Sunset 2026
Meeting 2 - Reviews
Handling Substances § 205.605(a), § 205.605(b), § 205.606
October 2024

Introduction

As part of the Sunset Process, the National Organic Program (NOP) announces substances on the National List of Allowed and Prohibited Substances (National List) that are coming up for sunset review by the National Organic Standard Board (NOSB). The following list announces substances that must be reviewed by the NOSB and renewed by the USDA before their sunset dates. This document provides the substance's current status on the National List, annotation, references to past technical reports, past NOSB actions, and regulatory history, as applicable. Substances included in this document may also be viewed in the NOP's Petitioned Substances Index.

Request for Comments

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

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

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

For Comments that Support the Continued Use of Substances in Organic Production at § 205.605(a), § 205.605(b), and/or § 205.606:

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

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

For Comments that Do Not Support the Continued Use of Substances in Organic Production at § 205.605(a), § 205.605(b), and/or § 205.606:

If you provide comments that do not support a substance on § 205.605(a), § 205.605(b), and/or § 205.606, you should provide reasons why the use of the substance should no longer be allowed in organic production. Specifically, comments that support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:

1. harmful to human health or the environment;
2. unnecessary because of the availability of alternatives; and

3. inconsistent with organic handling.

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

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

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

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

Written public comments will be accepted through September 30, 2024 via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

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

Acids - Citric
Acids - Lactic
Calcium chloride
Enzymes
L-Malic acid
Magnesium sulfate
Microorganisms
Perlite
Potassium iodide
Pullulan
Yeast

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

Activated charcoal

Ascorbic acid
Calcium citrate
Collagen gel
Ferrous sulfate
Hydrogen peroxide
Nutrient vitamins and minerals
Peracetic acid/Peroxyacetic acid
Potassium citrate
Potassium phosphate
Sodium acid pyrophosphate
Sodium citrate
Tocopherols

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

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

Acids Citric

Reference: § 205.605(a) Nonsynthetics allowed
(1) Acids (Citric – produced by microbial fermentation of carbohydrate substances; and Lactic).
Technical Report: 1995 TAP - Citric; 2015 TR - Citric; 1995 TAP - Lactic; 2015 TR - Lactic; 2023 Limited Scope TR (Citric acid and salts)
Petition(s): N/A
Past NOSB Actions: 04/1995 recommendation; 11/2005 sunset recommendation; 03/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

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

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

NOSB requested a limited scope TR for citric acid in preparation for this sunset review. The limited scope TR focused on the microorganisms used in the fermentation process to manufacture citric acid and what potential there is for these microorganisms to have been produced through excluded methods as defined by the NOP regulations. Based on available information, most citric acid manufacturers use wild type fungal strains or strains that are products of classical induced mutagenesis. The use of microorganisms developed using excluded methods appears to remain at an experimental phase and is not commercially available.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed in feed. Preference should be given to bacterial or enzymatic additives derived from bacteria, fungi, plants, and food by-products (such as molasses and whey). The following acids may be used: lactic, propionic, and formic. (Table 5.2, Hay or silage preservation products listing, CAN/CGSB-32.311-2020 page 24)

Allowed as food additives. (Table 6.3, CAN/CGSB-32.311-2020, page 30)

Allowed as processing aids from fruit and vegetable products or produced by microbial fermentation of carbohydrate substances. (Table 6.5, Citric acid listing, CAN/CGSB-32.311-2020, page 38)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Citric acid is allowed in plant & animal products as a processing aid. Lactic acid is allowed in the brine of cheese products (Annex V, Part A, Section A2, 2021/1165)

Both lactic and citric acids are allowed in animal and plant products as additives. (Annex V, Part A, Section A1, 2021/1165)

Both lactic and citric acids are allowed for the regulation of pH in primary yeast production. (Annex V, Part C, 2021/1165)

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Citric acid is allowed in the following foods of plant origin: Fruits and vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera, seaweeds, and nuts and seeds).

Citric acid is allowed in the following foods of animal origin: fats and oils essentially free from water, egg and egg products, and as a coagulation agent for specific cheese products and for cooked eggs. (Table 3 - page 24)

Lactic acid is allowed in the following foods of plant origin: Fermented vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes and aloe vera) and seaweed products. Not allowed in fermented soybean products.

Allowed in the following foods of animal origin: Dairy products and analogues. Not allowed in edible casings. (Table 3 - page 24)

International Federation of Organic Agriculture Movements (IFOAM)
The IFOAM NORMS for Organic Production and Processing allow citric acid as an additive and a processing and post-harvest handling aid in Appendix 4, Table 1.

Citric acid is allowed in equipment cleaners and disinfectants (Appendix 4, Table 2).

Japan Agricultural Standard (JAS) for Organic Production
Allowed as an additive. Limited to the use as a pH control agent or in processed vegetable products or processed fruit products. (Appended Table 1)

Ancillary Substances
Citric acid is commercially supplied as a pure compound and otherwise does not contain ancillary substances.

Human Health and Environmental Issues
Although it is a weak acid, exposure to pure citric acid may cause coughing, shortness of breath, and skin irritation. The fermentation process does produce by-products including oxalic acid. Citric acid will degrade

to produce non-toxic and non-persistent environmental products. The potential health hazard of citric acid is moderate based on systemic toxicity (EPA 2007). EPA listed citric acid as List 4A (minimal risk inert) in their 2004 list and currently list citric acid at 40 CFR 180.950(e) as a tolerance exempt inert ingredient.

Discussion
Citric acid remains an essential ingredient for organic food processors, and NOSB does not have any new information to suggest that citric acid should be removed from the National List at 7 CFR 205.605(a). NOSB requested a limited scope TR to evaluate the potential for microorganisms used in the fermentation process of citric acid manufacturing to be products of excluded methods. The TR indicated that the use of genetically modified microorganisms remains only in experimental phase in the production of citric acid, and it listed numerous suppliers of citric acid that utilize either wild type fungal strains or strains that are the product of classical induced mutagenesis. This indicates that there is ample supply of citric acid that complies with the prohibition on excluded methods in organic food.

There were numerous commenters who provided insight into the issue of whether a commercial availability requirement was appropriate for citric acid at this point. While conceptually, most commenters expressed a preference for an organic option and indicated that there is some organic citric acid available in the marketplace, it was also noted that the organic supply fails to meet the current demand. Discussion occurred regarding the impact a commercial availability clause for citric acid would have on the organic industry, and it appears as though it would create additional recordkeeping burden without having a significant impact on use of organic citric acid. Therefore, at this sunset review, NOSB does not recommend adding an annotation to citric acid requiring organic forms when commercially available. However, it is important to regularly revisit the potential for an organic version of any National List item to replace the non-organic version, and the use of a commercial availability annotation should be considered in that review.

Questions to our Stakeholders
There are now numerous suppliers of certified organic citric acid. Should NOSB consider recommending the addition of an annotation to citric acid requiring processors to use an organic version of citric acid when commercially available?

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

Subcommittee Vote:
Motion to remove citric acid from the National List
Motion by: Nate Lewis
Seconded by: Kyla Smith
Yes: 0 No: 9 Abstain: 0 Recuse: 0 Absent: 0

Acids Lactic

Reference: § 205.605(a) Nonsynthetics allowed
(1) Acids (Citric – produced by microbial fermentation of carbohydrate substances; and Lactic).
Technical Report: 1995 TAP - Citric; 2015 TR - Citric; 1995 TAP – Lactic; 2015 TR - Lactic; 2023 Limited Scope TR (Citric acid and salts)
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 03/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Lactic acid is widely used in almost every segment of the food industry, where it carries out a wide range of functions. The major use of lactic acid is in food and food-related applications, which in the U.S. accounts for approximately 85% of the demand. It is found naturally in milk, meat, and beer but is normally associated with sour milk. Lactic acid controls the growth of bacteria including listeria (NOSB Fall Meeting Transcript 2015 pp. 263). The other uses are non-food industrial applications. Lactic acid occurs naturally in many food products. It has been in use as an acidulant and pH regulator for many years. It regulates microflora in food and has been found to be very effective against certain types of microorganisms, giving it pronounced efficacy as a preservative (Vijayakumar, Aravindan and Viruthagiri 2008). Other uses include mixing with sodium, potassium, and distilled water to form intravenous fluids commonly used after blood loss. It is sometimes used in the pharmaceutical industry to adjust acidity. Lactic acid appears on the National List, 7 CFR Part 205.605(a), as a non-synthetic material without further annotation.
Common uses include, but are not limited to:

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

Manufacture
First isolated in 1780 from sour milk, lactic acid can be produced both naturally and synthetically. It can be produced in either a solid, water-soluble state, or a colorless liquid state. Lactic acid is produced on an industrial scale through carbohydrate fermentation performed by lactic acid bacteria converting simple carbohydrates such as glucose, sucrose, or galactose to lactic acid. A secondary manufacturing process involves chemical synthesis of adding hydrogen cyanide to acetaldehyde, an organic chemical compound found in coffee, bread, ripe fruit, coal, or crude oil. This process only exists today in Japan. There is also a group of microbes known broadly as Lactic Acid Bacteria which produce lactic acid as a result of carbohydrate fermentation.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed in feed. Preference should be given to bacterial or enzymatic additives derived from bacteria, fungi, plants, and food by-products (such as molasses and whey). The following acids may be used: lactic, propionic, and formic. (Table 5.2, Hay or silage preservation products listing, CAN/CGSB-32.311-2020 page 24)

Allowed as food additives. (Table 6.3, CAN/CGSB-32.311-2020, page 30)

Allowed as processing aids from fruit and vegetable products or produced by microbial fermentation of carbohydrate substances. (Table 6.5, Citric acid listing, CAN/CGSB-32.311-2020, page 38)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Citric acid is allowed in plant & animal products as a processing aid. Lactic acid is allowed in the brine of cheese products (Annex V, Part A, Section A2, 2021/1165)

Both lactic and citric acids are allowed in animal and plant products as additives. (Annex V, Part A, Section A1, 2021/1165)

Both lactic and citric acids are allowed for the regulation of pH in primary yeast production. (Annex V, Part C, 2021/1165)

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Citric acid is allowed in the following foods of plant origin: Fruits and vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera, seaweeds, and nuts and seeds).

Citric acid is allowed in the following foods of animal origin: fats and oils essentially free from water, egg and egg products, and as a coagulation agent for specific cheese products and for cooked eggs. (Table 3 - page 24)

Lactic acid is allowed in the following foods of plant origin: Fermented vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes and aloe vera) and seaweed products. Not allowed in fermented soybean products.
Allowed in the following foods of animal origin: Dairy products and analogues. Not allowed in edible casings. (Table 3 - page 24)

International Federation of Organic Agriculture Movements (IFOAM)
The IFOAM NORMS for Organic Production and Processing allow citric acid as an additive and a processing and post-harvest handling aid in Appendix 4, Table 1.

Citric acid is allowed in equipment cleaners and disinfectants (Appendix 4, Table 2).

Japan Agricultural Standard (JAS) for Organic Production
Allowed as an additive. Limited to the use as a pH control agent or in processed vegetable products or processed fruit products. (Appended Table 1)

Ancillary Substances
None

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

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

Lactic acid is one of the most widely distributed acids and preservatives in nature. It is produced naturally by humans, animals, and microorganisms. Lactic acid is an acidulate that is a natural organic acid present in milk, meat and beer, but is normally associated with sour milk. It occurs naturally in two isomers (D) and (L). (D) is harmful to humans so (L) is the preferred isomer for food and pharmaceuticals. It functions as a flavor agent, preservative and acidity adjuster in foods.

There is no known organic alternative to lactic acid.

Questions to our Stakeholders
None

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

Subcommittee Vote:
Motion to remove lactic acid from the National List
Motion by: Nate Lewis
Seconded by: Kyla Smith
Yes: 0 No: 9 Abstain: 0 Recuse: 0 Absent: 0

Calcium chloride

Reference: § 205.605(a) Nonsynthetics allowed
(7) Calcium chloride.
Technical Report: 1995 TAP, 2024 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 03/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Calcium chloride is used in a wide variety of food processing applications including the following, as listed in the Table 3 in the 2024 TR:

- Firming agent (fish, mushrooms, processed whole and cut vegetables)
- Flavor enhancer (beer, canned breadnut seeds, cucumber pickles, processed meat products)
- Nutrient supplement (dairy products, nutrition beverages, tofu)
- pH control agent (beer)
- Processing aid (bakery products, beer, cheese, tofu)
- Stabilizer and thickener (fruit jams and jellies)
- Synergist in combination with sodium alginate (dressings, fruit snacks, sauces, soups)
- Tenderizer/texturizer (beef, chicken, goose, lamb, rabbit)

Manufacture
According to the 2024 TR, calcium chloride can be produced from three different sources/processes:

- From natural brines
- Reaction of calcium hydroxide with ammonium chloride (Solvay ammonia-soda process)
- Reaction of hydrochloric acid with calcium carbonate

The TR also mentioned a fourth method claimed by TETRA Technologies, as a byproduct of the manufacturing of magnesium oxide. The TR authors couldn't find details on this process or mention of it elsewhere. [2024 TR 487-494]

Calcium chloride derived from brines are nonsynthetic in many cases. However sometimes depending on the brine process, classification becomes more complicated. The starting material is a natural brine solution that is pumped out from underground salt beds and calcium chloride is what is left when other materials are extracted from the brine. When calcium chloride uses evaporation for the extraction, it is effectively unchanged (more concentrated and some ions are removed). This process is nonsynthetic. However, sometimes other chemicals are added such as calcium hydroxide or slaked dolime. These substances are processing aids added to remove other substances and they may leave residues of calcium and chloride in the final calcium chloride product and would be indistinguishable from their natural counterparts. [2024 TR 496-628]

Calcium chloride may also be commercially obtained as a byproduct in the ammonia-soda (Solvay) process (synthetic). Soda ash can also be produced in other ways, such as through the chlor-alkali process or by utilizing an ore called "trona". According to the TR, trona is rare in the EU, so almost all of the soda ash

produced in the EU utilizes the Solvay process. However, trona is plentiful in the US and since that process is cheaper, very little soda ash is produced from the Solvay process in the US. Therefore, when calcium chloride is sourced from the US, the likelihood that it is processed using the Solvay process is quite low. [2024 TR 630-676]

Lastly, calcium carbonate can be produced from the reaction of hydrochloric acid with calcium carbonate, which is a process that renders the calcium chloride synthetic. However, the TR states that it is unclear how relevant this process is for current industrial production. [2024 TR 678-697]

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed as food additives in milk products; fat products; soybean products; and fruits and vegetables. (Table 6.3, CAN/CGSB-32.311-2020, page 30)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Allowed as a coagulation agent in dairy products. (Annex V, Part A, Section A1, 2021/1165)

Allowed as a coagulation agent in products of plant origin & sausages based on meat. (Annex V, Part A, Section A2, 2021/1165)

Allowed as a processing aid for the production of primary yeast. (Annex V, Part C, 2021/1165)

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Allowed in the following plant origin products: fruits and vegetables (including mushrooms, seaweeds, and nuts and seeds) and soybean products (excluding seasonings, condiments and fermented soybean products).

Allowed in the following animal origin products: Dairy products and analogues. Not allowed in processed meat, poultry, poultry and game products, edible casings. (Table 3 - page 28). Allowed as a firming/coagulation agent in cheese making. (Table 4 - pages 30-31)

International Federation of Organic Agriculture Movements (IFOAM)
Allowed as an as additive and processing/post-harvest handling aid. (Appendix 4 - Table 1 - page 80)

Japan Agricultural Standard (JAS) for Organic Production
Allowed as an additive. Limited to the use as a coagulant in processed products of plant origin/cheesemaking, or in edible oils or fats, processed vegetable products, processed fruit products, products containing beans, dairy products, or processed meat products. (Appended Table 1)

Ancillary Substances
None

Human Health and Environmental Issues
Environment: The 2024 TR indicated that calcium chloride, at the concentrations used for food commodities, is unlikely to negatively affect the environment when disposed, as it dissociates into calcium and chloride ions that can easily be taken up and metabolized by plants (at low concentrations). However, it was noted that calcium chloride can be toxic to plants and animals at high concentrations.

As with all mined substances on the National List, the biggest impact to the environment is caused by the manufacturing of calcium chloride. Calcium chloride utilizes similar extraction and recovery techniques used by the oil and gas industry. [2024 TR 944-1105]

Human Health: GRAS. When used in concentrations utilized in food products the 2024 TR stated that calcium chloride is unlikely to have a negative effect on human health as it readily dissociates into calcium and chloride ions which are both essential body constituents in all animal species.

The 2024 TR also stated that although rare, in certain circumstances, calcium chloride may cause soft tissue necrosis. [2024 TR 1110-1133]

Discussion
The Handling Subcommittee received the draft TR on January 22, 2024. It was reviewed and the Subcommittee had additional questions regarding the manufacturing process when calcium chloride is produced from soda ash derived from trona ore, as well as commercial availability of calcium chloride manufactured by the various processes. The Subcommittee received a revised TR on March 19, 2024 and deemed it sufficient.

The Subcommittee discussed the wide use of calcium chloride. The TR authors found no evidence of a single substance offering the versatility of calcium chloride that is also non-synthetic. [2024 TR 1166-1290]

The 2024 TR mentions the following alternatives by function:

- Anti-microbial agents: carbon dioxide and ozone
- Firming agent: ozone and other sources of calcium such as calcium sulfate, calcium citrate and monocalcium phosphate
- Coagulants: calcium phosphate, calcium sulfate and magnesium sulfate
- Curing/pickling: other salts such as sodium chloride, calcium hydroxide, magnesium chloride and potassium chloride
- Nutrient supplement: calcium carbonate, calcium citrate, calcium hydroxide, and calcium phosphate
- pH control in brewing: calcium sulfate
- Tenderizer/texturizer: sodium chloride, lactic acid

The Subcommittee discussed the various ways to manufacture calcium chloride, some of which are nonsynthetic and some synthetic, as noted in the 2024 TR. Calcium chloride is currently listed at §205.605(a), so only the nonsynthetic forms are allowed. The TR noted that some methods used to extract calcium chloride from the natural brine use chemicals as processing aids. According to the TR when evaluating the classification of this manufacturing process using the decision tree, this extraction process falls into a gray area. The Subcommittee determined that use of these chemicals as processing aids would result in a nonsynthetic classification as the calcium chloride did not undergo a chemical change (it is still calcium chloride) and the additional calcium or chloride ions that may still be present were not added with the intent of providing a technical effect. [2024 TR 476-782]

As part of the Spring 2024 agenda and review of this substance, about a dozen comments were submitted. All were in favor of relisting or didn't state their opposition. The Subcommittee posed questions related to the types of calcium chloride being used (synthetic vs. non-synthetic) and what types of documentation certifiers are obtaining to confirm the manufacturing process of calcium chloride is nonsynthetic. Some commenters responded stating that indeed the calcium chloride they are using is nonsynthetic. Certifiers commented stated that classification is confirmed through the receipt of processing descriptions and/or

attestations from the manufacturer. Two commenters stated that the HS should investigate the presence of calcium bromide and consider an annotation as applicable. Additionally, one commenter stated that since some processes for manufacturing calcium chloride result in a synthetic product, it should be annotated to ensure only calcium chloride from a nonsynthetic process is used. However, this seems redundant since it is listed on the nonsynthetics allowed part of the National List and the appears adequate based on responses from certifiers.

The Board seemed in alignment with both the Subcommittee's and commenter's position to relist calcium chloride, as no additional discussion was had during the Spring 2024 board meeting.

Based on the information provided in the TR and comments received at the spring meeting, the Handling Subcommittee is proposing that calcium chloride remain on the National List due to its essentiality, lack of alternatives and limited negative impact on the environment and human health.

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

Subcommittee Vote:
Motion to remove calcium chloride from the National List
Motion by: Kyla Smith
Seconded by: Allison Johnson
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

Enzymes

Reference: § 205.605(a) Nonsynthetics allowed
(11) Enzymes—must be derived from edible, nontoxic plants, nonpathogenic fungi, or nonpathogenic bacteria.
Technical Report: 1995 TAP (bacterial); 1996 TAP (plant); 1996 TAP (microbial); 2003 TAP (enzymes: plant, fungal); 2011 TR; 2015 TR; 2024 Limited Scope TR (enzymes, microorganisms, yeast)
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 10/1999 recommendation (plant, fungal): 11/2005 sunset recommendation; 04/2011 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Enzymes are naturally occurring proteins that act as highly efficient catalysts in biochemical reactions. Enzymes are produced by all living organisms; however, the 2024 Limited Scope TR only focuses on enzymes produced by microorganisms (including fungi). In some cases, enzymes are produced by microorganisms that are developed using excluded methods, which was the focus of the 2023 Limited Scope TR.

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

Manufacture

According to the 2023 draft TR, "Food-grade enzymes are typically produced in pure culture fermentation using "Current Good Manufacturing Practices" for food. Almost all fermentation processes used to produce enzymes are aerobic. Most industrial producers of food-grade enzymes use aerobic submerged fermentation or liquid fermentation (LF). Fungi produce approximately 50% of the enzymes used globally, bacteria produce 35%, and the remaining 15% are produced from non-fermentation organisms like plants and animals."

Some examples of different sources of food-grade enzymes include:

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

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

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

Fermentation produced chymosin (FPC) rennet is derived from genetically modified organisms and is not allowed in organic processing. The 2023 TR takes an intensive look at the excluded methods used to produce enzymes (such as using genetically modified organisms) and found that there is currently no capacity for regulators to determine the origin of an enzyme sample once it has been produced (Draft TR 2023 976-983).

International Acceptance

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

Allowed as food additives. The following sources of enzymes are allowed: a) any preparations of enzymes normally used in food processing derived from edible, non-toxic plants, non-pathogenic fungi or non-pathogenic bacteria; b) derived from animals—shall be organic if commercially available: rennet; catalase from bovine liver; animal lipase; pancreatin; pepsin; and trypsin. Animal-derived enzymes shall be free of Specified Risk Material (SRM); and c) egg white lysozyme. (Table 6.3, CAN/CGSB-32.311-2020, page 31)

Allowed as processing aids. The following sources of enzymes are allowed: a) any preparations of enzymes normally used in food processing derived from edible, non-toxic plants, non-pathogenic fungi or non-pathogenic bacteria; b) animal-derived—shall be organic if commercially available: rennet; catalase from bovine liver; animal lipase; pancreatin; pepsin; and trypsin. Animal-derived enzymes shall be free of Specified Risk Material (SRM); c) egg white lysozyme. (Table 6.5, CAN/CGSB-32.311-2020, page 39)

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

Allowed (Annex II, Part IV, 2.2.2 (a), 2018/848)

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

Allowed. Enzymes derived from genetic engineering organisms is prohibited. (Table 3-3.4, page 29 & 31)

International Federation of Organic Agriculture Movements (IFOAM)
Allowed if derived from naturally occurring organisms. Genetically engineered microorganisms and their products are prohibited. Nonorganic forms are allowed in organic products only if there are no organic sources. (7.2.5 - page 58 & 72)

Japan Agricultural Standard (JAS) for Organic Production
Allowed as an additive. (Appended Table 1)
Ancillary Substances
Ancillary substances are explained in the 2015 Technical Report:

"Enzyme products used in food processing may be single ingredient, stand-alone preparations of the enzyme, or formulated with other ingredients (OMRI, 2015). In many cases the enzyme product which results from a fermentation process is not effective in food applications without further formulation (Whitehurst & Van Oort , 2009). Enzyme preparations therefore commonly contain other substances, not only as incidental secondary metabolites and residual growth media from the enzyme production, but also intentionally added ingredients which function as diluents, preservatives, stabilizers, antioxidants, etc. (FDA, 2010). These additives must be generally recognized as safe (GRAS), or be FDA approved food additives for this use (FDA, 2014)."
To prevent the loss of enzyme activity, ancillary substances, such as stabilizers, are added. This is especially true for liquid enzyme preparations due to the destabilizing effect of water. Stabilizers are also used to combat the degradation of enzyme structures due to autolysis or proteolysis.
To control microbial contamination of enzyme preparations, preservatives are added. The development of alternatives to preservatives (plant extracts, peptides, compounds from herbs and spices) is increasing but there are microbial resistance challenges and the need for continued research. Currently it is unknown if natural preservatives are being used in any enzyme formulations.
The following additional ancillary substances were identified through public comment during the last sunset review:
Anti-caking & anti-stick agents: calcium stearate, magnesium silicate/talc, magnesium sulfate, sodium aluminosilicate.
Carriers and fillers: calcium phosphate, calcium acetate, calcium carbonate, calcium chloride, calcium sulfate, dextrin, dried glucose syrup, ethyl alcohol, glucose, glycol, lactic acid, maltose, mannitol, mineral oil, palm oil, propylene, purity gum (starch), saccharose, sorbitol, soy flour, soy oil, sunflower oil, trehalose, vegetable oil.
Preservatives: alpha (hops) extract, benzoic acids and their salts, calcium propionate, citric acid, potassium chloride, potassium phosphate, sodium acetate, sodium chloride, sodium propionate, sodium sulfate, sorbic acid and its salts, stearic acid, tannic acid, trisodium citrate, zinc sulfate.
Stabilizers: betaine (trimethylglycine), glucose, glycerol, sodium chloride, sodium phytate, sorbitol, sucrose.
pH control, buffers: acetic acid, citric acid anhydrous, sodium citrate, sodium phosphate, trisodium citrate.
Public comment submitted during the Spring 2019 NOSB meeting suggest adding several other ancillary substances to this list:
Anti-Caking & Anti-Stick Agents: manganese sulphate, magnesium sulphate, microcrystalline cellulose powder
Carriers and Fillers: corn gluten, corn steep powder, dextrose, lactose, propylene glycol, soya flour, soya oil, soyatone, sucrose.
Preservatives: propyl p-Hydroxybenzoate, sodium metabisulfite, sodium nitrate.
Stabilizers: calcium lactate, ethylene diamine tetra acetic acid, glycerin, sodium alginate.
pH control, Buffers: adipic acid, di potassium phosphate (K_2HPO_4), diammonium phosphate, disodium phosphate (Na_2HPO_4), hydrochloric acid, mono potassium phosphate (KH_2PO_4), tri ammonium citrate.

Human Health and Environmental Issues
The 2011 TR did not find the manufacture or use of enzymes to be harmful to the environment or biodiversity. Enzymes are used in small amounts, are biodegradable, and the release of enzymes into the environment is not an environmental concern.

The 2011 TR did not find significant effects upon human health. Enzymes can remain active after they are digested and, as proteins, cause allergic reactions in sensitive individuals. FDA reports it is not aware of any allergic reactions associate with the ingestion of food containing enzymes commonly used in food processing (TR 2011 752- 758).
The 2023 Limited Scope TR does not add any information about human health or environmental issues, beyond those which would be of concern should excluded methods be used.

Discussion
During the 2015 sunset review, a variety of organizations and manufacturers commented in support of keeping enzymes on the National List. There were no commenters opposed. One organization suggested that enzymes be classified as synthetic unless annotated to define those that have not undergone synthetic chemical change.

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

Stakeholder Comments Informing the Spring 2024 Meeting in Milwaukee: There were about 16 total stakeholder comments, both written and oral, with the majority being written. All, but one comment, were in favor of keeping enzymes on the National List. One commenting entity stated that they and their members would be willing to participate in a fermentation panel.

The presentation of the enzyme sunset document (among other sunsets) at the Spring 2024 NOSB meeting in Milwaukee generated considerable board discussion mostly regarding fermentation and excluded methods. This discussion provided details regarding certifiers process which includes the use of a risk-based approach for assessing the compliance of 205.605(a) inputs. This approach is described in the ACA Best Practice for Common Material Review Issues[1] which provides further information regarding classification verification and prohibitions of the use of excluded methods.

The new 2023 Limited Scope TR brings up a variety of new questions relevant to the use of excluded methods in the production of this material. As it was noted in several stakeholder comments this 2023 Limited Scope TR was first made available to the public shortly before the public comment period closed. We are therefore leaving the following “Questions to our Stakeholders” open for comment for the coming Fall 2024 session in Portland.

Questions to our Stakeholders
1. For manufacturers: describe how you ensure no excluded methods are used when including enzymes into your organic formulation.

[1] ACA Best Practice for Common Material Review Issues V4.4, January 2024 (ACA Materials Working Group)

2. For certifiers: describe how you ensure organic processors' compliance with the prohibition on excluded methods in organic products when enzymes are used in the formulation.
3. Are there ancillary substances that should be prohibited for use, due to concerns about excluded methods?

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

Subcommittee Vote:
Motion to remove enzymes from the National List
Motion by: Jerry D'Amore
Seconded by: Kyla Smith
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

L Malic acid

Reference: § 205.605(a) Nonsynthetics allowed
(16) L-Malic acid (CAS # 97-67-6).
Technical Report: 2003 TR; 2019 TR
Petition(s): 2002
Past NOSB Actions: 05/2003 sunset recommendation; 11/2009 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Added to National List 09/11/06 (71 FR 53299)
Renewed 08/03/2011 (76 FR 46595); Renewed 09/12/16 (81 FR 8821); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Malic acid exists in D-, L-, and racemic DL-forms, which is a mixture of equal parts of D- and L-. L-malic acid is the form listed at §205.605(a), while the D- and DL-forms are not approved for use in organic production. L-malic acid is used as a flavor enhancer, flavoring agent, adjuvant, and pH control agent in a variety of foods. The 2002 malic acid petition also notes it is used in dry mix beverages, carbonated beverages, bakery products, fruit juices, candies, gelatins, desserts, frozen specialties, and tea as a flavor enhancer and food acidulant, and that malic acid provides greater tartness and better taste retention than other major food acids. Malic acid has a smooth, persistent sourness and can be blended with other organic acids, sugars, sweeteners, and flavors. It also intensifies and extends the impact of flavors, allowing producers to reduce the amount of added flavoring. U.S. Food and Drug Administration (FDA) lists L-malic acid as a Generally Recognized as Safe (GRAS) food additive as a pH control agent, flavor enhancer, flavoring agent, and adjuvant in all food types except for baby food. The listing also includes maximum good manufacturing practice (GMP) levels for various applications (21 CFR 184.1069; U.S. FDA 2018).

Manufacture
L-malic acid occurs naturally in many fruits and vegetables, including apples and cherries, and can be obtained by enzymatic conversion of fumaric acid and by fermentation of glucose and other carbohydrates. It is not economical to extract L-malic acid from natural foodstuffs such as apple juice. In the first round of the Spring 2019 sunset review, a number of commenters questioned whether commercially available L-

malic acid comes from nonsynthetic sources, as this listing restricts. Commenters noted that while supporting documentation may state L-malic acid is produced naturally via enzymatic fermentation, this statement refers to only the second half of the process. Industrial quantities of L-malic acid are made using biological processes, with the major industrial process to produce L-malic acid being a two-step procedure:

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

More detailed information on the two-step process can be found in Appendix A of the 2019 Technical Report.

There are two options for obtaining the fumaric acid in the first step in this process: 1) The fumaric acid precursor is obtained through the fermentation of carbohydrates (i.e., *Rhizopus spp*.) or, 2) The fumaric acid precursor is obtained as a synthetic product from maleic acid of petroleum origin. Commercial quantities of nonsynthetic L-malic acid may also be produced using a one-step fermentation process through biological methods such as microbial fermentation using *Aureobasidium pullulans* and *Penicillium vitacola*, though it is not believed that this process is occurring on a scale that would accommodate the needs of the current market. The major commercial source of L-malic acid is enzymatic conversion of synthetic fumaric acid to L-malic acid by immobilized microbes (Chibata et al. 1983; Chi et al. 2016a; Dai et al. 2018). If the malic acid produced by this method is synthetic, most, if not all, of the L-malic acid on the market will also be synthetic (Goldberg et al. 2006; Chibata et al. 1983; Engel et al. 2008; Chi et al. 2016a; Dai et al. 2018).[All citations from 2019 TR]

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

L-malic acid can also be produced by microbes in a one-step fermentation process fueled by glucose or other carbohydrates. Reaction conditions are adjusted to cause overproduction of L-malic acid, which is an essential product of microbe metabolism. While this production process is possible, it is not clear how much is produced and whether it will be able to produce sufficient quantities to supply handlers currently relying on the L-malic acid produced by the synthetic process.

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

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

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed as ingredients classified as food additives: listed as malic acid (Table 6.3, CAN/CGSB-32.311-2020, page 33).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 & 2021/1165
Malic acid is allowed in products of plant origin (Annex V, Part A, Section A1, 2021/1165).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
In Table 3 of "Annex 2: "Permitted substances for production of organic foods," malic acid (INS no. 296) is a permitted food additive listed without conditions (Codex 2013). L-malic acid is not explicitly mentioned; DL-malic acid is allowed.

International Federation of Organic Agriculture Movements (IFOAM)
L-malic acid (INS no. 296) is listed on page 79 in Appendix 4, "Table 1: List of approved additives and processing/post-harvest handling aids." L-malic acid is listed both as a food additive and post-harvest handling aid without restrictions (IFOAM 2014).

Japan Agricultural Standard (JAS) for Organic Production
On page 6, "Appended Table 1-1, Additives," DL-malic acid (INS no. 296) is an approved food additive limited to use in processed foods of plant origin (JAS 2022). L-malic acid is not explicitly mentioned.

Ancillary Substances

The 2019 TR does not describe any ancillary substances in L-malic acid.

Human Health and Environmental Issues

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

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

Discussion

The ongoing discussion around L-malic acid is not whether it is essential to organic handling or if it has detrimental effects on the environment or human health. In fact, there is broad agreement that it is essential, particularly to juice manufacturers, and there is no evidence to suggest that it does not meet National List criteria. However, as the organic material review process has become more refined and the production methods of L-malic acid has changed, we now see that much of the L-malic acid used in organic

processing is “synthetic” while L-malic acid is currently listed at 7 CFR 205.605(a) as a “nonsynthetic” substance.

Previous Handling Subcommittees have suggested relisting L-malic acid on §205.605(b) as a “synthetic” substance to accurately reflect the predominant production method, and to ensure that the classifications inherent to the National List of nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” are consistent with NOP material classification guidance.

This Subcommittee agrees with the previous thinking of the Board and would like to suggest adding L-malic acid to §205.605(b) to reflect that most L-malic acid used in organic food processing is synthetic in origin. However, the Subcommittee also questions whether L-malic acid should be removed from §205.605(a), as there may be nonsynthetic forms of L-malic acid in use, and should commercial quantities of nonsynthetic L-malic acid become available, organic processors may show a preference for a nonsynthetic option.

Questions to our Stakeholders

1. Do any organic products contain nonsynthetic forms of L-malic acid?
2. Should L-malic acid should be reclassified as a synthetic substance and added to §205.605(b)?
3. If L-malic acid is added to §205.605(b), should its nonsynthetic listing be removed from §205.605(a)?

NOSB did not receive comments that quantified the amount of nonsynthetic L-malic acid currently in use, but comments related to this substance’s use in organic products confirmed that most of what is currently in use would be classified as ‘synthetic.’ There were numerous opinions regarding how ‘synthetic’ L-malic acid should be considered or added to the National List. Some commenters preferred adding L-malic to 205.605(b) and keeping the nonsynthetic listing at § 205.605(a). Some commenters preferred removing L-malic from 205.605(a) and requiring a petition to add at § 205.605(b). There appears to be general consensus that the substance currently in use by organic processors is classified as ‘synthetic’ and its allowance should be reflected by inclusion at § 205.605(b). However, there is disagreement about whether the nonsynthetic listing should remain or if NOSB should recommend addition at § 205.605(b) as part of the L-malic acid classification work agenda item or if a petition should be required for the reclassification.

HS does not see any justification for removal of L-malic acid and views the classification as a critical revision that must be made. However, the classification of L-malic acid used by organic processors (i.e., synthetic or nonsynthetic) does not impact the substance’s compatibility with National List criteria, and L-malic acid should remain on the National List. At this sunset review, HS proposes an additional classification and listing motion, so the National List accurately reflects the classification of the substance in use in organic processing. HS makes these recommendations in a separate proposal related to the classification of L-Malic acid. These motions are not contingent in any way on the motion to remove L-malic as part of the OFPA mandated regular sunset review process. HS believes that L-malic should remain at § 205.605(a) to clarify that nonsynthetic forms of this substance remain allowed in organic processing. Should, in future sunset reviews, new information raise clear concerns about either the nonsynthetic or synthetic form of the substance, NOSB will have the ability to remove it with a decisive vote.

Justification for Vote

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

Subcommittee Vote:
Motion to remove L-malic acid from the National List
Motion by: Nate Lewis
Seconded by: Kyla Smith
Yes: 0 No: 9 Abstain: 0 Recuse: 0 Absent: 0

Magnesium sulfate

Reference: § 205.605(a) Nonsynthetics allowed
(18) Magnesium sulfate, nonsynthetic sources only.
Technical Report: 1995 TAP; 2011 TR; 2024 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2011 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Magnesium sulfate is Generally Recognized as Safe (GRAS) and has a wide variety of uses in food processing and personal care products. It is used as a firming agent, and sometimes combined with other coagulators, in the production of tofu. Magnesium sulfate is also used as a nutrient in salt-replacer products, dietary supplements, carbonated beverages, sports drinks, and fortified water beverages, and as a fermentation and malting aid in beer, ale, and other malt beverages. In addition, magnesium sulfate has a variety of human medicine applications. Epson salts are a common form of magnesium sulfate.

Manufacture
Both nonsynthetic and synthetic forms of magnesium sulfate exist. The nonsynthetic forms are from naturally occurring salt deposits or rocks, with isolation from open-pit mines or salt ponds. Various levels of hydration create different crystalline structures that impact commercial viability, and manufacturers control humidity and temperature to isolate useful forms of magnesium sulfate. Magnesium sulfate can also be manufactured synthetically through the chemical reaction of magnesium containing materials and sulfuric acid.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed as food additive. (Table 6.3, CAN/CGSB-32.311-2020, page 33)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 & 2021/1165
Not addressed

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

International Federation of Organic Agriculture Movements (IFOAM)
Not addressed

Japan Agricultural Standard (JAS) for Organic Production
Not addressed

Ancillary Substances
None identified.

Human Health and Environmental Issues
Magnesium sulfate is primarily extracted from salt lakes in the northern part of the Tibet Autonomous Region and Qaidam Basin of the Qinghai Province using large-scale open-pit mining, which results in heavy damage to surface vegetation, as well as water and air pollution from equipment. There is limited information available about mining magnesium sulfate, specifically, relative to other magnesium materials.

Use of magnesium sulfate in food processing does not appear to cause significant health or environmental issues, particularly relative to industrial uses.

Discussion
There are alternatives to magnesium sulfate for at least some applications, including tofu and beer production, but they may change the properties of the finished product.

In public comments, just a few operations reported using magnesium sulfate as a yeast nutrient and for water adjustment. No commenters provided information about alternatives.

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

Subcommittee Vote:
Motion to remove magnesium sulfate from the National List
Motion by: Allison Johnson
Seconded by: Jerry D'Amore
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 3

Microorganisms

Reference: § 205.605(a) Nonsynthetics allowed
(19) Microorganisms—any food grade bacteria, fungi, and other microorganism.
Technical Report: 2003 TAP; 2014 TR; 2024 Limited Scope TR (enzymes, microorganisms, yeast)
Petition(s): 2002 petition
Past NOSB Actions: 05/2003 minutes and vote; 11/2009 sunset recommendation; 04/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Added to National List with annotation 09/11/06 (71 FR 53299)
Renewed 08/03/2011 (76 FR 46595); Renewed 09/12/16 (81 FR 8821); Renewed 8/3/2021 (86 FR 41699)
Sunset Date 9/12/2026

Subcommittee Review

Use
Microorganisms are organisms that are so small they can only be viewed with a microscope, broadly encompassing bacteria, fungi, viruses and other single-celled organisms. The microorganisms used in organic handling include bacteria, yeasts and viruses, but yeasts are reviewed separately as their applications are broad. Microorganisms are used as probiotics, for fermentation, and bacteriophages are used for food safety. Microorganisms are used by organic processors to make many well-known products including yogurts, miso, soy sauce and sake. The use of these microorganisms can increase the digestibility of products, create different flavors and textures, and provide potential health benefits to the consumer. Additionally, bacteriophages can work to decrease harmful food organisms and increase the safety of processed foods.

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

The 2024 Limited Scope TR stated that there is no direct evidence that microorganisms other than yeast were produced by excluded methods, but there were cases in which no methods were disclosed. It went on to say that for microorganisms created through solid state fermentation, many are genetically modified using recombinant DNA technology. Any microorganism that is genetically modified is not permitted in organic food.

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed in feed. If organic sources of yeast are not commercially available, non-organic yeast sources shall be used. (Table 5.2, Microorganisms and yeasts listing, CAN/CGSB-32.311-2020, page 24)

Allowed as ingredients not classified as food additives. Microbial preparations may contain substrates derived from agricultural or biological substances such as milk, lactose, soy, agar, etc. May also contain allowed carriers (see Table 6.3 & 6.4 Carriers). Starter and dairy cultures and other preparations of microorganisms normally used in product processing are allowed. (Table 6.4, CAN/CGSB-32.311-2020, page 36)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Allowed (Annex I, 3. Micro-organisms, 2021/1165)

Rules for the production of processed feed and food.
For the purpose of Article 19(2)(b) of Regulation (EC) No 834/2007, only the following substances can be used in the processing of organic food, with the exception of wine:

(a) substances listed in Annex VIII to this Regulation;

(b) preparations of micro-organisms and enzymes normally used in food processing.

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Allowed. Micro-organisms that are genetically engineered/modified are prohibited. (Table 3 - 3.4 - pages 29 & 31)

International Federation of Organic Agriculture Movements (IFOAM)
Allowed if derived from naturally occurring organisms. Genetically engineered microorganisms and their products prohibited. Nonorganic forms are allowed in organic products only if there are no organic sources. (7.2.5 - pages 58 & 72)

Japan Agricultural Standard (JAS) for Organic Production
JAS does not specifically mention microorganisms as an ingredient or additive to organic food.

Ancillary Substances
Ancillary substances may be present in microorganism cultures. Ancillary substances for microorganisms primarily include the growth media used to produce the microorganism, and fillers or carriers to bring the microorganisms to purchasers in a stable and predictable form. According to the 2024 Limited Scope TR, "growth media can be as simple as a single feedstock and water, or may be comprised of as many as 40 different components." These components may include corn steep liquor, molasses and horse manure extract. Additional preservatives or anti-caking agents are used with some species.

The 2024 Limited Scope TR includes the following table of allowed ancillary substances in organic microbial preparations.

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

Potential concerns have been raised about ancillary substances used in cultures and their compatibility with organic handling standards. It is unclear, for example, whether the corn used to make the starches and liquors mentioned above is required to be organic. Functional foods may contain a combination of probiotic culture with a prebiotic substrate that favors its growth (2014 TR). The use of ancillary substances has not prevented the relisting and general support for microorganisms. In general, they have not been implicated

in negative health effects, but are something that should be continually monitored. Additionally, as with all organic materials, any culture that is genetically modified is disallowed.

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

The 2024 Limited Scope TR did not bring up additional concerns for human health or the environment, beyond those that would occur through the use of excluded methods.

Discussion
In general, microorganisms are essential to the production of many organic foods, and they are widely used in the industry. A question could be posed regarding whether yeast should be grouped with other microorganisms, as they certainly fall within the classification of microorganisms. The definition is critical for microorganisms in use currently, and can be used to determine whether additional organisms, such as unicellular algae, should be considered microorganisms.

This discussion could be taken a step further to determine whether the products of microorganisms, substances such as citric acid, malic acid, and others, could also be grouped under the umbrella of microorganisms. As the primary concern for most of these microbial products is whether the microorganisms used to produce them were genetically modified, the broader guidelines may apply. These comments do not suggest that microorganisms should be delisted, but rather that additional attention needs to be paid to this particular listing and the definitions associated with it.

Stakeholder comments informing the Spring 2024 meeting in Milwaukee: There were about 19 total stakeholder comments, both oral and written, with the majority being written. All but two of the comments provided were in favor of keeping microorganisms on the National List with several pointing out that the 2024 limited scope TR was unavailable during much of the comment period. Many of the commenters gave detailed and informative answers to the “Questions for our Stakeholders” shown below.

The presentation of the microorganism Sunset document (among other sunsets) at the Spring 2024 board meeting in Milwaukee generated considerable board discussion mostly regarding fermentation and excluded methods. This discussion provided details regarding certifiers’ process, which includes the use of a risk-based approach for assessing the compliance of 205.605(a) inputs. This approach is described in the ACA Best Practice for Common Material Review Issues[2] which provides further information regarding classification verification and prohibitions of the use of excluded methods.

The new 2024 Limited Scope TR brings up a variety of new questions relevant to the use of excluded methods in the production of this material. As it was noted in several stakeholder comments, this 2024

[2] ACA Best Practice for Common Material Review Issues V4.4, January 2024 (ACA Materials Working Group)

Limited Scope TR was first made available to the public shortly before the public comment period closed. We are therefore leaving the following "Questions to our Stakeholders" open for comment for the Fall 2024 session in Portland.

Questions to our Stakeholders

1. For manufacturers: describe how you ensure no excluded methods are used when including microorganisms in your organic formulation.
2. For certifiers: describe how you ensure organic processors' compliance with the prohibition on excluded methods in organic products when microorganisms are used in the formulation.
3. Are there any ancillary substances that should be prohibited due to the potential for excluded methods?

Justification for Vote

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

Subcommittee Vote:

Motion to remove microorganisms from the National List
Motion by: Jerry D'Amore
Seconded by: Carolyn Dimitri
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

Perlite

Reference: § 205.605(a) Nonsynthetics allowed
(22) Perlite—for use only as a filter aid in food processing.
Technical Report: 1996 TAP; 2024 TR
Petition(s): N/A
Past NOSB Actions: 09/1996 NOSB minutes and vote; 11/2005 sunset recommendation; 03/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use

Perlite is used as a filter aid in food processing, such as in the filtration of juices, beer, wine, and vegetable oils. It is a budget-friendly, inorganic adsorbent in filter aids. Filter aids may be applied either as precoat on the filter material and/or as body feed in the liquid. In practice, a combination of the two approaches is the most common. Examples of successful perlite use in organic operations include removing yeast aflatoxins from milk and impurities in beer.

Manufacture

Perlite is produced from glassy volcanic rock raw materials and is formed naturally from the hydration of obsidian or pitchstone; it is sourced primarily from open mines in the U.S., Greece, Turkey and China. The raw materials are mechanically crushed. The high-water content of the mineral causes it to expand up to 20

times its original volume when exposed to temperatures of 760-1100°C. The process involves heating granulated perlite ore until it becomes molten glass.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed as a filtering aid. (Table 6.5, CAN/CGSB-32.311-2020, page 39)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 & 2021/1165
Perlite is allowed as a processing aid in products of plant origin and gelatine. (Annex V, Part A, Section A2, 2021/1165)

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Allowed as a processing aid for the preparation of products of agricultural origin. (Table 4, page 30)

International Federation of Organic Agriculture Movements (IFOAM)
Allowed as a processing/post-harvest handling aid. (Appendix 4, Table 1, page 81)

Japan Agricultural Standard (JAS) for Organic Production
Appended Table 1-1, Additives (Organic processed foods other than organic alcohol beverages); Appended Table 1-2 Additives (Organic alcohol beverages). In organic foods other than organic alcohol beverages: limited to the use in processed products of plant origin. In organic alcohol beverages: no restrictions

Ancillary Substances
None Identified

Human Health and Environmental Issues
Few studies have evaluated the environmental effects of perlite manufacturing on the environment. There is some concern with the potential human health hazard of inhalation of fine silica dust when using this material. Personal protective equipment such as a dust mask can minimize this risk.

Discussion
Public comments and discussion at the Spring 2024 meeting were brief and overall supportive to relist. Technical report was received after the deadline for the spring meeting , but it was reviewed prior to subcommittee vote. Technical report was used to expand the details of the sunset write up, but no substantive changes were made to alter the course of the review.

Justification for Vote
The Subcommittee finds perlite when used as a filtering aid to be compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600 and is not proposing removal.

Subcommittee Vote:
Motion to remove perlite from the National List
Motion by: Kim Huseman
Seconded by: Nate Lewis
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 3

Potassium iodide

Reference: § 205.605(a) Nonsynthetics allowed
(24) Potassium iodide.
Technical Report: 1995 TAP; 2011 TR; 2023 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2011 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Potassium iodide is used as a form of iodine in trace mineral supplements. Iodine is an essential component of the thyroid hormones that regulate basal metabolism. Iodine deficiency causes thyroid enlargement (goiter), mental retardation that can be severe (cretinism in 10% of the population), and hypothyroidism. The developing brain is the most sensitive organ; iodine deficiency reduces IQ by 13.5 points [2011 TR 356-359]. Iodization of salt eliminated new cases of cretinism in Switzerland. According to FDA, potassium iodide may be used as a food additive in the following functions:

- A nutrient in table salt as a source of iodine.
- A dietary supplement for human consumption and in animal feeds.
- A sanitizing agent for food processing equipment. [2011 TR 35-38].

Manufacture
Potassium iodide can be refined non-synthetically from sea water and in salt deposits. It can be produced synthetically by reacting hydriodic acid with potassium bicarbonate or by electrolysis of hydriodic acid and potassium bicarbonate or, industrially, by treating potassium hydroxide with iodine. [21 CFR 184.1634] [2011 TR 200-201].

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed as ingredients not classified as food additives. Use when legally required or allowed (Table 6.4, CAN/CGSB-32.311-2020, page 36).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 & 2021/1165
Allowed for use as feed or in feed production (Annex III, Part B, 3(b), 2021/1165). Not explicitly mentioned for use in/on processed products.

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

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

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

Ancillary Substances
No identified.

Human Health and Environmental Issues
Potassium iodide may be added to food as a nutrient/nutritional supplement for human consumption or to animal feeds. Iodine (in the form of iodide) is a necessary human nutrient that is required for proper functioning of the human endocrine system, specifically synthesis of thyroid hormones—thyroxine (T4) and triiodothyronine (T3) [2011 TR 352-354]. It is well-documented that pre-existing nutritional deficiency of iodine in the diet can perturb levels of thyroid hormones which cause a spectrum of disorders that include in increasing order of severity, goiter and hypothyroidism, mental retardation, and cretinism. There are no indications of special sensitivity of infants or children resulting from exposure to iodine. Therefore, the Food Quality Protection Act (FQPA) Safety Factor has been removed (i.e., reduced to 1x) for iodine [2011 TR 396-397].

Based on a review of the available toxicology data, the U.S. Environmental Protection Agency (EPA) has concluded that iodine and iodophor complexes are of very low toxicity by the oral, dermal, and inhalation routes of exposure. Acute and chronic risks to non-target birds, aquatic invertebrates, and fish are highly unlikely [2011 TR 345-346].

Discussion
Potassium iodide is an important material that helps prevent a range of health issues caused by iodine deficiencies. In previous sunset reviews the NOSB asked questions to stakeholders regarding the use of this substance as a sanitizer, but no feedback was received. Stakeholders favored keeping this listing in addition to the current Nutrient Vitamin and Mineral listing. The NOSB has unanimously supported relisting potassium iodide at each sunset date.

Written comments were all in support for relisting potassium iodide. One commentor supported listing this material as a synthetic. There were no oral comments for the 2024 spring meeting. There was little to no discussion at the full board meeting.

Questions to our Stakeholders
None.

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

Subcommittee Vote
Motion to remove potassium iodide from the National List
Motion by: Logan Petrey
Seconded by: Dilip Nandwani
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

Pullulan

Reference: § 205.605(a) Nonsynthetics allowed
(25) Pullulan—for use only in tablets and capsules for dietary supplements labeled "made with organic (specified ingredients or food group(s)).
Technical Report: 2018 TR
Petition: 2004; 2018
Past NOSB Actions: 04/2019 recommendation to add
Recent Regulatory Background: Added to National List effective 07/26/2021 (86 FR 33479)
Sunset Date: 7/26/2026

Subcommittee Review

Use
According to the U.S. Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER), pullulan is a "product used for tablet coating, as an excipient to aid tableting processes, in the production of edible films, and as an alternative to gelatin in capsule production" (FDA 2014). The unique film-forming property of pullulan enables the production of clear capsules and coatings for dietary supplements [2018 TR 72-75].

In addition to the petitioned use of pullulan as an ingredient in tablets and capsules for dietary supplements, edible pullulan films are used to extend the shelf life of various foods. These films prevent moisture loss and reduce surface exposure to oxygen and spoilage bacteria in intact berries, Brussels sprouts, baby carrots, nuts, fresh eggs, intact apples, and cut fruits such as apple slices [2018 TR 88-94].

Manufacture
All pullulan is created by microbial fermentation. The microorganism is usually the black, yeast-like fungus *A. pullulans*, although other species from this genus of black fungus—such as *A. fermentans* and *A. melanogenum*—have also been shown to produce pullulan. Nitrogen is provided in the growth medium in the form of inorganic nitrogen sources such as ammonium salts, nitrates, and biological sources such as glutamate, peptone, yeast extract, and corn steep liquor. Essential nutrient minerals are provided as phosphates, magnesium salts, and the sulfates of iron, manganese, and zinc [2018 TR 219-225].

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

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

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

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

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

Ancillary Substances
None

Human Health and Environmental Issues
No adverse effects on human health and environmental issues were mentioned in the 2018 technical report.

Discussion
The NOSB asked stakeholders whether organic, agricultural pullulan is commercially available. One commenter stated that there is a company that is manufacturing organic pullulan, but it is not yet producing at the scale necessary to consider it commercially available. It is possible that by the next sunset review, that threshold could be met.

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

Subcommittee Vote:
Motion to remove pullulan from the National List
Motion by: Dilip Nandwani
Seconded by: Allison Johnson
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

Yeast

Reference: § 205.605(a) Nonsynthetics allowed

> (30) Yeast—When used as food or a fermentation agent in products labeled as "organic," yeast must be organic if its end use is for human consumption; nonorganic yeast may be used when organic yeast is not commercially available. Growth on petrochemical substrate and sulfite waste liquor is prohibited. For smoked yeast, nonsynthetic smoke flavoring process must be documented.

Technical Report: 1995 TAP (smoked yeast); 1995 TAP (baker's yeast); 1995 TAP (autolysate); 1995 TAP (brewers); 2014 TR; 2024 Limited Scope TR (enzymes, microorganisms, yeast)
Petition(s): 2006 Petition; 2010 Petition Supplement; 2010 Petition memo
Past NOSB Actions: 10/1995 sunset recommendation; 11/2005 sunset recommendation; 3/2007 NOSB committee recommendation; 10/2010 NOSB recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290): Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Yeast is widely used and has been for centuries. Yeast is a microorganism that is commonly used for fermentation, baking, food flavors, adding nutritional value and providing health benefits. Yeasts are in kingdom Fungi and are single celled eukaryotic organisms. They utilize organic materials for energy by releasing enzymes that digest organic matter or by absorbing simple molecules directly through their cell

walls. Yeasts differ from other fungi, such as molds and mushrooms, in that they exist as individual cells rather than forming hyphae that interconnect with other cells.

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

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

Manufacture

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

The 2023 Limited Scope TR made it clear that yeast may be genetically modified, primarily within brewing and fermentation applications. Yeast manufacturers are increasingly using tools like CRISPR to edit genes and add desirable traits from wild strains [2023 TR 499-504]. These genetically modified yeast would be prohibited under current NOP regulations.

International Acceptance

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

Allowed as ingredients classified as food additives. If organic sources of yeast are not commercially available, these alternative sources of yeast may be used: a) autolysate; b) bakers' (may contain lecithin, as listed in Table 6.3); c) brewers'; d) nutritional; and e) torula. Growth on petrochemical substrate and sulphite waste liquor is prohibited. Yeast may be smoked or smoke-flavoured. When smoked, the smoke shall come from concentrated, condensed smoke from wood without additional ingredients (unless listed in

Tables 6.3, 6.4 or 6.5). (Table 5.2, CAN/CGSB-32.311-2020, page 35)

Allowed as ingredients not classified as food additives: If organic sources of yeast are not commercially available, these alternative sources of yeast may be used: a) autolysate; b) bakers' (may contain lecithin, as listed in Table 6.3); c) brewers'; d) nutritional; and e) torula. Growth on petrochemical substrate and sulphite waste liquor is prohibited. Yeast may be smoked or smoke-flavoured. When smoked, the smoke shall come from concentrated, condensed smoke from wood without additional ingredients (unless listed in Tables 6.3, 6.4 or 6.5). (page 37)
European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Allowed (Annex II, Part VII, 2021/1165)

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Not explicitly mentioned; may be considered a micro-organism, which is allowed. Micro-organisms that are genetically engineered/modified are prohibited. (Table 3 - 3.4 - page 29 and 31)

International Federation of Organic Agriculture Movements (IFOAM)
Allowed if derived from naturally occurring organisms. Genetically engineered microorganisms and their products are prohibited. Cultures that are prepared or multiplied in house shall comply with the requirements for the organic production of microorganisms. Nonorganic forms are allowed in organic products only if there are no organic sources. (7.2.5 - page 58 and 72).

Japan Agricultural Standard (JAS) for Organic Production
JAS does not specifically mention yeast as an additive or ingredient to organic food.

Ancillary Substances
During the 2015 sunset review, the following Functional Classes were reviewed for ancillary substances in yeasts: Antioxidants, preservatives, emulsifiers, defoaming agents, and substrate that may remain in the final product. It was suggested that starch be added to this list during that review. One substance, BHT, was questioned as problematic for exposure.

According to the 2014 TR, there are a few yeast species that are formulated with no ancillary substances; however, many commercially available yeasts are formulated with other ingredients. These substances, such as ascorbic acid, may be listed on the National List. However, other ancillary ingredients not appearing on the National List are routinely combined with yeast on a commercial scale. These may be water, emulsifiers, and cutting oils. The compounds used for emulsifiers are enumerated in the TR (2014 TR) and that extensive list should be referred to for specific details of ancillary substances in yeast products.

The 2023 Limited Scope TR indicates that for yeast to be certified as organic, the inputs such as molasses or corn steep liquor must also be organic and no synthetic substance that is not on the National List may be included [2023 TR 1255-1261].

Human Health and Environmental Issues
It should be noted that while yeast itself is often considered of minimal risk to both the environment and in human use, there can be negative environmental impacts from the manufacturing processes used to create yeast formulations. Appropriate mitigation strategies for these impacts, such as the emissions of acetaldehyde and ethanol, exist and when appropriately used minimize environmental impact (2014 TR). The 2023 Limited Scope TR did not provide additional information on the potential impacts to human

health or environmental issues, aside from those that could potentially occur through the use of excluded methods.

Discussion
Public comment from the Spring and Fall 2019 meetings was overwhelmingly in favor of relisting of yeasts as annotated. Commenters noted that since yeast is commonly not available in organic form necessary for certain flavors, yeasts are not always available in the quantities needed, and that organic yeast quality can vary, the annotation and listing should remain as is. It isn't currently clear how to determine whether a non-organic form of yeast may be used in an organic product.
Stakeholder Comments Informing the Spring 2024 meeting in Milwaukee: There were about 13 total stakeholder comments, both written and oral, with the majority being written. All comments were in favor of keeping yeast on the National List. Much like comments made in 2019, some commenters expressed concern that organic yeast is not consistently commercially available. One commenter noted that ancillary substance used in the formation process could be problematic.

The presentation of the yeast sunset document (among other sunsets) at the Spring 2024 board meeting in Milwaukee generated considerable board discussion mostly regarding fermentation and excluded methods. This discussion provided details regarding certifiers process which includes the use of a risk-based approach for assessing the compliance of 205.605(a) inputs. This approach is described in the ACA Best Practice for Common Material Review Issues[3] which provides further information regarding classification verification and prohibitions of the use of excluded methods.

The new 2023 Limited Scope TR brings up a few new questions relevant to the use of excluded methods in the production of this material. As it was noted in several stakeholder comments, this 2023 Limited Scope TR was first made available to the pubic shortly before the public comment period closed. We are therefore leaving the following "Questions to Our Stakeholders" open for comment for the coming Fall 2024 session in Portland.

Questions to our Stakeholders
1. For manufacturers: describe how you ensure no excluded methods are used when including yeast into your organic formulation.
2. For certifiers: describe how you ensure organic processors' compliance with the prohibition on excluded methods in organic products when yeast is used in the formulation.
3. Are there ancillary substances that should be prohibited for use, due to concerns about excluded methods?

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

Subcommittee Vote:
Motion to remove yeast from the National List
Motion by: Jerry D'Amore
Seconded by: Dilip Nandwani
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

[3] ACA Best Practice for Common Material Review Issues V4.4, January 2024 (ACA Materials Working Group)

Activated charcoal

Reference: § 205.605(b) Synthetics allowed

(2) Activated charcoal (CAS #s 7440-44-0; 64365-11-3)—only from vegetative sources; for use only as a filtering aid.

Technical Report: 2002 TAP; 2024 TR

Petition(s): 2002 petition

Past NOSB Actions: 09/2002 sunset recommendation; 11/2009 sunset recommendation; 04/2015 sunset recommendation; 10/2019 sunset recommendation

Regulatory Background: Added to National List with annotation 9/11/06 (71 FR 53299); Renewed 8/03/2011 (76 FR 46595); Renewed 09/12/16 (81 FR 8821); Renewed 8/3/2021 (86 FR 41699)

Sunset Date: 9/12/2026

Subcommittee Review

The Subcommittee had a brief discussion of the 2024 technical review (TR) and the Spring 2024 public comments. The Subcommittee members were all in support of relisting.

Use

Activated charcoal is used in processing for mechanical filtration involving the physical separation of suspended solids from a liquid passing through carbon arrayed as a porous media in a column or bed [2002 TR, lines 142-143]. This type of filtration is used as a taste and odor-removing agent and purification agent in water and food. Activated carbon has a very large surface area and pore volume that gives it its unique adsorption capacity [2002 TR, lines 57-58].

Manufacture

Activated charcoal of vegetative origin can be made from a large variety of sources such as hardwoods, grain hulls, corn cobs and nut shells [2024 TR, lines 59-60]. The material undergoes pyrolysis at a very high heat, and may be chemically activated using acids (acetic acid), bases (potassium hydroxide and sodium hydroxide), or through exposure to oxygenated gas or steam [2024 TR, lines 328-334].

International Acceptance

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

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

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

Lists activated carbon for the preparation of foodstuffs of plant and animal origin.

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

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

International Federation of Organic Agriculture Movements (IFOAM)

IFOAM Norms Appendix 4 – Table 1 lists activated carbon as allowed for use as a processing and postharvest handling aid. Synthetic forms are allowed if organic or natural sources are not commercially available. May be used as a processing or a post-harvest handling aid.

Japan Agricultural Standard (JAS) for Organic Production
Appended Table 1-1, Additives (Organic processed foods other than organic alcohol); Appended Table 1-2, Additives (Organic alcohol beverages). Limits the use of active carbon for processed foods of plant origin and also beverages.

Ancillary Substances
None identified.

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

Discussion
The new 2024 TR was received during subcommittee review. There were a handful of public comments in support of activated charcoal remaining on the National list; the question posed to stakeholders was not addressed in comments or during board discussion.

Questions to our Stakeholders
Are there any industry changes that would challenge the current listing for activated charcoal?

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

Subcommittee Vote
Motion to remove activated charcoal from the National List
Motion by: Kim Huseman
Seconded by: Jerry D'Amore
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 3

Ascorbic acid

Reference: § 205.605(b) Synthetics allowed
(6) Ascorbic acid.
Technical Report: 1995 TAP; 2019 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Ascorbic acid is used as a dietary supplement and nutrient, flavor ingredient, used in meat and meat containing products, curing and pickling, in flour to improve baking quality, as an antioxidant in fats and oils, and a wide variety of other food processing uses. It is also used in frozen and precut fruits as an antioxidant. Industrially produced L-ascorbic acid is widely used in the feed, food, and pharmaceutical sector as a nutritional supplement and preservative, making use of its antioxidative properties. Ascorbic acid is often added to processed foods for nutritional purposes and is one of the most common sources of Vitamin C, which provides many important biological functions. Several animals, including humans, a variety of primates and guinea pigs have lost the ability to produce ascorbic acid and must obtain this essential vitamin through their diets. As it is water soluble, and cannot be stored in the body, it must be consumed daily. However, its addition as a nutritional fortifier also provides preservative properties. The preservative nature of the compound is derived from its reducing nature, through which it reacts with oxidized species (including radicals and molecular oxygen) to prevent enzymatic browning and food spoilage. Ascorbic acid is GRAS as a chemical preservative (21 CFR 182.3013), a dietary supplement (21 CFR 182.5013), and nutrient (21 CFR 182.8013) when used in accordance with Good Manufacturing Practices. The FDA has identified ascorbic acid as a required nutrient in infant formula (21 CFR 107.100).

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

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed as ingredients classified as food additives. (Table 6.3, CAN/CGSB-32.311-2020, page 30)

Allowed as processing aid, specifically anti-browning agents prior to the extraction or concentration of fruit or vegetable juice. (Table 6.5, CAN/CGSB-32.311-2020, page 38)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Allowed in products of plant origin & meat products. (Annex V, Part A, Section A1, 2021/1165)

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Allowed in food of plant origin, provided natural sources are not available. Allowed in the following foods of animal origin, provided natural sources are not available: processed meat, poultry, game products, poultry and edible casings. (Table 3 - page 24)

International Federation of Organic Agriculture Movements (IFOAM)
Allowed as an as additive. (Appendix 4 - Table 1 - page 79)

Japan Agricultural Standard (JAS) for Organic Production
Allowed as an additive. Limited to the use in processed products of plant origin. (Appended Table 1)

Ancillary Substances
No discussion of ancillary substances in the 2019 TR.

Human Health and Environmental Issues
The 2019 Technical Report found no published studies on the persistence or impacts to biodiversity of ascorbic acid. Given the natural prevalence of the substance in plants and animals, the incorporation of ascorbic acid in the handling/processing of organic food products is unlikely to provide any significant increase to environmental levels of the substance.

Discussion
Ascorbic acid is a vital nutrient necessary for humans and other primates. Humans cannot synthesize Vitamin C and must rely on dietary intake. Modern production techniques rely on fermentation of glucose, but addition of synthetic acids in the process render the final ascorbic acid product a "synthetic" substance according to NOP 5033-1. Previous sunset reviews of the substance asked whether excluded methods are used in the production of ascorbic acid, and the 2019 TR indicates that the microorganisms used in its manufacture are not the product of excluded methods.

Some stakeholders have identified ascorbic acid's use as a preservative incompatible with the requirements in organic handling, however, other stakeholders report it remains essential for numerous functions in food including protein processing in cheese, color stabilization in fruit juice, and as an antioxidant and vitamin C source. The Subcommittee notes that evaluation criteria at 7 CFR 205.600(b) restricting a material's use as a preservative or its use to recreate or improve flavors, colors, textures, or nutritive value lost during processing is limited to processing aids and adjuvants.

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

At the Spring 2024 meeting, one commenter indicated the use of organic cherry powder as an alternative to ascorbic acid in some preserved meat products, but this alternative is not feasible in other types of products due to off flavors. Some commenters supported removal of ascorbic acid due to the availability of natural and organic alternatives, but did not provide evidence to support these statements. Public comments indicated that ascorbic acid remains widely used and compatible with National List Criteria.

Questions to our Stakeholders
Do stakeholders have any experience with natural or organic alternatives to ascorbic acid for some or all of its uses in organic handling?

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

Subcommittee Vote:
Motion to remove ascorbic acid from the National List
Motion by: Nate Lewis
Seconded by: Jerry D'Amore
Yes: 0 No: 9 Abstain: 0 Recuse: 0 Absent: 0

Calcium citrate

Reference: § 205.605(b) Synthetics allowed
(7) Calcium citrate.
Technical Report: 1995 TAP; 2015 TR; 2023 Limited Scope Technical Report (pdf) (citric acid and salts)
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 4/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Calcium citrate is used as an ingredient in dietary supplements, where it provides calcium. It is also used as a nutrient; sequestrant; buffer; antioxidant; firming agent; acidity regulator in jams and jellies, soft drinks and wines; raising agent; an emulsifying salt; to improve the baking properties of flours; a stabilizer; to remove scale from boilers, evaporators and other processing equipment; to wash equipment to remove off flavors; in cosmetic and personal care items; and as a water softener.

Calcium citrate may be added to foods to supplement calcium per FDA nutrition guidelines, although there are other calcium sources for supplementation purposes including calcium carbonate, calcium oxide, calcium sulfate, etc., all of which are permitted per a separate listing on §205.605(b) as Nutrient Vitamins and Minerals.

Manufacture
Citric acid is a naturally-produced, non-volatile organic acid with a long history of use in food processing. The 2015 TR considered production of citric acid by microbial fermentation with *Aspergillus niger* or *Candida* yeasts from carbohydrate sources but includes additional information regarding production from plant sources.

Note that the process that creates citric acid is fermentation of carbohydrates. In terms of concern about excluded methods, the 2015 TR indicates that the organisms underlying the fermentation process are considered 'classical mutants,' and further notes that the prohibition on excluded methods in food by the European countries suggests the underlying citric acid is unlikely to include carbohydrates that have manipulated genes.

The citrate salts – calcium citrate, potassium citrate and sodium citrate – are all derived from citric acid. The citrate salts are produced by chemical reaction with citric acid and the hydroxide or carbonate of the respective salt (calcium, sodium or potassium).

Calcium citrate is the calcium salt of citric acid. It is prepared by neutralizing citric acid with calcium hydroxide or calcium carbonate and subsequent crystallization. It is most commonly found in the tetrahydrate form.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed as food additives (Table 6.3, CAN/CGSB-32.311-2020, page 30).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Allowed as a food additive and processing aid in products of plant origin (Annex V, Part A, A1, 2021/1165).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Calcium citrate is allowed in food of plant origin and dairy products/analogues. Not allowed in fats, oils, and fat emulsions (page 25).

International Federation of Organic Agriculture Movements (IFOAM)
Allowed as an additive (Appendix 4 - Table 1 - page 79).

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

Ancillary Substances
None.

Human Health and Environmental Issues
There are no expected significant human health impacts or remarkable environmental issues, according to the 2015 TR.

Discussion
The bulk of the discussion about this product addresses the production process for citric acid.

The nine public comments made prior to the Spring 2024 meeting were largely supportive of relisting; one commenter mentioned it was especially useful when trying to avoid sulfates. Another cautioned about the ensuring that nanoparticles are not intentionally added.

The Board had no comments.

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

Subcommittee Vote:
Motion to remove calcium citrate from the National List
Motion by: Carolyn Dimitri
Seconded by: Nate Lewis
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 3

Collagen gel

Reference: § 205.605(b) Synthetics allowed
(13) Collagen gel—as casing, may be used only when organic collagen gel is not commercially available.
Technical Report: 2019 TR
Petition(s): 2018 (for addition at 205.606)
Past NOSB Actions: 04/2019 Recommendation to add
Recent Regulatory Background: Added to NL 07/26/2021 (86 FR 33479)
Sunset Date: 7/26/2026

Subcommittee Review
Subcommittee discussion was centered around commercial availability of organic collagen gel and what criteria would need to be met to be deemed 'commercially available'. A board member encouraged wild marine materials be allowed as certified organic; it could then be a potential source of organic collagen gel.

Use
Collagen gel acts as an edible film used to produce meat products (e.g. sausage) as an alternative to casings which is listed under §205.606(b). The collagen casing protects the meat product from oxidation and discoloration by acting as a semipermeable membrane for gases, moisture, and other solvents. The casing also provides a more desirable bite and texture to meat products as well as aids in additional flavorings to the product (Savic and Savic 2002, Han and Gennadios 2005, Harper et al. 287 2012, Ioi 2013, Marousek et al. 2015). Collagen gel is a more affordable, efficient, and sanitary means of manufacturing meat products and increases opportunities to produce a larger variety of organic meat products. It allows production of single-species products that can meet the needs and preferences of different consumer populations.

Manufacture
Collagen is a natural animal protein found in skin, bones, muscle, and connective tissues that is isolated from mostly bovine and porcine sources at USDA inspected facilities following all pertinent regulations. The animal-based collagen source is partially hydrolyzed through enzymatic, thermal, or acid treatment from meat processing byproducts to cleave the protein. Once cleaved, the collagen extract is decalcified and ground to uniformity within the collagen fibers. The collagen fibers are then swollen with an acid treatment before the extrusion process.
According to the TR, collagen gel is comprised of 3.0–4.5% collagen, < 3% cellulose, and 95.5-97% water. Collagen is a naturally occurring protein that is abundant in the connective tissue, bones, blood vessels, skin, and muscles of animals (Kim and Mendis 2006, Sahithi et al. 2013, Oechsle et al. 2014, Marousek et al. 2015). The unique structural properties of collagen's triple helix provide the desirable qualities of high-tensile strength and flexibility important to edible film casings (Oechsle et al. 2014, Oechsle et al. 2017).

Cellulose is currently approved for use as a synthetic substance "in regenerative casings [extruded collagen casing that is dried prior to use], as an anti-caking agent (non-chlorine bleached) and filtering aid," and for processed products labeled "organic or made with organic," at 7 CFR 205.605.

Marine collagen is rarely used. Dark coloration and odor have been difficult to overcome. Isolating collagen from marine sources are based on processing fish by-products. Sources are not well defined and may vary from bones and skins to include viscera and heads [2019 TR 99-102]. At the time of the technical review, marine sources of collagen remained largely in research state.

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Collagen is listed in the Canadian General Standards Board Permitted Substances List (CAN/CGSB-32.311-2015) in Table 6.4 as allowed for "ingredients not classified as food additives" in the form of "collagen casings." Collagen casings are required to "be derived from animal sources," and "if derived from cattle, shall be guaranteed free of specified risk materials." Moreover, collagen casings are permitted to include "other ingredients (such as, but not limited to cellulose, calcium coatings, glycerin, etc.) added to collagen casings during their manufacture, which remain in the collagen casing."

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

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

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

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

Ancillary Substances

Cellulose powder, derived from plant sources, is an inert substance in collagen gel. Cellulose's functionality is, however, critical once collagen gel has been coextruded into an enrobed extruded sausage. Cellulose adds permeability to the sausage's skin, allowing for the release of the meat emulsion's oil and fats during the sausage's cooking process. In finished collagen gel, cellulose is present in the range of 2 – 5%, depending on targeted product characteristics.

Human Health and Environmental Issues

Collagen gel has no known toxicities and breaks down into its constituent amino acids upon digestion. It has no environmental persistence and use of collagen gel is unlikely to have any additional adverse impact on the environment.

Discussion

Collagen gel, added to the National List in 2021, has provided more options for edible films and thus created a bigger market for organically produced meat; it is consistent with current regulations.

Collagen gel is GRAS (Generally Recognized as Safe) for use in meat products.

Questions to our Stakeholders

1. Is there a method of production for nonsynthetic collagen gel?
2. Are organic livestock by-products commercially available for organic collagen gel production?
3. Have advancements been made with testing the viability of marine sourced collagen gel?

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

Subcommittee Vote:
Motion to remove collagen gel from the National List
Motion by: Kim Huseman
Seconded by: Allison Johnson
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 3

Ferrous sulfate

Reference: § 205.605(b) Synthetics allowed
(15) Ferrous sulfate—for iron enrichment or fortification of foods when required by regulation or recommended (independent organization).
Technical Report: 1995 TAP; 2015 TR (Nutrient Vitamins and Minerals)
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Renewed 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Ferrous sulfate is commonly added to flours and cereal products to make an optional enriched claim and often found in baked products and infant snacks (oat cereal, teething biscuits, etc.).

Manufacture
Ferrous sulfate is made by reacting sulfuric acid with iron.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Ferrous sulphate is allowed for use if legally required and may be used, on a voluntary basis, if legally allowed. (Table 6.4, Vitamins and mineral nutrients listing, CAN/CGSB-32.311-2020, page 37)

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

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

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

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

Ancillary Substances
The 2015 TR for nutrient vitamins and minerals notes that ferrous sulfate is sometimes encapsulated to prevent the iron from catalyzing oxidation reactions that lead to rancidity, color and taste changes, or other undesirable effects. It is usually encapsulated in hydrogenated vegetable fat, with lecithin as an optional ingredient.

Human Health and Environmental Issues
Iron is an essential component of hemoglobin, enzymes involved in energy metabolism, and other enzymes. Hemoglobin transports oxygen to body tissues.

Iron deficiency leads to anemia, poor work performance and endurance, persistent cognitive and developmental impairment, increased maternal perinatal mortality and a greater rate of premature labor and delivery, and depressed immune function.

However, excess dietary iron can also cause health problems. Accidental overdose of ferrous sulfate drops is the most common cause of poisoning deaths in children in the U.S. Chronic excess consumption can cause constipation, nausea, vomiting, iron accumulation in the liver, higher cancer risk, and hemochromatosis.

Ferrous sulfate may also be hazardous in cases of skin contact (irritant), eye contact (irritant), ingestion, or inhalation. Possibly hazardous short term biodegradation products are not likely. However, long term biodegradation products may arise. The products of biodegradation are less toxic than the product itself.

The 2015 TR does not include information on environmental concerns for ferrous sulfate.

Discussion
There has been past discussion about whether ferrous sulfate is encompassed within the nutrient vitamins and minerals listing or needs to be listed separately. The NOSB recommended identical annotations for ferrous sulfate and nutrient vitamins and minerals in 1995, but they were ultimately listed with different annotations. The nutrient vitamins and minerals annotation is broader and would encompass ferrous sulfate and potentially allow other uses. However, because of the risks of excess iron consumption, it is unlikely that it would be added to products outside the uses currently allowed under the ferrous sulfate annotation.

Several public comments supported keeping ferrous sulfate on the National List.

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

Subcommittee Vote:
Motion to remove ferrous sulfate from the National List
Motion by: Allison Johnson
Seconded by: Kim Huseman
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 3

Hydrogen peroxide

Reference: § 205.605(b) Synthetics allowed
(17) Hydrogen peroxide.
Technical Report: 2015 TR (Crops)
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Hydrogen peroxide (CAS# 7722-84-1) is a very simple molecule with a formula of H2O2. It is a weak acid but also a strong oxidizer which makes it an effective microbial pesticide for organic handling purposes. It is used as a disinfectant and sanitizer and also for post-harvest treatment of produce. USDA organic regulations currently allow the use of hydrogen peroxide in organic crop production under 7 CFR §205.601(a) as an algicide, disinfectant and sanitizer, and under 7 CFR 205.601(i) for plant disease control as a fungicide. Hydrogen peroxide is also permitted for use in organic livestock production as a disinfectant, sanitizer and medical treatment (7 CFR 205.603(a)). Lastly, synthetic hydrogen peroxide may be used as an ingredient in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).” (7 CFR 205.605(b)).

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

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Permitted for many uses including as food-grade cleaners, disinfectants and sanitizers that are allowed without mandatory removal of residues; cleaners, disinfectants and sanitizers allowed on food contact surfaces including equipment, provided that substances are removed from food contact surfaces prior to organic production; and as a food-grade processing aid for bleaching proteins and starches.

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Allowed as a processing aid for gelatine. (Annex V, Part A, Section A2, 2021/1165)

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

International Federation of Organic Agriculture Movements (IFOAM) Norms
Allowed as an equipment cleanser and disinfectant. (Appendix 4 - Table 2- page 82).

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

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

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

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

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

During the previous sunset cycle, it was supported by the prior Handling Subcommittee without dissent and

was relisted by the full NOSB without dissent.
The Subcommittee previously asked stakeholders to weigh in on whether hydrogen peroxide is an effective alternative to other more problematic sanitizers and whether certifiers allow it to be used in direct contact with products. The Subcommittee did not hear significant comments in direct response to these questions, although it welcomes responses to these legacy questions at any time.

Discussion during this sunset cycle at the subcommittee level has focused on the need to understand disposal factors for this substance, the essentiality of this material in the overall rotation of allowed sanitizers, and whether it has specific value in one sector or another. Questions emerged about the fact the annotation on this substance differs from that on peracetic acid (another sanitizer) and why that might be. At the Spring 2024 NOSB meeting, the Board received thirteen total written comments and some oral comments, all strongly in favor of relisting. The Board had no substantive discussion and is not proposing removal from the National List.

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

Subcommittee Vote
Motion to remove hydrogen peroxide from 205.605(b) of the National List
Motion by: Wood Turner
Seconded by: Jerry D'Amore
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

Nutrient vitamins and minerals

Reference: § 205.605(b) Synthetics allowed
(20) Nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines For Foods.
Technical Report: 1995 TAP - Minerals; 1995 TAP - Vitamins; 2015 TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 03/2011 Handling Subcommittee Proposal; 04/2011 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
This listing allows nutrient vitamins and minerals to be added to organic food in accordance with 21 CFR 104.20, which is the U.S. Food and Drug Administration's (FDA) fortification policy. That policy lays out principles intended to serve as a model for the rational addition of nutrients to food and promote a balanced and nutritious food supply, while avoiding over- or under- fortification of consumer diets. It outlines situations in which it may be appropriate to add nutrients to food, including certain situations

where needed to correct a dietary insufficiency recognized by the scientific community to exist and known to result in nutritional deficiency; to restore nutrients lost in storage, handling, or processing; to avoid nutritional inferiority of a food that replaces a traditional food; as well as where required by regulation. It states that FDA does not encourage indiscriminate addition of nutrients to foods, nor does it consider it appropriate to fortify fresh produce; meat, poultry, or fish products; sugars; or snack foods such as candies or carbonated beverages. Manufacturers are urged to use these principles to design fortified foods.

The 2015 TR breaks this umbrella listing into five categories: fat-soluble vitamins (Vitamins A, D, E, K, carotenoids), water-soluble vitamins (Vitamins C, B1, B2, B6, B12, niacin, folate, pantothenic acid, biotin, choline, inositol), trace mineral elements (chromium, copper, iodine, iron, manganese, molybdenum, selenium, zinc), major minerals in bone (calcium, phosphorus, magnesium, fluorine), and major electrolyte minerals (potassium, sodium, chloride).

Manufacture
Because this listing encompasses a wide range of substances with nutritional value, the processes used to create them also vary widely. Vitamins can be extracted from food, synthesized, produced via fermentation, or some combination of these methods. Of note, fermentation methods may involve genetically engineered microorganisms. Minerals are pulled from the environment, including brines, salt deposits, and mineral ores.

International Acceptance
In addition to the categorical listings described below, all international standards also individually list some substances that may be considered vitamins and minerals (i.e. ascorbic acid or calcium carbonate).

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Vitamins and mineral nutrients are allowed as ingredients not classified as food additives in three situations:

1. Shall be used if legally required (e.g., fluid milk, white flour, infant formula, meal replacement, etc.).
2. The following non-dairy substitute products may be fortified on a voluntary basis, if legally permitted: plant-based beverages, products that resemble cheese, and butter substitutes.
3. Ferrous sulphate shall be used if legally required and may be used, on a voluntary basis, if legally permitted.

European Economic Community (EEC) Council Regulation, EC No. 2018/848 & 2021/1165
Vitamins are allowed in the processing of food if their use is legally required. (Annex II, Part IV, 2.2.2 (f), 2018/848)

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Vitamins and minerals are allowed if their use is legally required in the food products in which they are incorporated. (3.5, page 29)

International Federation of Organic Agriculture Movements (IFOAM)
Minerals (including trace elements), vitamins, essential fatty, amino acids, and other isolated nutrients allowed when their use is legally required or strongly recommended in the food products in which they are incorporated. (Processing and Handling, page 19)

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

Ancillary Substances
The 2015 TR states that ancillary substances are used to limit oxidation and promote even distribution of fat-soluble vitamins. Substances used to limit oxidation may include tocopherols, fat-soluble ascorbic acid (ascorbyl palmitate), carotenoids (e.g., beta carotene), and GRAS synthetic chemical antioxidants (BHT, BHA, PG, and TBHQ). Fat-soluble vitamin materials usually can be obtained free of BHT, BHA, PG, and TBHQ. Emulsifiers like lecithin are used to disperse fat-soluble vitamins in baby formula, and microencapsulation in starch, gums, gelatin, casein, and a wide range of other GRAS substances help with dispersion in other foods. Encapsulation is also used to protect and disperse water-soluble vitamins and minerals in substances including fats, waxes, and cellulose. Many, but not all, of these substances are included on the National List.

Human Health and Environmental Issues
The 2015 TR does not identify significant human or environmental issues connected with this categorical listing.

Discussion
The NOSB's original 1995 recommendation for the nutrient vitamins and minerals listing included this annotation: "Accepted for use in organic foods for enrichment or fortification when required by regulation or recommended by an independent professional organization," but the final rule published in 2000 (65 FR 13512) included the current annotation, which references FDA's fortification policy.

The Board and NOP have considered various proposals to change this listing to align more closely with the NOSB's original recommendation, to specifically address concerns about fortification of infant formula, and to consider nutrients that may fall in gray areas. According to the Board's 2019 sunset recommendation, in 2011 the Handling Subcommittee proposed to change the annotation at sunset but received approximately 2000 comments against it. The Subcommittee withdrew the proposal prior to the April 2011 NOSB meeting, and the NOSB supported relisting with the existing annotation for the 2012 sunset review. The NOSB also recommended listing certain nutrients (DHA, ARA), but not some amino acids and antioxidants.

Several subsequent actions were considered, but nothing further appears to have progressed after the current listing was retained in the 2021 sunset, in alignment with the Board's 2019 recommendation. Specifically, no action has been taken to:

- Act on the 2016 Handling Subcommittee discussion document, which outlined several options for annotation changes.
- Finalize or withdraw the January 12, 2012 Proposed Rule (77 FR 1979), which would have changed the listing to: "Vitamins and minerals. For food- vitamins and minerals identified as essential in 21 CFR 101.9. For infant formula-vitamins and minerals as required by 21 CFR 107.100 or §107.10." NOP published an Interim Rule on September 27, 2012 (77 FR 59287), effective October 21, 2012, which renewed the current listing until completion of the Proposed Rule.

It appears that there has not previously been sufficient public demand, regulatory challenge, or consensus to carry through with changes to this listing. The current reference to 21 CFR 104.20 in the annotation essentially commits the use of nutrient vitamins and minerals to an organic food manufacturer's discretion, within the principles the FDA has set out.

Public comments generally supported relisting nutrient vitamins and minerals, but demonstrated that there is still confusion about the annotation and what materials may be allowed under it. One certifier reported following the proposed rule from January 2012 that was never finalized, and another certifier reported following the current rule with the existing annotation (but also noted that they receive limited fortification

requests). A certifier noted that they do not review ancillary substances for nutrient vitamins and minerals and requested that the NOSB review ancillaries in the sunset process and identify them as allowed or prohibited. Several commenters noted that algal DHA is used in milk to add omega 3 fatty acids; the inclusion or exclusion of that material from the current listing remains unclear, and DHA has not been added to the National List individually.

The Board discussed various options for moving forward and clarifying this annotation, including proposing adoption of the annotation from the January 2012 proposed rule that was not finalized. The Board noted that certain vitamins and minerals required for fortification effectively cannot be removed by sunset, because they are legally required in certain food products, and considered the potential for recommending that those materials move to another place in the NOP regulations that is not subject to the sunset process. The Board also considered retaining the current listing with the explicit option to exclude materials by annotation.

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

Subcommittee Vote:
Motion to remove nutrient vitamins and minerals from the National List
Motion by: Allison Johnson
Seconded by: Nate Lewis
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 3

Peracetic acid/Peroxyacetic acid

Reference: § 205.605(b) Synthetics allowed
(22) Peracetic acid/Peroxyacetic acid (CAS # 79-21-0)—for use in wash and/or rinse water according to FDA limitations. For use as a sanitizer on food contact surfaces.
Technical Report: 2000 TAP; 2016 TR
Petition(s): 2008 Petition (Crops)
Past NOSB Actions: 11/2000 recommendation (Periacetic [sic] acid p. 467); 04/2004 resolution (periacetic [sic] acid p. 2740); 11/2009 sunset recommendation; 04/2015 sunset recommendation; 10/2019 sunset recommendation.
Recent Regulatory Background: Added to National List with annotation 9/11/2006 (71 FR 53299); Renewed 8/03/2011 (76 FR 46595); Renewed 09/12/2016 (81 FR 8821); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Peracetic acid (CAS # 79-21-0) is currently allowed for use in organic handling in wash water and rinse water, including during post-harvest handling, to disinfect organically produced agricultural products, such as fruits and vegetables, according to FDA limitations. It is also used to sanitize food contact surfaces, including dairy-processing equipment, food-processing equipment, and utensils. It is an important sanitizer used in organic handling.

Peracetic acid/peroxyacetic acid was added to §205.605(b) on September 12, 2006 It is also on the National List at §205.601 and §205.603 for use in crops and livestock, respectively. Peracetic acid disinfects by oxidizing the outer cell membrane of vegetative bacterial cells, bacterial spores, endospores, yeast, and mold spores, making it an effective sanitizer against many microorganisms [2016 TR, lines 265-267]. The end products of peracetic acid oxidation are acetic acid and water.

Manufacture

According to the 2016 technical report (TR), solutions of peracetic acid used as sanitizers are created by combining aqueous mixtures of two substances: acetic acid (the acid in vinegar) and hydrogen peroxide. At cool temperatures, acetic acid and hydrogen peroxide react over a few days to form an equilibrium solution containing peracetic acid, acetic acid, and hydrogen peroxide. The equilibrium solution is the substance sold commercially as the sanitizer "peracetic acid." Solutions of peracetic acid, hydrogen peroxide, acetic acid and water are produced by reacting glacial acetic acid with hydrogen peroxide, often in the presence of a catalyst such as a mineral acid (e.g., sulfuric acid) [2016 TR, lines 451-458]. Commercial grades are available in concentrations ranging from about 0.3 to 40% by weight. A peracetic acid solution can also be generated in situ by dissolving an activator and a persalt in water or on site by adding sodium hydroxide to triacetin and hydrogen peroxide [2016 TR, lines 53-62].

International Acceptance

Canadian General Standards Board Permitted Substances List

Not explicitly mentioned for processed products. On food and plants, peracetic acid may be used in wash or rinse water and on food contact surfaces. (Table 7.3, page 42)

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

Allowed for cleaning and disinfection. (Annex IV, Part D, 2021/ 1165)

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

Not explicitly mentioned for processed products.

International Federation of Organic Agriculture Movements (IFOAM) Norms

Allowed as an equipment cleanser and disinfectant. (Appendix 4, Table 2, page 82)

Japan Agricultural Standard (JAS) for Organic Production

Not explicitly mentioned.

Environmental Issues

Peracetic acid likely has no significant environmental impacts. Like other oxidative sanitizers (i.e., chlorine compounds), concentrated solutions of peracetic acid are strong irritants to the skin, eyes, mucous membranes, and respiratory system. As reviewed in the TR, when using fully diluted sanitizing solutions, no special eye, hand, skin, or respiratory protective equipment is normally required [2016 TR, lines 647-651]. No risk through dietary exposure is anticipated. All uses of this material should be consistent with FDA, USDA, and EPA labels and regulations and utilize personal protective equipment as needed.

Ancillary Substances

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

Discussion
Peracetic acid has been relisted each time it was reviewed during the sunset review process. There has been strong support for continued availability of this material. Oral and written comments submitted for the Spring 2019 NOSB meeting represent hundreds, if not thousands, of crop and livestock farmers and processors who uniformly support relisting this essential and relatively safe material. In particular, many processors identified the need for a "no-rinse" material as essential for treating equipment and other food contact surfaces. Overall, this material is considered effective and offers a less toxic profile compared to several other sanitizing materials, including many chlorine compounds. The 2016 TR does not offer new evidence of unacceptable adverse impacts on human health or the environment.

During the last review, use of a synthetic stabilizer such as 1-hydroxyethylidene-1,1- diphosphonic acid (HEDP) or 2,6- pyridinedicarboxylic (dipicolinic) acid to slow the rate of oxidation or decomposition were judged to be "inerts" for EPA registration as an antimicrobial and not subject to review as an ancillary substance. However, comments submitted for the Spring 2019 NOSB Meeting stated that dipicolinic acid is a former List 3 inert, is not allowed in products used in organic production, and identifies additional inert materials that warrant review. Only products with allowable inert ingredients should be used.

During the previous sunset cycle, the Handling Subcommittee supported relisting without dissent and this substance was recommended for relisting by the full NOSB without dissent.

Discussion during this sunset cycle at the Subcommittee level has focused on the need to understand disposal factors for this substance, the essentiality of this material in the overall rotation of allowed sanitizers, whether it has specific value in one sector or another, and how stakeholders might become more open to using sanitizers like peracetic acid that are less corrosive without losing efficacy. Questions emerged about the fact that the annotation on this substance differs from that on hydrogen peroxide (another sanitizer) and why that might be. At the Spring 2024 NOSB meeting, the Board received seventeen total written comments and some oral statements, all strongly in favor of relisting. The Board had no substantive discussion and is not proposing removal from the National List.

Questions to Stakeholders

1. Are certifiers looking at ancillary substances in peracetic acid? Are there always ancillary substances that should be considered with respect to peracetic acid?

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

Subcommittee Vote
Motion to remove peracetic acid from 205.605(b) of the National List
Motion by: Wood Turner
Seconded by: Dilip Nandwani
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

Potassium citrate

Reference: § 205.605(b) Synthetics allowed
(25) Potassium citrate.
Technical Report: 1995 TAP; 2015 TR; 2023 Limited Scope Technical Report (pdf) (citric acid and salts)
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Potassium and sodium citrate are used as ingredients where they function as acidulants, pH controls, flavoring agents, sequestrants, and buffering or emulsifying agents. Potassium citrate is used to replace sodium citrate whenever a low sodium content is desired. The three citrates are also used as dispersants in flavor or color additives, and to wash processing equipment to remove off flavors.

Potassium citrate is commonly used in biscuits, baby food, soup mixes, soft drinks, and fermented meat.

Manufacture
Citric acid is a naturally-produced, non-volatile organic acid with a long history of use in food processing. The 2015 TR considered production of citric acid by microbial fermentation with *Aspergillus niger* or *Candida* yeasts from carbohydrate sources but includes additional information regarding production from plant sources.

Note that the process that creates citric acid is fermentation of carbohydrates. In terms of concern about excluded methods, the 2015 TR indicates that the organisms underlying the fermentation process are considered 'classical mutants,' and further notes that the prohibition on excluded methods in food by the European countries suggests the underlying citric acid is unlikely to include carbohydrates that have manipulated genes.

The citrate salts – calcium citrate, potassium citrate and sodium citrate – are all derived from citric acid. The citrate salts are produced by chemical reaction with citric acid and the hydroxide or carbonate of the respective salt (calcium, sodium or potassium).

Potassium citrate is the potassium salt of citric acid. It is prepared by neutralizing citric acid with potassium hydroxide or potassium carbonate and subsequent crystallization. It is most commonly found in the monohydrate form.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed as food additives (Table 6.3, CAN/CGSB-32.311-2020, page 33).

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

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

International Federation of Organic Agriculture Movements (IFOAM)
Allowed as an additive (Appendix 4 – Table 1 – page 79).

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

Ancillary Substances
None

Human Health and Environmental Issues
There are no expected significant human health impacts or remarkable environmental issues, according to the 2015 TR.

Discussion
The bulk of the discussion about this product addresses the production process for citric acid.

The nine public comments made prior to the Spring 2024 meeting were largely supportive of relisting; concern was raised about fermentation for citric acid, which this product is derived from.

The Board had no comments.

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

Subcommittee Vote
Motion to remove potassium citrate from the National List
Motion by: Carolyn Dimitri
Seconded by: Kim Huseman
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 3

Potassium phosphate

Reference: § 205.605(b) Synthetics allowed
(28) Potassium phosphate—for use only in agricultural products labeled "made with organic (specific ingredients or food group(s))," prohibited in agricultural products labeled "organic".
Technical Report: 1995 TAP; 2016 TR
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Potassium phosphate can be used as for pH control in milk and dairy products, to make acidified milk products, and in milk protein stabilization. Potassium phosphate interacts with milk proteins, such as casein, to function as emulsifiers that prevent the separation of fat and water in cheese, and to stabilize milk and cheese by chelating (sequestering) calcium [2016 TR, lines 191-193].

Potassium phosphate can also be used as a nutritional additive as a source of potassium, as a nutrient in yeast, and in prepared meat applications and liquid eggs. The 1995 Technical Advisory Panel report (TAP) included a recommendation to list this material as an approved synthetic in products labeled "organic," but was only approved for use in "made with" products.

Manufacture
The 1995 TAP noted potassium phosphates are isolated from brines or salt deposits. However, the 2016 technical report (TR) explained that all of the orthophosphate derivatives of potassium can be generated by the neutralization of phosphoric acid with potassium hydroxide. Phosphoric acid is produced by treating phosphate rock (tricalcium phosphate) with sulfuric acid, forming phosphoric acid and calcium sulfate. Potassium hydroxide is obtained commercially from the electrolysis of potassium chloride solution in the presence of a porous diaphragm [2016 TR, Table 5].

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed as ingredients classified as food additives. For use in products whose contents are ≥ 70% and < 95% organic ingredients. (Table 6.3, CAN/CGSB-32.311-2020, page 33)

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

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

https://www.ifoam.bio/our-work/how/standards-certification/organic-guarantee-system/ifoam-normsInternational Federation of Organic Agriculture Movements (IFOAM)
Not explicitly mentioned

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

Ancillary Substances
Not identified

Human Health and Environmental Issues
During the last sunset review, commenters noted a concern with the use of phosphates in the production of processed foods and that phosphorus may not appear on the nutritional panel, making it difficult to be informed about total phosphorous intake– although they would appear on the ingredient list. There were concerns raised about the cumulative health impacts of phosphorous additives in food and, in 2015, the NOSB requested a technical review and work agenda item to study this issue further. According to the 2016

TR, since most dairy foods naturally contain substantial amounts of both sodium and phosphorus from milk, the small incremental amount of sodium and phosphorus contributed by a sodium phosphate stabilizer may exempt sodium phosphate from the requirement to be declared as an ingredient on the label; this would not be allowed in hypoallergenic foods and infant foods [2016 TR, lines 135-139]. The TR indicates that small amounts of sodium phosphates may not cause human health problems, but long-term cumulative impacts are not fully understood.

Discussion
Concerns were based on peer reviewed research indicating that the cumulative effects of phosphates as a group contribute to renal damage and failure, osteoporosis, and heart failure. Sodium phosphate was reviewed in 2017 and the NOSB concluded that no single phosphate food additive or ingredient can be implicated as an isolated risk factor. Concerns arise from the increase in cumulative use of phosphates and possible health effects on the general population.

There were no oral comments about this material for the Spring 2024 NOSB meeting. All written comments supported relisting potassium phosphate. The Subcommittee asked stakeholders for information regarding human health concerns with phosphates. No new data was presented; however, there is a pending petition to remove the restriction that potassium phosphate can only be used in products labeled 'made with organic' ingredients and to change "potassium phosphate" to "potassium phosphates," which would allow new types of potassium phosphates (*e.g.,* diphosphates and triphosphates) in organic food products.
Questions to our Stakeholders
None

Justification for Vote
The Subcommittee finds potassium phosphate compliant with the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600, however, the group has concerns about effects of cumulative use of phosphates on human health.

Subcommittee Vote:
Motion to remove potassium phosphate from the National List
Motion by: Logan Petrey
Seconded b: Kyla Smith
Yes: 3 No: 4 Abstain: 0 Recuse: 0 Absent: 2

Sodium acid pyrophosphate

Reference: § 205.605(b) Synthetics allowed
(30) Sodium acid pyrophosphate (CAS # 7758-16-9)—for use only as a leavening agent.
Technical Report: 2001 TAP (Sodium Phosphates); 2010 TR; 2016 TR
Petition(s): 2002; 2007 (Petition for expanded use)
Past NOSB Actions: 05/2003 recommendation; 11/2009 sunset recommendation; 04/2011 recommendation; 10/2019 sunset recommendation
Regulatory Background: Added to National List 09/12/06 (71 FR 53299); Renewed 8/03/2011 (76 FR 46595); Renewed 09/12/16 (81 FR 8821); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
The 2010 Technical Report (TR) indicates that sodium acid pyrophosphate is used in conventional foods as a chemical leavening agent in baked goods; a sequestrant (chelating agent) to maintain the appearance of cooked and uncooked fruits and vegetables, particularly processed potatoes; an emulsifying agent and stabilizer in cheeses and related products; an inhibitor of struvite formation in canned tuna; and a curing accelerator in processed meat and poultry products [2010 TR, lines 36-40]. The NOP regulations at 7 CFR 205.605(b) limit the use of sodium acid pyrophosphate in organic foods to use only as a leavening agent. Sodium acid pyrophosphate is used as a component of chemical leavening agents (baking powder).

In some meat- and poultry-containing processed foods, sodium acid pyrophosphate is used to accelerate color fixing or to preserve color during storage of cured pork and beef cuts, cured poultry, and cured comminuted poultry and meat food products. However, in organic foods, sodium acid pyrophosphate is permitted solely for leavening, so this color-fixing use is not permitted.

Manufacture
Sodium carbonate is reacted with phosphoric acid to form monosodium phosphate, followed by heating the monosodium carbonate to 220°C to form sodium acid pyrophosphate. It is expressed by the formula $Na_2H_2P_2O_7$ and is composed of 20.72% Na, 0.91% H, 27.91% P, and 50.46% O. Sodium is isolated from brines or salt deposits. Phosphorous is isolated from phosphate rock. Food-grade phosphates are formed by reacting purified phosphoric acid with sodium, potassium, or calcium hydroxides.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed in ingredients classified as food additives. For use as a leavening agent. (Table 6.3, CAN/CGSB-32.311-2020, page 34)

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

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

https://www.ifoam.bio/our-work/how/standards-certification/organic-guarantee-system/ifoam-normsInternational Federation of Organic Agriculture Movements (IFOAM)
Not explicitly mentioned

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

Ancillary Substances
None identified

Human Health and Environmental Issues
The 2016 TR on phosphates includes extensive discussion on the impact of phosphorous on the human diet, with particular focus on health effects of phosphorous provided by phosphate additives versus natural phosphorous in foods. Added phosphorous, as is found in sodium acid pyrophosphate, is immediately and

completely bioavailable upon consumption, whereas “food” phosphorous is much less available. High blood-phosphate levels are associated with kidney and vascular disease. A sufficiently high intake of calcium appears to counteract some of the ill effects of excess dietary phosphorus, but leads to an increased requirement for magnesium. Due to the restrictions on phosphate use in organic foods, it would be expected that basing a diet on organic foods would reduce phosphorus intake.

Discussion
Yeast is a natural leavener, but results in a different physical texture and requires more time than chemically-leavened foods. Chemical leavening is used instead of yeast for products where fermentation flavors would be undesirable or where the batter lacks the elastic structure to hold gas bubbles for more than a few minutes, such as muffins, pancakes and cookies.

Many manufacturers provided comments during the 2019 sunset review about the essentiality of sodium acid pyrophosphate because it is the only chemical leavening agent available.

There were no oral comments about this material for the Spring 2024 NOSB meeting. All written comments supported the relisting of sodium acid pyrophosphate. The Subcommittee asked stakeholders for information regarding human health concerns. No new data was presented. There was little to no discussion during the full board meeting.

Questions to our Stakeholders
None

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

Subcommittee Vote:
Motion to remove sodium acid pyrophosphate from the National List
Motion by: Logan Petrey
Seconded by: Kyla Smith
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

Sodium citrate

Reference: § 205.605(b) Synthetics allowed
(31) Sodium citrate.
Technical Report: 1995 TAP; 2015 TR; 2023 Limited Scope Technical Report (pdf) (citric acid and salts)
Petition(s): N/A
Past NOSB Actions: 04/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 10/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Potassium and sodium citrate are used as ingredients where they function as acidulants, pH controls, flavoring agents, sequestrants, and buffering or emulsifying agents. Potassium citrate is used to replace sodium citrate whenever a low sodium content is desired. These materials are also used as dispersants in flavor or color additives, and to wash processing equipment to remove off flavors.

Sodium citrate is used as an emulsifier in dairy products to keep fats from separating, and in cheese making where it allows the cheeses to melt without becoming greasy.

Sodium citrate is chiefly used as a food additive, usually for flavoring or as a preservative. Sodium citrate gives club soda both its sour and salty flavors. It is common in lemon-lime soft drinks, and it is partly what causes them to have their sour taste. Additionally, it is used in jams, jellies, meat products, baby foods, and milk powder.

Manufacture
Citric acid is a naturally-produced, non-volatile organic acid with a long history of use in food processing. The 2015 TR considered production of citric acid by microbial fermentation with *Aspergillus niger* or *Candida* yeasts from carbohydrate sources but includes additional information regarding production from plant sources.

Note that the process that creates citric acid is fermentation of carbohydrates. In terms of concern about excluded methods, the 2015 TR indicates that the organisms underlying the fermentation process are considered 'classical mutants,' and further notes that the prohibition on excluded methods in food by the European countries suggests the underlying citric acid is unlikely to include carbohydrates that have manipulated genes.

The citrate salts – calcium citrate, potassium citrate and sodium citrate – are all derived from citric acid. The citrate salts are produced by chemical reaction with citric acid and the hydroxide or carbonate of the respective salt (calcium, sodium or potassium).

Sodium citrate is the sodium salt of citric acid. It is prepared by neutralizing citric acid with sodium hydroxide or sodium carbonate and subsequent crystallization. It is most commonly found in the anhydrous or dihydrate forms.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed as food additives (Table 6.3, CAN/CGSB-32.311-2020, page 34).

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Allowed as a food additive and processing aid in products of plant and animal origin (Annex V, Part A, A1, 2021/1165).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Sodium Dihydrogen Citrate is not allowed in food of plant origin. Allowed in milks/cream, dairy-based drinks, unripened cheese, and yogurt as a stabilizer only. Allowed in processed cheese as an emulsifier only.

Allowed in whey and whey products; excluding whey cheeses; processed meat; poultry, and game products; and egg white products (page 25).

International Federation of Organic Agriculture Movements (IFOAM)
Allowed as an additive (Appendix 4 - Table 1 - page 79).

Japan Agricultural Standard (JAS) for Organic Production
Sodium citrate is allowed, but limited to use for dairy products, or for albumen and sausage as low temperature pasteurization.

Ancillary Substances
None

Human Health and Environmental Issues
There are no expected significant human health impacts or remarkable environmental issues, according to the 2015 TR.

Discussion
The bulk of the discussion about this product addresses the production process for citric acid.

Twelve written comments prior to the 2024 public meeting were supportive of relisting, and one commenter mentioned this product was a good alternative to phosphates, and for this reason should remain on the list.
The Board members did not say much about this material.

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

Subcommittee Vote
Motion to remove sodium citrate from the National List
Motion by: Carolyn Dimitri
Seconded by: Jerry D'Amore
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 3

Tocopherols

Reference: § 205.605(b) Synthetics allowed
(36) Tocopherols—derived from vegetable oil when rosemary extracts are not a suitable alternative.
Technical Report: 1995 TAP; 2015 Limited Scope TR; 2024 Limited Scope TR
Petition(s): N/A
Past NOSB Actions: 10/1995 NOSB minutes and vote; 11/2005 sunset recommendation; 04/2011 sunset recommendation; 10/2015 sunset recommendation; 09/2016 Handling Subcommittee proposal to add listing; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

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

Manufacture
Tocopherols are a group of lipophilic phenolic antioxidants that occur naturally in a variety of plant species.

The main sources of tocopherols are plant derivatives (such as various ground meals) and, more commonly, the deodorized distilled sludge (DD) obtained from conventional vegetable oil refining. Soybean oil deodorized distillate is the primary source of tocopherols due to soybean oil's low cost, although corn and rapeseed oil are also sometimes used. Table 2 in the 2024 TR summarizes the source materials and the extraction method commonly used.

As described in the 2024 TR, tocopherols are separated from the other compounds in the oil distillate by multiple extraction and refining steps. These steps can include solvent extraction, pressurized liquid extraction, extraction using matrix solid phase dispersion, superficial fluid extraction, ultrasonic assisted extraction or molecular distillation.

Being that there are several source materials and several manufacturing processes, it is not possible to categorically state that tocopherols are nonsynthetic or synthetic. Table 3 from the 2024 TR summarizes the classification of tocopherols as nonsynthetic or synthetic.

The total tocopherol content of the resulting product is usually 30 - 80%. Liquid forms of mixed tocopherols are commercially available diluted in vegetable oils and are also available as mixtures with rosemary extracts, ascorbyl palmitate/ascorbic acid, lecithin and/or citric acid. Powdered forms of tocopherols are produced by spray-drying the liquid tocopherol oils onto a carrier or mixture of carriers.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed as ingredients classified as food additives. Tocopherols may be derived from vegetable oil when rosemary extract is not a suitable alternative. (Table 6.3, CAN/CGSB-32.311-2020, page 34)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Allowed as an antioxidant in products of plant & animal origin. (Annex V, Part A, Section A1, 2021/1165)

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Natural tocopherols allowed. (Table 3 - page 24)

International Federation of Organic Agriculture Movements (IFOAM)
Allowed as a processing/post-harvest handling aid if from a natural source. (Appendix 4 - Table 1 - page 79)

Japan Agricultural Standard (JAS) for Organic Production

Allowed as an additive when used in products of livestock origin. Limited to the use in processed meat. (Appended Table 1)

Ancillary Substances
The following ancillaries were listed in the 2015 TR: sunflower oil, soybean oil, gum acacia, sterols, squalene, monodiglycerides, calcium carbonate, silica, rice maltodextrin, organic sunflower oil, tapioca starch. The 2015 TR also listed "unknown" in the ancillary column for several tocopherol products. [2015 TR, Table 1]

Human Health and Environmental Issues
Environment: Tocopherols are abundant in plant tissues and therefore are naturally abundant in the environment. Potential contamination could result from the manufacturing process of tocopherols if organic solvents and other chemicals are used. If these are released into the environment through waste streams, then environmental contamination could occur. The 2015 TR found no sources that discussed the possible persistence of tocopherols in the environment nor that concentrations of tocopherols or its breakdown products were present in the environment. [2015 TR 476-486]

Human Health: GRAS. It is unlikely that the use of tocopherols as an antioxidant in foods is harmful to human health. Tocopherols are a natural part of the human diet, with a large portion coming from naturally present in vegetable oils [2015 TR 507-509]

Discussion
During previous reviews, the Board has consistently relisted tocopherols due to their wide use in many processed foods even though stakeholders have been divided about relisting.

Those in favor stated that tocopherols are critically essential to maintaining food safety, preventing rancidity, and providing nutrients to their products, and that rosemary oil imparted off flavors or fragrances to their products that were not acceptable to consumers.

Those opposed stated that the material's primary use is as a preservative and therefore inconsistent with organic production, along with the assertion that non-synthetic tocopherols are commercially available and should be used instead of synthetic.

At the Fall 2019 meeting, the 2017 decision by the Handling Subcommittee to not move forward with an annotation change was reiterated, noting that if there were sufficient commercial availability of tocopherols in another form that members of the public were encouraged to submit a petition.

The Handling Subcommittee requested a limited scope TR to address the following: update to evaluation questions 1, 2, 3 and 13 to clarify the different manufacturing process of non-synthetic and synthetic tocopherols, as well as the commercial availability of the different forms (non-synthetic vs. synthetic).

As part of the Spring 2024 agenda and review of this substance, about a dozen comments were submitted. All were in favor of relisting or didn't state their opposition. Some commenters did report that they don't use rosemary because of the flavor it imparts in their product. We had some commenters again ask us to investigate the availability of natural tocopherols.

The 2024 TR provides updated information regarding the manufacturing of tocopherols. As stated above in the manufacturing section there are several sources of tocopherols with varying extraction methods, resulting in the classification as nonsynthetic or synthetic.

Also, the TR included several spice extracts that could be used to prevent lipid oxidation. It would seem that these would have a similar issue as the rosemary extract – in that operations would not want to use them since they would impart potentially unwanted flavor.

While it does appear that tocopherols are available in nonsynthetic form (as well as one certified organic tocopherol product), it is unclear if the predominant source currently in use is nonsynthetic or synthetic. It is still the view of the Subcommittee that if there is an adequate and suitable supply of tocopherols that a petition should be submitted for the addition of tocopherols at §205.605(a) or §205.606, and the removal from §205.605(b).

Questions to our Stakeholders

1. Are organic tocopherols commercially available?
2. Is there an adequate and suitable supply of non-synthetic tocopherols to meet commercial needs?

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

Subcommittee Vote
Motion to remove tocopherols from the National List
Motion by: Kyla Smith
Seconded by: Dilip Nandwani
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

Celery powder

Reference: § 205.606 Nonorganic agriculturals allowed
(c) Celery powder
Technical Report: N/A
Petition(s): 2007 Petition
Past NOSB Actions: 03/2007 NOSB recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Celery powder serves a dual purpose in the formulation of meat products. In addition to flavor, its primary function is as a natural source of nitrate which cures meat without relying on synthetic nitrates and nitrites and has been used in this application for millennia. There are other vegetables and minerals which contain natural nitrates including beets, spinach and sea salt. Although each has its benefits and challenges, none is an ideal substitute for natural celery powder in quality, form and function.

In the organic sector, celery powder is used in a variety of processed meat products (hot dogs, bacon, ham, corned beef, pastrami, pepperoni, salami, etc.) to provide “cured” meat attributes without using prohibited

nitrites. Celery powder is naturally high in nitrates that are converted to nitrites during fermentation by a lactic acid culture. Celery powder and the presence of nitrate and nitrites protects against spoilage (as an antioxidant) and also reduces risk from food borne pathogens, including clostridium botulinum, which produces botulin toxin. Celery powder is used in place of synthetic chemical nitrate and nitrite which are not currently permitted in U.S. organic agriculture. Although functionally similar to the use of synthetic nitrate and nitrite, meat products processed with celery powder must be labeled "uncured."

Manufacture
Celery is cleaned, macerated, physically separated (liquid/solid), and the liquid is concentrated by evaporation, then heated and vacuum dried. According to the original 2007 petition, 0.2-0.5% celery powder and 0.01-0.5% of lactic acid starter culture are used to convert the nitrates to nitrite and thus create the curing agent. According to the Kerry Inc. patent (https://patentimages.storage.googleapis.com/1b/75/a5/082eb2538620f2/US20080305213A1.pdf), "the curing agent can further comprise additional components, including but not limited to, yeast extract, protein hydrolyzates, amino acids, vitamins, minerals, and carbohydrates. Prior to the conversion of nitrate to nitrite, the pH and salt content of the plant material can be adjusted with the addition of a suitable acid, base, salt, or combination thereof. The plant material can be subjected to additional processing steps prior to conversion of nitrate to nitrite. Such processing steps can include, but are not limited to, heat treatment, filter sterilization, or a process which reduces the initial microbial load." Celery powder is typically standardized to a specific nitrite content. See discussion below for more information about source material.

International Acceptance
Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed as food additives: Extracts, juice, or cultured powder of celery or chard are allowed. Shall be organic if commercially available. (Table 6.3, Meat curing agents listing, CAN/CGSB-32.311-2020, page 33)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Not explicitly mentioned, although sodium nitrate (an alternative to celery powder) is allowed.

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

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

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

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

powder would pose similar risks. Nitrates in food may provide some health benefits. For example, formation of nitrous oxide may result in lowered blood pressure and better cardiovascular function.

Ancillary Substances
Possibly materials listed in the patent and 2007 petition: “including but not limited to, yeast extract, protein hydrolyzates, amino acids, vitamins, minerals, and carbohydrates.”

Discussion
In the organic sector, celery powder is used in a variety of processed meat products (hot dogs, bacon, ham, corned beef, pastrami, pepperoni, salami, etc.) to provide “cured” meat attributes without using prohibited nitrites. Celery powder is naturally high in nitrates that are converted to nitrites during fermentation by a lactic acid culture.

Concerns were raised about the direct dependence on a conventionally grown agricultural product in organic trade and concomitant impacts on human health and the environment. Particular concerns have been raised about the possibility of enhanced use of nitrate fertilizers to “supercharge” the product used for celery powder manufacture.

In lieu of a technical report, a celery powder expert panel was convened for the April 2019 NOSB meeting. Experts spoke to key questions addressing nitrate safety, organic celery powder production, processing and manufacture of celery powder, progress toward organically sources celery or other substrates that could be used process organic meats, and the scale of the organic processed meat industry.

Overall, trade and industry members of the organic community supported relisting of celery powder at §205.606, with the caveat that more research is needed to produce a viable organic alternative. Given the importance of the organic processed meat industry, public and NOSB comments encouraged the USDA to fund additional research to develop organic alternatives to conventionally produced celery powder. It continues to be included in the Handling Subcommittee annual research priorities (most recently on the approved proposal from the Fall 2023 NOSB meeting).

Celery powder was relisted by the NOSB in 2017 on a split vote (9-5). It was recommended by the Handing Subcommittee for relisting in 2019 with no dissent and relisted by the full board with one member in dissent.

Discussion during the current sunset cycle on this substance has focused on questions of ancillary substance review, fermentation, and an interest in understanding environmental impacts from conventional celery production. At the Spring 2024 NOSB meeting, the board received twelve unique written comments. Most of the comments supported continued relisting, asserting the essentiality of the material in key applications. Certifiers attested to substantial use among clients. Others, representing non-profits, retailers, and coalitions, urged strongly for the material’s removal from the National List, largely on the grounds of potential human health impacts from nitrate and nitrite exposure some suggested was similar to or even exceeding conventional cured meats. Board discussion was substantive and largely focused on positive research (supported by significant grants informed by ongoing NOSB Research Priorities) from the University of Wisconsin-Madison about effective organic curing sources – including Swiss chard -- that currently would not meet the needs of the entire organic meat industry but are likely to within a few short years.

Questions to our Stakeholders

1. Is there stakeholder concern about ongoing non-specified ancillary substances used in this material?
2. Is organic supply commercially available for this material? What are the barriers to organic production?
3. Is the organic version of the same caliber as the nonorganic?
4. Are stakeholders comfortable with the state of emerging research around alternatives?

Justification for Vote

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

Subcommittee Vote

Motion to remove celery powder from the National List
Motion by: Wood Turner
Seconded by: Jerry D'Amore
Yes: 2 No: 7 Abstain: 0 Recuse: 0 Absent: 0

Fish oil

Reference: § 205.606 Nonorganic agriculturals allowed

(f) Fish oil (Fatty acid CAS #'s: 10417–94–4, and 25167–62–8)—stabilized with organic ingredients or only with ingredients on the National List, §§ 205.605 and 205.606

Technical Report: 2015 TR
Petition(s): 2007
Past NOSB Actions: 03/2007 recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Added to NL 6/21/2007 (72 FR 35137); Renewed 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use

Fish oil is currently included on the National List as a nonorganically produced ingredient allowed in or on processed products labeled as "organic" when the substance is not commercially available in organic form (7 CFR 205.606). FDA GRAS notices (GRNs) exist for several variations of the term fish oil.

- fish oil concentrate (GRN 105)
- fish oil (GRN 138)
- fish oil (predominantly sardine and anchovy); tuna oil (GRN 193)

Fish oil is used in organic processing and handling as an ingredient to increase the content of omega-3 fatty acids—primarily, eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA)—in foods to benefit human health by contributing to healthy brain development and reducing risks of cardiovascular disease, diabetes, inflammation, atherosclerosis. Fish oil is used in a variety of food products, including breads, pies, cereals, yogurt, cheese products, frozen dairy products, meat products, cookies, crackers, snack foods, condiments, sauces, and soup mixes. [2015 TR 19-25]

Fish oil is also used in aquaculture as a feed supplement for farmed fish (Naylor et al., 2001). The farmed fish are fed fish oil because their diets are typically deficient in plants and animals that lead to the inherent production of fish oil (Naylor et al., 2001). [2015 TR 148-150]

In addition to aquaculture—estimated to use about 81% of the fish oil produced worldwide—fish oil is used in feed for livestock such as pigs, cattle, poultry, and sheep. Industrial applications of fish oil include paint production, leather making, and biodiesel manufacture. Historically, fish oil was used as lamp oil, among other uses (Rizliya and Mendis, 2014). [2015 TR 155-158]

Manufacture

Fish oil is produced from fish byproducts or from fish that are caught specifically for the purpose of making fish oil (Kim and Venkatesan, 2014). Between 20 and 80 kilograms of fish oil can be extracted per ton of fish waste (Karadeniz and Kim, 2014). The steps for fish oil extraction are-

- Once the raw fish or fish parts are obtained, they are cooked in steam at 100 °C in a process called wet reduction (U.S. EPA, 1995; Kim and Venkatesan, 2014). The cooked material is then strained and sent to a press, where liquid, including the oil, is pressed from the cooked fish (U.S. EPA, 1995). The oil is decanted from the pressing liquid, and separation is accomplished using a centrifuge (U.S. EPA, 1995; Kim and Venkatesan, 2014). The oil may be further washed with hot water in a process called polishing (U.S.EPA, 1995). The oil is stored in tanks until it is used for its commercial purpose as a food ingredient or supplement, and any remaining fish solids or fish solubles from the process are dried and used as fish meal (Kim and Venkatesan, 2014). At this point in the process, the only additions to the fish oil are water, heat, and pressure. The waste streams from this process include emissions of volatile organic compounds (VOCs) hydrogen sulfide and trimethylamine and wastewater. VOC emissions result during both the pre- of fish solids and fish solubles into fish meal (U.S. EPA, 1995). [2015 TR 283-296]

Fish oil may be further processed by hardening, which is performed to further purify the oil (U.S. EPA, 1995). [2015 TR 304-305]

Further extraction and purification of the oil can be performed by selective hydrolysis, followed by filtration, neutralization with sodium hydroxide, removal of oxidized oil by clay, and deodorization using steam distillation (EPAX Norway, undated; U.S. FDA, 2002). [2015 TR 311-313]

International Acceptance

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

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Fish oil is allowed in feed for carnivorous aquaculture animals (EC No 2018/848, General requirements, 3.1.3.3, page 76).

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

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

Japan Agricultural Standard (JAS) for Organic Production

Not explicitly mentioned.

Ancillary Substances
None.

Human Health and Environmental Issues
The 2015 TR notes that although there are potential human health benefits of consuming fish oil, including reduced risk of various cardiovascular and digestive diseases, there are also risks; fish oil consumption may increase exposure to mercury and other contaminants that may interfere with early brain development and may increase risk of bleeding. A laboratory analysis of 31 fish oil supplements found that every product contained measurable amounts of mercury, PCBs might also be present in fish oil. Dioxins and furans are hazardous environmental compounds that may also be found in fish and fish oil.

The environmental impacts of fishing are severe. The number of collapsed fish stocks has increased exponentially since the 1950s and demands on fisheries may overburden the current supply of fish. Exploitation of fisheries is also the largest contributor to marine extinctions, above habitat loss, climate change, invasive species, pollution, and disease. Aquaculture is the largest use of fish oil worldwide.

Discussion
In Fall 2021, the Board unanimously recommended an amendment to the annotation on fish oil restricting sources to fishing by-products only and to fishing industries that meet third-party sustainability standards:

> §205.606 (e) Fish oil (Fatty acid CAS #'s: 10417-94-4, and 25167-62-8) - stabilized with organic ingredients or only with ingredients on the National List, §§205.605 and 205.606. Sourced from fishing industry by-product only and certified as sustainable against a third-party certification that is International Social and Environmental Accreditation and Labeling (ISEAL) Code Compliant or Global Seafood Sustainability Initiative (GSSI) recognized.

The recommendation is now listed as "Closed" in the NOSB Recommendations Library, with the note "AMS does not plan to act on this recommendation at this time." At the Fall 2023 NOSB meeting, the NOP indicated that they would not be moving forward with that recommendation, or related recommendations from the Crops and Materials subcommittees, in part due to the complexity of identifying appropriate third-party sustainability standards.

Some commenters continued to note that moving forward with the organic aquaculture standard and developing an organic production standard for wild caught fish would facilitate the production of certified organic fish oil and could alleviate concerns about overfishing and toxic contaminants present in fish oil.

The Handling Subcommittee discussed fish oil extraction, the manufacturing process, and environmental issues. The Subcommittee understands the challenges with referencing third-party standards in NOP regulations, but also remains concerned about the environmental impacts of overfishing. As described above, the Canadian and European Union organic standards for aquaculture both allow fish oil to be used in aquaculture, with limitations that promote sustainability. The Canadian annotation, which references the FAO Code of Conduct for Responsible Fisheries, appears relatively simple and appropriate to implement in the United States. In the meantime, fish oil remains an essential ingredient in organic products, and its use in processed organic products has a small impact on fisheries, relative to its use in aquaculture. The Subcommittee does not recommend removing it at this time.

Questions to our Stakeholders

1. Should the Board consider updating the 2021 recommendation to align the fish oil annotation with the Canadian annotation for fish oil used in aquaculture?
2. Should NOSB prioritize completing a recommendation for wild seafood standards, pursuant to OFPA, 7 U.S.C. section 6506(c)?

Justification for Vote

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

Subcommittee Vote

Motion to remove fish oil from the National List
Motion by: Dilip Nandwani
Seconded by: Jerry D'Amore
Yes: 0 No: 6 Abstain: 1 Recuse: 0 Absent: 2

Gelatin

Reference: § 205.606 Nonorganic agriculturals allowed
(h) Gelatin (CAS # 9000-70-8).
Technical Report: 2002 TAP; 2019 TR gelatin, collagen gel, and casings
Petition(s): 2001; 2002 (addition as ingredient (capsules); 2007 Petition (addition to 205.606)
Past NOSB Actions: 05/2002 NOSB recommendation; 05/2007 recommendation to add; 04/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 09/12/2026

Subcommittee Review

The NOSB had a brief discussion of public comments and the Spring 2024 review, and the Board members were all in support of relisting.

Use

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

Manufacture

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

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Allowed as ingredients classified as food additives: shall be organic if commercially available. Gelatine may be sourced from plants or animals. If derived from cattle, gelatine shall be guaranteed free of Specified Risk Material (SRM). (Table 6.3, CAN/CGSB-32.311-2020, page 32)

Allowed as processing aids: shall be from organic sources if commercially available. Allowed sources are plants and animals. Animal gelatine may be used in preparations of canned meat or as a gelling agent for gummed candy. If derived from cattle, gelatine shall be guaranteed free of Specified Risk Material (SRM). (Table 6.5, CAN/CGSB-32.311-2020, page 39)

European Economic Community (EEC) Council Regulation, EC No. 2018/848 and 2021/1165
Allowed in products of plant origin. (Annex V, Part A, Section A2, 2021/1165)

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Allowed as a processing aid for the preparation of products of agricultural origin. (Table 4 - page 30)

International Federation of Organic Agriculture Movements (IFOAM)
Allowed as a processing/post-harvest handling aid. (Appendix 4 - Table 1 - page 80)

Japan Agricultural Standard (JAS) for Organic Production
Additive allowed. Limited to the use in processed products of plant origin. (Appended Table 1)

Ancillary Substances

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

Human Health and Environmental Issues

There have been no published studies on the impact of gelatin on human health. Gelatin has been widely incorporated into a range of industries, including food and medicine, and is widely regarded as biocompatible and biodegradable. It is not anticipated to have a negative impact on human health or have a negative impact on the environment or biodiversity.

Discussion

The 2019 TR did not contain new information indicating that organic gelatin would be commercially available in the near future. In 2021 the Handling Subcommittee hoped that at the next sunset review, the barriers to production of organic gelatin will no longer be present.

Gelatin has been granted GRAS status by the FDA for “substances migrating from cotton and cotton fabrics used in dry food packaging,” at 21 CFR 182.70. Moreover, gelatin is generally recognized as safe (GRAS) when used “to clarify juice or wine,” at 27 CFR 24.246.

Questions to our Stakeholders

1. Is there sufficient commercially available organic gelatin?
2. What gaps persist that necessitate gelatin to be on the national list?

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

Subcommittee Vote
Motion to remove gelatin from the National List
Motion by: Kim Huseman
Seconded by: Carolyn Dimitri
Yes: 0 No: 6 Abstain: 0 Recuse: 0 Absent: 3

Orange pulp, dried

Reference: § 205.606 Nonorganic agriculturals allowed
(m) Orange pulp, dried.
Technical Report: N/A
Petition(s): 2008 Petition
Past NOSB Actions: 11/2008 NOSB recommendation for addition to the National List; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Added to NL effective 03/15/2012 (77 FR 8089); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Dried orange pulp is used as a moisture retention agent and fat substitute in baked goods, pastas, salad dressing, confectionary, processed cheese spreads, beverages, meat products and frozen foods. Dried orange pulp is used in rates up to 5 percent depending on use but is self-limiting after that point due to loss of desirable eating qualities.

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

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

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

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Not listed individually as non-organic agricultural commodities allowed. However, CODEX allows for up to 5% non-organic content.

International Federation of Organic Agriculture Movements (IFOAM)
Not listed individually as non-organic agricultural commodities allowed. However, IFOAM allows for up to 5% non-organic content.

Japan Agricultural Standard (JAS) for Organic Production
Not listed individually as non-organic agricultural commodities allowed. However, JAS allows for up to 5% non-organic content.

Ancillary Substances
No ancillary substances are indicated.

Human Health and Environmental Issues
The only noted concern pertaining to orange pulp is the use of conventional pesticides in conventional orange production that may negatively impact the environment and potentially leave residue in the final product of orange pulp, dried.

Discussion
During the Spring 2019 review, the Handling Subcommittee voted to remove this item from the National List because orange pulp, dried, does not seem to be necessary for or consistent with organic handling (failing OFPA criteria at 7 U.S.C. 6517(c)(ii)–(iii)), and alternatives exist (failing OFPA criteria at § 6518(m)(6)). There were no comments that supported its use, nor any known organic products that include it as an ingredient. However, orange peel and orange pulp were listed as ingredients in organic products. It was noted that this listing also has a patent which may limit its use in organic products. Additionally, during the in-person Fall 2019 NOSB meeting, the petitioner for this substance provided verbal comment, and stated that they wished to continue the listing. They indicated that they have customers who wish to continue the use of this nonorganic product in their organically labeled foods. The petitioner also clarified the supply of organic oranges is located about an hour too far away from their processing facility to use their patented process and make their dried orange pulp.

While numerous NOSB members felt that the use of dried orange pulp is very small, and in the future, the distance issues and other barriers may be overcome, a decisive vote to remove it from §205.606 was not reached, therefore the motion to remove orange pulp from §205.606 failed (7/5).

As part of the Spring 2024 agenda and review of this substance eight comments were submitted. While two were generally supportive of relisting, most were opposed or didn't state their opinion. Those that didn't state their opinion were mostly certifiers that were reporting numbers of operations that use this substance. Of the certifiers that commented it was reported that only two operations were using this substance. The Subcommittee posed questions related to the supply of organic orange pulp and what organic products would no longer be able to be produced if orange pulp, dried were to be removed from the National List. The sufficient and adequate supply is still a question. However, based on the certifiers that reported (which we acknowledge is only a subset) it appears that this substance isn't in wide use. Perhaps that is due to operations switching to using an organic form of this substance.

A search in September 2023 of the Organic Integrity Database for the following products yielded the below results:

- orange pulp, dried = 0 results
- dried orange pulp = 0 results
- orange pulp = 6 results
- orange powder = 29 results

After the Spring 2024 board meeting additional research determined that FiberStar, the original petitioner is now certified, and offers an organic citrus fiber. Based on that information along with comments received during the Spring 2024 meeting most of which were either in favor of removal or were certifiers that reported limited use, the Handling Subcommittee is proposing to remove orange pulp, dried from the National List.

Justification for Vote
The Subcommittee proposes removal of orange pulp, dried from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600: lack of essentiality due to the presence of organic forms of orange pulp, dried.

Subcommittee Vote
Motion to remove orange pulp, dried from the National List
Motion by: Kyla Smith
Seconded by: Allison Johnson
Yes: 5 No: 2 Abstain: 0 Recuse: 0 Absent: 2

Seaweed, Pacific kombu

Reference: § 205.606 Nonorganic agriculturals allowed
(q) Seaweed, Pacific kombu.
Technical Report: 2016 TR (Marine Plants & Algae)
Petition(s): 2007 Petition
Past NOSB Actions: 05/2008 NOSB recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Added to NL effective 03/15/12 (77 FR 8089); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 09/12/2026

Subcommittee Review
At §205.606 (d)(3), (n), (v) and (z), four substances from marine plants and algae are specifically identified as nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as ''organic'' when the specific product is not commercially available in "organic" form: (d)(3) beta-carotene extract color, derived from algae (CAS #1393– 59 63–1), not produced using synthetic solvents and carrier systems or any artificial preservative; (n) Kelp used only as a thickener and dietary supplement; (v) Pacific kombu; and (z) Wakame seaweed (*Undaria pinnatifida*) [2016 TR 55-61]

Use
Seaweed is used as food, in cosmetics and fertilizers, processed to extract thickening agents, and as an additive to animal feed (FAO, 2014). Increasing demand over the last fifty years outstripped the ability to supply the market from natural (wild) stocks. Cultivation industries now produce more than 90 percent of the markets' demand. Some commercial organizations have been promoting seaweed for restaurant and domestic use, with some success. An informal market exists among coastal dwellers in some developing countries where there has been a tradition of using fresh seaweeds as vegetables and in salads (FAO, 2012). [2016 TR 193-195]

Kombu, produced from hundreds of hectares of brown seaweed, *Laminaria japonica* that is grown on suspended ropes in the ocean.

Seaweeds as a source of hydrocolloids dates back to 1658, when the gelling properties of agar that is extracted with hot water from a red seaweed were first discovered in Japan. Extracts of Irish moss, another red seaweed, contain carrageenan and were popular as thickening agents in the nineteenth century. [2016 TR 217-219]

Seaweed meal, used an additive to animal feed, has been produced in Norway, where its production was pioneered in the 1960s. It is made from brown seaweeds that are collected, dried and milled.

Cosmetic products, such as creams and lotions, sometimes show on their labels that the contents include "marine extract", "extract of alga", "seaweed extract" or similar. Usually this means that one of the hydrocolloids extracted from seaweed has been added. 2016 TR 252-254]

Manufacture

Kelps are seaweed and recognized as Kombu in Japan and various kinds of food made from Kombu, one of the most important of the marine vegetable preparations. The seaweeds used in the manufacture of Kombu are coarse, broad-fronded members of the kelp family (Laminariaceae), and until *Laminaria japonica* was introduced. Other kelps utilized in Kombu manufacture are *Arthrothamnus bifidus* and *kurilensis, Alaria fistulosa* (Smith, 1904). [2016 TR 858-866] The gathering of kelp begins in July and ends in October and is engaged in by many fishermen. The fishermen go to the kelp grounds in open boats, each boat with one to three men and a complement of hooks with which the kelp is torn or twisted from its strong attachment on the rocky bottom. The hooks are of various patterns; some are attached to long wooden handles, and some are weighted and dragged on the bottom by means of ropes while the boats are under way (Smith, 1904). [2016 TR 868-872]

Uses of the Argentinian seaweeds have expanded to new markets for human consumption, nutraceuticals, and cosmetics including the fucoidan industries. Local farmers directly sell the seaweeds to the processing companies or companies with concessions which directly employ their own workers for harvesting during the year and contracted divers in the summer. The National Center of Patagonia (CENPAT) guarantees that the harvesting methods are performed in a sustainable way. Regulations for the management of brown seaweeds and marine concessions are particularly well developed, and the supply in brown seaweed to the alginate industry is well managed and organized (Rebours et al., 2014). [2016 TR 889-892]

An Icelandic company whose products include rockweed (*Acophyllum nodosum*) and kelp (*Laminaria digitata*). Mechanical harvesting uses specialized equipment and takes place between April and October. As with other areas where *Ascophyllum nodosum* and *Laminaria digitata* are harvested commercially, ecological concerns about changes in species diversity resulting from harvesting have been noted (Ingolfsson, 2010). [2016 TR 893-897]

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Seaweed and seaweed products are allowed in crop production (Table 4.2, page 19). Seaweed meal is allowed as feed, feed additives, and feed supplements (Table 5.2, page 25).

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

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Seaweeds and seaweed products are allowed for use in soil fertilizing and conditioning (Table 1, page 19). Seaweed, seaweed meal, seaweed extracts, sea salts, and salty water are allowed for plant pest and disease control (Table 2, page 22).

International Federation of Organic Agriculture Movements (IFOAM)
Seaweed and seaweed products allowed as fertilizers and soil conditioners if obtained by physical processes, extraction with water or potassium hydroxide solutions when the minimum amount of solvent necessary for extraction is used, and fermentation (Appendix 2, page 75).

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

Ancillary Substances
None.

Human Health and Environmental Issues
No known impact on human health impact and environmental issues, per 2016 TR.

Discussion
Public comment from the previous sunset review indicated that the two seaweed materials be reviewed within the broader context of marine materials. At that time, commenters suggested that as part of the review, the NOSB should consider the addition of an annotation related to harvest restrictions and risk-based testing for toxic materials, using a decision tree to identify harvesting areas where testing would need to be performed. At the Fall 2023 meeting, the NOP stated that it will not take action on the NOSB's Fall 2020 recommendations on other marine materials, in light of the "technical complexity of marine environments."

At the Spring 2024 NOSB meeting a stakeholder commented on environmental concerns of harvesting seaweeds. In 2020 an NOSB member wrote an extensive proposal on the sustainable harvest of seaweed for use in organic products: https://www.ams.usda.gov/sites/default/files /media/MSMarine MaterialsRec_webpost.pdf. The health of our oceans, the fish, plants and other species is an important topic and organic seaweed must meet the highest standard of sustainability and protection of the resource. Once it is over-harvested or severely damaged through poor practices, it is very difficult or even impossible to bring back to health. Seaweed is important for the health of the oceans, not only for food, but also as habitat for fish and other creatures, and most harvesting practices do have a negative impact on these non-target species. The organic label must not represent the degradation of an important worldwide resource and ecosystem.

The Handling Subcommittee discussed seaweed extraction, the manufacturing process, and environmental issues. The Subcommittee understands the challenges with referencing third-party standards in NOP regulations, but also remains concerned about the environmental impacts of harvesting seaweeds. Based on the comments received and board discussion, the Handling Subcommittee is recommending that Pacific Kombu seaweed remain on the National List.

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

Subcommittee Vote
Motion to remove Pacific kombu seaweed from the National List
Motion by: Dilip Nandwani
Seconded by: Kim Huseman
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2

Wakame seaweed

Reference: § 205.606 Nonorganic agriculturals allowed
(t) Wakame seaweed (*Undaria pinnatifida*).
Technical Report: 2016 TR (Marine Plants & Algae)
Petition(s): 2007 Petition
Past NOSB Actions: 04/2007 NOSB recommendation; 04/2010 sunset recommendation; 10/2015 sunset recommendation; 10/2019 sunset recommendation
Recent Regulatory Background: Sunset renewal notice published 06/06/12 (77 FR 33290); Renewed 03/15/2017 (82 FR 14420); Renewed 8/3/2021 (86 FR 41699)
Sunset Date: 9/12/2026

Subcommittee Review

Use
Seaweed is used as food, in cosmetics and fertilizers, processed to extract thickening agents, and as an additive to animal feed (FAO, 2014). As the world has internationalized, seaweed consumption as food including wakame, has expanded from China, Japan and Korea to the entire world. Farming seaweed on lines in the ocean has expanded globally for production of alginates, carrageenans, other chemicals and the edible seaweed varieties, as management of harvest of wild seaweed forests continues throughout the world (Hunter, 1975). [2016 TR 379-383] Increasing demand over the last fifty years outstripped the ability to supply the market from natural (wild) stocks. Cultivation industries now produce more than 90 percent of the markets' demand. Some commercial organizations have been promoting seaweed for restaurant and domestic use, with some success. [2016 TR 192-193]

Seaweed meal, used an additive to animal feed, has been produced in Norway, where its production was pioneered in the 1960s. It is made from brown seaweeds that are collected, dried and milled. Cosmetic products, such as creams and lotions, sometimes show on their labels that the contents include "marine extract", "extract of alga", "seaweed extract" or similar. Usually this means that one of the hydrocolloids extracted from seaweed has been added.

Whole algae incorporated into food and food additives has been used to develop healthier and more nutritious foods particularly because there is a technical advantage in the use of algae as natural ingredients in food reformulation for healthy foods and beverages. Wakame (*Undaria pinnatifida*) a widely consumed brown algae contains high levels of dietary fiber and minerals. [2016 TR 505-508]

Manufacture
The edible seaweed wakame is produced by drying *Undaria pinnatifida* and is generally regarded as safe (FDA GRN No. 565 — 21 CFR 184.1120). The Republic of Korea grows three different species, and about 50 percent of this is for wakame, produced from a different brown seaweed, *Undaria pinnatifida*, grown in a similar fashion to *Laminaria* in China.

Undaria pinnatifida (wakame) and *Saccharina latissima* (sugar kombu) are two of the most valuable seaweeds in northern Spain due to their high demand and economic value. On a commercial basis along the Atlantic coast of Europe, particularly in northern Spain, water movement is a key factor controlling the production and quality of kelp. *U. pinnatifida* is best cultured at more exposed sites rather than at sheltered sites, whereas both sheltered and exposed sites are suitable for *S. latissima* cultivation; hanging rope culture is best in sheltered areas, while horizontal rope culture is better suited for exposed locations. The fixed-pole anchor system for raft culture has been used successfully in exposed open-ocean sites as an alternative to the traditional system with concrete blocks; outplanting dates for the *U. pinnatifida* and *S. latissima* on the Atlantic coast of southern Europe are from October to November and from November to December, respectively. Harvesting is conducted from March to April and from April to May for these two outplanting seasons, respectively. Seawater temperature and seawater nitrogen concentration are the main determinants of the start and end of culture in the sea for both species. *S. latissima* is more economically and environmentally advantageous 1057 than *U. pinnatifida* (Peteiro et al., 2016). [2016 TR 1046-1057]

In Argentina, the National Center of Patagonia (CENPAT) guarantees that the harvesting methods are performed in a sustainable way. Regulations for the management of brown seaweeds and marine concessions are particularly well developed, and the supply in brown seaweed to the alginate industry is well managed and organized (Rebours et al., 2014). [2016 TR 889-892]

International Acceptance

Canadian General Standards Board Allowed Substances List (CAN/CGSB 32.311-2020)
Seaweed and seaweed products are allowed in crop production (Table 4.2, page 19). Seaweed meal is allowed as feed, feed additives, and feed supplements (Table 5.2, page 25).

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

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)
Seaweeds and seaweed products are allowed for use in soil fertilizing and conditioning (Table 1, page 19). Seaweed, seaweed meal, seaweed extracts, sea salts, and salty water are allowed for plant pest and disease control (Table 2, page 22).

International Federation of Organic Agriculture Movements (IFOAM)
Seaweed and seaweed products allowed as fertilizers and soil conditioners if obtained by physical processes, extraction with water or potassium hydroxide solutions when the minimum amount of solvent necessary for extraction is used, and fermentation (Appendix 2, page 75).

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

Ancillary Substances

None.

Human Health and Environmental Issues

No known impact on human health impact and environmental issues, per 2016 TR.

Discussion
Public comment indicated that the two seaweed materials be reviewed within the broader context of Marine Materials. At that time, commenters suggested that as part of the review, the NOSB should consider the addition of an annotation related to harvest restrictions and risk-based testing for toxic materials, using a decision tree to identify harvesting areas where testing would need to be performed.

At the Spring 2024 NOSB meeting a stakeholder commented on environmental concerns of harvesting seaweeds. In 2020 an NOSB member wrote an extensive proposal on the sustainable harvest of seaweed for use in organic products. https://www.ams.usda.gov/sites/default/files /media/MSMarine MaterialsRec_webpost.pdf. The health of our oceans, the fish, plants and other species is an important topic and organic seaweed must meet the highest standard of sustainability and protection of the resource. Once it is over-harvested or severely damaged through poor practices, it is very difficult or even impossible to bring back to health. Seaweed is important for the health of the oceans, not only for food, but also as habitat for fish and other creatures, and most harvesting practices do have a negative impact on these non-target species. The organic label must not represent the degradation of an important worldwide resource and ecosystem.

The Handling Subcommittee discussed seaweed extraction, the manufacturing process, and environmental issues. The Subcommittee understands the challenges with referencing third-party standards in NOP regulations, but also remains concerned about the environmental impacts of harvesting seaweeds. Based on the comments received and board discussion, the Handling Subcommittee is recommending that wakame seaweed remain on the National List.

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

Subcommittee Vote
Motion to remove wakame seaweed from the National List
Motion by: Dilip Nandwani
Seconded by: Kim Huseman
Yes: 0 No: 7 Abstain: 0 Recuse: 0 Absent: 2