock (§205.603).
4. **Material Review:** This is outside of the purview of the NOSB, but it is important to capture within the sunset review. Some certifiers, but not all, require that all ingredients in a cleaner/sanitizer product must be allowed on the National List for the product to be allowed without a rinse. Most phosphoric acid products will require a rinse because they contain inactive (inert) ingredients not on the National List. Should the multi-ingredient material contain only phosphoric acid and water, according to these certifiers, it would be allowed without a rinse. This should be clarified in an annotation or in guidance.

In summary, the Subcommittee is asking that action be taken to clarify the use of phosphoric acid. The Subcommittee is also seeking clarification and confirmation that the Accredited Certifiers Association (ACA) has a working taskforce reviewing these issues.

Justification for Vote:
The Subcommittee finds phosphoric 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 phosphoric acid from the National List
Motion by: Amy Bruch
Seconded by: Nate Lewis
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 0

Lime, hydrated

Reference: 205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.
(6) Lime, hydrated - as an external pest control, not permitted to cauterize physical alterations or deodorize animal wastes.
Technical Report: 1995 TAP; 2015 TR
Petition(s): N/A

Past NOSB Actions: 11/1995 NOSB minutes and vote (pg. 24); 04/2006 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Technical correction annotation change published 10/31/2003 (68 FR 61987); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
Information and data was taken from the 2015 TR.

Under the USDA organic regulations for livestock production, hydrated lime is only permitted for use as an external parasiticide. Regarding livestock applications, the final rule states that hydrated lime may not be used to cauterize physical alterations (medical treatment) or deodorize animal wastes.

This NOSB sunset review of hydrated lime pertains to applications of the substance for parasitic mite control in sheep, goats, cattle, and other livestock. Mange caused by parasitic mites is highly irritating for animals and can result in economic losses from wool damage (lamb and sheep) and reduced production of meat products (McNeal, 1999). Sheep scab—caused by the parasitic mite *Psoroptes ovis*—is a contagious, highly pruritic (i.e., itching) disease that results in the development of large, yellowish, scaly, crusted lesions, accompanied by damage to wool and hide. Sarcoptic and demodectic mange are problematic for producers of sheep and goats (CFSPH, 2009). In U.S. cattle production, sarcoptic mange (scabies), psoroptic mange, chorioptic mange, demodectic mange and psorergatic mange (itch mite) continue to be problematic skin diseases. Dips consisting of 2% hot lime sulfur (i.e., hydrated lime, elemental sulfur, and water) are recommended as treatments for parasitic mites associated with these diseases (Losson & Mignon, 2011).

Composition of hydrated or "slaked" lime consists primarily of calcium hydroxide [$Ca(OH)_2$] and magnesium hydroxide [$Mg(OH)_2$] at 50 - 95% and 0 - 50% of the substance, respectively. High purity forms of the substance contain greater than 90% calcium hydroxide.

Manufacture:
The industrial production of hydrated/slaked lime involves two elementary reactions beginning with naturally occurring limestone deposits. In the first step, ground limestone—which contains predominantly calcium carbonate ($CaCO_3$) with smaller amounts of magnesium, silicon, aluminum, and iron oxide compounds—is thermally transformed into quicklime. Specifically, heating raw or minimally processed limestone to temperatures in excess of 900 degrees Celsius results in conversion of the calcium carbonate content of limestone to calcium oxide (CaO) in a material known as quicklime (2015 TR, line 236). This thermal transformation occurs with liberation of carbon dioxide (CO2) gas. In the slaking process, quicklime reacts exothermically (releases heat) with two equivalents of water to produce hydrated/slaked lime consisting primarily of calcium hydroxide [Ca(OH)2] (equation 2). The normal hydration process is carried out at atmospheric pressure and temperatures of approximately 100 ºC. A variation of the normal hydration process involves reaction of quicklime and water under a high steam pressure of up to 1 MPa and at temperatures approaching 180 ºC to form hydrates. After

hydration, the hydrated lime product is dried, milled, and air classified. Equations 1 and 2 below provide molecular depictions of the overall synthetic process.

	heat		
$CaCO_3$	→	$CaO + CO_2$ (g)	(2015 TR, line 245)
$CaO + H_2O$	→	$Ca(OH)_2$	(2015 TR, line 246)

International Acceptance:

Canadian General Standards Board Permitted Substances List

Canadian organic regulations permit the use of hydrated lime as a health care product and/or production aid in organic livestock production under Section 5.3 of the Permitted Substances Lists. According to this rule, hydrated lime is not allowed for use to cauterize physical alterations (medical treatment) or deodorize animal wastes. Hydrated lime is also listed in Section 4.3—Crop Production Aids and Materials—for use as a plant disease control agent only (CAN, 2011).

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

Organic regulations from the European Union do not permit the use of hydrated lime/calcium hydroxide as an external parasiticide in livestock production. However, Annex I of the European regulations allow "industrial lime from sugar production"—a byproduct of sugar production from sugar beet—as a fertilizer or soil conditioner. Calcium hydroxide may be used as a fungicide on fruit trees to control Nectria galligena in organic crop production under Annex II and as a processing aid in the production of processed organic foods of plant origin under Annex VIII (EC, 2008).

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

The Codex Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods (CAC/GL 32-1999) do not list hydrated lime/calcium hydroxide for use in organic livestock or crop production. However, calcium hydroxide is included in the list of "processing aids which may be used for the preparation of products of agricultural origin referred to in Section 3 of these guidelines" (Codex, 2013).

International Federation of Organic Agriculture Movements (IFOAM)

IFOAM Norms permit the use of "milk of lime" (i.e., hydrated/slaked lime, calcium hydroxide) for pest and disease control and disinfection in livestock housing and equipment (IFOAM, appendix 5). Likewise, calcium hydroxide (slaked lime) is included in the "Indicative List of Equipment Cleansers and Equipment Disinfectants" (IFOAM, appendix 4 – Table 2) for organic handling/processing. Calcium hydroxide is also listed as an approved food additive for maize tortilla flour and processing aid for sugar (IFOAM, appendix 4 – Table 1). Lastly, application of calcium hydroxide (hydrated lime) is allowed on aerial plant parts only for plant disease control according to Appendix 3 of the IFOAM Norms (IFOAM, 2014). Hydrated lime is not explicitly listed as an approved miticide according to IFOAM.

Japan Agricultural Standard (JAS) for Organic Production

According to Table 4 of the Japanese Agricultural Standard (JAS) for organic livestock products, slaked lime (calcium hydroxide) is an approved agent for cleaning or disinfecting of housing for livestock. Calcium hydroxide derived from calcium oxide (slaked lime) is also listed in Table 1 of JAS as an approved fertilizer and soil improvement substance (JMAFF, 2012). Hydrated lime is not explicitly approved as a miticide according to Japanese organic regulations.

Environmental Issues:
Hydrated lime is released to the environment through various industrial waste streams and according to its use in agricultural production (2015 TR, line 399-400). Both calcium and hydroxide—the principal atomic/molecular subunits of hydrated lime—are abundantly present in natural waters (2015 TR, line 401); therefore, it is unlikely that small to moderate releases will adversely affect the aquatic or terrestrial environment. Large-volume accidental releases, however, could significantly raise the pH of receiving waters and soils, resulting in toxic effects to non-target organisms. Hydrated lime is considered practically non-toxic to slightly toxic to freshwater fish and invertebrates when added in quantities that do not lead to significant changes in water pH (2015 TR, line 406). While certain strains of soil bacteria can tolerate extreme pH levels (e.g., pH 1.0 or 11.0), larger soft-bodied soil organisms are significantly more sensitive to changes in soil pH. Earthworms, for example, can only survive in the physiological pH range of 4.0 to 8.0 (2015 TR, line 408). Changes in soil pH due to application of alkaline hydrated lime can also affect the bioavailability of toxic heavy metal contaminants as well as essential micronutrients (2015 TR, line 409-410). It is highly unlikely that hydrated lime from livestock treatments will be released to nearby soils in sufficient quantities to adversely impact the environment. Industrial production of the chemical precursor, quicklime (CaO), uses considerable amounts of energy and may release dust into the atmosphere. The use of more efficient modern kilns and bag filters can minimize the environmental impact of this process (2015 TR, line 414-415).

Treatment and disposal is a potential complication associated with the use of hydrated lime and other miticide treatments in large volumes. In some cases, operators have discharged spent dip directly into watercourses or allowed the chemicals to soak into the ground near the dip facility (PAN-UK, 1997). Livestock operators using hydrated lime dipping stations for external parasite control should ensure that the resulting highly alkaline waste solutions are properly treated and disposed of to minimize the likelihood of environmental contamination.

Discussion:
Comments from the Spring 2023 meeting were mostly supportive of relisting hydrated lime. It was mentioned by a few that the actual use of hydrated lime may not be as intended, and rather it may be used more as a white-wash or in bedding. Many of the commenters suggested that hydrated lime was essential for organic production in that it prevents the spread of pests among herds. A few commenters said that there are no alternatives to hydrated lime.

Questions to our Stakeholders:
None

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

Subcommittee Vote:
Motion to remove hydrated lime from the National List
Motion by: Kim Huseman
Seconded by: Brian Caldwell
Yes: 0 No: 4 Abstain: 0 Recuse: 0 Absent: 2

Mineral oil

Reference: 205.603(b) As topical treatment, external parasiticide or local anesthetic as applicable.
(7) Mineral oil - for topical use and as a lubricant.
Technical Report: 2002 TAP; 2015 TR; 2021 Limited Scope TR
Petition(s): 2002 (medical treatment and feed additive)
Past NOSB Actions: 11/1995 NOSB minutes and vote (pg. 24); 05/2003 NOSB recommendation (feed additive, not recommended) (pg.1443-1444); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
The USDA organic regulations currently permit the use of mineral oil in organic livestock production for direct topical application and as a lubricant under 7 CFR 205.603(b)(7). Regarding this use pattern, mineral oil acts as an external parasiticide when applied topically to animals infested with mites, lice, and other parasites. External parasites such as lice, mange mites, and various insects can adversely impact the health of individual animals and lead to economic losses for livestock producers. These parasites do not generally kill their hosts, but they can weaken the animal and, in some cases, transmit diseases to the host animals. Mineral oil is also used as a lubricant during artificial insemination.

In a separate listing (§ 205.603(a)(20)) that is not the subject of this sunset review, mineral oil is administered internally to lubricate the intestinal tract to treat bloat and dislodge intestinal obstructions in cattle and other ruminants.

Manufacture:
From the 2015 Technical Report (TR), line 55-60:

> "Crude petroleum oil is the predominant source of mineral oils used in organic and conventional agriculture, as well as food for human consumption, cosmetic products, and drugs… Refined mineral oils are obtained through physical separation, such as distillation and solvent extraction, and chemical conversion processes, including cracking, hydrogenation, alkylation, isomerization and/or other chemical transformations."

2015 TR, line 38-40:

> "The composition of mineral oil is dependent upon the crude oil source (e.g., location of procurement) and the processing that occurs in the refinery, such as physical separations and chemical conversions."

2015 TR, line 61-63:

> "As complex mixtures, refined mineral oils are identified using several CAS numbers depending on the treatment processes utilized and the intended use pattern of the mineral oil product."

2015 TR, line 33-38:

> Mineral oils used in organic livestock production are hydrocarbon molecules containing 15 to about 50 carbon atoms (US EPA, 2007; EFSA, 2012)… These untreated mineral oils may also contain small amounts of nitrogen- and sulfur containing compounds (EFSA, 2012)."

Crude, untreated mineral oil mixtures also include aromatics, including polycyclic aromatic hydrocarbons (PAHs). PAHs may be toxic, and some are carcinogenic in long-term exposures. [2015 TR]

2015 TR, line 423-435:

> "The industrial production of highly refined, food-grade mineral oils involves chemical processing and refinement using various chemical reagents and/or catalysts. Specifically, crude oil is desalted, distilled, and subjected to solvent extraction, de-aromatization with fuming sulfuric acid or sulfur trioxide, and/or catalytic hydrocracking treatments to reduce the concentration of polar constituents containing heteroatoms (nitrogen, oxygen and sulfur atoms) as well as PAHs and other aromatic compounds (EFSA, 2012; Wright, 2012). Crude oil is considered an economically significant natural resource throughout the world, and would likely be classified as a naturally derived, non-synthetic substance according to NOP definitions. To produce mineral oil, the chemical composition of natural crude oil is altered through physical separation (distillation) followed by reactions/combination with synthetic substances and reagents (aromatic solvents, strong acids and/or catalysts). Mineral oil is therefore considered a synthetic material. As such, the NOSB classified mineral oil as "synthetic" since initially recommending addition of the substance to the National List (USDA, 2002)."

International Acceptance:

Canadian General Standards Board Permitted Substances List

2015 TR, line 273-275:

> Canadian regulations permit numerous uses for mineral oils of varying purity. Mineral oils are allowed for external application only under Section 5.3 (health care products and production aids) of the permitted substances list for livestock production (CAN, 2011)."

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

2015 TR, line 287-288:

> "According to Annex II of the European Organic Regulation (EC) No 889/2008, mineral oil may be used as an insecticide and/or fungicide only in fruit trees, vines, olive trees and tropical crops (e.g., bananas)."

Mineral oils are not mentioned specifically in 834/2007 for the use in livestock. However, Annex V, Feed Materials of Mineral Origin (EU EEC 2008, Article 14 Section 1 (e) (ii) states:

> "chemically synthesized allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions" (EU EEC 2007).

While there is no specific listing for mineral oils in livestock, Article 14 notes that:

> "suffering shall be kept to a minimum during the entire life of the animal, including at the time of slaughter."

The regulation further notes:

> "disease shall be treated immediately to avoid suffering to the animal; chemically synthesized allopathic veterinary medicinal products including antibiotics may be used where necessary and under strict conditions, when the use of phyto-therapeutic, homeopathic and other products is inappropriate. In particular 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)

Part B, Section 22, The Codex Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods (CAC/GL 32-1999) indicate that mineral oil is only permitted for use in traps for organic crop production. Mineral oils are not specifically mentioned for livestock applications. However, under Health Care, Section 22:

> "where specific disease or health problems occur, or may occur, and no alternative permitted treatment or management practice exists, or, in cases required by law, vaccination of livestock, the use of parasiticides, or therapeutic use of veterinary drugs are permitted."

International Federation of Organic Agriculture Movements (IFOAM)

2015 TR, line 299-301:

> The IFOAM Norms permit the use of "light mineral oils (paraffin)" under Appendix 3 (crop protectants and growth regulators). There are no approved uses for mineral oils or related substances in organic livestock production under the IFOAM Norms (IFOAM, 2014).

Japan Agricultural Standard (JAS) for Organic Production

The Japanese Agricultural Standard (JAS) for Organic Production originally considered only crops and processing (JAS 2005) with later revisions including livestock. 2015 TR, line 294-297:

> "Japanese regulations for the organic production of livestock only mentions the use of "petroleum oil aerosol" and "petroleum oil emulsion" for plant pest and disease control (Table 2). Otherwise, it does not appear that Japanese organic regulations permit the use of mineral oil or related products in organic livestock production (JMAFF, 2012)."

Environmental Issues:

2015 TR, line 481-490:

> "Mineral oils may be classified as highly refined or mildly treated/untreated. The white mineral oils that are likely to be used for lubrication and external parasite control in organic livestock production are highly refined oils that contain negligible quantities of toxic contaminants *[such as PAHs]* compared to untreated and mildly treated oils.
>
> Testing in laboratory animals has demonstrated that mineral oils are slightly to practically non-toxic to mammals on an acute exposure basis. Mineral oils are mild irritants, classified as Toxicity Category IV (lowest toxicity) for skin irritation and Category III for eye irritation (US EPA, 2007). Highly refined "white" mineral oils produced no sensitization reactions in guinea pigs repeatedly exposed to the substance…"

2015 TR, line 518-521:

> "The carcinogenicity and genotoxicity potential for mineral oils is generally dependent upon the degree of refinement and presence of PAHs in the mixture. White mineral oils—which have

> undergone the most severe acid, solvent or hydrocracking treatment—showed no activity in a series of skin-tumor bioassays (IARC, 2012)."

2015 TR, line 534-535:

> "Much like the mammalian studies, the results of avian and honeybee studies suggest that refined mineral oils are practically non-toxic to birds and honeybees via acute oral and contact exposure, respectively."

2015 TR, line 548-549:

> "Refined mineral oils are generally characterized as minimally toxic to aquatic organisms on an acute exposure basis."

Discussion:
White mineral oil for veterinary uses including for treatment of external parasites, appear to have little negative effect on the animal or the environment, while being critical for humane treatment of some serious animal health issues. Public comments submitted to the Board prior to the Spring 2023 meeting were strongly in favor of relisting. Mineral oil is shelf stable and very widely used.

This listing covers its use as a topical parasiticide and external lubricant. Other veterinary uses are covered separately at §205.603(a).

Justification for Vote:
The Subcommittee finds mineral 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 mineral oil from the National List
Motion by: Brian Caldwell
Seconded by: Kim Huseman
Yes: 0 No: 5 Abstain: 0 Recuse: 0 Absent: 1

National Organic Standards Board
Certification, Accreditation, Compliance Subcommittee (CACS)
Oversight Improvements to Deter Fraud: Consistent Location Identification Proposal
August 1, 2023

Intro:
Since the fall of 2022, the Certification, Accreditation, Compliance Subcommittee (CACS) has received feedback from the community that parcel location collection is inconsistent across NOP accredited certifiers. While some certifiers have a complete database of the location of every parcel they certify, other certifiers have no ability to independently verify the location and boundaries of the fields they certify based on the information they collect from their clients. The CACS heard from stakeholders across the community that generally there is consensus that a consistent, industry-wide standard parcel location collection system would boost certifiers' ability to verify information and more effectively monitor those parcels they certify.

At the spring 2023 National Organic Standards Board (NOSB) meeting, public commenters requested clarification on how the CACS defined a parcel of land. Certifiers use various names such interchangeably: sites, fields, and parcels. For the purpose of this proposal the CACS is defining "parcel" as the legal parcel included within the boundaries of the legal property lines for that unit of land. The CACS acknowledges that farmers may subdivide their legal parcels into sub-field designations.

The CACS recommends that NOP provide guidance to certifiers that all parcels should be located via GPS, and it will be the responsibility of the certifier and inspector to coordinate the intake of information to meet this requirement. The goal of this guidance is database consistency.

Challenge:
The location of certified organic operations, including each production parcel, must be more consistently recorded and managed across certifiers. This challenges the industry, leading to a gap in certifiers' ability to accurately cross-check the operations and fields they certify with other certifiers. Furthermore, some certifiers cannot conduct independent verification or unannounced inspections of fields because they don't have mapping capabilities of all field locations.

Solution:
Certifiers located both domestically and internationally can harmonize the data intake from clients when producers request to certify new fields for organic certification. By requesting the geolocation or information that can lead to geolocation information (Global Positioning Coordinates, parcel identification numbers, street address, etc.) of certified operations, certifiers will be able to receive consistent data that is easily managed while also allowing the inspectors to confirm the accuracy of the data during the inspection and use it as a cross-check.

Background:
The Strengthening Organic Enforcement (SOE) rule will make supply chain tracebacks and mass balances mandatory. Complete supply chain tracebacks will require certifiers to work bi-directionally up and down the supply chain in cooperation with other certifying bodies.

In addition to the SOE, the USDA Organic Transition Initiative currently being rolled out across the US discusses ways to improve existing programs that support organic transition and markets. Consistency of certified operation location identification and verification of land eligibility is essential. It can be accomplished by requiring geolocation data for all certified operations.

Applications for certification for a new field typically include a name for the field and the number of acres. Some certifiers also request the address or driving directions. Still, many certifiers confirmed that if asked, they could not locate each field they certify via google maps or other interactive GPS database . This lack of data impedes certifiers' ability to act quickly in the case of aggregated mass balance investigations across clients or in the case of a major contamination event.

Consistent Location Identification:
Consistency in parcel identification and location should be required to comply with the SOE-mandated supply chain traceback requirements.

In the Fall of 2021, the NOSB received the following comment/question regarding the proposed rule on Strengthening Organic Enforcement (SOE): "Will the final rule require mandatory data reporting to NOP by crop type, acreage, and location; and a number of animals by livestock type and location, at least on an annual basis to the Organic Integrity Database (OID)? A requirement for certifying agents to report production area certified by crop/livestock and location, on at least an annual basis, to the OID is one of the most impactful single actions that can be taken to increase integrity in the global organic control systems." This commenter's question provided a road map for CACS.

1. At the Fall 2022 NOSB meeting, the proposal, "Oversight Improvements to Deter Fraud: Acreage Reporting," was unanimously passed by the Board.
    a. The key aspect of the recommendation was a balance and cross-check to ensure that the volume of certified acres (under the NOP) ultimately supports the volume of organic products produced and sold (under the NOP).

2. At the Spring 2023 NOSB meeting, the discussion document "Oversight Improvements to Deter Fraud: Consistent Location Identification" received public comment and was discussed by the NOSB. For the Fall 2023 NOSB meeting, the community will review a proposal with the same topic, and the NOSB will vote on it.
    a. The proposal aims to establish the structure and system for universal field location identification for organic producers, certifiers, inspectors, and the NOP, to register, verify, and cross-check the location of all acres certified under the NOP, both domestically and internationally.

The Strengthening Organic Enforcement (SOE) Rule:
The SOE states, "Certifying agents must be able to conduct unannounced inspections of any operation they certify. Therefore, AMS requires that certifying agents only accept applications for certification or continue certification from operations for which the certifying agent can conduct unannounced inspections. To ensure consistency, transparency, and accountability, certifying agents are expected to describe the areas where they operate in the written materials they provide to applicants and certified operations and review the locations of all operations during their application or annual review. A certifying agent that cannot conduct unannounced inspections in an applicant's or certified operation's location due to logistical challenges, staffing, security, or other reasons, is considered not to have the administrative capacity for certification activities in that area, consistent with § 205.501(a)(19)".

As one commenter mentioned, "The Strengthening Organic Enforcement Rule should reduce the risk of fraud in the organic marketplace. However, enforcement efforts depend upon sufficient and accurate information about each operation." A consistent process for locating certified organic operations, including fields, would aid in executing parts of the SOE, including cross-checking and supply chain verification.

An additional certifier commenter stated, "Geolocation will enable greater ease in organic oversight across certifiers and supply chains by applying fixed, traceable, and universally understood markers on individual plots of land that will not change over time."

History, Evolution, and Benchmarking of Geo-Referencing Information:

1. **Global Navigation Satellite Systems (GNSS) and Global Positioning Systems (GPS)** - In the 1970s, the United States military began using a form of GNSS called GPS for navigation, which became publicly available in the early 2000s.
    a. GPS allows for navigation to any point of interest, anywhere in the world.
    b. According to GPS.gov, "GPS is a U.S. - owned utility that provides users with positioning, navigation, and timing (PNT) services…..24 operating satellites are transmitting one-way signals that give current GPS satellite position and time." GPS is generally expressed as specific latitude and longitude coordinates
    c. Russia, China, and the European Union also have a GNSS similar to GPS.
        i. Japan and India have regionally based systems.
    d. The GPS is the oldest of all the GNSS.
        i. GPS.gov states, "the American taxpayer pays for the GPS service enjoyed throughout the world. All GPS program funding comes from general U.S. tax revenues….there are no plans to privatize GPS, as US Law and policy require the civil GPS service to be provided free of direct user fees."
        ii. One commenter highlighted that three certifiers are currently requesting GPS coordinates (CCOF, OOTC, and WSDA), with several other certifiers requesting GPS coordinates from international operations that are certified to NOP standards.

2. **Keyhole Markup Language (KML) and Keyhole Markup Language Zipped (KMZ)**
    a. KML is a file responsible for storing map locations that can be viewed with the following:
        i. Geographical Information Systems (GIS) such as ArcGIS
        ii. Geospatial Tools such as Google Earth Pro
    b. KMZ is a Zip-compressed version of a KML
        i. One commenter highlighted that KMZ files, which display field shapes and acreages, are maintained in WSDA's database.

The precedence of geo-referenced data is found within the USDA currently:

1. **Risk Management Agency (RMA):**
    a. Having exact location information provides enhanced transparency and oversight. The Risk Management Agency's General Standards Handbook Section 1.c. of the Maintaining Organic Records states, "a requirement for organic producer's record keeping is that "insured must have, e.g., aerial or GIS (Geographical Information System) maps, from the organic farming operation that show the exact location of each field for certified organic, transitional, buffer zone, and conventional acreage not maintained under an organic practice."

2. **Certifier Community + Neighbors to the South:**
    a. Several Certifiers are already collecting town, range, and section (TRS) data with others using "GPS Coordinates." How can those certifiers share with other ACAs their intake process?

b. One certifier creates a KMZ, in Google Earth Pro, for every "site" (synonymous with field or parcel). The business provides location and latitude/longitude; inspectors verify that info and create a KMZ file.

c. Several certifiers require GPS coordinates for all farms outside of the USA that are certified to the NOP standard.

   i. A public commenter mentioned that “the practice of incorporating and tracking GPS coordinates, whether as degrees-minutes-seconds or digital coordinates, is universal among those certifiers that are accredited to the Mexican “Ley de Productos Orgánicos” Standard (LPO), as the practice is already required under that standard.”

Low Burden - One-Time Collection:
By requiring a consistent method of location identification information through GPS coordinates, it will be easy and low-burden to achieve consistency across all geographic locations, domestic and international. The information can be easily obtained once and then used from that point forward for organic operations that do not have access to this information. GPS is free and accessible globally and can be the logical path forward for consistently capturing location information domestically and internationally. According to two certifiers, via the public comment process, the burden is low and outweighed by improved resolution. Additionally, a certifier went on to state that the “benefits will be seen internally for each certifier with greater long-term visibility and tracking on field data and management and that the use of geolocation will enable greater ease in organic oversight across certifiers and supply chains by applying fixed, traceable, and universally understood markers on individual plots of land that will not change over time.”

GPS proposed framework for location information:
1. One GPS coordinate (including latitude and longitude) for identification of each location, such as a certification office, brokerage or importer office, manufacturing facility, handling facility, field, production unit - a field in a grower group, etc.
   a. A GPS coordinate in the center of the field can be a best practice.

Spring 2023 Discussion Summary:
During the Spring 2023 meeting, the NOSB discussed the Consistent Location Identification discussion document and reviewed public comments, which involved answering several questions regarding collecting field-level location information and verification methods.

The inspector community that commented was in complete support of requiring more consistent methods of field location information. Inspector comments from the Spring of 2023 consistently confirmed the challenge. They even stated, “The pandemic presented an opportunity to test the ability to verify the location of a field without the operator being available. In the best case - each field has an address & each address maps to the frontage of the field, and in the worst case - a field without means to navigate to and/or a hand-drawn or low-quality map with indistinguishable features, often due to having been faxed and/or copied too many times. In these cases, there is practically no way to identify where a field is located without the operator. Most fields can be found eventually, but only after extensive effort and significant time.” The NOSB is requesting that we commit as a community to solving this easy challenge, so inspectors have more time to find the fraud versus spending time finding the field.

The NOSB reviewed comments from members of the community, including certifiers that wanted to ensure clarity of the information; through public comments and NOSB discussion, clarity was received, and a summary is listed below:

1. Several members noted that trying to keep GPS locations updated for diverse and small farms is difficult.
    a. Once the farm is located, GPS, a standardized system, doesn't deviate and doesn't need to be continuously updated by the operation.
        i. This recommendation does not require annual GPS information for each crop nor does is require details such as row feet.
    b. The macro field border or parcel does not change based on crop production, the type of crop, or how a producer segments the field or parcel. The recommendation is for the macro border of each field or parcel, not how a producer segments out the field or parcel to grow crops.
    c. Should GPS coordinates be unavailable due to technology access or other barriers, the following suggestions based on public comment should be used as acceptable alternatives as all three ways, with additional steps, will lead to GPS-coordinate capture.
        i. Parcel numbers (standard property identifiers that each county recognizes)
        ii. Address (not mailing route such as Rt 2 Box 176, but a street address if applicable)
        iii. Legal address including Section / Township / Range

Recommendation:
The CACS recommends that the NOP provide guidance to all accredited certifiers to obtain consistent location information (geocodes) that can lead to GPS coordinates of all applicants for certification and certified operations (parcels, production units - grower groups, handling locations, importers, brokers, etc.). This will result in harmonization of location data of all parcels enabling certifiers to streamline cross-checks and share information internally between operator, certifier, and inspector..

Vote in Subcommittee:
Motion to accept the proposal on Oversight Improvements to Deter Fraud: Consistent Location Identification
Motion by: Amy Bruch
Seconded by: Nate Powell-Palm
Yes: 9 No: 0 Abstain: 0 Recuse: 0 Absent: 0

National Organic Standards Board
Certification, Accreditation, Compliance Subcommittee
Climate Induced Farming Risk and Crop Insurance Discussion Document
(Risk mitigation on organic farms in the United States:
Strengths and limitations of organic crop insurance)

July 11, 2023

Summary

Crop insurance is currently the primary federal program available for farmers. When considering agriculture as a whole, row crop producers use crop insurance most often, while usage is relatively low for specialty crop producers. Thus, when farmers who are accustomed to using insurance transition their operations to organic, they want to buy crop insurance and expect that it will work for their organic crops as well as it does (or did) for their nonorganic crops.

There are farmers who find that crop insurance works well for their operations. Some farmers who do not buy insurance would like to do so, but only if it worked better. Another group of farmers buys crop insurance, either as catastrophic coverage or because their lenders require them to do so. Another group is not interested in crop insurance.

The goal of this Fall 2023 discussion document is to continue building the body of evidence that (1) clearly specifies problems organic farmers are experiencing and (2) offers concrete ways to improve organic crop insurance. This document continues the work presented in the Spring 2023 meeting. It provides a summary of the findings of the Spring 2023 public meeting in addition to providing new information obtained through interviews with farmers and other representatives of the organic sector.

The NOSB firmly believes that crop insurance should provide adequate risk management for organic producers. The increasing frequency of climate events means that more organic farmers require strong risk mitigation tools that add a layer of protection to the benefits provided by their organically managed soil.

While every nonorganic farmer who wants crop insurance is currently able to purchase an effective policy, this is not true for organic farmers. We want to see the Risk Management Agency improve crop insurance for the organic farm sector, so that every farmer who wants insurance will be able to buy a policy that provides more than catastrophic coverage.

Questions for public commenters

1. Does this document accurately reflect the challenges organic farmers face, regarding crop insurance?
2. Is this document missing any important problems or factors or topics?

3. For each problem identified (or for some of the problems), please offer a solution that will improve crop insurance for organic producers.

Introduction

As the Transition to Organic Partnership program rolls out nationwide, with USDA investing up to $100 million to support transitioning organic farmers, the need for improved risk management tools for organic farmers takes on heightened urgency. The potential expansion of acreage under organic management, which comes with important environmental benefits, means that more organic farmland will be exposed to the on-farm risks that come with climate change. For farmers in transition, who already face new challenges regarding farming methods, yields, on-farm production practices and marketing, some may be unable to successfully manage the transition to organic production. Existing organic farmers also face risks caused by climate change, as reflected by the increasing frequency of events such as flooding, drought, and hail.

In the U.S., the primary risk management tool available to farmers is crop insurance. Evidence is strongly suggestive that crop insurance, in its current iteration, does not work as well as it could for organic farmers and, consequently, does not adequately help organic farmers manage their risk. While the extant body of literature has made great strides towards pointing out problems with organic crop insurance, there is still work to be done, and at the time of this writing there is an insufficient body of evidence documenting the shortfalls of crop insurance for the organic sector.

This discussion document offers new insights into how crop insurance is working for organic farmers. We build on the Spring 2023 discussion document and start by including important background information describing the evolution of crop insurance for organic farmers and a synthesis of the existing related literature and available data. In addition, we provide a summary of primary data, which includes an analysis of public comments submitted for the Spring 2023 NOSB meeting and interviews with organic farmers, technical assistance providers and policy.

Through this discussion document, the NOSB seeks concrete information about which aspects of crop insurance are most problematic for organic farmers and potential solutions. We aim to represent the needs of all organic farmers, not just those who traditionally have used crop insurance to manage their risks.

Background information

Crop insurance is currently the primary federal policy available to help farmers manage their risk from production (low yields) or price (as reflected by uncertainty of input and output prices). Overseen by the Risk Management Agency of USDA, the Federal Crop Insurance Program is a market-based insurance program (USDA RMA, undated). Producers of crops that lack insurance programs are eligible to enroll in the noninsured crop disaster payment program under the purview of the Farm Service Agency, which targets losses due to natural disasters (USDA FSA, undated).

Historically, crop insurance was one of many federal programs that supported farm income. Insurance would cover losses caused by low prices or low yields. The statute that created crop insurance requires premiums are actuarially fair, so that payouts for crop insurance plus a small reserve are equal to the premiums paid. In addition to setting the insurance premiums correctly, crop insurance policies need to be designed to attract enough farmers so that the program effectively pools risk (Hamilton, 2020). Adverse selection, where only the highest risk individuals opt for insurance, is a well-known problem for insurance, and crop insurance is not exempt from this undesirable possible outcome. An analysis of crop insurance data for farms in Iowa finds that premiums are too high for highly productive land and too low for less productive land (Price et al., 2019). The 2014 Farm Act eliminated many farm income support programs, and made crop insurance the dominant method of federal support for farmers.

Crop insurance for organic farms has been addressed in multiple farm bills; the changes mandated by Congress illuminate the struggles RMA faces regarding creating and operating crop insurance for organic producers. Until the passage of the Farm Act of 2000, organic farming was not a ‘good farming practice,’ so organic farms were excessively risky from an actuarial standard (Morris et al., 2019). Even after Congress stipulated that organic was to be considered as good farming practice, and producers were able to buy crop insurance for their organic operations, it was unlikely that farmers would receive payment for their losses. Other changes legislated through the Farm Bill followed starting in 2008. The organic price election was required for cotton, corn, soybeans, and processing tomatoes in the 2008 Farm Bill (Carlson et al., 2023). The 2014 Farm Act required RMA to expand organic price elections by 2015 and to allow producers to select a Contract Price Addendum for their crops sold via contract (Carlson et al., 2023). In 2015, Whole-Farm Revenue Protection (WFRP) was introduced, designed for diversified operations including specialty crop farms. The 2018 Farm Act added cover crops to the list of good farming practices, so cover cropping was to be treated like other fertilizer and tillage practices (Carlson et al., 2023). The 2018 Farm Act also required continuing education for crop insurance agents and loss adjusters so they would be familiar with organic practices (Carlson et al., 2023).

Despite the switch to defining organic methods as good farming practices, organic producer use of crop insurance is relatively low (Raszap Skorbiansky et al., 2022). Morris et al. (2019), however, suggest that comparisons of crop insurance adoption should be based on crop type rather than in the aggregate. Grain growers are more likely to use crop insurance (Belasco, 2013). In 2016, between 50-100 percent of the value of organic corn, almonds, rice, wheat, and soybean crops were insured, which was roughly in line with the insurance coverage for agriculture as a whole (Morris et al., 2019).

It is also important to keep in mind that the organic farm sector, compared to the rest of agriculture, has a greater share of farms and acres devoted to specialty crops and a lower share to field crops, in terms of value of sales. More specifically, in 2021, organic farm level sales for fruits, nuts, berries and vegetables comprised 37 percent of total farm level sales while field crops made up 13 percent (USDA NASS, 2022). In contrast, in 2017, for the agricultural sector as a whole, fruits, nuts, berries and vegetables comprised just 12 percent of total farm level sales while field crops made up 28 percent (USDA NASS, 2019). Thus, given cultural norms, it seems reasonable to expect a slightly lower percentage of organic farmers (as a whole) to use crop insurance.

Moreover, as Morris et al. (2019) report, in many ways organic farming systems and crop insurance are not incentive compatible. Organic farmers manage their risks through improving soil organic matter, rotating crops, and diversifying their operations (Hanson et al., 2004). Improving soil health is viewed as on-farm risk management by many organic producers (Snyder et al., 2022). Other types of risk are price risk related to market access and other market factors. Some producers, especially those growing specialty crops, manage market risk by creating a CSA or by marketing to multiple outlets (Snyder et al., 2022).

Crop insurance addresses risks created by yield or price variability (although a few policies address quality). Decisions to purchase insurance are part of a broader set of farmer actions. For example, crop insurance is often required for producers seeking financing or for participating in some federal farm programs (Raszap Skorbiansky et al., 2022). Highly leveraged producers are more likely to purchase crop insurance (DeLay et al., 2022).

Implications of low adoption of crop insurance by organic farmers are many, including preventing RMA from collecting data on organic production outcomes (Delbridge and King, 2019). At the same time, in 2021, for nine of the ten top organic crops the payouts exceeded the premiums received.[1] For every year between 2012 and 2021, for all crop insurance policies, the payouts exceeded the premiums received (USDA RMA, 2022). Thus, the organic crop insurance program is not meeting its mandate to be actuarially fair. A simulation of the 2014 shift to using organic specific yields (referred to as t-yield) indicates that the use of organic t-yields did improve the actuarial fairness, but farmers might have responded by not purchasing crop insurance (Delbridge and King, 2019).

The work by Morris et al. (2019), funded by OREI, suggests that if more farmers transitioned their operations to organic, overall farm level risk would be reduced, which would translate to lower public expenditures on crop insurance. However, this conclusion is based on the potential for organic farmers to reduce or manage their on-farm risks through their farming practices in addition to purchasing crop insurance. If all farmers who can manage risk through their farm practices opt not to purchase crop insurance, only riskier producers would buy crop insurance. And, at the time of this writing, the evidence points to the need to change the parameters of organic crop insurance to meet the mandate for actuarial fairness, unless the Risk Management Agency agrees to place organic and conventional crops in the same insurance pools.

[1] The ten top organic crops, in terms of liability, are corn, apples, soybeans, wheat, blueberries, potatoes, grapes, citrus fruit, tomatoes and peanuts (RMA, USDA 2022).

Since crop insurance is the primary instrument for sharing producer risk, improving the product to better meet the needs of organic producers is an important next step. A question that remains outstanding is how to design the crop insurance program in a way that is sound and provides the correct incentives to organic farmers. Another related question is whether it is essential to assess organic products separately and require organic farm products to be actuarially fair on their own. As Morris et al. (2019) explain, creating a strong crop insurance product for the organic sector has been problematic.

Adoption of crop insurance by organic producers

Understanding trends in organic farmer crop insurance usage by crop, by region, and over time is challenging because of the lack of publicly available data. Furthermore, there are inconsistencies in the data collected over time. Using data from USDA's Organic Survey and RMA's administrative data, this section outlines the general understanding of crop insurance use by organic farmers in the US.

The Organic Survey includes some data on crop insurance for the years 2008, 2014, 2019, and 2021. Crop insurance adoption by organic farmers ranged from 20-27 percent of certified organic farms during the years 2008, 2014, 2019 and 2021 (see table 1). While the number of organic farms with crop insurance rose over the 13 years, the percent of farms increased only slightly suggesting that adoption rates remain relatively constant over time. For 2014, 2019 and 2021, approximately 60 percent of those using crop insurance chose to cover all their farmland.

Table 1. Organic farm crop insurance use: 2008, 2014, 2019, 2021

Year	Operations			Share of farmland insured				
	Insured	Total farms	Share insured	L.T. .25	.25 to .49	.50 to .74	.75 - .99	All
	Number		*Percent of farms in each category*					
2008	2,141	10,903	20	n/a	n/a	n/a	n/a	n/a
2014	2,781	11,715	24	8	11	14	10	58
2019	4,255	15,548	27	5	10	16	12	56
2021	4,501	16,194	26	5	7	14	15	60

Note: Share of farmland insured presents the percent of operations in each category of farmland insured for those choosing crop insurance.
Source: USDA Organic Surveys 2008, 2014, 2019 and 2021.

A different perspective on the use of crop insurance by organic farmers is provided by the Risk Management Agency's administrative data, which reports annually on the number of organic crop insurance policies purchased (USDA RMA, 2022). The average number of organic policies per farm (for those using crop insurance), shown in Table 2, increased from 2.18 policies per farm in 2014 to 2.46 in 2021. One notable trend is the decrease in the number of whole farm revenue protection crop insurance policies purchased between 2017 and 2021.

Table 2. Crop insurance policies 2012-2021

Year	Organic policies	Policies per organic farm	Organic Specialty Crop policies	Whole Farm Revenue Protection
	Number			
2012	5,152		na	*
2013	5,716		na	*
2014	6,073	2.18	na	*
2015	6,827		1,789	1,122
2016	7,936		1,922	2,204
2017	8,442		1,984	2,722
2018	9,161		2,213	2,490
2019	9,815	2.30	2,429	2,156
2020	10,763		2,608	2.029
2021	11,078	2.46	na	1,934
2022	11,147		na	na

Notes: Policies per farm are calculated by dividing the number of organic policies in this table by the number of farms opting for crop insurance. *Whole Farm Revenue Protection was created in the 2014 Farm Act, and thus not available prior to 2015. na = data not publicly available. Blank cells similarly refer to data that are not available.
Sources: Raszap Skorbiansky et al., 2022; USDA RMA, 2022.

In 2019 and 2021, the primary reason farmers gave for not using crop insurance is they don't need it or want it (see table 3). In 2021, the next most often given reason for not using crop insurance is lack of familiarity with crop insurance, followed by the cost of insurance. Note that the price of crop insurance was considered prohibitive by a smaller share of producers in 2019 and 2021, compared to 2014.

Table 3. Organic farmer reasons for not buying crop insurance

Year	Too expensive	Farmer unfamiliar	Agent unfamiliar	Not available for crop	No organic price elections	Don't need or want	Other
	percent of farms						
2014	22	24	na	na	na	na	na
2019	11	15	1	9	1	53	10
2021	11	18	1	8	1	50	11

Note: na = not available
Source: Organic Surveys, 2014, 2019 and 2021

Recent work based on primary data shows that the more diverse the organic operation (measured by growing a higher number of farm products) the less likely a farmer is to adopt crop insurance (Belasco and Fuller, 2022). Similarly, farms with more years of experience in the organic sector are less likely to adopt crop insurance, while organic farms with higher gross sales are more likely to adopt crop insurance (Belasco and Fuller, 2022). In contrast, research using USDA's ARMS data finds that relatively more diverse organic farms are more likely to adopt crop insurance, but Belasco and Fuller argue this may result from the ARMS data, which includes farms with relatively low levels of crop diversity. The ARMS data also suggest that the higher the share of farmland that is organic, the lower the likelihood of purchasing crop insurance. Network effects may be present, as well, given that the more organic farms in a county, the higher the likelihood of buying crop insurance. Relatedly, Morris et al. (2019) find a positive relationship between peer use of crop insurance and producer interest in crop insurance.

Qualitative data suggests that organic farmers who do not buy crop insurance believe their farms are too diversified or too small to make insurance worthwhile (Belasco and Fuller, 2022). Other research, conducted by ERS, suggests that organic producers believe that crop insurance and other USDA programs benefit large scale operations, and furthermore, completing the paperwork tracking yields for each crop is prohibitive (Raszap Skorbiansky et al., 2022). The same study found that specialty crop producers prefer to manage risk through their production practices, rather than purchasing crop insurance (Raszap Skorbiansky et al., 2022).

Organic farmers who purchase insurance based on organic t-yields tend to have higher losses, when compared to organic farmers who have a long enough production history to base insurance on their actual production history (Delbridge and King, 2019). The use of t-yields may be a barrier to organic insurance adoption by beginning farmers. This is especially problematic for the organic sector since, in 2021, 54 percent of organic farmers were farming organically for less than 10 years and thus considered beginning farmers (USDA NASS, 2022).

Crop insurance payouts

The Environmental Working Group's Farm Subsidy database includes aggregated data on crop insurance. Note that organic specific insurance information is not included in the EWG database. Insurance payouts for the period 1995 - 2020 totaled $144 billion, and four crops accounted for 77 percent of these payouts: corn, soybeans, wheat and cotton (EWG, 2022). For organic crop insurance, for the years from 2012-2021, $1.4 billion of indemnity payments were made to farmers (USDA RMA, 2022). Four crops – corn, soy, wheat and rice – accounted for 53 percent of the total payments to farmers.

For the years 1995-2020, 61 percent of indemnity payments were for losses farmers realized due to drought (34 percent) and excessive moisture (27 percent) (EWG, 2022). Payments for hail damage made up 7 percent of payouts (EWG, 2022). Since 2000, payments to farmers have increased by an average 15.8 percent annually (USDA ERS, 2023). Since 2000, drought and high temperature has been a leading cause of indemnified loss, accounting for 42 percent of total indemnity payments (USDA ERS, 2023). Excess moisture was the source of 28 percent of payments for the same period (USDA ERS, 2023).

Even though the statistics above do not explicitly refer to organic farms, some conclusions can be drawn from the data. The first is that field crop producers are the most reliant on crop insurance for managing their farm level risk. According to RMA, this is also true for organic field crop operations, although their share of payouts is slightly less than for conventional producers. Secondly, and most important, drought, heat and excess moisture were the causes of 70 percent of the indemnity payouts since 2000. Changing climate conditions and the recent increase in the number of adverse weather events suggests this trend will continue.

The high taxpayer cost of farm loss from drought and excess moisture similarly suggests that it might be more cost effective to take a different approach to risk management. The Intergovernmental Panel on Climate Change (IPCC) recommends, with high confidence, that resilience to climate change would be increased by using ecosystem based agricultural methods (IPCC, 2022). Thus, organic farming systems are likely to be an important component of managing farm risks related to adverse weather. Supporting organic farming systems may provide important risk mitigation benefits.

Methods used for primary data collection

Analysis of two sources of data form the next section of this document. One source is the set of public comments for the Spring 2023 CACS NOSB Discussion document. Commenters were asked to provide feedback on six questions:

1. What has been your experience (or your members' experience) with crop insurance?
2. What do you see as the most significant obstacle to organic farmer adoption of crop insurance?
3. What benefit do organic producers receive from crop insurance (on other words, what is working for them?)
4. What problems have farmers experienced with their crop insurance policies?
5. What recommendations would you make to improve the functioning of crop insurance for organic producers?
6. In your view, are there other, perhaps better, mechanisms for organic farmer risk mitigation?

For the second source, a research team from NYU (Duncan Orlander, Julia Balsam, and SJ Whelan, under the leadership of Professor and NOSB member Carolyn Dimitri) conducted interviews with organic farmers between January and March 2023. This included 13 interviews with farmers of diversified operations, 2 organic fruit farmers, and 7 organic grain farmers. The team also interviewed 11 representatives of organic organizations, which included technical assistance providers and organic policy experts from different organic organizations. These interviews were conducted as part of a research project examining how well farm policy works for organic farmers, which includes but is not limited to crop insurance.

In the results that follow, ideas, thoughts, and quotes arising from the interviews are referred to as "grain farmer" or "technical assistance provider." Those obtained from the public comments are referred to as "public comment" or are not identified (in other words, if the text does not identify the concept as coming from an interview, it is summarized from the public comments.)

The following sections provide an initial analysis of the qualitative data.

Perceptions of crop insurance for organic producers

While it is true that some producers have terrific experiences with crop insurance, there is a general widespread frustration regarding access to crop insurance. Speaking generally, the interviews and public comments indicate that many organic farmers feel that crop insurance does not work for their operations. One frequent complaint, expressed both through the public comment and interviews, is that the paperwork for crop insurance is onerous, followed by a sense that the payouts for losses incurred by organic crops are unreasonably low.

The farmers who have the best experience with crop insurance tend to grow organic commodity crops, such as soy or corn. That said, according to the public comments, some row crop producers using crop insurance feel that they are taking a gamble when they buy crop insurance. Producers with diversified operations or small-scale farms are either unable to use crop insurance or believe that the crop insurance programs do not work for them. An organic nonprofit reflects this viewpoint in the public comment that their members have a "Range of experiences with insurance …. from pretty good to very difficult."

New or beginning farmers struggle with many of the requirements for crop insurance. It is not unusual that farmers in transition to organic production, who are still learning how to farm organically, do not receive adequate payouts in time of loss, the result of either misinformation from crop insurance agents or general complexity of the program. Farmers contemplating transitioning their operations to organic may be unwilling to do so because of the lack of adequate risk management programs, which are equivalent or comparable to those they currently use on their non-organic operations.

Organic producers have mixed views about crop insurance and USDA programs in general. According to one public comment, organic farmers "agree that a farm safety net is important. Possessing crop insurance, regardless of how well it actually functions, has the beneficial side effect of allowing farmers to receive bank loans." There is a (relatively small) group of producers who have figured out how to make crop insurance work for their operations. Some farmers are not interested in USDA programs or crop insurance. A technical assistance provider suggested that cultural differences means that some farmers take "…pride in the organic movement, of being self-sufficient, and taking care of … own needs. Not anti-government per se, but wanting to work without government support." Others, particularly those using Whole Farm Revenue Protection, gave up insurance because of the high paperwork burden and low payouts. But some farmers who believe that crop insurance is not available or suitable for their diversified operations would like to purchase crop insurance, but only if it worked for their operation. Working means it would be easy to use, requiring less time and paperwork, with farmers 'actually receiving' money when a loss is experienced, as a farmer expressed in an interview.

Operators of diversified farms provided examples of how crop insurance failed them. One diversified operator told us his farm experienced "… a terrible freeze and it wiped out all the radishes. …but I thought I have insurance, this is great. The adjuster came to my farm and then I heard nothing. I kept reaching out and got no response." The farmer eventually received $140 and was very upset because he lost about $7,000. Another diversified producer indicated that he put in a claim because of a drought. Someone came out to the farm to inspect the crop, and saw evidence of pests and disease on crops, disqualifying him from payment. The farmer mentioned that he stopped caring for the crop because of the drought. Another diversified farmer put in a claim and retrospectively reported that "the process was hell." The process was stressful, the paperwork was endless, and there was no payout: an inspector could not figure out how much the crop was worth.

An organic policy analyst stated that, "In general some folks in organics feel like USDA - points back to rightsizing programs for organics - is not as responsive to organics as for conventional." The Executive Director of a nonprofit said, "organic producers tend to be outside of the USDA system" and many feel like "second class citizens." Feeling excluded from USDA farm programs, or not being understood by USDA, may lead some producers to give up on federal programs such as crop insurance. But others acknowledged the challenges as stemming from a resource allocation issue. As one organic advocate pointed out, organic is such a small share of total USDA expenditures and so has a small voice, while an organic extension agent mentioned that "lawmakers …. want programs to fit the masses" and that the number of organic farmers is miniscule.

The wide range of perspectives suggests that improving crop insurance for organic producers may result in more producers opting to use crop insurance to manage their risks. That said, it seems that tweaks around the edges of the crop insurance program won't be sufficient to make insurance compatible with organic farming systems.

Data needs on multiple scales

The public comments reflected a theme of needing more data. Three specific needs were mentioned: macro level data covering the organic market and farm sector; improved data on organic farmgate prices; and yield data. The overarching goal of improved data is to improve the underlying information on the organic farm sector so that the Risk Management Agency is better able to assess and establish fair actuarial rates and standards.

A public commenter stated a need for "Trusted and timely data … to support the development of insurance products and risk management solutions that reflect the unique needs and market conditions of organic farmers." This commenter pointed out the need to recognize the farming systems used by organic producers, along with the wide range of market channels used by organic farmers. Local and regional market channels are important to organic farmers, and in 2021, 54 percent of organic producers sold directly to consumers (including community supported agriculture), through intermediated market channels, and sold value added products (USDA NASS, 2022).

Macro level needs

The availability of data describing the organic sector, through the Organic Census or Organic Survey, provides useful information on farm level growth. The data make it possible to understand how the patterns of farm production – including crops grown and approximate yields – evolve over time. Data collected by NASS and ERS through the Agricultural and Management Resource Survey (ARMS) are especially important for understanding the financial position of organic farms, efficiency measures, farm program participation, and other aspects of the farm operation such as the extent of off-farm work. This level of detail is critical to understanding how well organic farms are coping with stress, which are likely to increase because of climate change. We encourage ERS and NASS to return to oversampling organic producers in the Phase 3 studies, to ensure that the data on organic farms is representative, and so that researchers can effectively study cost of production, farm productivity, and other important economic aspects of the organic farm.

Farm level prices

The Title 1 farm programs (Price Loss Coverage, Agricultural Risk Coverage, Nonrecourse Marketing Assistance Loan, and Noninsured Crop Disaster Assistance Program) depend on market prices (USDA ERS, 2019). The Dairy Margin Coverage Program payments are based on the difference between milk prices and input (feed costs) (USDA ERS, 2019).

Crop insurance, a Title IX program, is based on RMA's projected prices, which is also referred to as the insured price. The extension literature includes guidance on how insurance prices are set; examples include wheat in the Pacific Northwest (Fortenbery, undated) and livestock in Iowa (Christensen, 2023). RMA's method for calculating the insured prices for the organic products is less clear. Two obvious obstacles to estimating the insured price are (1) the thinness of the organic market and (2) differences in production patterns between the organic sector and the rest of agriculture.

One grain farmer thought RMA did a pretty good job forecasting the fall corn and soybean prices. But an organic extension agent stated that organic prices for crop insurance, and the payouts, do not reflect the market. For example, cotton in winter 2023 was over $3 a pound but the insured price was well below that, at about $1.50. Another technical assistance provider reported that organic corn is always underinsured, since the insured price is based on a formula that has little to do with the actual market prices.

In addition, USDA's reporting on organic feed prices and other commodities lags far behind the price reporting for the farm sector, as one public comment indicated.

There are many potential benefits from improved knowledge of organic prices. First, the farm bill programs which help farmers manage their risk, including crop insurance, could be improved for organic producers if organic farm level prices were readily available and used for the insurance policies. Benefits extend beyond the application of prices to farm programs.

Organic buyers of livestock and livestock products would be better positioned to adjust prices they pay farmers if they have knowledge of organic feed prices in different regions of the country. All organic farmers would have easier access to knowledge of overall trends in prices of the organic products they sell, which would help them receive prices that are fair. This type of price transparency may even help to identify fraud, such as when an organic product is selling for a low price.

Insured prices for direct marketers

Farmers selling into direct markets receive the retail price, which exceeds the price farmers receive when they sell to a handler (the farm price). Crop insurance does not reflect the direct market or retail price when the insurance price is set; thus, the insurance price is always too low (from the perspective of the direct marketer) and may not provide sufficient coverage. One public commenter indicated that the amount of coverage direct marketers receive may be just 25 percent of the total loss.

Direct markets are important for some organic producers, and furthermore, are an essential entryway for beginning farmers. Many beginning farmers opt to use direct markets rather than intermediated or wholesale markets, as they start out, and the current system means that beginning organic farmers purchasing crop insured would be underinsured. Adjusting the insurance price for direct marketing producers (organic and others) would strengthen the ability of crop insurance to mitigate risk, and potentially reduce a barrier to the organic transition faced by beginning farmers.

Yield data

The yield data used for crop insurance is problematic. From the broadest perspective, because certified organic farming systems have a relatively short history – at least in terms of what we currently know as organic – the understanding of organic's *potential* production is limited. As one commenter stated, "Agronomic research is still catching up to what best practices and best yields can be for organic." Delate et al. (2016) examine six long term cropping systems, which point to an improvement in yields as farmers develop experience with weed control and organic farming methods. Anecdotal evidence, including the experience of some organic farmers on the NOSB, indicates that many US organic farms have yields equivalent to their counterparts. In contrast, Carlson et al. (2023) find, based on analysis of the ARMS economic survey of farms, lower yields on organic farms. The closure of the yield gap on organic farms that the long-term cropping systems trials and some farmers have accomplished has not yet been met on the average organic farm, suggesting that there is a large potential payoff from additional research into best practices and the development of organic system specific seed varieties.

The public comments point to several other shortcomings to the current use of yields for crop insurance.

First, experienced farmers who are transitioning to organic production systems and beginning farmers are treated the same way. Forcing transitioning farmers to completely rebuild their actual production history gives those in transition no credit for their prior farming experience. It seems reasonable to assume a good farmer will transition to a good organic farmer, yet RMA does not explicitly recognize the skill transfer. The erasure of prior farming history may be a disincentive for undertaking the transition to organic. A public commenter stated, “This offers poor risk protection to transitioning farmers at time when they are learning a new production system.”

Because organic farmers rotate their crops, getting a production history for four to ten years on the same piece of land would take a very long time. An incentive created by the production history requirement is for farmers to adopt crop rotations that lack diversity, which is likely to constraint improvements to soil health. Furthermore, crop rotation is one of the essential aspects of an organic farm. Risk-sharing programs should not interfere with the very heart of the organic farming system by reducing incentives for on farm diversity.

A grain farmer said that to build robust crop rotations, a farm needs lots of different crops. But since RMA has no actuarial experience with many crops, the farmer must go through written agreements which is time consuming.

The t-yield is used during the transition period before a production history is established for a crop on an organic farm. It is quite clear from the public comments: the t-yield is not liked by anyone. The t-yield is meant to be an estimate of the county average for yields and is assigned to producers without four or more years of production history. One commenter stated “OEFFA farmers are unclear on the source of these numbers and find them to be lacking in logic.”. Another commenter reflected that “T-yields… are confusing in origin and cannot easily be questioned.”

A crop insurance agent, during the oral comment, mentioned that the t-yield for a conventional irrigated corn producer was 223 while an organic farmer has a t-yield that is 67 bushels lower, at 156, which translates to a $400 per acre difference using this year’s prices. Research suggests that good conventional farmers become good organic farmers, and that the t-yields RMA uses may be too low for an average yielding conventional farmer who is transitioning to organic (Delbridge and King, 2014).

Insights into Whole Farm Revenue Program (WFRP)

It is widely accepted that the whole farm revenue program (WFRP) has a lot of promise, but its current form and the lack of agent knowledge about the program means that farmers find the product unhelpful. This belief appears to be supported by the general decline in WFRP enrollment, as shown in Table 2.

WFRP has many challenges, which include being complicated and confusing. Organic producers are reliant on having a good agent who can run the numbers for different scenarios, to identify the best options for producers. A technical assistance provider stated that paperwork is more difficult for the agent, when compared to a single crop policy. The same technical assistance provider expounded that once a producer buys an insurance policy for corn, for example, renewing the policy is automatic and easy. The WFRP is more work because it is a different system and uses different forms. Thus, many agents do not want to bother with it. The technical assistance provider continued the "....farm can provide historical revenue, and RMA will support up to 85 percent and it should not matter what is grown."

There is confusion about whether subsidies are available for WFRP, confirming that the insurance product is complex and confusing. One fruit farmer mentioned that the lack of subsidies for WFRP seems biased against organic farmers and suggested that the logical first step would be to take "..any given year, calculate percentage of subsidy that conventional farms receive, and apply that discount to premiums that specialty crop pays for WFRP…" A technical assistance provider mentioned that there are subsidies under WFRP, which are "just as good and sometimes better than other policies." The technical assistance provider went on to say that after having done many scenarios with WFP, about 64 percent of the insurance cost is subsidized.

A grain farmer stated that WFRP works better for farms that have achieved their ideal size, but for farms that are expanding there is no production history on the new acres which means the new acres revert to county averages (even when the farmer has other acres with a higher production history). Another grain farmer remarked "If WFRP worked correctly and was easy to use – there should be no need for another insurance." In contrast, a diversified producer stated that the paperwork for whole farm insurance is too cumbersome for use by diversified operations.

A technical assistance provider suggested that every county around the country should have the same policy and that the insurance policies should let farmers decide what to grow. The premium should decrease as the number of crops grown increases, which would provide incentives for increased diversity.

Access to crop insurance agents with knowledge of organic systems

The availability of organic crop insurance and the ability to find the optimal policy to support an organic farm has long been a problem faced by organic farmers. Whether an organic producer is satisfied with their crop insurance is highly dependent on the effectiveness of their agent. A common theme in the public comments is "...need for better education of agents on organic systems," although many of the farmers interviewed mentioned having stellar agents that helped them find the right insurance product.

One public commenter mentioned that, in some regions, finding an agent who "would consider organic" is still a problem. Many agents do not understand organic systems, and furthermore do not understand how existing crop insurance programs work for organic farmers. Another public comment called for "....organic literacy within RMA….to better serve organic clients."

Finally, another stated that the need for "...more education of insurance agents on the body of agronomic evidence on organic practices is necessary to convince insurance that organic best practices and innovation is insurable."

Agent knowledge of whole farm insurance varies, which limits the effectiveness of the WFRP. Organic producers who are interested in using the whole farm insurance need an agent that understands the program and can run different scenarios to guide the farmer. As one public commenter stated ".....it is imperative to find a good agent familiar with whole farm since the paperwork and payouts can vary depending on how the numbers are entered and compiled."

Good farming practices definitions

The definition of a good farming practice for crop insurance can still be challenging for organic farmers. One public commenter mentioned that some growers need to help their crop insurance agent understand organic practices as well as explain why organic good practices differ. Specific examples of difficulties reported by farmers include "...difficulty getting coverage for fallow fields, companion planting, no-till (roller crimper) and wider rows for weed suppression."

There is no consistency across federal agencies about good practices and best management practices. For example, there is no agreement between RMA's "good farming practice" and NRCS's "best management practice." One commenter stated that RMA should recognize that "....any practice approved in a farmer's Organic System Plan by a USDA-accredited ….. be recognized and approved as a "Good Farming Practice" as defined by the RMA."

One commenter pointed to tension between the approaches used by RMA and NRCS; while RMA uses historical data from conventional farms over the last 30 years NRCS is looking forward and thinking through what is best for soil health. These differences reflect the divergent purposes of the two federal agencies: RMA is concerned with insurance and risk mitigation, and NRCS is interested in soil and natural resource conservation. Innovative thinking about farming systems from a holistic or broad perspective may be able to reduce the burden on organic farmers caused by the different agendas of the two agencies.

Deadlines and dates do not work for organic producers

The dates set by RMA for crop insurance, which work quite well for nonorganic farms, do not work with organic farming systems. Date specific problems mentioned in the public comments are listed:

1. The crop reporting deadlines (July 15) are difficult to fit within the organic certification process for the crop season. Some organic farmers have had difficulty in obtaining crop insurance when incorporating cover crops in the late spring and inter seeding cover crops into their crops during the growing season.

2. Some crop insurance deadlines come before a grower has had a chance to analyze all the numbers from a previous year. This means a farmer may lock themselves into a policy that runs counter to their needs in the subsequent year. Making last minute changes can be very difficult, if not impossible, and the farmer may be penalized for making a change that would otherwise make economic sense.
3. A policy analyst mentioned that crop insurance premiums are due in August, which does not always work for organic producers.
4. Crop insurance system deadlines do not dovetail well with organic certification deadlines. The systems seem to have no knowledge of one another. This is burdensome for organic producers who are often caught between the two sets of planning, paperwork, and requirements.
5. Planting date requirements are another example of an element of crop insurance that is not designed with organic systems in mind. Cultural practices such as cover cropping which are both typical and necessary in organic systems require time. Additional considerations include waiting for optimal field conditions for planting and coordinating with neighbors utilizing GE seeds. In addition, organic farmer use of untreated, non-GMO seeds which will rot in cold conditions, means organic producers habitually plant later. Crop insurance penalizes late planting by dropping the guarantee by one percentage point each day until planting occurs, even though the previous year's yields were often also planted at that time, because later planting benefits organic farmers' and fits with their systems of management. This means organic producers are penalized coming and going, which is both unfair and unwise in terms of risk management.

A grain farmer said that the final planting date is a huge problem. In his area, the final planting date for corn is too early (June 5). He routinely plants later because of his cover crops, which research suggests should be left on the fields for a longer time. Incorporating the cover crop, while avoiding being out on wet fields, is not easy to do. Another grain farmer spoke about the conflict between the date your cover crop is supposed to be terminated by and leaving the cover crop long enough to fix nitrogen in the soil. These dates are determined based on data from conventional rather than organic farms, and the dates don't work for organic farms.

The planting dates vary by region and appear to work for some, but not all, regions. A public commenter suggested that RMA establish a unique final planting date for certified organic crops in each region *with a non-penalizing grace period* so that organic producers can maintain both productivity and organic status.

Small grains, fruit, and crop insurance

Another way that organic crop insurance does not work well is related to the types of crops that can be covered. Several public commenters mentioned that insurance covers main crops but not small grains. These small grains, or minor crops, are important for organic rotations. Some farmers have petitioned for coverage for the small grains. As one grain farmer stated, "The crops that are most important to the rotation are the least insurable." A technical assistance provider recognized this problem, mentioning that farmers grow cover crops to improve the soil, but they are not cash crops.

A fruit farmer mentioned that only peaches and apples are insurable, and the remainder of the fruit crops rely on the FSA programs for non-insurable crops. A technical assistance provider acknowledged there is a challenge with insuring specialty crops, and that it is far easier to get coverage for commodity crops.

Special needs of dairy producers and pasture, range and forage land

Several comments pointed to the needs of dairy producers. Rather than being able to rely on RMA risk management programs, dairy producers use Dairy Margin Coverage. The Pasture, Rangeland, Forage Pilot Project could be better utilized by organic farmers. This program provides insurance against drought, and calculates forage losses resulting from lack of precipitation. A commenter suggests that USDA can better promote this program, increase accessibility and awareness, and create improved incentives for enrollment.

Other considerations

Operators of diversified farms self-insure through the diversification of their operations. Furthermore, a technical assistance provider stated that farmers in the northeast learned to mitigate risk in other ways. These farmers felt that crop insurance never helped them, and so they are biased against it and don't look at the program.

A pattern related to crop insurance adoption was observed by an organic researcher: growers of crops like dry beans and corn are more likely to have loans and are required to have insurance. Similarly crops that are concentrated in a geographic area, such as organic apples, are more likely to purchase insurance while growers of crops that are more dispersed geographically are less likely to participate in crop insurance.

One diversified operator mentioned a desire to be able to insure against a weather event in general, including events that corn and soy people wouldn't have to worry about.

Concluding thoughts

This document presents evidence on the organic farmer experience with crop insurance. The CACS committee (and the entire board) appreciate the extensive input provide through written and oral public comment. Similarly, the research team from NYU thanks those who spoke with us in Winter 2023.

The analysis of the comments and interviews identifies the key problem areas with crop insurance by type of farmer. In the next phase, we aim to identify solutions or improvements that will address the problems with the program.

Questions for Fall 2023 meeting

1. Does this document accurately reflect the challenges organic farmers face, regarding crop insurance?
2. Is this document missing any important problems or factors or topics?
3. For each problem identified (or for some of the problems), please offer a solution that will improve crop insurance for organic producers.

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Subcommittee Vote
Motion to accept the discussion document on Climate Induced Farming Risk and Crop Insurance
Motion by Carolyn Dimitri
Seconded by Amy Bruch
Yes: 6 No: 0 Abstain: 0 Recusal: 0 Absent: 3

National Organic Standards Board
Certification, Accreditation, Compliance Subcommittee (CACS)
Oversight to Deter Fraud: Residue Testing in a Global Supply Chain
Discussion Document
August 8, 2023

Background:
Residue testing is an essential tool for ensuring compliance with organic regulations. Preharvest residue testing can support evaluating an organic producer's efforts to prevent contamination, provide objective data when prohibited substance use is suspected, and monitor unavoidable residual environmental contamination levels. Postharvest residue testing can support the evaluation of contamination prevention in postharvest handling activities and across supply chains and provide objective data when prohibited substance use or when commingling or substituting conventional products is suspected. 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 Organic Foods Production Act (OFPA) and USDA organic regulations include apparent authority and guidelines for accredited certification agencies (ACAs) to collect residue samples and to respond to results from those samples. These regulations are outlined at 7 CFR 205.670 and 7 CFR 205.671, and they are further clarified by NOP Handbook documents NOP 2610, NOP 2611, NOP 2611-1, NOP 2613, and NOP 2613-1.

On January 1, 2013, USDA finalized the Organic Periodic Residue Testing rule, which clarified that ACAs must conduct residue testing on a minimum of 5% of their certified clients and clarified that tests might include collection and testing of soil, water, waste, seeds, plant tissue, and plant-animal and processed products samples. Since the finalization of this rule, ACAs have effectively utilized residue sampling to bolster compliance with organic regulations, deter fraud, and prevent contaminated organic products from entering the marketplace.

In the past ten years, the U.S. organic industry retail sales has more than doubled from $28B in 2012 to over $60B in 2022. Organic products are being shipped from across the globe through increasingly complex supply chains, and the organic certification structure is undergoing dramatic changes through the finalization of the Strengthening Organic Enforcement (SOE) rule in response to this growth in scale and complexity.

Discussion Document Goals
The CACS is considering whether updates to periodic residue testing programs will augment ACA's ability to verify compliance, deter fraud, and prevent contaminated products from entering the organic marketplace. The goal of this discussion document is to:

1. Gather stakeholder feedback on a proposed framework to evaluate the risk that prohibited substances, which are not typical targets for residue testing, pose to organic integrity.
2. Identify accepted testing and sampling methodologies to detect and quantify these prohibited substances.
3. Recommend necessary updates to guidance or regulation that may be necessary to ensure that ACAs have the authority and sufficient guidance to respond to positive results they may find.

Challenge

The National Organic Program (NOP) is in the Strengthening of Organic Enforcement Rule (SOE) implementation process. This incredible accomplishment will propel the industry to increase oversite as a global industry. The SOE will provide the supply chain transparency that is needed in a growing organic global economy, which will solidify the foundation upon which the organic market is built

CACS is considering whether verification of a global supply chain through testing is the next chapter in continuous improvement that needs to be embraced as an encore to the SOE. Of particular interest to the CACS, is the new requirement in SOE for operations importing products to the United States to ensure their shipments have not had contact with prohibited substances or exposure to ionizing radiation and to have a documented organic control system to conduct this verification. Since the current landscape of residue testing only partially covers the concerns related to imported products, CACS believes building out this area will be beneficial for importers and for certifiers verifying compliance to the new regulations. Testing can complement the organic program post-SOE and assist certifiers in validating compliance while providing the ability to rapidly detect evidence of commingling/contamination in operations deemed to be high risk. The NOP has well-established parameters for GMO testing and residue testing of pesticides. To continue to assist certifiers and inspectors, clear testing levels and parameters are needed for solvents, fumigants, and other prohibited substances that may pose a risk to organic product integrity. As a starting place, CACS is working to develop a framework by which substances are evaluated for testing protocols and seeks to apply this framework initially by looking at synthetic solvents used for oilseed extraction and volatile fumigants used on bulk shipments at ports of entry.

Proposed Framework

CACS is proposing to evaluate potential updates to the periodic residue sampling framework on a substance or class of substances basis. Each substance or class of substances would be evaluated based on what organic regulation testing can support, whether other federal regulations govern the use of the substances, whether there are accepted testing methodologies that provide reliable and quantifiable results, whether there is clarity around how ACAs might respond to a positive result, and what additional research, guidance, or rulemaking may be needed to close any gaps identified in the evaluation.

CACS proposes the following evaluation of testing for synthetic solvents used in the extraction of oils as an illustration of this draft framework:

Synthetic Solvents (e.g., hexane or methanol)

1. **Compliance Verification:** *How would testing for these substances support compliance verification of the organic standards?*

Synthetic solvents are used to extract oil from seed meals in conventional markets, which are typically used as livestock feed. No synthetic solvents are allowed for use at 7 CFR 205.605 to extract oils from seed meals in organic processing, and such substances would be prohibited. Synthetic solvents are also often used to extract flavors and other herb and spice extracts, a process prohibited in organic processing. Testing for these residues in organic supply chains would help to support compliance verification in 7 CFR 205.105 (Use of prohibited substances), 7 CFR 205.272 (comingling/contamination prevention), and 7 CFR 205.273 (Imports to the United States).

2. **Oversight:** *What additional federal oversight exists over the use and residues of this substance?*

FDA regulates the use of hexane to extract spice oleoresins and hop extracts 21 CFR 173.270 with residue limits. American Association of Feed Control Officers (AAFCO) includes a definition for "solvent extracted" when used on feed labels.

3. **Testing:** *Can reliable, quantifiable, and widely accepted testing methodologies provide certifiers with objective test results to support compliance verification?*

Synthetic solvent residues can be detected in food and feed using methods accepted by ISO-accredited labs. Levels can be quantified. American Oil Chemists Society (AOCS) maintains extensive testing methodologies to detect and quantify synthetic solvent residues in agricultural products.

4. **Responding to Positive Results:** *Are there clear guidelines and regulatory authorities to exclude organic products from the organic supply chain contaminated with this substance?*

Current regulations allow ACAs to collect samples and test for any prohibited substances encompassing synthetic substances. There are only published residue limits for hexane in spice resins and hop extracts. Test results quantifying synthetic solvents in organic products can be used as evidence that the product was contaminated or exposed to prohibited substances and could be used as evidence that conventional product was fraudulently represented as organic. However, the current regulations need clear language regarding thresholds of synthetic solvents in organic products and when these products must be excluded from the organic marketplace.

Summary:

CACS supports continuous improvement in oversight and enforcement to build on the foundation of the SOE. Testing is an important tool that can assist in compliance verification for organic regulations. Ensuring the framework is developed so that there is consistent enforcement by certifiers. CACS looks forward to stakeholder comments and engagement on this discussion document.

Questions for Stakeholders

1. Certifiers: Describe your experience with prohibited residue testing in extended supply chains and describe challenges that you have encountered
2. Certifiers: How do you evaluate the risk of your certified clients, and how do you determine which operations to target for periodic residue sampling?
3. Inspectors: Describe challenges with residue sampling on farms and handling facilities when sampling imported, processed, or aggregated products.
4. Testing Labs: What tests are available for synthetic solvents and fumigants, and what issues do you encounter when conducting residue tests submitted by organic certifiers, organic inspectors, and other organic stakeholders?
5. Substances for NOSB focus: NOSB intends to evaluate testing options for organic solvents and fumigants. Are there additional substances NOSB should evaluate that are not currently encompassed by periodic residue sampling guidance and practices?
6. Comments on proposed evaluation framework: Do stakeholders have recommendations for refining the proposed framework within which we will evaluate prohibited substance residue testing?
7. What else should the NOSB consider to strengthen periodic residue sampling as an organic compliance verification tool?

Subcommittee Vote:

Motion to accept the discussion document on Residue Testing in a Global Supply Chain
Motion by: Nate Lewis
Seconded by: Nate Powell-Palm
Yes: 7 No: 0   Abstain: 0   Recuse: 0 Absent: 2

National Organic Standards Board
Certification, Accreditation, Compliance Subcommittee (CACS)
Improving Support for Organic Transition
Discussion Document
July 11, 2023

Summary

The CACS has created a work agenda item on improving support for transitioning producers and optimizing use of resources for transition to Organic. More programs to support organic transition are becoming available, and the NOP and NOSB have a shared interest in ensuring that these resources are used effectively and efficiently to expand organic production and markets in the long-term. In addition, there is a need for deeper understanding of how improvements in diversity, equity, and inclusion in the organic sector could expand the relevance of organic – to producers and consumers alike. The purpose of this discussion document is to gather feedback from inside and outside the organic community on effective tools, resources, and alignment strategies to support organic transition and requirements for participation in programs that support organic transition. The NOSB will make recommendations to the NOP based on this gathered feedback.

Background

Organic agriculture offers significant climate, health, and economic benefits, for producers and consumers. Organic market growth has been strong for decades, with domestic organic food sales surpassing $60 billion in 2022. But still less than 1% of U.S. agricultural land is managed organically and the U.S. remains a net importer of organic products.

Numerous barriers may deter producers from pursuing organic certification, including – but certainly not limited to: certification costs, challenges with the process, and proximity to certification services and inspection capacity; limited access to land and capital; insufficient regionally-relevant technical assistance for organic management systems; lack of regional market opportunities or necessary organic supply chain infrastructure; agricultural training that does not present organic as an option; and inadequate access to organic mentorship and peer networks.

Producers who may be interested in transitioning to organic come from diverse backgrounds and career paths – from farmworkers seeking to become organic farm owners to seasoned producers considering a different approach to farming. This diversity means that the most successful approaches to overcoming barriers may vary significantly. In addition, many beginning producers and producers of color face heightened challenges related to language, cultural competency, and discrimination that must be addressed. Increasing diversity among organic producers and handlers could contribute to a stronger sense of inclusion and opportunities in organic.

In 2022, the U.S. Department of Agriculture announced an unprecedented $300 million Organic Transition Initiative (OTI), with three main elements designed to address many of these barriers: funding to build a transition support network, with organic certifiers in the lead; an organic practice standard for conservation programs and a crop insurance discount; and market development grants. Each of these elements is currently in process.

While formal public comment processes for OTI have been limited, the NOSB is well-positioned to gather input on stakeholder experiences with organic transition programs generally, and OTI specifically, and make recommendations to USDA to maximize the benefits of public investments in organic transition. In addition, the NOSB seeks to advise USDA on how OTI and other programs can help ensure that organic is relevant to a more diverse population – as an environmental stewardship strategy, a career path, and a source of sustenance.

To these ends, the NOSB seeks input on the following organic transition questions:

- Have you been involved in the USDA Organic Transition Initiative? Describe your experience to date. What is working well? What could be improved? What barriers to organic transition need more attention?
- Have you recently transitioned to organic, or do you help operations transition to organic? What are the most significant remaining barriers to organic transition? What works well to reduce those barriers? What have you tried that didn't work? How do support organizations find farms or ranches interested in transitioning? How do organizations advance racial equity in outreach?
- What impacts do choices and availability of organic-compliant inputs and ingredients have on organic transition? Are there particular materials or ingredients that have an outsized impact on operations' decisions to go organic?
- How do transitioning producers plan for the first few years after achieving certification? How does support for organic transition also support retention?
- What could be done to foster a more diverse, equitable, and inclusive organic sector?

Motion to accept the discussion document on Improving Support for Organic Transition
Motion by: Allison Johnson
Seconded by: Kim Huseman
Yes: 6 No: 0 Abstain: 0 Recuse: 0 Absent: 3

National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal
Potassium Sorbate as an active ingredient for plant disease and insect control/suppression
August 1, 2023

Summary of Petition:

Potassium sorbate, referred to as KS throughout the 2023 technical report (TR), is being petitioned for use as an active ingredient for plant disease and insect control/suppression in field and greenhouse applications. The petition states that potassium sorbate will be an effective tool in a crop disease-resistance program with its contact mode of action and that it is not suspected to contribute to the phytotoxicity of crops.

The petition identifies the substance as 100% food-grade KS with no ancillary substances. The proposed end-use fungicide/insecticide contains 45% KS, with the remaining 55% comprised of the inert ingredients' urea and citric acid, both appearing on the 2004 EPA List 4A: Inerts of Minimal Concern. With KS as an active ingredient, the end-use product would be used to target crop disease and insects such as powdery mildew, downy mildew, and whiteflies, on many crops, including grapes, cucurbits, roses, stone fruit, pome fruit, nuts, solanaceae vegetables, and cannabaceae plants.

Summary of Review:
KS is petitioned for addition to the National List at 7 CFR 205.601(e) for use as an insecticide and at 7 CFR 205.601(i) for use as a plant disease control. KS currently is on FIFRA's (Federal Insecticide, Fungicide Rodenticide Act) list 25(b), which is for active and inert ingredients (of chemicals) that are considered a minimum risk, and therefore, do not require an EPA registration number and are exempt from EPA regulations on efficacy and toxicity. KS is generally recognized as safe (GRAS) by the Food and Drug Administration (FDA).

KS has been petitioned unsuccessfully three times for inclusion on the National List. KS is not internationally approved for the petitioned use.

1. 1995, seed treatment, production aid 7 USC 6517(c)(1)(B)(1)
    a. Petitioned (sorbic acids and its salts) for use in food processing
    b. Conclusion: sorbic acid was synthetic and not compatible with organic processing or handling

2. 2002 Crops, 205.601:
    a. Petitioned for use in seed film coating as a preservative.
        i. Potassium sorbate is a weak acid antimicrobial known to cause resistance and is used in the food industry.
        ii. Conclusion: potassium sorbate was not allowed as a synthetic substance for use as a preservative, as more information was needed for justification.

3. 2002 Livestock, 205.603:
    a. Petitioned for use in organic livestock production as a mold inhibitor (preservation in aloe vera - aloe vera can be used as an alternative for antibiotics when treating livestock)

i. Conclusion: Additional information on the ingredients in the manufacturing of potassium sorbate is questioned.

KS used as an active ingredient would function in a contact mode of action form. Many alternative products and cultural practices exist. The petition states that the degradation products (sorbic acid and potassium hydroxide) are more hazardous than the product itself.

In food additives, sorbic acid interacts negatively with nitrite and is known to create direct-acting mutagens and genotoxic agents. The extent of these interactions in field conditions is unknown. The TR indicates that limited information on KS, as petitioned, exists. Thus, there needs to be more available information regarding the potential interactions of KS with other crop production inputs. (TR 579-583).

In addition, the TR indicates that there was little to no information on KS as petitioned to understand its chemical interactions or its use in conventional crop pesticide application (TR 579-581), how KS interacts with soil organisms, the use of KS as a foliar spray on growing crops (TR 758-759), and persistence of KS in the environment or its by-products (TR 468-470), thus in many cases the TR leverages information that was available regarding KS as a post-harvest treatment and/or as a conventional food additive (TR 74, 470-472, 857-862).

Note: *The board is reviewing the substance potassium sorbate; however, the formulation of the finished product provided in the petition elicited concerns from stakeholders. If the petitioned substance is approved and added to the national list, then a material review organization will need to further review the complete composition of formulated products as this is outside of the Board's jurisdiction. Comments centered around the inerts in the finished product; urea and citric acid. Both of these substances have pesticidal actions, and urea is a synthetic substance not on the National List for use as an active ingredient. The evaluation of urea as an active ingredient is outside the scope of this review. Citric acid is a nonsynthetic substance so it would be allowed as an active (not the same level of concern as urea which is synthetic).*

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.

Potassium sorbate is not explicitly listed anywhere in the Organic Foods Production Act of 1990 (OFPA) nor the USDA organic regulations at 7 CFR 205. It is implicitly on the National List as an inert ingredient of minimal concern on the National List at 205.601(m)(1) and 205.603(e)(1).

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?

The petitioner is requesting that potassium sorbate be used as an active ingredient for plant disease and insect control/suppression under the following conditions:

1. § 205.601(e): Synthetic substances allowed for use in organic crop production – as insecticides
2. § 205.601(i): Synthetic substances allowed for use in organic crop production – as plant disease control

Note: The TR states that KS is one of the most common food preservatives; In contrast, most food preservation with KS occurs as part of food processing; it is the application during crop production and post-harvest handling of raw agricultural commodities that are considered within the scope of the current petition. Post-harvest use would have to be annotated explicitly for any KS listed at 205.601 according to the National Organic Program (NOP) Guidance 5023. (TR 99-103)

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)]**

Potassium sorbate, due to its antimicrobial properties, has been historically used in the food processing industry as a preservative and is used in a wide range of food products, including meats, cheeses, baked goods, fresh and fermented vegetables, dried fruit, fish, processed food, and carbonated beverages. There is little historical use of KS in organic agricultural production.

The TR notes that before receiving the 25(b) exemption, potassium sorbate was used as an active ingredient in several EPA-registered pesticides. The last of these registrations was canceled in 1989. KS is also on the 2004 EPA List 4A – Minimal risk inert ingredients. Thus, it is currently permitted as an inert ingredient in combination with permitted active ingredients in pesticide formulations used in organic crop production according to 205.601 (m) (1) (TR 206-213).

Two notable points were brought up in the TR relating to KS (and/or sorbic acid used to make KS):

1. Processed food products with sorbate and nitrite preservatives may form mutagens and genotoxic agents under certain conditions.
    a. In vitro studies on bone marrow chromosomes of mice showed that the combination of sorbic acid and nitrite creates a synergistic effect, severely affecting the spindle apparatus and chromosomal structure.
    b. Research on how these two substances would interact with humans and the field environment is unavailable.
2. Ames test and rec-assay mutagenicity found DNA-damaging activity when combined with KS, ascorbic acid, and iron salts. (TR 585-597).

2. What is the toxicity and mode of action of the substance, its breakdown products or any contaminants, and their persistence and areas of concentration in the environment?

Few studies in the literature report on using KS as a crop fungicide. Thus, information regarding its persistence or that of its by-products in the environment is limited. (TR 467-468).

The TR states that crystalline KS is relatively stable; its behavior in solutions and foods depends on factors like temperature, pH, food combination, water activity, packaging, and various metals and other additives. (TR474-477). The presence of KS in natural environments after its commercial use is considered safe. KS has a contact mode of action.
The TR notes that since KS inhibits microorganisms from colonizing a "new" substrate, KS is an effective antimicrobial. However, this bacteriostatic effect is likely to be overwhelmed in a natural community, where microorganisms can quickly degrade KS into readily metabolized compounds such as sorbitol, potassium, and sorbic acid. (TR 454-457). In general, sorbic acid and its salts have been considered compounds of low ecotoxicity.

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

KS is a potassium salt of sorbic acid. Sorbic acid (synthetically manufactured using ketene and crotonaldehyde) is neutralized with potassium hydroxide (manufactured through chemical synthesis) to yield potassium sorbate, the petitioned substance. Several methods are described for isolating the KS solid, including filtration, centrifugation spraying, or crystallization of KS and subsequent distillation. The petition states that the source of potassium sorbate is food grade and manufactured in a closed system, waste disposal certified, and chlorine-free production with multiple accreditations such as Food Safety System Certification, HACCP, and ISO 9001.

Potassium hydroxide (KOH) is considered a category-one hazardous substance under the Clean Water Act due to its impact on pH and potassium levels in wastewater. Although KOH itself may be corrosive in solid form and is listed as a hazardous substance under the Clean Water Act, it is considered a GRAS substance when produced with good manufacturing practice and currently appears on the National List at 205.605(b)(26) for use in processed products.

KS and its by-products are disposed of by landfilling in closed containers or incarceration. The TR states that KS has no potential for environmental accumulation.

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

Potassium sorbate is listed as Generally Recognized as Safe (GRAS) by the U.S. Food and Drug Administration (US FDA) at 183.3640, with the only specification being that it be used according to good manufacturing practices (GMPs). The TR states that KS and its residues are exempt from the requirement of a tolerance in food per 40 CFR 180.1233.

Since minimal data is available on potassium sorbate as petitioned, the TR provides information regarding other uses of KS (food preservation, cosmetics, personal care products, washing and cleaning products, pharmaceuticals, and other manufactured industrial products) and not necessarily for the petitioned use.

The current TR discusses the consumption of processed products that use KS as a food additive. Most of the KS is dispelled when consumed, however 12.6% is retained (studies on rats) by internal organs, skeletal muscles, and other body parts (TR 516-519). An increased KS intake (>25mg/kg) may lead to cytotoxic and genotoxic effects by producing mutagenic compounds and inducing chromosome aberrations and DNA breakage (cancers and diabetes mellitus). Wide use of KS in food, cosmetics, cleaners, etc., could lead to higher-than-normal buildup.

On the contrary, the petition references the 2002 Technical Advisory Panel Review (TAP) that was contracted to support earlier reviews of KS. The TAP states that potassium sorbate is the potassium salt of an unsaturated fatty acid, which participates in the normal fat metabolism in the human body and will be oxidated into carbon dioxide and water finally. It will not be accumulated in the human body. The 2002 TAP states that KS is safe and has the lowest allergenic potential of all food preservatives.

The petition states that although allergic reactions to KS can be described as unusual: There was a reported incident of severe rashes by a worker in a dairy plant who had repeated occupational exposure. The petition also states that KS is a category 2B serious eye damage/eye irritation health hazard with a WARNING signal word. As petitioned to be used in the OR-159-B end-use product with KS at 45%, KS is classified by OSHA Hazard Communication Standards as not hazardous.

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)].

Few studies are found in the literature that report on the use of KS as a crop fungicide, thus, information regarding its persistence or that of its by-products in the environment resulting from this use is limited. No studies on KS used to control the target organism identified on the petitioned product's label were found to expound on its potential effects on soil microbial communities. (TR 467-470). One public commenter mentioned, "the petition does not provide sufficient information for the evaluation of Potassium sorbate against some of the required evaluation criteria: Potassium sorbate is used as a preservative in processing, raising the issue of potential for impacts on soil microbes. However, the petition presents speculation instead of providing clear information about the mechanisms and levels of Potassium sorbate's impacts on soil microbes, stating, "Sorbic acid should inhibit the growth of soil bacteria and fungi."

For crops: The TR mentions KS being tested for phytotoxicity in cotton in the 1970s. The treatments caused a reduction in the primary root elongation at three different concentrations and showed that the KS severely affected the dry weight of cotton seedling shoots and roots (TR 606-608). The TR mentions that further field research is needed on any possible adverse effects that KS could have on the bacterial communities necessary for healthy soil and optimal microbe-plant interactions, as early testing demonstrated that KS addition slightly increased the pH of the soil and soil pH is essential in bacterial community structure and diversity (TR 618-620).

For Livestock: The TR mentions that when KS was petitioned in 2002 for use in livestock, one Technical Advisory Panel (TAP) reviewer stated that one should determine directly at what level KS, as an anti-bacterial, will interfere with ruminant metabolism. The TR noted that future research that identifies the concentrations of KS affecting the ruminant microbiome is needed (TR 633-637).

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

KS antimicrobial properties and characteristics could alter the microbiome in the soil. The petition states that it is reasonable to expect that it would inhibit the growth of soil microorganisms, and additionally, that a significant number of organisms regarded as beneficial are suppressed.

The TR mentions that further field research is needed on any possible adverse effects that KS could have on the bacterial communities necessary for healthy soil and optimal microbe-plant interactions (TR 618-

620), as early testing demonstrated that KS addition slightly increased the pH of the soil and soil pH is essential in bacterial community structure and diversity.

In general, sorbic acid and KS are considered compounds of low ecotoxicity. However, the TR states that high concentrations of KS can impair photosynthetic functions in algae, negatively affect the microbiome of fishes, inhibit mycelial growth in fungi, and affect the soil pH (TR 615, 617, 669).

Category 3: Alternatives/Compatibility

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

The petition states that KS is necessary as an organic input pesticide active ingredient because it has a contact mode of action where organic crop farmers in the US can use the petitioned product in a disease resistance management program rotating with fungicides with different modes of action. The petition includes testing data showing efficacy on powdery mildew, downy mildew, and white fly, and observed no phytotoxicity even at double the use rate on the crops tested. No other trials on the effectiveness of KS were found.

The petition discusses efficacy, indicating that KS is comparable to conventional pesticides and carries a higher efficacy rate than other allowed organic or natural actives. The petition included research regarding in vitro efficacy of eight food additives as possible alternatives to synthetic fungicides for controlling soil-borne pathogens. Also included in the petition is a breakdown of a comparison study of the efficacy of potassium salts against soil-borne and air-borne fungi reviewing KS and potassium bicarbonate (active ingredient listed on 7 CFR 205.601i(9)). According to the petition, in tests done at Michigan State University, KS significantly outperformed potassium bicarbonate and sulfur in controlling downy mildew, an important, difficult-to-control grape disease. Few other published pesticide trials have been done with this material. However, the petition also notes that there are currently non-synthetic and natural substances that could be used in place of potassium sorbate.

A literature review for KS uncovered limited information on use as a foliar spray for growing crops (TR 758-759). The TR indicates that over 750 biological controls were approved for use as crop pests, weeds, and disease controls under NOP standards on the OMRI Products List (OMRI 2022) (TR 764-765). The petition states that searching in the OMRI database under the "Crop Pest, Weed, and Disease Control" keyword "fungicide" yields 464 fungicide products that are OMRI approved. The TR indicated that there were over 500 pesticides formulated with plant-derived active ingredients on the OMRI Products List (OMRI, 2022). Fixed coppers and copper sulfate, potassium silicate, lime sulfur, hydrogen peroxide, horticultural oils, potassium bicarbonate, and polyoxin D zinc salt are all alternative products.

In terms of cultural practices, applying a systems-based approach and deploying preventive practices and ecological processes to promote beneficial microbial diversity in the soil and biodiversity to attract beneficial insects, as well as cover cropping, crop rotations, and cropping schedules, are examples of management practices that can also assist in insect and disease mitigation.

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

KS is already used in organic crop production as an inert ingredient in accordance with § 205.601(m)(1) - EPA List 4—Inerts of Minimal Concern.

As petitioned, KS is not approved to be used internationally. However, it is permitted under the European Economic Community Council Regulations as a preservative in organic livestock feed. KS has been petitioned twice, in crops as a seed treatment and once in livestock as a mold inhibitor, and was not added to the national list due to reasons discussed in the summary of the review section. In addition, KS is not made from renewable resources, the materials used to produce KS are not recyclable, do not complement the use of natural and biological controls, and many alternative substances and practices exist currently.

As the TR states in several places, more research is needed to understand the impacts of allowing KS to be used as an active ingredient for insect and plant disease control; therefore, an abundance of caution needs to be considered.

2023 Spring Meeting Discussion Summary:
The Board reviewed and discussed the discussion document, the TR, and public comments for the petitioned substance, KS. Many community members, including certifiers and advocacy groups, have concerns with potassium sorbate due to the limited information available, efficacy data, essentiality, environmental impact, and effects on health. Farmers tended to be in favor of this product as well as grower groups. However, several farmers encouraged more research and supported listing potassium sorbate only if it meets OFPA criteria. Several groups favoring this substance noted that potassium sorbate is already allowed since it's on the National List as an approved inert ingredient. One additional public comment of note stated that the, "We know we need tools in this area. We're just not sure if this is the right tool for the situation".

Oral and written public comments introduced additional background regarding the history of KS as a registered pesticide until 1989. The NOSB discussed whether potassium can be a part of an integrated pest management program (IPM), whether its efficacious and available alternatives. The petition provided limited information regarding efficacy, and the Crops Subcommittee has not been able to verify the data with independent studies.

New Information from Petitioner Summary:
At the Spring 2023 NOSB meeting, the NOSB requested additional information from the community comparing the use of KS in conventional production, efficacy, effects on health, and environmental impact. The petitioner provided additional information in July 2023. A few notable items are as follows:

1. Conventional Products Using KS as an Active:
    a. Since KS is listed at FIFRA 25(b), US EPA does not monitor products under this category.
    b. Registration is required at the state level; currently, no database exists.
2. KS as a Fungicide:
    a. KS end-use product depends on the spray solution being between a pH of 4.5 and 5.
    b. Additional Efficacy Data was made available by the petitioner, who stated, “KS is comparable to conventional and organic certified active ingredients.”
    c. The petitioner mentioned that KS could reduce the dependency on copper and sulfur products.
1. KS as an Insecticide:
    a. The limited exploratory insect trials conducted by Oro Agri show that KS will suppress whiteflies.
    b. Insect suppression may be selective and variable due to a possible indirect mode of action (MOA).

        i. *Note: observed suppression may be indirect via induced plant health due to the bio-available potassium supplied by KS*.

2. Health and Environmental Concerns:
    a. The petitioner stated, "Due to the regulatory status and extensive regulatory review of KS to date, we have reason to believe that the industry will conduct little to no research to add to the health and environmental data already available for KS."
    b. The EPA continues to monitor KS as a preservative/antioxidant on the Safer Chemical Ingredients List (SCIL)
        i. KS is a "green circle" ingredient, verified as low concern.
    c. The petitioned use of KS is for foliar application with no tolerance requirement. Little interaction with the soil is expected.

Question for stakeholders: At the Spring 2023 NOSB meeting the Crops Subcommittee asked the following question and is re-asking for the Fall 2023 meeting.

1. Is there any additional known research available to understand KS's potential and efficacy if used as an insecticide or plant disease control?

Subcommittee Vote:

1. Motion to classify potassium sorbate as synthetic
Motion by: Amy Bruch
Seconded by: Mindee Jeffery
Yes: 7 No: 0 Abstain: 0 Recuse: 0 Absent: 1

2. Motion to add potassium sorbate to the National List at § 205.601(e): Synthetic substances allowed for use in organic crop production – as insecticides
Motion by: Amy Bruch
Seconded by: Logan Petrey
Yes: 1 No: 5 Abstain: 1 Recuse: 0 Absent: 1

3. Motion to add potassium sorbate to the National List at § 205.601(i): Synthetic substances allowed for use in organic crop production – as plant disease control
Motion by: Amy Bruch
Seconded by: Brian Caldwell
Yes: 2 No: 4 Abstain: 1 Recuse: 0 Absent: 1

Sunset 2025
Meeting 2 - Reviews
Crops Substances § 205.601 & § 205.602
October 2023

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. If a new technical report has been requested for a substance, it is noted in this list. Substances included in this document may also be viewed in the NOP's Petitioned Substances Index.

Request for Comments

Written public comments will be accepted through September 28, 2023 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

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 §205.601 Substances in Organic Production:

If you provide comments supporting the allowance of a substance at §205.601, you should provide information demonstrating that the substance is:

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

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

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

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

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

For Comments that Do Not Support the Continued Prohibition of §205.602 Substances in Organic Production:
If you provide comments that do not support the prohibition of a substance at §205.602, you should provide reasons why the use of the substance should no longer be prohibited in organic production. Specifically, comments that support the removal of a substance from the §205.602 section of the National List should provide 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:

1. Alternative management practices or natural substances that would eliminate the need for the specific substance;
2. Other substances that are on the National List that are better alternatives, which could eliminate the need for this specific substance; and/or
3. 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 28, 2023 via 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:

- Alcohols: Ethanol
- Alcohols: Isopropanol
- Sodium carbonate peroxyhydrate
- Newspaper or other recycled paper, without glossy or colored inks (§205.601(b) - mulch)
- Newspaper or other recycled paper, without glossy or colored inks (§205.601(c) - compost feedstock)
- Plastic mulch and covers
- Aqueous potassium silicate (§205.601(e) - insecticide)
- Aqueous potassium silicate (§205.601(i) - plant disease control)
- Elemental sulfur (§205.601(e) - insecticide; §205.601(i) - plant disease control; §205.601(j) - plant or soil amendment
- Lime sulfur (§205.601(e) - insecticide)
- Lime sulfur (§205.601(i) - plant disease control)
- Hydrated lime
- Liquid fish products
- Sulfurous acid
- Ethylene gas
- Microcrystalline cheesewax

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

- Potassium chloride

Alcohols: Ethanol

Reference: 205.601(a) As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems.
(1) Alcohols. (i) Ethanol.
Technical Report(s): 1995 TAP; 2014 TR
Petition(s): N/A
Past NOSB Actions: 11/1995 NOSB minutes and vote (pg. 17-18); 11/2005 NOSB sunset recommendation; 04/2011 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
Ethanol is used in organic crop production as an algicide, disinfectant, and sanitizer, including irrigation system cleaning.

Manufacture:
Ethanol can be produced by fermentation and chemical synthesis through direct or indirect hydration of ethylene. Fermentation to produce ethanol can use starch, sugar, or cellulose using either natural or genetically engineered strains of bacteria or yeast.

International Acceptance:
Canadian General Standards Board Permitted Substances List
Ethanol is listed as a synthetic for organic crop and livestock production.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Ethanol is listed as a synthetic for organic crop and livestock production.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Ethanol is listed as a synthetic for organic crop and livestock production.

International Federation of Organic Agriculture Movements (IFOAM)
Ethanol is listed as a synthetic for organic crop and livestock production.

Japan Agricultural Standard (JAS) for Organic Production
Ethanol is listed as a synthetic for organic crop and livestock production.

Environmental Issues:
According to the United States Environmental Protection Agency (EPA), the agency that regulates all non-food applications of ethanol, ethanol is practically non-toxic based on acute oral and inhalation

toxicity tests. Ethanol is biodegradable in air, soil, and water. Ethanol can contribute to smog but would be minimal in the quantities used.

Discussion:
During the Spring 2023 NOSB meeting, the Board reviewed both ethanol and isopropanol, noting that there is little to no environmental or human health impacts associated with the use of ethanol. Members were supportive of relisting. The NOSB also reviewed public comments. Farmers indicated that ethanol and isopropanol could be used for cleaning tools and pruning shears, cleaning drip lines that become clogged, and during post-harvest handling to sanitize and disinfect equipment. Ethanol and Isopropanol are readily available in rural areas.

One question was posed to the community about requiring organically-produced ethanol if sufficient quantities are available for organic production and there was agreement that this conversation points to a larger discussion about whether all crop inputs, including manures, should be sourced organically.

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

Subcommittee Vote:
Motion to remove alcohols: ethanol from the National List
Motion by: Logan Petrey
Seconded by: Brian Caldwell
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 0

Alcohols: Isopropanol

Reference: 205.601(a) As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems.
(1) Alcohols. (ii) Isopropanol.
Technical Report(s): 1995 TAP; 2014 TR
Petition(s): N/A
Past NOSB Actions: 11/1995 NOSB minutes and vote (pg. 17-18); 11/2005 NOSB sunset recommendation; 04/2011 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/20 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
Isopropanol is used for a variety of industrial and consumer uses. In organic crop production, isopropanol can be used as an algicide, disinfectant, and sanitizer, including irrigation system cleaning. Isopropanol has broad-spectrum antimicrobial activity against vegetative bacteria, viruses, and fungi.

Manufacture:
Isopropanol is a synthetic compound that is manufactured by hydration of petroleum-derived propylene. Acetone can also be used as a hydrated base chemical over a metal catalyst.

International Acceptance:
Canadian General Standards Board Permitted Substances List
Canadian organic production standards permit the use of isopropanol for a number of agricultural applications.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Alcohols, presumably including isopropanol, may be used for cleaning and disinfecting livestock building installations and utensils.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
"Need recognized by certification body or authority"

International Federation of Organic Agriculture Movements (IFOAM)
No information found

Japan Agricultural Standard (JAS) for Organic Production
No information found

Environmental Issues:
The United States Environmental Protection Agency (EPA) considers isopropanol slightly toxic to practically non-toxic on acute oral and inhalation toxicity tests. The alcohol can contribute to smog and ozone formation, but large-scale releases are unlikely based on prescribed use in organic agriculture.

Discussion:
The NOSB reviewed the use, manufacturing, and environmental concerns of isopropanol, and previous NOSB reviews, and supports relisting. The NOSB discussed comments from the Spring 2023 meeting. Farmers indicated that ethanol and isopropanol could be used for cleaning tools and pruning shears, cleaning drip lines that become clogged, and during post-harvest handling to sanitize and disinfect equipment. Ethanol and isopropanol are readily available in rural areas.

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

Subcommittee Vote:
Motion to remove alcohols: isopropanol from the National List
Motion by: Logan Petrey
Seconded by: Amy Bruch
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 1

Sodium carbonate peroxyhydrate

Reference: 205.601(a) As algaecide, disinfectants, and sanitizer, including irrigation system cleaning systems.
(8) Sodium carbonate peroxyhydrate (CAS #-15630-89-4)—Federal law restricts the use of this substance in food crop production to approved food uses identified on the product label.
Technical Report: 2006 TR; 2014 TR
Petition(s): 2005
Past NOSB Actions: 11/2007 NOSB recommendation; 10/2014 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 12/13/2010 (75 FR 77521); Sunset renewal notice published 06/19/2015 (80 FR 35177); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
According to the 2014 TR and previous reviews by the Board, sodium carbonate peroxyhydrate (SCP) has been used in organic production as an algaecide in rice fields, ponds, ditches, and irrigation lines. It was added to the National List in 2007 as an alternative to materials such as copper and chlorine; it has been registered for use in rice since 2010. In wider legal uses of the substance, "In its primary registration by the US Environmental Protection Agency (EPA) as a biopesticide, use sites for sodium carbonate peroxyhydrate include ornamental plants, turf grasses, terrestrial landscapes, commercial greenhouses, garden centers, nurseries and storage areas. Target pests included algae, moss, liverworts, slime molds and their spores. There was no food use authorized. (TR 104-107)

Manufacture:
According to the 2014 TR, "Sodium carbonate peroxyhydrate is the chemical name for an addition product produced by drying hydrogen peroxide in the presence of sodium carbonate (CAS No. 497-19-8). The pure substance contains 32.5 % hydrogen peroxide and 67.5 % sodium carbonate (based on weight)" (TR 51-53).

The TR lists three common manufacturing processes via drying, crystallization and a spray granulation process. "The dry process involves spraying an aqueous stabilized hydrogen peroxide solution on solid sodium carbonate with continuous agitation. A solid-liquid reaction yields sodium carbonate peroxyhydrate" (TR 232-33). "In the spray granulation process, solutions of sodium carbonate and aqueous stabilized hydrogen peroxide are sprayed onto a bed of sodium carbonate peroxyhydrate nuclei in a fluid-bed granulator. The product bed is kept in movement by a stream of heated air. Product is continuously withdrawn from the dryer and the desired grain-size fraction is obtained by classification" (TR 235-238). "The crystallization process takes advantage of the high solubility of sodium carbonate peroxyhydrate. In this method, sodium carbonate peroxyhydrate is salted out of aqueous solutions with sodium chloride. A sodium carbonate/NaCl suspension is reacted with stabilized hydrogen peroxide under stirring and cooling. The crystallized sodium carbonate peroxyhydrate is separated from the mother liquor by centrifugation, and drying in a fluid-bed dryer" (TR 240-244).

International Acceptance:

Canadian General Standards Board Permitted Substances List

(As of 2014 TR) "Hydrogen peroxide is on the Canadian Organic Production Systems Permitted Substances Lists (CAN/CGSB-32.311-2006). It is listed for use as a fungicide. Sodium carbonate (soda ash) is considered a natural substance in the Canadian system. Sodium carbonate peroxyhydrate is not included in any of the Canadian permitted substance lists" (TR 168-171).

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008 (As of 2014 TR) "Sodium carbonate peroxyhydrate is not listed as a permitted substance for organic production"(TR 187)

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

(As of 2014 TR) "Although Codex Alimentarius permits the use of sodium carbonate peroxyhydrate as an anti-bactericide in raw milk, it is not included in any list for organic use" (TR 176-77).

International Federation of Organic Agriculture Movements (IFOAM) Norms

(As of 2014 TR) "Sodium carbonate peroxyhydrate is not listed or discussed for use in the IFOAM norms" (TR 201).

Japan Agricultural Standard (JAS) for Organic Production

(As of 2014 TR) "Sodium carbonate peroxyhydrate, hydrogen peroxide and sodium carbonate are not specifically listed in the Japanese Agricultural Standard for Organic Plants" (TR 195-196).

Environmental Issues:

An emission of sodium carbonate peroxyhydrate to the environment could occur during production, formulation, and use of the substance (TR lines 323-24). Sodium, carbonate, and hydrogen peroxide do not adsorb to sediment (TR line 333). No new concerns were raised about human health or environmental effects since the earlier review in 2006; however, the substance can have negative impacts on fish, birds and bees. "Aquatically, toxic effects of sodium carbonate peroxyhydrate on fish have been reported, but the sensitivity of different fish species depends on final hydrogen peroxide concentration, water temperature, and life stage" (TR 395-397). "Undissolved sodium carbonate peroxyhydrate is toxic to birds when ingested. However, once applied and dissolve in water sodium carbonate peroxyhydrate is not expected to be toxic to birds. Sodium carbonate peroxyhydrate is also highly toxic to bees and it should not be allowed to drift to flowering plants or used when contact with bees might occur" (TR 404-407).

Discussion:

The Crops Subcommittee took note of previous reviews of this substance. In the last review, the Subcommittee sought input comparing this material with copper sulfate for control of algal scum in rice production and asked if it could replace copper sulfate for that use. Limited and conflicting comments were received. Points raised in favor of renewing the substance stated that it provides better control of algae, and its breakdown components of water and oxygen are more favorable than the accumulation of elemental copper associated with copper sulfate. Additionally, when utilized in irrigation ponds sodium carbonate peroxyhydrate has fewer corrosion issues with irrigation equipment than copper sulfate.

The Subcommittee expressed value in the continued presence of the substance on the National List, even if it is not a commonly used material. Additionally, the potential for inadvertent use as a fungicide in branded products marketed for both uses was discussed by the Subcommittee.

Public comments from the Spring meeting were supportive of relisting with a couple of notable details. A couple of stakeholders reminded the community that SCP was originally considered for use as a replacement for copper sulfate in rice production, does not fall under an OPFA category for crops use and the NOSB should consider whether the intended use is happening in practice and whether the listing should be more narrowly annotated. Consulting the transcripts for previous decision making, the NOSB recommendation at the time reflects that the Crops Subcommittee was originally unconvinced of the need and compatibility of the substance but that "(R)esulting public comment at the full NOSB meeting presented additional information that convinced most board members that the material's environmental impacts were minimal and much more environmentally friendly than the copper sulfate now used as the principal farm pond and rice production algaecide".

A farmer group described SCP as functioning better than copper sulfate for algae control; specifically noting that copper sulfate only reduces bloom whereas SCP prevents the growth of algae. Another farmer noted that the loss of this material could negatively impact farm economies and organic agricultural production. Certifiers listed low levels of use in OSPs in most regions of the country, except in rice growing regions, where a certifier listed 127 users, specifically reflecting support for SCP as an alternative to copper use.

Other public comments support this listing as a variety of options are needed for each application in order to prevent the buildup of microbial resistance; noted that this material breaks down into hydrogen peroxide and sodium carbonate, which further qualifies SCP as a material compatible with National List evaluation and criteria. Another commenter noted that their organization has observed efficacy and utility of the substance in practice.

The Subcommittee has a question about the EPA designation of SCP as a biopesticide and may seek information from EPA on its definitions. This is not an NOSB/OFPA concern, but the Subcommittee is interested in receiving clarity from the EPA.

Justification for Vote:
The Subcommittee finds sodium carbonate peroxyhydrate (SCP) 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 carbonate peroxyhydrate from the National List at 205.601(a)(8)
Motion by: Mindee Jeffery
Seconded by: Brian Caldwell
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 2

Newspaper or other recycled paper, without glossy or colored inks

Reference: 205.601(b) As herbicides, weed barriers, as applicable.
(2) Mulches. (i) Newspaper or other recycled paper, without glossy or colored inks.
Technical Report: 1995 TAP; 2006 TR; 2017 TR
Petition(s): N/A
Past NOSB Actions: 11/1995 NOSB minutes and vote (pg. 19); 11/2005 NOSB sunset recommendation; 04/2011 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/20 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
Newspaper and other recycled paper is commonly used in organic agriculture as a non-chemical means of weed management and soil moisture retention, soil temperature moderation, and boosts to soil organic matter. It is also used to shade out plant growth; it then degrades into the soil.

Manufacture:
A 2017 Technical Report (TR, line 82) on this material reports that one-third to one-half of all paper in the United States is recycled into other paper products, and reports EPA figures from 2013 data that paper is recycled at a rate of 63% in the United States (line 87).

Recycled paper comes from a number of different sources that affect the grade of the recycled paper product; old corrugated containers, mixed paper, old newspapers, high grade de-inked paper, and pulp substitutes. These larger categories are further segmented into as many as 50 different sub-grades of recycled paper. Paper recovered for recycling is ultimately shredded and pulped to produce new paper products.

Some recycled paper cannot be made into other paper products but can become a feedstock for compost products, while some recycled paper carries too many contaminants – some of it toxic -- including plastics, motor oil, paint, glass, and other non-paper materials.

An important consideration of newspaper and recycled paper in organic production relates to the inks that are printed onto the paper. Black ink has historically been derived from vegetable- or petroleum-based sources that involve the use of solvents that can damage the environment in a variety of ways. Increasingly, black inks have become water-based, though not 100% solvent-free. The use of various heavy metal compounds in colored ink has been an important consideration in excluding colored inks from use in organic production. Similarly, while glossy inks can gain their functional components from nonsynthetics like bentonite or kaolinite, those functions can also come from petrochemical synthetic polymers like acrylonitrile, polyethylene (LDPE), styrene, butadiene, vinyl acetate, and polyvinyl chloride, excluding them from any use in organic production.

Adhesives, glues, waxes, and resins are also among the materials that could be found in newspaper and recycled paper products and raise similar questions to those posed during prior reviews of the separate National List substance, biodegradable biobased mulch film.

Paper mulches are not regulated as an herbicide by the EPA and are considered inert.

It is worth noting that virgin, or non-recycled paper, comes from a variety of plant materials, including wood, trees, straw, hemp, sugarcane bagasse, bamboo, reeds, and kenaf, with the majority coming from wood fibers. As noted in the 2017 TR (line 68), most of the wood fibers derived from trees used for paper production do not incorporate methods considered to be excluded from organic production. However, some genetically modified trees are being produced that could potentially be used in paper production in the future. Some sources have reported that as many as 200 different chemicals can be used to make it possible to use tree fiber as a feedstock for paper production (Discover Magazine, April 4, 2014).

International Acceptance:
Canadian General Standards Board Permitted Substances List
Permitted for use but only "without glossy paper and coloured ink."

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Not specified as permitted for use.

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

International Federation of Organic Agriculture Movements (IFOAM) Norms
Not specified as permitted for use.

Japan Agricultural Standard (JAS) for Organic Production
Not specified as permitted for use.

Environmental Issues:
While recycled paper production is assumed to have fewer environmental impacts than virgin paper production, it still presents issues. Sodium hydroxide and other chemical additives and surfactants may be introduced into the process. The de-inking sludge – or wastewater byproduct – that is produced from paper recycling can contain a number of synthetic materials and is typically landfilled, burned, or co-composted with sewage and poultry litter.

That said, the use of recycled paper ensures that trees are not harvested for the production of paper, a process that has much more far-reaching impacts including the loss of habitat, disturbance or destruction of soils, and the destabilization of carbon sinks.

Discussion:
At the 2015 NOSB sunset review, it came to the attention of both the NOSB and the public that there are new, less toxic materials used in production of newspaper and other recycled paper products which could stimulate the NOSB to consider a change to the annotation for this material. A technical report

(TR) was requested and subsequently completed in summer 2017. The TR revisited the ingredients and colored inks in newspaper as well as their effect on the environment.

While there has been progress towards less toxic materials used in inks, and more recycling of paper products since the original listings and annotation of newspaper and recycled paper, it is difficult-to-impossible to determine if the inks present in the newspaper are ones that are less problematic. There is no methodology to distinguish between color inks that might be more acceptable for direct application to organic land and those that are not. When reviewing the 2017 TR, the Crops Subcommittee decided the current annotation for newspaper and recycled paper, which prohibits glossy or colored inks, should remain. This conclusion was presented as an update to the full NOSB at the Fall 2017 NOSB meeting. The NOSB unanimously voted to continue this listing at § 205.601(b) in 2018.

There was continued support for this material to remain on the National List with the current annotation. Certifiers, grower groups, and individual growers all submitted comments in favor of retaining this material in both locations on the National List (§§ 205.601(b) and 205.601(c)). While some stated there was currently not much use of this material in organic crop production, they also stated it should continue to be allowed for those who wish to continue using it. One certifier noted that newspaper could be included in manure that is cleaned out of livestock barns, supporting the relisting as a compost feedstock.

At the Spring 2023 NOSB meeting, the full Board discussed this material at some length. Discussion focused on whether it is reasonable to assume that all/most newspaper and other recycled paper would be produced with the inks required by the annotation and, if not, how that would create issues for certifiers. This discussion continued in subcommittee after the Spring 2023 meeting, noting that the assumption that all recycled paper is using less-problematic inks may not be correct. The Board considered whether the listing also included cardboard and confirmed its understanding that it did. The Board also discussed the separate Spring 2021 vote to approve paper pots and paper-based planting aids and the findings during that process that some of the materials of potential concern found in paper pots are also the components of newspaper and other recycled paper.

Questions to our Stakeholders:
1. Should there be an annotation for this listing that attempts to further clarify what uses are acceptable within organic production? Can certifiers appropriately oversee the ink requirement in this annotation?
2. How widely used are these materials in organic production?
3. What is the scale of use of this material for this purpose in organic production (specifically number of users, farms, acres, geographical reach)?

Justification for Vote:
The Subcommittee finds newspaper or other recycled paper, without glossy or colored inks compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR205.601(b) and is not proposing removal.

Subcommittee Vote:
Motion to remove newspaper or other recycled paper, without glossy or colored inks from the National List at 7 CFR 205.601(b)
Motion by: Wood Turner
Seconded by: Mindee Jeffery
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 1

Newspaper or other recycled paper, without glossy or colored inks

Reference: 205.601(c) As compost feedstocks—Newspapers or other recycled paper, without glossy or colored inks.
Technical Report: 1995 TAP; 2006 TR; 2017 TR
Petition(s): N/A
Past NOSB Actions: 11/1995 NOSB minutes and vote (pg. 19); 11/2005 NOSB sunset recommendation; 04/2011 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
Newspaper and other recycled paper is commonly used in organic agriculture as a compost feedstock. Effectively, the newspaper or recycled paper is a carbon source – or food -- for active compost processing.

Manufacture:
A 2017 Technical Report (TR, line 82) on this material reports that one-third to one-half of all paper in the United States is recycled into other paper products, and reports EPA figures from 2013 data that paper is recycled at a rate of 63% in the United States (line 87).

Recycled paper comes from a number of different sources that affect the grade of the recycled paper product: old corrugated containers, mixed paper, old newspapers, high grade de-inked paper, and pulp substitutes. These larger categories are further segmented into as many as 50 different sub-grades of recycled paper.

Some recycled paper cannot be made into other paper products but can become a feedstock for compost products, while some recycled paper carries too many contaminants – some of it toxic -- including plastics, motor oil, paint, glass, and other non-paper materials.

An important consideration of newspaper and recycled paper in organic production relates to the inks that are printed onto the paper. Black ink has historically been derived from vegetable- or petroleum-based sources that involve the use of solvents that can damage the environment in a variety of ways. Increasingly, black inks have become water-based, though not 100% solvent-free. The use of various heavy metal compounds in colored ink has been an important consideration in excluding colored inks from use in organic production. Similarly, while glossy inks can gain their functional components from nonsynthetics like bentonite or kaolinite, those functions can also come from petrochemical synthetic polymers like acrylonitrile, polyethylene (LDPE), styrene, butadiene, vinyl acetate, and polyvinyl chloride, excluding them from any use in organic production.

Adhesives, glues, waxes, and resins are also among the materials that could be found in newspaper and recycled paper products and raise similar questions to those posed during prior reviews of the separate National List substance, biodegradable biobased mulch film.

Composting is not federally regulated therefore, neither is the use of paper as a compost feedstock. However, components of paper feedstock, such as heavy metals, could be regulated at the state level.

It is worth noting that virgin, or non-recycled paper, comes from a variety of plant materials, including wood, trees, straw, hemp, sugarcane bagasse, bamboo, reeds, and kenaf, with the majority coming from wood fibers. As noted in a 2017 TR (line 68), most of the wood fibers derived from trees used for paper production do not incorporate methods considered to be excluded from organic production. However, some genetically modified trees are being produced that could potentially be used in paper production in the future. Some sources have reported that as many as 200 different chemicals can be used to make it possible to use tree fiber as a feedstock for paper production (Discover Magazine, April 4, 2014).

International Acceptance:
Canadian General Standards Board Permitted Substances List
Permitted for use but only "without glossy paper and coloured ink."

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Not specified as permitted for use.

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

International Federation of Organic Agriculture Movements (IFOAM) Norms
Not specified as permitted for use.

Japan Agricultural Standard (JAS) for Organic Production
Not specified as permitted for use.

Environmental Issues:
While recycled paper production is assumed to have fewer environmental impacts than virgin paper production, it still presents issues. Sodium hydroxide and other chemical additives and surfactants may be introduced into the process. The de-inking sludge – or wastewater byproduct – that is produced from paper recycling can contain a number of synthetic materials and is typically landfilled, burned, or co-composted with sewage and poultry litter.

That said, the use of recycled paper ensures that trees are not harvested for the production of paper, a process that has much more far-reaching impacts including the loss of habitat, disturbance or destruction of soils, and the destabilization of carbon sinks.

Discussion:
At the 2015 NOSB sunset review, it came to the attention of both the NOSB and the public that there are new, less toxic materials used in production of newspaper and other recycled paper products which could stimulate the NOSB to consider a change to the annotation for this material. A technical report

(TR) was requested and subsequently completed in summer 2017. The TR revisited the ingredients and colored inks in newspaper as well as their effect on the environment.

While there has been progress towards less toxic materials used in inks, and more recycling of paper products since the original listings and annotation of newspaper and recycled paper, it is difficult to impossible to determine if the inks present in the newspaper are ones that are less problematic. There is no methodology to distinguish between color inks that might be more acceptable for direct application to organic land and those that are not. When reviewing the 2017 TR, the Crops Subcommittee decided the current annotation for newspaper and recycled paper, which prohibits glossy or colored inks, should remain. This conclusion was presented as an update to the full NOSB at the Fall 2017 NOSB meeting. The NOSB unanimously voted to reinstate continue this listing at § 205.601© in 2018.

There was continued support for this material to remain on the National List with the current annotation. Certifiers, grower groups, and individual growers all submitted comments in favor of retaining this material in both locations on the National List (§§ 205.601(b) and 205.601(c)). While some stated there was currently not much use of this material in organic crop production, they also stated it should continue to be allowed for those who wish to continue using it. One certifier noted that newspaper could be included in manure that is cleaned out of livestock barns, supporting the relisting as a compost feedstock.

At the Spring 2023 NOSB meeting, the full Board discussed this material at some length. Discussion focused on whether it is reasonable to assume that all/most newspaper and other recycled paper would be produced with the inks required by the annotation and, if not, how that would create issues for certifiers. This discussion continued in subcommittee after the Spring 2023 meeting, noting that the assumption that all recycled paper is using less-problematic inks may not be correct. The Board considered whether the listing also included cardboard and confirmed its understanding that it did. The Board also discussed the separate Spring 2021 vote to approve paper pots and paper-based planting aids and the findings during that process that some of the materials of potential concern found in paper pots are also the components of newspaper and other recycled paper. Finally, the board noted that municipal compost is allowed within organic production and could, thus, include some of the elements of potential concern by virtue of newspaper being a municipal compost feedstock in certain contexts. The Board acknowledged that it would be extremely helpful to understand this issue in terms of what substances are present at the end of the compost process as a means of understanding whether and what adverse impact may result.

Questions to our Stakeholders:
1. Should there be an annotation for this listing that attempts to further clarify what uses are acceptable within organic production? Can certifiers appropriately oversee the ink requirement in this annotation?
2. How widely used are these materials in organic production?
3. What is the scale of use of this material for this purpose in organic production (specifically number of users, farms, acres, geographical reach)?

Justification for Vote:
The Subcommittee finds newspaper or other recycled paper, without glossy or colored inks compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR205.601(c) and is not proposing removal.

Subcommittee Vote:
Motion to remove newspaper or other recycled paper, without glossy or colored inks from the National List 7 CFR 205.601(c)
Motion by: Wood Turner
Seconded by: Jerry D'Amore
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 1

Plastic mulch and covers

Reference: 205.601(b) As herbicides, weed barriers, as applicable.
(2) Mulches. (ii) Plastic mulch and covers (petroleum-based other than polyvinyl chloride (PVC)).
Technical Report: 1995 TAP
Petition(s): N/A
Past NOSB Actions: 11/1995 NOSB minutes and vote (pg. 20); 11/2005 NOSB sunset recommendation; 04/2011 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
Plastic mulches and covers provide multiple functions in organic production including, but not limited to, weed barrier, soil, nutrient and water retention, soil warming, soil solarizing, high and low tunnels, and reflective barriers for insect pests.

Manufacture:
Plastic mulches and covers are thermoplastic resins of high melt viscosity, usually polyethylene. Resin pellets are melted into an extruder and pumped or blown through a die or tube to form the plastic in the desired shape.

International Acceptance:
Canadian General Standards Board Permitted Substances List
Plastic mulches: non-biodegradable and semi-biodegradable materials shall not be incorporated into the soil or left in the field to decompose. Use of polyvinyl chloride as plastic mulch or row cover is prohibited.

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

[CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)]
No reference

[International Federation of Organic Agriculture Movements (IFOAM) Norms]
No reference

[Japan Agricultural Standard (JAS) for Organic Production]
Plastic mulch (limited to those to be removed after use)

Environmental Issues:
Although there is significant support for its relisting, plastic mulch has many environmental concerns, most of which are related to disposal after each season. The recycling of plastic mulch seems to be a diminishing option. The product is easily damaged and contaminated, which makes recycling a less viable option. Other concerns include the breakdown of microplastics and litter from damaged product remaining in the field. These pieces are considered foreign materials and contaminate organic soils. The labor cost to remove plastic is very expensive and often is a challenge for growers. Because of this, many growers are excited for the development of biodegradable mulches.

Discussion:
The Crops Subcommittee discussed the use, manufacturing, and environmental issues with plastic mulches. The expansiveness of the listing and annotations were reviewed, and it was noted that the term, "covers," can refer to high and low tunnels as well as ground coverings. Members of the Subcommittee discussed the significance of recycling as a diminishing option and reviewed the social concerns about recycling of plastic mulches not being a viable option. Many members of the Subcommittee have expressed concern in the lack of progress in reducing the dependency of plastic mulch and covers in certain areas of organic production.
Plastic mulch is discussed directly in the Organic Foods Production Act (OFPA). OFPA 6508(c)(2) prohibits the use plastic mulches unless such mulches are removed at the end of each growing or harvest season. Because of this listing, plastic mulch is also found in the crop, pest, weed and disease management practice standard under §205.206(c)(6):

> Plastic or other synthetic mulches: *Provided,* That, they are removed from the field at the end of the growing or harvest season.

Under this Practice Standard listing, all synthetic mulches are permitted. The listing for Plastic Mulch and Covers in the National List (§205.601(b)(2)(ii)) broadens the allowance of "plastic or other synthetic mulches" to include "covers" and prohibits polyvinyl chloride (PVC).

Questions to our Stakeholders:
1. Which crops depend most on plastic mulch, and why?
2. What alternatives are there for weed management?

Justification for Vote:
After much discussion, the Subcommittee concluded that removing plastic mulch and covers from the National List would not prohibit the use of plastic mulch in organic production. If plastic mulch and covers were removed from the National List, all plastic mulches would be allowed, due to the allowance of plastic mulch in OFPA and the organic regulation practice standard at §205.206. Additionally, removing plastic mulch and covers from the National List would remove the prohibition of PVC-based

mulch., therefore allowing PVC mulch to be used. While there is strong support in the Subcommittee to encourage organic producers to reduce their dependency on plastic mulch and covers, the Subcommittee does not intend to remove a restrictive annotation that keeps PVC mulch out of organic production.

The Subcommittee vote was ambiguous, however, at this time, the Subcommittee finds plastic mulches and covers compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote:
Motion to remove plastic mulch and covers from the National List
Motion by: Logan Petrey
Seconded by: Mindee Jeffery
Yes: 0 No: 3 Abstain: 4 Recuse: 0 Absent: 1

Aqueous potassium silicate

Reference: 205.601(e) As insecticides (including acaricides or mite control).
(2) Aqueous potassium silicate (CAS #-1312-76-1)—the silica, used in the manufacture of potassium silicate, must be sourced from naturally occurring sand.
Technical Report: 2003 TAP; 2014 TR; 2023 Limited Scope TR
Petition(s): 2002; 2006 (Addendum #1)
Past NOSB Actions: 11/2007 NOSB recommendation; 10/2014 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 12/13/2010 (75 FR 77521); Sunset renewal notice published 06/19/2015 (80 FR 35177); Sunset renewal notice published 05/07/2020 (85 FR 27105).
Sunset Date: 6/22/2025

Subcommittee Review

Use:
Aqueous potassium silicate is used as an insecticide for insects and mites. Formulations of aqueous potassium silicate are either sprayed on the foliage of plants or incorporated in the soil with the goal of plant uptake across root and leaf boundaries. The silica tetrahedra are purported to be incorporated in boundary cells (in roots and leaves) inhibiting insect feeding and the onset of plant disease infection. The action of applying potassium silicate in a foliar spray serves to induce production of phytoalexins, chitinases and that in turn strengthen stroma and cell walls.

Manufacture:
Aqueous potassium silicate is manufactured by combining high purity silica sand and potassium carbonate (both mined materials) and heating to a high temperature (2000 degrees F). The potassium carbonate and silicon dioxide fuse to form a molten potassium silicate glass with the evolution of carbon dioxide gas. This glass can either be 1) cooled and ground into a powder or 2) dissolved in water to form

a potassium silicate solution. The solution may subsequently be spray dried to form hydrous powder granules of potassium silicate.

International Acceptance:
Canadian General Standards Board Permitted Substances List
Potassium silicate is listed as approved for crop protection.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
No silicates were listed at this website.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Silicates allowed only as ground powders.

International Federation of Organic Agriculture Movements (IFOAM)
Silicates are allowed as plant protectants.

Japan Agricultural Standard (JAS) for Organic Production
No information found.

Environmental and Health Issues:
The 2014 Technical Report (TR) states that:

- "Potassium silicate will not adversely affect birds."
- It is "practically non-toxic to fish."
- "Potassium silicate is not toxic to honeybees at the concentration administered for the foliar spray."
- "The overall toxicological risk from human exposure to potassium silicate is negligible."
- "Risks from aggregate exposure via oral, dermal and inhalation exposure are … considered negligible."

Discussion:
Written comments submitted to the NOSB prior to the April 2023 NOSB meeting were mostly in favor of relisting, with 4 in favor, 1 opposed, and 1 unclear.

Based on information in the 2014 TR, concerns were raised by NOSB members in 2018, during the 2020 sunset review. Concerns raised by the NOSB included:

1. Skin irritation from handling aqueous potassium silicate.
2. Effects on farmworkers making the foliar application.
3. Effects on human or animal consumers because of its reported effect of making forage plants less digestible.
4. Its reported effect of elongation and thickening of stems.
5. Delayed antithesis and flower deformation in some plant species.
6. Whether it is essential to and compatible with organic production.

Following up on these concerns (please refer to the 2014 TR for references):

- Investigation of the effect of aqueous potassium silicate on flowers showed that the articles cited (TR pp. 487-490) were greenhouse studies in soilless media. One study showed that applications of potassium silicate "either increased or decreased height, diameter, fresh weight, dry weight, flower diameter, and leaf thickness." The other study found that drenches with higher rates of potassium silicate resulted in stunted plants with deformed flowers. However, substrate pH was not carefully controlled with the addition of such high-pH drenches. These studies have little to do with use of aqueous potassium silicate as a foliar spray in organic agriculture.

- Similarly, the study (TR pp. 477-481) showing that aqueous potassium silicate could make forages "more difficult to chew and digest" was unrelated to the use pattern of aqueous potassium silicate in organic agriculture. The study looked at forages harvested at different growth stages and showed that overmature grass forages contained high levels of silicon and were less digestible.
- A new, 2023 limited scope TR says that aqueous potassium silicate does not present an inhalation hazard to farmworkers.
- Aqueous potassium silicate products are used by some organic fruit and vegetable growers. Public comments that these organic producers submitted to the NOSB prior to the April 2023 NOSB Meeting did not report adverse effects on their produce, in contrast to the suggestion (TR pp. 479-481) that produce might become less palatable. On the contrary, they advocated for its relisting. One grower reported that two early sprays of aqueous potassium silicate eliminated several late sprays of sulfur.

The Subcommittee requested a limited scope technical report (TR) in 2022 to address the following questions:

1. What is the fate of potassium silicate on the plant leaf surface? When sprayed, potassium silicate dries on the leaves. What happens to it there? Does it stay in that form for several days and act as a barrier? Does it transform and become absorbed into the plant as silicic acid? Does it re-dissolve and run off to the ground in rains?

2. What is its effect on the plant leaf microbial community?

3. When sprayed under low humidity conditions, can aqueous potassium silicate crystallize in the air and present an inhalation hazard?

The 2023 limited scope TR indicated that aqueous potassium silicate was very unlikely to be hazardous to the applicator. Its presence on leaves tends to favor bacterial over fungal organisms, which may account for some of its fungicidal effects. Its fate on the leaf surface is highly dependent on the pH of the spray mixture. At lower pH values, close to 5, aqueous potassium silicate may be deposited just below the leaf cuticle layer and present a barrier to fungus infection. At higher pH values, surface deposits (quickly washed off by rain or irrigation) may perform the same function. The 2023 limited scope TR mentioned that aqueous potassium silicate in spray solution can form nanoparticles, but these are common in nature. The TR did not mention any adverse effects from nanoparticles.

The 2023 limited scope TR clarified important points but did not report any negative information regarding the safety of the product. Reviewing its environmental and health effects, the Crops Subcommittee finds that aqueous potassium silicate is compatible with organic agriculture.

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

Subcommittee Vote:
Motion to remove aqueous potassium silicate from the National List at §205.601(e)(2)
Motion by: Brian Caldwell
Seconded by: Wood Turner
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 1

Aqueous potassium silicate

Reference: 205.601(i) As plant disease control.
(1) Aqueous potassium silicate (CAS #-1312-76-1)—the silica, used in the manufacture of potassium silicate, must be sourced from naturally occurring sand.
Technical Report: 2003 TAP; 2014 TR; 2023 Limited Scope TR
Petition(s): 2002; 2006 (Addendum #1)
Past NOSB Actions: 11/2007 NOSB recommendation; 10/2014 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 12/13/2010 (75 FR 77521); Sunset renewal notice published 06/19/2015 (80 FR 35177); Sunset renewal notice published 05/07/2020 (85 FR 27105).
Sunset Date: 6/22/2025

Subcommittee Review

Use:
Aqueous potassium silicate is used as a crop protectant for disease control and suppression. Formulations of aqueous potassium silicate are either sprayed on the foliage of plants or incorporated in the soil with the goal of plant uptake across root and leaf boundaries. The silica tetrahedra are purported to be incorporated in boundary cells (in roots and leaves) inhibiting insect feeding and the onset of plant disease infection. The action of applying potassium silicate in a foliar spray serves to induce production of phytoalexins, chitinases and that in turn strengthen stroma and cell walls.

Manufacture:
Aqueous potassium silicate is manufactured by combining high purity silica sand and potassium carbonate (both mined materials) and heating to a high temperature (2000 degrees F). The potassium carbonate and silicon dioxide fuse to form a molten potassium silicate glass with the evolution of carbon dioxide gas. This glass can either be 1) cooled and ground into a powder or 2) dissolved in water to form a potassium silicate solution. The solution may subsequently be spray dried to form hydrous powder granules of potassium silicate.

International Acceptance:
Canadian General Standards Board Permitted Substances List
Potassium silicate is listed as approved for crop protection.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
No silicates were listed at this website.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Silicates allowed only as ground powders.

International Federation of Organic Agriculture Movements (IFOAM)
Silicates are allowed as plant protectants.

Japan Agricultural Standard (JAS) for Organic Production
No information found.

Environmental and Health Issues
The 2014 Technical Report (TR) states that:

- "Potassium silicate will not adversely affect birds."
- It is "practically non-toxic to fish."
- "Potassium silicate is not toxic to honeybees at the concentration administered for the foliar spray."
- "The overall toxicological risk from human exposure to potassium silicate is negligible."
- "Risks from aggregate exposure via oral, dermal and inhalation exposure are … considered negligible."

Discussion:
Written comments submitted to the NOSB prior to the April 2023 NOSB meeting were mostly in favor of relisting, with 4 in favor, 1 opposed, and 1 unclear.

Based on information in the 2014 TR, concerns were raised by NOSB members in 2018, during the 2020 sunset review. Concerns raised by the NOSB included:

7. Skin irritation from handling aqueous potassium silicate.
8. Effects on farmworkers making the foliar application.
9. Effects on human or animal consumers because of its reported effect of making forage plants less digestible.
10. Its reported effect of elongation and thickening of stems.
11. Delayed antithesis and flower deformation in some plant species.
12. Whether it is essential to and compatible with organic production.

Following up on these concerns (please refer to the 2014 TR for references):

- Investigation of the effect of aqueous potassium silicate on flowers showed that the articles cited (TR pp. 487-490) were greenhouse studies in soilless media. One study showed that applications of potassium silicate "either increased or decreased height, diameter, fresh weight, dry weight, flower diameter, and leaf thickness." The other study found that drenches with higher rates of potassium silicate resulted in stunted plants with deformed flowers. However, substrate pH was not carefully controlled with the addition of such high-pH drenches. These studies have little to do with use of aqueous potassium silicate as a foliar spray in organic agriculture.

- Similarly, the study (TR pp. 477-481) showing that aqueous potassium silicate could make forages "more difficult to chew and digest" was unrelated to the use pattern of aqueous potassium silicate in organic agriculture. The study looked at forages harvested at different growth stages and showed that overmature grass forages contained high levels of silicon and were less digestible.
- A new, 2023 limited scope TR says that aqueous potassium silicate does not present an inhalation hazard to farmworkers.
- Aqueous potassium silicate products are used by some organic fruit and vegetable growers. Public comments that these organic producers submitted to the NOSB prior to the April 2023 NOSB Meeting did not report adverse effects on their produce, in contrast to the suggestion (TR pp. 479-481) that produce might become less palatable. On the contrary, they advocated for its relisting. One grower reported that two early sprays of aqueous potassium silicate eliminated several late sprays of sulfur.

The Subcommittee requested a limited scope technical report (TR) in 2022 to address the following questions:

1. What is the fate of potassium silicate on the plant leaf surface? When sprayed, potassium silicate dries on the leaves. What happens to it there? Does it stay in that form for several days and act as a barrier? Does it transform and become absorbed into the plant as silicic acid? Does it re-dissolve and run off to the ground in rains?
2. What is its effect on the plant leaf microbial community?
3. When sprayed under low humidity conditions, can aqueous potassium silicate crystallize in the air and present an inhalation hazard?

The 2023 limited scope TR indicated that aqueous potassium silicate was very unlikely to be hazardous to the applicator. Its presence on leaves tends to favor bacterial over fungal organisms, which may account for some of its fungicidal effects. Its fate on the leaf surface is highly dependent on the pH of the spray mixture. At lower pH values close to 5, aqueous potassium silicate may be deposited just below the leaf cuticle layer and present a barrier to fungus infection. At higher pH values, surface deposits (quickly washed off by rain or irrigation) may perform the same function. The 2023 limited scope TR mentioned that aqueous potassium silicate in spray solution can form nanoparticles, but these are common in nature. The TR did not mention any adverse effects from nanoparticles.

The 2023 limited scope TR clarified important points but did not report any negative information regarding the safety of the product. Reviewing its environmental and health effects, the Crops Subcommittee finds that aqueous potassium silicate is compatible with organic agriculture.

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

Subcommittee Vote:
Motion to remove aqueous potassium silicate from the National List at §205.601(i)(1)
Motion by: Brian Caldwell
Seconded by: Jerry D'Amore
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 1

Elemental sulfur

Reference: 205.601(e) As insecticides (including acaricides or mite control). (5) Elemental sulfur.
Reference: 205.601(i) As plant disease control. (10) Elemental sulfur.
Reference: 205.601(j) As plant or soil amendments. (2) Elemental sulfur.
Technical Report: 1995 TAP; 2018 TR
Petition(s): 2017 (slug or snail bait, separate sunset review)
Past NOSB Actions: 04/1995 NOSB minutes and vote (pg. 345); 11/2005 NOSB sunset recommendation; 04/2010 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
Approved legal uses of the substance (TR 67-75): Elemental sulfur is currently on the National List of Allowed and Prohibited Substances as a synthetic substance allowed for use in organic crop production for the following categories:

1. For uses as an insecticide, including acaricides or mite control (7 CFR 205.601 (e)(5).
2. For plant disease control (7 CFR 205.601(i)(10)).
3. As plant or soil amendments (7 CFR 205.601(j)(2)).

The current sunset review includes all three listings of sulfur, used as an insecticide, plant disease control, and as a plant or soil amendment.

Sulfur is an essential plant nutrient, naturally present in our food and soil, and is part of normal human biochemistry. When sulfur is used as a soil amendment it can have a strong acidifying effect by replacing sodium with calcium in high pH alkali soils. Sulfur is considered the fourth major plant nutrient after nitrogen, phosphorus, and potassium-. Sulfur can also be used to control insects and/or diseases. It is approved for use on conventional and organic crops to help control fungi and other pests and is commonly used on farms domestically and internationally.

Manufacture:
Sulfur is one of few elements found in its elemental form in nature, typically in limestone/gypsum formations, limestone/anhydrite formations associated with salt domes, or volcanic rock (d'Aquin 2007).

Currently, elemental sulfur is produced as a by-product from natural gas or petroleum operations and refinery processes. The latter is the primary source of most elemental sulfur currently being used.

International Acceptance:

Canadian General Standards Board Permitted Substances List

Sulfur is allowed by the Canadian Organic Standards. The Canadian General Standards Board (CGSB) includes non-synthetic elemental sulfur as a permitted substance for organic production systems (CAN/CGSB-32.311-2015) for use as a soil amendment and as a foliar application. The CGSB also permits using sulfur to control external parasites and sulfur smoke bombs in conjunction with other methods used for rodent control when a pest control program is temporarily overwhelmed.

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

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

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

Codex Alimentarius Commission (CAC GL 32-1999) permits the use of sulfur for pest and disease control when the certification body or authority recognizes the need for plant protection (Codex, 2013).

International Federation of Organic Agriculture Movements (IFOAM)

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

Japan Agricultural Standard (JAS) for Organic Production

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

Environmental Issues:

Elemental sulfur is relatively innocuous in the environment when used according to the product label. It is also low in toxicity. It should not be used within one month of any horticultural oil product, as currently stated on most sulfur labels.

An updated Technical Report (TR) was completed on April 19, 2018. There was no new information contradicting historical information that characterizes sulfur as an important and relatively safe material for organic agriculture.

Although low in acute toxicity, sulfur is a respiratory, ocular, and dermal irritant that can significantly impact farmworker health. Farmworker exposures can be mitigated if label recommendations and proper PPE recommendations are followed.

Discussion:

2018 NOSB Review: Historically, there has been strong support for the continued listing of sulfur, particularly for use against various bacterial and fungal diseases, insects, and as a plant and soil amendment. It was noted that several agricultural commissioners in California had encouraged a shift to wettable formulations in vineyard applications, and anecdotal information suggests fewer drift and regulatory problems.

Based on the extensive public comment and discussions, new technical reviews, previous committee votes & discussions, and historical public comment, the 2018 NOSB review concluded that elemental sulfur still appears to be necessary in organic crop production. The NOSB should continue to monitor sulfur use in organic agriculture and respond to any new information raising environmental or, in particular, public health concerns.

2023 NOSB Review: The NOSB reviewed all three listings for elemental sulfur. In the public comments, farmer advocacy groups and consultants spoke about the importance of this substance, that elemental sulfur has been included on the original national list since 1995, and that alternatives are not as effective.

There were a few comments from advocacy groups that wanted further annotations for worker protection due to respiratory concerns, and potential limits to control heavy contamination since synthetic elemental sulfur comes from scrubbers from fossil fuel plants. The Board reviewed in further detail respiratory concerns and the potential increased risk that children have, and discussed both a journal article, and a study completed at Oregon State University about the effects on children's respiratory health.

The Board also reviewed the insight gained from the question regarding the use of wettable sulfur products. Some in the community favored a potential annotation, however it was learned that it is common for produce growers to use both dusting sulfur and wettable sulfur in rotation with each other due to different efficacies. When fruit is present, wettable formulations increase the risk of residue on the fruit, and specialized application equipment for dusting sulfur can be used to reduce dusting sulfur drift.

*NOTE: in the listing at 205.601(e), the Board recommends consistency with definitions -As a**caricides need not be insecticides** and insecticides need not be acaricides. During the review, the NOP suggested that this could be a technical correction as part of the inerts rulemaking.*

Questions to our Stakeholders
None.

Justification for Vote:
The Subcommittee finds all listings of elemental sulfur compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote:
Motion to remove elemental sulfur from the National List at 205.601(e)
Motion by: Amy Bruch
Seconded by: Mindee Jeffery
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 2

Subcommittee Vote:
Motion to remove elemental sulfur from the National List at 205.601(i)
Motion by: Amy Bruch
Seconded by: Wood Turner
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 2

Subcommittee Vote:
Motion to remove elemental sulfur from the National List at 205.601(j)
Motion by: Amy Bruch
Seconded by: Mindee Jeffery
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 2

Lime sulfur

Reference: 205.601(e) As insecticides (including acaricides or mite control). (6) Lime sulfur—including calcium polysulfide.
Technical Report: 2014 TR
Petition(s): N/A
Past NOSB Actions: Actions: 04/1995 NOSB minutes and vote (pg. 341); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
Lime sulfur is on the National List at §205.601(e)(6) as an insecticide (including acaricide or mite control) and at §205.601 (j)(6) for plant disease control. As an insecticide, lime sulfur is used to control mites (spider mites and rust mites), aphid, and San Jose scale in tree fruit and other organic crops.

Manufacture:
Lime sulfur is often referred to by its chemical name, calcium polysulfide. It is considered to be synthetic and is produced by reacting boiling calcium hydroxide [$CaOH2_2$] and ground sulfur (2014 TR).

International Acceptance:
Canadian General Standards Board Permitted Substances List
Allowed as a production aid

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Permits the use of lime sulphur (calcium polysulfide) as a fungicide, insecticide, acaricide.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Does not appear on this listing

International Federation of Organic Agriculture Movements (IFOAM)
Allowed as a crop protectant

Japan Agricultural Standard (JAS) for Organic Production
Lime sulfur powder allowed as Substances for Plant Pest and Disease Control

Environmental Issues:
Residues of lime sulfur are exempt from the requirement of a tolerance under 40 CFR 180.1232 as determined by the U.S. EPA because the calcium polysulfides found in lime sulfur products rapidly degrade to calcium hydroxide and sulfur in the environment and human body.

Discussion:
All public commenters were in favor of relisting lime sulfur for control of fungal and bacterial diseases as well as its uses for various insects. One commenter requested specifying only essential uses. Use is widespread across many crops and regions, and many comments note that there are not viable alternatives for its various uses.
Lime sulfur can cause phytotoxicity in some crops, however, rate and timing of application can be used to avoid this problem. In fact, lime sulfur pesticide applications during and shortly after bloom can have a desirable crop-thinning effect on apples. The TR notes that lime sulfur may impair some beneficial insects and mites, but timing of use can minimize the negative effects. It also noted potential human health concerns from lime sulfur primarily due to the highly caustic nature of the undiluted product or the release of hydrogen sulfide. This concern can be mitigated if proper safety procedures are followed during mixing and label directions including personal protective equipment (PPE) are followed. The TR also provided an extensive list of alternative materials and practices, however, if an outbreak of mites or scale occurs, lime sulfur is an effective option.
The Crops Subcommittee (CS) discussion noted that some label-allowed uses of lime sulfur could negatively affect beneficial arthropods. To avoid this, the CS requested a separate work agenda item for an annotation change regarding timing and rates of lime sulfur use.

Justification for Vote:
The Crops Subcommittee finds lime sulfur compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR205.600 and is not proposing removal.

Subcommittee Vote:
Motion to remove lime sulfur from the National List at 205.601(e)(6)
Motion by: Brian Caldwell
Seconded by: Jerry D’Amore
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 1

Lime sulfur

Reference: 205.601(i) As plant disease control. (6) Lime sulfur.
Technical Report: 2014 TR
Petition(s): N/A
Past NOSB Actions: Actions: 04/1995 NOSB minutes and vote (pg. 341); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
Lime sulfur is on the National List at §205.601(e)(6) as an insecticide (including acaricide or mite control) and at §205.601 (j)(6) for plant disease control. As a fungicide, it is used to control powdery mildew, anthracnose, scab, peach leaf curl, fire blight, and several other plant diseases in tree fruit and berry crops.

Manufacture:
Lime sulfur is often referred to by its chemical name, calcium polysulfide. It is considered to be synthetic and is produced by reacting boiling calcium hydroxide [$CaOH2_2$] and ground sulfur (2014 TR).

International Acceptance:
Canadian General Standards Board Permitted Substances List
Allowed as a production aid

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Permits the use of lime sulphur (calcium polysulfide) as a fungicide, insecticide, acaricide.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Does not appear on this listing

International Federation of Organic Agriculture Movements (IFOAM)
Allowed as a crop protectant

Japan Agricultural Standard (JAS) for Organic Production
Lime sulfur powder allowed as Substances for Plant Pest and Disease Control

Environmental Issues:
Residues of lime sulfur are exempt from the requirement of a tolerance under 40 CFR 180.1232 as determined by the U.S. EPA because the calcium polysulfides found in lime sulfur products rapidly degrade to calcium hydroxide and sulfur in the environment and human body.

Discussion:
All public commenters were in favor of relisting lime sulfur for control of fungal and bacterial diseases as well as its uses for various insects. One commenter requested specifying only essential uses. Use is widespread across many crops and regions, and many comments note that there are not viable alternatives for its various uses.
Lime sulfur can cause phytotoxicity in some crops, however, rate and timing of application can be used to avoid this problem. In fact, lime sulfur pesticide applications during and shortly after bloom can have a desirable crop-thinning effect on apples. The TR notes that lime sulfur may impair some beneficial insects and mites, but timing of use can minimize the negative effects. It also noted potential human health concerns from lime sulfur primarily due to the highly caustic nature of the undiluted product or the release of hydrogen sulfide. This concern can be mitigated if proper safety procedures are followed during mixing and label directions including personal protective equipment (PPE) are followed. The TR also provided an extensive list of alternative materials and practices; however, an important benefit of lime sulfur is that it can be effective even after a fungus infection has taken place. Almost all other organic alternatives have only preventative action.
The Crops Subcommittee (CS) discussion noted that some label-allowed uses of lime sulfur could negatively affect beneficial arthropods. To avoid this, the CS requested a separate work agenda item for an annotation change regarding timing and rates of lime sulfur use.

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

Subcommittee Vote:
Motion to remove lime sulfur from the National List at 205.601(i)(6)
Motion by: Brian Caldwell
Seconded by: Jerry D'Amore
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 1

Hydrated lime

Reference: 205.601(i) As plant disease control.
(4) Hydrated lime.
Technical Report: 1995 TAP; 2001 TAP; 2002 TR (calcium hydroxide); 2015 TR (Livestock)
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote (pg. 345); 04/2006 sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation

Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Technical correction annotation change published 10/31/2003 (68 FR 61987); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
Hydrated lime is a synthetic substance limited for use in organic crop production for plant disease control (7 CFR 205.601(i)(4). It is also allowed as an external pest control in livestock production 21 (7 CFR 205.603(b)(5)). Regarding livestock applications, the final rule states that hydrated lime may not be used to cauterize physical alterations (medical treatment) or deodorize animal wastes. Hydrated Lime, also known as calcium hydroxide, is listed for handling as an allowed synthetic, nonagricultural substance which may be used as an ingredient in or on processed products (7 CFR 205.605(b)(8).

Manufacture:
According to the technical review (TR), the "industrial production of hydrated/slaked lime involves two elementary reactions beginning with naturally occurring limestone deposits. In the first step, ground limestone—which contains predominantly calcium carbonate ($CaCO_3$) with smaller amounts of magnesium, silicon, aluminum and iron oxide compounds—is thermally transformed into quicklime (Oates, 2010). Specifically, heating raw or minimally processed limestone to temperatures in excess of 900 ºC results in conversion of the calcium carbonate content of limestone to calcium oxide (CaO) in a material known as quicklime (equation 1). This thermal transformation occurs with liberation of carbon dioxide (CO_2) gas. In the slaking process, quicklime reacts exothermically (releases heat) with two equivalents of water to produce hydrated/slaked lime consisting primarily of calcium hydroxide [$Ca(OH)_2$] (equation 2). The normal hydration process is carried out at atmospheric pressure and temperatures of approximately 100 ºC (Kenny & Oates, 2007). A variation of the normal hydration process involves reaction of quicklime and water under a high steam pressure of up to 1 MPa and at temperatures approaching 180 ºC to form hydrates. After hydration, the hydrated lime product is dried, milled, and air classified" (TR 231-243).

International Acceptance:
Canadian General Standards Board Permitted Substances List
Hydrated lime is also listed in Section 4.3—Crop Production Aids and Materials—for use as a plant disease control agent only (CAN, 2011). Canadian organic regulations also permit the use of hydrated lime as a health care product and/or production aid in organic livestock production under Section 5.3 of the Permitted Substances Lists. According to this rule, hydrated lime is not allowed for use to cauterize physical alterations (medical treatment) or deodorize animal wastes. (2015 TR 177-181)

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Annex I of the European regulations allow "industrial lime from sugar production"—a byproduct of sugar production from sugar beet—as a fertilizer or soil conditioner. Calcium hydroxide may be used as a fungicide on fruit trees to control Nectria galligena in organic crop production under Annex II and as a processing aid in the production of processed organic foods of plant origin under Annex VIII (EC, 2008). European Union Organic regulations from the European Union do not permit the use of hydrated lime/calcium hydroxide 189 as an external parasiticide in livestock production. (TR 188-93)

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
The Codex Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods (CAC/GL 32-1999) do not list hydrated lime/calcium hydroxide for use in organic livestock or crop production. However, calcium hydroxide is included in the list of "processing aids which may be used for the preparation of products of agricultural origin referred to in Section 3 of these guidelines" (Codex, 2013). (TR 183-86)

International Federation of Organic Agriculture Movements (IFOAM) Norms
IFOAM Norms permit the use of "milk of lime" (i.e., hydrated/slaked lime, calcium hydroxide) for pest and disease control and disinfection in livestock housing and equipment (Appendix 5). Likewise, calcium hydroxide (slaked lime) is included in the "Indicative List of Equipment Cleansers and Equipment Disinfectants" (Appendix 4 – Table 2) for organic handling/processing. Calcium hydroxide is also listed as an approved food additive for maize tortilla flour and processing aid for sugar (Appendix 4 – Table 1). Lastly, application of calcium hydroxide (hydrated lime) is allowed on aerial plant parts only for plant disease control according to Appendix 3 of the IFOAM Norms (IFOAM, 2014). Hydrated lime is not explicitly listed as an approved miticide according to IFOAM. (TR 201- 208).

Japan Agricultural Standard (JAS) for Organic Production
Calcium hydroxide derived from calcium oxide (slaked lime) is listed in Table 1 of the standard as an approved fertilizer and soil improvement substance (JMAFF, 2012). Hydrated lime is not explicitly approved as a miticide according to Japanese organic regulations. (TR 195-199)

Environmental Issues:
Hydrated lime is released to the environment through various industrial waste streams and according to its use in agricultural production. Both calcium and hydroxide—the principal atomic/molecular subunits of hydrated lime—are abundantly present in natural waters; therefore, it is unlikely that small to moderate releases will adversely affect the aquatic or terrestrial environment. Large-volume accidental releases, however, could significantly raise pH of receiving waters and soils, resulting in toxic effects to non-target organisms. Hydrated lime is considered practically non-toxic to slightly toxic to freshwater fish and invertebrates when added in quantities that do not lead to significant changes in water pH. While certain strains of soil bacteria can tolerate extreme pH levels (e.g., pH 1.0 or 11.0), larger soft-bodied soil organisms are significantly more sensitive to changes in soil pH. Earthworms, for example, can only survive in the physiological pH range of 4.0 to 8.0. Changes in soil pH due to application of alkaline hydrated lime can also affect the bioavailability of toxic heavy metal contaminants as well as essential micronutrients. It is highly unlikely that hydrated lime from livestock treatments will be released to nearby soils in sufficient quantities to adversely impact the environment. Industrial production of the chemical precursor, quicklime (CaO), uses considerable amounts of energy and may release dust into the atmosphere. The use of more efficient modern kilns and bag filters can minimize the environmental impact of this process.

Discussion:
The Crops Subcommittee (CS) discussed this substance and the way it is listed and used across all areas of the National List, including Crops, Livestock, and Handling, on which it is listed as calcium hydroxide. Two Technical Advisory Panels (TAPs) and a Technical Report (TR) were compiled in 1995, 2001 and 2015, respectively. The use of hydrated lime (as has been practiced in organic production) is known to be an effective disease suppression practice. A previous sunset review noted that the use of hydrated lime in Bordeaux mix to make copper available for disease suppression is highly effective and widely

used by fruit and vegetable growers. The Subcommittee discussed the history of the substance and expressed a desire to receive further information on the current extent of the use of the substance.

Public comments from the Spring 2023 NOSB meeting were supportive of relisting hydrated lime. Growers illuminated the importance of this substance in organic tree fruit production to control diseases. A producer group emphasized that allowed alternatives such as horticultural oils and elemental sulfur may have limited efficacy. Use of the material is important as an ingredient in Bordeaux mixes, especially for treating bacterial gummosis in organic cherries. Growers were clear in the importance of hydrated lime as a tool for integrated pest management. An association expressed support for relisting, reporting a wide range of applications including in Bordeaux mix, fire blight, leaf curl, downy mildew, powdery mildew, peacock spot, walnut blight, etc. Certifiers listed low levels of users in Organic System Plans (OSPs) in some regions of the country, but listed numerous uses in regions with a higher density of orchards and vineyards. A stakeholder also noted that hydrated lime does not demonstrate phytotoxicity on either leaves or fruit.

The Crops Subcommittee discussed the potential for environmental issues especially in regard to aquatic environments. The TR notes that there is very little chance of contamination and the CS expressed comfort with continuing to list this material.

Justification for Vote:
The Crops Subcommittee finds hydrated lime compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR205.600 and is not proposing removal.

Subcommittee Vote:
Motion to remove hydrated lime from the National List
Motion by: Mindee Jeffery
Seconded by: Amy Bruch
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 2

Liquid fish products

Reference: 205.601(j) As plant or soil amendments.
(8) Liquid fish products - can be pH adjusted with sulfuric, citric or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5.
Technical Report: 1995 TAP; 2006 TR (fish-based fertilizers); 2019 TR (liquid fish products)
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote (pg. 346); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
Liquid fish products are used as fertilizers in the production of organic crops. Liquid fish products contain fundamental nutrients and many trace minerals critical for use in organic farming. Liquid fish foliar application can deliver important nutrients that can reduce certain nutrient stresses which can, in turn, improve crop yields.

Manufacture:
Liquid fish products are fish hydrolysates that are made from chopped fish byproducts that are (1) enzymatically digested and heated, or (2) enzymatically processed without heat (cold processing). Liquid fish products are then stabilized with an acid, such as phosphoric, sulfuric, or citric acid, to prevent microbial growth. The use of formic acid is prohibited due to phytotoxicity. A third method of liquid fish product manufacture utilizes fermentation by bacteria that produce lactic acid, which preserves the fish. All three methods of liquid fish product manufacture cannot result in a pH below 3.5.

International Acceptance:
Canadian General Standards Board Permitted Substances List
The Canadian Organic Standard allows for the use of liquid fish products. Acids are permitted to lower the pH to 3.5, but no prohibited preservatives can be used.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Liquid fish is not on the EU Annex I list of approved fertilizers, but the EU does allow fish meals.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Contingent upon recognition from a certification body or authority.

International Federation of Organic Agriculture Movements (IFOAM)
The International Federation of Organic Agriculture Movements (IFOAM) permits using fish and shell products and food processing of animal origin.

Japan Agricultural Standard (JAS) for Organic Production
The Japanese Organic Standard permits the use of food industry byproducts of fish origin if they are derived from natural sources.

Environmental Issues:
Nutrient runoff from excessively or improperly applied fertilizers can cause eutrophication of surface waters, potentially harming fish, and other aquatic animals.

Global impacts of commercial fisheries on marine ecosystems include documented fish population decline (and in some cases, ecosystem collapse) due to overharvesting. Liquid fish products are derived from several sources, including fish waste and bycatch/mortalities. To a lesser extent, fish are harvested for meal, oil, and solubles (also known as the wet reduction process). Large-scale population declines have occurred, with at least three fish species harvested for meal, oil, and soluble production. Considering this information, during the previous sunset review, conducted in 2018, the Crops Subcommittee added a work agenda item regarding liquid fish products. At the October 2020 meeting, the Board proposed, approved, and recommended to the NOP to add an annotation to liquid fish products at § 205.601(j)(8) to limit the use to fish sourced from waste left over aftermarket food fish are processed for human consumption, bycatch, and invasive species.

Discussion:

Previous NOSB sunset review summary: Historically, there has been strong support for keeping liquid fish products on the National List, and public comment at the October 2018 NOSB meeting reiterated the strength of that support. Farmers consider liquid fish products essential for many crops, including foliar and other applications. Concerns about the sustainability of source fish, including the possible use of wild fish harvested for the sole purpose of producing liquid fertilizers, were raised by the Crops Subcommittee, and extensive discussion during the October 2018 NOSB meeting focused on production methods and sources of raw fish material for the production of fish-based fertilizers. These discussions resulted in a work-agenda request to assess the environmental impact of harvesting wild, native fish for all fertilizer purposes, to protect natural fish populations, and to ensure that liquid fish and other fish-based fertilizer products used in organic production are not harmful to the environment. Information from this review could inform future policy recommendations regarding the use of wild fish for organic fertilizers but is beyond the scope of review for this sunset review.

The current Crops Subcommittee discussed the uses of liquid fish products as a plant or soil amendment, the manufacturing process, and environmental issues. The Subcommittee also reviewed the October 2020 NOSB recommendation on Wild, Native Fish for Liquid Fish Products, which the NOP has not implemented; it is currently listed as "Closed" in the NOSB Recommendations Library.

Spring 2023 Sunset Review: The NOSB reviewed liquid fish products, and Board members and commenters supported relisting, as liquid fish products deliver needed nutrients to a wide variety of crops and growing environments. Two commenters requested more rigor with the annotations to reduce environmental impact. The community also expressed support for the 2020 NOSB Recommendation on Wild Native Fish and called for its implementation. The 2020 recommendation limits liquid fish products to be made with fish "sourced only from fish waste, bycatch, or invasive species." The NOP stated at the Spring 2023 meeting that the recommendation regarding the annotation was currently on hold.
The Subcommittee continued discussing the importance of the annotation and reviewed the history of previous marine material votes, including the fish oil annotation (handling) from the Fall 2021 NOSB meeting, which included the reliance on a third-party certification until organic aquaculture standards are approved. The Subcommittee also reviewed the 2016 NOSB recommendation to add squid byproducts to the National List with the rationale that "the addition of squid byproducts is consistent with the National List listing for liquid fish products that are pH adjusted with synthetic sulfuric, citric or phosphoric acid (7 CFR 205.601(j)(7)). Only squid byproducts originating from the food processing waste stream are acceptable for use in organic agriculture. Whole squid caught for fertilizer purposes would not be included in this listing". Since there seems to be a precedent for the term byproducts (similar to bycatch) being accepted, the Subcommittee was hopeful that the liquid fish annotation from 2020 could eventually be completed. At the time of this writing, the

The NOSB Recommendations Library lists the recommendation for Wild, Native Fish for Liquid Fish Products, as closed, and the reason stated is "technical complexity of marine environments makes rulemaking on these topics problematic. NOP does not currently plan to move this item forward".

Commenters also expressed concerns that even if fish do not have commercial value they may have ecological value. Commenters also noted that use of discarded fish parts for fertilizer may remove food from marine ecosystems; there' a potential for contamination with PFAS, and more restrictive annotations could be added to reduce environmental impact. The Board also considered that farming practices need to be leveraged when applying liquid fish products.

Lastly, one commenter noted concerns about the potential of fortification with phosphorus. The Board will review further information regarding the essentiality of phosphorus versus the other acids allowed for use to adjust pH listed in the annotation.

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

Subcommittee Vote:
Motion to remove liquid fish products from the National List
Motion by: Amy Bruch
Seconded by: Mindee Jeffery
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 1

Sulfurous acid

Reference: 205.601(j) As plant or soil amendments.
(11) Sulfurous acid (CAS # 7782-99-2) for on-farm generation of substance utilizing 99% purity elemental sulfur per paragraph (j)(2) of this section.
Technical Report: 2010 TR; 2014 TR; 2023 Limited Scope TR
Petition(s): 2008
Past NOSB Actions: 05/2009 NOSB recommendation; 10/2014 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 07/07/2010 (75 FR 38693); Sunset renewal notice published 06/19/2015 (80 FR 35177); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
The primary use of sulfurous acid is as an acidifying agent to neutralize and reduce excessive alkalinity in soil and/or water. The resulting acidic irrigation water can be helpful with nutrient deficiencies that arise when saline or alkaline conditions tie up essential micronutrients. This use supports improved crop yields and can help to reduce soil degradation from salinity build up.

Manufacture:
The primary ingredients used in the preparation of sulfurous acid are water and elemental sulfur. Almost all elemental sulfur is produced as a byproduct of coal, natural gas, and petroleum refinement. Sulfurous acid is manufactured by spraying water through smoke and fumes created by burning

elemental sulfur. Several substances are created in this process, including sulfur dioxide, hydrogen sulfide, and hydrogen sulfite.

International Acceptance:
Canadian General Standards Board Permitted Substances List
Sulfurous acid can be used in the production of Canadian Organic Products as a preservative in alcoholic beverages made from grapes or other fruit, although minimum use is recommended. No mention is made of sulfurous acid as a soil amendment (CGSB, 2011a,b).

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Sulfurous acid is allowed in wine production only.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Sulfurous acid is allowed in wine production only.

International Federation of Organic Agriculture Movements (IFOAM)
Sulfurous acid is allowed by IFOAM in wine production, as a pH adjuster in sugar production, and is a permitted soil amendment.

Japan Agricultural Standard (JAS) for Organic Production
JAS does not mention sulfurous acid but allows sulfuric acid as a pH adjuster in sugar production.
Environmental Issues:
Sulfurous acid appears on the EPA non-food inert list and does not require a tolerance or an exemption from tolerance. According to a sulfurous acid manufacturer (and noted in the 2014 TR, lines 229-232) sulfur dioxide released into the atmosphere by a sulfurous acid generator is minimal. The EPA does not regulate this emission. Sulfurous acid contains no persistent substances of record. Hydrogen sulfite present in the solution is metabolized by sulfite-reducing bacteria and plants that recycle sulfurous acid into bioavailable sulfur compounds. Water and other dissolved compounds leach into the soils. Functionally sulfurous acid serves to condition soils by adjusting pH.

Regarding human health concerns and per the 2014 TR, sulfurous acid is not expected to be carcinogenic (2014 TR, lines 370-371). Sulfur dioxide is approved by the US Food and Drug administration for use as a food preservative and food colorant (2014 TR, lines 371-372).

Discussion:
During the Fall 2018 meeting, the NOSB voted unanimously to keep sulfurous acid on the National List. Most of the written comments at the Fall 2018 meeting supported the relisting, several indicated "no reported use" and one commented that no synthetic fertilizers should be permitted.

The NOSB discussed this listing at its Spring 2023 meeting with some members referencing stakeholder comments, which declared sulfurous acid highly essential in the Pacific Northwest. The Board also noted that sulfurous acid has broader base applications as it removes contaminants as well as adjusts pH.

A limited scope TR was received by the Crops Subcommittee in early February 2023 and was declared sufficient during the Subcommittee meeting held on February 9th, 2023. The TR authors did a seemingly complete job of listing potential alternatives and then evaluating these alternatives as being less effective than sulfurous acid.

Questions to our Stakeholders:
None.

Justification for Vote:
The Subcommittee finds sulfurous 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 sulfurous acid from the National List
Motion by: Jerry D'Amore
Seconded by: Brian Caldwell
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 1

Ethylene gas

Reference: 205.601(k) As plant growth regulators.
(1) Ethylene gas—for regulation of pineapple flowering.
Technical Report: 1999 TAP; 1999 TAP (handling) (pg. 14-54); 2000 TAP (supplemental information); 2007 TAP; 2011 Limited Scope TR; 2023 TR (crops, handling)
Petition(s): N/A
Past NOSB Actions: 10/1999 NOSB recommendation (handling) (pg. 443); 10/2001 recommendation (handling) (pg. 2); 11/2005 NOSB sunset recommendation; 04/2011 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Technical correction annotation change published 10/31/2003 (68 FR 61987); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published and was effective 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
Ethylene gas is on the National List for use as a plant growth regulator, for organic pineapple production only. Ethylene gas is used to induce uniform flowering in pineapples and is applied 7-15 months after planting. Application can be repeated two to three times after the initial application (2011 TR 53-56). Ethylene gas is made from hydrocarbon feedstocks, such as natural gas liquids or crude oil. Operators should be well trained and prepared. However, the safety concern to workers is limited when correctly used and monitored (2007 TAP, pg. 4).

Manufacture:
The principal source of commercial ethylene is from thermal or catalytic cracking of hydrocarbon feedstocks such as natural gas or crude oil. During this process chemical bonds within the hydrocarbon molecules are broken, and a different chemical substance is produced.

Ethylene is the petrochemical produced in the largest quantities worldwide (IARC, 1994). In 2014, world ethylene production was 134 million (metric) tonnes (Lazonby, 2017). As of 1994, over 95% of worldwide annual production is based on thermal "cracking" of petroleum hydrocarbons with steam (IARC, 1994). These fractions are obtained from drilling (or hydrofracturing) of oil or natural gas. Thermal cracking (sometimes referred to as pyrolysis) is a chemical process by which long chain hydrocarbons with higher molecular masses are converted to short chain hydrocarbons of lower molecular mass [2023 TR 304-309].

All of these methods involve reactions that produce a chemically changed substance (ethylene) from either petroleum feedstocks, or from dehydration of ethanol mediated by catalysts. Thus, all these forms should be considered synthetic (NOP, 2016a) and from nonagricultural sources (NOP, 2016b). [2023 TR 369-371]

Various feedstocks, including ethane, propane, butanes, naphthas, and gas oils are used to produce ethylene, depending on availability, price, and products desired (Lazonby, 2017). Naphthas are the principal raw material used in western Europe and Japan, accounting for over 80% of the ethylene produced. Ethane is the primary feedstock in the U.S., followed by propane, naphthas, gas oils, and butane (Zimmerman & Waltz, 2011) [2022 TR 311-315].

In thermal cracking, the feedstock gases (ethane, propane or butane) or the liquids (naphtha or gas-oil) are preheated and vaporized, and are mixed with steam and heated to 1050-1150 K (777-877 °C) in a tubular reactor. The high temperature and pressure cause the long chain hydrocarbon to be converted to low relative molecular mass alkenes plus by-products (Lazonby, 2014). [2022 TR 317-320]

<u>Catalytic cracking</u>
Catalytic cracking uses a catalyst, typically a zeolite, which adsorbs the long-chain hydrocarbon feedstocks and removes hydrogen atoms. [1] This causes the long chains to split into shorter chain molecules with double bonds, which are useful to the petrochemical industry. The feedstock is gas oil, which is vaporized, passed through a fine zeolite powder, and heated to 700-800 K (427 - 527 °C) in a reactor. The products behave like a fluid and continuously flow out of the furnace with the cracking products. The temperature, residence time, and the catalyst determine the product proportions (Lazonby, 2014) [2022 TR 332-338].

<u>Dehydration of ethanol</u>
Dehydration of ethanol is another commercial route to ethylene (IARC, 1994; Zimmerman & Waltz, 2011; Fan 2013). In the catalytic dehydration of ethanol to form ethylene, an acid catalyst first protonates the hydroxyl group, which leaves as a water molecule. The conjugate base of the catalyst then deprotonates the methyl group, and the hydrocarbon rearranges into ethylene (Fan, 2013). This method is not commonly used to produce large volumes of ethylene, as it is endothermic with a high optimal reaction temperature (180-500 °C), which makes the ethylene expensive to produce. Dehydration of bioethanol is occurring in Brazil and India and holds promise for producing ethylene from non-fossil fuel sources (bioethanol from sugar cane or cellulose). At present, the output is relatively

limited and used for further production of polyethylene (Fan, 2013; Lazonby, 2017; Schill, 2010) [2022 TR 340-349].

Catalytic generators

Small catalytic generators are used in sealed ripening rooms to dehydrate ethanol into ethylene, and can deliver controlled levels of ethylene gas to ripen fruit, e.g., 100-150 ppm for bananas. (NWHort 2008, Catalytic Generators 2022). This process uses dehydration of ethanol by passing it over a bed of solid catalyst held at high temperatures. The catalysts are typically activated alumina and phosphoric acid or zinc oxide with alumina (Kays & Beaudry, 1987) [TR 351-356].

International Acceptance:

Canadian General Standards Board Permitted Substances List

Allowed for use in Canadian organic production for post-harvest ripening of tropical fruit and de-greening of citrus and to control sprouting of potatoes post-harvest in holding bins.

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

Allowed for use in Europe organic production in the degreening of bananas, kiwis, and kakis; Degreening of citrus fruit only as part of a strategy for preventing fruit fly damage in citrus; Flower induction of pineapple; sprouting inhibition in potatoes and onions.

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

CODEX indicates:

"For degreening of citrus for fruit fly prevention and as a flowering agent for pineapples. As sprouting inhibitor for potatoes and onions: Need recognized by the certification body or authority for sprout inhibition of stored potatoes and onions where varieties that have long dormancy characteristics are not available, or these varieties are not suited to local growing conditions. Must be used in a manner that minimizes exposure to operators and workers."

International Federation of Organic Agriculture Movements (IFOAM)

Ethylene gas is allowed in organic production by IFOAM for the de-greening and ripening of citrus.

Japan Agricultural Standard (JAS) for Organic Production

JAS limits the allowed use of ethylene gas to the ripening of bananas, kiwifruits, and avocados after harvest.

Environmental Issues:

According to the 2023 TR, the manufacturing process through cracking is highly energy intensive. Extraction and transport contribute significantly to increasing greenhouse gas emissions, acidification and eco-toxicity (air and water). [TR 479-482]

Petroleum refineries are a major source of hazardous and toxic air pollutants. In the TR, manufacture of ethylene does produce "significant" amounts of carbon dioxide, and notes that this may be a factor in development of alternative technologies for production of ethylene. Ethylene, one of the most important chemicals in use, consumes 30% of the total energy of the chemical industry. This study found that China reduced CO_2 emissions by 29.4% per ton of ethylene produced from 2000-2016 due to improvements in technology and evaluated various methods for future increased reductions (2022 TR 488-495).

As for ethylene's impact on the environment during postharvest handling, the 2023 TR states that since the ethylene is a gas at environmental temperatures, this is the primary route of exposure to the environment. Health Canada considered environmental modelling studies and found that ethylene released to the air will remain in the air, and that only negligible amounts will partition to soil, water and sediment [TR 507-511]. The same study concluded that there is little risk of harm to the environment or to organisms since the substance is not present in quantities or concentrations that could cause long term harmful effects on the environment or biodiversity. [2023 TR 531-536]

If every acre in pineapple production (organic and conventional) was treated with high application rates, it would be 5% of the total ethylene emissions (2023 TR lines 513-521). No new issues of human health or environmental concerns were raised that had not been addressed in previous NOSB Sunset review cycles. The main safety concern in relation to ethylene use has been the explosive nature of the gas in the air. Operators should be well trained and prepared, though the safety concern to workers is low when correctly used and monitored (2007 TAP, pg. 4). Ethylene is not considered a food ingredient, and is not regulated by FDA. It is exempt from residue tolerances established by EPA when used as a postharvest plant growth regulator on food crops (2023 TR lines 455-457).

Discussion:
The Crops Subcommittee discussed the use, manufacturing, and environmental issues, and previous NOSB reviews of ethylene gas.

As part of the Spring 2018 public meeting, the Crops Subcommittee requested additional information regarding the issue of scale and the use of ethylene and alternative technologies. Written and oral commenters expressed continued support for this material.

At the Spring 2023 public meeting, the Crops Subcommittee requested additional information on the need for expanding the use of this material and if there were any alternatives. Again, written and oral commenters expressed continued support for this material, stating that it is an essential tool for the commercial production of pineapples for the export market and no viable alternatives exist. Without ethylene, commenters said, it would be impossible to achieve the uniform ripening necessary for timing the harvest for fruit shipment. There were 13 commenters that supported the relisting of this material with only one in opposition, stating that the material does not fit any OPFA criteria, and it is not essential to produce the crop but rather is employed for economic reasons. One member of the Subcommittee expressed concern about the use of this material to produce the crop during unfavorable growing times, which results in poor quality fruit.

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

Subcommittee Vote:
Motion to remove ethylene gas from the National List
Motion by: Logan Petrey
Seconded by: Jerry D'Amore
Yes: 1 No: 6 Abstain: 0 Recuse: 0 Absent: 1

Microcrystalline cheesewax

Reference: 205.601(o) As production aids.
(1) Microcrystalline cheesewax (CAS #'s 64742-42-3, 8009-03-08, and 8002-74-2)-for use in log grown mushroom production. Must be made without either ethylene-propylene co-polymer or synthetic colors.
Technical Report: 2018 TR
Petition(s): 2007; 2008 (Addendum #1)
Past NOSB Actions: 05/2008 NOSB recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 03/15/2012 (77 FR 8089); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
Microcrystalline cheesewax has been used in agriculture as a production aid in log-grown shiitake mushrooms since the 1980s, and has been allowed in organic agriculture since 2012. Microcrystalline cheesewax is used to seal holes in hardwood logs (commonly oak) after the shiitake spawn is inserted.

Manufacture:
Microcrystalline cheesewax is a food-grade product made up of a mixture of microcrystalline wax, paraffin wax, and petroleum. All three of these materials come from refining crude oil, where these petroleum waxes are separated by fractional distillation followed by fractional crystallization.

International Acceptance:
Canadian General Standards Board Permitted Substances List
CAN/CGSB-32.311 "Table 6.5 Processing aids" prohibits microcrystalline wax "either alone or in formulation with paraffin wax."

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Neither microcrystalline cheesewax, nor its components, are listed in EC No. 834-2007 nor EC No.889/2008.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Neither microcrystalline cheesewax, nor its components, are listed in the CODEX (GL 32-1999).

International Federation of Organic Agriculture Movements (IFOAM)
Neither microcrystalline cheesewax, nor its components are listed in IFOAM.

Japan Agricultural Standard (JAS) for Organic Production
Neither microcrystalline cheesewax, nor its components, are listed in the JAS for organic food production.

Environmental Issues (and human health concerns):
Per the 2018 TR and referenced studies: "There have been no reports that indicate the likelihood of the bioaccumulation of either microcrystalline cheesewax or its breakdown products, nor any reports of associated ecotoxicity." Microcrystalline cheesewax is widely regarded as "readily biodegradable" [232-239].
Also, per the 2018 TR, "...microcrystalline cheesewax, its components, and its breakdown products are chemically stable and are not known to be health risks." [308-309]. Microcrystalline cheesewax is sometimes heated just before being used as a sealant, at which time caution should be used to avoid inhaling the vapor as this could cause respiratory irritation [317].

Discussion:
At the Fall 2018 meeting, the NOSB voted unanimously to keep microcrystalline cheesewax on the National List. Some of the written comments reviewed during the Fall 2018 meeting focused on the current need for microcrystalline cheesewax, saying that the production method (inoculated logs) was no longer used. This notion was countered by the assertion that there was still wide use by small growers.

During the April 2023 NOSB meeting this same question of continued use was discussed and reaffirmed as essential for small growers.

Questions to our Stakeholders:
None

Justification for Vote:
The Subcommittee finds microcrystalline cheesewax compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR205.601(o) and is not proposing removal.

Motion to remove microcrystalline cheesewax from the National List
Motion by: Jerry D'Amore
Seconded by: Brian Caldwell
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 1

Potassium chloride

Reference: 205.602(e) Potassium chloride—unless derived from a mined source and applied in a manner that minimizes chloride accumulation in the soil.
Technical Report: 1995 TAP; 2023 TR
Petition(s): N/A
Past NOSB Actions: 11/1995 NOSB minutes and vote (pg. 22); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
Potassium is required for health in humans, plants, and microorganisms (1995 TAP pg. 4, 14). Potassium is an essential element for plants as they use it to regulate movement of water and nutrients within the plant, photosynthesis regulation, and enzyme activation. While potassium is found in many soils, it may not exist naturally in a high enough concentration for optimal plant growth, and/or it may be present but in a bound format rendering it unavailable. Potassium is commonly used by growers either alone, as a complex in potassium chloride, or as an ingredient in a fertilizer blend for soil supplementation.

Chloride is also an essential element for plants (TAP pg. 12); however, monitoring of chloride use is required to assure soil salinity is managed appropriately. The current annotation in the USDA organic regulations stipulates chloride monitoring when potassium chloride is used to prevent chloride accumulation in soils.

Manufacture:
Potassium chloride is a mineral that occurs naturally and is a product of potash mining where water is forced into the ground to dissolve potassium chloride deposits (1995 TAP, pg. 3). Brine is brought back to the surface where the water is evaporated off to isolate the potassium chloride. Potassium chloride can similarly be produced from sea water extraction via solar evaporation.

International Acceptance:
Canadian General Standards Board Permitted Substances List
Permitted for use from mined sources such as sylvite, carnalite, and potash.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Not specified as permitted for use.

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

International Federation of Organic Agriculture Movements (IFOAM)
Permitted for use.

Japan Agricultural Standard (JAS) for Organic Production
Permitted as “fertilizers and soil improvement substances.”

Environmental Issues:
Potassium chloride is derived from energy-intensive mining activities, and there are impacts associated with its extraction and the processing wastes that can be generated. While heavy metals have been known to concentrate near potassium chloride production, there has not been widespread concern about significant impacts.

Discussion:
At the Fall 2018 meeting, the NOSB unanimously voted to relist potassium chloride at 7 CFR 205.602.

During 2018 meetings, public commenters were also unanimously supportive of continued listing with the current annotation, and there were no other non-chloride types reported by the public. At the time, one certifier recommended that the NOSB request a technical report (TR) on potassium chloride to thoroughly consider the use of synthetic dust suppressants or other synthetic additives.

A draft TR was provided to the Crops Subcommittee on December 2, 2022 and was deemed sufficient, although the Subcommittee requested additional information on effective organic alternatives to potassium chloride. This 2023 TR was pending at the time of deadlines for the Spring 2023 meeting and received by the board thereafter. The technical report is helpful in reiterating the importance of potassium in crop nutrition and outlines ongoing research for recent years into the complex relationship between potassium, plant tissue, and the environment, particularly with respect to plant resilience and stress response. Similarly, the report describes ongoing challenges in understanding the relationship between potassium and nitrogen in crop growth. It also discusses the tension between chlorine deficiency and excess chlorine in plants. Chloride ions are quite soluble and not easily absorbed by organic matter or clay in soils, hence the requirement to closely monitor chlorine accumulation that could result in the application of the listed substance (the TR offers some critique of the high end of the range of rates of application of the substance sometimes recommended by agronomists). The main concern with overapplication of potassium chloride is its contribution to soil and groundwater salinity (and the highest salt index of any common dry fertilizer), but little data could be present to suggest its toxicity to fauna. The TR did allude to the energy intensiveness of the production of potassium chloride and the associated contribution that production can have to atmospheric carbon concentrations and climate change.

The Crops Subcommittee has had anecdotal discussions about whether or not potassium chloride (per this listing) is being used by organic growers. Subcommittee members have acknowledged that potassium chloride is an inexpensive means of dealing with potassium deficiencies in the soil and is likely very geographically specific in its application (potassium is prevalent in high mineral soils, for example, and thus minimal need for supplemental potassium), but also noted that potassium sulfate may be another good cost-effective alternative with less adverse effect. Subcommittee members also discussed the nature of the annotated listing itself and whether it has been successful in reducing chloride leaching – and associated environmental impact -- where it is applied, and also noted that if chloride buildup in the soil is an issue that merits monitoring, there are likely other problematic accumulations in the soil in such contexts as well. The Crops Subcommittee discussed the wide use of potassium chloride in conventional agriculture and the fact that conventional growers are able to mitigate salt concerns by virtue of the conventional toolkit.

The full Board discussed this listing at its Spring 2023 meeting in the wake of strong continued support from the community for the listing to continue in its current incarnation. Board members noted that potassium chloride is used by some organic producers as a less expensive potassium source and without creating the chloride accumulation that was the primary concern from the annotation on this listing. Members also discussed the use of potassium sulfate as an alternative to potassium chloride and acknowledged the lower potassium levels in potassium sulfate and the substance's potential for soil acidification.

The Subcommittee discussed monitoring guidelines for chloride concentration.

Questions to our Stakeholders

1. Is potassium chloride widely used by producers of organic crops?

2. What is the process at certification for monitoring chloride concentration when this substance is listed for use on an organic system plan?

Justification for Vote:
The Subcommittee finds this listing of potassium 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 potassium chloride from the National List at 7 CFR 205.602(e)
Motion by: Wood Turner
Seconded by: Mindee Jeffery
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 1

National Organic Standards Board
Handling Subcommittee
Petitioned Material Discussion Document
Magnesium Carbonate
August 1, 2023

Summary of Petition [Magnesium carbonate petition]:
This document reviews the petitioned use and addition of magnesium carbonate as a processing aid to the National List at 7 CFR 205.605: Nonagricultural (non-organic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

Introduction:
In December 2022, Leroux petitioned the United States Department of Agriculture (USDA) National Organic Program (NOP) to add magnesium carbonate as a processing aid to the National List at § 205.605. The Handling Subcommittee requested a Technical Report (TR), which is still in process. Therefore, the information presented in this discussion document is solely from the petition.

Relevant Background:
Magnesium carbonate was previously listed at § 205.605(b) with the following annotation: "for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))," prohibited in agricultural products labeled "organic"." (65 FR 80547, page 1708)

In 2005, magnesium carbonate was petitioned for inclusion to the National List as a filtering aid at § 205.606. The petition was rejected by the NOP because it was incomplete, and magnesium carbonate was ineligible to be added at § 205.606 as it is not agricultural.

During the sunset review process in 2015, the Board voted to remove magnesium carbonate from the National List stating, "the material does not appear to be essential to organic handling." Magnesium carbonate was removed from the National List effective August 7, 2017. The final rule stated, "AMS received no public comments concerning the proposed removal of…magnesium carbonate from the National List." (82 FR 31241, page 14)

Use:
Magnesium carbonate is used as a drying agent/anti-caking agent. The petitioned use is focused on organic chicory production, specifically organic instant chicory powder. The petitioner notes that during the final steps of atomization and packing, instant chicory powder sticks to the walls of the installations, requiring several stops for cleaning which reduces the rate of production.

The petition states, "The use of magnesium carbonate as a processing aid is intended for the manufacture of the instant extract of chicory obtained by atomization. The incorporation of *[the petitioned substance]* is done in the crown of air at the bottom of the tower feeding the dryer in order to obtain re- aeration and very good homogeneity of the product (figures 1 and 2). The maximum amount used would be 0.05%." The petition includes several diagrams to pictorially represent the use of magnesium carbonate in the production of organic instant chicory powder.

The petitioner also petitioned magnesium carbonate hydroxide. These appear to be used interchangeably.

Summary of Review:
The Handling Subcommittee is waiting to receive the TR to fully evaluate the manufacturing process and review criteria for addition to the National List. However, the Subcommittee members did discuss this substances history along with current alternatives.

It appears that silicon dioxide is currently used as an alternative. However, the petitioner states that there have been some questions raised regarding the presence of nanotechnology in silicon dioxide. The NOP prohibits the use of nanotechnology (NOP Policy Memo 15-2), therefore the Subcommittee is unsure of the merit of this argument.

Questions to our Stakeholders:
1. What, if anything, has changed since 2017 when magnesium carbonate was removed from the National List due to essentially?
2. Why are other substances listed on the National List as drying agents/anti-caking agents not effective for organic instant chicory powder?
3. Are there other organic products that would benefit from the use of magnesium carbonate for this use as a processing aid or should use be restricted as an anticaking agent only in instant chicory powder?
4. When listed previously magnesium carbonate was restricted for use in “made with organic” products only. If the NOSB recommends listing, should it consider limiting for use only in “made with organic” products?

Subcommittee Vote:
Motion to accept the discussion document on magnesium carbonate
Motion by: Kyla Smith
Seconded by: Jerry D’Amore
Yes: 8 No: 0 Abstain: 0 Recuse: 0 Absent: 1

National Organic Standards Board
Handling Subcommittee
Petitioned Material Discussion Document
Magnesium Carbonate Hydroxide
August 1, 2023

Summary of Petition [Magnesium carbonate hydroxide petition]:
This document reviews the petitioned use and addition of magnesium carbonate hydroxide as a processing aid to the National List at §205.605(): Nonagricultural (non-organic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

Introduction:
In December 2022, Leroux petitioned the United States Department of Agriculture (USDA) National Organic Program (NOP) to add magnesium carbonate hydroxide as a processing aid to the National List at §205.605(b). The Handling Subcommittee requested a Technical Report (TR), which is still in process. Therefore, the information presented in this discussion document is solely from the petition.

Relevant Background:
Magnesium carbonate hydroxide has never been petitioned or included on the National List.

However, Leroux has also petitioned magnesium carbonate for the same use. Magnesium carbonate was previously listed at § 205.605(b) with the following annotation: “for use only in agricultural products labeled “made with organic (specified ingredients or food group(s)),” prohibited in agricultural products labeled “organic”.” (65 FR 80547, page 1708)

In 2005, magnesium carbonate was petitioned for inclusion to the National List as a filtering aid at § 205.606. The petition was rejected by the NOP because it was incomplete, and this substance was ineligible to be added at § 205.606 as it is not agricultural.

During the sunset review process in 2015, the Board voted to remove magnesium carbonate from the National List stating, “the material does not appear to be essential to organic handling.” Magnesium carbonate was removed from the National List effective August 7, 2017. The final rule stated, “AMS received no public comments concerning the proposed removal of…magnesium carbonate from the National List.” (82 FR 31241, page 14)

Use:
Magnesium carbonate hydroxide is used as a drying agent/anti-caking agent. The petitioned use is focused on organic chicory production, specifically organic instant chicory powder. The petitioner notes that during the final steps of atomization and packing that the instant chicory powder sticks to the walls of the installations, requiring several stops for cleaning which reduces the rate of production.

The petition states, “The use of magnesium hydroxide carbonate as a processing aid is intended for the manufacture of the instant extract of chicory obtained by atomization. The incorporation of E504(ii) is done in the crown of air at the bottom of the tower feeding the dryer in order to obtain re-aeration and very good homogeneity of the product (figures 1 and 2). The maximum amount used would be 0.05%.” The petition includes several diagrams to pictorially represent the use of magnesium carbonate hydroxide in the production of organic instant chicory powder.

The petitioner also petitioned magnesium carbonate. These appear to be used interchangeably.

Summary of Review:
The Handling Subcommittee is waiting to receive the TR to fully evaluate the manufacturing process and review criteria for addition to the National List. However, the Subcommittee members did discuss the history of the related petitioned substance magnesium carbonate along with current alternatives.

It appears that silicon dioxide is currently used as an alternative. However, the petitioner states that there have been some questions raised regarding the presence of nanotechnology in silicon dioxide. The NOP prohibits the use of nanotechnology (NOP Policy Memo 15-2), therefore the Subcommittee is unsure of the merit of this argument.

Questions:
1. Why are other substances listed on the National List as drying agents/anti-caking agents not effective for organic instant chicory powder?
2. Are there other organic products that would benefit from the use of magnesium carbonate hydroxide for this use as a processing aid or should use be restricted as an anticaking agent only in instant chicory powder?
3. When listed previously magnesium carbonate was restricted for use in “made with organic” products only. If the NOSB recommends listing, should it consider limiting magnesium carbonate hydroxide for use only in “made with organic” products?

Vote in Subcommittee:
Motion to accept the discussion document on magnesium carbonate hydroxide.
Motion by: Kyla Smith
Seconded by: Dilip Nandwani
Yes: 8 No: 0 Abstain: 0 Recuse: 0 Absent: 1

Sunset 2025
Meeting 2 - Reviews
Handling Substances § 205.605 & § 205.606
October 2023

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. If a new technical report has been requested for a substance, it is noted in this list. Substances included in this document may also be viewed in the NOP's Petitioned Substances Index.

Request for Comments
Written public comments will be accepted through September 28, 2023 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

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 § 205.605(a), § 205.605(b), and/or § 205.606 Substances in Organic Production:
If you provide comments supporting the allowance of a substance at § 205.605(a), § 205.605(b), and/or § 205.606, you should provide information demonstrating that the substance is:

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

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

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

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

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

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

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

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

Written public comments will be accepted through September 28, 2023 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

§205.605 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)).'':

§205.605(a): Nonsynthetic substances allowed in organic handling:

- Calcium carbonate
- Flavors
- Gellan gum (high-acyl form only)
- Oxygen
- Potassium chloride

§205.605(b): Synthetic substances allowed in organic handling:

- Alginates
- Calcium hydroxide
- Ethylene
- Glycerides (mono and di)
- Magnesium stearate
- Phosphoric acid
- Potassium carbonate
- Sulfur dioxide
- Xanthan gum

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

§205.606: Nonorganic agricultural substances allowed in organic handling:

- Fructooligosaccharides
- Gums - water extracted only (Arabic; Guar; Locust bean; and Carob bean)
- Lecithin - de-oiled
- Tamarind seed gum
- Tragacanth gum

Calcium carbonate

Reference: 205.605(a) Nonsynthetics allowed. (6) Calcium carbonate.
Technical Report: 1995 TAP; 2018 TR
Petition(s): N/A
Past NOSB Actions: 11/1995 NOSB minutes and vote (pg. 12); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review
Subcommittee discussion included review of the public comments from the spring meeting.

Use:
Calcium carbonate is widely used as a dietary supplement, antacid, dough conditioner, acidity regulator in wines, food stabilizer, anticaking agent, gelling agent, glazing and release agent, thickener, bulking agent, and nutritional fortification additive. The U.S. Food & Drug Administration (FDA) allows the use of calcium carbonate as a binding agent in meat and poultry pieces and a color additive mixture for coloring foods at 21 CFR 73.70. Calcium carbonate is also a precursor to the substance calcium citrate, which is identified on the National List in 7 CFR 205.605(b).

Manufacture:
Calcium carbonate is a fine, white microcrystalline mined powder which is stable in air. Calcium carbonate is a mined mineral of at least 98% purity that is ground and screened.

International Acceptance:
Canadian General Standards Board Permitted Substances List; CAN/CGSB-32.311-2015:
Allowed, prohibited for use as a coloring agent.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Appears in Annex VII, Section A - Food additives including carriers, shall not be used for colouring or calcium enrichment of products.

Appears in Annex VII, Section B – Processing aids and other products, which may be used for processing other ingredients of agricultural origin from organic production.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Appears on Table 3, Additives permitted for use under specified conditions in certain organic food categories or individual food items.

Appears on Table 4, Processing aids which may be used for the preparation of products of agricultural origin referred to in Section 3.

International Federation of Organic Agriculture Movements (IFOAM)
Appears in Appendix 4 – Table 1: List of approved additives and processing/post-harvest handing aids.

Japan Agricultural Standard (JAS) for Organic Production
Appears in Table 1, Food additives, Limited to be used for confectionary, sugar, processed bean foods, noodles and bread, or for dairy products as neutralizing substance.

Environmental Issues:
The mining and processing of calcium carbonate can have negative environmental impacts, which may include impacts on above and below ground water systems. Mining may have impacts on biological diversity as the mining may draw down the water table and impact surface water features that play host to a variety of species. Inhalation of calcium carbonate dust may cause upper respiratory irritation, and exposure may cause eye irritation. Personal protective equipment will avoid these issues. There are limited studies on the impact of calcium carbonate on humans. In the reported studies, increased intake of calcium can result in hypercalcemia and the formation of kidney stones when total daily calcium intake reaches levels at or above 2000 mg. This proposal to remove will be considered by the NOSB at its public meeting. The Handling Subcommittee has determined that calcium carbonate continues to be essential to organic production.

Ancillary Substances:
None

Discussion:
The Spring 2023 commentors were all supportive of relisting calcium carbonate. Many uses were mentioned in the comments, although no one use was mentioned more than others. It was mentioned that calcium carbonate is used in fresh vegetable and rice production, as a food stabilizer, acid reducer in wine production, antacid, dietary supplement, and anticaking agent; just to name a few. One certifier noted 74 applications of use for calcium carbonate. Supportive of relisting, one commentor requested an annotation by specific use to evaluate essentiality. During previous Board meetings, public comments also widely supported the relisting of this material as well noting its essentiality to organic production in the absence of viable alternatives.

Calcium carbonate is not listed in the Organic Foods Production Act of 1990.

Justification for Vote:
The Handling Subcommittee finds calcium carbonate 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 carbonate from the National List
Motion by: Kim Huseman
Seconded by: Wood Turner
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

Flavors

Reference: 205.605(a) Nonsynthetics allowed.
(12) Flavors - nonsynthetic flavors may be used when organic flavors are not commercially available. All flavors must be derived from organic or nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.
Technical Report: 2005 TR; 2023 Limited Scope TR
Petition(s): 2015 Petition (to amend)
Past NOSB Actions: 11/1995 NOSB minutes and vote (pg. 6); 04/2006 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Annotation change published 12/27/2018 (83 FR 66559); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
Flavors can be categorized in many ways. The most fundamental is the distinction between "natural" and "artificial" flavors. These terms have legal meanings defined by the FDA in the U.S. and by other authorities with somewhat different definitions in other countries (2023 TR, lines 664-665).
Natural flavors are typically used in very small amounts in products (approximately 0.05 to 0.40 percent of ingredients) that contain less than optimal amount of flavor necessary to give the finished products the desired flavor profile. Natural flavors are widely used in baked goods, dairy products, jams and jellies, snack foods, and juice products, as well as in many other foods. Natural flavors are often proprietary formulations developed specifically for their intended purpose and functionality of the finished product. The significant function of natural flavors must be flavor rather than nutrition.

Manufacture:
Flavors can be derived via several different methods. The oldest sources are from wild plants, animals, fungi, lichens, and algae. A single flavor chemical is a single molecule that provides flavor. These can be naturally or artificially derived, but they are specified to have a greater than 95% purity. Mixtures of these substances can also be considered natural flavors. A compounded flavor is a mixture of ingredients such as extracts, essential oils, and natural isolates. Processed flavors, also known as reaction flavors, are ones that are generated as a result of some form of processing upon a mixture of ingredients. A process flavor is a unique mixture of starting materials, like carbohydrates, proteins, and fat, which must then be heated for a length of time to yield the desired profile. The 2023 Technical review listed the current manufacturing processes for flavors.

<u>Cold pressing</u>
Cold pressing is a low energy, mechanical, non-chemical process and is one of the oldest and simplest methods. Liquids from the raw material are forced through screens. This is used for favors that may be altered with temperature or with solvents (2023 TR lines 579-590).

<u>Steam Distillation and Water Vapor Stripping</u>

Volatile oils have a higher vapor pressure than water and can be stripped from plants with the application of steam or water vapor. The water and oils can be separated with different apparatuses once cooled. Stripping involves boiling water under pressure and a shooting a jet of steam through plant material. Distillation is the immersion of plant material in boiling water (2023 TR lines 292-601).

Solvent extraction

Ethanol and other alcohols can be used to extract oils. Organic flavors would need to be made using organic ethanol. The use of isopropanol, methanol, hexane, butane, acetone, ethyl acetate, ethylene dichloride and methylene dichloride are solvents and considered chemical processing and generally unacceptable for extracting organic and non-organic flavors for use in organic processed products (2023 TR lines 603-622).

Supercritical carbon dioxide

A relatively new extraction technique involves the use of carbon dioxide at various temperatures and pressures. While carbon dioxide is a gas at standard temperature and pressure, starting at 73 bar pressure and 31°C (88°F) temperature it becomes a supercritical fluid (2023 TR lines 624-627).

International Acceptance:

Canadian General Standards Board Permitted Substances List.

- Permitted for use - derived from biological sources and substances. May contain permitted carriers.

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

- Flavoring substances in organic products must be natural or organic under European regulations. (EC 2018/848)

- The European Union's flavor regulations have a more limited number of processes that are acceptable for the production of natural flavors (Müller, 2007; Sabisch & Smith, 2020). Certain processes in Europe lead a substance to be classified as "artificial" that are considered "natural" in the U.S. (Müller, 2007).

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

- 3.2 Flavourings: Substances and products labelled as natural flavouring substances or natural flavouring preparations are defined in the General Requirements for Natural Flavourings (CAC/GL 29-1987).

International Federation of Organic Agriculture Movements (IFOAM) Norms

- The IFOAM Standards Appendix 4, Table 1, *List of Approved Additives and Processing/Post-harvest Handling Aids* includes "Flavoring Agents" with the following annotation (IFOAM, 2014):

  Operators may use:

  - organic flavoring extracts (including volatile oils), and, if not available,
  - natural flavoring preparations approved by the control body. Such approval shall include assessment that natural flavors shall meet the following criteria:
    - the sources are plant, animal, or mineral;

- The process of production is in accordance with a recognized organic standard;
- They are produced by means of solvents such as vegetal oils, water, ethanol, carbon dioxide and mechanical or physical processes."

Japan Agricultural Standard (JAS) for Organic Production

- The Japanese Agricultural Standard for Organic Processed Foods allows "Flavoring" with the annotation: "Limited only to those that are not chemically synthesized" (Japanese Agricultural Standard for Organic Processed Foods, 2020).

Environmental Issues:
None

Ancillary Substances:
Ancillary substances are present in flavors and are reviewed for compliance against the criteria in the annotation: "must not be produced using synthetic solvents and carrier systems or any artificial preservative." Flavoring constituents are considered proprietary by flavoring companies and are not normally disclosed.

Discussion:
During the 2018 sunset review, the National Organic Program (NOP) had not completed rulemaking on the petitioned annotation change requiring the use of organic flavors when commercially available. This was the main focus of comments at the time urging NOP to complete rulemaking. The annotation change was finalized in 2019 and is reflected in the currently listed on the National List.

The Handling Subcommittee's discussion focused on trying to get a better idea of sources and manufacturing processes for flavors in an effort to determine the current and future availability of organic flavors in the market.

The new Technical Review listed the organic availability and stated that certified organic flavors are relatively recent phenomenon (2023 TR lines 182-183). Information was gathered from documents published by USDA and by the Accredited Certifiers Association (ACA), the literature (with weight given to peer-reviewed journal articles), from data downloaded from the USDA's Organic Integrity Database (OID), and from interviews conducted with personnel working with USDA Accredited Certifying Agents (ACAs) that have expertise in organic and nonorganic flavors (lines 1418-1422). The research efforts found approximately 14,877 certified organic flavor products produced by about 154 certified organic handling operations contained in the OID. These operations were certified by 25 of the USDA ACAs (lines 1447-1449). Several certifiers interviewed indicated that they believed the new Strengthening Organic Enforcement regulation will make the certification of organic flavors more difficult (lines 1574-1576). Below are notes on specific flavor types and organic availability:

- Tea- A growing number of ready-to-drink teas are being marketed, many of which rely on various added tea flavorings. Many certified organic flavors are classified as tea, which may be Camillia sinensis, but flavors labeled as tea may also refer to un-caffeinated herbal tea blends (lines 1342-1343).
- MSG - It is unclear whether it would be possible to produce MSG in a way that would meet the criteria specified in the annotation for flavors in § 205.605(a). There are no certified organic sources of MSG (lines 1290-1292).

- Smoke flavor- Most smoke flavor comes from combustion or pyrolysis of industrial timber into charcoal. It may be possible to use wood gathered from certified organic fruit trees, but there is no evidence that this is currently done (lines 1407-1409).
- Orange essence- Only two products identified as organic flavors in the OID have "100% organic" in the product name, both of which are orange essences. Cold-pressed citrus extracts in general should be commercially available (TR lines 1484-1486).

From interviews with certifiers, developing an exhaustive list of what flavors could be certified organic would require a case-by-case review of every source of every flavor. Also, the interviewees didn't have the information or expertise to determine what certified organic flavors are infeasible.

The petitioner for the current annotation will be presenting data before the Fall 2023 NOSB meeting, showing the increase of organic flavor sourcing. . All commenters from the Spring meeting were in support of relisting this material with the current annotation. Mandating organically produced flavors at this time is premature and would hurt the industry.

Justification for Vote:
The Subcommittee finds flavors compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR205.600 and is not proposing removal.

Subcommittee Vote:
Motion to remove flavors from the National List
Motion by: Logan Petrey
Seconded by: Kyla Smith
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

Gellan gum (high acyl form only)

Reference: 205.605(a) Nonsynthetics allowed. (13) Gellan gum (CAS # 71010-52-1) - high-acyl form only.
Technical Report: 2006 TR; 2018 TR (gums)
Petition(s): 2005
Past NOSB Actions: 03/2007 NOSB recommendation (§205.605(b), not recommended for addition); 11/2007 NOSB recommendation (§205.605(a)); 10/2014 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to the National List 12/14/2010 (75 FR 77521); Sunset renewal notice published 06/19/2015 (80 FR 35177); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
Gums are used in organic handling for different reasons, including: (1) thickening and gelling, (2) stabilizing foams, emulsions, and dispersion, (3) inhibit ice and sugar crystal formation, (4) aiding formulation, and (5) to control the release of flavors.

Despite having similar characteristics, the gums are not interchangeable. Due to their structure, some gums behave differently in different temperatures, pH ranges, physical agitation, etc. (2018 TR 194-200). This variability requires formulations specific to the type of food product, intended shelf- life, and product use. Often the gums are used in combination to impart specific properties of the finished goods (2018 TR).

Table 1. Summary: General Properties of Gums

Property	Gum Arabic	Tragacanth gum	Guar gum	Locust bean gum	Gellan gum	Xanthan gum
Low viscosity (only becomes viscous at concentrations greater than 50%)	X					
High viscosity at 1% concentration		X				
High viscosity at low concentrations (but more than 1%)					X	X
Viscosity remains unchanged over time at low shear rates		X				
Viscosity decreases over time at low shear rates			X			
Forms thermo-reversible gels					X	
Thermally reversible					X	X
Thermally irreversible		X		X		
Insoluble in ethanol	X	X	X	X	X	X
Stable under acid conditions		X		X		X
Controls syneresis (weeping)			X	X		X

Source: Technical Report, 2018.

Material Use:
The 2018 TR specifies the functional uses of gellan gum as a thickener, gelling agent, and stabilizer. Gellan gum can be used at low levels in many products that require gelling, texturizing, stabilizing, suspending, film-forming, and structuring. Gellan gum is water soluble, heat stable, low pH stable, and is able to form thicker gels when positive ions (cations) are added to a solution. Gellan gum is considered a hydrocolloid and is very useful as a thickening and gelling agent in food products, including bakery fillings, confections, dairy products, dessert gels, frostings, icings, glazes, jams, and personal care items (2018 TR, 2006 TR). Typical use of gellan gum is at <0.5% of a finished product formula (Petition). The firmness of the gel can be enhanced by the addition of cationic materials such as potassium, calcium, etc. and this gives it numerous applications in different areas of food products.

Manufacture:
Gellan gum is a high molecular weight polysaccharide gum produced through fermentation by the bacterium *Sphingomonas elodea*. This aerobic, gram-negative bacterium produces the material through fermentation and then separation of the gellan gum by isopropyl alcohol or ethanol (2006 TR, 2018 TR). The 2018 Technical report notes that no known genetically modified strain of this bacteria exists (2018 TR). Isopropyl alcohol cannot be at greater than 0.075% in the finished materials as dictated by FDA (2006 TR). The firmness of the gellan gum can be adjusted by the removal of acetyl groups through addition of cations (e.g., potassium, calcium, magnesium); these deacylated forms are not approved on

205.605(a) (2006 TR). As a result, the generation of gellan gum approved for 205.605(a) is through a naturally-occurring biological process (2006 TR).

International Acceptance

Canadian General Standards Board Permitted Substances List

Gellan gum is permitted, and requires the use of allowable extraction solutions and precipitation aids. Isopropyl alcohols can be used for extraction as well.

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

There is no explicit mention of gellan gum in the EC regulation.

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

Gellan gum is not explicitly mentioned.

International Federation of Organic Agriculture Movements (IFOAM) Norms

Gellan gum is not explicitly mentioned.

Japan Agricultural Standard (JAS) for Organic Production

Gellan gum is not explicitly mentioned.

Environmental Issues:

The two available technical reports (TRs) (2018 and 2006) did not list any notable human health or environmental concerns regarding the use of gellan gum. A 2018 study, in response to an NOSB request for an updated study of the safety of gellan gum as a food additive, found no adverse health impacts of gellan gum and did not recommend establishing an acceptable daily intake level.[i]

Ancillary Substances:

According to the 2018 TR, no information was found indicating that any additional materials are generally added to commercially available forms of the gums.

Discussion of previous reviews:

During the 2018 spring public comment period, a number of manufacturers wrote in support of the material, with multiple manufacturers stating that they are using gellan gum as a carrageenan replacement due to customer concerns. Examples of specific products that use gellan gum include plant-based creamers and beverages, dairy beverages, and yogurt.

Summary of 2023 public comments and board discussions:

According to the public comments, gellan gum is used by a low to moderate number of handlers. Those using the product report that it is essential for their businesses, since gellan gum has specific properties that are not shared by other gums. Despite the TR's reference that organic versions are commercially available, users of the product report no commercial availability. There is concern about gellan gum derived from GMOs and several comments pointed to the need to ask about gellan gum produced by excluded methods. The issue of fermentation was raised for this product, similar to the comments regarding xanthan gum. There is support for relisting, but several commenters indicated the product should be relisted only if the excluded methods concerns are addressed. Another commenter requested that this listing be annotated by specific use or application.

Board discussion on the gums was not extensive; one member asked about essentiality, indicating that if gums are needed for a specific mouth feel is that enough to make it essential. Another member called for greater transparency regarding the availability of organic versions of the non-synthetic gums, to help foster the shift away from using non-organic ingredients.

Justification for Vote:
The Subcommittee finds gellan gum (high-acyl form) compliant with the Organic Foods Production Act (OFPA) and 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote:
Motion to remove gellan gum (high-acyl form) from the National List
Motion by: Carolyn Dimitri
Seconded by: Nate Lewis
Yes: 0 No: 9 Abstain: 0 Recuse: 0 Absent: 0

[1] Younes, M., Aggett, P., Aguilar, F., Crebelli, R., Filipic, M., Frutos, M.J., Galtier, P., Gott, D., Gundert-Remy, U. and Kuhnle, G.G., 2018. Re-evaluation of gellan gum (E 418) as food additive. *EFSA Journal*, *16*(6), p.e05296.

Oxygen

Reference: 205.605(a) Nonsynthetics allowed. (21) Oxygen - oil-free grades.
Technical Report: 1995 TAP
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote (pg. 329); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
Oxygen is used in modified atmosphere packaging, the processing of olives, and by wineries, breweries, and manufacturers of carbonated beverages.

Oxygen is an odorless and tasteless gas and is commonly used to help maintain color and prevent pallor in food (although in some volumes, it can have the opposite effect). It can also aid in inhibiting the growth of bacteria. Oxygen can be helpful in a modified atmosphere packaging environment because it can help prevent spoilage in products that are high in sugar or water.

Manufacture:
Oxygen is separated from air cryogenically, or the super-cold temperature liquefaction of air and fractional distillation.

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

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

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

International Federation of Organic Agriculture Movements (IFOAM) Norms
Permitted for use.

Japan Agricultural Standard (JAS) for Organic Production
Permitted for use.

Environmental Issues:
There does not appear to be significant environmental issues associated with the use of oxygen in modified atmosphere packaging. In fact, it can have the effect of extending shelf life or viability and reducing food waste/shrinkage.

No negative impacts on health or the environment have been previously expressed or brought to the attention of the Handling Subcommittee.

Ancillary Substances:
None.

Discussion:
The NOSB unanimously voted to relist oxygen in 2018.

Public comment prior to the Spring 2018 NOSB meeting was mostly in favor of relisting. One organization commented that oxygen should be removed from the National List if its necessity in organic production wasn't documented. According to public comment, it is used by wineries, breweries, and manufacturers of carbonated beverages. One certifier reported that it is listed on 14 Organic System Plans (OSPs). One winery commented they use it for micro-oxygenation, a process where oxygen is added to red wine at a controlled rate and flow to stabilize color, improve astringency, and aromatic components of the final wine. Micro-oxygenation also allows wines to be released to consumers at a younger age which in turn reduces the amount of sulfur dioxide that needs to be added during the wine making process.

The Handling Subcommittee discussed oxygen during its sunset review and currently supports relisting. Written comments before the Spring 2023 NOSB meeting were unanimously supportive of the continued listing of this material for organic use. Board members acknowledged at the meeting the indispensable role of oxygen in extending the market window for some organic foods by as much as 4-6 weeks.

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

Subcommittee Vote:
Motion to remove oxygen from the National List at 205.605(a)
Motion by: Wood Turner
Seconded by: Kyla Smith
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

Potassium chloride

Reference: 205.605(a) Nonsynthetics allowed. (23) Potassium chloride.
Technical Report: 1995 TAP; 2015 TR (nutrient vitamins and minerals); 2023 TR (crops, handling)
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote (pg. 335); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
According to the Food & Drug Administration (FDA), potassium chloride is generally recognized as safe (GRAS). Affirmed uses of potassium chloride in foods are as a flavor enhancer, flavoring agent, nutrient supplement, pH control agent, and stabilizer or thickener. Like salt, potassium chloride provides a salty flavor and can also often play other functional roles (such as microbial management, protein modification, flavor enhancement) that affect the taste, texture, and shelf life of food products. Potassium chloride is generally used for two main purposes in food products: to provide potassium enrichment to foods, and as a salt replacement to reduce the sodium content in foods.

Manufacture:
Potassium chloride is a mineral that occurs naturally and is a product of potash mining where water is forced into ground to dissolve potassium chloride deposits. Brine is brought back to the surface where the water is evaporated off. It can similarly be produced from seawater extraction via solar evaporation.

International Acceptance
Canadian General Standards Board Permitted Substances List
Permitted for use from mined sources such as sylvite, carnalite, and potash.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Not specified as permitted for use.

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

International Federation of Organic Agriculture Movements (IFOAM) Norms
Permitted for use.

Japan Agricultural Standard (JAS) for Organic Production
Permitted as “fertilizers and soil improvement substances.”

Environmental Issues:
Potassium chloride derives from mining activities, and there are impacts associated with its extraction. There has not been widespread concern about significant impacts.

The substance is considered to be of limited health concerns for people with normal kidney function; however, it is thought to create issues for people with conditions that make potassium excretion difficult.

At recommended daily rates of consumption, potassium chloride is thought to reduce health impacts typically associated with sodium chloride, such as high blood pressure and kidney stones.

Ancillary Substances:
None.

Discussion:
The National Organic Standards Board (NOSB) unanimously voted to relist potassium chloride in 2018 for its handling purposes.

At the time, public comment was unanimously in support of re-listing potassium chloride. Several commenters focused on potassium chloride as a key ingredient in low-sodium products. Another commenter stated that potassium chloride is essential in the fortification of infant baby formula.

A draft TR was submitted on December 2, 2022 and was deemed sufficient, although the Crops Subcommittee (which is also reviewing this material for different crop-related applications) requested additional information on effective organic alternatives to potassium chloride. Support for relisting among Handling Subcommittee members appears consistent with prior reviews. The draft TR primarily addressed crops-related applications of the substance.

Written comments to the NOSB in advance of its Spring 2023 were broadly supportive of this continued handling use of potassium chloride in organic. There was no discussion of this substance by the board in light of this community support.

Justification for Vote:
The Subcommittee finds potassium 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 potassium chloride from the National List at 205.605(a)
Motion by: Wood Turner
Seconded by: Nate Lewis
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

Alginates

Reference: 205.605(b) Synthetics allowed. (3) Alginates.
Technical Report: 1995 TAP; 2015 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote (pg. 331); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
Alginates are used in food production and handling as an emulsifier or emulsifier salt, firming agent, flavor enhancer or flavor adjuvant, formulation aid, processing aid, stabilizer or thickener, surface-active agent, and texturizer.
The use of alginates is not limited to foods. Industrial applications use alginates to improve the performance of products such as paper coating, textiles, adhesives, air freshener gels and ceramics Alginates are also utilized in a variety of ways in the medical field. Examples include wound dressings, surgical implants, pharmaceutical preparations, and as a source of dietary fiber (2015 TR 279 – 283].

Manufacture:
Alginates are produced from algin and are usually extracted from the cell walls of brown algae. Commercial alginates are isolated mainly from the following algal species: *Laminaria hyperborea, L. digitata, L. japonica, Ascophyllum nodosum, Macrocystis pyrifera, Eclonia maxima, Lessonia nigrescens, Durivillea antarctica,* and *Sargassum spp* (2015 TR lines 100-106). Alginic acid in brown seaweeds is mainly present as calcium, magnesium, and sodium salts. The first step in the manufacture of alginate is to convert the insoluble calcium and magnesium alginate into soluble sodium alginate by ion exchange under alkaline conditions (2015 TR lines 448-450). Extraction involves ion exchange in an alkaline medium followed by precipitation, purification and conversion to the appropriate salt (2015 TR lines 94-96). “Commercial manufacturing of alginate almost always involves a purification step where an acid treatment precipitates the alginate as alginic acid” (2015 TR lines 452-454). The extraction process renders alginates synthetic [2015 TR 444-454].

International Acceptance:
Canadian General Standards Board Permitted Substances List

The following alginates are permitted: a) alginic acid; b) potassium alginate; and c) sodium alginate

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Permitted: E401 Sodium Alginate and E402 potassium alginate in milk-based products

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
Sodium alginate (INS 401) and Potassium alginate (INS 402) are listed as approved additives.

International Federation of Organic Agriculture Movements (IFOAM) Norms
Sodium alginate (INS 401) and Potassium alginate (INS 402) are listed as approved additives.

Environmental Issues:
Seaweed cultivation is largely considered to be an environmentally friendly form of aquaculture due to the lack of added inputs for fertility, minimal changes in physical landscape and potential for bioremediation of polluted or nutrient rich waters (Eklof and Kautsky 2006) [2015 TR 704-706].
We are not aware of any evidence that the harvesting practices for brown seaweed are damaging to local ecosystems. Secondary environmental impacts of seaweed farming include depletion of nutrients in the coastal waters where the seaweed grows, which can affect primary food sources such as phytoplankton (Philips 1990). The use of plastic ties to secure seaweed fronds, Styrofoam floats and plastic bottle buoys has led to increased garbage and foreign debris on beaches, reefs, and mangroves. Given the insurmountable challenges of managing non-native seaweed populations, some researchers claim that it is preferable to focus on sustainable wild harvest techniques with regard to mitigating environmental impact (Titlyanov and Titlyanova 2010) [2015 TR 725-728].

Ancillary Substances:
Publicly available specification sheets and ingredient lists did not report any ancillary substances (e.g., stabilizers, preservatives, or anti-caking agents). Sodium alginate and propane-1,2-diol alginate (PGA) are commercially prepared as 100% freeze-dried material (FMC BioPolymer 2012) [2015 TR 351-354].

Discussion:
Alginates were added to the National List in 2022 and have been renewed at each sunset review.

Public comments from the previous sunset review demonstrated a continued need for this material. One stakeholder commented that alginic acid, like seaweed and fish oil, should be reviewed within the broader context of Marine Materials. Additionally, the Board was asked to 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.

The Subcommittee discussion centered on the current forms of alginates that are being used in organic production.

Public comments from the Spring 2023 meeting support relisting of alginates at 205.605(b). From the comment docket `Alginates are a versatile ingredient that provide unique stabilizing and thickening properties. In response to Handling Subcommittee questions, IFAC (International Food Additives Council) expects there will be increased organic community interest in sodium alginate in particular, based on its use in meat alternative products'.

The question asked of stakeholders was, what forms of alginates are currently being used in organic production? Public commenters stated that given the growing interest in plant-based meat alternatives, sodium alginate would be of particular interest for relisting. The Subcommittee discussion centered on the current forms of alginate that are being used in organic production along with sources of alginates used for organic production vs. bioremediation. The Subcommittee is still interested in knowing if there are additional forms (e.g., ammonium, calcium, potassium, propylene glycol) being used in organic production. The Subcommittee also discussed the seaweed used to produce alginates vs. that used for bioremediation and the potential for heavy metal contamination. It was determined that these are likely from different sources. Additionally, the Food and Drug Administration (FDA) regulates heavy metal testing of sodium alginates and therefore the Subcommittee is not concerned with the continued listing of alginates.

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

Subcommittee Vote:
Motion to remove alginates from the National List
Motion by: Dilip Nandwani
Seconded by: Kyla Smith
Yes: 0 No: 8 Abstain: 0 Recuse: 0 Absent: 1

Calcium hydroxide

Reference: 205.605(b) Synthetics allowed. (8) Calcium hydroxide.
Technical Report: 1995 TAP; 2023 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote (pg. 337); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
Calcium hydroxide is used in food processing as a buffer, neutralizing agent, and firming agent. It is used in making calcium acid phosphate (a component of aluminum-free baking powder) and in nutrient supplements. Calcium hydroxide is an available source of calcium, an essential nutrient. In this regard, limestone (calcium carbonate) and thus calcium hydroxide, an essential intermediate in the industrial utilization of limestone, have no alternatives.

Manufacture:
Calcium hydroxide is produced through four steps: 1) mining or quarrying raw limestone; 2) preparation of the limestone for the kilns; 3) calcining the limestone to produce quick lime (calcium oxide); and 4) hydrating (mixed with water) the quick lime. To produce calcium hydroxide, the temperature for calcining far exceeds temperatures achieved in the home kitchen, which the National Organic Standards Board (NOSB) has previously considered decisive in judging if a substance is synthetic.

According to the 2023 TR, new techniques for the manufacture of calcium hydroxide continue to develop. Nanoparticles of calcium hydroxide were reported to be synthesized as early as 2001 (Salvadori & Dei, 2001). One article described calcium hydroxide as "one of the most magnificent materials in nanotechnology by virtue of its unique physical and chemical properties" (Harish et al., 2022). Most literature cited refers to medical or dental applications of calcium hydroxide nanoparticles. However, with growing interest in food applications of nanotechnology, food-grade calcium hydroxide nanoparticles may become commercially feasible. Nanotechnology is not permitted in organic production (National Organic Program (NOP) Policy Memo 15-2: Nanotechnology).

International Acceptance:
Canadian General Standards Board Permitted Substances List
Listed in Organic Production Systems as Permitted Substances List as `Lime' in a table 7.4 'Cleaners, disinfectants and sanitizers permitted on organic product contact surfaces for which a removal event is mandatory'.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
There is no specific listing for calcium hydroxide in handling nor any information found.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
There is no specific listing for calcium hydroxide in handling nor any information found.

International Federation of Organic Agriculture Movements (IFOAM) Norms
Calcium hydroxide (hydrated lime) is listed as for the application on aerial plant parts only.

Japan Agricultural Standard (JAS) for Organic Production
Calcium hydroxide (slaked lime) listed as `those derived from natural sources, or natural sources without the use of chemical treatment.'

Environmental Issues:
According to the 2023 TR, literature on the environmental impacts of limestone quarrying and its processing into quick lime and hydrated lime is extensive. Limestone deposits occur in a wide range of geological formations that are connected to a variety of ecosystems. Almost all limestone is mined in open quarries or pit mines (Oates, 2008). Site preparation for open pit or quarry mining involves the clearing of trees, vegetation, and topsoil, resulting in the immediate loss of habitat (Ganapathi & Phukan, 2020). Some ecosystems are more sensitive to the intrusions of mining than others. The karst topography associated with limestone deposits creates a wide range of potential environmental impacts, including habitat and biota loss; air, noise, and water pollution; and cascading environmental impacts to natural systems far from the mining location (Langer, 2001). Limestone mining creates dust and other air pollution (U.S. EPA, 1998). Karst forms caves that are ideal bat habitat. The dust and noise from limestone mining can result in loss of that habitat and cause remaining bats to suffer increased

mortality and deafness (Langer, 2001). Discharges from limestone quarries can also result in surface water contamination with sediment, heavy metals, and asbestos. This in turn can result in adverse impacts on aquatic biota, including fish mortality (U.S. EPA, 1982).

Ancillary Substances:
None

Discussion:
During the previous sunset review, public comments submitted by organic manufacturers, trade associations, material suppliers and certifiers detailed calcium hydroxide use and necessity in the processing. The majority of public comments supported relisting of calcium hydroxide. One commenter suggested that the NOSB clarify which uses of calcium hydroxide are permitted, specifically if calcium hydroxide can be used as a firming agent. Additional commenters stated that they use calcium hydroxide in infant formula.

The NOSB received public comments that were all in favor of relisting of calcium hydroxide. The NOSB did not receive much response to the questions it asked in the Spring review. A couple of commentors said that they are not aware of any commercially available alternatives.

Justification for Vote:
The Subcommittee finds calcium hydroxide 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 hydroxide from the National List
Motion by: Dilip Nandwani
Seconded by: Jerry D'Amore
Yes: 0 No: 8 Abstain: 0 Recuse: 0 Absent: 1

Ethylene

Reference: 205.605(b) Synthetics allowed.
(14) Ethylene - allowed for postharvest ripening of tropical fruit and degreening of citrus.
Technical Report: 1995 TAP; 1999 TAP; 1999 TAP (pg. 14-54); 2023 TR (crops, handling)
Petition(s): 2008 (pears)
Past NOSB Actions: 11/1995 NOSB minutes and vote (pg. 14); 10/1999 NOSB minutes and vote (tropical fruit and citrus) (pg. 443); 10/2001 NOSB recommendation (reaffirmed 1999 recommendation) (pg. 2); 11/2005 NOSB sunset recommendation; 11/2008 NOSB recommendation (pears, not recommended for addition) (pg. 14459-14491); 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Annotation change published 10/31/2003 (68 FR 61987); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
Ethylene is used in the post-harvest ripening of tropical fruit and the de-greening of citrus. Ethylene produced naturally by fruits has not been commercialized, and the amounts produced for agriculture are small compared to emissions from car exhaust, petrochemical plants, or fires.

Manufacture:
The principal source of commercial ethylene is from thermal or catalytic cracking of hydrocarbon feedstocks such as natural gas or crude oil. During this process chemical bonds within the hydrocarbon molecules are broken, and a different chemical substance is produced.

Ethylene is the petrochemical produced in the largest quantities worldwide (IARC, 1994). In 2014, world ethylene production was 134 million (metric) tonnes (Lazonby, 2017). As of 1994, over 95% of worldwide annual production is based on thermal "cracking" of petroleum hydrocarbons with steam (IARC, 1994). These fractions are obtained from drilling (or hydrofracturing) of oil or natural gas. Thermal cracking (sometimes referred to as pyrolysis) is a chemical process by which long chain hydrocarbons with higher molecular masses are converted to short chain hydrocarbons of lower molecular mass [2023 TR 304-309].

All of these methods involve reactions that produce a chemically changed substance (ethylene) from either petroleum feedstocks, or from dehydration of ethanol mediated by catalysts. Thus, all these forms should be considered synthetic (NOP, 2016a) and from nonagricultural sources (NOP, 2016b). [2023 TR 369-371]

Various feedstocks, including ethane, propane, butanes, naphthas, and gas oils are used to produce ethylene, depending on availability, price, and products desired (Lazonby, 2017). Naphthas are the principal raw material used in western Europe and Japan, accounting for over 80% of the ethylene produced. Ethane is the primary feedstock in the U.S., followed by propane, naphthas, gas oils, and butane (Zimmerman & Waltz, 2011) [2023 TR 311-315].

In thermal cracking, the feedstock gases (ethane, propane or butane) or the liquids (naphtha or gas-oil) are preheated and vaporized, and are mixed with steam and heated to 1050-1150 K (777-877 °C) in a tubular reactor. The high temperature and pressure cause the long chain hydrocarbon to be converted to low relative molecular mass alkenes plus by-products (Lazonby, 2014). [2023 TR 317-320]

<u>Catalytic cracking</u>
Catalytic cracking uses a catalyst, typically a zeolite, which adsorbs the long-chain hydrocarbon feedstocks and removes hydrogen atoms. [1] This causes the long chains to split into shorter chain molecules with double bonds, which are useful to the petrochemical industry. The feedstock is gas oil, which is vaporized, passed through a fine zeolite powder, and heated to 700-800 K (427 - 527 °C) in a reactor. The products behave like a fluid and continuously flow out of the furnace with the cracking products. The temperature, residence time, and the catalyst determine the product proportions (Lazonby, 2014) [2023 TR 332-338].

<u>Dehydration of ethanol</u>
Dehydration of ethanol is another commercial route to ethylene (IARC, 1994; Zimmerman & Waltz, 2011; Fan 2013). In the catalytic dehydration of ethanol to form ethylene, an acid catalyst first

protonates the hydroxyl group, which leaves as a water molecule. The conjugate base of the catalyst then deprotonates the methyl group, and the hydrocarbon rearranges into ethylene (Fan, 2013). This method is not commonly used to produce large volumes of ethylene, as it is endothermic with a high optimal reaction temperature (180-500 °C), which makes the ethylene expensive to produce. Dehydration of bioethanol is occurring in Brazil and India and holds promise for producing ethylene from non-fossil fuel sources (bioethanol from sugar cane or cellulose). At present, the output is relatively limited and used for further production of polyethylene (Fan, 2013; Lazonby, 2017; Schill, 2010) [2023 TR 340-349].

Catalytic generators

Small catalytic generators are used in sealed ripening rooms to dehydrate ethanol into ethylene, and can deliver controlled levels of ethylene gas to ripen fruit, e.g., 100-150 ppm for bananas. (NWHort 2008, Catalytic Generators 2022). This process uses dehydration of ethanol by passing it over a bed of solid catalyst held at high temperatures. The catalysts are typically activated alumina and phosphoric acid or zinc oxide with alumina (Kays & Beaudry, 1987) [TR 351-356].

International Acceptance:

Canadian General Standards Board Permitted Substances List

- For post-harvest ripening of tropical fruit and de-greening of citrus and to control sprouting of potatoes post-harvest in holding bins.

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

- De-greening bananas, kiwis, and kakis; De-greening of citrus fruit only as part of a strategy for the prevention of fruit fly damage in citrus; Flower induction of pineapple; sprouting inhibition in potatoes and onions.

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

CODEX indicates:

"For degreening of citrus for fruit fly prevention and as a flowering agent for pineapples. As sprouting inhibitor for potatoes and onions: Need recognized by the certification body or authority for sprout inhibition of stored potatoes and onions where varieties that have long dormancy characteristics are not available, or these varieties are not suited to local growing conditions. Must be used in a manner that minimizes exposure to operators and workers."

International Federation of Organic Agriculture Movements (IFOAM) Norms

- De-greening and ripening of citrus

Japan Agricultural Standard (JAS) for Organic Production

- Limited to those used for ripening bananas, kiwifruits, and avocados after harvest.

Environmental Issues:

According to the 2023 TR, the manufacturing process through cracking is highly energy intensive. Extraction and transport contribute significantly to increasing greenhouse gas emissions, acidification and eco-toxicity (air and water). [TR 479-482] A study conducted by Zhao et al. in 2018 found that China reduced C02 emissions by 29.4% per ton of ethylene produced from 2000-2016 due to improvements in technology, and evaluated various methods for future increased reductions. [TR 493-495]

Petroleum refineries are a major source of hazardous and toxic air pollutants. [TR 497]

As for ethylene's impact on the environment during postharvest handling, the 2023 TR states that since the ethylene is a gas at environmental temperatures, this is the primary route of exposure to the environment. Health Canada considered environmental modelling studies and found that ethylene released to the air will remain in the air, and that only negligible amounts will partition to soil, water and sediment. [TR 507-511]

According to the U.S. EPA Toxic Release Inventory (EPA, 2021), in 2021 the total release of ethylene as airborne emissions in the U.S. was 18.2 million pounds. Of that, 17.2 million pounds was emitted by the chemical manufacturing industry, and 0.7 million pounds was from the petroleum industry. It is not known how much ethylene is released in the atmosphere due to ripening and degreening uses. It is no doubt much smaller than the amount estimated to be applied to pineapple crops in the field. The Food and Agriculture Organization of the United Nations estimates that in 2021, there were 1,046,712 hectares of pineapples grown worldwide (FAO, 2022). If every hectare in the world was treated with 800 grams of ethylene (unlikely, as the harvest takes 12-18 months from flower induction), that would result in application of 837,369 kg (1,846,082 pounds) totally. [2023 TR 513-521]

The 2023 TR states that no data was found showing an impact on invertebrates or birds, which are most likely exposed to ethylene. Ethylene is not expected to be released in the water; therefore, no unwanted exposure is expected. The TR stated the greatest eco-toxicity impact to be on terrestrial plants as they are highly sensitive to ethylene in the air. A 2016 Health Canada study concluded that there is little risk of harm to the environment or to organisms since the substance is not present in quantities or concentrations that could cause long term harmful effects on the environment or biodiversity. [2023 TR 531-536]

As for the impact on human health, the main concern is worker safety due to the explosive nature of the gas. The use of this material is highly regulated through labeling and registration requirements. Beyond the risk of harm due to an explosive accident, overexposure causes headache, drowsiness, and muscular weakness and high concentrations can cause dizziness or light-headedness. [2023 TR 551-554]

Ancillary Substances:
None

Discussion:
During the last review, commenters stated that no commercially viable alternatives exist. Without ethylene, commenters said, it would be impossible to achieve the uniform ripening necessary for timing the harvest for fruit shipment. Others commented that the material does not fit any OPFA criteria, and it is not essential to get the crop to market but rather is employed for economic reasons.

The Handling Subcommittee discussed the effects on the environment and human health, along with the apparent essentiality for the tropical fruit industry. Obviously, there is an alternative, which is to let fruit ripen naturally. However, as stated in the TR this is most ideal for local markets where fruit is picked closer to ripeness and time to market is short. According to the TR there are also alternative practices for degreening, such as being stored at low-moderate temperatures (6-15 C) for 28-42 days. However, when comparing degreening via reduced temperatures vs. ethylene, ethylene was significantly faster at fully degreening fruit. There were also additional nonsynthetic substance alternatives such as smoke utilized in the Sri Lankan pit method. However, this resulted in blackening and over softening leading to decreased marketability. Smoke was also used in the past for citrus degreening, although there were problems with fire hazards, heat, and decay.

At the Spring 2023 NOSB meeting, a board member stated that the organic banana market is dependent on the use of ethylene in post-harvest handling. It was also mentioned that most conventional tomato production is handled with this material, and it might be a benefit to the organic tomato industry. The 2008 petition for use in pear production was not passed on the grounds that it wasn't necessary for that commodity, however, multiple commenters this spring requested that the material be expanded to pears. Stakeholders listed avocados, bananas, mangos and papaya as tropical fruits currently treated with this material.

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

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

Glycerides (mono and di)

Reference: 205.605(b) Synthetics allowed.
(16) Glycerides (mono and di) - for use only in drum drying of food.
Technical Report: 1995 TAP; 2015 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote (pg. 334); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
Mono- and diglycerides have many applications as food processing aids. They are principally used as emulsifiers. This function also translates into stabilization, preventing food separation, stabilizing air pockets and extending shelf life (TR 2015 82-83). However, the only use for which mono- and diglycerides are permitted in organic food processing is in the drum drying of food. In this application, mono- and diglycerides can have various functions, but most significantly they act as an emulsifier and release agent. When mixed with food, mono- and diglycerides help prevent sticking during processing,

and in drum drying they help to strip the food from the cylinder walls once dried. In drum drying, a puree or slurry of food is added to one or two heated cylinders at varying feed rates depending on the particular food's viscosity. As the cylinders or drums rotate, the slurry dries. The process creates powder or very fine flakes that can serve as the basis for snacks, soups, baked chips, some bakery items and cereals (TR 2015 91-92). The use of mono- and diglycerides in dehydrated potatoes also aids in rehydration (TR 2015 105-106); at the spring 1995 NOSB meeting, it was noted that the food industry was trying to move away from use of mono- and diglycerides, but that they were still needed for potato flake products (TR 2015 168-172).

Manufacture:
Mono- and diglycerides occur naturally in food as minor constituents of fats, in combination with the major constituent of food fats: triglycerides. They are also metabolic intermediates of triglycerides. When manufactured, they are prepared by the glycerolysis of fats or oils, or from fatty acids derived from edible sources (TR 2015 56-59). These edible sources are commonly animal fats or vegetable oils such as soybean, canola, sunflower, cottonseed, coconut, or palm oil (TR 2015 59-60), and the main fatty acids used to manufacture mono- and diglycerides include lauric, linoleic, myristic, oleic, palmitic, and stearic acid (FDA 2014). The glycerol component of mono- and diglycerides is also derived from these edible fats and oils. (TR 2015 56-62).

International Acceptance:
Canadian General Standards Board Permitted Substances List.
Mono- and diglycerides are permitted under Canada's organic standards, with annotations: From organic sources if commercially available. For use in drum drying of products.

Mono- and diglycerides do not appear in the following organic standards: CODEX, EU, IFOAM or Japan.

Environmental Issues:
The 2015 TR does not identify any significant environmental impacts linked to mono- or diglycerides (TR 2015 433-459). Glycerides are derived from natural fats or oils that are produced conventionally; production of these agricultural source materials with synthetic pesticide and fertilizers may result in harm to the environment and biodiversity.

Ancillary Substances:
None

Discussion:
According to the 2015 TR, alternative ways to dry foods include spray drying, freeze drying, fluidized bed dryers, air lift dryers, scraped wall heat exchangers, etc. Drum drying is said to be preferred for potato flakes. Freeze drying has been suggested as an acceptable alternative to drum drying.

Evaluation question #13 in the 2015 TR suggested a few potential agricultural alternatives. One is a commercial product, made of organic rice bran extract, which is marketed as an emulsifier and drum release agent. Trials by the manufacturer concluded that rice bran extract had the highest capacity for oil-in-water binding. However, the hydrophilic–lipophilic balance of rice bran extract is narrower than that of mono- and diglycerides, which may make it less versatile as an emulsifier depending on the composition of the mix to which it is added.

Organic soy lecithin and gum arabic (both currently on the National List) were also raised as possible alternative substances to glycerides, although the use of gum arabic in drum dried food is not widely reported. The TR also considered the use of lecithin as an alternative but stated that as compared to mono- and diglycerides it provides much less emulsion stability, much less starch interaction, and more fat modification.

The TR concluded that in general, each emulsifier (and its form) is selected based on specification of the food and the processing application (TR 2015 522-547).

One certifier commented that they certify one operation that uses this material, and several certifiers commented that they have no clients using it. Several commenters supported relisting to keep the option available, and one of those commenters listed numerous (apparently nonorganic) products that include this ingredient. One commenter supported removal based on the alternatives described in the TR. An internet search identified several organic dried potato products that list this ingredient, but also several nonorganic products that contain only potato flakes.

The use of mono- and diglycerides appears to be limited, but compatible with OFPA because the health and environmental risks are minimal. It would be helpful to understand current uses in organic products.

Questions to our Stakeholders:

1. What organic products are mono- and diglycerides currently used in?
2. Have any alternatives emerged?

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

Subcommittee Vote:
Motion to remove glycerides (mono and di) - for use only in drum drying of food from the National List
Motion by: Allison Johnson
Seconded by: Jerry D'Amore
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

Magnesium stearate

Reference: 205.605(b) Synthetics allowed.
(19) Magnesium stearate - for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))," prohibited in agricultural products labeled "organic".
Technical Report: 1995 TAP; 2018 TR
Petition(s): N/A
Past NOSB Actions: 11/1995 NOSB minutes and vote (pg. 16); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
Magnesium stearate (CAS # 557-04-0) is not commonly used in organic products (TR 2018 102). In conventional production, it is routinely used as an anti-caking agent in salt, spices, powdered foods and drinks, leavening agents, and candy (TR 2018 103-105). It is a flow agent, food processing machine lubricant, and may be an incidental additive. The most common use of magnesium stearate is as a binding agent in dietary supplements. Magnesium stearate is permitted for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))" and is prohibited in agricultural products labeled "organic."

Manufacture:
Typically manufactured as a synthetic from hydrogenation of animal fats or vegetable oils, magnesium stearate is produced by adding an aqueous solution of magnesium chloride to sodium stearate. Stearic acid is made by saponification of edible fat (lye plus tallow) that is treated with an acid to form stearic acid.

International Acceptance:
Canadian General Standards Board Permitted Substances List.
Canada allows magnesium stearate for use as an anticaking or releasing agent in products whose contents are ≥70% and <95% organic ingredients.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
The 2018 TR stated that the Codex Alimentarius Commission's "Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods" lists magnesium stearate (INS No. 470(iii)) as a food additive that may be used in foods as an anticaking agent, emulsifier, or thickener under the conditions of good manufacturing practices (GL 32-1999). However, it does not appear to be listed currently.

Magnesium stearate does not appear in the following organic standards: EU, IFOAM, Japan.

Environmental Issues:
Magnesium stearate is derived from natural fats or oils that are produced conventionally; production of these agricultural source materials with synthetic pesticide and fertilizers may result in harm to the environment and biodiversity. In addition, while some of the substances involved in manufacturing of magnesium stearate could have water and soil health impacts at high concentrations, the amounts relevant here are not likely to pose significant environmental or biodiversity impacts.

Ancillary Substances:
None

Discussion:
Two certifiers commented that they certify several operations that use magnesium stearate, and one of those certifiers specified that the material is used as a binding agent in pharmaceutical and dietary products. Two other certifies commented that they do not have any clients using this material. Several commenters supported relisting, in part because the annotation limits its use to products labeled "Made

with Organic…" One of those commenters noted that while they have supported relisting in the past, they would like to see more information about the current need and alternatives.

The use of magnesium stearate appears to be limited, but compatible with OFPA because the health and environmental risks are minimal. It would be helpful to understand current uses.

Questions to our Stakeholders:

1. How is magnesium stearate currently used by organic processors?
2. Have any viable alternatives to magnesium stearate emerged?

Justification for Vote:
The Subcommittee finds magnesium stearate - for use only in agricultural products labeled 'made with organic (specified ingredients or food group(s)),' prohibited in agricultural products labeled 'organic' 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 stearate - for use only in agricultural products labeled 'made with organic (specified ingredients or food group(s)),' prohibited in agricultural products labeled 'organic' from the National List.
Motion by: Allison Johnson
Seconded by: Kyla Smith
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

Phosphoric acid

Reference: 205.605(b) Synthetics allowed.
(23) Phosphoric acid - cleaning of food-contact surfaces and equipment only.
Technical Report: 1999 TAP (pg. 9-20); 2003 TAP (pg. 1-7); 2021 TR
Petition(s): 2019 (to amend); 2020 (addendum #1); 2020 (addendum #2); 2022 (addendum #3)
Past NOSB Actions: 10/1999 NOSB minutes and vote (pg. 443); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review
See TRs for references

Use:
Phosphoric acid is used in organic handling and processing as a cleaning agent for "food contact surfaces and equipment," as described in 7 CFR 205.605(b). Phosphoric acid has been approved for pH

adjustment of some soil amendments (liquid fish products and squid byproducts) and as an equipment cleaner in both organic crop and livestock production. (7 CFR 205.601 and §205.603).

In addition to its appearance in 7 CFR 205.605, phosphoric acid has been used as an ingredient in plant extractions (USDA 2002, USDA 2019, USDA 2020a, USDA 2020b). When used in this manner, phosphoric acid acts as an acidifying agent and stabilizer to facilitate more efficient extraction of target compounds (Yoon et al. 2020).

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

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

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

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

Equation 6

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

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

Equation 7

Wet Process

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

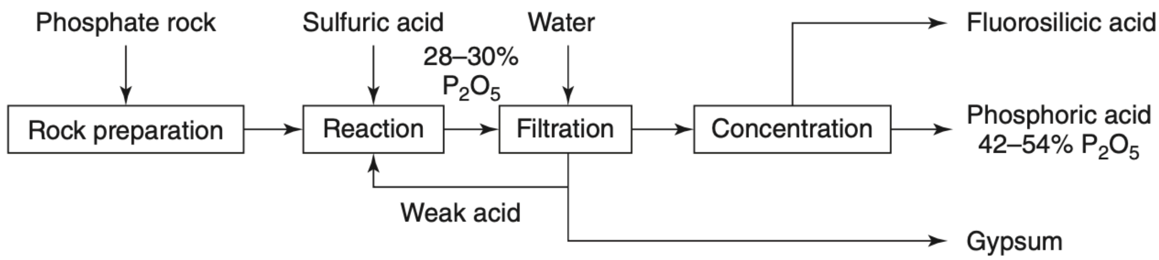

Figure 5

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

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

Equation 8

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

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

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

Wet process purification methods

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

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

International Acceptance

Canadian General Standards Board Permitted Substances List.

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

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

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

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

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

International Federation of Organic Agriculture Movements (IFOAM) Norms

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

Japan Agricultural Standard (JAS) for Organic Production
Phosphoric acid is not listed in the JAS. [TR 360-361]

Environmental Issues:
The TR indicates that phosphoric acid is relatively benign regarding its impact on the environment. However, its production does have the potential to be harmful to the environment. The thermal process for producing it is energy intensive and requires high temperatures. The high energy requirements of the thermal process may contribute to atmospheric CO_2 levels if the energy is produced from fossil fuels. The thermal process also requires the treatment of combustion gases by scrubbers, cyclonic separators, mist eliminators, and electrostatic precipitators to prevent the release of phosphoric acid to the environment (EPA 1995; Gilmour 2019). The small size (< 3 μm diameter) makes these phosphoric acid and phosphorus oxide (P_2O_5) particles difficult to capture, and contributes their release to the atmosphere at levels of "< 25 mg P_2O_5 per dry standard cubic meter of stack gas" (Gilmour 2019).

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

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

Ancillary Substances:
None

Discussion:
During the 2018 sunset review the NOSB unanimously voted to relist phosphoric acid. The discussion largely focused on the broader topic of sanitizers on the National List. It was stated at the time that while there is a general desire for a safer alternative to phosphoric acid, there didn't seem to be viable options at that time.

In 2020, the Board received a petition to expand the annotation of phosphoric acid "as an acidifier to adjust pH of an extraction solvent to extract antioxidants or other target molecules from *lamiaceae* plants, provided the amount of acid used shall not exceed the minimum needed to lower pH to 2.5" (USDA 2020b).

During the Fall 2022 Board meeting, the NOSB unanimously voted against the petitioned annotation expansion.

While there was a TR contracted in 2021 due to this petition, the TR focused on the petitioned use (not the current listing as an equipment sanitizer). Therefore, it did not specifically cover alternatives to phosphoric acid as an equipment sanitizer.

The Handling Subcommittee received several comments during the Spring 2023 meeting. Most comments seemed in favor of relisting based on essentiality. Phosphoric acid is widely used across several sectors. The focus of the comments in the Spring was on the broader topic of cleaners and sanitizers, along with questions related to consistency. This included consistency by certifiers when interpreting the annotation, as well as consistency of the listing and annotation across scopes, as phosphoric acid is listed on both the livestock and handling lists, and the annotations are slightly different.

During the Spring 2023 meeting the Board discussed these inconsistencies and seeks clarification prior to the Fall 2023 meeting.

The Handling Subcommittee discussed sanitizers and various options for how to address the broader topic, along with how to move forward to address the inconsistencies between the annotations as listed on the livestock list vs the handling list. At this time, the Subcommittee supports the continued listing of phosphoric acid.

Justification for Vote:
The Subcommittee finds phosphoric 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 phosphoric acid from the National List
Motion by: Kyla Smith
Seconded by: Allison Johnson
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

Potassium carbonate

Reference: 205.605(b) Synthetics allowed. (24) Potassium carbonate.
Technical Report: 1995 TAP; 2023 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote (pg. 338-339); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review
Subcommittee discussion included review of the public comments from the spring meeting.

Use:
Potassium carbonate is both a carbonate salt and a potassium salt with many uses. For processing and handling applications, the main uses are as follows:

Potassium carbonate is utilized in the production of yellow, alkaline wheat noodles found in both Chinese and Japanese cuisines. It is used in cocoa production during the "Dutching" process to restore the desired dark pigmentation. In raisin production, potassium carbonate can be used as a drying agent to decrease drying time and reduce spoilage from open air drying. Potassium carbonate is applied as a pre-harvest spray onto fruit, or as a pre-drying dip at an optimal 0.6% concentration, along with either olive oil or ethyl oleate[2023 TR 104 - 108]. Potassium carbonate is utilized to raise the pH in the deacidification of wine. It is also an allowed substance in the production of modified hop extract, as listed at 21 CFR 172.560. Potassium carbonate is approved for use as a boiler additive in the preparation of steam that will come in direct contact with food. Meat processors are exploring the use of potassium carbonate as a replacement for phosphates in processed meat products, along with a number of other alternatives. One study found that potassium carbonate, when applied at 0.3% or 0.5%, maintained the color of fresh pork, preserved tenderness, and reduced cooking loss when compared with an industry standard, sodium tripolyphosphate [2023 TR 124 - 127]. It is also used in soap production, soft drinks, and confections.

Manufacture:
Potassium carbonate is one of several potassium-containing compounds that may be referred to as potash. Traditionally, potash was created by leaching wood ashes with water, which extracted a crude form of potassium carbonate [2023 TR 51 - 53]. This type of potassium carbonate, and its more refined by-product, pearl ash, have been utilized for millennia, with applications in baking and glassmaking. Following the discovery of naturally occurring potassium salts (e.g., potassium chloride or potassium sulfate) in the 1860s, wood ash-derived potassium carbonate was replaced by mineral potassium salts obtained through shaft mining, dissolution mining, and evaporation methods [2023 TR 54 -57]. Potash mining is active worldwide, and commercial production of potassium carbonate depends primarily on potassium chloride brines, which are derived from potassium chloride salts that are found in mineral potash [2023 TR 57 - 59]

Modern, commercial production of potassium carbonate occurs through the reaction of potassium hydroxide with carbon dioxide, or CO2-containing off-gases from other industrial processes [2023 TR 61 - 62]

International Acceptance:
Canadian General Standards Board Permitted Substances List.
Potassium carbonate is listed in the Canadian General Standards Board Organic Production Systems Permitted Substances List (CAN/CGSB-32.311 - 2020) in the following locations:

- In Table 6.3, as a food additive, with no origin or usage annotations.
- In Table 6.5 as an allowed processing aid, with no origin or usage annotations.
- In Table 7.4 for allowed "cleaners, disinfectants and sanitizers permitted on organic product contact surfaces for which a removal event is mandatory" with the annotation that

"documentation shall demonstrate that effluent discharge was neutralized to minimize negative environmental impact."

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Potassium carbonate is listed in (EC) No 889/2008 under "Section A — Food Additives, Including Carriers" as an allowed substance for the "preparation of foodstuffs of plant origin." It is also listed under "Section B — Processing Aids and Other Products, Which May Be Used for Processing of Ingredients of Agricultural Origin from Organic Production" as allowed for the "preparation of foodstuffs of plant origin," and specifically for drying of grapes.

EU organic standards have been updated since 2008. (EU) 2018/848 is the current regulation. Its Article 24(2)(a) authorizes certain products and substances for use in the production of processed organic food as noted in restrictive lists. These lists are currently codified in (EU) 2021/1165. Part A of Annex V lists food additives and processing aids. Potassium carbonates, E 501, appear in "Section A1 - Food Additives, Including Carriers" for addition to products of plant origin. Potassium carbonate also appears in "Section A2 — Processing Aids and Other Products, Which May Be Used for Processing of Ingredients of Agricultural Origin from Organic Production," authorized only for the processing of organic grapes as a drying agent.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
Potassium carbonate is listed in the CODEX (GL 32-1999) guidelines in Table 3.1 as a "food additive, including carriers" for specific use in "cereals/cakes & biscuits/confectionary." It is also listed in Table 4 as "processing aids which may be used for the preparation of products of agricultural origin referred to in section 3 of these guidelines" and specific use for the "drying of grape raisins."

International Federation of Organic Agriculture Movements (IFOAM) Norms
Potassium carbonate is listed in the IFOAM Norms under the Standard for Organic Production and Processing in Appendix 4 – Table 1: List of Approved Additives and Processing/Post-Harvest Handling Aids for use as both an additive and a processing/post-harvest handling aid, without any limitation note.

Japan Agricultural Standard (JAS) for Organic Production
Potassium carbonate is listed in the Japanese Agricultural Standard for Organic Processed Foods under the "Appended Table 1 Additives," where it is stated to be "limited to the use in the drying of processed fruit products or in processed grain products, sugar, products containing legumes, noodles, bread, or confections."

Environmental Issues:
Emissions associated with manufacture include heat and CO_2 into air, as well as K^+ and OH^- in water [2023 TR 599 - 600].

As a food additive, potassium carbonate is utilized in small quantities compared to its applications as a livestock feed supplement or in other industrial processes)[2023 TR 640 - 643]. Negative effects on biodiversity or the general environment have not been reported in relation to the use of potassium carbonate as a food additive.

Ancillary Substances:
None

Discussion:
Potassium carbonate has a vast number of uses in organic production. There were only a handful of public comments from the Spring 2023 meeting; nearly all were supportive of relisting the material as it is currently listed. One commentor requested that of each of the many uses be reviewed independently for essentiality, while another suggested potassium carbonate be used only when sodium carbonate is not appropriate or to reduce sodium content in a product. The Board received no responses when asked if there were alternative products to displace the need for potassium carbonate.

Justification for Vote:
The Subcommittee finds potassium carbonate 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 carbonate from the National List
Motion by: Kim Huseman
Seconded by: Kyla Smith
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

Sulfur dioxide

Reference: 205.605(b) Synthetics allowed. (35) Sulfur dioxide - for use only in wine labeled "made with organic grapes," Provided, That, total sulfite concentration does not exceed 100 ppm.
Technical Report: 1995 TAP; 2011 TR
Petition(s): 2010 (to amend)
Past NOSB Actions: 04/1995 NOSB minutes and vote (pg. 333-334); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 12/2011 NOSB recommendation (annotation change not recommended); 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
Sulfur dioxide has been used as an antimicrobial and antioxidant in food, including wine, since Greek and Roman times. Sulfur dioxide is primarily used to inhibit microbial growth and prevent spoilage and oxidation in wine. It has also been used to preserve conventionally produced meats and avoid browning in fresh and dried produce and other products. The current National List annotation limits the use of sulfur dioxide to wine labeled "made with organic grapes" and further limits the sulfite concentration to not exceed 100 ppm.

Sulfur dioxide may play a number of roles in wine production, at multiple stages in processing. Cultivated yeasts added to enhance fermentation of wines have been selected to be more tolerant of sulfur dioxide than wild yeasts. Enough sulfur dioxide is added to deter growth of the wild yeasts or bacteria present in the grape juice, while not exceeding a level that will deter the growth of the desired, added, yeasts to the juice. This process helps to prevent the formation of "off" flavors. While sulfites occur naturally in wines, the level is too low to have a pragmatic effect.

Sulfites may be added to wine in various forms. Sulfur dioxide comes in pellet, liquid (sulfurous acid), or gaseous form. Potassium metabisulfite is commonly powdered; the 2022 Organic Materials Review Institute (OMRI) generic materials list states that potassium metabisulfite is prohibited.

Wine can be made successfully without added sulfites, but alternative interventions are often necessary to avoid microbial contamination, manage fermentation, and control oxidation. Sulfite reduction strategies include refrigerated fermentation in climate-controlled facilities, pasteurization via ultraviolet irradiation, and use of stable gases to fill the head space in packaging. Wines without added sulfur dioxide may also have a shortened shelf life.

Manufacture:
Sulfur dioxide can be produced commercially from several sources including elemental sulfur, ores of sulfide containing minerals, gypsum and anhydrite, and waste materials or flue gasses that contain sulfur. Most commonly, sulfur dioxide is generated by simply burning sulfur in devices that control air flow and that can capture the sulfur dioxide as it is generated.

International Acceptance:
Several major U.S. trade partners allow sulfur dioxide in "organic" wines and other alcoholic products produced from various fruits. Maximum sulfite levels vary depending on the product. Demeter Biodynamic standards also allow sulfur dioxide, potassium bisulfite, and potassium metabisulfite, up to 100 ppm sulfites at bottling.

Canadian General Standards Board Permitted Substances List.
Sulphur dioxide, sulphurous acid, and potassium metabisulphite are allowed as preservatives in organic alcoholic beverages under Canadian organic standards, with the following limitations/specifics:

- Sulphur dioxide includes sulphites from SO2-bottled gas; as liquid SO2; or liberated from ignition of asbestos-free sulphur wicks
- Minimal use of SO2 is recommended
- Maximum allowable levels of SO2 in parts per million (ppm) are:
  a) in alcoholic beverages containing less than 5% residual sugar, 100 ppm and 30 ppm for total and free sulphites, respectively;
  b) in alcoholic beverages containing 5%-10% residual sugar, 150 ppm and 35 ppm for total and free sulphites, respectively; and
  c) in alcoholic beverages containing more than 10%

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Sulphur dioxide, potassium bisulphite, and potassium metabisulphite allowed in products of the wine sector, with maximum sulphur dioxide limits set for certain product categories (EU 203/2012):

- Sulphur dioxide content not to exceed 100 milligrams per litre for certain red wines with a residual sugar level lower than 2 grams per litre;
- Sulphur dioxide content not to exceed 150 milligrams per litre for certain white and rosé wines

- with a residual sugar level lower than 2 grams per litre;
- For all other wines, the standard sulphur dioxide content allowed by EU regulations shall be reduced by 30 milligrams per litre

Sulphur dioxide and potassium metabisulphite allowed (EC 889/2008):

- In fruit wines (wine made from fruits other than grapes) without added sugar (including cider and perry) or in mead: 50 mg (maximum levels available from all sources, expressed as SO2 in mg/l)
- For cider and perry prepared with addition of sugars or juice concentrate after fermentation: 100 mg/l (maximum levels available from all sources, expressed as SO2 in mg/l)

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
Sulphur dioxide is listed in the Codex organic guidelines for use in cider and perry, grape wines, wines (other than grapes), and mead (GL-32-1999, Annex 2, Table 3).

International Federation of Organic Agriculture Movements (IFOAM) Norms
The IFOAM norms list sulfur dioxide and potassium metabisulphite for use in wine (IFOAM Norms 2014, Appendix 4 – Table 1).

Environmental Issues:
There are no expected adverse environmental effects from the use of sulfur dioxide as currently listed in on the National List.
Health Issues:
About 1% of the population reacts adversely to sulfites,[1] and reactions range from allergic reactions in individuals born without the enzyme needed to break down sulfur dioxide (sulfite oxidase), asthma attacks (which vary depending on individual sensitivity), hives and swelling, to anaphylaxis. Sulfite sensitivity may develop at any time, and reactions may not occur until middle age.[2]

U.S. law is highly protective of sensitive individuals. In the 1980s, widespread use of sulfites in restaurants, on products like salad bars and processed potatoes, led to several highly publicized deaths.[3] This prompted FDA to restrict the use of sulfites on some foods and implement labeling requirements.[4] Today, sulfur dioxide is not generally recognized as safe (GRAS) for use in meats, in food recognized as a source of vitamin B1 (because sulfites interfere with absorption), or fresh fruits and vegetables (e.g., salad bars, fresh produce in supermarkets).[5] Products with over 10 ppm sulfites must declare the presence of sulfites on the label.[6] The Bureau of Alcohol, Tobacco, Firearms created similar labeling requirements for alcoholic beverages.[7] Federal regulations allow up to 350 ppm sulfur dioxide in wine[8]

[1] Paul Grotheer et al., Sulfites: Separating Fact from Fiction (2011), *available at* http://edis.ifas.ufl.edu/fy731.

[2] Grotheer et al.

[3] Ruth Papazian, *Sulfites: Safe for Most, Dangerous for Some*, 30 FDA Consumer Magazine 10 (1996), *available at* http://permanent.access.gpo.gov/lps1609/www.fda.gov/fdac/features/096_sulf.html; Irvin Molotsky, *House Panel Hears Plea for Food Sulfite Ban*, N.Y. Times, Mar. 28, 1985, *available at* http://www.nytimes.com/1985/03/28/us/house-panel-hears-plea-for-food-sulfite-ban.html.

[4] Food Labeling: Declaration of Sulfiting Agents: Final Rule, 51 Fed. Reg. 25,012 (1986).

[5] 21 C.F.R. § 182.3862 (1997); Grotheer et al.

[6] 21 C.F.R. § 130.9 (1997); Grotheer et al.

[7] Labeling of Sulfites in Alcoholic Beverages, 51 Fed. Reg. 34,706 (Sept. 30, 1986).

[8] 27 C.F.R. § 4.22(b)(1) (2004).

and require a sulfite declaration for wines with 10 ppm or more total sulfur dioxide in the finished product.[9] Accordingly, sulfite sensitive consumers have strong access to the information they need to protect themselves from exposure.

Ancillary Substances:
None

Discussion:
Sulfur dioxide is considered safe at the levels allowed under the current annotation, which are more restrictive than those for nonorganic wines. Strict sulfite labeling requirements also allow sulfite-sensitive consumers to avoid products with added sulfites.

Wine can be made successfully without added sulfites, but many winemakers do not find alternative methods and materials satisfactory to prevent spoilage and oxidation in wine.

The current annotation allows the use of sulfur dioxide only in wines labeled "made with organic grapes," which continues to contribute to confusion in the marketplace. Internationally, the U.S. is an outlier in limiting use of sulfur dioxide to wines labeled "made with organic"; our major trade partners allow it in wines labeled "organic" as well as other fermented fruit products like cider and perry.

The labeling limitations for wine produced from organic grapes using sulfur dioxide have an important relationship with the potential growth of organic grape acreage. For example, in 2020, California had 625,000 acres of wine grapes, but only about 25,000 acres of harvested organic wine grapes.[10] Wine grapes are routinely treated with a wide range of pesticides, including glyphosate which has been found in wine.[11]

Several certifiers commented that very few or no operations use this material, while one certifier has over 70 wineries that use it. That certifier commented that they have clients who label wine "organic" and clients who label wine "made with organic grapes" and that sulfites are measured prior to bottling.

That certifier also noted that they have gotten questions about whether potassium metabisulfite and potassium bisulfite are allowed. They noted that they do not allow potassium metabisulfite, but that adding that material to water to generate sulfur dioxide may be allowed and that they have heard that form is safer. They also noted that potassium bisulfite is not addressed in the TR and that they have heard some European certifiers believe it is allowed. These materials should be addressed in the next TR for sulfur dioxide.

[9] 27 C.F.R. § 4.32(e) (2004).

[10] California Department of Food and Agriculture (CDFA), California Grape Acreage Report, 2021 Summary, https://www.nass.usda.gov/Statistics_by_State/California/Publications/Specialty_and_Other_Releases/Grapes/Acreage/2022/grpacSUMMARY2021Crop.pdf; CDFA, California Agricultural Organics Report, 2020-2021, https://www.cdfa.ca.gov/Statistics/PDFs/2021_Organics_Publication.pdf.

[11] California Department of Pesticide Regulation, Summary of Pesticide Use Report Data 2018, https://www.cdpr.ca.gov/docs/pur/pur18rep/pur_data_summary_2018.pdf (sulfur, allowed on organic and nonorganic acreage, contributes to the); Moms Across America, Widespread Contamination of Glyphosate Weedkiller in California Wine, 2016, https://d3n8a8pro7vhmx.cloudfront.net/yesmaam/pages/680/attachments/original/1458848651/3-24-16_GlyphosateContaminationinWineReport_(1).pdf?1458848651.

Several commenters supported relisting, in part due to the annotation limit on wines labeled "organic." One commenter noted that the use of elemental sulfur to produce sulfur dioxide presents health threats and that the material has inhalation risks.

The Board did not receive any comments on this material from winemakers.

The Board discussed the 100-ppm limitation and noted that European countries allow higher levels, as well as the allowance of sulfur dioxide in biodynamic wines. The Board may also wish to continue to discuss the forms allowed, the current annotation, and the best ways to balance the individual health risks associated with sulfites and the broader health and environmental threats of conventional wine production. It would be helpful to understand more about the current state of the organic and "made with organic" wine industry, label claims in use, and how sulfites are currently used in production of wine from organic grapes.

Questions to our Stakeholders:

1. Do you or your members/clients produce wine from organic grapes? What label claims do you use and why?
2. What form of sulfur dioxide do you use? Is there another form you would prefer, and if so, what and why?

Justification for Vote

The Subcommittee finds sulfur dioxide - for use only in wine labeled 'made with organic grapes,' Provided, That, total sulfite concentration does not exceed 100 ppm compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote:

Motion to remove sulfur dioxide - for use only in wine labeled 'made with organic grapes,' Provided, That, total sulfite concentration does not exceed 100 ppm from the National List
Motion by: Allison Johnson
Seconded by: Wood Turner
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

Xanthan gum

Reference: 205.605(b) Synthetics allowed. (37) Xanthan gum.
Technical Report: 1995 TAP; 2016 TR; 2018 TR (gums)
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote (pg. 332); 11/2005 NOSB sunset recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 11/2016 NOSB recommendation (none, reclassification not recommended); 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
Xanthan gums are one of the many gums used in organic handling for reasons including: (1) thickening and gelling, (2) stabilizing foams, emulsions, and dispersion, (3) inhibiting ice and sugar crystal formation, (4) aiding formulation, and (5) to control the release of flavors. Xanthan gum is an important ingredient for gluten-free products; it also is used in salad dressings, sauces, dairy products, along with other products.

Despite having similar characteristics and performing similar functions, gums are not interchangeable. Depending on their structure, each gum has a unique response to temperature, pH range, physical agitation, and so on (2018 TR). This variability requires gums to be matched to the type of food, intended shelf-life, and product use. Often several gums are used in combination to impart the correct properties in the finished goods (2018 TR). The table below is from the 2018 Technical Report, which distinguishes the different characteristics of common gums.

Table 1. Summary: General Properties of Gums

Property	Gum Arabic	Tragacanth gum	Guar gum	Locust bean gum	Gellan gum	Xanthan gum
Low viscosity (only becomes viscous at concentrations greater than 50%)	X					
High viscosity at 1% concentration		X				
High viscosity at low concentrations (but more than 1%)					X	X
Viscosity remains unchanged over time at low shear rates		X				
Viscosity decreases over time at low shear rates			X			
Forms thermo-reversible gels					X	
Thermally reversible					X	X
Thermally irreversible		X		X		
Insoluble in ethanol	X	X	X	X	X	X
Stable under acid conditions		X		X		X
Controls syneresis (weeping)			X	X		X

Xanthan gum was approved as a food additive by the Food and Drug Administration (FDA) in 1969 without restrictions on quantity in finished applications (2018 TR). The FDA specifies that the food additive xanthan gum may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is a polysaccharide gum derived from *Xanthomonas campestris* by a pure-culture fermentation process and purified by recovery with isopropyl alcohol. It contains D-glucose, D-mannose, and D-glucuronic acid as the dominant hexose units and is manufactured as the sodium, potassium, or calcium salt.

(b) The strain of *Xanthomonas campestris* is nonpathogenic and nontoxic in man or other animals.

(c) The additive is produced by a process that renders it free of viable cells of *Xanthomonas campestris.*

(d) The additive meets the following specifications:

(1) Residual isopropyl alcohol not to exceed 750 parts per million.

(2) An aqueous solution containing 1 percent of the additive and 1 percent of potassium chloride stirred for 2 hours has a minimum viscosity of 600 centipoises at 75 deg.F, as determined by Brookfield Viscometer, Model LVF (or equivalent), using a No. 3 spindle at 60 r.p.m., and the ratio of viscosities at 75 deg.F and 150 deg.F is in the range of 1.02 to 1.45.

Xanthan gum must pass the locust bean gum test and the pyruvic acid test. See 21CFR172.695 for more specificity.[12]

Manufacture:
Xanthan gum is a high-molecular weight polysaccharide produced though natural fermentation by *Xanthomonas campestris* and precipitation through addition of an alcohol; it subsequently is dewatered, possibly washed in a salt solution, dried, and milled (2018 TR). The gum is water soluble, stable at numerous pH, salt, and temperature ranges (including frozen temperatures) (2018 TR). The side chains carry negative charges and will associate with positive cations to increase the firmness of the solution (TR 2018). Overall, the structure of xanthan gum is such that it is a cellulose chain with trisaccharide side chains. In solution, the side chains wrap around the cellulose backbone and aid in the ability for xanthan gum to be stable in low pH and high salinity solutions (2018 TR). In addition to its wide applicability under differing food mediums, it also has pseudo-plastic characteristics which under shear force make the solution less viscous and thus easier to move during processing. When the shear force is removed, the solution will again exhibit its characteristic thickness. Xanthan gum is not a gelling agent, and as a result it is often used in combination with other materials including locust bean gum, guar gum, starches, carrageenan and konjac glucomannan to increase viscosity (2018 TR).

International Acceptance:
Canadian General Standards Board Permitted Substances List.
Permitted but must be derived using substances listed in Table 6.3 (page 32 on document linked above). Extraction solvents and precipitation aids. By exception, isopropyl alcohol may also be used to derive gums.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Allowed for use in products of plant and animal origin. Information sourced here (and not the link above).

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

Allowable in plant foods: for fats and oils, and fat emulsions; fruits and vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds; bakery wares; and salads (e.g., macaroni salad, potato salad). Not allowed in food of animal origin.

International Federation of Organic Agriculture Movements (IFOAM) Norms
Allowed as an approved additive, processing, and handling aid, with no limitations noted.

Japan Agricultural Standard (JAS) for Organic Production

[12] Code of Federal Regulations.
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=172.695

When used in processed products of livestock origin, limited to the use in dairy products or confections. Information found in this document.

Environmental Issues:
There was no mention in the TR of specific environmental issues regarding the production of xanthan gum.

Ancillary Substances:
According to the 2016 TR [258-263], ancillary substances are not commonly added to commercially available forms of xanthan gum for use in foods. The 2018 sunset review indicates that through a search of publicly available specification sheets, a few exceptions were identified: glucose in a xanthan and guar gum blend and polysorbate 60 in GRINSTED®. For 2023 sunset, a review of the GRINSTED® product literature reveals it is synergistic with guar and locust bean gum.

Discussion from 2018 review:
Xanthan gum has been used for decades globally in the food system and subsequently has undergone numerous clinical trials and studies to look for impacts on human health in adults, children, infants, and animals (TR 2018). Some studies have shown that xanthan gum is beneficial to human health; soluble fiber that may help improve colon health and reduce cholesterol (2018 TR).
A review of the safety of xanthan gum was conducted by the European Food Safety Authority Panel on Food Additives and Nutrient Sources found that xanthan gum can be classified as non-toxic. Xanthan gum would not be, they found, absorbed intact and would be partially fermented as it traveled through the large intestine. In studies on different animal species (dogs, rats, neonatal piglets) no adverse effects were observed. The panel recommended collecting data on usage and levels of xanthan gum to conduct a more realistic exposure level through diet.[13]

Recent research examines the impact of xanthan gum on the gut microbiome; the rationale for examining the impact is that xanthan gum is not similar to any existing dietary fiber.[14] Xanthan gum is an important ingredient for gluten-free products, and used in higher amounts for these products. Because of its 'low level but constant consumption,' a research team sought to try to understand its impact on gut microbiome health. The key finding is 'Our work demonstrates the existence of a potential xanthan gum food chain involving at least two members of different phyla of gut bacteria and provides an initial framework for understanding how widespread consumption of a recently introduced food additive influences human microbiomes.' The research team, in a different publication, indicate that in just 50 years, the introduction of xanthan gum to our diet has created a new chain (as described above).[15] Thus, the NOSB should keep abreast of this evolving line of research.

[13] EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS), Mortensen, A., Aguilar, F., Crebelli, R., Di Domenico, A., Frutos, M.J., Galtier, P., Gott, D., Gundert-Remy, U., Lambré, C. and Leblanc, J.C., 2017. Re-evaluation of xanthan gum (E 415) as a food additive. *EFSA Journal*, *15*(7), p.e04909.
[14] Ostrowski, M.P., La Rosa, S.L., Kunath, B.J., Robertson, A., Pereira, G., Hagen, L.H., Varghese, N.J., Qiu, L., Yao, T., Flint, G. and Li, J., 2022. Mechanistic insights into consumption of the food additive xanthan gum by the human gut microbiota. *Nature Microbiology*, *7*(4), pp.556-569.
[15] Ostrowski, M.P., La Rosa, S.L., Kunath, B.J., Robertson, A., Pereira, G., Hagen, L.H., Varghese, N.J., Qiu, L., Yao, T., Flint, G. and Li, J., 2021. The food additive xanthan gum drives adaptation of the human gut microbiota. *bioRxiv*.

The Handling Subcommittee's discussion centered around essentiality, the existence of an organic version, and questions about any environmental or human health concerns since last reviewed.

Summary of public comments and board discussions from 2023 Spring meeting:
Public comments for the Spring 2023 meeting numbered 16. Xanthan gum is the most widely used gum, and those using the product indicated that other gums had different properties and thus would be unable to replace xanthan. Two commenters asked USDA to reconsider the previous request to classify this as nonsynthetic. One commenter asked for a review of gellan and xanthan, since both are produced via fermentation, and one is classified as synthetic and the other as nonsynthetic. Other public comments stated there was a need to examine fermentation more carefully. Another commenter referred to emerging research that examines the impact of xanthan gum on the gut microbiome and urged the NOSB to look into the research. A few comments asked the NOSB to question and establish the essentiality of this ingredient. Most, but not all, comments were in support of relisting.

Board discussion on the gums was not extensive; one member asked about essentiality, indicating that if gums are needed for a specific mouth feel is that enough to make it essential. Another member called for greater transparency regarding the availability of organic versions of the non-synthetic gums, to help foster the shift away from using non-organic ingredients.

Subcommittee discussions focused on the fermentation process for the gums. The Subcommittee also discussed the different manufacturing processes as they relate to classification for synthetic and non-synthetic ingredients.

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

Subcommittee Vote:
Motion to remove xanthan gum from the National List
Motion: Carolyn Dimitri
Second: Kim Huseman
Yes: 0 No: 9 Abstain: 0 Recuse: 0 Absent: 0

Fructooligosaccharides

Reference: 205.606 Nonorganic agricultural substances allowed: (g) Fructooligosaccharides (CAS # 308066-66-2).
Technical Report: 2006 TR (FOS); 2015 TR
Petition(s): 2006
Past NOSB Actions: 04/2007 NOSB recommendation; 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 06/21/2007 (72 FR 35137); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
Fructooligosaccharides (FOS) is on the National List at § 205.606 as a non-organically produced agricultural product allowed as an ingredient in or on products labeled as "organic". As a non-digestible carbohydrate, this substance is used as a soluble prebiotic fiber ingredient in food products. While FOS is included in food products as a source of energy for probiotic bacteria residing in the gut of humans, it is not used as a nutrient source directly for humans. FOS is incorporated into milk products, cakes, biscuits, cookies, crackers, yogurt, ice cream, soup, and hard candy, among other foods.

Manufacture:
There are two common commercial methods of producing FOS:

1) **Inulin derived**. Inulin is a dietary fiber found in chicory (Belgian endive), Jerusalem artichoke, agave, and other plants. Chicory inulin is extracted from the source material via water extraction; the resulting inulin undergoes partial hydrolysis using the enzyme inulinase, which is extracted from an enzyme complex (carbohydrase) found in the fungus *Aspergillus niger.* The hydrolysis breaks long chain inulin into shorter chain FOS
2) **Sucrose derived**. Sugar cane or sugar beet extracted sugar is fermented with *Aspergillus japonicas.* The *A. japonicas* cells must be immobilized for the production of high-purity FOS, which can be accomplished by creating beads of the *A. japonicas* culture suspended in calcium alginate, a mobilizer. The *A. japonicas* cells hydrolyze (break) the sucrose molecules into glucose and fructose and then transfer molecules to an existing glucose-fructose chain to create one of the FOS complex sugars. Fermentation of sucrose by *A. japonicas* is generally inefficient. Higher purity FOS solutions can be achieved by several methods: filtration, enzyme extraction, or mixed culture fermentation with the yeast *P. heimii* to increase the purity of the FOS solution. Each of these methods introduces additional chemical or physical agents to the production process.

Both processes also use heat and pH control to speed up the enzyme reactions. Specifically, the adjustment of pH is accomplished using hydrochloric acid, which is a strong acid, or sodium hydroxide, a strong base. Potassium phosphate is also used for pH control. The FOS produced can then be further purified through filtration or further fermentation.

International Acceptance:
Canadian General Standards Board Permitted Substances List
FOS is not officially recognized as a dietary fiber source by Health Canada. This is because the fiber policy has not been updated since 1997 (Health Canada, 2012).

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

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

International Federation of Organic Agriculture Movements (IFOAM) Norms
FOS is not specifically listed.

Japan Agricultural Standard (JAS) for Organic Production
FOS is listed in the Approved FOSHU products list and classified as “foods to modify gastrointestinal conditions”.

Environmental Issues:
There is no information available from the Environmental Protection Agency (EPA) or the Food and Drug Administration (FDA) to suggest that environmental contamination results from the manufacture, use, misuse, or disposal of short-chain FOS. Regarding human health concerns, there are no known harmful effects on human health after exposure to short-chain FOS.

Ancillary Substances:
“There are no ancillary substances intentionally included in the FOS formulations as described in the petition, and no ancillary substances are intentionally added to the FOS products in the selected high-purity FOS fermentation.” [2015 TR 313-315]

Discussion:
During the last sunset review, FOS remained at § 205.606 by a vote of 14 to 1. Most stakeholder comments were in support of the continued listing of FOS. Further, there appear to be no new sources of organic FOS coming out of the last review session. Given that the strongest opposition to keeping FOS on the National List centers around the availability of organic supply, the Handling Subcommittee will focus on this aspect.

Questions to our Stakeholders:
None

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

Subcommittee Vote:
Motion to remove fructooligosaccharides (FOS) from the National List
Motion by: Jerry D’Amore
Seconded by: Dilip Nandwani
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

Gums water extracted only (Arabic; Guar; Locust bean; and Carob bean)

Reference: 205.606 Nonorganic agricultural substances allowed: (j) Gums - water extracted only (Arabic; Guar; Locust bean; and Carob bean).
Technical Report: 1995 TAP (acacia, arabic, locust bean, guar, carob bean); 2018 TR (gums)
Petition(s): N/A
Past NOSB Actions: 11/1995 NOSB minutes and vote (pg. 12-13); 10/2010 NOSB sunset recommendation; 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
Gum arabic, locust bean gum, carob bean gum, and guar gum are high molecular-weight-polysaccharides extracted via water processing and then drying and milling (2018 TR). The gums are extracted from the endosperm of plants of the *Leguminosae*. The specific plants are guar, carob, and locust bean. Gum Arabic is obtained from the exudate from the bark of the acacia tree and is one of the oldest known natural gums (1995 TAP; 2018 TR). These gums are used in various food applications due to their ability to modify the viscosity of products (hydrocolloid function) through the binding of water and generation of gelling effects (2018 TR). These properties are the primary function of gums and lend them to be common and popular thickeners and stabilizers in food products. Guar gum, gum Arabic, and locust bean/carob bean gum are also thickening agents, which makes them useful since not all hydrocolloids function as thickening agents (2018 TR).

Despite having similar characteristics and performing similar functions, gums are not interchangeable. Depending on their structure, each gum has a unique response to temperature, pH range, physical agitation, and so on (2018 TR). This variability requires gums to be matched to the type of food, intended shelf-life, and product use. Often several gums are used in combination to impart the correct properties in the finished goods (2018 TR). The table below is from the 2018 technical report, which distinguishes the different characteristics of common gums.

Gum Arabic is used in soft drinks, icing, fillings, chewing gum, confectionary treats, and for color stability (this is general use in food).

Guar gum is used in yogurt, ice cream, cheese, salad dressings, and sauces.

Locust bean/carob bean gum is used in ice cream, yogurt, sauces, prepared foods, and soups. In some cases, it is used with xanthan gum.

Table 1. Summary: General Properties of Gums

Property	Gum Arabic	Tragacanth gum	Guar gum	Locust bean gum	Gellan gum	Xanthan gum
Low viscosity (only becomes viscous at concentrations greater than 50%)	X					
High viscosity at 1% concentration		X				
High viscosity at low concentrations (but more than 1%)					X	X
Viscosity remains unchanged over time at low shear rates		X				
Viscosity decreases over time at low shear rates			X			
Forms thermo-reversible gels					X	
Thermally reversible					X	X
Thermally irreversible		X		X		
Insoluble in ethanol	X	X	X	X	X	X
Stable under acid conditions		X		X		X
Controls syneresis (weeping)			X	X		X

Source: Technical Report, 2018.

Manufacture:
Gum arabic is obtained from the exudate from dried sap collected from the stems and branches of the Acacia tree, both wild grown and cultivated. The gum is cleaned by mechanical sieves and graded, then milled to a powder (2018 TR).

Locust/carob bean gum is derived from the seeds of the carob tree, which are processed through a series of crushing, sifting, and grinding steps (2018 TR).

Guar gum is formed from the seeds of the guar bean plant. The endosperm is dehusked, milled and screened, and the gum is then clarified (2018 TR).

International Acceptance:
Canadian General Standards Board Permitted Substances List.
Is permitted but must be derived using substances listed in Table 6.3 (page 32 on document linked above). Extraction solvents and precipitation aids. By exception, isopropyl alcohol may also be used to derive gums.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Allowed for products of plant and animal origin.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
Allowed, although the restrictions of the General Standard for the Labeling of Prepackaged Foods apply.

International Federation of Organic Agriculture Movements (IFOAM) Norms
Allowed as an additive.

Japan Agricultural Standard (JAS) for Organic Production

- Carob bean/locust bean: Allowed, but when used in processed products of livestock origin, limited to the use in dairy products or processed meat products.
- Guar gum: Allowed, but when used in processed products of livestock origin, limited to use in dairy products, canned meats, or egg products. Gum Arabic: Allowed, but limited to the use in dairy products, edible oils or fats, or confections.

Environmental Issues:
No environmental or health concerns were noted in the manufacture or use of these gums in the general population. The EFSA (European Food Safety Authority) Panel on Food Additives and Nutrient Sources evaluated five gums in 2017 including arabic, guar, and locust. The panel found no need for a numerical acceptable daily intake (ADI) and no safety concerns for the general population. The panel also concluded there wasn't adequate data available to assess the effects of locust bean and guar gum on infants and young children and recommended that additional data be generated.

Ancillary Substances:
According to the 2018 TR, no information was found indicating that any additional materials are generally added to commercially available forms of the gums.

Discussion from prior review (for 2020 sunset):
Public comment received during the last review noted that while organic versions of these gums existed, the supply chain is inconsistent and therefore commenters supported continued listing at § 205.606.

There was also a request that the gums be listed individually so that organic supply of each specific gum could be considered on an individual basis.

The Handling Subcommittee's discussion centered around essentiality, the existence of an organic version and questions as to whether there are any environmental or human health concerns since last reviewed.

Summary of public comments and board discussion at Spring 2023 meeting:
According to the public comments, these are not widely used but those who use the gums consider them essential. At least one public commenter indicated using organic versions, and had no problem with sourcing organic versions (but hadn't decided yet if the non-organic version should be dropped from the National List). One commenter felt there was an insufficient supply of organic gums right now, especially given the growth in the organic sector. Two commenters suggested splitting the listing into three separate listings. There was no explicit request to remove the product from the list.

Board discussion on the gums was not extensive; one member asked about essentiality, indicating that if gums are needed for a specific mouth feel is that enough to make it essential. Another member called for greater transparency regarding the availability of organic versions of the non-synthetic gums, to help foster the shift away from using non-organic ingredients.

Justification for Vote:
The Subcommittee finds gums - water extracted only (Arabic; Guar; Locust bean; and Carob bean) compliant with the Organic Foods Production Act (OFPA) and 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote:
Motion to remove gums - water extracted only (Arabic; Guar; Locust bean; and Carob bean) from the National List.
Motion: Carolyn Dimitri
Second: Jerry D'Amore
Yes: 0 No: 9 Abstain: 0 Recuse: 0 Absent: 0

Lecithin de oiled

Reference: 205.606 Nonorganic agricultural substances allowed: (l) Lecithin - de-oiled.
Technical Report: 1995 TAP (bleached, unbleached); 2009 TR (bleached); 2023 TR
Petition(s): 2004 (to remove unbleached from §205.606); 2008 (to remove bleached from §205.605(b)); 2008 (to remove unbleached from §205.606)
Past NOSB Actions: 04/1995 NOSB minutes and vote (unbleached) (pg. 333); 05/2009 NOSB recommendation (unbleached/de-oiled) (to amend §205.606); 05/2009 NOSB recommendation (bleached to amend § 205.605(b); 10/2015 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to National List 04/21/2001 (65 FR 80547, 66 FR 15619); Sunset renewal notice published 10/16/2007 (72 FR 58469); Annotation change effective 03/15/2012 (77 FR 8089); Sunset renewal notice published 06/06/2012 (77 FR 33290); Sunset renewal notice published 03/15/2017 (82 FR 14420); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 6/22/2025

Subcommittee Review

Use:
The major uses for lecithin include as an emulsifier in margarine, chocolates, instantizing powders, release sprays, and baked goods. Lecithin is used as a natural surfactant between oil and water systems, as with margarine products. Lecithin also helps modify chocolates for better enrobing and reduces the crystallization of cocoa fat. With baked goods and dough, lecithin improves water absorption, increasing volume and shelf life, as well as improving uniformity. In addition, lecithin is used in pharmaceuticals for a wide range of purposes, including as a dietary supplement and an emulsifying agent for intravenous injections.

Manufacture:
Lecithin is extracted from soybeans and other plants. For example, soybeans are dried and flaked, and crude soybean oil is extracted almost exclusively with the use of hexane. Some expeller-pressed oil is processed further. The crude oil is filtered, hydrated, centrifuged, dried, and cooked. Standardized lecithin is the fraction of crude oil that is centrifuged. Some commercial lecithin is bleached with hydrogen peroxide or benzoyl peroxide to improve color.

International Acceptance:
Canadian General Standards Board Permitted Substances List
Lecithin-bleached is allowed only when the unbleached form is not available from organic sources. Lecithin is listed in the table of "Food Additives" of the "Non-organic Ingredients" section under the permitted substances list for processing and sanitation.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
The use of lecithin as 1) a fungicide, listed in the section, "Substances of crop or animal origin", for plant protection; and 2) a food additive, listed in the subsection "Food additives, including carriers" of the section "Ingredients of Non-Agricultural Origin", for preparation of foodstuffs composed of essentially one or more ingredients of plant and/or animal origin.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
Lecithin used for pest and disease control must be recognized by the certification body or authority, e.g., volume, frequency of application, specific purpose, etc. In addition, lecithin (obtained without bleaches and organic solvents) as a food additive is permitted for use in foods of plant origin and certain foods of animal origin.

International Federation of Organic Agriculture Movements (IFOAM) Norms
Lecithin (INS1: 322) functional uses as an antioxidant and emulsifier agent. Acceptable daily intake is not limited.

Japan Agricultural Standard (JAS) for Organic Production
There is no current mention of lecithin in JAS.

Environmental Issues:
Hexane is used to extract crude oil in soy flakes, as it gives the highest yield. Then, hexane is separated from the soybean oil using evaporators. The evaporated hexane is recovered and returned to the extraction process. Hydrogen peroxide or benzoyl peroxide is used in the bleaching process. Increased environmental concerns in using these chemicals have resulted in legislation which could restrict oil processing operations that use hexane. In 1979, a report contracted by the FDA [2009 TR 290-291] concluded that there is no evidence in the available information on lecithin and lecithin bleached with hydrogen peroxide that demonstrates or suggests reasonable grounds to suspect a hazard to the public when used at levels that are now current or that might reasonably be expected in the future.

Regarding human health, there were no acute exposure studies found for soybean-derived lecithin in humans. Lecithin, including bleached lecithin, is affirmed as Generally Recognized as Safe (GRAS) with no limitations other than current good manufacturing practice (GMP) by FDA in 21 CFR 184.1400.

Ancillary Substances:
Under current uses as an emulsifier, there are no ancillary substances required for use of lecithin.

Discussion:
During the last sunset review in 2018, the NOSB voted 12 to 3 to keep lecithin-de-oiled on the National List. Stakeholder comments tended to center around the availability of suitable and sufficient supply of organic raw material (mostly soybeans or corn). Five years ago, it was felt that there was not sufficient organic supply.

The question of suitable and sufficient supply of organic raw material was addressed by the 2023 TR which was received by the Board in early February 2023. While there appears to be some products that are organic, it was noted that these alternatives do not result in the same quality of finished product.

Question to our Stakeholders:
None.

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

Subcommittee Vote:
Motion to remove lecithin - de-oiled from the National List
Motion by: Jerry D'Amore
Seconded by: Kyla Smith
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

Tamarind seed gum

Reference: 205.606 Nonorganic agricultural substances allowed:
(r) Tamarind seed gum.
Technical Report: 2018 TR
Petition(s): 2017; 2017 (addendum #1)
Past NOSB Actions: 10/2018 NOSB recommendation
Regulatory Background: Added to National List 12/07/2020 (85 FR 70431)
Sunset Date: 12/07/2025

Subcommittee Review

Use:
Tamarind seed gum is a relatively new gum, that is used as a thickener, stabilizer, emulsifier, or gelling agent in processed foods. The peer reviewed literature lists the following uses for tamarind seed gum: emulsifier, stabilizer, gelling agent, palatability improver, antimicrobial agent, insulator, odor improver, glazing agent, stickiness preventer, and bodying agent. Converts organic waste into biofertilizers. Allows proliferation of gram-negative bacteria.[1] The product is a replacement for, or used with, other gums such as carob bean gum, guar gum, tragacanth gum, and xanthan gum. There are also pharmaceutical uses for this product. Tamarind seed gum is limited to non-acid hydrolyzed forms.

The primary use of tamarind seed gum is as a stabilizer and thickener, and it can be used to replace pectin when making jams and preserves.

Tamarind seed gum is agricultural and non-synthetic and might be an acceptable alternative to synthetic gums if organic tamarind kernels can be sourced in the future. The nonorganic form of the ingredient will only be permitted when organic tamarind seed gum is not commercially available.

The Food and Drug Administration (FDA) classified tamarind seed gum as Generally Recognized As Safe (GRAS) in 2014. The GRAS notice covers the use of tamarind seed polysaccharide as a thickener, stabilizer, emulsifier, and gelling agent in 12 food categories: ice cream, sauces and condiments, dressings and mayonnaise, fruit preserves, desserts, beverages, pickles, tsukudani, spreads and fillings, flour products, soup and all other food categories at levels ranging from 0.2–1.5 percent of product composition. Use levels are identified for each food category.

Table 2. Comparison of properties between tamarind seed gum and other gums on §205.605-606.

Property	Tamarind seed gum	Gum arabic	Tragacanth gum	Guar gum	Locust (Carob) bean gum	Gellan gum	Xanthan gum
Low Viscosity (only becomes viscous at concentrations greater than 50%)	Moderate viscosity	X					
High Viscosity at 1 % concentration			X				
High Viscosity at low concentrations (but above 1%)						X	X
Viscosity remains unchanged over time at low shear rates	X		X				
Viscosity decreases over time at low shear rates				X			
Forms thermo-reversible gels						X	
Thermally reversible						X	X
Thermally irreversible			X		X		
Insoluble in ethanol	X	X	X	X	X	X	X
Stable under acid conditions	X		X	X	X		X
Controls syneresis (weeping)	X			X	X		X

Source: Technical Report, 2018.

Manufacture:
Tamarind seed gum comes from an evergreen tree, *Tamarindus indica*, a species of *Caesalpiniaceae,* subfamily native to Africa and southern Asia. The tree can grow in many types of soil, including poor soils; it fixes nitrogen; and is drought tolerant (Hemshekhar, M., K. Kemparaju, K.S Girish. 2011).

The fruit is a pod with 3-10 seeds. To manufacture the gum, the seed is roasted to remove the seed coat. Next, the tamarind kernel is pulverized to a powder. Then, a water soluble galactoxyloglucan polysaccharide is extracted from the powder. The polysaccharide is dried, pulverized, sieved, and mixed with food-grade bulking agents such as sugars (sucrose, glucose, lactose, galactose and maltose), dextrin or maltodextrin to standardize the quality of the product for desired viscosity (FAO, 2017, Chemical). The powder is light brown in color.

Galactoxyloglucan is composed of a linear chain of (1→4)-β-d-glucan that is partially substituted with side chains of (1→6)-α-d-xylopyranose and β-d-galactopyranosyl linked with (1→2)-a-d-xylopyranose linked (1→6) to glucose residues. The ratio by weight of the three sugar constituents (glucose, xylose, and galactose) in tamarind gum is roughly 3:2:1 (Health Canada, 2017).

International Acceptance:
There is growing interest in tamarind seed polysaccharide. Tamarind seed polysaccharide has been used as a food additive in Japan for more than 50 years.[2] FAO (Food and Agriculture Organization of the United Nations) performed a technical review of tamarind seed in 2017.

Canadian General Standards Board Permitted Substances List
First permitted for general use in Canada (i.e., not organic specifically) in 2017. Not mentioned in the list of approved gums.

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

Not mentioned.

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

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

Japan Agricultural Standard (JAS) for Organic Production
While tamarind seed polysaccharide has been used as a food additive in Japan for more than 50 years.[2] It is not mentioned in their organic standards.

Environmental Issues:
There is little to no negative environmental impact from the use of tamarind seed gum. Because it has a structure similar to cellulose, soil bacteria existing in the natural environment have enzymes that can break down tamarind seed gum. There are no documented adverse human health impacts.

Ancillary Substances:
None identified

Discussion:
During the last review (which took place in 2018) the NOSB determined that tamarind seed gum posed no harm to the environment or human health and recommended to list it due to its compatibility with organic production and handling systems.

The Handling Subcommittee's discussion centered around essentiality, the existence of an organic version, and questions about any environmental or human health concerns since it was last reviewed.

Summary of public comments and board discussion (2023 Spring meeting):
Public comments indicated little-to-no use of this product. Comments focused on whether there is availability of organic tamarind seed gum, and argued that working with processors and producers could help build an organic supply chain (that is separate from the conventional supply chain). Another commenter suggested it is not essential and thus should be removed from the list.

Board discussion on the gums was not extensive; one member asked about essentiality, indicating that if gums are needed for a specific mouth feel is that enough to make it essential. Another member called for greater transparency regarding the availability of organic versions of the non-synthetic gums, to help foster the shift away from using non-organic ingredients.

Questions to our Stakeholders:
1. Is an organic version of tamarind kernels/seeds commercially available?
2. Is this product essential?
3. Are there any ancillary substances used with this product?
4. Have any environmental or health concerns emerged since the product was added to the National List?

Justification for Vote:
The Subcommittee finds tamarind seed gum compliant with the Organic Foods Production Act (OFPA) and 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote:
Motion to remove tamarind seed gum from the National List
Motion: Carolyn Dimitri
Second: Allison Johnson
Yes: 0 No: 9 Abstain: 0 Recuse: 0 Absent: 0

References

1. Hemshekhar, M., K. Kemparaju, K.S Girish. 2011. Chapter 131 - Tamarind (Tamarindus indica) Seeds: An Overview on Remedial Qualities, Editor(s): V.R. Preedy, R.R. Watson, V. B. Patel, Nuts and Seeds in Health and Disease Prevention, Academic Press, pp. 1107-1114, https://doi.org/10.1016/B978-0-12-375688-6.10131-8.
2. FAO. 2017. Chemical and technical assessment: Tamarind Seed Polysaccharide.
3. Health Canada, 2017. Health Canada's Proposal to Allow the Use of Tamarind Gum as and Emulsifying, Gelling, Stabilizing and Thickening Agent in Unstandardized Foods and Certain Standardized Foods.

Tragacanth gum

Reference: 205.606 Nonorganic agricultural substances allowed:
(s) Tragacanth gum (CAS #-9000-65-1).
Technical Report: 2018 TR (gums)
Petition(s): 2007
Past NOSB Actions: 05/2008 NOSB recommendation; 10/2014 NOSB sunset recommendation; 10/2018 NOSB sunset recommendation
Regulatory Background: Added to the National List 12/14/2010 (75 FR 77521); Sunset renewal notice published 06/19/2015 (80 FR 35177); Sunset renewal notice published 05/07/2020 (85 FR 27105)
Sunset Date: 06/22/2025

Use:
Tragacanth gum is a polysaccharide that forms a gel that can be used as a thickener and emulsifier. Tragacanth gum forms a gelatinous mass in water and is used as suspending agent, excipient, or emulsifier in food. This material is effective at low pH and at many temperatures. Its stability at low pH is noted as one of its distinguishing characteristics, and it is commonly used in high-acid products like salad dressings [2018 TR, 341]. Tragacanth is widely used in low-fat or non-fat products (Nejatian, M., Abbasi, S. and Azarikia, F., 2020.) The percentage of tragacanth gum in final formulations is usually low, below 1% of a total formula [2018 TR l337-338]. Tragacanth gum is listed as Generally Recognized as Safe (GRAS) by the FDA in 1972 (21 CFR 184.1351).

Despite having similar characteristics and performing similar functions, gums are not interchangeable. Depending on their structure, each gum has a unique response to different environments, such as temperature, pH range, and physical agitation (2018 TR). This variability requires gums to be matched to the type of food, intended shelf-life and product use. Often several gums are used in combination to impart the correct properties in the finished goods (2018 TR). The table below is from the 2018 TR, which distinguishes the different characteristics of common gums.

Table 1. Summary: General Properties of Gums

Property	Gum Arabic	Tragacanth gum	Guar gum	Locust bean gum	Gellan gum	Xanthan gum
Low viscosity (only becomes viscous at concentrations greater than 50%)	X					
High viscosity at 1% concentration		X				
High viscosity at low concentrations (but more than 1%)					X	X
Viscosity remains unchanged over time at low shear rates		X				
Viscosity decreases over time at low shear rates			X			
Forms thermo-reversible gels					X	
Thermally reversible					X	X
Thermally irreversible		X		X		
Insoluble in ethanol	X	X	X	X	X	X
Stable under acid conditions		X		X		X
Controls syneresis (weeping)			X	X		X

Source: Technical Report, 2018.

Manufacture:
Tragacanth gum is prepared from the sap of various species of legumes in the *Astragalus* species (small woody shrubs, which grow in Southwest Asia, Iran, Syria, Turkey, and Greece) during July to September. A mass of gum grows in the roots of the plant, which is collected from the taproot and mechanically ground to a fine powder (EFSA Panel on Food Additives and Nutrient Sources). It may undergo a mitigation step to reduce the microbial load of the powder (2018 TR).

International Acceptance:

Canadian General Standards Board Permitted Substances List
Tragacanth gum is permitted but must be derived using substances listed in Table 6.3 (Permitted Substances List, page 32). Extraction solvents and precipitation aids. By exception, isopropyl alcohol may also be used to derive gums.

European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008
Tragacanth gum is allowed as a food additive in compliance with the General Standard for Food Additives Annex II and III of the Regulation (EC) No. 1333/2008 on food additives (2018 TR, line 506-515).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CXG 32-1999)
Permitted, although exclusions of the general standards for food additives (GSFA) apply.

International Federation of Organic Agriculture Movements (IFOAM) Norms
Allowed as an additive.

Japan Agricultural Standard (JAS) for Organic Production
Allowed, with no listed restrictions.

Environmental Issues
No environmental or health concerns were noted in the manufacture or use of tragacanth gum.

Ancillary Substances
According to the 2018 TR (line 434-438), no information was found indicating that any additional materials are added to commercially available forms of the gums.

Discussion:
The Handling Subcommittee's discussion centered around essentiality, the existence of an organic version, and questions about any environmental or human health concerns since the last review.

From 2018 sunset review:
A review of the safety of tragacanth gum was conducted by the European Food Safety Authority Panel on Food Additives and Nutrient Sources, which found that humans tolerated a high dose for 21 days, with undesirable effects. There were no known carcinogenic effects for mice. The Panel recommended that the European Commission considers lowering the current limits for the toxic elements (lead, cadmium, mercury, and arsenic) in the EU specification to ensure that the food additive will not be a significant source of exposure to those toxic elements in food. The 2018 TR for gums summarized the results from the 2017 European Food Safety Authority Panel on Food Additives and Nutrient Sources Added to Food, and for tragacanth gum the panel found no need for a numerical acceptable daily intake (ADI) and no safety concerns for the general population.

Summary of public comments and board discussion from 2023 Spring meeting:
Seven written public comments addressed tragacanth gum. The gum is not widely used, with only one certifier reporting use, and that certifier indicated just four operations use the gum. One commenter asked what barriers exist regarding organic tragacanth. One commenter opposed relisting, while two support relisting. The commenter opposing relisting pointed out that the Center for Science in the Public Interest lists tragacanth gum as a food additive that certain people should avoid, and reiterated their earlier 2015 request that the NOSB look into this. There is a new, small body of research that examines the immune response to different gums, and this line of research does suggest examining these gums more closely (Vojdani, C., 2015. Immune reactivities against gums. *Alternative Therapies in Health and Medicine*, *21*, p.64.)

Board discussion on the gums was not extensive; one member asked about essentiality, indicating that if gums are needed for a specific mouth feel is that enough to make it essential. Another member called for greater transparency regarding the availability of organic versions of the non-synthetic gums, to help foster the shift away from non-organic ingredients.

Questions to our Stakeholders:
None.

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

Subcommittee Vote:
Motion to remove tragacanth gum from the National List
Motion: Carolyn Dimitri
Second: Kyla Smith
Yes: 0 No: 9 Abstain: 0 Recuse: 0 Absent: 0

National Organic Standards Board
Materials Subcommittee
2023 Research Priorities Proposal
Fall 2023

Executive Summary

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.

The following list contains a brief summary of each research priority, which is described in depth later in the document.

Livestock

1. 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.
2. Evaluate natural alternatives to DL-Methionine in a system approach for organic poultry feed program.
3. Develop a dairy program to address climate change mitigation strategies where production capabilities are not hindered, and effective forage rotations are maximized.
4. 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.
5. Elucidate the barriers to increased organic pork production.

Crops

Inputs

1. Examination of decomposition rates, the effects of residues on soil biology, and the factors that affect the breakdown of biodegradable bio-based mulch film.
2. The extent and impact of plastic use in organic crop production, and how we can start to reduce it.
3. Side-by-side trials of approved organic inputs, both synthetic and natural, and cultural methods, with a request for collaboration with the IR4 project.
4. 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.

5. Holistic soil research to quantify soil biology.
6. The demand for organic nursery stock far exceeds the supply. Research is needed to identify the barriers to expanding this market, then develop and assess organic methods for meeting the growing demand for organically grown nursery stock.
7. Comprehensive review of copper.

Contaminants

8. Alternatives to eliminate usage and remediation strategies to mitigate contaminated areas for Per- and Polyfluoroalkyl substances (PFAS).
9. Assessing the economic impact of GMO contamination on organic crops.
10. Investigate contaminated inputs from non-organic sources.

Systems

11. Conduct whole farm ecosystem service assessments to determine the economic, social, and environmental impact of farming systems choices.
12. Elucidate practices that reduce greenhouse gas emissions and that contribute to farming systems' resilience in the face of climate change.
13. Factors impacting organic crop nutrition, and organic/conventional nutrition comparisons.
14. Organic no-till practices for diverse climates, crops, and soil types.
15. Develop cover cropping practices that come closer to meeting the annual fertility demands of commonly grown organic crops.
16. Development of systems-based plant disease management strategies (including specific considerations related to copper use in organic rice production) are needed to address existing and emerging plant disease threats.
17. More research, extension, and education are needed to fully understand the relationship between on-farm biodiversity and pathogen presence and abundance.
18. Strategies for the prevention, management, and control of problem insects and weeds.

Food Handling and Processing

1. Sanitizers: Effective alternatives of sanitizers, effect on occupational human health and environment, effectiveness of rotational use strategies with the sanitizers currently on the National List.
2. Effect of various types of food packaging on organic products, including suitable alternatives to BPA (Bisphenol-A) for linings of cans used for various products, plastic use, antimicrobial nanoparticle surface coatings of packaging.

3. Research on the creation of an overarching ancillary ingredient review process for materials used in processing and handling vs reviewing ancillaries as part of the petition or sunset review process, including cost/benefit of each process.

4. Alternatives to conventional celery powder for curing organic meat.

5. Research on best practices for identifying potential vectors of heavy metal contamination in organic systems, including strategies for effective testing in soils, water, organic processing, etc. that could lead to the identification and prevention of heavy metals transgression in organic systems.

6. Evaluation of the essentiality of 205.605(a), 205.605(b), and 205.606 substances and the suitability of organic alternatives in applicable food formulations via laboratory testing, sensory evaluation, and/or market analysis.

Materials / Coexistence with GE and Organic Crops

1. Outcome of genetically engineered (GMO/GE) material in organic compost.
2. Evaluation of public germplasm collections of at-risk crops for the presence of GE traits, and ways to mitigate small amounts of unwanted genetic material in breeding lines.
3. Develop, then implement, methods of assessing the genetic integrity of crops at risk to quantify the current state of the organic and conventionally produced non-GMO seed.
4. Techniques for preventing adventitious presence of GE material in organic crops, and evaluation of the effectiveness of current prevention strategies.
5. Testing for fraud by developing and implementing new technologies and practices.
6. Improving our understanding of the (1) potential threats and (2) costs to the organic sector that result from the use of excluded methods.

General

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

National Organic Standards Board
Materials Subcommittee
2023 Research Priorities Proposal
Fall 2023

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 Spring 2023 Board meeting. The Board requested input from stakeholders on the 2023 research priorities and has reviewed those comments for the Fall 2023 proposal.

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

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

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

Livestock

1. 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.

2. Evaluation of Methionine in the Context of a System Approach in Organic Poultry Production - Methionine is an essential amino acid for poultry. Prior to the 1950's, poultry and pigs were fed a plant and meat-based diet without synthetic amino acids such as methionine. One former NOSB member stated, in 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.

3. 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.

[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.

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.

4. 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.

5. Elucidate the barriers to increased organic pork production. 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.

Crops

Inputs

1. 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?

2. 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?

3. 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.

4. 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.

5. 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. Comprehensive, holistic assessments need to be developed and compared.

6. Identify Barriers and Develop Protocols for Organic Nursery Stock Production

The demand for organic nursery stock far exceeds the supply. Research is needed to identify the barriers to expanding this market, then develop and assess organic methods for meeting the growing demand for organically grown nursery stock. That work could include but is not limited to assessing phytosanitary rules for shipping plants and quantifying the production and demand for organic rootstock. Research has shown that application of the correct ectomycorrhizal inoculants to roots can substantially (50% or more) enhance establishment and early growth of woody perennial horticultural crops. How can fine tuning the use of mycorrhizal inoculants make organic nursery stock production easier and more profitable, thereby helping to close the demand/supply gap?

Research centered on development of practical organic methods for the nursery industry to implement is needed, including:

- Disease and insect control materials that are allowed under organic standards and may be accepted under specific phytosanitary regulatory requirements.
- New materials for controlling pests addressed by phytosanitary rules that show promise of compatibility with National List review criteria.
- Alternative protocols for phytosanitary certification of nursery stock that are based on outcomes (such as testing or inspection) rather than requirements for use of synthetic materials during production.

7. 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

8. 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.

9. 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.

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?

10. 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

11. 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?

12. Climate Change (Reducing Greenhouse Emissions and Sequestering Carbon)

A growing body of research demonstrates that organic farming can help prevent anthropomorphic climate change, and some strategies employed by organic farming can also help with resilience to current climate challenges such as drought and flooding. Although 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.

13. 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.

14. 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.

15. 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.

16. Disease Management

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

17. 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.

18. Management of Problem Insects and Weeds

There is a large pool of research on the control of insects 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

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, pest, 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.

Handling

1. 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?

2. Effect of various types of food packaging on organic products, including suitable alternatives to BPA (Bisphenol-A) for linings of cans used for various products, plastic use, antimicrobial nanoparticle surface coatings of packaging.

3. Research on the creation of an overarching ancillary ingredient review process for materials used in processing and handling vs reviewing ancillaries as part of the petition or sunset review process, including cost/benefit of each process.

- Full proposal draft language: 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.

4. Production of celery for celery powder yielding nitrates sufficient for cured meat applications, and investigation of agriculturally derived alternatives.

- Full Proposal: 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?

5. Research on best practices for identifying potential vectors of heavy metal contamination in organic systems, including strategies for effective testing in soils, water, organic processing, etc. that could lead to the identification and prevention of heavy metals transgression in organic systems.

- *[intentionally does not include further detail]*

6. Evaluation of the essentiality of 205.605(a), 205.605(b), and 205.606 substances and the suitability of organic alternatives in applicable food formulations and/or analysis of the barriers to organic production via laboratory testing, sensory evaluation, and/or market analysis

- Full proposal draft language: 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.

Materials/GMO

In previous years, the Materials Subcommittee has prioritized the Reduction of Genetically Modified Content of Breeding Lines (2013) and Seed Purity from GMOs (2014), issues which are currently being addressed through a comprehensive stream of work on Excluded Methods. The following research priorities are among the areas that the Excluded Methods work continues to elevate:

1. Fate of Genetically Engineered Plant Material in Compost - What happens to transgenic DNA in the composting process? Materials such as cornstalks from GMO corn or manure from cows receiving rBGH are often composted, yet there is little information on whether the genetically engineered material and traits break down in composting process. Do these materials affect the microbial ecology of a compost pile? Is there trait expression of Bt (bacillus thuringiensis) after composting that would result in persistence in the environment or plant uptake?

2. Integrity of Breeding Lines and Ways to Mitigate Small Amounts of Unwanted Genetic Material - Are public germplasm collections that house at-risk crops threatened by transgenic content? Breeding lines may have been created through genetic engineering methods such as doubled haploid technology, or they may have had inadvertent presence of GMOs from pollen drift. The extent of this problem needs to be understood.

3. Assess the Genetic Integrity of Organic Crops At Risk - Develop then implement methods of assessing the genetic integrity of crops at risk to quantify the current state of the organic and conventionally produced non-GMO seed. Such assessments are needed on the front (seed purchased by farmers) and back end (seed harvested from a farmer's field) of the production chain as well as on points of contamination in the production chain.

4. Prevention of GMO Crop Contamination: Evaluation of effectiveness - How well are some of the prevention strategies proposed by the NOSB working to keep GMOs out of organic crops? For instance, how many rows of buffer are needed for corn? How fast does contamination percentage go up or down if there are more or fewer buffer rows? Other examples could be whether cleanout of combines and hauling vehicles reduces contamination using typical protocols for organic cleaning, whether situating at-risk crop fields upwind from GMO crops can reduce contamination, and what the role may be of pollinators in spreading GMO pollen. Lastly, research is needed on a mechanism to provide conventional growers incentives to take their own prevention measures to prevent pollen drift and its impact on organic and identity-preserved crops. This is policy research rather than field research but is equally as important.

5. Testing for Fraud: Developing and implementing new technologies and practices - new technologies, tests, and methodologies are needed to differentiate organic crop production from conventional production to detect and deter fraud. Testing to differentiate conventional and organic livestock products, for example omega 3 or other indicators, is also needed. Additional tools to identify fraudulent processed and raw organic crops require research to combat this problem. Current methodologies include pesticide residue testing, in field soil chemical analysis, and GMO testing. Areas in need of further testing methodology include phostoxin residues, fumigant residues, carbon isotope rations for traceability, validating nitrogen sources using nitrogen isotope rations, or other experimental testing instruments that can be utilized to distinguish organic raw and/or processed crops from conventional items. Additionally, there is a need to develop rapid detection technologies for adaptation to field-testing capacities.

6. 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

1. Increasing Access to Organic Foods - What factors influence access to organically produced foods? Individual-based studies are needed to assess the constraints to accessing 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.

> *A. In the quest to understand barriers to organic food access in minority communities, and other under-resourced populations, is there a causal relationship between the total funds received by those research institutions who serve said communities and the rate of consumption of organic foods in those communities?*

2. Barriers to Transitioning to Organic Production - What are the specific production barriers and/or yield barriers that farmers face during the three-year transition period to organic? Statistical analysis of what to expect economically during the transition is needed to help transitioning growers prepare and successfully complete the transition process.

Subcommittee Vote:
Motion to accept the proposal on the 2023 NOSB Research Priorities
Motion by: Wood Turner
Seconded by: Dilip Nandwani
Yes: 6 No: 0 Abstain: 0 Recuse: 0 Absent: 1

Approved by Wood Turner, Materials Subcommittee Chair, to transmit to NOSB, August 8, 2023